

## (1) PROVISIONS OF LAW ON TRANSITION PERIODS

ARGENTINA: *Sections 100 and 101 of the Law No. 24.481 of 23/05/1995 on Patents and Utility Models (as last amended by Law No. 24.572)*

100. Inventions relating to pharmaceutical products shall not be patentable until five years have elapsed following the publication of this Law in the Official Gazette. Until that date, none of the Articles contained in this Law that provide for the patentability of inventions of pharmaceutical products shall have effect, neither shall any other provisions that are inseparably related to such patentability.

101. Without prejudice to the provisions of the foregoing Article, patent applications may be filed for pharmaceutical products in the form and under the conditions laid down in this Law, provided that the patents shall be granted as from five years following publication of this Law in the Official Gazette.

The term of the patents mentioned above shall be that arising from the application of Article 35.

The owner of the patent shall have exclusive rights in his invention as from five years following the publication of this Law in the Official Gazette, except where the third party or parties making use of his invention without his authorization guarantee that the domestic market will be fully supplied at the same actual prices.

In such case the owner of the patent shall have the right only to collect fair and reasonable remuneration from the said third parties who are making the use from the time of the patent grant until the expiration thereof. If there is no agreement between the parties, the National Institute of Industrial Property shall set the remuneration in accordance with Article 46. The provisions of this paragraph shall apply unless the amendment thereof is required to implement decisions of the World Trade Organization adopted by virtue of the TRIPS Agreement, compliance with which decisions shall be mandatory for the Argentine Republic.

BURUNDI: *Article 17 of the Law No. 1/13 of 28/072009 on Industrial Property*

*Article 17*

Sont exclus de la protection par brevet:  
- les produits pharmaceutiques, jusqu'au 1er janvier 2016.

CAMBODIA: *Articles 4 (iv) and 136 of the Law on Patents, Utility Models and Industrial Designs of 22/01/2003*

*Article 4*

The following inventions, shall be excluded from patent protection:  
(iv) pharmaceutical products as provided in Article 136 of this Law;

*Article 136*

The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 01, 2016, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated November 14, 2001 in Doha of Qatar.

EGYPT: *Articles 43 and 44 of the Law on the Protection of Intellectual Property Rights No 82 of 03/06/2002*

*Article 43*

The Patent Office shall receive patent applications with regard to food-related agrochemical products and to pharmaceuticals, and shall maintain such applications, along with applications relating to the same products and filed as of 1st January 1995, pending their examination as of 1st January 2005. In the case of a patent granted for the inventions relating to the products mentioned in the preceding paragraph, the protection shall begin from the date of granting the patent until the end of the period provided for in Article 9, calculated from the date of application.

*Article 44*

Without prejudice to the date set for the examination of patent applications relating to the products mentioned in Article 43, the applicant shall be entitled to request from the competent public authority to be granted exclusive marketing rights for his product in Egypt, provided that:

- (1) the applicant has submitted an application for this product to the Patent Office in Egypt as of 1st of January 1995;
- (2) the same product was patented in a country member of the World Trade Organization on the basis of an application submitted in that country as of 1st January 1995;
- (3) the applicant has obtained the approval for the circulation of that product in the same country where he was granted the patent as of 1st January 1995;
- (4) the applicant has obtained the approval of the competent ministry for the circulation of that product within Egypt;

The Patent Office in Egypt shall grant an exclusive marketing right certificate upon the approval of a ministerial committee established for this purpose by a decision of the Prime Minister.

The exclusive marketing right shall not be granted when it is clear, prima facie, from the papers submitted to the Patent Office to obtain the exclusive marketing right, that the patent application has been filed with the Office was already published one year prior to the date of filing the request.

Where an exclusive marketing rights have been granted by the competent public authority, the applicant shall enjoy such rights for his product until a decision is rendered by the Egyptian Patent Office on the patent application, or for a period of five years as from the date of approval to grant him such rights, whichever comes first.

A previously granted exclusive marketing right shall be revoked by a decision of the competent ministry which has approved the circulation or where the owner of such right abuses its exercise.

INDIA: *Sections 5 and 24A, 24B and 24D of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005*

[5. Inventions where only methods or processes of manufacture patentable

(1) In the case of inventions

- a) claiming substances intended for use, or capable of being used, as food or as medicine or drug, or
- b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors and inter-metallic compounds);

no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable.

[(2) Notwithstanding anything contained in sub-section (1), a claim for patent of an invention for a substance itself intended for use, or capable of being used, as medicine or drug, except the medicine or drug specified under sub-clause (v) of clause (1) of sub-section (1) of section 2, may be made and shall be dealt, without prejudice to the other provisions of this Act, in the manner provided in Chapter IVA.]

*Explanation:* for the purposes of this section "chemical processes" includes biochemical, biotechnological and microbiological processes.] (Section omitted by Patent amendment Act of 2005)

[24A. Application for grant of exclusive rights – (1) Notwithstanding anything contained in sub-section (1) of section 12, the Controller shall not, under that sub-section, refer an application in respect of a claim for a patent covered under sub-section (2) of section 5 to an Examiner for making a report till the 31st day of December, 2004 and shall, where an application for grant of exclusive right to sell or distribute the article or substance in India has been made in the prescribed form and manner and on payment of prescribed fee, refer the application for patent, to an Examiner for making a report to him as to whether the invention is not an invention within the meaning of this Act in terms of section 3 or the invention is an invention for which no patent can be granted in terms of section 4.

(2) Where the Controller, on receipt of a report under sub-section (1) and after such other investigation as he may deem necessary, is satisfied that the invention is not an invention within the meaning of this Act in terms of section 3 or the invention is an invention for which no patent can be granted in terms of section 4, he shall reject the application for exclusive right to sell or distribute the article or substance.

(3) In a case where an application for exclusive right to sell or distribute an article or a substance is not rejected by the Controller on receipt of a report under sub-section (1) and after such other investigation, if any, made by him, he may proceed to grant exclusive right to sell or distribute the article or substance in the manner provided in section 24B.

*Explanation:* It is hereby clarified that for the purpose of this section, exclusive right to sell or distribute any article or substance under this section shall not include an article or substance based on the system on Indian Medicine as defined in clause (e) of sub-section (1) of section 2 of the Indian Medicine Central Council Act, 1970 (48 of 1970), and where such article or substance is already in the public domain. ] (Omitted by Act No. 15 of 2005)

[24(B). Grant of exclusive of rights – (1) Where a claim for patent covered under sub-section 2 of section 5 has been made and the applicant has –

a) where an invention has been made whether in India or a country other than India and before filing search a claim, filed an application for the same invention claiming identical article or substance in a convention country on or after the 1st day of January, 1995 and the patent and the approval to sell or distribute the article or substance on the basis of appropriate tests conducted on or after the 1st day of January, 1995 in that country has been granted or after the date of making claim for patent covered under sub-section 2 of section 5; or

b) where an invention has been made in India and before filing search a claim, made a claim for patent on or after the 1st day of January, 1995 for method or a process of manufacture for that invention relating to identical article or substance and has been granted in India the patent therefore on or after the making the claim for patent covered under sub-section 2 of section 5, and has been received the approval to sell or distribute the article or substance from the authority specify in this behalf by the Central Government, then, we shall have the exclusive right by himself, his agents or licensee to sell or distribute in India the article or the substance on or from the date of approval granted by the Controller in this behalf till a period of five years or till the date of grant of patent or the date of rejection of application for the grant of patent, whichever is earlier.

(2) Where, the specifications of an invention relating to an article or a substance covered under sub-section (2), of Section 5 have been recorded in a document or the invention has been tried or used, or, the article or the substance has been sold, by a person, before a claim for a patent of that invention is made in India or in a convention country, then, the sale or distribution of the article or substance by such person, after the claim referred to above is made shall not be deemed to be an infringement of exclusive right to sell or distribute under sub-section (1).

Provided that nothing in this sub-section shall apply in a case where a person makes or uses an article or a substance with a view to sell or distribute the same the details of invention relating thereto were given by a person who was holding an exclusive right to sell or distribute the article or substance. ] (Omitted by Act No. 15 of 2005)

[24D. Special provision for selling or distribution

Without prejudice to the provisions of any other law for the time being in force, where, at any time after an exclusive right to sell or distribute any article or substance has been granted under sub-section 91)

of Section 24B, the Central Government is satisfied that it is necessary or expedient in public interest to sell or distribute the article or substance by a person other than a person to whom exclusive right has been granted under sub-section (1) of Section 24B; it may, by itself or through any person authorized in writing by it in this behalf, sell or distribute the article or substance. The Central Government may, by notification in the Official Gazette and at any time after an exclusive right to sell or distribute an article or a substance has been granted, direct, in the public interest and for reasons to be stated, that the said article or substance shall be sold at a price determined by an authority specified by it in this behalf. ] (Omitted by Act No. 15 of 2005)

LEBANON: *Article 36 of the Law on Patents of Invention No. 32 for the Year 1999(as last amended by Law No. 71 of 2001)*

*Article 36*

A. Patents of invention shall be granted for manufacturing and chemical processes relating to chemical products, pharmaceuticals and foodstuffs.

B. After the enforceability date of this law, it shall be permissible to file patent applications for registering inventions involving the protection of final products for chemicals relating to pharmaceuticals or medicines or foodstuffs.

C. Deciding the applications referred to in the previous paragraph (B) shall only be made after the enforceability date of this Article.

D. Without prejudice to the provisions of any other law, the Minister may grant the applicant for a patent registration the exclusive right to market the chemical products relating to medicines or pharmaceuticals or foodstuffs covered by the patent subject for five years or until the date of patent grant or rejection whichever is shorter if the following takes place after the enforceability date of this Article:

1. Filing an application for obtaining a patent of invention in the Kingdom relating to the products mentioned in this Article.

2. Filing an application for an invention patent in another country member of the World Trade Organization and the patent has been granted.

3. Granting a permit for marketing the product in the other country.

4. Granting a permit to register the medicine in the Kingdom by the Ministry of Health.

E.1. The provisions of paragraphs (C) & (D) of this Article shall come into force after the elapse of one month as of the Cabinet's decision to do so, within 3 years as of the date of Jordan's joining the World Trade Organization.

2. In case of non-issuance of the decision referred to in item (1) of this paragraph, the provisions of the said two paragraphs shall come into force under the law when the 3-year period elapses.

MADAGASCAR: *Section 1. 8 (1) (v) of the Ordinance No. 89 019 Establishing Arrangements for the Protection of Industrial Property of 31/07/1989*

8. (1) Subject to the specific regulations in respect of the subject matters listed below, applications for patents or inventors' certificates shall not be admissible or shall be rejected where they concern:

(v) pharmaceutical, veterinary, cosmetic and food products.

PAKISTAN: *Section 13 (9) of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

13. (9) An application for availing exclusive marketing rights for a patentable invention relating to pharmaceutical or agricultural chemical product shall be filed in the mailbox provided for this purpose by the Controller who may require the form and manner for submitting such application as may be prescribed.

URUGUAY: *Article 127 of the Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs No. 1.827\*R of 02/09/1999*

127. Inventions of pharmaceutical and agrochemical products may not be patented until November 1, 2001.

Without prejudice to the foregoing, a patent may be sought for these products in accordance with the provisions and requirements of this Law, but the patent shall not be granted until the date laid down in the previous paragraph.

Where patents for pharmaceutical and agrochemical products claim the priority right provided in Article 4 of the Paris Convention for the Protection of Industrial Property, the first deposit may not under any circumstances be made prior to January 1, 1994.

RWANDA: *Article 18 (1) 8) of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property*

The following shall be excluded from patent protection even if they constitute inventions under article 5 (7): of this Law;

8° pharmaceutical products, for the purposes of international conventions to which Rwanda is party;

## (2) PROVISIONS OF LAW ON PATENTABILITY OF SUBSTANCES EXISTING IN NATURE

ALBANIA: *Art.4 no.7-11, Art. 5(2) (a) and(5) and Art.6 (2) and (3) of the Industrial Property Law Nr. 9977 of 07/07/2008*

### *Article 4*

7. "Biotechnological inventions" means inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used;

8. "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;

9. "Plant variety" means any plant grouping with a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

a) defined by the expression of the characteristics that result from a given genotype or combination of genotypes;

b) distinguished from any other plant grouping by the expression of at least one of the said characteristics; and

c) considered as a unit with regard to its suitability for being propagated unchanged;

10. "Essentially biological process for the production of plants or animals" means a process consisting entirely of natural phenomena such as crossing or selection;

11. "Microbiological process" means any process involving or performed upon or resulting in microbiological material;

*Articles 5 (2) (a) and (5)*

2. The following in particular shall not be regarded as inventions within the meaning of paragraph 1:  
a) discoveries, scientific theories and mathematical methods;

5. Biotechnological inventions shall also be patentable if they concern:

- a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;
- b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
- c) microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety;
- d) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

*Article 6*

Exceptions to patentability

Patents shall not be granted in respect of:

2. Plant or animal varieties or essentially biological processes for the production of plants or animals, without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;

3. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene.

*ALGERIA: Articles 7 (1) and 8 (1) of the Ordinance No. 03-07 of 19/07/2003*

7. Au sens de la présente ordonnance, ne sont pas considérés comme inventions:

- 1) les principes, théories et découvertes d'ordre scientifique ainsi que les méthodes mathématiques;

*Article 8*

- En vertu de la présente ordonnance, les brevets d'invention ne peuvent pas être obtenus pour :

- 1) les variétés végétales ou les races animales, ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux ;

*ANDORRA: Article 2 (2) (a) of the Patent Law of 1999*

*Article 2*

Conditions of patentability

(2) The following, in particular, shall not be regarded as inventions within the meaning of paragraph (1):

- (a) discoveries, scientific theories and mathematical methods;

ANTIGUA AND BARBUDA: *Section 2 (2) (i), (iv) and (v) of the Patents Act No. 23 of 29/12/2003*

(2) The following, even if they are inventions within the meaning of subsection (1), shall be excluded from patent protection:

(i) discoveries, scientific theories and mathematical methods;

(iv) plants and animals other than micro-organisms;

(v) essentially biological processes for the production of plants or animals other than non-biological and microbiological processes;

ARGENTINA: *Sections 6 (a) and (g) and 7 (b) of the Law No. 24.481 of 23/05/1995 on Patents and Utility Models (as last amended by Law No. 24.572)*

6. The following shall not be considered inventions for the purposes of this Law:

(a) discoveries, scientific theories and mathematical methods;

(g) any kind of live material or substances already existing in nature.

7. The following shall not be patentable:

(b) all biological and genetic material existing in nature or derived therefrom in biological processes associated with animal, plant and human reproduction, including genetic processes applied to the said material that are capable of bringing about the normal, free duplication thereof in the same way as in nature.

ARMENIA: *Section 10 (1) (a) and (3) of the Industrial Property Law of 10/06/2008*

*Article 10*

The Exception to Legal Protection (1) Within the meaning of Article 9 of this Law the following shall not be subject to legal protection:

(a) scientific discoveries;

(3) Within the meaning of this Law, the following shall not constitute patentable inventions:

(a) plant and animal varieties, as well as the natural biological processes of their raising;

AUSTRIA: *Section 2 (3) of the Patents Law BGBl. No. 259/1970 as last amended by BGBl. No. 143/2001*

Section 1 - Patentable Inventions

(2) The following in particular shall not be regarded as inventions:

1. discoveries, scientific theories, and mathematical methods;

Section 2 - Exceptions to Patentability

Patents shall not be granted in respect of:

3. plant or animal varieties (animal races) or essentially biological processes for the production of plants or animals; these exceptions shall not apply to microorganisms as such nor to microbiological processes and the products obtained by means of such processes.

BARBADOS: *Section 11(a) and (e) of the Patents Act No. 18 of 26/07/2001*

11 (1) Whether or not they constitute an invention within the meaning of this Act, the following are not patentable under this Act, namely:

(a) discoveries, scientific theories and mathematical methods;

(e) plant varieties, animal varieties and essentially biological processes for the production of plants other than microbiological processes and the products of those processes;

*BELARUS: Article 2 (2) of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/2002 as last amended on 29/10/2004*

2. (2) The following shall not be recognized as inventions:  
- discoveries, scientific theories and mathematical methods;

*BELGIUM: Articles 2, 3 (1) 1) and 4 (4) of the Patent Law of 28/03/1984 (Consolidated version as of 01/01/2010)*

#### *Article 2*

Sous les conditions et dans les limites fixées par la présente loi, il est accordé sous le nom de "brevet d'invention", appelé ci-après brevet, un droit exclusif et temporaire d'exploitation pour toute invention qui est nouvelle, implique une activité inventive et est susceptible d'application industrielle.

[Sont brevetables les inventions nouvelles, impliquant une activité inventive et susceptibles d'application industrielle, même lorsqu'elles portent sur un produit composé de matière biologique ou en contenant, ou sur un procédé permettant de produire, de traiter ou d'utiliser de la matière biologique.

Une matière biologique isolée de son environnement naturel ou produite à l'aide d'un procédé technique peut être l'objet d'une invention, même lorsqu'elle préexistait à l'état naturel.]

#### *Article 3*

§ 1er. Ne sont pas considérées comme des inventions au sens de l'article 2 notamment :

1) les découvertes ainsi que les théories scientifiques et les méthodes mathématiques ;

#### *Article 4*

[§ 4. Le corps humain, aux différents stades de sa constitution et de son développement, ainsi que la simple découverte d'un de ses éléments, y compris la séquence ou la séquence partielle d'un gène, ne peuvent constituer des inventions brevetables.

Un élément isolé du corps humain ou autrement produit par un procédé technique, y compris la séquence ou la séquence partielle d'un gène, peut constituer une invention brevetable, même si la structure de cet élément est identique à celle d'un élément naturel.

L'application industrielle d'une séquence ou d'une séquence partielle d'un gène qui sert de base à une invention doit être concrètement exposée dans la demande de brevet.]

*BELIZE : Article 12 (1) (a) of the Patents Act (Ch. 253), No. 14 of 21/06/2000*

#### Matters Excluded from Patent Protection

12.-(1) The following, even if they are inventions within the meaning of this Act, shall not be protected as patents:

(a) a discovery, scientific theory or mathematical method;

*BHUTAN: Section 4 (3) (i) of the Industrial Property Act of 2001*

4. (3) The following, even if they are inventions within the meaning of subsection (2), shall be excluded from patent protection:  
(i) discoveries, scientific theories and mathematical methods;

*BOTSWANA: Section 9 (1) (a) of the Industrial Property Act No. 14 of 21/08/1996*

9. (l) For the purposes of this Act, the following shall, even if they are inventions, not be protected as patents  
a) a discovery;

*BRAZIL: Sections 10 (I) and (IX) and 18 II of the Industrial Property Law No. 9.279 of 14/05/1996 (as last amended by Law No.10.196, of 14/02/2001) and Article 31 of the Provisional measure No. 2.186-16*

10. The following are not considered to be inventions or utility models:  
I. discoveries, scientific theories, and mathematical methods;

IX. all or part of natural living beings and biological materials found in nature, even if isolated therefrom, including the genome or germoplasm of any natural living being, and the natural biological processes.

18. The following are not patentable:

II. substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical- chemical properties and the respective processes for obtainment or modification, when resulting from the transformation of the atomic nucleus;

*Article 31 of the Provisional measure No. 2.186-16*

The grant of industrial property rights by the component bodies for a process or product obtained using samples of components of the genetic heritage is contingent on the observance of this Provisional Measure, the applicant being obliged to specify the origin of the genetic material and the associated traditional knowledge, as the case may be.

*BRUNEI DARUSSALAM: Section 13 (2) (a) of the Emergency Patents Order of 29/06/1999*

13. (2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Order, that is to say, anything which consists of:

(a) a discovery, scientific theory or mathematical method;

*BULGARIA: Articles 6(2) (1), 7 (1) 4), 7a of the Law on Patents and Utility Model Registration No. 27/2 of 1993 as last amended on 20/07/2007*

Patentable Inventions

*Article 6*

(2) The following shall not be regarded as inventions:

1. discoveries, scientific theories and mathematical methods;

Exceptions to Patentability

*Article 7*

(1) Patents shall not be granted for:

4. essentially biological processes for obtaining plants and animals.

Patentability of biotechnological inventions

*Article 7a (1)* - Patents shall be granted for inventions relating to a product consisting of or containing biological material, or to a method of obtaining, processing or use of biological material, provided that they satisfy the requirements of Art. 6(1).

(2) Biological material isolated from its natural environment or obtained by a technical process may be regarded as the subject matter of an invention, even if it existed in nature before that.

(3) Inventions relating to plants or animals shall be considered patentable, if the technical realization of the invention is not reduced to a certain plant or animal variety.

(4) The prohibition under Art. 7, paragraph 1(4) shall not apply to the patentability of inventions relating to microbiological or other technical processes or products obtained by such processes, provided that they satisfy the requirements of Art. 6(1).

*CAMBODIA: Articles 4(i) and (v) of the Law on Patents, Utility Models and Industrial Designs of 22/01/2003*

*Article 4*

The following inventions, shall be excluded from patent protection:

(i) discoveries, scientific theories and mathematical methods;

(v) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals;

*CHILE: Article 37 (a), (b) and (f) of the Industrial Property Law No. 19.039 of 24/01/1991 (consolidated version of 2005 as last amended on 2007),*

*Article 37*

The following shall not be considered inventions and shall be excluded by the patent protection of this Law:

(a) Discoveries, scientific theories and mathematical methods.

(b) Plants and animals, except microorganisms that meet the general conditions of patentability. Plant varieties shall be protected only in accordance with the provisions of Law No. 19.342 on the Rights of Breeders of New Plant Varieties. Also non patentable are essentially biological procedures for producing plants and animals, except microbiological procedures. For these purposes, an essentially biological procedure is one that consists entirely of natural phenomena, such as crossing and selection.

(f) Any partial living thing as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing. However, protection may be afforded to procedures that use one or more of the aforementioned biological materials and products directly obtained through them, provided that they satisfy the requirements laid down in Article 32 of the present Law, that the biological material is appropriately described and that its industrial application is explicitly included in the patent application.

*CHINA: Article 25 (1) of the Patent Law of 28/12/2008*

*Article 25*

For any of the following, no patent right shall be granted:

(1) scientific discoveries;

*COSTA RICA: Article 1 (2) (a) of the Law No.6867 of 25/04/1983 as last amended on 12/10/2000 and Article 78 1), 3), 6) of the Law no. 7788 of 23/04/1998 on Biodiversity*

2. Para los efectos de esta ley no se considerarán invenciones:

a) Los descubrimientos, las teorías científicas, los métodos matemáticos y los programas de ordenador considerados aisladamente.

Article 78 of the Law no. 7788 of 23/04/1998 on Biodiversity

Forma y Límites de la Protección

78. El Estado otorgará la protección indicada en el artículo anterior, entre otras formas, mediante patentes, secretos comerciales, derechos del fitomejorador, derechos intelectuales comunitarios sui géneris, derechos de autor, derechos de los agricultores. Se exceptúan:

1. Las secuencias de ácido desoxirribonucleico per se.
3. Los microorganismos no modificados genéticamente.
6. Las invenciones esencialmente derivadas del conocimiento asociado a prácticas biológicas tradicionales o culturales en dominio público.

*CROATIA: Articles 5 (2), (3), (4), (5), (6.1) and 6 (1) and (2) of the Patent Act No. 173/2003 of 31/10/2003as last amended by Law OG No 76/2008 of 23/07/2007*

*Article 5*

(2) According to the conditions set out in paragraph (1) of this Article, a patent shall also be granted for an invention which concerns:

1. a product consisting of or containing biological material;
2. a process by means of which the biological material is produced, processed or used;
3. a biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature.

(3) The biological material referred to in paragraph (2) of this Article shall be any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

(4) According to the conditions set out in paragraph (1) of this Article, an invention which concerns plants or animals shall be considered patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety and if the process for carrying out the invention is not essentially biological.

(5) A process for the production of plants and animals referred to in paragraph (4) of this Article is essentially biological if it entirely consists of natural processes such as crossing or selection.

(6) The following in particular shall not be considered to be the inventions within the meaning of paragraph (1) of this Article:

1. discoveries, scientific theories and mathematical methods,

*Article 6*

Excluded from patent protection shall be:

1. inventions which concern animal breeds, plant varieties and essentially biological processes for the production of plants or animals, with the exception of inventions which concern non-biological and microbiological processes and products resulting from such processes, as provided for in Article 5, paragraph (4) of this Act; a microbiological process shall imply, under this Act, any process involving or performed upon or resulting in microbiological material.

2. the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene. An invention relating to an element isolated from the human body or otherwise produced by means of a technical process,

including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as originally filed.

CYPRUS: *Article 5 (2) (a) of the Patent Law N° 16(1) of 01/04/1998*

5. (2) The following, in particular, shall not be regarded as inventions within the meaning of paragraph (1):

(a) discoveries, scientific theories and mathematical methods;

CZECH REPUBLIC: *Sections 3 (2) (a), (3) and (4) and 4 (b) of the Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of November 27/11/1990 as last amended by Law No. 116 of 06/04/2000 and Act No. 206/2000 Coll. of 21/06/2000 on the Protection of Biotechnological Inventions*

Patentability of Inventions

3 (2) The following shall not be regarded as inventions:

(a) discoveries, scientific theories and mathematical methods;

Exclusions from Patentability

4 - Patents shall not be granted in respect of:

(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and products thereof.

*Section 2 of the Act No. 206/2000 Coll. of 21/06/2000 on the Protection of Biotechnological Inventions*

Section 2

Patentable biotechnological inventions

Biotechnological inventions are patentable, if they concern

a) biological material, which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,

b) plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety, or

c) microbiological or other technical process and a product, other than a plant or animal variety, obtained by this way.

DENMARK: *Sections 1 (2) (i), (5) and (6) and 1a of the Consolidated Patent Act No.91 of 28/01/2009*

1 (2) In particular the following subject-matter or activities as such shall not be regarded as inventions:  
(i) discoveries, scientific theories and mathematical methods,

(5) Patents shall not be granted in respect of essentially biological processes for the production of plants or animals. In this Act an "essentially biological process" means a process consisting entirely of natural phenomena such as crossing or selection.

Patents may, however, be granted for microbiological processes or other technical processes or products obtained by such processes. In this Act a "microbiological process" means any process involving microbiological material, performed on microbiological material or resulting in microbiological material.

(6) Inventions may be patentable even if they relate to a product consisting of or containing biological material or to a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical

process may be the subject-matter of an invention even if it previously occurred in nature. In this Act "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

1a. (1) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) Notwithstanding subsection 1 an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

*DJIBOUTI: Articles 26 (a) and (c) and 27(a) of the Protection of Industrial Property Law No.50/AN/09/6th L of 21/06/2009*

*Article 26*

Ne sont pas considérées comme des inventions :

- a) les découvertes, les substances, matières et organismes tels qu'ils existent dans la nature, ainsi que leurs parties ou éléments;
- c) le corps humain et les matières qui composent le corps humain, .aux différents stades de sa constitution et de son développement ainsi que ses éléments y compris la séquence ou la séquence partielle d'un gène;

*Article 27*

Ne sont pas brevetables :

- a) les végétaux et les animaux autres que les microorganismes;

*DOMINICA: Section 12(1) (a) of the Patents Act No. 8 of 07/10/1999*

12. (1) The following, even if they are inventions within the meaning of this Act, shall not be protected as patents

- (a) a discovery, scientific theory or mathematical method;

*DOMINICAN REPUBLIC: Article 2 (1) (a) and (g) of the Industrial Property Law No. 20-00 of 08/05/2000*

*Article 2*

Items excluded from Protection by Patent of Invention

1) That which does not fall within the definition of Article 1 of this Law is not considered to be an invention, and thus are excluded from protection by patent of invention. The following, in particular, are not considered inventions:

a) Discoveries that consist of making known something which already exists in nature, scientific theories and mathematical methods.

g) All kinds of living matter and substances preexisting in nature.

*EGYPT: Article 2 (2), (4) and (5) of the Law on the Protection of Intellectual Property Rights No 82 of 03/06/2002*

*Article 2*

Patents shall not be granted for:

- (2) Discoveries, scientific theories, mathematical methods, programs and schemes.

(4) Plants and animals, regardless of their rarity or peculiarity, and essentially biological processes for the production of plants or animals, other than microorganisms, non-biological and microbiological processes for the production of plants or animals.

(5) Organs, tissues, live cells, natural biological substances, nuclear acid and genome.

EL SALVADOR: *Article 105 (a) of the Intellectual Property Legislative Decree No. 604 of 15/07/1993 No. 604 as last amended by Legislative Decree No. 912 of 14/12/2005*

*Article 107*

Patents shall not be available for the following:

(a) discoveries, scientific theories and mathematical methods;

ESTONIA: *§ 6(1), (2.1) and (3) and 7 of the Patent Act (RT I 1994, 25, 406) of 16/03/1994 as last amended by Law RT I 2004, 20, 141 of 10/03/2004*

§ 6. Subject of invention

(1) The subject of an invention may be a device, process, material, including biological material, or a combination thereof.

(2) The following, inter alia, shall not be regarded as the subject of inventions:

1) discoveries, including descriptions of the formation or development of the human body or sequence or partial sequence of human gene, scientific theories and mathematical methods;

(3) For the purposes of this Act, "biological material" means any material, including micro-organisms, which contains genetic information and is capable of reproducing itself or being reproduced in a biological system.

§ 7. Unpatentable inventions

(2) The following biotechnological inventions shall not be protected by a patent:

1) processes for cloning human beings;

2) processes for modifying the germ line genetic identity of human beings;

3) uses of human embryos for commercial purposes, including processes prohibited by the Artificial Insemination and Embryo Protection Act ;

4) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and animals resulting from such processes;

5) essentially biological processes for the derivation of biological materials or the production of plant or animal varieties, except microbiological processes for the derivation of micro-organisms;

6) inventions the application of which is confined to a single plant or animal variety.

(3) For the purposes of this Act, "essentially biological process for the derivation of a biological material or production of plant or animal varieties" means a process which consists entirely of natural phenomena, including crossing and selection.

(4) For the purposes of this Act, "microbiological process" means any process involving or performed upon or resulting in microbiological material.

ETHIOPIA: *Section 4(1) (b) and (d) of the Proclamation concerning Inventions, Minor Inventions and Industrial Designs No. 123 of 10/05/1995*

4. Non-Patentable inventions

1. The following shall not be patentable:

b) Plant or animal varieties or essentially biological processes for the production of plants or animals.

d) Discoveries, scientific theories and mathematical methods.

FINLAND: Sections 1 (2.1), (5) and (6) and 1a of the Patents Act No. 550 of 15/12/1967 as last amended by Act No. 684 of 21/07/2006

Section 1

2. The following, as such, shall not be regarded as inventions:

(1) discoveries, scientific theories and mathematical methods;

5. Patents shall not be granted for essentially biological processes for the production of plants or animals. For the purposes of this Act a process for the production of plants or animals shall be considered essentially biological if it consists entirely of natural phenomena such as crossing or selection. What is said above shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process. For the purposes of this Act 'microbiological process' means any process involving or performed upon or resulting in microbiological material.

6. Inventions shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. For the purposes of this Act 'biological material' means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

Section 1 a

The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may, without prejudice to the provisions of subsection (1), where the requirements for patentability are fulfilled, constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

FRANCE: Articles L611-10 (2) (a) and (4) and L611.18-L611.19 (3) of the Intellectual Property Code No. 92-597 of 01/07/1992 (Consolidated version of 2010)

Article L611-10

2. Ne sont pas considérées comme des inventions au sens du premier alinéa du présent article notamment :

a) Les découvertes ainsi que les théories scientifiques et les méthodes mathématiques ;

4. Sous réserve des dispositions des articles L. 611-16 à L. 611-19, sont brevetables aux conditions prévues au 1 les inventions portant sur un produit constitué en totalité ou en partie de matière biologique, ou sur un procédé permettant de produire, de traiter ou d'utiliser de la matière biologique.

Est regardée comme matière biologique la matière qui contient des informations génétiques et peut se reproduire ou être reproduite dans un système biologique.

Article L611-18

Le corps humain, aux différents stades de sa constitution et de son développement, ainsi que la simple découverte d'un de ses éléments, y compris la séquence totale ou partielle d'un gène, ne peuvent constituer des inventions brevetables.

Seule une invention constituant l'application technique d'une fonction d'un élément du corps humain peut être protégée par brevet. Cette protection ne couvre l'élément du corps humain que dans la mesure nécessaire à la réalisation et à l'exploitation de cette application particulière. Celle-ci doit être concrètement et précisément exposée dans la demande de brevet.

Ne sont notamment pas brevetables :

- a) Les procédés de clonage des êtres humains ;
- b) Les procédés de modification de l'identité génétique de l'être humain ;
- c) Les utilisations d'embryons humains à des fins industrielles ou commerciales ;
- d) Les séquences totales ou partielles d'un gène prises en tant que telles.

*Article L611-19*

III. - Les dispositions du 3° du I n'affectent pas la brevetabilité d'inventions ayant pour objet un procédé technique, notamment microbiologique, ou un produit obtenu par un tel procédé ; est regardé comme un procédé microbiologique tout procédé utilisant ou produisant une matière biologique ou comportant une intervention sur une telle matière.

*GEORGIA: Sections 16 (a) and 17 (c) of the Patent Law of 05/02/1999*

16. The following shall not be regarded as an invention, or utility model:

(a) a discovery, scientific theory, or mathematical method;

17. A patent is not granted:

(c) for the invention relating to the varieties of plants and breeds of animals, as well as for particularly biological methods for raising varieties of plants and breeds of animals. This rule does not extend on micro-biological methods and products obtained through these methods;

*GERMANY: Sections 1(2) and (3.1), 1a, 2a (2.2) and (3) of the Patent Act of 16/12/1980 as last amended by Act of 31/07/2009*

Section 1

(2) Patents shall be granted for inventions within the terms of subsection (1) even if the subject matter concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material that has been isolated from its natural environment or produced by means of a technical process may be the subject matter of an invention even if it had previously occurred in nature.

(3) In particular, the following shall not be regarded as inventions within the terms of subsection (1):  
1. discoveries, scientific theories and mathematical methods;

Section 1a

(1) The human body at its various stages of formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute a patentable invention.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene shall have to be specifically disclosed in the application by indicating the function fulfilled by the sequence or partial sequence.

(4) Where the subject matter of an invention is a sequence or a partial sequence of a gene, the structure of which is identical to the structure of a natural sequence or partial sequence of a human gene, the use thereof, for which industrial application is specifically described in subsection (3), shall have to be included in the patent claim.

#### Section 2a

(2) Patents can be granted for inventions

2. having as subject matter a microbiological or other technical process or a product obtained by means of such a process, unless a plant or animal variety is concerned.  
Section 1a(3) shall apply *mutatis mutandis*.

(3) In accordance with this Act:

1. "biological material" shall denote any material containing genetic information and capable of reproducing itself or being reproducible in a biological system;
2. "microbiological process" shall denote any process involving the use of or intervention in microbiological material or by which microbiological material results;
3. "an essentially biological process" shall denote any process for breeding plants or animals based entirely on natural phenomena such as crossing or selection;

*GHANA: Section 1(3) (a) and (b) of the Patent Law No. 305A of 30/12/1992*

1 (3) The following shall not be regarded as inventions within the meaning of subsection (1) of this section:

- (a) discoveries, scientific and mathematical theories;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such processes;

*GREECE: Article 5 (2) (a) and (8) (b) of the Law on "Technology transfer, inventions, and technological innovation" No. 1733/1987 (FEK 171, A' of 22/9/1987) as last amended by Law No. 2359 of 15/11/1995*

#### *Article 5*

2. The following shall not be regarded as inventions within the meaning of paragraph 1:  
a. discoveries, scientific theories, and mathematical methods;

8. Patents shall not be granted in the following cases:

b. plant or animal varieties or biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

*GRENADA: Section 3 (3) (a) of the Industrial Property Act of 2002*

(3) The following, even if they are inventions, are excluded from patentability -

(a) a discovery, scientific theory or mathematical method;

*GUATEMALA: Articles 91 (a), (b) and (c) of the Industrial Property Law, Decree No. 57-2000 of 18/09/2000*

Materia que no constituye Invención

91. No constituirán invenciones, entre otros:

- a) Los simples descubrimientos;
- b) Las materias o las energías en la forma en que se encuentran en la naturaleza;

- c) Los procedimientos biológicos tal como ocurren en la naturaleza y que no supongan intervención humana, salvo los procedimientos microbiológicos;
- d) Las teorías científicas y los métodos matemáticos;

HONDURAS: *Articles 5 (3) and (4) and 7 (1) of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

*Artículo 5*

No se considerará invención, y en tal virtud quedará excluida de protección por patente:

3) Los descubrimientos que consistan en dar a conocer o revelar algo que ya existía en la naturaleza, aún cuando anteriormente fuese desconocido para el hombre;

4) El material biológico que existe en la naturaleza;

*Artículo 7*

No serán patentables:

1) los procesos esencialmente biológicos para la obtención o reproducción de plantas, animales o sus variedades, incluyendo los procesos genéticos relativos a material capaz de conducir su propia duplicación, por si mismo o por cualquier otra manera indirecta, cuando consistan en seleccionar o aislar material biológico disponible y dejarlo que actúe en condiciones naturales;

HUNGARY: *Articles 1(2) (a) and 5a of the of the Act XXXIII of 1995 on the protection of inventions by patents (Consolidated text of 01.04.2010)*

Patentable inventions

*Article 1*

(2) The following in particular shall not be regarded as inventions within the meaning of paragraph (1):  
(a) discoveries, scientific theories and mathematical methods,

Patentable biotechnological inventions

*Article 5/A*

(1) Inventions meeting the requirements of Article 1 to 5 shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material means any material containing genetic information which is capable of reproducing itself or being reproduced in a biological system.

(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

(3) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(4) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

ICELAND: *Articles 1 (2.1), (5) and (6) and 1a of the Patents Act No. 17/1991 as last amended by Law no. 167/2007*

*Article 1*

(2) The principal innovations which are not considered to be inventions are those which concern exclusively:

1. a discovery, scientific theory or mathematical method;

(5) A patent shall not be granted on an essentially biological process for producing plants or animals. By an essentially biological process, this Act refers to a method that on the whole is based on natural phenomena such as crossing and selection. Nonetheless, patents may be granted for processes in the field of microbiology or other technical methods or the products of such processes. Process in the field of microbiology refers to any method that exploits microbiological material or produces microbiological material.

(6) An invention may be patentable even though it involves a product consisting of or containing biological material, or pertains to a method for producing, processing or using biological material. Biological material which has been isolated from nature or produced by a technical process may be considered an invention, even if it is found in nature. In this Act, biological material refers to material containing genetic information and capable of reproducing itself or being reproduced in a biological system.]

*Article 1 a*

The human body in its various stages of formation or development and the mere discovery of any of its elements, such as nucleotide sequences or partial nucleotide sequences of genes, cannot be considered patentable inventions.

Notwithstanding Paragraph 1, an element of the human body, including a nucleotide sequence or partial nucleotide sequence of a gene, which is isolated from the body or produced in another way by a technical process may be considered a patentable invention even if the structure of such an element is identical to the structure of a natural element.

INDIA: *Section 3 (c) and (j) of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005*

3. What are not inventions

The following are not inventions within the meaning of this Act;

c) the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;

j) plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species essentially biological processes for production or propagation of plants and animals;

INDONESIA: *Article 7(d) of the Law on Patents No. 14 of 01/08/2001*

*Article 7*

A Patent shall not be granted to an Invention regarding:

- d. i. all living creatures, except micro-organism
- ii. any biological process which is essential in producing plant or animal, except non- biological process or microbiological process.

IRELAND: *Sections 9 (2)(a) and 10 (1) (b) of the Patent Act No. 1 of 1992 as last amended by Act no. 31 of 2006 and the European Communities (Legal Protection of Biotechnological Inventions) Regulations of 2000*

9 (2) Any of the following in particular shall not be regarded as an invention within the meaning of subsection (1):

(a) a discovery, a scientific theory or a mathematical method,

10 (1) A patent shall not be granted in respect of

(b) a plant or animal variety or an essentially biological process for the production of plants or animals other than a microbiological process or the products thereof;

*Sections 4 and 5 of the European Communities (Legal Protection of Biotechnological Inventions) Regulations of 2000*

4. (1) An invention that complies with section 9(1) of the Act of 1992 is patentable even if it concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(2) Biotechnological inventions shall be patentable, in particular, if they concern

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature,

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety, or

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

5. (1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, shall not be patentable.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) If an invention concerns the sequence or partial sequence of a gene the industrial application thereof shall be disclosed in the patent application as filed.

*IRAN: Article 4 (a) and (d) of the Patents, Industrial Designs and Trademarks Registration Act of 29/10/2007*

*Article 4*

The following shall be excluded from the scope of the protection of a patent:

a) Discoveries, scientific theories, mathematical methods and works of art;

d) Genetic resources and genetic components comprising the same, as well as biological processes for the production of the same.

*ISRAEL: Section 7(2) of the Patents Law No. 5727 of 08/08/1967*

Restriction on granting of patents]

7. Notwithstanding the provisions of section 2, no patent shall be granted for-

(2) new varieties of plants or animals, except microbiological organisms not derived from nature.

*ITALY: Article 45 (2)(a) and (5) of the Code of the Industrial Property, Legislative Decree No. 30 of 15/02/2005 and Article 3 of the Decree-Law No. 3 of 2006*

*Article 45*

Oggetto del brevetto

2. Non sono considerate come invenzioni ai sensi del comma 1 in particolare:

a) le scoperte, le teorie scientifiche e i metodi matematici;

5. Non possono costituire oggetto di brevetto le razze animali ed i procedimenti essenzialmente biologici per l'ottenimento delle stesse. Questa disposizione non si applica ai procedimenti microbiologici ed ai prodotti ottenuti mediante questi procedimenti.

*Article 3 - DL no. 3/2006*  
Brevettabilita'

1. Sono brevettabili purché abbiano i requisiti di novità e originalità e siano suscettibili di applicazione industriale

a) un materiale biologico, isolato dal suo ambiente naturale o prodotto tramite un procedimento tecnico, anche se preesistente allo stato naturale;

b) un procedimento tecnico attraverso il quale viene prodotto, lavorato o impiegato materiale biologico, anche se preesistente allo stato naturale;

c) qualsiasi applicazione nuova di un materiale biologico o di un procedimento tecnico già brevettato;

d) un'invenzione relativa ad un elemento isolato dal corpo umano o diversamente prodotto, mediante un procedimento tecnico, anche se la sua struttura è identica a quella di un elemento naturale, a condizione che la sua funzione e applicazione industriale siano concretamente indicate, descritte e specificatamente rivendicate. Per procedimento tecnico si intende quello che soltanto (( l'essere umano )) è capace di mettere in atto e che la natura di per se stessa non è in grado di compiere;

e) un'invenzione riguardante piante o animali ovvero un insieme vegetale, caratterizzato dall'espressione di un determinato gene e non dal suo intero genoma, se la loro applicazione non è limitata, dal punto di vista tecnico, all'ottenimento di una determinata varietà vegetale o specie animale e non siano impiegati, per il loro ottenimento, soltanto procedimenti essenzialmente biologici, secondo le modalità previste dall'articolo 5, comma 6.

*JORDAN: Article 4 (4), (6) and (7) of the Law on Patents of Invention No. 32 for the Year 1999(as last amended by Law No. 71 of 2001)*

*Article 4*

A patent shall not be granted in the following cases:

(4) Discoveries, scientific theories and mathematical methods.

(6) Plants and animals other than microorganisms.

(7) Biological methods for the reproduction of plants and animals other than non-biological and microbiological methods.

*KAZAKHSTAN: Article 6(3) of the Patent Law of 16/07/1999*

6. (3) The following shall not be recognized as patentable inventions:

- discoveries, scientific theories and mathematical methods;

*KENYA: Section 21 (3) (a) of the Industrial Property Act No. 3 of 27/07/2001*

21-(3) The following shall not be regarded as inventions and shall be excluded from patent protection:

(a) discoveries, scientific theories and mathematical methods;

*LAO'S PEOPLE DEMOCRATIC REPUBLIC: Section 21 of the Intellectual Property Laws No. 08/NA of 24/12/2007*

Section 21 - Invention and Devices which are not eligible for patent and petty patent

The invention and devices which are not eligible for granting patent and petty patent are discovery of invention already existed, discovery of scientific rules and theories, mathematics, business plans, regulations or methods, mental treatments or gambles, human and animal treatment, microorganisms and any components of natural microorganisms or extracts from animals or plants; the invention and devices contrary to state peaces and social order, health, environments, rules and laws, and national good traditional cultures.

LATVIA: *Sections 9 (1) and (2.1) and 10 of the Patent Law of 15/02/2007*

#### Section 9 - Subject-matter of an Invention and Non-patentable Subject-matter

(1) The subject-matter of an invention may be a device, method, substance, composition of substances, or biological material.

(2) Within the meaning of this Law, the following shall not be considered as inventions:

1) discoveries, scientific theories and mathematical methods;

#### Section 10 - Biotechnological Inventions

(1) A patent shall be granted to biotechnological inventions, which:

1) contain biological material, which is isolated from its natural environment or produced by means of a technical method, even if it previously occurred in nature;

2) pertain to plants or animals, if the technical feasibility of the invention does not confine itself to a particular plant or animal variety; and

3) pertain to microbiological or other technical method, or to the product obtained by means of such method, if it is not a plant or animal variety.

(2) A patent shall not be granted to plant or animal varieties or basically biological methods for the production of plant or animal varieties.

(3) In accordance with Section 9, Paragraph four of this Law, a patent shall not be granted to biotechnological inventions that pertain to:

1) human cloning;

2) modification of the genetic identity of human beings in germ cells;

3) use of human embryos for industrial or commercial purposes; and

4) methods for modifying the genetic identity of animals, which are likely to cause them suffering without any substantial medical benefit to people or animals, as well as animals resulting from such methods.

(4) A human body in different stages of formation and development and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot be patented.

(5) An element, which has been isolated from the human body or produced otherwise with a technical method, including the sequence or partial sequence of a gene, may be patented, even if the structure of this element is identical to the natural element.

(6) The industrial application of the sequence or partial sequence of a gene must be disclosed in the patent application.

LEBANON: *Articles 3 (1) of the Patent Law No. 240 of 14/08/2000*

*Article 3*

A patent is not to be granted to:

1. Scientific discoveries and theories and absolute mathematical methods that are not industrially applicable.

LIBERIA: *Section 8 (3)(I) of the Industrial Property Act of 20/03/2003*

(3) The following, even if they are inventions within the meaning of subsection (2), shall be excluded from patent protection

(I) discoveries, scientific theories and mathematical methods,

LIECHTENSTEIN: *Article 1a (II) of the Federal Patent Law of 25/06/1954 as last amended on 24/03/1995*

*Article 1a*

II. Cas spéciaux

Il n'est pas délivré de brevets d'invention pour les variétés végétales ou les races animales ni pour les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux ; toutefois les procédés micro-biologiques et les produits obtenus par ces procédés sont brevetables.

LITHUANIA: *Article 2(2) 1 and 5, (3.2) and (5) of the Patent Law No. I-372 of 18/01/1994 as last amended by Law No. X-1119 of 10/05/2007*

*Article 2*

Patentable Inventions

(2) The following shall not be regarded as inventions:

1) discoveries, scientific theories and mathematical methods;

5) the human body or its element, including the sequence or partial sequence of a gene, at the various stages of its formation and development. This provision shall not apply to an element isolated from the human body or otherwise produced by means of a technical process, as well as to the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

(3) Patents shall not be granted for:

2) plant or animal varieties or essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes for the production of plants or animals or the products thereof, as well as to plants or animals, if technical implementation of the invention is not restricted to a concrete plant or animal variety;

(5) inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used, may be recognized as patentable. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

LUXEMBOURG: *Articles 4 (2) (a) and 5 (2) of the Patent Act of 20/07/1992*

*Article 4*

Inventions brevetables

2. Ne sont pas considérés comme des inventions au sens du paragraphe 1er notamment :

a) les découvertes ainsi que les théories scientifiques et les méthodes mathématiques ;

*Article 5*

Exceptions à la brevetabilité

Sont exclues de la protection prévue par la présente loi :

2) les variétés végétales ou les races animales ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux, cette disposition ne s'appliquant pas aux procédés microbiologiques et aux produits obtenus par ces procédés.

*MALAYSIA: Section 13(1) (a) and (b) of the Patents Act No. 291 of 1983 as last amended by Act No. 1264 of 2006*

*Section 13*

Non-patentable inventions.

(1) Notwithstanding the fact that they may be inventions within the meaning of section 12, the following shall not be patentable:

(a) discoveries, scientific theories and mathematical methods;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than man-made living micro-organisms, micro-biological processes and the products of such micro-organism processes;

*MALTA: Articles 4 (1), (2) (a) and (5) (b), (f) and (g) of the Patents and Designs Act, Chapter 417, of 01/06/2002 as last amended by Act XVIII of 2005*

4. (1) Inventions which are new, involve an inventive step and are susceptible of industrial applications, shall be patentable:

Provided that such inventions shall also be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used:

Provided further that biological material which is isolated from its natural environment or produced by means of a technical process may be subject of an invention if it previously occurred in nature.

(2) The following, in particular, shall not be regarded as inventions within the meaning of subarticle (1):

(a) discoveries, scientific theories and mathematical methods;

(5) A patent shall not be granted in respect of:

(b) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene:

Provided that an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element;

(f) essentially biological process of the production of plants or animals:

Provided that this is without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process;

(g) DNA sequence not containing any technical information and in particular any indication of its function.

MAURITIUS: *Article 11 (3) (a) and (f) of the Patents, Industrial Designs and Trademarks Act No. 25 of 2002*

(3) The following, even if they are inventions within the meaning of subsection (1), shall be excluded from patent protection:

(a) discoveries, scientific theories and mathematical methods;

(f) essentially biological processes for the production of plants and animals;

MEXICO: *Articles 16 (I), (II) and (IV) and 19 (II) of the Industrial Property Law of 25/06/1991 as last amended on 06/12/2005*

*Article 16*

Inventions that are new, the result of an inventive step and industrially applicable under the terms of this Law shall be patentable, with the exception of:

I. essentially biological processes for obtaining, reproducing and propagating plants and animals;

II. biological and genetic material as found in nature;

IV. the human body and the living matter constituting it;

*Article 19*

The following shall not be considered inventions for the purposes of this Law:

II. discoveries that consist in making known or revealing something that already existed in nature, even though it was previously unknown to man;

MONGOLIA: *Article 4 (5) 1) and 6) of the Patent Law of 25/06/1993, as last amended in 1999*

5. The followings shall not be considered to be inventions:

1) discoveries, scientific theories and mathematical methods;

6) biological processes for the production of animals, or plants other than micro-organisms. This shall not include non-biological, and microbiological processes;

MOROCCO: *Article 23 1) of the Law No. 17-97 concerning Protection of Industrial Property as implemented by Law No. 31-05 of 02/03/2006*

*Article 23*

Ne sont pas considérées comme des inventions au sens de l'article 22 ci-dessus:

1) les découvertes ainsi que les théories scientifiques et les méthodes mathématiques;

MOZAMBIQUE: *Article 30 (1) (b) and (2) (b) of the Industrial Property Code, Decree No. 04 of 12/04/2006*

*Article 30*

Exceptions to patentability

1. The following shall not be considered inventions for the purposes of this diploma:

b) Discoveries aimed at making known or revealing something which already exists naturally, notwithstanding that it was heretofore unknown to man;

2. The following are excluded from patent protection:

b) All or part of living beings, although microbiological processes and products obtained from such processes are patentable.

*NAMIBIA: Article 8 (a) and (c) of the Industrial Property Act of 1999*

Matters excluded from patent protection

8. The following, even if they are inventions in terms of section 1, shall be excluded from patent protection -

(a) discoveries, scientific theories and mathematical methods;

(c) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such processes.

*NETHERLANDS: Articles 2 (2)(a), 2a and 3 (1) (b) and (d) of the Patents Act of 15/12/1995(Text as it applies on 03/06/2009)*

*Article 2*

2. The following in particular shall not be regarded as inventions within the meaning of the first paragraph:

a. discoveries, as well as scientific theories and mathematical methods;

*Article 2a*

1. The inventions referred to in Article 2(1) are also taken to mean inventions that relate to a product that consists of or contains biological material or that relates to a process through which biological material is obtained, processed or used.

2. Inventions within the meaning of the first paragraph in any event include inventions with respect to:

a. biological material that is isolated from its natural environment or is obtained using a technical process, even if that material occurs in nature;

b. a part of the human body that is isolated or that is otherwise obtained using a technical process, including a sequence or partial sequence of a gene, even if the structure of that part is identical to that of a natural part;

c. plants or animals, provided that the practicability of that invention is not technically limited to certain plant or animal varieties; or

d. a microbiological or other technical process through which biological material is obtained, processed or used, or a product obtained using such a process.

*Article 3*

1. No patent shall be issued for:

b. the human body in its various stages of its formation and its development, as well as the sole discovery of one of its parts, including a sequence or partial sequence of a gene;

d. essentially biological processes consisting entirely of natural phenomena such as hybridisations or selections in order to produce plants or animals and the products obtained thereby;

*NICARAGUA: Article 6 (a), (b) and (c) of the Law on Patents, Utility Models and Industrial Designs No. 354 of 19/09/2000 as last amended by Law No. 634 of 13/09/2007*

Subject Matter not Constituting an Invention

6. The following among other things shall not constitute inventions:

(a) mere discoveries;

(b) material or energy in the form in which it is found in nature;

(c) biological processes as occurring in nature which do not entail human intervention for the production of plants and animals, with the exception of microbiological processes;

*NORWAY: Sections 1 (2) 1), (3) and (5), 1a and 3c of the Patents Acts No.9 of 15/12/1967 as last amended by Act No.80 of 29/06/2007*

#### Section 1

(2) Subject matters not regarded as inventions include anything which merely consists of:

1. discoveries, scientific theories and mathematical methods;

(3) Inventions may also constitute patentable inventions when they concern a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used. Biological material, which is isolated from its natural environment or produced by means of a technical process, may be the subject of an invention even if it already occurs in nature. Biological material means, for the purpose of this legal text, material that contains genetic information, and can reproduce itself or be reproduced in a biological system.

(5) A patent cannot be granted for what are essentially biological processes to produce plants or animals. An essentially biological process means, for the purpose of this legal text, a process, which consists entirely of natural phenomena such as crossing or selection. A patent may, on the other hand, be granted for microbiological or other technical processes or for a product produced by such processes.

A microbiological process means, for the purpose of this legal text, any process involving, performed upon or resulting in the production of microbiological material.

Section 1 a. The human body, at all of the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

An element which is isolated from the human body or otherwise produced by means of a technical process, including the sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a naturally existing element.

Section 3 c. The protection conferred by a patent on biological material, which already exists in nature, shall only extend to the part of the material that is necessary for the industrial application specified in the patent application. It shall be evident from the patent application how the biological material may be used for industrial purposes.

*OMAN: Article 2 (1) (a) and (d) of the Law on Industrial property Rights, Royal Decree No. 67 of the 2008*

#### *Article (2)*

1- The following shall be excluded from patent protection:

a) Discoveries, scientific theories and mathematical methods

d) Natural substances; this provision shall not apply to the processes of isolating those natural substances from their original environment.

*PAKISTAN: Section 7 (2) (a) and (e) and (4) (b) of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

7.-(2) Subject to sub-section (3), the following shall not be regarded as invention within the meaning of sub-section (1), namely:-

(a) a discovery, scientific theory or mathematical method;

(e) substances that exist in nature or if isolated therefrom

(4) A patent shall not be granted

(b) for plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes;

PANAMA: *Articles 14 2) and 15 1), 3) and 4) of the Law No. 35 of 10/05/1996 Enacting Provisions on Industrial Property*

14. The following in particular shall not be considered inventions for the purposes of this Law:

2. discoveries that consist in publicizing or revealing something that already existed in nature, even where previously unknown;

15. The following inventions relating to live material are excluded from patentability:

1. essentially biological means of breeding or propagating plants, animals or varieties or breeds thereof insofar as DIGERPI considers them a violation of morality or the integrity or dignity of mankind;

3. biological material as encountered in nature;

4. live material that forms part of the human body;

PARAGUAY: *Articles 4 and 5 of the Patents Law No. 1630 of 29/11/2000*

*Artículo 4°.- De las materias excluidas como invención. No se considerará invención, entre otras, las siguientes:*

- los simples descubrimientos, las teorías científicas y los métodos matemáticos;

*Artículo 5°.- De las materias excluidas de protección por patente. Son materias excluidas de protección por patente:*

- las plantas y los animales, excepto los microorganismos y los procedimientos esencialmente biológicos para la producción de plantas o animales, que no sean procedimientos no biológicos o microbiológicos.

PHILIPPINES: *Sections 22 (1) and (4) of the Intellectual Property Code, Act No. 8293 of 06/06/1997 as last amended by Act No. 9502 of 2008*

Non-Patentable Inventions

22. The following shall be excluded from patent protection:

1. Discoveries,(...);

4. Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to micro-organisms and non-biological and microbiological processes.

Provisions under this subsection shall not preclude Congress to consider the enactment of a law providing sui generis protection of plant varieties and animal breeds and a system of community intellectual rights protection:

POLAND: *Articles 28 (i), 29(1) (ii) and (2) and 93<sup>1</sup>- 93<sup>3</sup> of the Industrial Property Law of 30/06/2000, as last amended by Act of 29/06/2007*

*Article 28*

The following in particular shall not be regarded as inventions within the meaning of Article 24:

- (i) discoveries, scientific theories and mathematical methods,

*Article 29*

1. Patents shall not be granted for:

- (ii) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof,

2. The process for the production of plants or animals, referred to in section (1)(ii), is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

*Article 93<sup>1</sup>*

Any reference in this Chapter:

- (i) to "biotechnological invention" means the invention, within the meaning of Article 24, concerning a product consisting of or containing biological material, or a process by means of which biological material is produced, processed or used,

- (ii) to "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system,

- (iii) to "microbiological process" means any process involving or performed upon or resulting in microbiological material.

*Article 93<sup>2</sup>*

1. The following, in particular, shall be considered as biological inventions eligible for patent protection:

- (i) inventions, the subject of which is biological material which is isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature,

- (ii) elements isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element,

- (iii) inventions which concern plants or animals, if the technical feasibility of the invention is not confined to a particular plant or animal variety.

2. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

*Article 93<sup>3</sup>*

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. The following, in particular, shall be considered as biotechnological inventions, whose exploitation would be contrary to Public order or morality within the meaning of Article 29(1)(i), or with public morality:

- (i) processes for cloning human beings,

- (ii) processes for modifying the germ line genetic identity of human beings,

- (iii) uses of human embryos for industrial or commercial purposes,

- (iv) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

PORTUGAL: *Articles 52 (1) (a) and (b), 53 (3) (a) and (b), 54 (1) (c), (e) and (f), (2), (3) and (4) of the Industrial Property Code, Decree-Law No. 36 of 05/03/2003 as last amended by Law No. 16 of 01/04/2008*

*Article 52*

Limitations on object

1 The following are exceptions to the previous article:

- a) Discoveries, scientific theories and mathematical methods;
- b) Materials or substances already existing in nature and nuclear materials;

*Article 53*

Limitations on patent

3 The following are also not patentable:

- a) The human body, at the various stages of its formation and development and the simple decoding of one of its elements, including the discovery of a sequence or partial sequence of a gene, without prejudice to (1)(c) of the following article;
- b) Plant and animal varieties and essentially biological processes for obtaining plants or animals;

*Article 54*

SPECIAL CASES OF PATENTABILITY

1 The following may be patented:

c) A new invention that involves an inventive step and is susceptible of industrial application relating to any isolated element of the human body or produced in any other way by a technical process, including a sequence or partial sequence of a gene, even though the structure of this element is identical to that of a natural element, provided that the industrial application of a sequence or partial sequence of a gene is expressly observed and specifically described in the patent application;

e) A biological material isolated from its natural environment or produced on the basis of a technical process, even if it pre-exists in a natural state;

f) An invention relating to a microbiological process or other technical processes or products obtained by means of these processes.

2 An essentially biological process for obtaining plants or animals is any process that consists wholly of natural phenomena, such as crossing or selection.

3 A microbiological process is any process involving or performed upon or resulting in microbiological material.

4 Biological material is any material that contains genetic information and is capable of reproducing itself or being reproduced in a biological system.

QATAR: *Article 4 (b) of the Patent Law no. 30 of 2006*

*Article 4*

The patent subject may be in the form of material product, an industrial process or a manufacturing technique.

Subject to the law hereby, patentability shall not include:

- b) Plants and animals researches, and essentially biological processes for the production of plants or animals other than microbiological processes and its productions;

REPUBLIC OF MOLDOVA: *Articles 6 (2) (a) and (4) and 7 (1) (c) and (d) and (2) of the Law on the protection of Inventions No. 50-XVI of 07/03/ 2008*

*Article 6*

Patentable Inventions

(2) The following shall not be regarded as inventions within the meaning of paragraph (1):

a) discoveries, scientific theories and mathematical methods;

(4) Inventions in the field of biotechnology shall be deemed patentable if they concern:

a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

c) a microbiological process or other technical process, or a product obtained by means of such a process other than a plant or animal variety;

d) an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

*Article 7*

Exceptions to Patentability

(1) Patents shall not be granted within the meaning of this Law in respect of:

c) essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

d) inventions concerning the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

(2) Patents shall not be granted within the meaning of paragraph 1(a) in respect of biotechnological inventions which, in particular, concern the following:

a) processes for cloning human beings;

b) processes for modifying the germ line genetic identity of human beings;

c) uses of human embryos for industrial or commercial purposes;

d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

ROMANIA: *Articles 7 (2) (a), (c) and (d), 8 (a) and 9 (b) and (c) of the Patent Law No. 64/1991 as republished in the OJ, Part I, No. 638/18.IX.2007*

*Article 7*

Inventions in the field of biotechnology shall be patentable if they relate to:

a) biological material which is isolated from its natural environment or produced by any technical process, even if it previously occurred in nature;

c) a microbiological process or other technical process or a product, other than a plant variety or animal breed, obtained by means of said process;

d) an element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical to that of a natural element.

*Article 8*

The following in particular shall not be considered as inventions, within the meaning of Article 7:

a) discoveries, scientific theories and mathematic methods;

*Article 9*

Patents shall not be granted under this Law in respect of:

b) plant varieties and animal breeds, as well as the essentially biological processes for the production of plants or animals. This provision shall not apply to microbiological processes or products obtained thereby;

c) the inventions having as a subject-matter the human body in its various stages of formation and development, as well as the mere discovery of one of its elements, including the sequence or partial sequence of a gene;

RUSSIAN FEDERATION: *Article 1350 (5) 1) and (6) 1) of the Patent Act (Chapter 72)*

*Article 1350 - Conditions of Patentability of an Invention*

5. The following shall not be deemed inventions:

1) discoveries;

6. Legal protection as inventions shall not be granted to:

1) varieties of plants, breeds of animals and biological methods of obtaining thereof with the exception of microbiological methods and products obtained by the use of such methods;

RWANDA: *Article 18 (1) 1), 4) and 6) of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property*

The following shall be excluded from patent protection even if they constitute inventions under article 5 (7): of this Law;

1) discoveries, scientific theories and mathematical methods;

4) substances, even if purified, synthesized or otherwise isolated from nature; nevertheless, this provision shall not apply to the processes of isolating those substances from their original environment;

6) plants and animals, including their parts, other than micro-organisms, and essentially biological processes for the production of plants or animals and their parts, other than non-biological and microbiological processes and products obtained from those processes;

SAINT LUCIA: *Section 9 (2) (a) (i) of the Patents Act No. 16 of 27/08/2001*

Patentable inventions

9.-(2) The following, among other things, are not inventions for the purposes of this Act —

(a) anything which consists of-

(i) a discovery, scientific theory or mathematical method;

SAN MARINO: *Article 2 (2) (a), (4) (c) and (d), (5), (6) and (7) of the Law on Industrial Property No. 79 of 25/05/2005*

*Article 2*

(Oggetto del brevetto ed esclusioni dalla brevettabilità)

2. Non sono considerate come invenzioni ai sensi dell'articolo 1 in particolare:

a) le scoperte, le teorie scientifiche e i metodi matematici,

4. Non sono brevettabili le invenzioni:

c) riguardanti le razze animali ed i procedimenti essenzialmente biologici per l'ottenimento delle stesse; questa disposizione non si applica ai procedimenti microbiologici e ai prodotti ottenuti mediante questi procedimenti;

d) riguardanti il corpo umano, nei vari stadi della sua costituzione e del suo sviluppo, nonché la mera scoperta di uno dei suoi elementi, ivi compresa la sequenza o la sequenza parziale di un gene.

5. Un procedimento di produzione di vegetali o di animali è essenzialmente biologico quando consiste integralmente in fenomeni naturali quali l'incrocio o la selezione.

6. Un materiale biologico che viene isolato dal suo ambiente naturale o viene prodotto tramite un procedimento tecnico può essere oggetto di invenzione, anche se preesisteva allo stato naturale.

7. Ai fini del presente Testo Unico si intende per:

a) "materiale biologico", un materiale contenente informazioni genetiche, auto-riproducibile o capace di riprodursi in un sistema biologico;

b) "procedimento microbiologico", qualsiasi procedimento nel quale si utilizzi un materiale microbiologico, che comporta un intervento su materiale microbiologico, o che produce un materiale microbiologico.

SAUDI ARABIA: *Article 45 (a) and (c) of the Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs of 2004*

*Article Forty Five*

In the application of provisions of this Law, the following shall not be regarded as inventions:

(a) Discoveries, scientific theories and mathematical methods.

(c) Plants, animals and processes – which are mostly biological – used for the production of plants or animals, with the exception of micro-organisms, non- biological and microbiology processes.

SERBIA: *Articles 5, 6 and 7 (3) of the Patent Law of 10/07/2004*

Patentable Inventions

*Article 5*

The subject matter of an invention protected by a patent may be a product (ex. a device, substance, composition, biological material) or a process.

The subject matter protected by a patent may also be related to:

1) a product consisting of or containing biological material;

2) a process by means of which biological material is produced, processed or used;

3) a biological material isolated from its natural environment or produced by means of a technical process, even if it previously occurred in nature.

Within the terms of this Law, "biological material" shall mean any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (ex. microorganisms, plant and animal cell cultures, sequence of genes).

The following, in particular, shall not be regarded as inventions, within the meaning of this Law:

1) discoveries, scientific theories and mathematical methods;

#### *Article 6*

The human body, at any stage of its formation and development, and the simple discovery of one of its elements, including sequences or partial sequences of genes, shall not be regarded as invention.

An element isolated from the human body or produced by means of a technical process, including the sequences or partial sequences of genes, may be patentable, even where the structure of that element is identical to that of a natural element.

The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application on the day of its filing.

#### Exceptions to Patentability

#### *Article 7*

Patent protection shall not be granted in respect of:

3) a plant or animal variety or an essentially biological process for the production of a plant or animal, except:

- a biotechnological process concerning a plant or animal, if the technical feasibility of the invention is not confined to a particular plant or animal variety;

- a microbiological or other technical process, or a product obtained by means of such process.

Within the terms of this Law:

- "plant variety" is used in the meaning laid down in the law governing the protection of new plant varieties;

- an "essentially biological process" for the production of plants or animals is a process consisting entirely of natural phenomena such as crossing or selection;

- a "microbiological process" is a process involving or performed upon or resulting in microbiological material.

*SLOVAKIA: Articles 5 (2) and (3) (a) and 6 (1) (b) and (d) of the Patent Act No. 435/2001 as last amended by Act No. 202/2009 Coll.*

#### *Article 5*

#### Patentable subjects

(2) Patents pursuant to paragraph 1 shall be also granted for biotechnological inventions concerning to a product consisting of or containing biological material, or to a process by means of which biological material is produced, processed or utilised, including cases when invention relates to

a) biological material which is isolated from its natural environment or is produced by means of a technical process, already occurred in a nature,

b) a plant or an animal, if a technical feasibility of an invention is not reduced to a particular plant or animal variety<sup>2)</sup>

c) a microbiological or other technical process or to a product obtained by such process,

d) an element isolated from a human body or produced by other means of a technical process, including a sequence or partial sequence of a gene also in the case when the structure of such element is identical with a structure of a naturally existing element.

(3) The following shall not be regarded as inventions pursuant to paragraph 1:

a) discoveries, scientific theories and mathematical methods,

*Article 6*

Exceptions to patentability

(1) Patents shall not be granted to

b) essentially biological processes for creation plants or animals,

d) inventions relating to human body in different stages of its formation or development or relating only to discovery of some elements of human body, including sequences or partial sequence of a gene, with an exception pursuant to Article 5(2)(d),

*SLOVENIA: Article 11 (1) of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006 and the Decree on the legal protection of biotechnological inventions of 2003*

*Article 11*

Exceptions to patent protection

(1) Discoveries, scientific theories, mathematical methods, and other rules, schemes, methods and processes for performing mental acts as such shall not be considered inventions within the meaning of Article 10.

*Articles 3-6 of the Decree on the legal protection of biotechnological inventions of 2003*

*Article 3*

(1) For the purposes of this Decree, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

(2) Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

*Article 4*

(1) The following shall not be patentable:

(a) plant and animal varieties; and

(b) essentially biological processes for the production of plants or animals.

(2) Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

(3) Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

*Article 5*

(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

*Article 6*

(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

(2) On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) uses of human embryos for industrial or commercial purposes;
- (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

*SOUTH AFRICA: Section 25 (2) (a) and (4) (b) of the Patents Act No. 37 of 1952 as last amended by Act No. 20 of 2005*

25. Patentable inventions

(2) Anything which consists of

(a) a discovery;

(4) A patent shall not be granted

(b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process or the product of such a process.

*SPAIN: Articles 4 (2), (3), (4) (a) and 5 (3) and (4) of the Law about Patents of Invention and Utility Models No. 11 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

*Artículo 4*

2. La materia biológica aislada de su entorno natural o producida por medio de un procedimiento técnico podrá ser objeto de una invención, aun cuando ya exista anteriormente en estado natural.

3. A los efectos de la presente Ley, se entenderá por "materia biológica" la materia que contenga información genética autorreproducible o reproducible en un sistema biológico y por "procedimiento microbiológico", cualquier procedimiento que utilice una materia microbiológica, que incluya una intervención sobre la misma o que produzca una materia microbiológica.

4. No se considerarán invenciones en el sentido de los apartados anteriores, en particular:

a) Los descubrimientos, las teorías científicas y los métodos matemáticos.

*Artículo 5*

No podrán ser objeto de patente:

3. Los procedimientos esencialmente biológicos de obtención de vegetales o de animales. A estos efectos se considerarán esencialmente biológicos aquellos procedimientos que consistan íntegramente en fenómenos naturales como el cruce o la selección.

Lo dispuesto en el párrafo anterior no afectará a la patentabilidad de las invenciones cuyo objeto sea un procedimiento microbiológico o cualquier otro procedimiento técnico o un producto obtenido por dichos procedimientos.

4. El cuerpo humano, en los diferentes estadios de su constitución y desarrollo, así como el simple descubrimiento de uno de sus elementos, incluida la secuencia o la secuencia parcial de un gen. Sin embargo, un elemento aislado del cuerpo humano u obtenido de otro modo mediante un procedimiento técnico, incluida la secuencia total o parcial de un gen, podrá considerarse como una invención patentable, aún en el caso de que la estructura de dicho elemento sea idéntica a la de un elemento natural.

La aplicación industrial de una secuencia total o parcial de un gen deberá figurar explícitamente en la solicitud de patente.

*SRI LANKA: Section 62 (3) (a) and (b) of the Intellectual Property Act No. 36 of 2003*

Definition of invention. 62

(3) The following, notwithstanding they are inventions within the meaning of subsection (1), shall not be patentable:

(a) discoveries, scientific theories and mathematical methods ;

(b) plants, animals and other micro organism other than transgenic micro organism and an essentially biological process for the production of plants and animals other than non-biological and microbiological processes :

Provided however, that a patent granted in respect of micro-organisms shall be subject to the provisions of this Act;

*SWAZILAND: Section 3 (a) of the Industrial Property Law No. 6 of 04/09/1997*

Definition of patents and of invention and matter excluded from patents protection.

3.. For the purposes of this Act -

a "patent" means the title 'granted to protect an invention;

"invention" means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology and may be or may relate to a product or a process but the following, even if they are inventions, shall be excluded from patent protection –

(a) discoveries, scientific theories and mathematical methods:

*SWEDEN: Articles 1 1), 1a (2) and (3), and 1b of the Patents Act No. 837 of 01/12/1967 as last amended by Law No. 161 of 01/04/2004*

1. Anyone who has made an invention that is susceptible of industrial application, or anyone to whom the rights of the inventor have been assigned, may, pursuant to Chapters 1 to 10 of this Act, be granted a patent for the invention in Sweden and thereby acquire an exclusive right to exploit the invention commercially. Provisions concerning European patents are included in Chapter 11.

As an invention shall never be considered what is solely

1. a discovery, scientific theory or mathematical method,

1a. (2) Patents are not granted for essentially biological processes for the production of plants or animals. As an essentially biological process for the production of plants or animals shall be considered any process which in its entirety consists of natural phenomena such as crossing or selection. A patent may, however, be granted for an invention that concerns a microbiological process or another technical process or a product made by means of such a process. As a microbiological process shall be considered any process which is performed on microbiological material or through which such material is used or is produced.

(3) An invention may be patentable even if it concerns a product which consists of, or contains, biological material or a process through which biological material is produced, processed or used. A biological material which is isolated from its natural environment, or which is produced by means of a technical process, may be the subject of an invention even if it previously occurred in nature. Biological material comprises material that contains genetic information and which is itself capable of reproduction or which may be reproduced in a biological system.

1b. The human body at the various stages of its formation and development as well as the simple discovery of one of its elements, including the sequence of a gene or a partial sequence of a gene, can not constitute a patentable invention.

An isolated element of the human body or an element otherwise produced by means of a technical process, including the sequence of a gene or a partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical with that of a natural element.

SWITZERLAND: *Articles 1a, 1b and 2 (2) (b) of the Federal Patents Law of 25/06/1954 as last amended on 01/07 2009*

*Article 1a*

Le corps humain et ses éléments

1 Le corps humain en tant que tel, aux différents stades de sa constitution et de son développement, y compris l'embryon, ne peut être breveté.

2 Les éléments du corps humain, dans leur environnement naturel, ne peuvent pas être brevetés. Un élément du corps humain constitue toutefois une invention brevetable lorsqu'il est préparé techniquement, si un effet utile de nature technique est indiqué et si les autres conditions de l'art. 1 sont remplies; l'art. 2 est réservé.

*Article 1b*

Séquences géniques

1 Une séquence génique ou une séquence génique partielle existant à l'état naturel n'est en soi pas brevetable.

2 Une séquence dérivée d'une séquence génique ou d'une séquence génique partielle existant à l'état naturel constitue toutefois une invention brevetable lorsqu'elle est préparée techniquement, que sa fonction est décrite concrètement et que les autres conditions de l'art. 1 sont remplies; l'art. 2 est réservé.

*Article 2*

Exclusion de la brevetabilité

2 Ne peuvent pas non plus être brevetés:

b. les variétés végétales et les races animales, ainsi que les procédés essentiellement biologiques d'obtention de végétaux ou d'animaux; sont toutefois brevetables, sous réserve de l'al. 1, les procédés microbiologiques, ou d'autres procédés techniques, les produits ainsi obtenus et les inventions qui portent sur des plantes ou des animaux et dont la faisabilité technique n'est pas limitée à une variété végétale ou à une race animale.

THAILAND: *Section 9 1) of the Patent Act B.E. 2522 of 11/03/1979 as amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542*

Section 9 - The following inventions are not protected under this Act:

(1) naturally occurring microorganisms and their components, animals, plants or extracts from animals or plants;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA: *Articles 25 (2), (3) 1) and 5), (5) and 26 of the Law on Industrial Property No. 07-1006/1 of 12/02/2009*

*Article 25*

(2) If the requirements referred to in paragraph (1) of this Article are fulfilled, a patent shall also protect an invention that referred to:

- a product comprising of or containing biological material; and
- a method for obtaining biological material, for processing it or for using it.

(3) An invention shall not be considered as invention within the meaning of paragraphs (1) and (2) of this Article if it is:

1) a discovery, scientific theory and mathematic method;

5) human body in different stages of its formation and development or simple discovery of one of its elements, including a sequence or a partial sequence of a gene.

(5) Element which is isolated from the human body or produced by means of a technical process containing a sequence or a partial sequence of a gene may also be protected by a patent when the structure of that element is identical with the one of the natural element, whereby the industrial applicability must be contained in the description of invention included in the application form.

Exceptions to patentability

*Article 26*

A patent may not protect an invention:

- which relates to new animal types and plant varieties and clear biological procedures for creating animals and plants, with the exception of biotechnological inventions, for which the technical feasibility is not restricted to a certain type, and microbiological processes and products generated from such processes;

*TONGA: Section 4 (a) of the Industrial Property Act No. 19 of 09/11/1994*

4 Matters excluded from patent protection.

The following, even if they are inventions in terms of section 2, shall be excluded from patent protection, —

(a) discoveries, scientific theories and mathematical methods;

*TRINIDAD AND TOBAGO: Section 12 (a) of the Patents Act No. 21 of 1996*

Exclusions from patentability)

12.-(1) It is hereby declared that the following are excluded from patentability that is to say, anything which consists of-

(a) a discovery, scientific theory or mathematical method;

*TUNISIA: Articles 2 (2) (b) and (f) and 3 of the Patents Law No.2000-84 of 24/08/2000*

2. (2) The following in particular shall not be considered inventions within the meaning of the first paragraph of this Article:

(b) discoveries, scientific theories and mathematical methods;

(f) all types of live substance existing in nature.

The exceptions to the provisions of the second paragraph of this Article with regard to the patentability of the subject matter listed shall apply only to that subject matter as such.

3. A patent may not be issued for:

- varieties of plants, animal breeds or essentially biological processes for the production of plants or animals, provided that this provision shall not apply to biological processes used in medicine or to products obtained using such processes;

*TURKEY: Article 6(1) (a) and (2) (b) of the Decree-Law No. 551 on the Protection of Patent Rights of 27/06/1995 as last amended by Law No. 4128 of 7/11/1995*

Non-Patentable Subject Matter and Inventions

6. (1) The following, not being inventions by nature, shall remain outside the scope of this Decree-Law:

(a) discoveries, scientific theories, mathematical methods;

(2) Patents shall not be granted for inventions relating to the following:

(b) plant and animal varieties or processes for breeding plant or animal varieties that are based mainly on biological factors.

UGANDA: *Section 7 (2) (a) and (b) of the Patents Act of 15/10/1993*

7. Definition of invention

(2) The following shall not be regarded as inventions within the meaning of subsection (1)—

(a) discoveries and scientific and mathematical theories;

(b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than biological processes and the products of those processes;

UNITED ARAB EMIRATES: *Article 6 (1) (a) and (c) of the Federal Law No (31) of 2006 pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs*

*Article ( 6 )*

1- No letters patent or utility certificate shall be issued for the following: -

a - Plant varieties , animal species , or biological methods of producing plants or animals .  
Exceptions shall be allowed for the microbiological methods and their products .

c - Scientific and Mathematical principles , discoveries and methods .

UNITED KINGDOM: *Section 1 (2) (a) and 76A and Schedule A2 (Section 76) (1)-(6) and (11) of the Patents Act of 1977, consolidated version of 01/01/2010*

Patentable inventions

1.-(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of –

(a) a discovery, scientific theory or mathematical method;

Biotechnological inventions

76A.-(1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.

(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.

Schedule A2 (section 76A)

Biotechnological inventions

1. An invention shall not be considered unpatentable solely on the ground that it concerns -

(a) a product consisting of or containing biological material; or

(b) a process by which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

3. The following are not patentable inventions -

(a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

- (b) processes for cloning human beings;
  - (c) processes for modifying the germ line genetic identity of human beings;
  - (d) uses of human embryos for industrial or commercial purposes;
  - (e) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
  - (f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.
4. Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.
5. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.
11. In this Schedule:
- “essentially biological process” means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection;
- “microbiological process” means any process involving or performed upon or resulting in microbiological material;
- “plant variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be:
- (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes; and
  - (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
  - (c) considered as a unit with regard to its suitability for being propagated unchanged.

UNITED REPUBLIC OF TANZANIA: *Section 7 (2)(a) and (b) of the Patents Act No. 1 of 20/01/1987*

Definition 7 : (2) The following shall not be regarded as inventions within the meaning of subsection (1):

- (a) discoveries, and scientific and mathematical theories;
- (b) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological and the products of such processes;

URUGUAY: *Article 13 (a), (b) and (g) of the Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs No. 1.827\*R of 02/09/1999*

13. The following shall not be considered inventions for the purposes of this Law:

- (a) discoveries, scientific theories and mathematical methods;
- (b) plants and animals, with the exception of microorganisms and essentially biological processes for the production of plants or animals, except for non-biological or microbiological processes;
- (g) biological or genetic material existing in nature.

VIET NAM: *Article 59 1) and 6) of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005 as last amended by Order No. 12/2009/L-CTN of 29/06/2009*

*Article 59*

Subject matters not protected as inventions

The following subject matters shall not be protected as inventions:

1. Scientific discoveries or theories, mathematical methods;

6. Processes of plant or animal production which are principally of biological nature other than microbiological ones;

ZAMBIA: *Section 14 (7) of the Patent Act of 1958 (Chapter 400) as last amended by Act No. 26 of 28/12/1987*

14. Contents of specification

(7) Where a complete specification claims a new substance, the claim shall be construed as not extending to that substance when found in nature.

ZIMBABWE: *Section 9 (7) of the Patents Act (Chapter 26:03) no. 26 of 1971 as last amended by Act 20/1994 (S.7)*

Contents of specification

9.-(7) Where a complete specification claims a new substance, the claims shall be construed as not extending to that substance when found in nature.

ANDEAN COMMUNITY: *Articles 15 (a) and (b) and 20 (c) of the Decision No. 486 of 14/09/2000 of the Commission of the Andean Community - Common Industrial Property Regime*

15. The following shall not be considered inventions:

(a) discoveries, scientific theories and mathematical methods;

(b) the entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germ plasm of any natural living being;

20. The following shall not be patentable:

(c) plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes;

EUROPEAN UNION: *Articles 3-6 of the Directive 98/44/EC of 06/07/1998 on the legal protection of biotechnological inventions*

*Article 3*

1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

*Article 4*

1. The following shall not be patentable:

(a) plant and animal varieties;

(b) essentially biological processes for the production of plants or animals.

2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process.

*Article 5*

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

*Article 6*

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

OAPI: *Article 6 (b) and (c) of the Bangui Agreement of 02/03/1977, as revised on 24/02/1999*

*Article 6*

Non-Patentable Subject Matter

Patents shall not be granted for the following:

(b) discoveries, scientific theories and mathematical methods;

(c) inventions having as their subject matter plant varieties, animal species and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes

(3) PROVISIONS OF LAW ON DISCLOSURE RELATED FLEXIBILITIES

ALBANIA: *Articles 19, 28 and 73(1) (b) of the Industrial Property Law Nr. 9977 of 07/07/2008*

*Article 19*

Disclosure of the Invention

1. The disclosure of the invention in the patent application shall be clear and shall contain the necessary information for a person skilled in the art to be able to carry it out.

2. If the invention involves the use of or concerns biological material which is not available to the public and that cannot be described in the application, in order to make it possible for a person skilled in the art to carry it out, the application would have to be accompanied by the filing of the necessary materials at an appropriate institution designated for this purpose.

#### *Article 28*

##### Examination of the Application and Grant of the Patent

After verifying that the application filed is in conformity with articles 17, 18, 19, 20, 21, 22 and 24 of this Law, the GDPT shall grant the respective patent, subject to the payment of the relevant fee. If the application does not meet, or partially meets, the requirements of paragraph 1 of this article, the GDPT shall notify the applicant, who, within a three months period, shall correct the deficiencies. If the deficiencies are not corrected in due time, the application shall be rejected and the GDPT shall notify the applicant of this decision.

A decision taken in conformity with paragraph 2 of this article may be appealed to the appeal board of the GDPT within a three months period from the date of receipt of notification, subject to the payment of a fee. The decision of the appeal board may be appealed to the court within a period of 30 days from the date of receipt of notification.

The GDPT shall not make a substantive examination of the invention, in conformity with articles 5, 6, 7, 9 and 10 of this Law. Therefore, the patent granted by GDPT shall have legal effect only if within 10 years from the filing date, the patent's owner files an examination report issued by an institution authorized in substantial examination of inventions, otherwise the patent shall be considered invalid. Immediately after a decision to grant the patent, the GDPT shall publish it as provided in article 26 (4) of this Law.

#### *Article 73*

##### Revocation of a Patent

Where the validity of a patent has been contested, the court shall have the right to revoke or limit the patent if:

b) the invention is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

*ALGERIA: Articles 22, 30 and 53 2) of the Ordinance No. 03-07 of 19/07/2003*

#### *Article 22*

- La demande de brevet d'invention ne peut porter que sur une seule invention ou sur une pluralité d'inventions liées entre elles de telle sorte qu'elles ne forment qu'un seul concept inventif général.

Elle ne peut contenir ni restrictions, ni conditions, ni réserves ni limitations ou attributions de droits.

La description doit divulguer l'invention d'une manière suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter.

La ou les revendications doivent définir l'étendue de la protection demandée. Elles doivent être claires et concises et se fonder entièrement sur la description. L'abrégé sert exclusivement à des fins d'information technique.

#### *Article 30*

- Avant la délivrance d'un brevet d'invention, le service compétent peut exiger du demandeur, toute information relative à tout titre de protection qu'il aurait demandé ou obtenu dans d'autres pays et portant sur la même invention que celle qui a fait l'objet d'une demande déposée auprès du service compétent.

*Article 53*

La nullité totale ou limitée à une ou plusieurs revendications du brevet d'invention, est prononcée par la juridiction compétente, à la demande de tout intéressé:

2) si la description de l'invention ne satisfait pas aux prescriptions de l'article 22 (alinéa 3) ci-dessus ou si les revendications du brevet d'invention ne définissent pas la protection demandée;

Lorsque la décision de nullité est devenue définitive, la partie la plus diligente la notifie de plein droit au service compétent qui procède à son inscription et à sa publication.

ANDORRA: *Articles 12 and 20(1), (2) and (3) of the Patent Law of 10/06/1999*

*Article 12*

Disclosure of invention

(1) The application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

(2) Where the application refers to biological material which cannot be disclosed in the application in such a way as to enable the invention to be carried out by a person skilled in the art and such material is not available to the public, the application shall be supplemented by a deposit of such material with a recognized depositary institution as prescribed in the Implementing Regulations.

*Article 20*

Examination of application and grant of patent

(1) If an application has been accorded a filing date, the Patent Office shall examine whether the application complies with the requirements of Articles 9 and 10.

(2) The Patent Office is under no obligation to examine whether the application and the invention to which it relates comply with the requirements under Articles 2 to 5, 12, 13, 15 and 18 (2).

(3) Where the Patent Office finds that the application does not comply with the requirements referred to in paragraph (1), it shall indicate the deficiencies to the applicant and give him an opportunity to correct them in accordance with the Implementing Regulations. The application shall be rejected if the applicant fails to correct the deficiencies indicated by the Patent Office.

ANTIGUA AND BARBUDA: *Sections 5 (5), 8, 9 (5) and (6), 10 (3) and 15 (2) of the Patents Act No. 23 of 29/12/2003*

5. (5) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

8. (1) The applicant shall, at the request of the Registrar, furnish him with the date and number of any application for a patent filed by him abroad ("foreign application") relating to the same or applications essentially the same invention as that claimed in the application filed with the Intellectual Property Registry.

(2) The applicant shall, at the request of the Registrar, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1):

(a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(b) a copy of the patent granted on the basis of the foreign application;

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(3) The applicant shall, at the request of the Registrar, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in subsection (2).

(4) Subsection (2)(a) and (c) shall not apply in respect of information relating to the examination of the same international application in another elected office where the Intellectual Property Office is an

elected office in the meaning of section 16 and has received or will receive an international preliminary examination report.

9.- (5) Where the Registrar is of the opinion that the application complies with the requirements indicated in subsection (4), the Registrar shall take a decision as to whether the requirements of sections 2(l)(ii) and (2), 3, 5(5), (6), (7) and (8) and 6 and the Regulations pertaining thereto are fulfilled and for this purpose may, as provided for in the Regulations, cause the application to be examined.

(6) The Registrar shall take into account, for the purposes of subsection (5):

(i) the results of any international search report and any international preliminary examination report established under the PCT in relation to the application; and/or

(ii) a search and examination report submitted under section 8(2)(a) relating to, or a final decision submitted under Section 8(2)(c) on the refusal to grant a patent on, a corresponding foreign application; and/or

(iii) a search and examination report which was carried out upon his request by an external search and examination authority.

10.- (3) The Registrar shall, upon request of the owner of the patent, make changes in the text or drawings of the patent in order to limit the extent of the protection conferred thereby, provided that the change would not result in the disclosure contained in the patent going beyond the disclosure contained in the initial application on the basis of which the patent was granted.

15.- (2) The court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of sections 2(1)(ii), and (2), 3 and 5(5), (6), (7) and (8) is not fulfilled or if the owner of the patent is not the inventor or his successor in title.

*ARGENTINA: Articles 20, 27 (1 and 2) and 59 of the Law No. 24.481 of 23/05/1995 on Patents and Utility Models (as last amended by Law No. 24.572)*

20. The application shall describe the invention with sufficient clarity and completeness for an expert with average knowledge in the field concerned to be able to carry it out. It shall likewise include a clear and accurate account of the best known method of carrying out and implementing the invention, and of the materials and components used.

The methods and processes described must be directly applicable in production.

In the case of applications relating to microorganisms, the product obtainable by means of a claimed process shall be described as well as the process itself in the relevant application, and a strain of the microorganism shall be deposited with an institution authorized for the purpose, as provided by regulation.

The public shall have access to the microorganism culture at the depository institution, as from the day of publication of the patent application, on conditions laid down by regulation.

27. On payment of the fee laid down in the implementing decree, the National Patent Administration shall undertake a substantive examination to determine compliance with the conditions set forth in Title II, Chapter I of this Law.

The National Patent Administration may request a copy of any substantive examination conducted by foreign examining offices according to the procedure laid down in the implementing decree, and may likewise seek expert opinions from researchers working in universities or science and technology institutes in the country, who in each case shall be rewarded as provided in the implementing decree.

*Article 59*

Patents and utility model certificates shall be wholly or partly null and void when they have been granted in violation of the provisions of this Law.

ARMENIA: *Articles 53 (2) and (3), 57 (1) and 58 of the Industrial Property Act of 10/06/2008*

*Article 53*

Contents of Requirements to Application

(2) The description of the invention shall include the technical problem, for the solution of which the invention is intended, the technical result which may be reached using the invention, information on the state of the art or of other technical solutions which have become available to the public before the priority date of the invention and technical matter, as well as the reasons causing barriers to obtaining the required technical results, as well as the description of technical solution of the technical problem. The description of the invention shall disclose the invention clearly and completely for it to be sufficiently carried out by a person skilled in the art.

(3) If an invention relates to biological material, which is not available to the public and can not be described in a manner to be sufficiently carried out by a person skilled in the art, the description of the invention shall be supplemented by a certificate on the deposit of biological material issued under Article 7 of the Regulations of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure or issued by the Authorized Body of the Government of the Republic of Armenia for deposit of microorganisms.

(4) The claims shall define the subject matter of the invention through the totality of its technical character for which protection is sought. The claim, which is submitted in one or more points must be clear and concise and be totally based on the description.

*Article 57*

Term for Submission of Written Evidence (1) The owner of a patent or holder of exclusive rights issuing from the patent shall no later than the expiry of the ninth year of the patent validity submit to the State Authorized Body written evidence that the patented invention meets the requirements of Articles 9, 11, 13 and 14 of this Law.

*Article 58*

Forms of Written Evidence (1) The written evidence under Article 32 of the PC'I' enjoys the status of International Preliminary Examining Authority, or by any other patent office with which the State Authorized Body has a contract. (2) If the submission of written evidence, according to paragraph (1) of this Article, is not complete for the granting proceedings, the applicant shall inform the State Authorized Body accordingly in the time limit prescribed in Article 57(1) of this Law. On the basis of that information, the State Authorized Body shall interrupt the proceedings. The proceedings shall continue if the applicant submits evidence under this Article within three months after the established term. If the evidence under this Article is not submitted in the established time, the patent shall lapse on the date of the expiry of the ten-year term of the patent validity. (3) When the written evidence is submitted pursuant to paragraph (1) of this Article, the owner of a patent or holder of exclusive right issuing from the patent shall submit a list and copies of all other patents, which could be considered as evidence, including the list of refused applications and data thereon. In case the list and copies of the patents to the written evidence are not submitted in due time, the evidence is deemed not to have been submitted and the applicant is notified about it. (4) If the State Authorized Body establishes that the written evidence under this Article is forged or is not true, it declares the patent to be void. (5) When the owner of a patent or holder of exclusive right issuing from a patent does not have written evidence he may request, against payment of the state fee, that the State Authorized Body obtains relevant data or opinions to be used as the basis for the publication of one of the conclusions under Article 59 of this Law

AUSTRALIA: *Sections 6, 8, 40 (1) and (2) (a), 41 (1) and (2), 45 (3), (4) and (5), 59 (c), 100A (1) and (2) and 100 (1) and (2) of the Patents Act No. 83 of 1990 as amended by Act No. 106 of 2006*

6 - Deposit requirements

For the purposes of this Act, the deposit requirements are to be taken to be satisfied in relation to a micro-organism to which a specification relates if, and only if:

- (a) the micro-organism was, on or before the date of filing of the specification, deposited with a prescribed depositary institution in accordance with the rules relating to micro-organisms; and
- (b) the specification includes, at that date, such relevant information on the characteristics of the micro-organism as is known to the applicant; and
- (c) at all times since the end of the prescribed period, the specification has included:

- (i) the name of a prescribed depositary institution from which samples of the micro-organism are obtainable as provided by the rules relating to micro-organisms; and
- (iii) the filing, acceptance or registration number of the deposit given by the institution; and
- (d) at all times since the date of filing of the specification, samples of the micro-organism have been obtainable from a prescribed depositary institution as provided by those rules.

#### 8 - Disclosure in basic applications

Subject to the regulations, account must not be taken, for the purposes of this Act, of a disclosure in a specification or other document filed in respect of, and at the same time as, a basic application unless the following documents are filed within the prescribed period:

- (a) a copy of the specification or document;
- (b) if the specification or document is not in English - a translation of the specification or document into English.

#### 40 - Specifications

(1) A provisional specification must describe the invention.

(2) A complete specification must:

- (a) describe the invention fully, including the best method known to the applicant of performing the invention; and

#### 41 - Specifications: micro-organisms

(1) To the extent that an invention is a micro-organism, the complete specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if the deposit requirements are satisfied in relation to the micro-organism.

(2) Where:

- (a) an invention involves the use, modification or cultivation of a micro-organism, other than the micro-organism mentioned in subsection (1); and
- (b) a person skilled in the relevant art in the patent area could not reasonably be expected to perform the invention without having a sample of the micro-organism before starting to perform the invention; and
- (c) the micro-organism is not reasonably available to a person skilled in the relevant art in the patent area;

the specification is to be taken to comply with paragraph 40(2)(a), so far as it requires a description of the micro-organism, if, and only if, the deposit requirements are satisfied in relation to the micro-organism.

#### 45 - Examination

(3) The applicant must inform the Commissioner, in accordance with the regulations, of the results of the following searches carried out for the purpose of assessing the patentability of an invention disclosed in the complete specification or a corresponding application filed outside Australia:

- (a) any documentary searches by, or on behalf of, a foreign patent office, other than searches prescribed by the regulations;
- (b) the documentary searches prescribed by the regulations.

(4) Subsection (3) only applies to searches completed before the grant of the patent.

(5) In subsection (4):

completed, in relation to a search, has the meaning prescribed by the regulations.

#### 59 - Opposition to grant of standard patent

The Minister or any other person may, in accordance with the regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground:

- (c) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3).

#### 100A Refusal to grant patent - re-examination before grant

(1) Where the Commissioner makes an adverse report on a re-examination under subsection 97(1), the Commissioner may refuse to grant the patent (see subsection 61(1)).

(2) The Commissioner cannot refuse to grant a patent under this section unless the Commissioner:  
(a) has given the applicant a reasonable opportunity to be heard; and  
(b) has, where appropriate, given the applicant a reasonable opportunity to amend the relevant specification for the purpose of removing any lawful ground of objection and the applicant has failed to do so.

#### 101 - Revocation of patent - re-examination after grant

(1) Where the Commissioner makes an adverse report on a re-examination under subsection 97(2), the Commissioner may, by notice in writing, revoke the patent, either wholly or so far as it relates to a particular claim, as the case requires.

(2) The Commissioner must not revoke a patent under this section unless the Commissioner:  
(a) has given the patentee a reasonable opportunity to be heard; and  
(b) has, where appropriate, given the patentee a reasonable opportunity to amend the relevant specification for the purpose of removing any lawful ground of objection and the patentee has failed to do so.

*AUSTRIA: Sections 48 (1) 2) and 3), 87a and 102 (2) 2) and 4) of the Patents Law BGBl. No. 259/1970 as last amended by BGBl. No. 143/2001*

#### Section 48 - Declaration of Nullity

(1) A patent shall be declared null and void if:

2. the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

3. the microorganism deposited according to Section 87a(2)1 has not been permanently accessible at the original depositary institution as defined by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure dated April 28, 1977, Federal Law Gazette No. 104/1984 as amended (Budapest Treaty) or at another depositary institution to which it has been passed on according to that Treaty unless the patentee proves

(a) that he has deposited the microorganism again and that such deposit is deemed, under Art. 4 of that Treaty, to have been made on the day of the original deposit, or

(b) that he was prevented from such a new deposit by an unforeseeable or unavoidable event and that he has made such a deposit within two months after the obstacle ceased to exist.

#### Section 87a - Disclosure

(1) The patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(2) If an invention relates to a microorganism, a microbiological process or a product obtained by such process and if the microorganism is not accessible to the public and cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall be deemed disclosed according to subsection (1) only if

1. a culture of the microorganism was deposited with a depositary institution as defined by the Budapest Treaty on the date of filing the application at the latest,

2. the application as originally filed contains the authoritative data available to the applicant concerning the features of the microorganism, and

3. if the Patent Office was notified of the depositary institution and the file number of the deposit of the culture prior to taking the publication decision (Sec. 101(1)).

#### Section 102

(2) Opposition shall be in writing and submitted in duplicate. It may be based only on the following grounds, which must be substantiated by definite facts:

2. that the published application does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

4. that the microorganism deposited according to Section 87a(2)1. has not been permanently accessible either at the original depositary institution as defined by the Budapest Treaty or at another depositary institution to which it has been passed on according to that Treaty unless the patentee proves

(a) that he has deposited the microorganism again and that such deposit is deemed under Art. 4 of that Treaty to have been made on the day of the original deposit, or

(b) that he was prevented from such a repeated deposit by an unforeseeable or unavoidable event and that he made such a deposit within two months after the obstacle ceased to exist;

*BAHRAIN: Article 16 of the Industrial Property Law as last amended by Law No. 14 of 28/05/2006*

*Article (16)*

a. An application for a patent shall be filed by the inventor or the one who has acquired the rights thereof at the competent authority on a special form designed for this purpose to which the set designs are attached, in accordance with the provisions prescribed in this Law and the requirements, conditions and procedures defined by the Executive By-laws. The application in particular shall entail details of the invention and the requested protection, and any graphics stipulated in the details or in any of the requests. The application details must entail sufficient and adequate disclosure of the patent.

The patent subject of the request must also be sufficiently supported in terms of disclosure.

b. For purposes of the previous Clause, the application in particular shall disclose a detailed specification of the invention that gives full account of the subject invention and the best ways for one skilful in the art to implement and use it without the need for unnecessary experiments upon filing the application. The invention shall be considered sufficiently support in terms of disclosure when such a specification appears reasonable for one skilful in the art that the applicant acquired the proclaimed patent at the time of filing the application

c. Each request must clarify the required subject for protection, and it should be clear, concise, supported with the necessary details, and for one invention or a group of inventions that are interconnected forming a complete creative idea.

d. The Applicant shall comply with submitting all statements and data related to any previous applications submitted by him about the same patent subject abroad, and the decisions made thereof.

*BARBADOS: Sections 17 (2) (a) and (b), 20 (1) (a), 23, 26 (1) (d), (2) and (3) and 27 (1) (d), (2), (3), (4) and (5) of the Patents Act No. 18 of 26/07/2001*

17.-(2) An application must be in the prescribed form and must contain

(a) a petition as described in section 18;

(b) a description of the invention for which the patent is requested

(i) that is sufficiently clear and complete to enable the invention to be evaluated and tested by a person having ordinary skill in the art; and

(ii) that indicates at least one mode known to the applicant for using the invention;

23.-(1) An applicant for a patent shall, at the request of the Director, furnish the Director with

(a) the date and number of any other application for a patent or other title of protection made in an industrial or intellectual property office of any other country, or within a regional industrial or intellectual property office, in this section called a "foreign application", relating to the same or essentially the same invention as that claimed in the application filed with the Director;

(b) the following documents relating to foreign applications:

(i) a copy of any communication received by the applicant concerning the result of any search or examination carried out in respect of the foreign application;

(ii) a copy of the patent granted on the basis of the foreign application; and

(iii) a copy of any final decision rejecting the foreign application or refusing the patent requested in the foreign application; and

(c) a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in paragraph (b).

(2) The Director may not request the documents specified under subparagraphs (i) and (iii) of paragraph (b) of subsection (1) where the Intellectual Property Office has received an international preliminary examination report in accordance with the Patent Co-operation Treaty.

(3) Documents furnished pursuant to subsection (1)

(a) shall, if not in English, be accompanied by a translation thereof in English verified by the translator that the translation is to the best of his knowledge complete and faithful; and

(b) may be used only for facilitating the evaluation of the novelty and inventive step of the invention for which the patent application is made.

Examination 26.

(1) Where an application has been accorded a filing date, upon payment of the prescribed fee, the Director shall examine each application for a patent of invention to determine

(d) whether the description, claims and, if applicable, drawings comply with the prescribed physical requirements for descriptions, claims and drawings; and

(2) If, the Director determines that any requirement mentioned in subsection (1) has not been complied with, he shall require the applicant to make such corrections in his application as are necessary to comply with that requirement; and, if an applicant fails to make the required corrections, the Director shall, subject to subsection (3), refuse to grant the patent requested by the application.

(3) Where the correction required by the Director is the filing of an abstract, the Director may, upon payment of the prescribed fee, prepare the abstract for the application; but if the prescribed fee for an abstract remains unpaid after the expiration of the time prescribed for its payment, the Director shall refuse the requested patent.

27. (1) The Director shall examine each application for a patent of invention to determine

(d) whether the description and the claims for the invention are in compliance with the requirements of subsection (2) of section 17 and the regulations;

(2) If the Director determines that any requirement mentioned in subsection (1) has not been complied with in respect of an application, the Director shall notify the applicant accordingly and invite the applicant to submit any comments the applicant wishes to make regarding his failure to comply with that requirement; and an invitation made to an applicant under this section may include an invitation to amend or divide the application.

(3) Where, notwithstanding any comment, amendment or division of the application submitted to the Director by the applicant, the Director is of the opinion that a requirement mentioned in subsection (1) has not been complied with, the Director may refuse to grant a patent on that application; but any refusal to grant a patent and the reasons therefor must be communicated to the applicant in writing by the Director as soon as practicable.

(4) For the purposes of examination under subsection (1), the Director shall take into account  
(a) the results of any international search and any International preliminary examination report submitted in accordance with the Patent Co-operation Treaty;

(b) any document submitted under paragraph (i) or (iii) of section 23(1)(b); or

(c) a search and examination report which was carried out upon the request of the Director by an external search and examination authority pursuant to subsection (5).

(5) For the purposes of the examination under this section the Director may transmit the application to a duly authorised authority with which an arrangement to that effect has been made by the Minister.

*BELARUS: Article 13 (1) and (2) 2), 3) and 4) of the of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/2002 as last amended on 29/10/2004*

*Article 13*

Application to Issue the Patent on the Invention

1. Application on issue of the patent on invention (further-the application on invention) shall relate to one invention or the group of inventions connected between each other to such extent that they form the one invention idea (requirement of the unity of the invention).

2. The application on invention shall contain:

2.2. description of the invention revealing it fully so that enough for its realization;

2.3. formula of the invention expressing its essence and fully based on the description;

2.4. sketches and other materials, if they are necessary for understanding of the essence of invention;

*BELGIUM: Articles 15 (1) 2), 4) and 6), 17 (1), 20 (1), 22 (3) and 49 (1) 2) of the Patent Law of 28/03/1984 (Consolidated version as of 01/01/2010)*

*Article 15*

§ 1er. La demande de brevet doit contenir :

2) une description de l'invention ;

4) les dessins auxquels se réfèrent la description ou les revendications ;

[6) une mention de l'origine géographique de la matière biologique d'origine végétale ou animale à partir de laquelle l'invention a été développée, lorsque celle-ci est connue. Le Roi peut fixer les conditions et les mesures d'exécution applicables.]

*Article 17*

§ 1er. La demande de brevet doit contenir une description de l'invention suffisamment claire et complète pour qu'un homme du métier puisse la mettre en œuvre.

[Lorsqu'une invention porte sur de la matière biologique non accessible au public et ne pouvant être décrite dans la demande de brevet pour permettre à une personne du métier de réaliser l'invention ou implique l'utilisation d'une telle matière, la description, pour l'application du droit des brevets, n'est réputée suffisante que si la matière biologique a été déposée au plus tard le jour du dépôt de la demande de brevet auprès d'une institution de dépôt reconnue et si les exigences fixées par le Roi sont remplies.]

*Article 20*

§ 1er. Si la demande de brevet satisfait aux conditions fixées à l'article 16 mais ne répond pas aux autres conditions légales ou réglementaires, le demandeur peut procéder à la régularisation de la demande dans le délai prescrit et moyennant le paiement d'une taxe. Au terme du délai, la demande non régularisée est rejetée.

*Article 22*

§ 3. La délivrance des brevets se fait sans examen préalable de la brevetabilité des inventions, sans garantie du mérite des inventions ou de l'exactitude de la description de celles-ci et aux risques et périls des demandeurs.

[L'opinion écrite visée à l'article 21, § 1er, ne lie aucunement l'Office et ne peut valoir à titre d'examen de la brevetabilité de l'invention.]

*Article 49*

§ 1er. Le brevet est déclaré nul par le tribunal :

2) s'il n'expose pas l'invention de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter ;

*BELIZE: Articles 17 (1) (b) and (4), 23 and 27 of the Patents Act (Ch. 253), No. 14 of 21/06/2000*

*Application for a Patent*

17.-(1) Every application for a patent shall be filed with the Registrar in the prescribed form and shall contain:

(b) a description;

(4) The description shall disclose the invention in a manner which is sufficiently clear and complete to permit a person having ordinary skill in the art to carry out the invention, and shall, in particular, indicate at least one mode known to the applicant in which the invention can be carried out.

*Information Concerning Corresponding Foreign Applications*

23.-(1) The applicant shall, if requested by the Registrar, furnish him with the date and number of any application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed in the application filed with the Registrar.

(2) The applicant shall also, if requested by the Registrar, furnish him with the following documents relating to any foreign application referred to in subsection (1):-

(a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(b) a copy of the patent granted on the basis of the foreign application;

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; and

(d) a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in subsection (1).

(3) Subsection (2) (a) and (c) shall not apply where the Office of the Registrar is an elected Office within the meaning of section 55 and has received or will receive an international preliminary examination report.

(4) Any document furnished pursuant to this section:-

(a) shall, if not in English, be accompanied by a translation thereof in English, verified by the translator that the translation is, to the best of his knowledge, complete and faithful; and

(b) may be used only for facilitating the evaluation of the novelty and inventive step of the invention for which the patent application is made.

*Refusal or Grant of Patent*

27.-(1) Subject to section 25 (2) to (4), where the Registrar is not satisfied that the requirements of the Act and the Regulations have been complied with, he shall refuse the application and so inform the applicant in writing, stating the reasons for the refusal.

*BHUTAN: Sections 7(1) and (3), 10 and 16 (2) of the Industrial Property Act of 2001*

Application

7. (1) The application for a patent shall be filed in the prescribed manner with the Registrar and shall contain a request, a description, one or more claims, one or more drawings (where required), and an abstract. It shall be subject to the payment of the prescribed application fee.

(3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

Information Concerning Corresponding Foreign Applications for Patents

10. (1) The applicant shall, at the request of the Registrar, furnish him with the date and number of any application for a patent filed by him abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the Industrial Property Registry.

(2) (a) The applicant shall, at the request of the Registrar, furnish him with the following documents relating to any of the foreign applications referred to in subsection(1):

(i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(ii) a copy of the patent granted on the basis of the foreign application;

(iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(b) The applicant shall, at the request of the Registrar, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in paragraph (a).

16. Invalidation

(2)The Court or the Registrar shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of Section 4(2) and (3), Section 5 and Section 7(3), (4) and (5) are not fulfilled or if the owner of the patent is not the inventor or his successor in title.

*BOTSWANA: Sections 13(1) (b), and 20 of the Industrial Property Act No. 14 of 21/08/1996*

13. (1) Every application for a patent shall be filed with the Registrar and shall be accompanied by such fee as may be prescribed, as well as the following -

(b) a description of the invention which shall disclose the invention in a manner which is sufficiently clear and complete to permit a person having ordinary skill in the art to carry out the invention, and which shall indicate at least one mode known to the applicant in which the invention can be performed;

Information concerning corresponding foreign applications for patent

20. (1) The applicant shall, if requested by the Registrar, furnish him with the date and number of any applications filed by him outside Botswana relating to the same or essentially the same invention as that claimed in the application filed with the Registrar.

(2) That applicant shall also, if requested by the Registrar, furnish him with the following documents relating to one of the applications referred to in subsection (1)-

(a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the said application:

(b) a copy of the patent or other title of protection granted in respect of that application:

(c) a copy of any final decision rejecting the application or refusing the grant requested in respect of the application; and

(d) a copy of any final decision revoking or invalidating the patent or other title of protection granted in respect of that application.

*BRAZIL: Articles 19 (II), 24, 34 (I) and 50 (2) of the Industrial Property Law No. 9.279 of 14/05/1996 (as last amended by Law No. 10.196, of 14/02/2001) and Article 31 of the Provisional Act No. 2,186-16 of 23/08/2001*

19. A patent application, in accordance with the conditions established by the INPI, shall contain:

II. the specifications;

24. The specifications shall clearly and sufficiently describe the object, so as to permit its reproduction by a technician versed in the subject, and shall indicate, when applicable, the best way of doing it.

Sole Paragraph. In the case of biological material that is essential to the practical execution of the object of the application, which cannot be described in accordance with this Article and which is not accessible to the public, the specifications shall be supplemented by the deposit of the material with an institution authorized by the INPI or indicated in an international agreement.

34. After the examination has been requested, the following must be submitted, within a period of 60 (sixty) days, whenever requested, under penalty of having the application dismissed:

I. objections, search for prior art and results of examination for granting of a corresponding application in other countries, when priority is claimed;

Article 31 of the Act No. 2,186-16 of 23/08/2001. Granting of industrial property rights by the competent bodies over the process or product obtained from samples of genetic heritage components is subject to compliance with this Provisional Act. The person or institution applying for the property rights must inform the origin of the genetic material and the genetic knowledge and the associated traditional knowledge, as appropriate.

50. Nullity of a patent shall be administratively declared when:

II. the specifications and claims did not comply with the provisions of Articles 24 and 25, respectively;

*BULGARIA: Articles 37 and 46a of the Law on Patents and Utility Model Registration No. 27/2 of 1993 as last amended on 20/07/2007*

Description of Invention

*Article 37*

(1) The description shall contain the title and the technical field to which the invention belongs; the prior art, as far as known to the applicant, with citation of the documents in which it is described; clear and adequate disclosure of the essential technical features of the invention and its advantages, in such manner that the invention may be carried out by a person skilled in the art; brief explanations of the drawings and at least one embodiment of the invention using examples, if necessary, and reference to the drawings, if any, as well as the manner of working the invention in industry, where this is not obvious from the description or the character of the invention.

(2) Where the patent application refers to the use of biological material or to material such that is not available to the public and cannot be described in the patent application in such a way as to enable the invention to be carried out by a person skilled in the art, the description shall contain the biological material deposit data -- the number and date of the deposit and the name and address of the international depositary authority according to Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the deposit being made no later than the priority date. The description of the application shall contain all information on the characteristics of the deposited biological material the applicant disposes of.

(3) If the biological material is deposited outside the Republic of Bulgaria, the applicant shall, within three months following publication of a mention about the patent application, make a deposit of that material in the National Industrial Microorganisms and Cell Cultures Bank too, so that any person who has the right of access could get a biological material sample in the Republic of Bulgaria in accordance with a procedure as laid down in a regulation of the Council of Ministers concerning the deposit and access for the purposes of patent procedure.

(4) If biological material deposited in accordance with paragraph (3) is no longer available in the National Industrial Microorganisms and Cell Cultures Bank due to the fact that it is no longer viable or for some other reason, the applicant shall make another deposit of the material within a term and in a manner as laid down in the regulation referred to in paragraph (3).

(5) Where an invention relates to a sequence or partial sequence of a gene, the patent application shall contain a disclosure of the industrial applicability of such sequence.

*Article 46a* (new, State Gazette No. 64/2006, in force as from 09.11.2006)

Within three months following the examination referred to in Article 46, an examiner from the Examination Department shall carry out preliminary examination under Articles 37, 38 and 40. If deficiencies are ascertained, the applicant shall be informed thereof and shall be given three months to eliminate them. If the applicant fails to respond within this period or fails to remove the deficiencies, a decision shall be taken to terminate the procedure.

*BURUNDI: Articles 20-23, 35 and 175 of the Law No. 1/13 of 28/07/2009 on Industrial Property*

*Article 20*

La description doit divulguer l'invention d'une manière suffisamment claire et complète pour qu'une personne du métier ayant des connaissances et une habileté moyennes puisse l'exécuter. Elle doit notamment indiquer au moins un mode d'exécution de l'invention connu de l'inventeur à la date de dépôt ou, lorsqu'une priorité est revendiquée, à la date de priorité de la demande.

Aux fins du présent article, une personne du métier ayant des connaissances et une habileté moyennes désigne un citoyen du Burundi qui a étudié et exerce sa profession au Burundi et qui a acquis des compétences et une expérience moyennes dans le domaine de la technique auquel appartient l'invention revendiquée.

Pour évaluer si la divulgation est suffisante, il convient de prendre en considération ce qui est contenu dans la description, les revendications et les dessins tels qu'ils figurent à la date à laquelle le caractère suffisant de la divulgation a été examiné.

*Article 21*

La description doit contenir une indication claire de l'origine des ressources génétiques ou biologiques prélevées sur le territoire du Burundi et qui ont été directement ou indirectement utilisées dans la réalisation de l'invention revendiquée ainsi que tout élément des savoirs traditionnels lié ou non à ces ressources qui est protégé en vertu du titre V de la présente partie et qui a été directement ou indirectement utilisé dans la réalisation de l'invention revendiquée sans le consentement préalable en connaissance de cause de ses créateurs individuels ou collectifs.

*Article 22*

Le Directeur de la propriété industrielle peut, à tout moment avant la délivrance du brevet, exiger que la description figurant dans les demandes de brevets étrangères soient adaptées aux compétences ordinaires des citoyens burundais afin d'assurer la diffusion de la technologie.

*Article 23*

En cas de demande de brevet relative à des micro-organismes, le Directeur de la propriété industrielle reconnaît le dépôt et la date de dépôt indiquée par l'autorité de dépôt internationale ainsi que l'échantillon du micro-organisme déposé à condition que le déposant lui remette une copie du reçu du dépôt délivré par l'autorité du dépôt internationale.

*Article 35*

Quiconque entend se prévaloir d'un dépôt d'une demande antérieure portant sur la même invention que celle revendiquée dans la demande déposée au Burundi doit produire:

- 1 Un document indiquant la date et le numéro du dépôt effectué à l'étranger ;
- 2 Une copie de toute communication reçue par le déposant au sujet des résultats de toute recherche ou de tout examen effectué en rapport avec la demande étrangère ;
- 3° Un exemplaire du brevet délivré sur base de la demande étrangère;
- 4° Une copie de toute décision définitive portant rejet de la demande étrangère ou de la requête en délivrance formulée dans la demande étrangère ;

5° Une copie de toute décision définitive annulant le brevet délivré sur base de la demande étrangère.

*Article 175*

Le tribunal du commerce annule le certificat de modèle d'utilité ou le brevet si la personne qui demande l'annulation prouve que l'une des conditions prévues aux articles 8 à 32 relatifs aux brevets et aux articles 91 à 96 et l'article 103 relatifs aux certificats de modèle d'utilité n'est pas remplie ou si le titulaire du certificat n'est pas l'inventeur ni son ayant cause.

*CAMBODIA: Articles 18, 30, 31, 32, 36, 38 and 66 of the Law on Patents, Utility Models and Industrial Designs of 22/01/2003*

*Article 18*

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate the best mode known to the applicant for carrying out the invention, at the filing date or, where priority is claimed, at the priority date of the application.

*Article 30*

The applicant shall, at the request of the Registrar, furnish him with the date and number of any application for a patent filed by him abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the Ministry in charge of industry.

*Article 31*

The applicant shall, at the request of the Registrar, furnish him with the following documents relating to one or more of the foreign applications referred to in Article 30 of this Law:

- (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (ii) a copy of the patent granted on the basis of the foreign application;
- (iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

The applicant shall, at the request of the Registrar, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in the 1st paragraph of this Article.

*Article 32*

Items (i) and (iii) of the 1st paragraph of Article 31 of this Law shall not apply in respect of information relating to the examination of the same international application in another elected Office where the Registration Department established under Article 117 of this Law, is an elected Office in the meaning of Article 83 of this Law.

*Article 36*

Where the Registrar is of the opinion that the application complies with the requirements indicated in the Article 35, the Registrar shall take a decision as to whether the requirements of the 2nd and 3rd paragraph of Article 3, Articles 4 to 9, Articles 18 to 20 and Articles 23 to 26 of this Law and the Regulations pertaining thereto are fulfilled.

*Article 38*

Where the Registrar finds that the conditions referred to in Articles 35 and 36 of this Law are fulfilled, he shall proceed to grant the patent. Otherwise, he shall refuse the application and notify the applicant of that decision.

*Article 66*

The competent Court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of the 2nd and 3rd paragraph of Article 3, Articles 4 to 9 and Articles 18 to 20 of this Law is not fulfilled or if the owner of the patent is not the inventor or his successor in title.

CANADA: Sections 27 (3), (6) and (7), 38.1, 38.2 and 47 (1) of the Patent Act (R.S., 1985, c. P-4) as on 30/04/2010

Application for patents

27. Specification

(3) The specification of an invention must

(a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;  
(b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it;

(c) in the case of a machine, explain the principle of the machine and the best mode in which the inventor has contemplated the application of that principle; and

(d) in the case of a process, explain the necessary sequence, if any, of the various steps, so as to distinguish the invention from other inventions.

(6) Where an application does not completely meet the requirements of subsection (2) on its filing date, the Commissioner shall, by notice to the applicant, require the application to be completed on or before the date specified in the notice.

(7) The specified date must be at least three months after the date of the notice and at least twelve months after the filing date of the application.

Biological material may be deposited

38.1 (1) Where a specification refers to a deposit of biological material and the deposit is in accordance with the regulations, the deposit shall be considered part of the specification and, to the extent that subsection 27(3) cannot otherwise reasonably be complied with, the deposit shall be taken into consideration in determining whether the specification complies with that subsection.

Deposit not required

(2) For greater certainty, a reference to a deposit of biological material in a specification does not create a presumption that the deposit is required for the purpose of complying with subsection 27(3).

38.2 (1) Subject to subsections (2) and (3) and the regulations, the specification and any drawings furnished as part of an application for a patent in Canada may be amended before the patent is issued.

(2) The specification may not be amended to describe matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

(3) Drawings may not be amended to add matter not reasonably to be inferred from the specification or drawings as originally filed, except in so far as it is admitted in the specification that the matter is prior art with respect to the application.

47. (1) Whenever any patent is deemed defective or inoperative by reason of insufficient description and specification, or by reason of the patentee's claiming more or less than he had a right to claim as new, but at the same time it appears that the error arose from inadvertence, accident or mistake, without any fraudulent or deceptive intention, the Commissioner may, on the surrender of the patent within four years from its date and the payment of a further prescribed fee, cause a new patent, in accordance with an amended description and specification made by the patentee, to be issued to him for the same invention for the then unexpired term for which the original patent was granted.

CHILE: Articles 43, 43bis and 46 of the Industrial Property Law No. 19.039 of 24/01/1991 (consolidated version of 2005 as last amended on 2007) and Article 39 of the Regulations thereto

Article 43

The following documents should accompany the patent application:

- An abstract of the invention.
- Description of the invention.

- Claims sheet.
- Drawings of the invention (where appropriate).

#### *Article 43 bis*

The abstract shall have a purely technical purpose and cannot be considered for any other purpose, not even to determine the sphere of protection applied for.

The claims sheet shall define the subject of the protection applied for. Claims shall be clear and concise and must be based on the description.

The description shall be clear and complete, so as to enable an expert in such matters to reproduce the invention without the need for other information.

Article 46. Applicants for patents that have already been applied for abroad shall present the result of the search and the examination carried out by the foreign office, if they have been carried out, regardless of whether they resulted in the granting of the patent.

#### *Regulations*

##### *Artículo 39*

La memoria descriptiva del invento se deberá presentar en texto formando cuerpo aparte e incluirá una descripción de lo conocido en la materia, una descripción de los dibujos (si los hay), una descripción de la invención y un ejemplo de aplicación, cuando corresponda.

La descripción de lo conocido en la materia comenzará introduciendo el campo de aplicación preferente de la invención, citando el problema técnico que ésta aborda y hará una referencia a las soluciones dadas a dicho problema, procurando que estas soluciones sean lo más cercanas y actuales posibles -desde el punto de vista tecnológico- destacando sus inconvenientes o desventajas técnicas.

La descripción de la invención es una explicación detallada y clara de la invención en referencia a las partes o piezas numeradas de los dibujos si ellos existieren y debe ser lo suficientemente completa como para que cualquier persona especializada en el sector industrial al que se refiere pueda "reproducir la invención".

Cuando la invención comprenda un material biológico vivo, incluyendo virus, o su procedimiento de obtención, de tal manera que la invención no pueda ser reproducida cabalmente en la memoria descriptiva, el Departamento podrá solicitar que dicho material sea depositado en un organismo internacionalmente reconocido para tales efectos, debiendo indicarse la institución y número de registro respectivo.

El ejemplo de aplicación de la invención consistirá en una exposición detallada de, a lo menos, un modo de realización de la invención y podrá apoyarse o ilustrarse con ayuda de los dibujos si los hubiere, de tal forma que sirva para hacer reproducible la invención.

#### *CHINA: Articles 26 and 36 of the Patent Law of 27/12/2008*

##### *Article 26*

Where a patent application for invention or utility model is filed, a request, a specification and its abstract, and claims shall be submitted.

The written request shall state the title of the invention or utility model, the name of the inventor, the name and address of the applicant and other related matters.

The specification shall describe the invention or utility model in a manner sufficiently clear and complete so that a person skilled in the relevant field of technology can accurately produce it; where necessary, drawings shall be appended.

The abstract shall describe briefly the technical essentials of the invention or utility model.

The patent claim shall, on the basis of the specification, clearly and briefly specify the scope of the patent protection claimed.

An applicant who files a patent application for an invention-creation completed on the basis of genetic resources shall in the patent application document indicate the direct and indirect source of the genetic resources; the applicant unable to indicate the original source of the genetic resource must provide an explanation.

*Article 36*

When requesting substantive examination of an invention patent application, the applicant shall furnish reference materials concerning the invention that were available prior to the filing date of the application.

For an patent application for an invention that has been already filed in a foreign country, the patent administrative department under the State Council may ask the applicant to furnish within a specified time limit documents concerning any search made for the purpose of examining that application, or concerning the results of any examination made, in that country. If, at the expiration of the specified time limit, without any justified reason, the said documents are not furnished, the application shall be deemed to have been withdrawn.

*COSTA RICA: Articles 6 (1) and (4), 13 (1), (3) and (4) and 14 (1), (3) and (4) of the Patents Law No. 6867 of 25/04/1983 (as last amended by Law No. 8039 of 12/10/2000) and Article 80 of the Law no. 7788 of 23/04/1998 on Biodiversity*

*Solicitud*

6.-1. La solicitud de patente ser presentada ante el Registro de la Propiedad Industrial, acompañada de una descripción, de las reivindicaciones, de los dibujos que fuesen necesarios para comprender la invención, y de un resumen de estos documentos. Se acompañarán también al comprobante de haber pagado la tasa de presentación establecida en el reglamento de esa ley.

4. La descripción deberá especificar la invención de manera suficientemente clara y completa para poder evaluarla para que una persona versada en la materia técnica correspondiente pueda ejecutarla y, en particular, deberá indicarse expresamente la mejor manera que el solicitante conozca para ejecutar la invención, dando uno o más ejemplos concretos cuando fuera posible, e identificando, en su caso, aquel que daría los resultados más satisfactorios en su explotación industrial.

13.-1. El Registro de la Propiedad Industrial examinará si la invención es patentable, de conformidad con los artículos 1 y 2, así como si la solicitud satisface el requisito de la unidad de la invención, según el artículo 7, y si en su caso, la modificación o la solicitud fraccionada están conformes con lo dispuesto en el artículo 8. También se examinará si la descripción, las reivindicaciones y los dibujos se ajustan a los requisitos señalados en el artículo 6, párrafos 2, 3, 4, y 5 y a las disposiciones correspondientes al reglamento.

3. En caso de observarse que no se han cumplido las condiciones del párrafo 1, el Registro de la Propiedad Industrial lo notificará al solicitante para que presente, dentro del mes siguiente, sus observaciones, y en su caso, corrija o complete la documentación aportada, que modifique o divida la solicitud, con observación de lo prescrito en el artículo 8.

4. Si el solicitante no cumpliera con lo prevenido por el Registro, dentro del plazo prescrito, o si el Registro comprobara, que pese a la respuesta del solicitante, no se satisfacen las condiciones previstas en el párrafo 1, denegará la concesión de la patente. La denegatoria estará fundamentada y será notificada por el Registro al solicitante.

14.-1. El solicitante o titular de una patente en Costa Rica deberá indicar la fecha y el número de toda solicitud de patente u otro título de protección que haya presentado, o del derecho que hubiese obtenido, ante una oficina de propiedad industrial en cualquier otro país o ante una oficina regional de propiedad industrial, y, que se refiera total o parcialmente a la misma invención reivindicada en la solicitud presentada en Costa Rica.

3. El solicitante o titular de una patente deberá proporcionar los siguientes documentos en relación con las solicitudes o títulos extranjeros:

a) Copia de toda comunicación recibida por el solicitante que se refiera a los resultados de la búsqueda de anterioridades o de exámenes efectuados respecto a la solicitud extranjera.

b) Un ejemplar de la patente u otro título de protección concedido con base en la solicitud extranjera.

c) Copia de toda decisión definitiva que rechace la solicitud extranjera o deniegue la concesión solicitada.

d) Información sobre litigios o reclamaciones que conozca sobre su invención o que están relacionados con la misma.

4. El solicitante de una patente deberá asimismo proporcionar al Registro de la Propiedad Industrial, a petición de este, copia de cualquier decisión definitiva que invalide la patente, u otro título de protección que hubiese sido concedido con base en la solicitud extranjera a que se refiere el párrafo 1.

*Article 80 of the Law no. 7788 of 23/04/1998 on Biodiversity*

Consulta Previa Obligada

80. Tanto la Oficina Nacional de Semillas como los Registros de Propiedad Intelectual y de Propiedad Industrial, obligatoriamente deberán consultar a la Oficina Técnica de la Comisión, antes de otorgar protección de propiedad intelectual o industrial a las innovaciones que involucren elementos de la biodiversidad. Siempre aportarán el certificado de origen emitido por la Oficina Técnica de la Comisión y el consentimiento previo.

La oposición fundada de la Oficina Técnica impedirá registrar la patente o protección de la innovación.

*CROATIA: Articles 20 (4), (5) and (6), 34 (1) 1), (2) and (4) and 79 4) of the Patent Act No. 173/2003 of 31/10/2003as last amended by Law OG No 76/2008 of 23/07/2007*

*Article 20*

(4) The patent application must disclose the invention in a manner sufficiently clear and precise for it to be carried out by a person skilled in the art.

(5) If the invention concerns viable biological material which cannot be disclosed in a manner enabling it to be carried out by a person skilled in the art, the application must be accompanied by proof to the effect that a sample of such material has been deposited with the competent institution not later than on the filing date of the patent application.

(6) The competent institution referred to in paragraph (5) of this Article shall be considered an institution which complies with the requirements prescribed by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977 and last revised on 26 September 1980.

*Article 34*

(1) The examination of pre-requisites for the publication of a patent application shall establish whether the application complies with the following requirements:

1. whether it contains all the elements referred to in Article 20 of this Act drafted in the prescribed manner, and the necessary attachments prescribed by this Act,

(2) If such examination establishes that the requirements referred to in paragraph (1) of this Article are not complied with, the Office shall invite the applicant to correct the deficiencies expressly indicated in the invitation within a reasonable time limit. This time limit shall not be less than 2 months and not more than 3 months from the date of receipt of the invitation.

(4) If the applicant does not correct the deficiencies referred to in paragraph (1) of this Article within the prescribed time limit, the Office shall issue a decision on the rejection of the patent application.

*Article 79*

A patent may be declared null and void at any time, on the proposal of any natural or legal person or a State Attorney, if the patent has been granted:

4. for an invention which is not disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art,

CYPRUS: *Articles 15 and 58 (1) (ii) of the Patent Law No. 16(1) of 01/04/1998*

Requirements of Application

Description

*Article 15*

The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

*Article 58.-(1)*

The Court may, on the application of any person, invalidate a patent, in whole or in part, on any of the following and no other grounds:

(ii) that the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

CZECH REPUBLIC: *Sections 23 (1) (b) and 26 (2) of the Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of November 27/11/1990 as last amended by Law No. 116 of 06/04/2000*

Section 23

Revocation of the patent

(1) The Office shall revoke the patent, if it is ascertained subsequently:

b) that the invention is not disclosed in the patent so clearly and completely, to be carried out by a person skilled in the art;

26.-(2) The invention must be disclosed in an application for an invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the invention concerns an industrial microorganism for the purposes of production, the microorganism must be kept in a public collection as from the date on which the applicant's priority right begins.

DENMARK: *Sections 8 (2), 8a, 21 (2) (ii) and 52 (1) (ii) of the consolidated Patents Act No. 91 of 28/01/2009 and Rule 3 (4) and (5) of the Order No. 93 of 29/01/2009*

8.-(2) The application shall contain a description of the invention, including drawings where necessary, and a precise statement of the matter for which protection by the patent is sought (claims). The fact that the invention relates to chemical compound shall not imply that a specific use shall be indicated in the claim. The description shall be sufficiently clear to enable a person skilled in the art to carry out the invention. An invention which relates or involves the use of biological material shall, in the cases specified in section 8a, only be regarded as disclosed in a sufficiently clear manner if also the requirements of section 8a are fulfilled.

8a.-(1) If carrying out the invention involves the use of biological material which is not available to the public or which cannot be described in the documents of the application in such a manner as to enable a person skilled in the art to carry out the invention, a sample of the biological material shall be deposited not later than on the date of filing of the application. The sample shall thereafter always be deposited in such manner that any person entitled to the furnishing of a sample may have the sample furnished in Denmark.

The Minister of Economic and Business Affairs shall lay down rules as to where deposits may be made.

(2) If a deposited sample ceases to be viable, or if for any other reason a sample cannot be furnished, the sample shall be replaced by a new sample of the same biological material within the time limit prescribed and in accordance with the rules laid down by the Minister of Economic and Business Affairs.

The new deposit shall be deemed to have been made already on the date of the previous deposit.

21-(2) An opposition may only be based on the grounds that the patent has been granted irrespective of the fact that

(ii) it relates to an invention which is not disclosed in a manner sufficiently clear to enable a person skilled in the art to carry out the invention on the basis of the description,

52.-(1) A patent may be revoked by a court decision if

(ii) it relates to an invention which is not disclosed in a manner sufficiently clear to enable a person skilled in the art to carry out the invention on the basis of the description,

Order of 29/01/2009

3.-(4) If an invention relates to or makes use of a biological material of vegetable or animal origin, the patent application shall contain information about the geographical origin of the material if the applicant is aware thereof. If the applicant is not aware of the geographical origin of the material, that shall appear from the application. Lack of information about the geographical origin of the material or about the applicant's non-awareness thereof shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.

(5) If an invention relates to or makes use of a biological material of human origin, it shall appear from the patent application whether the person from whom the biological material originates has given his consent to the filing of the application. The information about consent shall not affect the examination and other processing of the patent application or the validity of the rights conferred by the granted patent.

5.-(4) Where part of the description seems to be missing from the application, or where the application refers to a drawing which seems to be missing, the Patent and Trademark Office shall invite the applicant to submit the missing part or drawing before the expiry of a time limit of two months from the notification thereof.

(5) Where a missing part of the description or a missing drawing is filed with the Office before the expiry of a time limit of two months calculated from the date on which one or more of the conditions pursuant to section 8b(1) of the Patents Act are fulfilled or from the forwarding of the invitation referred to in subsection 4 to the applicant, that part of the description or the drawing shall be included in the application and, subject to subsections 6 and 7, the date of filing shall then be the date on which the Patent and Trademark Office has received the said part of the description or the said drawing.

*DJIBOUTI: Articles 32, 34, 35, 41 (g) and 84 (b) of the Protection of Industrial Property Law  
No.50/AN/09/6th L of 21/06/2009*

#### *Article 32*

Le dépôt de la demande est soumis au paiement d'une redevance prescrite.

Le déposant doit fournir avec sa demande de brevet la date et le numéro de toute demande de brevet que lui ou son prédécesseur en droit a disposée à l'étranger ("demande étrangère) et qui porte sur la même invention, ou essentiellement sur la même invention, que celle qui est revendiquée dans la demande déposée auprès de l'Office Djiboutien de la Propriété Industrielle et commerciale.

Le déposant est tenu de fournir à l'Office Djiboutien de la Propriété Industrielle et commerciale, une copie de toute décision définitive annulant le brevet qui a été délivré sur la base de la demande étrangère visée à l'alinéa précédent.

#### Article 34

La description de l'invention doit divulguer l'invention d'une manière suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter.

La description de l'invention doit notamment .

- a) préciser le domaine technique auquel se rapporte l'invention;
- b) indiquer l'état de la technique antérieure qui, dans la mesure où le demandeur le connaît, peut être considéré comme utile pour l'intelligence de l'invention et pour la recherche et l'examen de l'invention en cas de litige; les documents servant à refléter l'état de la technique antérieure doivent être cités de préférence; lorsque l'invention revendiquée a été développée ou obtenue directement de ressources génétiques ou biologiques obtenues d'une source particulière, ou de l'utilisation de connaissances traditionnelles obtenues d'une communauté particulière, la description doit indiquer la source de ces ressources ou connaissances ainsi que la manière dont ils ont été obtenus ;
- c) exposer l'invention revendiquée en des termes permettant la compréhension du problème technique, même s'il n'est pas expressément désigné comme tel, et celle de la solution de ce problème, ainsi que, le cas échéant, les avantages apportés par l'invention par rapport à l'état de la technique antérieure ;
- d) indiquer en détail au moins un mode de réalisation de l'invention dont la protection est demandée, qui, en principe, doit comporter des exemples, s'il y a lieu, et des références aux dessins, s'il en existe.
- e) décrire brièvement les figures des dessins s'il en existe ;
- f) expliciter, dans le cas où elle ne résulte pas à l'évidence de la description ou de la nature de l'invention, la manière dont celle-ci est susceptible d'application industrielle.

Lorsqu'une invention comporte l'utilisation d'une matière biologique ou qu'elle concerne une matière biologique, à laquelle le public n'a pas accès et qui ne peut être décrite dans la demande de brevet de façon à permettre à un homme du métier d'exécuter l'invention, celle-ci n'est considérée comme suffisamment exposée que si:

- a) un échantillon de la matière biologique a été déposé, au plus tard à la date de dépôt de la demande, auprès d'une autorité de dépôt habilitée;
- b) la demande telle que déposée contient les informations pertinentes dont dispose le demandeur sur les caractéristiques de la matière biologique;
- c) la demande comporte le nom et l'adresse de l'autorité de dépôt, la date du dépôt et le numéro d'ordre de la matière biologique déposée;
- d) le déposant fournit le certificat de dépôt du matériel biologique.

Lorsque la matière biologique a été déposée par une personne autre que le demandeur, le nom et l'adresse du déposant sont mentionnées dans la demande et est fourni à l'Office Djiboutien un document prouvant que le déposant a autorisé le demandeur à se référer dans la demande à la matière biologique déposée et a consenti sans réserve et de manière irrévocable à mettre la matière déposée à la disposition du public.

Seront fixées par voie réglementaire d'autres formalités pour la description et les formalités quant aux délais de présentation et de communication des informations et relatives à la matière biologique utilisée pour l'invention, ainsi que les questions relatives au dépôt prévu à cet article et l'accès aux échantillons.

#### Article 35

Les revendications définissent l'étendue de la protection demandée: la description et les dessins peuvent servir à interpréter les revendications. Les revendications doivent être claires et concises. Elles se fondent entièrement sur la description.

#### Article 41

Est rejetée toute demande de brevet:

- g) dont la description ou les revendications ne remplissent manifestement pas les conditions prévues aux articles 34 et 35, notamment dans le cas où les revendications ne se fondent pas sur la description;

#### Article 84

La nullité du brevet est prononcée par le Tribunal à la demande de toute personne y ayant intérêt:

b) si la description de l'invention n'expose pas l'invention d'une façon suffisante pour qu'un homme du métier puisse l'exécuter;

*DOMINICA: Sections 17 (4) and 23 of the Patents Act No. 8 of 07/10/1999*

17. (4) The description shall disclose the invention in a manner which is sufficiently clear and complete to permit a person having ordinary skill in the art to carry out the invention, and shall, in particular, indicate at least one mode known to the applicant in which the invention can be carried out.

*Information concerning corresponding foreign applications*

23. (1) The applicant shall, if requested by the Registrar, furnish him with the date and number of any application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed in the application filed with the Registrar.

(2) The applicant shall also, if requested by the Registrar, furnish him with the following documents relating to any foreign application referred to in subsection (1)-

(a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(b) a copy of the patent granted on the basis of the foreign application;

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; and

(d) a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in subsection (1).

(3) Subsection (2)(a) and (c) shall not apply where the Office of the Registrar is an elected Office within the meaning of section 55 and has received or will receive an international preliminary examination report.

(4) Any document furnished pursuant to this section-

(a) shall, if not in English, be accompanied by a translation thereof in English, verified by the translator that the translation is, to the best of his knowledge, complete and faithful; and

(b) may be used only for facilitating the evaluation of the novelty and inventive step of the invention for which the patent application is made.

*DOMINICAN REPUBLIC: Articles 13, 22 (2), (5) and (6) and 34 (1) (c) and (e) of the Industrial Property Law No. 20-00 of 08/05/2000*

*Article 13*

*Description*

1) The description must disclose the invention in a sufficiently clear and complete fashion so as to be able to evaluate it and so that a person knowledgeable in the corresponding technical subject can execute it.

2) The description of the invention shall indicate the name of the invention and shall include the following information:

a) the technological, agricultural, scientific, etc. sector to which the invention belongs or to which it is applied.

b) the earlier technology known to the applicant which could be considered useful for the comprehension and the examination of the invention, and references to earlier documents and publications related to said technology.

c) a description of the invention in terms permitting the understanding of the technical problem and the solution contributed by the invention and indicating the advantages it may have over the earlier technology.

d) a brief description of the drawings, if any.

e) the best way known to the applicant to execute or put into practice the invention, using examples and references to the drawings.

f) the way in which the invention lends itself to industrial application, except when this is evident from the description or the nature of the invention.

3) When the invention concerns biological material which cannot be described in such a manner that the invention could be executed by a person knowledgeable in the subject, and such material is not available to the public, the description will be complemented by the deposit of said material in a deposit institution designated beforehand by the General Agency for Industrial Property.

4) When the deposit of biological material to complement the description has been made, this circumstance shall be indicated in the description together with the name and address of the institution of deposit, the date of the deposit and the order number given to the deposit by the institution. It shall also describe the nature and characteristics of the material deposited when this is relevant to the disclosure of the invention.

#### *Article 22*

##### Examination of the Merits

2) The patent application shall be examined to determine if its object constitutes an invention according to Articles 309 and 310.1, if the invention is patentable according to Articles 1 and 2 and Articles 3, 4, 5 and 6 if it fulfills the requirements of Articles 13, 14, 15, 16 and 17 and, when such is the case, Articles 18, numeral 1) and 135, and the corresponding regulatory provisions.

5) If any of the requirements for granting the patent are not fulfilled, the General Agency for Industrial Property shall notify the applicant so that he or she may, within a period of three months, complete the documentation filed, correct, modify or divide the application, or present such comments or documents as he may deem advisable.

6) If the applicant should not respond to the notification within the established time limit, or if, in spite of the reply, the General Agency for Industrial Property should find that the requirements for granting the patent are not satisfied, it shall be denied by means of a substantiated resolution.

#### *Article 34*

##### Annulment and Expiration of the Patent

1) Patents granted in violation of the provisions of this law shall automatically be null and void. The action for annulment or expiration may be carried out by any interested person via defense or exception. In particular, the General Agency for Industrial Property may at any time, at the request of any interested person or competent authority, declare a patent null and void in any of the following cases:

c) the patent does not disclose the invention pursuant to Articles 13 and 14.

e) The patent granted contains a broader disclosure than that contained in the initial application.

*EGYPT: Articles 13 and 14 of the Law on the Protection of Intellectual Property Rights No. 82 of 03/06/2002*

#### *Article 13*

The patent application shall be accompanied by a detailed description of the invention, including a full statement of the subject matter and of the best way to enable a person of expertise to execute it, and of each product or method for which protection is sought.

The description shall also include in a clear manner the new elements for which the applicant seeks protection accompanied, where necessary, by an illustrative drawing of the invention.

Where the invention involves biological, plant or animal product, or traditional medicinal, agricultural, industrial or handicraft knowledge, cultural or environmental heritage, the inventor should have acquired the sources in a legitimate manner.

Where the invention involves microorganisms, the applicant shall disclose the identity of such organisms and deposit a live culture thereof with the authority designated in the Regulations.

Without prejudice to the provisions of Article 38 of this Law, the applicant shall, in all cases, provide full data and information on any applications relating to the same invention or its subject matter, that he previously filed abroad, as well as the outcome of such applications.

The Regulations shall determine the required annexes to be attached to the patent application, the time limits for their submission and as well as the conditions justifying its refusal.

#### *Article 14*

The Patent Office may, as stipulated in the Regulations, require the applicant to make any amendments or complements which it shall deem necessary to comply with the provisions of Article

13. If the applicant fails to comply within three months of notification, he shall be considered as having withdrawn his application.

The applicant may, within 30 days and in accordance with the conditions stipulated in the Regulations, appeal such request by the Patent Office before the Committee provided for in Article 36.

EL SALVADOR: *Articles 138, 153 and 163 (1) (b) of the Intellectual Property Legislative Decree No. 604 of 15/07/1993 No. 604 as last amended by Legislative Decree No. 912 of 14/12/2005*

*Article 138*

The description shall disclose the invention in a sufficiently clear and complete way for it to be assessed and for the invention to be carried out by a person skilled in the art without excessive experimentation.

The description shall give the name of the invention or utility model and shall include the following information:

- (a) the area of technology to which it refers or applies;
- (b) the prior art known to the applicant that might be considered useful for the understanding and examination of the invention or utility model, and references to previous documents and publications relating to the technology concerned;
- (c) a description of the invention or utility model in terms that allow the technical problem and the solution provided to be understood and explain the advantages of the invention or utility model in relation to earlier technology;
- (e) a description of the best method known to the applicant for carrying out the invention or making the utility model, using examples and references to drawings;
- (f) the manner in which the invention or utility model may be produced or used in any activity, except where that is clearly apparent from the description or the nature of the invention or model.

Where the invention refers to a biological product or process requiring the use of biological material that is not available to the public and cannot be so described that the invention may be carried out by a person skilled in the art, the description shall be completed with the deposit of such material at a depository institution that complies with the requirements specified in the Regulations under this Law. In such a case the deposit shall be made not later than on the filing date of the domestic application or, where priority is claimed, not later than on the priority date.

Where the deposit of biological material is made to complete the description, that fact shall be specified in the description, together with the name and address of the depository institution, the date of the deposit and the number assigned to it by the institution. The nature and characteristics of the material deposited shall likewise be described where necessary for the disclosure of the invention.

*Article 153*

For the purposes of the substantive examination, the Registry may require the applicant to provide, duly translated into Spanish, one or more of the following documents relating to foreign applications mentioned in the application:

- (a) Copy of the foreign application and its accompanying documents;
- (b) Copy of any communication or report referring to the results of searches for anticipation or examinations carried out in relation to the foreign request;
- (c) Copy of the patent or other title of protection granted on the basis of the foreign application.

When the application filed in El Salvador includes inventions claimed in two or more foreign applications, in such a way that none of these totally includes what is claimed in the application filed,

the Registry may ask the applicant to submit the documents mentioned in the above letters that relate to other foreign applications that correspond partially or totally to the application filed in El Salvador.

*Article 163*

Any patent or certificate registration shall be declared invalid in the following cases:

(b) if the disclosure of the invention in the patent is not sufficiently clear for a person skilled in the relevant technical field to be able to carry it out, or if the claims are not supported by the disclosure;

*ESTONIA: § 19 (1) 2) and (2) 3), 23 (3) and 50 (1) and (2) 2) of the Patent Act (RT I 1994, 25, 406) of 16/03/1994 as last amended by Law RT I 2004, 20, 141 of 10/03/2004*

§ 19. Patent application

(1) A patent application shall include the following documents:

2) a description of the invention must be disclosed in a sufficiently clear and concise manner which enables a person skilled in the art to carry out the invention

(2) The following documents shall be annexed to a patent application:

3) a document certifying the deposit of a biological material, including micro-organism strain, if the subject of the invention is a biological material or the invention requires the use of a biological material and if the said biological material is not available to the public and it cannot be described in the description of the invention in a manner which would enable a person skilled in the art to make the invention.

§ 23 Examination

(3) The Patent Office has the right to request from an applicant copies of decisions of patent offices of other countries regarding the applicant's analogous patent applications and to exchange information regarding the patent application with patent offices of other countries.

§ 50. Contestation of patent in Board of Appeal

(1) Any person may file a revocation application with the Board of Appeal and request the revocation of a patent within nine months after the publication date of the notice of issue of the patent.

(2) A patent may be contested on the basis of the following allegations:

2) the invention is not disclosed in the description of the invention in a sufficiently clear and concise manner to enable a person skilled in the art to make the invention;

*ETHIOPIA: Sections 9 (3) and (4) (b), 10 and 36 (1) (b) of the Proclamation concerning Inventions, Minor Inventions and Industrial Designs No. 123 of 10/05/1995 and Section 17 14) of the Proclamation No. 482/2006 to provide for access to Genetic resources and Community Knowledge and Community Right*

9. Application

3. The application shall contain a request for the grant of a patent and include a description of the invention, one or more claims, an abstract, and where necessary drawings.

4. In accordance with sub-article (3) of this article:

b) the description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention. The description may be used to interpret the claims;

10. Information Concerning Corresponding Foreign Application for Patents

1. The applicant shall, at the request of the Commission, furnish it with the date and number of any application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed with the Commission.

2. The applicant shall, at the request of the Commission, furnish it with the following documents relating to the foreign applications referred to in sub-article (1) of this article:

a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

b) a copy of the patent granted on the basis of foreign patent application;

c) a copy of any final decision rejecting the foreign application or refusing the grant of the patent requested in the foreign application.

3. The applicant shall, at the request of the Commission, furnish it with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in sub-article (2) of this article.

### 36. Invalidation of a Patent

1. A patent shall be invalidated in whole or in part by the court upon request by an interested party if it is proved that:

b) the description does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

### *Proclamation No. 482/2006*

### 17. Obligations of Access Permit Holder

A person who shall be given an access permit shall have the following obligations:

14. recognize the locality where the genetic resource or community knowledge accessed from as origin in the application for commercial property protection of the product developed there from

*FINLAND: Sections 8 (2), 8a, 25 (1) 2) and 52 (1) 2) of the Patents Act No. 550 of 15/12/1967 as last amended by Act No. 684 of 21/07/2006*

Section 8 - The application shall contain a description of the invention, together with drawings where necessary, and a precise statement of the subject matter for which patent protection is sought (one or more claims). The fact that the invention relates to a chemical compound shall not mean that a specific use must be disclosed in the claim. The description shall be sufficiently clear to enable a person skilled in the art, with the guidance thereof, to carry out the invention. An invention relating to a biological material or involving the use of biological material when being carried out shall be regarded, in the cases referred to in section 8a, as disclosed with sufficient clarity only if the requirements set out in that section are also satisfied. (30.6.2000/650)

Section 8 a - Where an invention concerns biological material or the carrying out thereof involves the use of a biological material which neither is available to the public nor can be described in the application documents in such a manner as to enable a person skilled in the art to carry out the invention, a sample of the biological material shall be deposited no later than on the date the application was filed. The biological material shall be continuously on deposit thereafter so that any person entitled under this Act to a sample of the deposited material may have the sample furnished in Finland. The Government shall decree where deposits may be made.

If a deposited biological material ceases to be viable or if samples of the material cannot be furnished for other reasons, it may be replaced by a new deposit of the same biological material, as decreed by the Government. Once this has been done, the new deposit shall be deemed to have been made on the date of the previous deposit.

Section 25.- The Patent Authority shall revoke a patent on account of an opposition:

(2) if the patent relates to an invention the description of which is not sufficiently clear to enable a person skilled in the art to carry out the invention;

Section 52 - The court shall declare a patent invalid, in a relevant action:

(2) if the patent relates to an invention the description of which is not sufficiently clear to enable a person skilled in the art to carry out the invention;

FRANCE: *Articles L612-5, L612-12 6) and L613-25 (b) of the Intellectual Property Code No. 92-597 of 01/07/1992 (Consolidated version of 2010)*

*Article L612-5*

L'invention doit être exposée dans la demande de brevet de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter.

Lorsqu'une invention impliquant une matière biologique à laquelle le public n'a pas accès ne peut être décrite de manière à permettre à l'homme du métier d'exécuter cette invention, sa description n'est jugée suffisante que si la matière biologique a fait l'objet d'un dépôt auprès d'un organisme habilité. Les conditions d'accès du public à ce dépôt sont fixées par décret en Conseil d'Etat.

*Article L612-12*

Est rejetée, en tout ou partie, toute demande de brevet :

6° Dont la description ou les revendications ne permettent pas d'appliquer les dispositions de l'article L. 612-14 ;

*Article L613-25*

Le brevet est déclaré nul par décision de justice :

b) S'il n'expose pas l'invention de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter ;

GEORGIA: *Sections 26 (3) and (4), 42 (1) (d) and 57 (1) (b) of the Patent Law of 05/02/1999*

26 (3) The description of the invention and utility model shall be filed in respect to the established rule and in full form as to enable the skilled person in the art to realize it.

(4) If the application concerns the biological reproducible material, which cannot be described in the application completely as to enable the skilled person to realize it or, if this biological material is not commonly available, the application shall be completed by the document confirming the deposit of the biological material issued by the Depository.

42 (1) Sakpatenti refuses the granting of a patent for the whole invention and utility model, or for its part, if the application:

(d) does not satisfy the requirement of the paragraph (3) Article 26 of this Law;

57 (1) A patent shall be considered invalid if the following is ascertained:

(b) the patent does not describe an invention, utility model and industrial design completely as to make its embodiment possible;

GERMANY: *Sections 21 (1) 2), 22, 34 (4), (7) and (8) and 34a of the Patent Act of 16/12/1980 as last amended by Act of 31/07/2009*

Section 21

(1) A patent shall be revoked (Section 61) if it arises that

2. the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

#### Section 22

(1) Nullity of a patent shall be declared on request (Section 81) if it arises that one of the grounds given in Section 21(1) exists or if the scope of the patent has been extended.

(2) Section 21(2) and (3) shall apply *mutatis mutandis*.

#### Section 34

(4) An application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(7) At the request of the Patent Office, the applicant shall indicate the state of the art fully and truthfully to the best of his knowledge and incorporate it in the description (subsection (3)).

(8) The Federal Ministry of Justice shall have power to issue by statutory order regulations concerning the deposit of biological material, access to such material, including those persons entitled to have access, and the repeated deposit of biological material should an invention include the use of biological material or concern such material that is not accessible to the public and cannot be described in the application in such a way that a person skilled in the art could carry out the invention (subsection (4)). It may delegate such power by statutory order to the German Patent and Trademark Office.

#### Section 34a

Should an invention be based on biological material of plant or animal origin or if such material is used therefor, the patent application is to include information on the geographical origin of such material, if known. This shall not prejudice the examination of applications or the validity of rights arising from granted patents.

GHANA: *Sections 12 (1) (b), 16, 20 (4) (c) and 56 (2) (a) of the Patent Law No. 305A of 30/12/1992*

#### Application for patent

12 (1) The application for a patent, accompanied by the prescribed fee, shall be made to the Registrar and shall contain

(b) a description disclosing the invention in a manner sufficiently clear and complete for the invention to be evaluated, carried out or worked by a person possessing average skill in and average knowledge of the art to which the invention relates and in particular indicating the best mode known to the applicant for carrying out the invention;

(c) one or more claims which define the matter for which protection is sought; in clear and concise language and in a manner fully supported by the description;

(d) an abstract to serve the purpose of technical information which shall not be taken into account when interpreting the scope of the protection sought; and

(e) where necessary, one or more drawings for the better understanding of the invention.

#### Amendment and division of application

14 (1) The applicant may amend the application provided that the amendment shall not go beyond the disclosure in the initial application.

(2) The applicant may divide out from the application one or more applications, described as "divisional applications", provided that each divisional application shall not go beyond the disclosure in the initial application.

#### Information concerning corresponding foreign applications and grants

16 (1) The applicant shall, at the request of the Registrar, furnish him with the date and number of any foreign application, for a patent or other title of protection filed by the applicant relating to the same or essentially the same invention as that claimed in the application filed with the Registrar.

(2) The applicant shall, at the request of the Registrar, furnish him with the following documents in respect of foreign applications referred to in subsection (1) of this section, namely

(a) copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(b) a copy of the patent or other title of protection granted on the foreign application; and

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(3) The applicant shall, at the request of the Registrar, furnish him with a copy of any decision invalidating the patent or other title of protection granted to the applicant on the basis of the foreign application referred to in subsection (2) of this section.

(4) The applicant shall, at the request of the Registrar, furnish him with copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of any foreign application other than an application referred to in subsections (2) and (3) of this section.

(5) The documents furnished under this section shall serve the purpose of facilitating the evaluation of novelty and inventive step with respect to the invention claimed in the application filed with the Registrar or in the patent granted on the basis of that application.

(6) The applicant shall have the right to submit comments on the documents furnished under this section.

#### Search and examination as to substance

20. 4) If, in the opinion of the Registrar, the subject matter of an invention for which a patent is sought does not fall within the terms of direction given under subsection (2) of this section, he shall cause a search and examination to be carried out as to whether—

(c) the description and the claims comply with the requirements prescribed by sections 12(1)(c) and 13 of this Law and rules pertaining thereto;

#### Invalidation of patent

56. (2) The grounds for invalidation of a patent shall be any of the following—

(a) that any of the conditions specified in section 20(4) of this Law were not fulfilled;

*GREECE: Articles 7 (1) (b) and (4), 11 (a) and 15 (1) (c) of the Law on "Technology transfer, inventions, and technological innovation" No. 1733/1987 (FEK 171, A' of 22/9/1987) as last amended by Law No. 2359 of 15/11/1995*

#### Article 7

##### Filing of application - Acceptability - Publication

1. For the grant of a patent an application shall be filed with O.B.I. including:

b. Description of the invention and determination of one or more claims. O.B.I. may request completion or rewording of the description or the claims in order to comply with the dispositions of the present law. By claim shall be held in the present law the extent and the content of the requested protection;

4. The description of the invention shall be so compiled as to be sufficiently carried out by a third person skilled in the art.

*Article 11*

OBI grants a patent following completion of the procedure of the preceding paragraphs. The patent certifies the complete and orderly nature of the patent application. The patent indicates its classification and its period of life, whereas the following shall be attached thereto:

a. The original of the description of the invention together with the claims, the abstract, and drawings, if any;

*Article 15*

Nullification

1. The patent shall be declared null by Court decision if:

c. The description attached to the patent is insufficient for the invention to be carried out by a person skilled in the art;

*GRENADA: Sections 6 (4), 9, 10 (6) and 11 (1) of the Industrial Property Act of 2002*

6. (4) The description must disclose the invention in a manner which is clear and complete enough for the invention to be carried out by a person having ordinary skill in the art, and must, in particular, indicate at least one mode known to the applicant for carrying out the invention.

Information concerning corresponding foreign applications for patent

9. (1) The applicant must upon request furnish the Registrar with the date and number of any application for a patent filed by the applicant abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the registry.

(2) The applicant must, upon request, furnish the Registrar with the following documents relating to any of the foreign applications referred to in subsection (1) -

- (a) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (b) a copy of the patent granted on the basis of the foreign application;
- (c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application;
- (d) a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in subsection (1).

Filing date 10. (6) If the Registrar is of the opinion that the application complies with the requirements of subsection (5), the Registrar must take a decision as to whether the requirements of sections [3](2) and (3), [4], [6](4), (5) and (6) and [7] and the relevant regulations are fulfilled and for this purpose may, as provided for in the regulations, cause the application to be examined.

Grant of patent; 11. (1) If the Registrar is of the opinion that the application complies with changes in the requirements of section [10](6), the Registrar must grant the patent. Otherwise the Registrar must refuse the application and notify the applicant of the decision.

*GUATEMALA. Articles 108, 109, 118 and 139 (a) of the Industrial Property Law, Decree No. 57-2000 of 18/09/2000*

Descripción

108. La descripción deberá divulgar la invención reivindicada de manera suficientemente clara y completa, de modo que una persona capacitada en la materia técnica correspondiente pueda ejecutarla. La descripción también deberá divulgar la mejor manera conocida por el solicitante para ejecutar la invención reivindicada.

Descripción de Material Biológico

109. Cuando la invención se refiera a un producto o a un procedimiento relativo a un material biológico, que no se encuentre a disposición del público y la invención no pueda describirse de manera que pueda comprenderse y ser ejecutada por una persona capacitada en la materia técnica, se complementará la descripción mediante el depósito de una muestra de dicho material.

El depósito de la muestra del material biológico deberá efectuarse en una institución de depósito establecida dentro o fuera del país y reconocida por el Registro, a más tardar en la fecha de presentación de la solicitud o, cuando se invoque un derecho de prioridad, en la fecha de presentación de la solicitud prioritaria, debiendo acreditarse con la documentación pertinente. Sin perjuicio del reconocimiento que el Registro realice respecto a otras instituciones, se reconocen a partir de la vigencia de esta ley las autoridades internacionales de depósito designadas conforme al Tratado de Budapest sobre el Reconocimiento Internacional del Depósito de Microorganismos a los fines del Procedimiento en materia de Patentes de 1977.

Cuando se efectuare un depósito de material biológico para los efectos de una solicitud de patente, ello se indicará en la descripción junto con el nombre y dirección de la institución de depósito, la fecha del depósito y el número de depósito atribuido por la institución. También se describirá la naturaleza y características del material depositado cuando ello fuese necesario para efectos de la divulgación de la invención.

El depósito de material biológico sólo será válido para efectos de la concesión de una patente si se hace bajo condiciones que permitan a cualquier persona interesada obtener muestras de dicho material, a más tardar a partir de la fecha de publicación de la solicitud de patente correspondiente.

#### Otros Documentos

118. Para los efectos del examen de fondo, el Registro podrá requerir al solicitante que presente, dentro de un plazo de dos meses contados a partir de la notificación respectiva, prorrogable a un mes más en casos calificados por el Registro, una copia sin legalización y con traducción simple de cualquier material contenido en un expediente administrativo o judicial del extranjero, relacionado con la solicitud en trámite, incluyendo, entre otras:

- a) La propia solicitud;
- b) Los resultados de exámenes de novedad o de patentabilidad;
- c) La patente u otro título de protección que se hubiese concedido;
- d) Cualquier resolución o fallo por el cual se hubiese rechazado, denegado u otorgado la solicitud o patente; y
- e) Cualquier resolución o fallo por el cual se hubiese revocado, anulado, invalidado o cancelado la patente u otro título de protección concedido.

A pedido del solicitante o bien de oficio, el Registro podrá suspender la tramitación de la solicitud de patente cuando algún documento que deba presentarse por el solicitante, conforme a este artículo, no se hubiese emitido en el país de que se trate.

El solicitante podrá, respecto a la información o documentos que proporcione, formular las observaciones y comentarios que estime pertinentes.

Si del examen de fondo resultare que previo al otorgamiento de la patente es necesario completar la documentación presentada, corregir, modificar o dividir la solicitud, el Registro lo notificará al solicitante para que, dentro de los tres meses siguientes, cumpla con lo requerido o presente los comentarios o documentos que convinieran en sustento de la solicitud. Este procedimiento podrá realizarse cuantas veces lo estime necesario el Registro.

#### Nulidad de la Patente

139. La patente será nula en cualquiera de los siguientes casos:

- a) Total o parcialmente, cuando la invención no se ajuste a lo dispuesto en los artículos 91, 92, 93, 94, 95, 96, 97, 98, 108, 109, 110 y 111 de esta ley;

GUYANA: Sections 4, 5 (2), 9 (2), (3) and (4), 14 (1) (d) and 29 (2) (h) and (j) of the Industrial Property, Act (Consolidation Ch. 90:3) No. 9 of 1937 as last amended by Act No. 4 of 23/09/1972

#### 4. Specification

- (1) A provisional specification must describe the nature of the invention.
- (2) A complete specification must particularly describe and ascertain the nature of the invention and the manner in which the same is to be performed.
- (3) In the case of any provisional or complete specification where the Registrar deems it desirable he may require that suitable drawings shall be supplied with the specification, or at any time before the acceptance of the same, and such drawings shall be deemed to form part of the said specification.
- (4) A specification, whether provisional or complete, must commence with the title, and in the case of a complete specification must end with a distinct statement of the invention claimed.
- (5) Where the invention in respect of which an application is made is a chemical invention, then, subject to the prescribed rules, typical samples and specimens shall, if in any particular case the Registrar considers it desirable so to require, be furnished before the acceptance of the complete specification, and the applicant shall be at liberty, where he so desires, and subject to the prescribed rules, so to furnish any typical samples and specimens, unless the Registrar in any particular case considers that it is undesirable that any should be received.

#### 5. Proceedings upon application

- (2) If the Registrar is of opinion, or if, after reference to an examiner, the examiner reports that the nature of the invention is not fairly described, or as respects a complete specification that the nature of the invention or the manner in which it is to be performed is not therein particularly described and ascertained, or that the application, specification, or drawings have not been prepared in the prescribed manner, or that the title does not sufficiently indicate the subject-matter of the invention, the Registrar may refuse to accept the specification or require that the application, specification, or drawings be amended before he proceeds with the application; and in the latter case the application shall, if the Registrar so directs, be deemed to have been made on the date on which the requirement is complied with.

#### 9. Investigation of previous specifications in Guyana on applications for patents

- (2) If on investigation it appears that the invention claimed has been wholly or in part claimed or described in any such specification, the applicant shall be informed thereof, and the applicant may, within such time as may be prescribed, amend his specification, and the amended specification shall be investigated in like manner as the original specification.
- (3) If the Registrar is satisfied that no objection exists to the specification on the ground that the invention claimed thereby has been wholly or in part claimed or described in a previous specification as before mentioned, he shall, in the absence of any other lawful ground of objection, accept the specification.
- (4) If the Registrar is not so satisfied, he shall, unless the objection is removed by amending the specification to the satisfaction of the Registrar, determine whether a reference to any, and, if so, what prior specifications ought to be made in the specification by way of notice to the public. Provided that the Registrar, if satisfied that the invention claimed has been wholly and specifically claimed or wholly and specifically described in any specification to which the investigation has extended, may in lieu of requiring references to be made in the applicant's specification as aforesaid, refuse to grant the application for a patent.

#### 14. Opposition to grant a patent.

- (1) Any person may at any time within two months from the date of the advertisement of the acceptance of a complete specification or within such further period, not exceeding one month, as the Registrar may on an application made to him within the said period of two months; and subject to the payment of the prescribed fee, allow, give notice to the Registrar of opposition to the grant of the patent on any of the following grounds:

(d) that the nature of the invention or the manner in which it is to be performed is not sufficiently and fairly described and ascertained in the complete specification; or

#### Revocation of patent. 29

- (2) A patent may be revoked upon any of the following grounds:

(h) that the complete specification does not sufficiently and fairly describe and ascertain the nature of the invention and the manner in which the invention is to be performed;

(j) that the complete specification does not disclose the best method of performance of the invention known to the applicant for the patent at the time when the specification was left at the Patent Office;

HONDURAS: *Articles 39, 50 and 57 of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

*Artículo 39*

A requerimiento de Registro de la Propiedad Industrial, el solicitante deberá proporcionar, debidamente traducidos cuando así se hubiese indicado, uno o más de los siguientes documentos relativos a una de las solicitudes extranjeras referidas en el Artículo 35, párrafo tercero de esta Ley, a elección del Registro.

1) Copia de la solicitud extranjera y de sus documentos acompañantes o en su caso, certificación de no haber presentado dicha solicitud;

2) Copia de toda comunicación o informe recibido por el solicitante o por su causante que se refiera a los resultados de búsquedas de anterioridades o de exámenes efectuados respecto a la solicitud extranjera; y,

3) Copia de la patente u otro título de protección que se hubiese concedido en base a la solicitud extranjera.

Cuando la solicitud presentada en Honduras abarcara invenciones reivindicadas en dos (2) o más solicitudes extranjeras de modo que ninguna de éstas correspondiera totalmente con 10 reivindicado en aquella solicitud, el Registro de la Propiedad Industrial, podrá pedir al solicitante que presente los documentos referidos en el párrafo primero de este Artículo, relativos a otras solicitudes extranjeras presentadas en Honduras.

Cuando ello fuese necesario para resolver mejor sobre la concesión de una patente o la validez de una patente concedida, el Registro de la Propiedad Industrial, podrá pedir al solicitante o el titular de la patente que presente los siguientes documentos relativos a la solicitud extranjera o al título de protección referido en el párrafo primero de este Artículo:

1) Copia de toda resolución o fallo por el cual se hubiese rechazado la solicitud extranjera o denegado la concesión solicitada en la petición extranjera: y,

2) copia de cualquier resolución o fallo por el cual se hubiese anulado o invalidado la patente u otro título de protección que hubiese sido concedido en base a la solicitud extranjera.

Si el solicitante, teniendo a su disposición la información o la documentación solicitada de conformidad con el párrafo primero, numerales 1) y 2) de este Artículo, no cumpliera con proporcionarla dentro del plazo señalado, se denegará la patente solicitada. A requerimiento del solicitante, o de oficio, el Registro de la Propiedad Industrial, podrá suspender la tramitación de la solicitud de patente cuando se requiera un documento de los indicados en el párrafo primero, numerales 1) y 2), o en el párrafo segundo de este Artículo, y ese documento estuviese aún en trámite ante la autoridad extranjera correspondiente.

El solicitante podrá presentar observaciones y comentarios sobre cualquier información o documento que proporcione en cumplimiento del presente Artículo.

*Artículo 50*

La descripción deberá divulgar la invención de manera suficientemente clara y completa, para poder evaluarla previo dictamen de un técnico versado en la materia.

La descripción de la invención indicará el nombre de invención e incluirá la información siguiente:

1) El sector tecnológico al que se refiere o al cual se aplica la invención;

2) La tecnología anterior conocida por el solicitante que pueda considerarse útil para la comprensión y el examen de la invención, y referencias a los documentos y publicaciones anteriores relativos a dicha tecnología;

- 3) Descripción de la invención en términos que permitan la comprensión del problema técnico y la solución aportada por la invención y exponer las ventajas que hubiere con respecto a la tecnología anterior;
- 4) Descripción de los dibujos, de haberlos;
- 5) Descripción de la mejor manera conocida por el solicitante para ejecutar o llevar a la práctica la invención, utilizando ejemplos y referencias a los dibujos; y,
- 6) La manera en que la invención es susceptible de aplicación industrial y la forma como puede ser producida i utilizada, salvo cuando ello resulte evidente de la descripción o de la naturaleza de la invención.

Cuando la invención se refiera a material biológico que no pueda ser descrito de manera que la misma pueda ser ejecutada por una persona versada' en la materia, y dicho material no se encuentre a disposición del público, se completará la descripción mediante un depósito de dicho material en una institución de depósito. En tal caso, éste se efectuará a más tardar en la fecha de presentación de la solicitud en Honduras 0, en la fecha prioritariamente definida.

Cuando se efectuare un depósito de material biológico para complementar la descripción, esta circunstancia se indicará junto con el nombre y dirección de la institución de depósito, la fecha del mismo y el número de orden respectivo atribuido por la institución. También se describirá la naturaleza y características del material depositado cuando ello fuese pertinente a la divulgación de la invención.

El depósito del material biológico deberá efectuarse en una institución destinada a ese fin, dentro o fuera del país, reconocida por el Registro de la Propiedad Industrial. En todo caso, serán reconocidas las instituciones que tengan carácter de Autoridades Internacionales de Depósito, conforme el Tratado de Budapest de 1977, sobre el Reconocimiento Internacional en esa materia de Micro Organismos a los fines del procedimiento en Materia de Patentes. El depósito en referencia sólo será válido para estos efectos si se hace bajo condiciones que permitan a cualquier persona interesada obtener muestras de dicho material, a más tardar a partir de la fecha de publicación de la solicitud de patente correspondiente conforme a esta Ley, sin perjuicio de las demás condiciones que pudieran determinar las disposiciones reglamentarias.

#### *Artículo 57*

Cualquier persona podrá pedir la nulidad de la patente, debiendo demostrar el solicitante que la patente fue concedida en contravención de alguna de las disposiciones de los Artículos 5, 6, 7, 8, 9, 10, 50, 51 y 52 de la presente Ley.

*HUNGARY: Articles 42 (1) (b), 60, 63 and of the Act XXXIII of 1995 on the protection of inventions by patents (Consolidated text of 01.04.2010)*

#### *Article 42*

(1) The patent shall be revoked ex tunc:

(b) the description does not disclose the invention in a clear and complete manner as required by this Act [Article 60(1)];

Disclosure of invention claims and abstract

#### *Article 60*

(1) A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings. The industrial applicability of a sequence or a partial sequence of a gene shall be disclosed in the patent application.

(2) If an invention involves the use of or concerns biological material which is not available to the public and which cannot be disclosed as required by paragraph (1), the invention shall be considered disclosed in a sufficient and detailed manner prescribed by this Act, provided that

(a) the biological material has been deposited in compliance with the provisions of Article 63;

(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

(c) the patent application states the name of the depositary institution and the accession number.

(3) The claims shall define clearly the scope of the protection sought, in accordance with the description.

(4) The abstract shall merely serve for use as technical information and may not be taken into account either for the purpose of interpreting the scope of the protection sought or for the purpose of defining the state of the art under Article 2(3).

#### Deposit and access of a biological material

##### *Article 63*

(1) If an invention involving the use of or concerning biological material which is not available to the public cannot be disclosed in the patent application as required in Article 60(1), it must be proved that the biological material has been deposited no later than the date of filing of the patent application under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure.

(2) If the biological material is deposited after the filing of the patent application, the date of deposit shall be regarded as the date of filing.

(3) The proof referred to in paragraph (1) shall be submitted within a period of sixteen months after the date of the earliest priority.

(4) Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the publication of the patent application, to those persons who are authorised to inspect the files under the provisions of Article 53(1);

(b) between the publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation thereof, to anyone requesting it.

(5) The person to whom a sample has been supplied may not make the sample or any material derived from it available to third parties before the termination of the patent granting procedure or before the lapse of definitive patent protection and, with the exception of a holder of a compulsory license, he may use the sample or any material derived from it only for experimental purposes, unless the applicant or the patentee expressly waives the prescription of such obligation. A material is deemed to be derived if it has those characteristics of the deposited biological material, which are essential to carry out the invention.

(6) At the applicant's request, where an application is refused, withdrawn or considered withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date of filing of the patent application. In that case, the provisions of paragraph (5) shall apply.

(7) The applicant's requests referred to in paragraph (4)(b) and in paragraph (6) may only be submitted up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

(8) If the biological material deposited in accordance with the provisions of paragraphs (1) to (7) ceases to be available from the recognised depository institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

(9) Any new deposit shall be accompanied by a statement of the depositor certifying that the newly deposited biological material is the same as that originally deposited.

(10) The biological material may be deposited by a person other than the applicant, provided that the name and address of the depositor are stated in the patent application and a declaration is submitted that the depositor has authorised the applicant to refer to the deposited biological material in the patent description and has given his unreserved and irrevocable consent to the biological material being made available to the public in accordance with paragraphs (1) to (9).

*ICELAND: Articles 8 §§ (2), (6) and (7), 21 2) and 52 2) of the Patents Act No. 17/1991 as last amended by Law no. 167/2007 and Article 29 of the regulations thereto*

##### *Article 8*

The application shall contain a description of the invention, also comprising drawings if such are necessary, and a distinct statement of what is sought to be protected by the patent (patent claims). The description shall be so clear as to enable a person skilled in the art to carry out the invention with the guidance thereof. If an invention concerns or requires the use of biological material, it shall be considered inadequately described unless the requirements according to Paragraph 6 are fulfilled.

If it is necessary for the invention to use biological material which is neither available to the public nor can be described in the application in such a manner that, based on the application, a person skilled in the art would be able to execute the invention, a sample of the biological material must be deposited

no later than the filing date of the application. From that time on, the sample shall remain constantly on deposit so that whoever has authorization according to this Act will be able to receive a sample of the biological material in this country. Regulations shall stipulate where such deposits may be made.

If a deposited biological material becomes inactive or it is impossible for other reasons to supply samples of it, it may be exchanged with a sample of the same culture within the prescribed time and in other aspects in accordance with the provisions of regulations. In such instances, the new deposit is considered to have been made on the same date as the previous deposit.

#### *Article 21*

Anyone may file an opposition against the patent granted with the Patent Authority. Opposition shall be made in writing and reasoned and must be filed with the Patent Authority within nine months from the date the granting of the patent was advertised.

Opposition may only be based on the contention that the patent was granted despite the following:

2. the invention is not described clearly enough to enable a person skilled in the art to carry out the invention on the base of the description,

#### *Article 52*

A patent may be revoked [in its entirety or in part by a court decision if:

2. it relates to an invention which is not disclosed in a manner sufficiently clear to enable a person skilled in the art to carry out the invention;

#### *Regulations*

#### *Article 29*

An applicant who has applied for a patent abroad at the same time as making an application in Iceland shall, within the limitations specified in subarticle 2, paragraph 3, Article 69 of the Patent Act, be obliged, if the Patent Authority so requires, to pass on information which the foreign institution has provided regarding novelty or patentability of the application in other respects. If the Patent Authority so requests, the applicant shall be obliged to declare at which patent institution he has applied for a patent for an invention and shall submit a copy or transcript of all communications that he has received in relation to novelty or the patentability of the invention in other respects and of the correspondence with the patent institution or he shall make a declaration that he has received no such communications.

If the examination of an application is carried out by a foreign patent authority in accordance with the provisions of paragraph 3, Article 69 of the Patent Act, the Patent Office may, on the basis of an agreement with the said patent authority regarding exchange of information on patentability, postpone discussion of an application which corresponds to an application that has been filed earlier at the said foreign patent authority, until the said application has been processed according to the terms of the agreement.

Documents relating to the application and which have not been made available to the public may be furnished by the Patent Office to the foreign patent authority with which an agreement has been reached under the provisions in the above paragraphs, provided that the said patent authority has undertaken not to make them available to the public.

INDIA: Sections 8, 10 (1), (2), (3), (4), (4A) and (7), 25 (1) (g), (h) and (j) of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005

#### 8. Information and undertaking regarding foreign applications

(1) Where an applicant for a patent under this Act is prosecuting either alone or jointly with any other person an application for a patent in any country outside India in respect of the same or substantially the same invention, or where to his knowledge such an application is being prosecuted by some person through whom he claims or by some person deriving title from him, he shall file along with his application or subsequently within the prescribed period as the Controller may allow -

(a) a statement setting out detailed particulars of such application; and

(b) an undertaking that, up to the date of grant of patent in India, he would keep the Controller informed in writing, from time to time, of detailed particulars as required under clause (a) in respect of every other application relating to the same or substantially the same invention, if any, filed in any country outside India subsequently to the filing of the statement referred to in the aforesaid clause, within the prescribed time.

(2) At any time after an application for patent is filed in India and till the grant of patent or refusal to grant of a patent is made thereon, the Controller may also require the applicant to furnish details, as may be prescribed, relating to the processing of the application in a country outside India, and in that event the applicant shall furnish to the Controller information available to him within such period as may be prescribed.

#### 10. Contents of specifications

(1) Every specification, whether provisional or complete, shall describe the invention and shall begin with a title sufficiently indicating the subject-matter to which the invention relates.

(2) Subject to any rules that may be made in this behalf under this Act, drawings may, and shall, if the Controller so requires, be supplied for the purposes of any specification, whether complete or provisional; and any drawings so supplied shall, unless the Controller otherwise directs, be deemed to form part of the specification, and references in this Act to a specification shall be construed accordingly.

(3) If, in any particular case, the Controller considers that an application should be further supplemented by a model or sample of anything illustrating the invention or alleged to constitute an invention, such model or sample as he may require shall be furnished before the application is found in order for grant of a patent, but such model or sample shall not be deemed to form part of the specification.

(4) Every complete specification shall-

- a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;
- b) disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
- c) end with a claim or claims defining the scope of the invention for which protection is claimed;
- d) be accompanied by an abstract to provide technical information on the invention.

Provided that-

(i) the Controller may amend the abstract for providing better information to third parties; and  
(ii) if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses a) and b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty as may be notified by the Central Government in the Official Gazette and by fulfilling the following conditions, namely:-

- (A) the deposit of the material shall be made not later than the date of the patent application in India and a reference thereof shall be made in the specification within the prescribed period;
- (B) all the available characteristics of the material required for it to be correctly identified or indicated are included in the specification including the name, address of the depository institution and the date and number of the deposit of the material at the institution;
- (C) access to the material is available in the depository institution only after the date of the application for patent in India or if a priority is claimed after the date of the priority;
- (D) disclose the source and geographical origin of the biological material in the specification, when used in an invention.

(4A) In case of an international application designating India, the title, description, drawings, abstract and claims filed with the application shall be taken as the complete specification for the purposes of this Act.

(7) Subject to the foregoing provisions of this section, a complete specification filed after a provisional specification may include claims in respect of developments of, or additions to, the invention which

was described in the provisional specification, being developments or additions in respect of which the applicant would be entitled under the provisions of section 6 to make a separate application for a patent.

#### 25. Opposition to the patent

(1) Where an application for a patent has been published but a patent has not been granted, any person may, in writing, represent by way of opposition to the Controller against the grant of patent on the ground-

(g) that the complete specification does not sufficiently and clearly describe the invention or the method by which it is performed;

(h) that the applicant has failed to disclose to the controller the information required by Section 8 or has furnished the information which in any material particular was false to his knowledge;

(j) that the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention;

#### 64. revocation of Patents

(1) Subject to the provisions contained in this Act, a patent, whether granted before or after the commencement of this Act, may, be revoked on a petition of any person interested or of the Central Government by the Appellate Board or on a counter-claim in a suit for infringement of the patent by the High Court on any of the following grounds, that is to say

(h) that the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, that is to say, that the description of the method or the instructions for the working of the invention as contained in the complete specification are not by themselves sufficient to enable a person in India possessing average skill in, and average knowledge of, the art to which the invention relates, to work the invention, or that it does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection;

(p) that the complete specification does not disclose or wrongly mentions the source of geographical origin of biological material used for the invention;

*INDONESIA: Articles 24 (2) (i), 52(1), 53, 56 and 91 (1) (a) of the Law on Patents No. 14 of 01/08/2001*

#### *Article 24*

(2) The Application form must contain: i. a written description of the Invention which contains a complete information on the ways of implementing the Invention;

#### *Article 52*

(1) Where the Examiner reports that an Invention for which a Patent has been requested evidently contains vagaries or other significant deficiencies, the Directorate General shall notify the Applicant or his Proxy and request comments or the completion of such deficiencies.

#### *Article 53*

If following the notification as referred to in Article 52 paragraph (1) the Applicant does not provide any clarification or complete the deficiencies, or does not make any changes or improvements on the Application within the period stipulated by the Directorate as referred to in Article 51 paragraph (2), the relevant Application shall be deemed withdrawn and the Directorate General shall notify the Applicant in writing.

#### *Article 56*

(1) If the result of the examination carried out by the Examiner indicates that the Invention for which a Patent has been requested is not the Invention as referred to in Article 1, Article 2 or has not fulfilled the provisions of Article 2, Article 3, Article 5, Article 6, Article 35, Article 52 paragraphs (1) and (2), or

is included among Inventions as referred to in Article 7, the Directorate General shall refuse the relevant Application and shall notify the Applicant in writing.

*Article 91*

(1) A lawsuit for revocation of a Patent may be granted where:

a. the relevant Patent should not have been granted according to Article 2, Article 6, or Article 7;

*IRELAND: Sections 19, 30 (1), (2), (3), (4) and (5) and 58 (b) of the Patent Act No. 1 of 1992 as last amended by Act no. 31 of 2006*

Disclosure of Invention

19. (1) A patent application shall disclose the invention to which it relates in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

(2) Without prejudice to the generality of subsection (1), rules may prescribe the circumstances in which an application for a patent for an invention which requires for its performance the use of a micro-organism is to be treated for the purposes of this Act as complying with that subsection and may specify other provisions, in relation to such applications.

Use of foreign specification or search report

30. (1) In lieu of making the request provided for in section 29 (1), an applicant for a patent under this Part may, within the time, prescribed for the purpose of section 29 (1), submit a statement to the Controller that an application for a patent for the same invention has been made in a prescribed foreign state or under the provisions of any prescribed convention or treaty and where such a statement is submitted the applicant shall submit, within the prescribed period, such evidence as may be prescribed of either

( a ) the results of the search carried out on the said application, or

( b ) the grant of a patent in pursuance of the said application.

(2) The applicant shall, if so required by the Controller, also furnish to the Controller within the prescribed time such information as may be prescribed with regard to the filing of foreign applications for protection of the invention for which a patent is sought.

(3) The evidence submitted under subsection (1) shall be accompanied by the prescribed fee. Unless the application is subsequently withdrawn within a prescribed period the evidence shall be published by the Controller.

(4) Where the evidence submitted is that referred to in subsection (1) (a) the Controller shall, unless the application is withdrawn, allow the applicant an opportunity to amend the application in the light of that evidence. Any amendments shall be submitted within the prescribed period. If the applicant fails, before the expiry of the prescribed period, either to submit amendments to the application or a statement that no amendment is considered necessary, the application may be refused by the Controller.

(5) Where the evidence submitted is that referred to in subsection (1) (b) the Controller shall, unless the application is withdrawn, allow the applicant an opportunity to amend the application in the light of that evidence. The applicant shall in particular submit such amendments as are required to the specification so that the subject-matter claimed therein does not extend beyond that of the evidence. Any amendments shall be submitted within the prescribed period. If the applicant fails, before the expiry of the prescribed period, either to submit amendments to the application or a statement that no amendment is considered necessary the application may be refused by the Controller.

Grounds for revocation.

58. An application for revocation of a patent may be made only on the grounds that

(b) the specification of the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

ISRAEL: Sections 12, 18 and 27 of the Patents Law No. 5727 of 08/08/1967

[Specification]

12.-(a) The specification shall include a title by which the invention can be identified, its description with drawings that may be necessary, and also a description of the manner in which the invention can be performed, enabling a skilled person to perform it.

(b) For purposes of subsection (a), if the subject of the invention is a biological material or a process for the production of a biological material or an invention that involves the use of a biological material, and if the biological material was deposited with a deposit institution, then part of the description of the invention or of the manner of its performance may consist of referral to that deposit, all in a manner and on conditions to be prescribed by the Minister of Justice with approval by the Knesset Constitution, Law and Justice Committee.

For purposes of this section

"biological material"-a biological material not easily available to the public, which cannot be described in a manner that will enable a skilled person to perform the invention, on condition that the biological material can be duplicated or reproduced, either independently or in a host animal or plant cell;

"deposit institution"-an institution recognized as an international deposit authority under section 7 of the Budapest Convention, or an institution which the Registrar recognized for purposes of this section, notice thereof having been published in Reshumot;

"Budapest Convention"-the Budapest Convention for the International Recognition of Living Matter for Patent Proceedings, signed on April 28, 1977, as amended on September 26, 1980; the Convention is available in the Office for inspection by the public.

[Additional means of examination]

18.-(a) The examiner shall use at least one of the following additional means of examination:

(1) the list of documents used by patent authorities in any foreign state in the examination of a patent application on the same patent application, submitted in a foreign country by the applicant or by his predecessor in title to the invention;

(2) a list of documents published before the application date, known to the applicant and directly connected with the invention;

(3) copies of publications and documents, a list of which the applicant must submit under this Article, if the examiner so demands;

(4) copies of publications and documents mentioned in publications and documents, a list of which the applicant must submit under this Article, if the examiner so demands;

(5) transmission of the specifications of the application-in order to search for material that will enable the Office make the examination-to an institution in Israel or abroad, with which the Office contracted under any Law by an agreement drawn up by the Registrar, including a section on keeping any patent application confidential and on nondisclosure under section 165;

and to that end he may do one or more of the following:

(1) require the applicant to submit to him all the documents specified in paragraphs (1) to (4);

(2) transmit the specification in the application for the search said in paragraph (5).

[Description not evidence of specification]

27. The description of the essence of the invention, as published under section 26(b)(5), shall not be evidence when the Court or the Registrar construe the specification in any legal proceeding.

ITALY: *Articles 51, 76 (1) (b) and 162 (1) of the Code of the Industrial Property, Legislative Decree No. 30 of 15/02/2005*

*Art. 51*

Sufficiente descrizione

1. Alla domanda di concessione di brevetto per invenzione industriale debbono unirsi la descrizione e i disegni necessari alla sua intelligenza.

2. L'invenzione deve essere descritta in modo sufficientemente chiaro e completo perche' ogni persona esperta del ramo possa attuarla e deve essere contraddistinta da un titolo corrispondente al suo oggetto.

3. Se un'invenzione riguarda un procedimento microbiologico o un prodotto ottenuto mediante tale procedimento e implica l'utilizzazione di un microrganismo non accessibile al pubblico e che non può essere descritto in modo tale da permettere ad ogni persona esperta del ramo di attuare l'invenzione, nella domanda di brevetto si dovranno osservare, quanto alla descrizione, le norme previste nel regolamento.

*Art. 76*

Nullita'

1. Il brevetto e' nullo:

b) se, ai sensi dell'articolo 51, l'invenzione non e' descritta in modo sufficientemente chiaro e completo da consentire a persona esperta di attuarla;

*Art. 162*

Procedimento microbiologico

1. Una domanda di brevetto riguardante un procedimento microbiologico o un prodotto ottenuto secondo tale procedimento sarà considerata descritta qualora:

a) una coltura del microrganismo sia stata depositata, al più tardi il giorno stesso del deposito della domanda di brevetto, presso un centro di raccolta di tali colture;

b) la domanda depositata contenga le informazioni pertinenti di cui il richiedente dispone sulle caratteristiche del microrganismo;

c) la domanda venga completata con l'indicazione di un centro di raccolta di colture abilitato presso il quale una coltura del microrganismo sia stata depositata, nonché con il numero e la data di deposito di detta coltura, salva la facoltà per l'Ufficio italiano brevetti e marchi di chiedere copia della ricevuta di deposito.

JAPAN: *Articles 36 (2), (3) and (4), 49 (iv) and (v), 123 and 134-2 (1) (iv) of the Patent Act No. 121 of 1959 as last amended by Act No. 109 of 2006(Effective September 30, 2007)*

*Article 36 (Patent applications)*

(2) The description, scope of claims, drawings (where required), and abstract shall be attached to the application.

(3) The description as provided in the preceding paragraph shall state the following:

(i) the title of the invention;

(ii) a brief explanation of the drawing(s); and

(iii) a detailed explanation of the invention.

(4) The statement of the detailed explanation of the invention as provided in item (iii) of the preceding Paragraph shall comply with each of the following items:

(i) in accordance with Ordinance of the Ministry of Economy, Trade and Industry, the statement shall be clear and sufficient as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention; and

(ii) where the person requesting the grant of a patent has knowledge of any invention(s) (inventions as provided in Article 29(1)(iii), hereinafter the same shall apply in this item) related to the said invention, that has been known to the public through publication at the time of filing of the patent application, the statement shall provide the source of the information concerning the invention(s) known to the public through publication such as the name of the publication and others.

*Article 49 (Examiner's decision of refusal)*

The examiner shall render an examiner's decision to the effect that a patent application is to be refused where the patent application falls under any of the following:

(iv) the patent application does not comply with the requirements under Article 36(4)(i), 36(6), or 37;

(v) where notice under the preceding Article has been given, following the amendment of the description or submission of the written opinion, the patent application does not comply with the requirements under Article 36(4)(ii);

*Article 123 (Trial for patent invalidation)*

(1) Where a patent falls under any of the following, a request for a trial for patent invalidation may be filed. In the event of two or more claims, a request for a trial for patent invalidation may be filed for each claim.

(iv) where the patent has been granted on a patent application not complying with the requirements as provided in Article 36(4)(i) or 36(6) (excluding 36(6) (iv));

*Article 134-2 (Request for correction in a trial for patent invalidation)*

(1) The demandee in a trial for patent invalidation may file a request for a correction of the description, scope of claims or drawing(s) attached to the application only within the time limit designated in accordance with paragraph (1) or (2) of the preceding Article, paragraph (1) or (2) of the following Article or Article 153(2); provided, however, that such correction shall be limited to the following purposes:

- (i) restriction of the scope of claims;
- (ii) correction of errors in the description or of incorrect translations; and
- (iii) clarification of an ambiguous description.

(2) Upon receipt thereof, the chief trial examiner shall serve to the demandant a copy of the written request for correction as well as the corrected description, scope of claims or drawings attached to the request under the preceding paragraph.

(3) The trial examiner may examine grounds that have not been pleaded by a the party in the case or an intervenor in determining whether the request for correction under paragraph (1) is not for any of the purposes provided in the items of the proviso to the said paragraph, or does not conform the provisions of Paragraphs(3) to (5) of Article 126 that shall be applied mutatis mutandis upon reading the specified terms in accordance with paragraph (5). In such a case, where the request for correction on the above grounds is not approved of, the chief trial examiner shall notify the parties in the case and the intervenors of the result of the proceedings and shall give them an opportunity to state their opinions, designating an adequate time limit.

(4) Where a request for correction under paragraph (1) is made, if another request for correction has been previously made in the said trial, such previous request shall be deemed to have been withdrawn.

(5) Articles 126(3) to (6), 127, 128, 131(1) and (3), 131-2(1) and 132(3) and (4) shall apply mutatis mutandis to the case of paragraph (1). In this case, the term "item (i) or (ii) of the proviso to paragraph (1)" in Article 126(5) shall be deemed to be replaced with "item (i) or (ii) of the proviso to paragraph (1) pertaining to a claim or claims for which a request for a trial for patent invalidation is not filed."

JORDAN: *Article 8 (1) and (2) of the Law on Patents of Invention No. 32 for the Year 1999(as last amended by Law No. 71 of 2001)*

*Article 8*

A. Any person shall be entitled to file a patent application on the form prescribed for this purpose as per the following procedure:

1. A patent application shall be submitted to the Registrar with the detailed description of the invention. The description shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person having ordinary skill in the art while stating the best mode for carrying out the invention known to him on the application date or the priority date.
2. The patent owner shall file complete particulars on the applications on the same patent subject matter which he filed in other countries including the results of such applications. If applications relating to biologic substances or microorganisms are filed, the applicant shall submit a proof that he filed specimen to one of the specialized centers.

KENYA: *Section 34 (1) (b) and (5), 38, 41 (7) (b) and (d) and (8), 43 (5) (a), 44 (3) (b) and (8) and 103 (3) (f) and (g) of the Industrial Property Act No. 3 of 27/07/2001*

Application

34.-(1) An application for a patent shall be filed with the Managing Director and shall contain

(b) a description;

(5) The description shall disclose the invention and at least one mode for carrying out the invention, in such full, clear, concise and exact terms as to enable any person having ordinary skills in the art to make use and to evaluate the invention and that description shall include any drawing and relevant deposits as in the case of micro-organisms and self-replicable material which are essential for the understanding of the invention.

Information Concerning Corresponding Foreign Applications and Grants

38.-(1) At the request of the Managing Director, the applicant shall furnish him with the date and number of any application for a patent or other title of protection filed by the applicant with a national industrial property office of another country or with a regional industrial property office (in this Act referred to as a "foreign application"), relating to the same invention as that claimed in the application filed with the Managing Director.

(2) The applicant shall, at the request of the Managing Director, furnish him with the following documents relating to one of the foreign applications

(a) copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(b) a copy of the patent or other title of protection granted on the foreign application; and

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(3) The applicant shall, at the request of the Managing Director, furnish him with a copy of any decision revoking or invalidating the patent or any other title of protection granted by the applicant on the basis of the foreign application.

(4) The applicant shall, at the request of the Managing Director, furnish him with copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of any foreign application other than the one referred to in subsection (2).

(5) The documents furnished under this section shall merely serve the purpose of facilitating the evaluation of novelty claimed in the application filed with the Managing Director or in the patent granted on the basis of that application.

(6) The applicant shall have the right to submit comments on the documents furnished under this section.

(7) The details of the requirements under this section shall be prescribed by the regulations.

Filing date and examination of application as to form, etc

*Article 41*

(7) The Managing Director shall cause an examination to be carried out as to whether there are any of the following defects with respect to the application:

(b) the description, the claims and, where applicable, the drawings do not comply with the physical requirements prescribed by the regulations;

(d) the applicant has not complied with a request of the Managing Director under section 38; or

(8) If the Managing Director finds any of the defects referred to under subsection (7), he shall invite the applicant to remedy such defects provided that any corrections made to the application shall not be such that they would require a change of the filing date and if the applicant does not comply with the invitation, the application shall be rejected by the Managing Director.

International type search

*Article 43*

(5) If it is apparent from the report on the international-type search or from the declaration on the non-establishment of the report, that:

a) the description, the claims or, where applicable, the drawings do not comply, in whole or in part, with the prescribed requirements to such an extent that no meaningful search could be carried out; or (...)

the Managing Director shall reject the application unless the applicant either satisfies him that the requirements have been fulfilled or amends or divides the application so as to comply with the requirements.

Examination as to substance

*Article 44*

(3) Where a request is filed under subsection (2), the Managing Director shall cause an examination of the application to be made as to whether:

(b) the application complies with the requirements of subsections (5) and (6) of section 34.

(8) Where, despite any observation or amendment submitted by the applicant, the Managing Director finds that any of the conditions referred to in subsection (2) are not fulfilled, he shall refuse the grant of a patent and notify the applicant accordingly.

Revocation or invalidation

*Article 103*

(3) The Tribunal shall revoke or invalidate the registration of the patent or the utility model or industrial design on any of the following grounds:

(f) that the patent does not fully describe and ascertain the invention and the manner in which it is to be performed;

(g) that the patent does not disclose the best method of performing the invention known to the owner of the patent at the time when the specification was lodged at the Institute;

KYRGYZSTAN: *Articles 18 § 2 2), 3), 4) and 5) and 22 §1 of the Patent Law No. 8 of 14/01/1998, as last amended by Law No. 46 of 27/02/2003*

*Article 18*

Application for the Grant of a Patent for an Invention

The application for an invention must include:

- 2) description of the invention disclosing it fully enough to embody it by the specialist in this field;
- 3) the formula of an invention expressing its essence and fully based on the description;
- 4) draughts and other materials if these are necessary for understanding the subject matter\essence of an invention;
- 5) essay.

*Article 22*

Correction of the Application Documents at the Initiative of the Applicant

During two months from the date of receipt of the application, an applicant shall have the right to introduce amendments and specifications to the documents without changing the essence of the object of an industrial property.

LAO PEOPLE'S DEMOCRATIC REPUBLIC : *Sections 30 3) and 35 of the Intellectual Property Law of 14704/2008*

Section 30: Application for Invention or Device

Application for invention or device patent shall comprise the following documents:

3. Specifications

Section 35: Response to Request for Additional Information

Upon having requested by the Registration Office, the applicant must provide with information on registration of industrial property in foreign country, especially the industrial property corresponding to those being applied for in Lao PDR. Such information shall comprise.

1. Copy of examination report of industrial property in foreign country
2. Copy of registration certificate of industrial property obtained in foreign country

LATVIA: *Sections 27 (1) 2), 28 (7), 30 (1) and (2) and 37 (1), (3) and (4) of the Patent Law of 15/02/2007*

Section 27. Patent Application

(1) The patent application shall include:

- 2) a description of the invention;

Section 28. Submission of the Patent Application and Filing Date

(7) If the invention provides for the use of such biological material, which is not publicly available and which cannot be described in the application, so that it might be implemented by a person skilled in the art, a statement regarding the deposition of the biological material in an internationally recognized depository shall be filed together with the application in accordance with the Budapest Treaty of 28 April 1977 on the international recognition of the deposit of micro-organisms for the purposes of patent procedure. If the biological material, which has been deposited, is no longer available at the internationally recognised depository, it shall be permitted to deposit the material once again with the same conditions that have been included in the contract referred to in this Paragraph. The procedures according to which the biological material is available shall be determined by the Cabinet.

#### Section 30. Description, Claims and Abstract of the Invention

- (1) The description of the invention shall disclose the invention in a manner sufficiently clear and complete so that a person skilled in the art would be able to carry out this invention. The invention shall not be in conflict with the scientifically attested laws of nature.
- (2) The claims shall define the subject to which the patent protection is sought, and the extent of the protection conferred by patent, using the technical features of the invention. The claims shall be clear and concise and substantiated in the description.

#### Section 37. Substantive Examination of the Patent Application

(1) The Patent Office shall examine whether the patent application conforms with the requirements of Section 8, Paragraph two, Section 9 and 10, Section 30, Paragraphs one and two and Section 36 of this Law. The Patent Office shall not carry out the patentability examination of an invention during the process of the substantive examination of a patent in conformity with the requirements of Sections 5 and 7 and Section 8, Paragraph one of this Law.

(3) If the patent application does not conform or partially conforms with the requirements of this Section, the Patent Office shall notify the applicant thereof, explaining the non-conformity, and shall determine a time period of three months for the elimination of the specified deficiencies.

(4) If the applicant has not eliminated the deficiencies specified by the Patent Office, the Patent Office shall take the decision regarding the rejection of the application. It shall be notified to the applicant in writing.

LEBANON: *Articles 8 (2) (b) 1) and (3) and 31 3) of the Patent Law No. 240 of 14/08/2000*

#### *Article 8*

2. The application shall include:

b. A stamped envelope containing two copies of the following:

First: Description of the invention and abstract.

3. If the invention is related to a Micro Organism or a plant product a sample should be delivered to the central lab of the Ministry of Public Health within fifteen days from the day of application which in turn provides the applicant with a numbered and dated evidence of receipt of such sample. The Intellectual Property Protection Authority is to be notified of such action.

#### *Article 31*

The patent is cancelled by a judicial ruling in the following cases.

3. If the invention description is not sufficient for a person skilled in the art to apply it.

LIBERIA: *Sections 11 (3) and 14 of the Industrial Property Act of 20/03/2003*

11.(3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

#### Information concerning foreign application

14.(1) The applicant shall, at the request of the Director General furnish him with the date and number of any application for a patent filed by him abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the Office of the Director General,

(2)(a) The applicant shall, at the request of the Director General, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1)

- (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (ii) a copy of the patent granted on the basis of the foreign application,

(iii) a copy of any final decision rejecting the foregoing application or refusing the grant requested in the foreign application.

(b) The applicant shall, at the request of the Director General, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foregoing application referred to in paragraph (a)

(3) Subsection (2)(a)ii) and (iii) shall not apply in respect of information relating to the examination of the same International application in another elected office where the Industrial Property Registry is an elected Office in the meaning of Section 21(ii) and has received or will receive an international preliminary examination report.

LITHUANIA: *Articles 11 §1 2), 13, 19, and 45 2) of the Patent Law No. I-372 of 18/01/1994 as last amended by Law No. X-1119 of 10/05/2007*

#### *Article 11*

##### A Patent Application

A patent application shall contain:

2) a description of the invention;

#### *Article 13*

##### Disclosure

A specification must disclose the invention in such full and clear terms as to enable any person skilled in the art to which it pertains to use the invention.

Where a patent application is filed for an invention involving the use of or concerning biological material which is not available to the public and which cannot be described in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description of the invention shall be considered inadequate. This provision shall not apply, if the biological material has been deposited no later than the date on which the patent application was filed with a depositary institution.

#### *Article 19*

##### Examination

The State Patent Bureau shall make an examination of a patent application and establish whether the application complies with the requirements provided for in paragraphs 2 and 3 of Article 2, in Article 11, paragraphs 2 and 3 of Article 13, as well as in Articles 14 and 18.

After having found that the application does not meet the requirements of the Articles set out in paragraph 1 of this Article, the State Patent Bureau shall invite the applicant to meet such requirements within a period prescribed by the State Patent Bureau. If the applicant fails to do so, the application shall be deemed to be withdrawn.

After having determined that an invention is unpatentable on the grounds laid down in paragraphs 2, 3 and (or) 4 of Article 2 of this Law, the State Patent Bureau shall make a decision to refuse granting a patent.

#### *Article 45*

##### Invalidation

On the request of any persons concerned the court may invalidate a patent, in whole or in part, on one of the following grounds:

2) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

LUXEMBOURG: *Articles 19 (1) (b), 22, 39 (2) and (5) and 73 (1) (b) of the Patent Act of 20/07/1992*

#### *Article 19*

Conditions auxquelles doit satisfaire la demande de brevet

1. La demande de brevet doit contenir :

b) une description de l'invention ;

#### *Article 22*

##### Exposé de l'invention

1. L'invention doit être exposée dans la demande de brevet de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter.
2. Lorsque l'invention concerne l'utilisation d'un micro-organisme auquel le public n'a pas accès, la description n'est pas considérée comme exposant l'invention d'une manière suffisante si une culture de micro-organisme n'a pas fait l'objet d'un dépôt auprès d'un organisme habilité à cet effet par règlement ministériel.

#### *Article 39*

##### Régularisations concernant le rapport de recherche

2. Si l'organisme chargé de l'établissement du rapport de recherche estime
  - a) que la description, les revendications ou les dessins ne remplissent pas les conditions prescrites, dans une mesure telle qu'une recherche significative ne peut pas être effectuée, ou
  - b) que la demande de brevet concerne un objet ne répondant pas à la notion d'invention ou de matière brevetable ou à l'égard duquel il n'est pas tenu, pour d'autres raisons, de procéder à la recherche, et déclare qu'un rapport de recherche ne sera pas établi, le service transmet la déclaration y relative au demandeur, auquel il impartit un délai de quatre mois pour corriger les éléments défectueux de la demande de brevet par application de l'article 37 et renouveler la requête en vue de l'établissement du rapport de recherche.

Si, après le renouvellement de la requête en vue de rétablissement du rapport de recherche, l'organisme international estime ne pas être en mesure de modifier ses conclusions au regard de la demande de brevet, telle que corrigée une première fois, le demandeur peut introduire une pétition par laquelle il sollicite d'emblée la délivrance de son brevet, ainsi qu'une brève justification de cette pétition. La pétition n'est recevable que sous la condition qu'elle soit remise avant l'expiration du nouveau délai imparti par le service conformément à l'alinéa 1er, pour autant toutefois que ce nouveau délai expire postérieurement au terme d'un délai à fixer par règlement grand-ducal ou, à défaut, postérieurement au terme du délai qui est visé à l'article 35, paragraphe 1er.

Dans l'hypothèse de l'alinéa 2, le service peut proposer au ministre de ne pas délivrer le brevet, en émettant un avis motivé à cet effet. Les conditions d'application des dispositions du présent alinéa ainsi que les modalités de l'avis seront fixées par règlement grand-ducal.

5. Le délai imparti par le service en vertu des paragraphes qui précèdent peut dépasser le terme du délai qui est prévu à l'article 35, paragraphe 1er. Si le titulaire de la demande de brevet ne se conforme pas à l'invitation du service dans le délai imparti, la délivrance du brevet est refusée par arrêté ministériel.

Toutefois, si à la date d'expiration du délai imparti par le service, le délai de l'article 35, paragraphe 1<sup>er</sup> n'est pas encore venu à échéance, seules sont refusées la requête en vue de l'établissement du rapport de recherche et les pièces visées à l'article 35, paragraphe 1er, litt. b) ou c) respectivement. Le cas échéant, les taxes de recherche sont remboursées sous déduction des frais encourus à l'occasion du remboursement.

#### *Article 73*

##### Causes de nullité du brevet

1. La demande en nullité d'un brevet ne peut être fondée que sur les motifs selon lesquels :

- b) le brevet n'expose pas l'invention de façon suffisamment claire et complète pour qu'un homme du métier puisse l'exécuter ;

MADAGASCAR: *Article 18 (1) of the Industrial Property Law, Ordinance No. 89 019 of 31/07/1989*

18.-(1) The description shall set out the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art without him being obliged to himself undertake an inventive activity. It shall describe the best manner of carrying out the invention to the knowledge of the applicant.

*MALAYSIA: Sections 28 (1) (c), 29A (4) and (5) (b) and 56 (2) (b) of the Patents Act No. 291 of 1983 as last amended by Act No. 1264 of 2006 and Rule 12 of the Patent Regulations P.U.(A) 327/86 as last amended on 19/06/2003*

Section 28. Filing date.

(1) The Registrar shall record as the filing date the date of receipt of the application: Provided that the application contains  
(c) a description;

Section 29A. Request for substantive examination or modified substantive examination.

(4) The Registrar may require the applicant to provide, at the time of filing a request for a substantive examination

(a) any prescribed information or prescribed supporting document concerning the filing of any application for a patent or other title of industrial property protection filed outside Malaysia by such applicant or his predecessor in title with a national, regional or international industrial property office;  
(b) any prescribed information concerning the results of any search or examination carried out by an International Searching Authority under the Patent Cooperation Treaty, relating to the same or essentially the same invention as that claimed in the application for which the request for a substantive examination is being filed.

(5) If the applicant

(b) fails to provide the information or document referred to in subsection (4) as required by the Registrar,

within the prescribed period, the application for a patent shall, subject to subsection (6), be deemed to be withdrawn at the end of that period.

Section 56. Invalidation of patent.

(2) The Court shall invalidate the patent if the person requesting the invalidation proves –

(b) that the description or the claim does not comply with the requirements of section 23;

## REGULATIONS

Regulation 12. Description.

(1) The description shall first state the title of the invention as appearing in the request and shall  
(a) specify the technical field to which the invention relates; (b) indicate the background art which, as far as is known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, wherever possible, cite the documents reflecting such art;  
(c) disclose the invention in such terms that it can be understood and in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art, and state any advantageous effects of the invention with reference to the background art;  
(d) briefly describe figures in the drawings, if any; (e) describe the best mode contemplated by the applicant for carrying out the invention, using examples where appropriate and referring to the drawings, if any; and (f) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable and the way in which it can be made and used or, if it can only be used, the way in which it can be used.

(2) The description shall be presented in the manner and order specified in sub-regulation (1) unless, because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economical presentation. (3) The description shall not contain drawings.

*MALTA: Articles 13 (1) (b), 15 and 44 (1) (b) of the Patents and Designs Act, Chapter 417, of 01/06/2002 as last amended by Act XVIII of 2005*

Requirements of application

13. (1) An application for a patent shall be made in the prescribed form and shall be filed at the Office of the Comptroller and shall contain -

(b) a description of the invention;

15. (1) The application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

(2) (a) Where an application refers to an element isolated from the human body or otherwise produced by means of a technical process including the sequence or partial sequence of a gene, the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

(b) When the application concerns a sequence or a partial sequence of a gene used to produce a protein or part of a protein, it is necessary to specify which protein or part of protein is produced or function or sequence it performs.

(3) Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purpose of this Act unless:

(a) it is supplemented by a deposit of such material with a depository institution as may be prescribed; and

(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited.

(4) Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application, only to those persons who are authorized under this Act;

(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

(5) The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make it or any material derived from it available to third parties; and

(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

(6) Where an application is refused or is withdrawn, then at the applicant's request, access to the deposited material shall be limited to an independent expert for twenty years from the date on which the patent application was filed, and in such case the provisions of subarticle (5) shall apply.

(7) The applicant's requests referred to in subarticle (4)(b) and in subarticle (6) may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

(8) If the biological material deposited in accordance with this article ceases to be available from the recognized depository institution, a new deposit of the material shall be permitted on the same terms as those laid down in the Budapest Treaty.

(9) Any new deposit shall be accompanied by a statement signed by the depositor certifying that the new deposited biological material is the same as that originally deposited.

#### Invalidation of patents

44. (1) The Civil Court, First Hall may on a writ of summons filed by a third party or the Comptroller, invalidate a patent, in whole or in part, on any of the following and may not do so on any other ground

(b) that the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art as stipulated in article 15;

*MAURITIUS: Articles 14 (2) (b) and (3), 17, 19 (1), 20 (2) and 25 (1) and (2) of the Patents, Industrial Designs and Trademarks Act No. 25 of 2002*

#### Application

14 (2) An application for a patent shall contain

(b) a description of the invention, any claim and any drawing and an abstract;

(3) Any description, referred to in subsection (2)(b), shall disclose the invention in a manner which is sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

#### Information Concerning Corresponding Foreign Applications and Patents

17 (1) An applicant shall, where requested to do so by the Controller, furnish him with the date and number of any application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed in the application filed with the Controller.

(2) An applicant shall, where requested to do so by the Controller, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1)

(a) a copy of any communication received by the applicant concerning the results of any search and examination carried out in respect of the foreign application;

(b) a copy of the patent granted on the basis of the foreign application;

(c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(3) An applicant shall, where requested to do so by the Controller, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in subsection (2).

#### 19. Examination

(1) The Controller shall, after according a filing date, examine

(a) whether the application complies with section 14 and any other provisions of this Act; and

(b) whether any information requested under sections 16 and 17 has been provided.

#### 20. Grant of patent

(2) Where an application fails to comply with the conditions referred to in section 19 (1), the Controller shall reject the application and notify the applicant of his decision.

#### 25. Invalidation

(1) Any interested person may request the Tribunal to invalidate a patent.

(2) The Tribunal may invalidate the patent where the person requesting the invalidation proves that any of the requirements of sections 11,12 and 14 have not been fulfilled or where the owner of the patent is not the inventor nor his successor in title.

*MEXICO: Articles 47 I, 54 and 78 I of the Industrial Property Law of 25/06/1991 as last amended on 06/12/2005*

#### *Article 47*

The patent application shall be accompanied by:

I. a description of the invention, which shall be sufficiently clear and complete to be fully understood and, where appropriate, to serve as a guide for a person with average skill in the art to make it; it shall also mention the best method known to the applicant of carrying out the invention, when this is not clear from the description of the invention.

In the case of biological material where the description of the invention cannot itself be sufficiently detailed, the application shall be completed with a record of the deposit of the material at an institution recognized by the Institute, in accordance with the provisions of the Regulations under this Law;

#### *Article 54*

The Institute may accept or request the findings from substantive examinations or the equivalent thereof conducted by foreign patent offices or, where appropriate, a plain copy of the patent granted by any of said foreign offices.

*Article 78*

The patent or registration shall be invalid in the following cases:

I. When it is granted in violation of the provisions on the requirements and conditions for the grant of patents or registrations of utility models and industrial designs. For the purposes of the provisions of this subparagraph, the requirements and conditions for the grant of patents and registrations shall be those laid down in Articles 16, 19, 27, 31 and 47;

MONGOLIA: *Article 6 (3), 10 (2) and 26 (2) of the Patent Law of 25/06/1993, as last amended in 1999*

*Article 6*

Filing of patent applications for inventions and industrial designs

3. The application for an invention shall contain a request, a description of the invention, an abstract and a brief explanatory note. If required, it shall also contain relevant drawings and certificates. The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall indicate at least one mode known to the applicant for carrying out the invention.

The claim shall define the matter for which protection is sought and shall be clear and concise. One invention may contain one or more claims.

The description and the drawings may be used to interpret the claims.

The abstract shall merely serve the purpose of technical information; in particular, it shall not be taken into account for the purpose of interpreting the scope of protection.

*Article 10*

Examination of patent application

2. The applicant shall, on request, supply to the Intellectual Property Office information on any application for a patent or other form of entitlement to protection which has been filed by the applicant in any other country and which relates to the same or essentially the same invention as that to which the application filed with the Intellectual Property Office relates.

*Article 26*

Invalidation of patents

2. If a patent is granted in breach of Articles 4, 6, 8, 10, or 12 of this law the Court shall invalidate the patent. In that case, the Intellectual Property Office shall record the corresponding changes in the State register and shall publish notices of the invalidation of the invention or industrial design in the Patent Gazette.

MOROCCO: *Articles 34 and 85 (1) (b) of the Law No. 17-97 concerning Protection of Industrial Property as implemented by Law No. 31-05 of 02/03/2006*

*Article 34*

La description de l'invention comprend :

- 1) l'indication du domaine technique auquel se rapporte l'invention;
- 2) l'indication de l'état de la technique antérieure, connu du demandeur, pouvant être considéré comme utile pour la compréhension de l'invention;
- 3) un exposé de l'invention, telle que caractérisée dans les revendications, permettant la compréhension du problème technique ainsi que la solution qui lui est apportée; sont indiqués, le cas échéant, les avantages de l'invention par rapport à l'état de la technique antérieure;
- 4) une brève description des dessins s'il en existe;
- 5) un exposé détaillé d'au moins un mode de réalisation de l'invention; l'exposé est en principe assorti d'exemples et de références aux dessins, s'il en existe;
- 6) l'indication de la manière dont l'invention est susceptible d'application industrielle, si cette application ne résulte pas à l'évidence de la description ou de la nature de l'invention.

La description de l'invention doit exposer l'invention d'une façon suffisamment claire et complète en divulguant des informations suffisantes permettant à un homme du métier, sans expérimentation excessive, d'exécuter l'invention connue de l'inventeur à la date du dépôt.

Une invention revendiquée est suffisamment étayée par les informations divulguées lorsque lesdits renseignements montrent raisonnablement à un homme du métier que le demandeur était en possession de l'invention revendiquée, à la date du dépôt de la demande de brevet de l'invention.

*Article 85*

La nullité du brevet est prononcée par le tribunal à la demande de toute personne y ayant intérêt :

b) si la description de l'invention n'expose pas l'invention d'une façon suffisante pour qu'un homme du métier puisse l'exécuter;

*MOZAMBIQUE: Articles 46 (1), 49 and 54 of the Industrial Property Code, Decree No. 04 of 12/04/2006*

*Article 46*

Description of the invention

1. The report shall describe the invention sufficiently clearly and fully so as to enable a person skilled in the art to execute the invention, and shall indicate at least one way of executing the invention known to the applicant, on the date of filing or, in the case of a claim for priority, on the date of priority of the application.

*Article 49*

Inadequate description or claim

An applicant who has submitted an application in which the description or the claim is inadequate shall rectify the shortcoming within sixty days from the date on which he is notified to do so.

*Article 54*

Foreign applications for patents or similar rights of protection

The applicant is under an obligation to inform the IPI of the date and number of every application for a patent or other right of protection filed in any other country in respect of the same invention applied for in Mozambique, and must also furnish the following:

- a) A copy of any communication received by the applicant in relation to the results of searches or examinations conducted abroad;
- b) A copy of the patent or other right of protection granted on the basis of the foreign application;
- c) A copy of any final or provisional decision to refuse or grant the foreign application;
- d) A copy of any decision to grant a patent or other right of protection granted on the basis of the foreign application

*NAMIBIA: Articles 11(3), 14, 15 (6) and 20 (2) of the Industrial Property Act of 1999*

Application for a patent. 11

(3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

Information concerning corresponding foreign applications for patents or other titles of protection. 14

(1) The applicant shall, at the request of the Registrar, furnish him or her with the date and number of any application for a patent or other title of protection filed by him or her abroad herein referred to as a "foreign application" relating to the same or essentially the same invention as that claimed in the application filed with the office of the Registrar.

(2) (a) The applicant shall, at the request of the Registrar, furnish him or her with the following documents relating to one of the foreign applications referred to in subsection (1)

- (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (ii) a copy of the patent or other title of protection granted on the basis of the foreign application;

(iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(b) The applicant shall, at the request of the Registrar, furnish him or her with a copy of any final decision invalidating the patent or other title of protection granted on the basis of the foreign application referred to in paragraph (a).

Filing date and examination. 15

(6) Where the Registrar is of the opinion that the application complies with the requirements indicated in subsection 5, the Registrar shall cause the application to be examined as to whether the requirements of sections 7, 8, 9, 11(3), (4), (5), (6), (7), 12 and 14 and the regulations relating thereto are complied with.

Invalidation. 20

(2) The court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of sections 7, 8, 9, and 11 (3), (4) and (5) and the regulations relating thereto is not fulfilled or if the owner of the patent is not the inventor or his or her successor in title.

NETHERLANDS: *Articles 24 (1) (e) and (4), 25 (1), (2) and (3), 35 and 75 (1) (b) of the Patents Act of 15/12/1995(Text as it applies on 03/06/2009)*

*Article 24*

1. An application for a patent must be filed with the Office in writing and must:  
e. be accompanied by a description of the invention containing, in one or more claims at the end, a description of the subject matter for which an exclusive right is being sought;  
4. The application, the description of the invention, the drawings and the abstract must also be in accordance with the other formal regulations laid down by ministerial order.

*Article 25*

1. The description of the invention must be clear and complete and worded such that an expert can understand the invention and use it on the basis of that description. The specifications provided in one or more claims at the end of the definition must be precise. The description should be accompanied by corresponding drawings if necessary.  
2. In an invention relates to biological material that is not accessible to the public and cannot be explained in the definition such that an expert could use the invention on that basis, or if an invention implies the use of such biological material, the description will be deemed to be sufficient only if the biological material has been filed with an institution that has been designated for that purpose under or by virtue of a general order in council for the Kingdom no later than the date on which the application is filed.  
3. If an invention relates to a sequence or partial sequence of a gene, the description shall contain a concrete description of the function and the industrial application of that sequence or partial sequence. In the event that a sequence or a partial sequence of a gene is used for the production of a protein or partial protein, the description of the industrial applicability shall contain a specification of the protein or partial protein that has been produced and its function.  
4. Further regulations may be stipulated by general order in council for the Kingdom with respect to:  
a. the information to be included in the application with respect to the characteristics and the identification of the biological material to be filed; and  
b. the accessibility and availability of the biological material to be filed.

*Article 35*

1. If the Office is of the opinion that the search of the state of the art cannot be conducted owing to the application's lack of clarity, it shall so inform the applicant as quickly as possible in a substantiated, written notification.  
2. If the defects are not remedied within two months of the dispatch of the notification referred to in paragraph (1), or if the applicant gives notice before that time that he does not wish to remedy them, the Office shall decide not to process the application. The Office shall inform the applicant of its decision as quickly as possible.

*Article 75*

1. A patent shall be invalidated by the court insofar as:

b. the patent specification does not contain a description of the invention that, in appropriate cases with the application of Article 25(2) and (3), is sufficiently clear and complete to allow a person skilled in the art to use the invention;

NEW ZEALAND: *Sections 10 (3), 12 (2), 21 (1) (g) and 41 (1) (h) of the Patents Act No 64 of 1953 (as at 01/01/2011)*

#### 10. Contents of specification

##### (3) Every complete specification

- (a) Shall particularly describe the invention and the method by which it is to be performed; and
- (b) Shall disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and
- (c) Shall end with a claim or claims defining the scope of the invention claimed.

#### 12. Examination of application

(2) If the examiner reports that the application or any specification filed in pursuance thereof does not comply with the requirements of this Act or of any regulations made thereunder, or that there is lawful ground of objection to the grant of a patent in pursuance of the application, the Commissioner sic: Commissioner may either

- (a) Refuse to proceed with the application; or
- (b) Require the application or any such specification as aforesaid to be amended before he proceeds with the application.

Commissioner may require information as to corresponding applications overseas(1) Subject to subsection (2) of this section, for the purposes of the investigation required under this Act an applicant, if so required by the Commissioner shall,

(a) State whether a corresponding or substantially corresponding application has been filed in any of the following countries, namely,

- (i) The United Kingdom, Canada, Australia, or the United States of America; or
- (ii) Any other country for the time being declared by Order in Council to be a country to which this paragraph applies:

(b) With respect to any such application in any such country, furnish (so far as it is reasonably available to the applicant) the following information:

- (i) The number and filing date of the application; and
- (ii) Particulars sufficient to identify the prior art cited against the application; and
- (iii) The number allotted to the patent when granted on the application and the form of the claims allowed; and
- (iv) Particulars of any other application or patent with which the corresponding application is or has been involved in opposition, conflict, interference, or similar proceedings.

#### 21 Opposition to grant of patent

(1) At any time within the period prescribed by subsection (2) of this section any person interested may give notice to the Commissioner of opposition to the grant of the patent on any of the following grounds:

(g) That the complete specification does not sufficiently and fairly describe the invention or the method by which it is to be performed:

#### 41 Revocation of patent by Court

(1) Subject to the provisions of this Act, a patent may, on the application of any person interested, be revoked by the Court on any of the following grounds, that is to say,

(h) That the complete specification does not sufficiently and fairly describe the invention and the method by which it is to be performed, or does not disclose the best method of performing it which was known to the applicant for the patent and for which he was entitled to claim protection.

*NICARAGUA: Articles 21 (1), 22, 23, 35 and 57 (c) of the Law on Patents, Utility Models and Industrial Designs No. 354 of 19/09/2000 as last amended by Law No. 634 of 13/09/2007*

#### Description

21. The description of an invention shall be clear and complete so that a person skilled in the corresponding technical field may understand it and carry it out. The description shall specify:

1. the technological sector to which the invention refers or relates;
2. the prior art known to the applicant that may be useful for the understanding and examination of the invention, and a reference to earlier documents and publications concerning the same technology;
3. a description of the invention in terms that permit the technical problem and the solution provided by the invention to be understood, with an explanation of the differences and possible advantages in relation to the earlier technology;
4. an explanation of the drawings, if any have been filed;
5. a description of the best method known to the applicant of carrying out the invention, which shall make use of examples and references to the drawings, if any have been filed;
6. a description of the manner in which the invention is industrially applicable, if it is not obvious from the description or nature of the invention.

#### Description of Biological Material

22. Where the invention relates to a product or process concerning biological material that is not available to the public, and the invention cannot be described in such a way as to be understood and carried out by a person trained in the technical field concerned, the description shall be supported by the deposit of a sample of that material. The deposit of the material shall be made with an institution inside or outside the country that is recognized by the Intellectual Property Registry. The deposit shall take place no later than on the filing date of the application in Nicaragua or on the priority date where applicable.

If the deposit has been made, it shall be mentioned in the description together with the name and address of the depositary institution, and the deposit date and number assigned to it by that institution.

#### Validity of the Deposit

23. The deposit of biological material shall be valid for the grant of a patent only if it takes place under conditions that enable any interested party to obtain samples of the material not later than on the publication date of the corresponding patent application, without prejudice to any other conditions that may be specified in the regulations under this Law.

#### Documents Relating to Foreign Applications

35. For the purposes of the patentability examination, the applicant shall, at the request

of the Intellectual Property Registry, provide the following, with the corresponding translation:

- (a) a single copy of the foreign application and the results of the novelty and patentability examination conducted in relation to that application;
- (b) a single copy of the patent or other title of protection granted by the patent office of the issuing country.

Where necessary for a better decision on a patent application or on the validity of a granted patent, the Intellectual Property Registry may at any time request the applicant or patent owner to submit a copy of any decision or ruling that has rejected, refused, revoked, cancelled or invalidated the foreign application or the patent or other title of protection granted thereon.

Where the applicant who has the required information or document at his disposal does not comply with the request that he submit it within the period specified in the request, which shall be three months from the date thereof, the patent applied for shall be refused. At the request of the applicant or ex officio, the Intellectual Property Registry may suspend the processing of the patent application where any document that should be submitted under this provision is still pending before a foreign authority.

The applicant may submit observations and comments on any information or document supplied pursuant to this Article. Where necessary or where there is reasonable doubt as to the legitimacy of a document, the Intellectual Property Registry may request that it be legalized or authenticated.

#### Invalidation of the Patent

57. The Intellectual Property Registry shall, at the request of an interested party or competent authority or ex officio, declare the absolute invalidity of a patent where:

- (c) the patent does not disclose the invention as required by Articles 21 and 22 of this Law;

*NIGERIA: Sections 3 (1) (a) (ii) and (2) and 9 (1) (b) of the Industrial Property Act (Chapter 344) of 1990*

3. (1) Every patent application

(a) shall be made to the Registrar and shall contain-

(ii) a description of the relevant invention with any appropriate plans and drawings,

(2) The description referred to in subsection (1)(a)(ii) of this section shall disclose the relevant invention in a manner sufficiently clear and complete for the invention to be put into effect by a person skilled in the art or field of knowledge to which the invention relates; and the claim or claims referred to in subsection (1)(a)(iii) of this section shall define the protection sought and shall not go beyond the limits of the said description.

9. (1) Subject to this section, on the application of any person (including a public officer acting in the exercise of his functions) the court shall declare a patent null and void-

(b) if the description of the invention or the claim does not conform with section 3(2) of this Act; or

*NORWAY: Sections 8-8c, 25 (1) 2) and 52 (1) 2) of the Patents Acts No.9 of 15/12/1967 as last amended by Act No.80 of 29/06/2007 and Section 30 of the Regulations thereto*

Section 8. An application for a patent shall be filed in writing with the Norwegian Industrial Property Office or, in the cases referred to in Chapter 3, with a patent authority or an international organization as referred to in section 28.

The application shall contain a description of the invention, including drawings where necessary, and a precise statement of the subject matter for which protection by the patent is sought (patent claims).

The fact that the invention relates to a chemical compound shall not imply that a specific use must be disclosed in the claim. The description shall be sufficiently clear to enable a person skilled in the art to

carry out the invention on the basis thereof. An invention which relates to or uses biological material, in the cases referred to in section 8a, only be considered to be disclosed in a sufficiently clear manner if the requirements of section 8a are also complied with. (...)

Section 8a. If, when carrying out an invention, this involves the use of biological material which is not available to the public and cannot be described in the application documents in such a manner as to enable a person skilled in the art to carry out the invention on the basis thereof, a sample of the biological material shall be deposited not later than on the date of filing of the application. The sample shall thereafter always be deposited so that anyone who under this Act is entitled to be furnished with a sample of the biological material should be furnished with a sample in Norway. The King shall decree where deposits may be made.

If a deposited culture of a microorganism ceases to be viable or a sample of the culture cannot be furnished for other reasons, it may be replaced by a new culture of the same microorganism within the prescribed time limit and on the other conditions laid down by the King.

In that case, the new deposit shall be deemed to have been made on the date that the previous deposit was made.

Section 8 b. If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the providing country is not the same as the country of origin of the biological material, the application shall also state the country of origin. The country of origin means the country from which the material was collected from its natural environment. If the national law in the country of origin requires that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall state that.

The duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the received material. The duty to disclose information does not apply to biological material derived from the human body.

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Section 8 c. If an invention concerns or uses biological material from the human body, the patent application shall include information on whether the person from whom the material has been derived has given his/her consent to the use of the biological material, in accordance with the law of 21st February 2003 no 12 about bio banks.

Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code § 166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.

Section 25. Subsequent to an opposition the Norwegian Industrial Property Office shall revoke the patent if

2) it relates to an invention which is not disclosed in a manner sufficiently clear as to enable a person skilled in the art to carry out the invention on the basis of the description; or

Section 52. A patent may be fully or partially invalidated by a court decision if:

2) it relates to an invention the description of which is not sufficiently clear to enable a person skilled in the art to carry out the invention on the basis thereof;

### *Regulations*

Section 30. Written Opinion from Another Searching Authority

If an application is filed for a patent for an invention for which the same applicant has filed a patent application outside Norway, the applicant shall, at the request of the Norwegian Industrial Property Office, provide information about the written opinion that

the patent authority in question has provided regarding the novelty search and patentability. Within a time limit stipulated by the Norwegian Industrial Property Office, the applicant shall submit:

a copy of the written opinion that the patent authority in question has provided regarding the novelty search and patentability in general, or

a declaration that the applicant has not yet received such a written opinion.

If the applicant fails to meet the time limit fixed by the Norwegian Industrial Property Office, the application will be shelved in accordance with section 15 of the Patents Act. If the applicant expressly refuses to submit a copy of the written opinion or the declaration, the application shall be rejected in accordance with section 16 of the Patents Act.

*OMAN: Articles 5 (3) and (4) and 8 of the Law on Industrial Property Rights (Royal Decree No. 67/2008)*

*Article (5)*

Anyone submitting an application claiming patent right should abide by the following:

3 - The description shall disclose the invention in a manner sufficiently clear and complete by providing the information that enables a person having ordinary skill in the art to execute, and use the invention without unnecessary experimentations.

4 - To submit a written undertaking declaring that the micro-organisms to which the application relates have been deposited with an international depositary authority, in accordance with the Budapest Treaty and its Regulations, provided that the applicant provides a copy of the receipt of the deposit issued by the international depositary authority.

*Article (8)*

If the Applicant filed, by himself or by his predecessor, a patent application out side the Sultanate, for the same or essentially the same invention as that claimed in the application filed in Oman, the Registrar may request the applicant to furnish him with the following documents:

1 - Date and number of any application filed abroad;

2 - A copy of any communication concerning the date of any search or examination carried out in respect of the foreign application;

3 - A copy of the patent granted on the basis of the foreign application;

4 - A copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; and

5 - A copy of any final decision invalidating the patent granted on the basis of the foreign application.

*PAKISTAN: Sections 15 (1), (2), (2A), (2B) and (3), 20 and 23 (1) (c) of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

15. Contents of specification.- (1) Every specification, whether complete or provisional, shall describe in the form and manner as may be prescribed.

(2) subject to any rules made in this behalf, drawings may, and shall if the Controller so requires, be supplied for the purposes of any specification, whether complete or provisional, and any drawings so supplied shall, unless the Controller otherwise directs, be deemed to form part of the specification, and reference in this Ordinance to a specification shall be construed accordingly.

(2A) For a chemical product intended for use in medicine or agriculture, the specification shall be specific to one chemical product only describing the physical, chemical, pharmacological and pharmaceutical properties or, as the case may be, the properties related to its use in agriculture and its impact on environment.

(2B) Where a biological material is used, the specification shall disclose the place of origin and source of such biological material and shall also exhibit compliance with the relevant applicable rules on access, export and use of that material and where such a material is obtained from Pakistan for use outside Pakistan, the permission of the Federal Government shall be necessary as may be prescribed.

(3) Every complete specification shall-

(a) fully and particularly describe the invention and the method by which it is to be performed.

- (b) disclose the invention which is known to the applicant and for which he is entitled to claim protection; and
- (c) end with a claim or claims concisely defining the scope of the invention for which protection is claimed.

20. Power of Controller to require certain information and documents relating to foreign application.- (1) The applicant shall, when required by the Controller, furnish him with the date and number of any application for a patent filed by him abroad, hereinafter referred to as foreign application, relating to the same or essentially the same invention as that claimed in the application filed in Pakistan.

(2) The applicant shall, when required by the Controller, furnish him with the following documents relating to one of the foreign applications referred to in sub-section (1), namely:-

- (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (ii) a copy of the patent granted on the basis of the foreign application; and
- (iii) a copy of any final decision rejecting the foreign application.

(3) The applicant shall, when required by the Controller, furnish him with a copy of any final decision invalidating the patent granted on the basis of foreign application referred to in sub-section (1).

23. Opposition to the grant of patent.- (1) At any time within four months from the date of advertisement of the acceptance of a complete specification under this Ordinance, any person may give notice to the Controller of opposition to the grant of patent on any of the following grounds, namely:

- (c) that the specification does not disclose the invention in a manner clear and complete enough for it to be carried out by a person skilled in the art;

*PANAMA: Articles 30, 31 and 50 of the Law No. 35 of 10/05/1996 Enacting Provisions on Industrial Property and Article 23 (f) of the Executive Decree No. 257 of 17/10/2006*

30. The description shall consist in the disclosure of the invention in a manner sufficiently clear and complete for it to be evaluated and for a person skilled in the relevant technical field to be able to carry it out.

The description shall state the name of the invention and include the following information:

1. the sector of technology to which the invention refers or applies;
2. the prior technology known to the applicant that may be considered useful for the understanding and examination of the invention, and also references to earlier documents and publications relating to the said technology;
3. a description of the invention in terms that allow the technical problem and the solution provided by the invention to be understood and also the advantages thereof compared with earlier technology to be explained;
4. an explanation of the drawings, if any;
5. a description of the best method known to the applicant of carrying out the invention or putting it into practice, making use of examples and references to the drawings;
6. the manner in which the invention may be produced or used in a given activity, except where this is obvious from the description or nature of the invention.

31. Where the invention relates to a biological product or process requiring the use of biological material that is not available to the public and cannot be so described as to allow the invention to be carried out by a person skilled in the art, the description shall be complemented with a deposit of the said material at a depositary institution such as those recognized under the 1977 Budapest Treaty on

the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or any other institution recognized by DIGERPI. In such a case the deposit shall be made no later than on the filing date of the application in Panama, or where appropriate on the date of the priority claim.

When a deposit of biological material is made to complement the description, that fact shall be mentioned in the description together with the name and address of the depositary institution, the date of deposit and the deposit number assigned by the institution. The nature and characteristics of the material deposited shall likewise be described where necessary for the disclosure of the invention. The biological material deposited shall form an integral part of the description.

50. Where lack of clarity in the description or claims prevents the production of the report on the state of the art from proceeding, either entirely or in part, DIGERPI shall refuse the grant of the patent to the corresponding extent.

Before taking a final decision to refuse the grant of a patent, DIGERPI shall address the appropriate notification to the applicant, and shall allow him a period of six months, which may be extended for an additional two months, within which to present such arguments as he considers appropriate.

Executive Decree No. 257 of 17/10/2006

#### *Artículo 23*

Todos los Contratos de Acceso serán válidos por el periodo que determine la UNARGEN en consulta con el CCT e incluirán las siguientes obligaciones con el Estado:

f) Toda solicitud de patente de invención o procedimiento que sea elevada a la Dirección General de Propiedad Industrial del Ministerio de Comercio e Industrias y/o cualquier oficina de patentes de los países miembros de la Organización Mundial de la Propiedad Intelectual (OMPI) deberá comunicar por escrito el origen y procedencia del material genético. recurso genético y/o biológico utilizado en el desarrollo de la invención o el procedimiento, a título de información;

PAPUA NEW GUINEA: *Sections 19 (2) (a) (ii), (5) and (6) (c), 24 and 26 of the Industrial Property Act No. 30 of 19/07/2000*

#### 19. Application

(2) An application under Subsection (1)

(a) shall contain -

(ii) a description in accordance with Subsection (5); and

(5) The description referred to in Subsection (2)(a)(ii) shall

(a) disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the applicable art; and

(b) indicate the best method known to the applicant at the filing date, or where priority is claimed at the priority date, of the application, for carrying out the invention.

(6) The claim or claims referred to in Subsection (2)(a)(iii) shall

(a) define the matter for which protection is sought; and

(b) be clear and concise; and

(c) be fully supported by the description, which, with the drawings may be used to interpret the claims.

#### 24. Information concerning corresponding foreign applications and patents

Where the Registrar so requests, an applicant under Section 19 (1) shall, within a time limit specified by the Registrar -

(a) provide such information as is requested by the Registrar, including but not limited to, the date and number of any application for a patent filed by the applicant in another country or jurisdiction (in this section referred to as "foreign application"), relating to the same or essentially the same invention as that claimed in the application filed with the Registrar; and

(b) furnish to the Registrar the following documents relating to any foreign application:

(i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(ii) a copy of any patent granted on the basis of the foreign application;

- (iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; or
- (iv) a copy of any final decision invalidating the patent granted on the basis of the foreign application.

#### 26. Examination of patent

After recording a filing date under Section 25 for an application under Section 19 -

(a) the Registrar shall examine whether

(i) the application complies with the requirements of Section 19 (2) and (4) and any Regulations pertaining thereto; and

(ii) the application complies with those requirements of this Act, and the Regulations which are designated by the Regulations as formal requirements for the purposes of this Act; and

(iii) information requested under Section 24, if any, has been provided; and

(b) where the Registrar is of the opinion that the application does not comply with the requirements of Paragraph (a) he may invite the applicant to file, within a time limit specified by the Registrar and in a manner directed by the Registrar,

(i) a correction or amendment; or

(ii) a submission as to whether the application complies with the requirements of Paragraph (a); or

(iii) both (i) and (ii),

and where after the expiration of the time limit specified by the Registrar, whether or not the applicant has responded to the invitation of the Registrar under this paragraph, the Registrar is still of the opinion that the application does not comply with the requirements of Paragraph (a) the Registrar shall refuse the application and notify the applicant in writing of his decision.

PARAGUAY: *Articles 15, 16, 25 (3), 26 and 38 (c) of the Patents Law No. 1630 of 29/11/2000*

#### *Artículo 15*

Del descripción. Cuando fuese necesario, la descripción estará acompañada de los dibujos pertinentes para que la divulgación de la invención sea suficientemente clara y completa, para que sea comprensible y para que pueda ejecutarla.

La descripción de la invención indicará su nombre, el sector al cual se refiere o al cual se aplica; la tecnología anterior conocida y referencias, documentos y publicaciones anteriores relativas a dicha tecnología.

La descripción detallará el problema técnico y la solución aportada por la invención, así como la mejor manera de ejecutar o llevar a la práctica la invención utilizando ejemplos y referencias a los dibujos, indicando el modo en que la invención puede ser producida o utilizada en alguna actividad productiva.

#### *Artículo 16*

De la descripción del material biológico. Cuando la invención se refiera a un producto o procedimiento relativo a algún material biológico que no se encuentre a disposición del público y no pueda describirse de manera que la invención pueda ser ejecutada por una persona capacitada en la materia, se complementará la descripción mediante el depósito de dicho material en una institución de depósito reconocida por la Dirección de la Propiedad Industrial.

Tal depósito se efectuará a más tardar dentro de los sesenta días siguientes a la fecha de presentación de la solicitud, o cuando se invoque un derecho de prioridad, a más tardar en la fecha de prioridad, de la solicitud original.

No se exigirá dicho depósito si ya se lo hubiese realizado en algún país miembro de la Organización Mundial de Comercio o ya se hubiese realizado el examen de novedad por la autoridad de cualquiera de tales países. En este caso, se indicará el nombre y la dirección de la institución de depósito, así como la fecha de presentación y el número de depósito atribuido por la institución. También se describirá la naturaleza y características del material depositado cuando ello fuese necesario para la divulgación de la invención.

#### *Artículo 25*

(3) Cuando sea aplicable, la Dirección de la Propiedad Industrial podrá requerir al solicitante los documentos relativos a los exámenes de novedad o de patentabilidad efectuados por otras oficinas de propiedad industrial o dentro del procedimiento previsto en algún tratado internacional del que el Paraguay sea parte. La Dirección de la Propiedad Industrial podrá reconocer los resultados de tales exámenes como suficientes para acreditar el cumplimiento de las condiciones de patentabilidad.

#### *Artículo 26*

De las solicitudes extranjeras correspondientes. A efectos de verificar el cumplimiento de los requisitos de patentabilidad, el solicitante proporcionará a la Dirección de la Propiedad Industrial, junto con la traducción correspondiente, los siguientes documentos de las solicitudes extranjeras relativas a la misma invención que se examina:

- a) copia de la solicitud extranjera y de sus documentos acompañantes;
- b) copia de los resultados de exámenes de novedad o de patentabilidad efectuados respecto a la solicitud extranjera; y,
- c) copia de la patente u otro título de protección que se hubiese concedido con base en la solicitud extranjera.

El solicitante podrá presentar observaciones y comentarios adicionales sobre cualquier información o documento en cumplimiento del presente artículo.

#### *Artículo 38*

De la nulidad de la patente. La patente será nula:

- c) si la patente no divulga la invención de manera suficientemente clara y completa para poder comprenderla y para que una persona capacitada en la materia técnica correspondiente pueda ejecutarla;

PHILIPPINES: *Sections 35 (1), 39 and 61 (1) (b) of the Intellectual Property Code, Act No. 8293 of 06/06/1997 as last amended by Act No. 9502 of 2008*

#### Disclosure

35.-1. The application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. Where the application concerns a microbiological process or the product thereof and involves the use of a micro-organism which cannot be sufficiently disclosed in the application in such a way as to enable the invention to be carried out by a person skilled in the art, and such material is not available to the public, the application shall be supplemented by a deposit of such material with an international depository institution.

#### Description

2. The Regulations shall prescribe the contents of the description and the order of presentation.

#### The Claims

36.-1. The application shall contain one (1) or more claims which shall define the matter for which protection is sought. Each claim shall be clear and concise, and shall be supported by the description.

#### Information Concerning Corresponding Foreign Application for Patents

39. The applicant shall, at the request of the Director, furnish him with the date and number of any application for a patent filed by him abroad, hereafter referred to as the "foreign application," relating to the same or essentially the same invention as that claimed in the application filed with the Office and other documents relating to the foreign application. (n)

#### Amendment of Application

49. An applicant may amend the patent application during examination: Provided that such amendment shall not include new matter outside the scope of the disclosure contained in the application as filed.

#### Cancellation of Patents

61.-1. Any interested person may, upon payment of the required fee, petition to cancel the patent or any claim thereof, or parts of the claim, on any of the following grounds:

- (b) That the patent does not disclose the invention in a manner sufficiently clear and

complete for it to be carried out by any person skilled in the art; or

*POLAND: Articles 33 (1) and 93.6 of the Industrial Property Law of 30/06/2000, as last amended by Act of 29/06/2007*

*Article 33*

1. Subject to Article 936(1), the description referred to in Article 31(1)(ii) shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In particular, the description shall contain the title of the invention designating the subject matter of the invention, specify the technical field to which the invention relates, as well as indicate the background art known to the applicant; it shall also present the invention in a detail manner, describe the figures in the drawings (if any), and indicate the way or ways of carrying out or exploiting the invention claimed using examples.

*Article 93.6*

1. Where an invention involves the use of biological material which is not available to the public and which cannot be described in the description in such a manner as to enable the invention to be reproduced by a person skilled in the art, the disclosure thereof may be made by reference to the material deposited, at the latest at the filing date, in a depositary institution recognised under an international agreement or in a national depositary institution, which is mentioned by the President of the Patent Office in an announcement published in the Official Gazette of the Republic of Poland "Monitor Polski".

2. The President of the Patent Office shall announce the acquisition of the status of the national depositary institution, referred to in paragraph (1), after having received, at the request of the institution concerned, acceptance from the minister competent in respect of the subject of deposited biological materials.

3. Where the deposit referred to in paragraph (1) has been made, the application must be accompanied by an attestation issued by the depositary institution, furnished by the applicant. The attestation should include at least the name of the institution, the date of the deposit and the accession number given to the biological material.

4. The attestation issued by a depositary institution may be furnished within six months from the filing date. In case of late furnishing of the said attestation the deposit of the biological material shall not be considered equivalent to its disclosure in the application.

5. Access to the deposit referred to in paragraph (1) before the publication of the particulars of the patent application shall be limited to the parties mentioned in Article 251(1). At the applicant's request submitted to the Patent Office before the publication of the particulars of the patent application, the above limitation shall extend for the entire term during which the application is processed.

6. After the particulars of the application have been published, unless the request referred to in paragraph (5) has been submitted, and after the patent has been granted, access to the deposit may not, subject to the condition referred to in paragraph (7), be denied to third parties. This provision shall apply accordingly notwithstanding invalidation or lapse of the patent.

7. The sample of the biological material shall be supplied only if the person requesting it undertakes in writing, vis-à-vis the applicant or the holder of the patent, for the term during which the patent remains in force:

- (i) not to make it or any material derived from it available to third parties,
  - (ii) not to use it or any material derived from it except for experimental purposes
- unless the applicant or the holder of the patent expressly waives such an undertaking.

8. Where the Patent Office makes a decision to refuse the grant of a patent or to discontinue the patent granting proceeding, access to the deposited biological material, at the applicant's request submitted within the term provided for in paragraph (5), shall be limited to the parties, mentioned in paragraph (5), for 20 years from the date on which the patent application was filed. The provision of paragraph (7) shall apply accordingly.

PORTUGAL: *Articles 62 (1) (b) and (4), 63, 73 (1) (d) and 113 (d) of the Industrial Property Code, Decree-Law No. 36 of 05/03/2003 as last amended by Law No. 16 of 01/04/2008*

*Article 62*

Documents to be submitted

1 The application shall be accompanied by the following information in Portuguese:

b) Description of the invention;

4 The description shall give a brief, clear indication, with no reservations or omissions, of everything making up the invention and contain a detailed explanation of at least one way of making the invention, so that any person skilled in the art may carry it out.

*Article 63*

Biotechnological inventions

1 If an invention concerns biological material not accessible to the public and cannot be described in the patent application so that a person skilled in the art could carry it out, or entails the use of a material of this type, the description shall only be considered sufficient for the purpose of obtaining a patent, if:

a) The biological material has been deposited up to the date of submission of the patent application at a recognized depositary institution, such as international depositary institutions that have acquired this status under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 28 April 1977;

b) The application as filed gives such relevant information as is available to the applicant on the characteristics of the biological material deposited;

c) The depositary institution and the accession number of the deposited biological material are stated in the application.

2 Access to the deposited biological material must be ensured by submission of a sample:

a) By the first publication of the patent application, solely to persons who are so entitled under national law;

b) Between the first publication of the patent application and the grant of the patent, to any person so requesting or, at the request of the depositor, solely to an independent expert;

c) After the grant of the patent, and even in the event of cessation of the patent due to invalidity or expiry, to anyone requesting it.

3 The material will only be handed over if the person requesting it undertakes, for the duration of the patent:

a) Not to allow access by third parties to any sample of the deposited biological material or a material derived from it;

b) Not to use any sample of the deposited biological material or of a material derived from it, except for experimental purposes, unless the applicant or patent holder expressly waives this undertaking.

4 If the patent application is refused or withdrawn, access to the deposited material may, at the depositor's request, be confined to an independent expert for 20 years as of the date of submission of the patent application, in which case paragraph 3 applies.

5 The requests from the depositor referred to in paragraph 2(b) and 4 may only be submitted up to the date on which the technical preparations for publication of the patent application are considered complete.

6 If biological material deposited as set forth in the previous paragraphs ceases to be available at the recognised depositary institution, a new deposit of the material is allowed under the conditions of the Budapest Treaty.

7 Any new deposit shall be accompanied by a statement signed by the depositor certifying that the biological material in the new deposit is identical to that originally deposited.

*Article 73*

Reasons for refusal

1 In addition to the provisions of Article 24, a patent shall be refused if:

d) Its object is not described in such a way as to allow the invention to be carried out by a person skilled in the art;

*Article 113*

Nullity

In addition to the provisions of Article 33, patents shall be null and void in the following cases:

d) If its object has not been described in such a way that anyone skilled in the art can carry it out.

REPUBLIC OF KOREA: *Articles 42 (2) (iii), (3), (5) and (7), 62 (iv) and 133 (1) (i) of the Patent Act No. 950 on 28/11/1949, as last amended by Act No. 9381 of 30/01/2009*

*Article 42*

Patent Application

(2) A written patent application under paragraph (1) shall be accompanied by an abstract, drawing(s) (if necessary) and a description stating the following:

(iii) a detailed description of the invention; and

(3) The detailed description of the invention referred to in paragraph (2)(iii) shall describe the invention clearly and in detail as prescribed by Ordinance of the Ministry of Knowledge Economy so that a person with ordinary skill in the art to which the invention pertains may easily work the invention.

(5) Notwithstanding paragraph (2), a patent applicant may, at the time the application is filed, attach the description, from which the scope of claims under paragraph (2)(iv) are omitted, to the written patent application. In such cases, the applicant shall amend the description to include the scope of claims by either of the following deadlines:

(i) the date marking the elapse of one year and six months from the date that falls under any of the subparagraphs of Article 64(1); or

(ii) the date marking the elapse of three months from the date on which notification is given under Article 60(3) for a request to examine a patent application before the deadline stipulated in subparagraph (i) of this paragraph (however, where the notification is given more than one year and three months after the date that falls under any subparagraph of Article 64(1), the date marking the elapse of one year and six months from that date).

(7) Where a patent applicant has filed a patent application but fails to subsequently amend the description to include the scope of claims by the relevant deadline stipulated in subparagraph (5)(i) or (ii), the application is deemed to have been withdrawn on the date immediately following the relevant deadline.

*Article 62*

Decision to Reject a Patent Application

An examiner shall make a decision to reject a patent application for any of the following grounds (referred to as "the grounds for rejection", hereinafter):

(iv) where the application does not comply with the requirements of Articles 42(3), (4), (8) or 45;

*Article 133*

Invalidation Trial of a Patent

(1) Where a patent falls under any of the following subparagraphs, an interested party or an examiner may request a trial to invalidate the patent. In such a case, if the patent contains two or more claims in the scope of claims, a request for an invalidation trial may be made for each claim. However, any person may request an invalidation trial on the grounds that the patent falls under any of the following subparagraphs (except subparagraph (ii)), provided the request is made after the registration date of establishment of the patent right and not more than three months after the publication date of the registration of the patent right:

(i) where the patent has been granted in violation of Articles 25, 29, 32, 36(1) to (3), 42(3), (4);

REPUBLIC OF MOLDOVA: *Articles 33 (1) (b) and (d) and (4), 36, 48 (2) (a), (3) and (4), 57 (2) (b) and 64 (1) (b) of the Law on the protection of Inventions No. 50-XVI of 07/03/2008*

*Article 33*

Requirements to Be Met by a Patent Application

- (1) A patent application shall contain:
- b) a description of the invention;
  - d) any drawings referred to in the description or the claims;

(4) If the invention concerns reproducible biological material, the patent application may contain, where appropriate, an attestation certifying the deposit of that biological material with a depositary institution, in accordance with Article 36 paragraph (2), submitted at the time of filing of the patent application or within 2 months following the filing date of the latter.

*Article 36*

Disclosure of the Invention

- (1) The patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
- (2) Where the invention refers to biologically reproducible material which is not available to the public, the conditions referred to in paragraph (1) shall only be fulfilled if the applicant proves with a document that, prior to the filing date of the patent application or the acknowledged priority, the biological material has been deposited with an international depositary authority or a depositary institution designated by the Government.

*Article 48*

Preliminary Examination

- (2) In the preliminary examination AGEPI shall examine whether:
- a) the patent application meets the requirements laid down in Article 33;
- (3) Where AGEPI notes that there are deficiencies which may be corrected, it shall give the applicant an opportunity to correct them in accordance with the Regulations.
- (4) Where the examination undertaken under paragraph (2) above finds that the requirements of Article 32 paragraph (3) and Article 33 paragraph (9) and (10) have not been satisfied, the patent application shall be refused. If the applicant disregards the provisions of Article 40 concerning the priority right, the deficiency shall lead to the loss of this right for the application.

*Article 57*

Opposition

- (2) Opposition shall only be filed in writing and on the grounds that:
- b) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

*Article 64*

Revocation of Patent

- (1) A patent may be revoked, in whole or in part, on the following grounds:
- b) if the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

ROMANIA: *Articles 14 (c), 18, 28 (c) and 52 (b) of the Patent Law No. 64/1991 as republished in the OJ, Part I, No. 638/18.IX.2007*

*Article 14*

The patent application drawn up in Romanian must contain:

- c) a description of the invention;

*Article 18*

The invention shall be disclosed in the patent application in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

If the invention relates to a biological material or to the use of a biological material which is not available to the public and which cannot be described in the patent application in such a manner as to enable the invention to be carried out by a person skilled in the art, the requirements prescribed in paragraph 1 shall only be considered fulfilled if the applicant produces a document attesting that, prior to the date of filing of the patent application, the biological material was deposited with an international depositary institution.

The claims shall define the matter for which protection is sought and shall be clear and concise and be supported by the description of the invention.

#### *Article 28*

On the basis of the patent application examination report, OSIM shall decide through the specialized Examination Board, to grant a patent or to refuse the patent application.

OSIM shall decide to refuse the patent application in the following cases:

c) the invention to which the application relates does not meet the requirements of Art. 18;

#### *Article 52*

Any interested person is entitled to apply with OSIM, in writing, on valid grounds, for the revocation of the patent, within 6 months of the publication of the mention of granting the patent, provided that:

b) the subject-matter of the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

#### RUSSIAN FEDERATION: *Article 1375 (2) 2) of the Patent Act (Chapter 72)*

##### *Article 1375*

Application for the Grant of a Patent for an Invention.

2. An application for an invention shall contain:

2) the description of the invention, disclosing it in sufficient details for it to be carried out;

#### RWANDA: *Articles 23 2), 25, 31, 33 (3), 34 (1) and 36 (2) of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property*

##### *Article 23*

Filing the application

Patent application shall be filed with the empowered authority. The application shall contain:

2° a description of the invention;

##### *Article 25*

Description of the invention

The description shall, subject to being declared invalid, explain and disclose the invention in a manner sufficiently clear, complete and intelligible so as to be used by a person skilled in the art and involved in that area. It shall indicate the best way to use the invention known to the applicant at the filing date or, where priority is claimed, at the priority date of the application. Where necessary, drawings shall be provided to understand the invention.

The disclosure of the claimed invention shall be considered sufficiently clear and complete if it provides information which is sufficient to allow that invention to be used by a person skilled in the art on the filing date, without undue experimentation. For the purposes of assessing sufficiency of disclosure, the disclosure contained in the description, claims and drawings, as established on the date in which the sufficiency of disclosure was examined, shall be taken into account.

In accordance with provisions of this article, a person having ordinary skill in the art is understood as a citizen of Rwanda, or any person with habitual residence located in Rwanda, who has studied and carries out his profession in Rwanda, having acquired an average expertise and experience in the technical field of the claimed invention.

The empowered authority may, at any time before the grant of the patent, require the description in foreign patent applications to be adapted to the ordinary skill in the art of the citizens of Rwanda, or

any person with habitual residence in Rwanda and carries out his profession in Rwanda, so as to ensure technology transfer and dissemination.

#### *Article 31*

Information relating to corresponding foreign applications

The applicant shall indicate to the empowered authority the date and number of any patent application or other title of protection filed by him or by his legal predecessor abroad, known as "foreign application", and which relates to the same invention, or essentially to the same invention, as that which is claimed in the application filed in Rwanda.

In order to facilitate the evaluation of novelty and inventive step as regards the claimed invention, the applicant shall supply the to the empowered authority with the following documents relating to one of the foreign applications referred to in paragraph (1) of this article:

1° a copy of any communication received by the applicant concerning the results of any search or examination carried out in relation to the foreign application;

2° a certified or ordinary copy of the patent or other title of protection granted on the basis of the foreign application;

3° a copy of any final decision rejecting the foreign application or refusing the grant required in the foreign application.

The applicant shall furnish the empowered authority with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in paragraph (2) of this article.

#### *Article 33*

Examination

(3) Where the empowered authority is of the opinion that the application complies with the formal requirements of the paragraph (1) of this article, he shall take a decision as to whether the requirements of articles 14 to 18, 25 and 26 and the administrative regulations pertaining thereto and cause, if appropriate, the application to be examined as to substance. For the purposes of examination as to substance, the empowered authority shall take into account:

1° the results of any international search report and any international preliminary examination report established under the Patent Cooperation Treaty in relation to the application filed in Rwanda; and/or

2° the results of any search and examination report and any decision submitted under article 31 of this Law; and/ or

3° the results of any search and examination report which was carried out upon his request by an external search and examination authority or by a specialized agency of the Government of Rwanda.

#### *Article 34*

Grant of the patent

Where the competent authority finds that the formal requirements of article 32 have been satisfied, it shall grant the patent. In the opposite case, he shall reject the application and shall notify the applicant of that decision in writing in a period provided by international conventions to which Rwanda is party.

#### *Article 36*

Invalidation of a patent

(2) The competent court shall invalidate the patent if the person requesting the invalidation proves that one of the requirements of paragraph (2) and (8) of article 5, articles 14 to 18, 25 and 26, has not been satisfied, or if the patent owner is not the inventor or his rightful claimant.

SAINT LUCIA: *Sections 21 (3) (b) and (4), 25 (3), 75 and 76 (1) (c) of the Patents Act No. 16 of 27/08/2001*

Making of application

21-(3) An application for a patent shall contain:

(b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and

(4) The specification of an application for a patent shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art.

Search and examination and corresponding international applications

25-(3) Upon receipt of the report of the search carried out under subsection (2), the Registrar shall send to the applicant a copy of the report, and the applicant may, within the prescribed period, file a request and pay the prescribed fee for an examination report on the application so as to determine whether the conditions specified in sections 9 and 21(4) and (5) have been complied with, taking into consideration all the relevant prior art, if any, referred to in the search report; and upon receipt of the report, the Registrar shall send to the applicant a copy of the report.

(4) Where the applicant has furnished the prescribed details under subsection (1) (c), he or she shall, subject to subsection (5), within the prescribed period, file the prescribed information in or translated into the English Language relating to any one of the corresponding international applications or other corresponding applications referred to in subsection (1) (c).

(5) The applicant may, instead of filing the prescribed information referred to in subsection (4), within the prescribed period, either:

- (a) file a copy of a search report in respect of any one of the corresponding international applications or other corresponding applications referred to in subsection (1) (c), together with a request in the prescribed form and the prescribed fee, for an examination report; or
- (b) file a request in the prescribed form and pay the prescribed fee for a search and examination report.

#### Information on result of corresponding international applications

75-(1) The Registrar may, on the application of any interested person and on the payment of the prescribed fee, request the proprietor of a patent to furnish to the Registrar, within such period as the Registrar may specify, the prescribed information on all corresponding international applications or corresponding applications for a patent made by him or her, or his predecessor in title at any prescribed patent office with respect to which details had been furnished to the Registrar under section 25 (1) (c).

(2) Where the proprietor of a patent has furnished the prescribed information under subsection (1) or where such information is available at the Registry, the Registrar shall as soon as practicable send to the interested person the prescribed information so furnished or available.

(3) Where the proprietor of a patent fails without good cause to comply with the request of the Registrar under subsection (1), the Registrar may by order revoke the patent with effect from the date of the grant of the patent.

(4) For the purpose of this section, "corresponding international application" and "corresponding application" have the same meanings as in section 25 (9).

#### Power to revoke patents on application

76-(1) Subject to the provisions of this Act, the Registrar may, on the application of any person, by order revoke a patent for an invention on, but only on, any of the following grounds

(c) the specification of the patent does not disclose the invention clearly and completely for it to be performed by a person skilled in the art;

*SAN MARINO: Articles 12 (1), 17, 23 (5) and 35 (1) (b) of the Law on Industrial Property No. 79 of 25/05/2005*

#### *Article 12(Description)*

1. The description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art and in particular, it must give one or more examples the applicant knows to perform the invention.

#### *Article 17(Deposit of microbiological material)*

1. If an invention concerns a microbiological process or a product thereof and involves the use of a micro-organism which is not available to the public and cannot be described in such a manner as to enable the invention to be carried out by a person skilled in the art, the invention shall only be regarded as being disclosed only if:

a) a sample of the micro-organism has been deposited with a depositary institution under the provisions of the Budapest Treaty, and not later than the date of filing of the patent application;

- b) the filed application contains the relevant information which is available to the applicant on the characteristics of the micro-organism;
- c) the application indicates a recognised depositary institution with which a sample of the micro-organism has been deposited and the number and date of the deposit of the sample, unless the Patents and Trade Marks State Office requires a copy of the receipt of the deposit. Depositary institutions are considered to be institutions recognised for the purposes of obtaining a European patent or any international authority which is recognised under a convention ratified by the Republic of San Marino.

2. The information referred to in letter c) may be submitted within a period of two months after the date of filing of the patent application. The communication of this information shall be considered as constituting the unreserved and irrevocable consent of the applicant to make the deposited sample available to any person making a request to the depositary institution from the date of publication of the patent application.

3. The request shall be notified to the applicant or the patent owner and it shall indicate:

- a) the name and address of the person making the request;
- b) the undertaking by the person presenting the request vis-à-vis the applicant or the patent owner not to make the sample available to any third party;
- c) the undertaking to use the sample through a named qualified expert only for experimental purposes up until the date on which the patent application is refused or withdrawn or the patent has finally expired or been declared to be null and void and can no longer be restored in favour of the applicant for or the proprietor of the patent.

4. The expert designated to use the sample shall be jointly responsible for any violation committed by the person making the request.

5. If the biological material, deposited in accordance with the previous paragraphs, is no-more available from the recognised institution with which it was deposited, it is allowed to make a new deposit of the material under the conditions laid down in this article.

6. Any new deposit shall be accompanied by a statement signed by the depositor certifying that the newly deposited biological material is the same as that originally deposited.

#### *Article 23 (Examination of the application and findings)*

5. The applicant shall provide, on request of the Patents and Trade Marks State Office, a copy of any communication received concerning the results of search activities or examinations related to a patent application or another title of protection filed by the applicant abroad, concerning the same or substantially the same invention claimed in the application filed with the Patents and Trade Marks State Office.

#### *Article 35 (Nullity of patent)*

1. The Patent is null and void:

- b) if the application does not meet the provisions contained in article 12, paragraph 1 above;

SERBIA: *Articles 25, 43 (1) 4), 45 and 87 (1) 4) of the Patent Law of 10/07/2004*

#### Description of the Invention

##### *Article 25*

An invention shall be described in a manner that is clear and complete enough for the invention to be carried out by a person skilled in the art.

If the invention concerns a biological material and cannot be carried out on the basis of the description of the invention, the description shall be deemed to fulfill the conditions laid down in paragraph 1 of this Article if a sample of the naturally reproducible biological material is deposited with a competent depositary institution not later than the filing date of the application.

The term "competent depositary institution" referred to in paragraph 2 of this Article shall mean an institution designated in accordance with the provisions the Budapest Treaty on the International

Recognition of the Deposits of Microorganisms for the Purpose of Patent Procedure concluded on 28 April 1977 and last revised on 26 September 1980.

#### Substantive Examination Procedure

##### *Article 43*

In the course of the substantive examination of an application, the competent authority shall examine whether the subject matter of the application:

4) is disclosed in a manner sufficiently clear and complete pursuant to Article 25 of this Law;

##### *Article 45*

An applicant, who has filed an application for the same invention in any other state, may furnish the competent authority with a certified translation of the examination report issued in the said state.

#### Grounds for Revocation

##### *Article 87*

At any time during the term of a patent, the competent authority shall revoke a decision on its grant on request of an interested person, if it establishes that:

4) the invention is not disclosed in a manner sufficiently clear and complete as defined in Article 25 of this Law;

SINGAPORE: *Sections 25 (3) and (4), 29 (2) (c) and 80 (1) (c) of the Patents Act No. 21 of 25/11/1994 as of 01/12/2008*

#### Making of application

25.-(3) Every application for a patent shall contain:

- (a) a request for the grant of a patent;
- (b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and
- (c) an abstract,

but this subsection shall not prevent an application being initiated by documents complying with section 26 (1).

(4) The specification of an application shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art.

#### Search and examination 29

(2) The applicant shall comply with any of the following paragraphs which is applicable within the period prescribed for that paragraph:

(c) where a corresponding application for a patent has been filed at any prescribed patent office

(i) file

- (A) a copy of the search report in respect of the corresponding application;
- (B) where the search report is not in English, an English translation of the search report;
- (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
- (D) a request in the prescribed form for an examination report, and pay the prescribed fee for an examination report; or

(ii) file

- (A) in the prescribed form, the prescribed information relating to the corresponding application; and
- (B) where the prescribed information includes any document that is not in English, an English translation of such document;

(d) where a corresponding international application for a patent has been filed

(i) file

- (A) a copy of the international search report in respect of the corresponding international application;
- (B) where the international search report is not in English, an English translation of the international search report;
- (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
- (D) a request in the prescribed form for an examination report,

and pay the prescribed fee for an examination report; or

(ii) file

- (A) in the prescribed form, the prescribed information relating to the corresponding international application; and
- (B) where the prescribed information includes any document that is not in English, an English translation of such document;

(e) where the application is an international application for a patent (Singapore) that has entered the national phase in Singapore under section 86 (3)

(i) file

- (A) a copy of the international search report issued in respect of the application;
- (B) where the international search report is not in English, an English translation of the international search report;
- (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
- (D) a request in the prescribed form for an examination report,

and pay the prescribed fee for an examination report; or

(ii) file a notice in the prescribed form of the applicant's intention to rely on the international preliminary report on patentability in respect of that application.

Power to revoke patents on application

80.-(1) Subject to the provisions of this Act, the Registrar may, on the application of any person, by order revoke a patent for an invention on (but only on) any of the following grounds:

(c) the specification of the patent does not disclose the invention clearly and completely for it to be performed by a person skilled in the art;

*SLOVAKIA: Articles 37 (4) and (5) (b), 38, 40 (4) and 46 (1) (b) of the Patent Act No. 435/2001 as last amended by Act No. 202/2009 Coll.*

*Article 37*

*Application*

(4) An invention shall be described and explained in an application clearly and completely so that it can be carried out by a person skilled in the art.

(5) Application shall contain:

b) description of an invention, abstract and drawings, if any,

*Article 38*

*Special provision on application of biotechnological invention*

(1) If a subject-matter of an invention is biological material or utilisation of biological material, which is not available to public and which cannot be described in an application in a manner that it can be carried out by a person skilled in the art, description shall be deemed sufficient only provided that

- a) biological material has been deposited in a recognised depository institution no later than by the filing date of an application,
- b) application as filed contains information on characteristics of deposited biological material, which has been available to an applicant,

c) application states name and seat of a recognised depository institution, as well as a deposit number of deposited sample.

(2) Deposited biological material shall be available by providing a sample on request from the publication day of an application up to granting a patent. An applicant shall be entitled on request filed with the Office before publication of an application to limit an access to deposited biological material only for independent experts.

(3) After granting a patent irrespective of its cancellation or lapse, deposited biological material shall be available by providing a sample on request

(4) Deposited sample may be provided only if a requesting person or independent expert pursuant to paragraph 2, second sentence, shall bound himself that during the term of a patent

a) he shall provide neither sample nor material derived from it to third party,

b) he shall utilise sample and material derived from it only for experimental purposes, unless an applicant or a patent owner explicitly repeals this obligation for him.

(5) Applicant shall be entitled on request filed with the Office before publication of an application to limit an access to deposited biological material for time limit of 20 years from the day of filing an application only for independent experts for case that an application would be refused or proceedings on application would be suspended; paragraph 4 shall apply *mutatis mutandis*.

(6) In case of doubts about accessibility of biological material to public or about sufficiency of description pursuant to paragraph 1, the condition of accessibility or sufficiency of description shall be considered not to be met until proved otherwise.

(7) If a sequence or partial sequence of a gene is a subject-matter of an application, industrial applicability of an invention must be explained in the application.

(8) The recognised depository institution is the institution for the deposition of biological material, which acquired a status pursuant to the international convention<sup>15)</sup> or it was recognised by the Office.

(9) Conditions pursuant to the international convention<sup>15)</sup> shall apply to re-deposit of a biological material in the recognised depository institution.

#### *Article 40*

(4) If an application fails to meet conditions pursuant to Article 37(1) and (4) or Article 38(1) to (3) or a subject-matter of an application evidently fails to meet conditions pursuant to Article 5(1), or it is not being considered to be an invention pursuant to Article 5(3), or is subject to exclusion from patentability pursuant to Article 6, or an assumption pursuant to paragraph 2 applies, the Office shall refuse an application. Before an application is refused, the Office shall enable an applicant to respond to ascertained reasons for refusal of an application.

#### *Article 46*

(1) The Office shall revoke a patent if during proceedings started on third party request or ex officio it is proved that

b) invention has not been disclosed and described in a patent so clearly and fully so that it could be carried out by a person skilled in the art,

*SLOVENIA: Articles 87 (2) and (3) and 112 (1) (b) of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

#### *Article 87*

Substance of requirements of a patent application

(2) The description of the invention shall include the presentation of the problem, information on the state of the art or of other solutions available by that time and their deficiencies which have been known to the applicant, together with a description of the new solution to the problem. The invention shall be described in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art to which the subject-matter of the invention relates.

(3) If an invention relates to biological material defined by an executive regulation, which is not available to the public and can not be described in a manner to be carried out by a person skilled in the art to which the subject-matter of the invention relates, the description of the invention shall be supplemented by a certificate of the deposit of biological material with an international depository authority under Article 7 of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure of 28 April 1997, and amended on 26 September 1980 (Official Gazette RS-MP No 21/97).

*Article 112*

Actions for a declaration of nullity of a patent

- (1) Actions to declare nullity of a patent may be filed on one or more of the following grounds:  
(b) the invention does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art to which the invention relates;

*SOUTH AFRICA: Sections 30 (3A) and (3B), 32 and 61 (1) (e) and (g) of the Patents Act No. 37 of 1952 as last amended by Act No. 20 of 2005*

30. Form of application for a patent

“(3A) Every applicant who lodges an application for a patent accompanied by a complete specification shall, before acceptance of the application, lodge with the registrar a statement in the prescribed manner stating whether or not the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.

(3B) The registrar shall call upon the applicant to furnish proof in the prescribed manner as to his or her title or authority to make use of the indigenous biological resource, genetic resource, or of the traditional knowledge or use if an applicant lodges a statement that acknowledges that the invention for which protection is claimed is based on or derived from an indigenous biological resource, genetic resource, or traditional knowledge or use.

32. Contents of specification

(1) Every specification shall indicate whether it is a provisional or a complete specification, and shall commence with a title sufficiently indicating the subject-matter of the relevant invention.

(2) A provisional specification shall fairly describe the invention.

(3) A complete specification shall

(a) have an abstract as prescribed;

(b) sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be performed by a person skilled in the art of such invention; and

(c) . . . . .

(d) end with a claim or claims defining the invention for which protection is claimed.

(4) The claim or claims of a complete specification shall relate to a single invention, shall be clear, and shall be fairly based on the matter disclosed in the specification.

(5) Drawings and illustrations, if any, shall be as prescribed.

(6) If a complete specification claims as an invention a micro-biological process or a product thereof and requires for the performance of the invention the use of a micro-organism which is not available to the public on the date of lodging of the application and which cannot be made or obtained on the basis of the description in the specification, the micro-organism shall be dealt with in the prescribed manner.

61. Grounds for application for revocation of patent

(1) Any person may at any time apply in the prescribed manner for the revocation of a patent on any of the following grounds only, namely:

(e) that the complete specification concerned does not sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be carried out by a person skilled in the art of such invention;

(g) that the prescribed declaration lodged in respect of the application for the patent or the statement lodged in terms of section 30(3A) contains a false statement or representation which is material and which the patentee knew ought reasonably to have known to be false at the time when the [declaration] statement or representation was made;

*SPAIN: Articles 21 (1) (b), 25, 35 and 112 (1) (b) of the Law about Patents of Invention and Utility Models No. 11 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

*Artículo 21*

1. Para la obtención de una patente será preciso presentar una solicitud, que deberá contener:

b) Una descripción del invento para el que se solicita la patente.

*Artículo 25*

1. La invención debe ser descrita en la solicitud de patente de manera suficientemente clara y completa para que un experto sobre la materia pueda ejecutarla.

2. Cuando la invención se refiera a una materia biológica no accesible al público, o a su utilización, y cuando la materia biológica no pueda ser descrita en la solicitud de patente de manera tal que un experto pueda reproducir la invención, sólo se considerará que la descripción cumple con lo dispuesto en el apartado anterior si concurren los siguientes requisitos:

a) Que la materia biológica haya sido depositada no más tarde de la fecha de presentación de la solicitud de patente en una Institución reconocida legalmente para ello. En todo caso, se considerarán reconocidas las autoridades internacionales de depósito que hayan adquirido dicho rango de conformidad con el artículo 7 del Tratado de Budapest, de 28 de abril de 1977, sobre el reconocimiento internacional del depósito de microorganismos a los fines del procedimiento de patentes, en lo sucesivo denominado el Tratado de Budapest.

b) Que la solicitud, tal como ha sido presentada, contenga la información relevante de que disponga el solicitante sobre las características de la materia biológica depositada.

c) Que en la solicitud de patente se indique el nombre de la Institución de depósito y el número del mismo.

3. Si la materia biológica depositada de acuerdo con lo previsto en el apartado anterior, dejase de estar disponible en la institución de depósito reconocida, se autorizará un nuevo depósito de esa materia, en condiciones análogas a las previstas en el Tratado de Budapest.

4. Todo nuevo depósito deberá ir acompañado de una declaración firmada por el depositante que certifique que la materia biológica objeto del nuevo depósito es la misma que se depositó inicialmente.

*Artículo 35*

1. Cuando la falta de claridad de la descripción o de las reivindicaciones impida proceder en todo o en parte a la elaboración del informe sobre el estado de la técnica, el Registro denegará en la parte correspondiente la concesión de la patente.

2. Antes de adoptar la resolución definitiva denegatoria de la concesión de la patente, el Registro efectuará la oportuna notificación al solicitante, dándole el plazo que reglamentariamente se establezca para que formule las alegaciones que estime oportunas.

*Artículo 112*

1. Se declarará la nulidad de la patente:

b) Cuando no describa la invención de forma suficientemente clara y completa para que pueda ejecutarla un experto sobre la materia.

*SRI LANKA: Sections 71 (1) (a) (ii), (3), (4), (5) and (6), 73 (3), 75 (1), 78 (1) (d) (g) and (2), and 99 (1) (b) of the Intellectual Property Act No. 36 of 2003*

71. (1) (a) An application for the grant of a patent shall be made to the Director-General in the prescribed form and shall contain:

(ii) a description of the patent;

(3) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be evaluated, and to be carried out by a person having ordinary skill in the relevant technology and shall, in particular, indicate the best mode known to the applicant for carrying out the invention.

(4) The claim or claims shall be clear, concise and supported by the description.

(5) Drawings shall be required when they are necessary for the understanding of the invention.

(6) The terms of any claim shall determine the scope and extent of the protection afforded by the patent, and the description and drawings may be used to interpret such claim.

#### Search Report 73

(3) (a) The applicant shall, at the request of the Director- General, furnish him with the following documents in respect of any foreign application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed in the application filed under this Act –

- (i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application ;
- (ii) a copy of the patent granted on the basis of the foreign application ; and
- (iii) a copy of any final decision rejecting the foreign application or refusing the grant of a patent requested in the foreign application.

#### Amendment and division of application

75. (1) An applicant may amend the application, provided that the amendment shall not exceed the limits of the disclosure in the initial application.

#### Examination of applications

78. (1) The Director-General shall examine the application and shall satisfy himself as to the fulfillment of the following :

(d) the description, the claims and where applicable, the drawings, which comply with the prescribed requirements ;

(g) the search report referred to in section 73 has been submitted.

(2) Where the Director-General finds that the conditions referred to in subsection (1) are not fulfilled he shall request the applicant to file the required correction within a period of three months from the date of such request ; where the applicant fails to so comply the application shall, subject to the provisions of subsection (3), be rejected.

#### Nullity of patent

99. (1) The Court may on the application of any person showing a legitimate interest, or of any Competent Authority including the Director-General, to which the owner of the patent and every assignee, licensee or sub-licensee on record shall be made party, declare the patent null and void on any one or more of the following grounds :

(b) that the description or the claims, fails to satisfy the requirements of subsections (3) and (4) of section 71;

*SWAZILAND: Sections 6 (3), 9, 10 (4), 11 (1) and 14 (2) of the Industrial Property Law No. 6 of 04/09/1997*

#### Application

6. (3) The description shall disclose the invention in a matter sufficiently clear and complete for the invention to be evaluated and to be carried out by a person having ordinary skill in the art and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

#### Information concerning corresponding foreign applications/or patents or other titles of protection

9. (1) The applicant shall, at the request of the Registrar of Patents, furnish him with the date and number of any application for a patent or other title of protection by him abroad ("foreign application") relating to the same or essentially the same invention as that claimed in the application filed with the Registrar of Patents.

(2) (a) The applicant shall, at the request of the Registrar of Patents, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1) -

(i) a copy of any communication received by the applicant, concerning the results of the search or examination carried out in respect of the foreign application;

(ii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(b) The applicant shall at the request of the Registrar of Patents, furnish him with a copy of any final decision invalidating the patent or other title of protection granted on the basis of the foreign application referred to in paragraph (a).

#### Filing date, examination

10 (4) Where the Registrar of Patents is of the opinion that the application complies with the requirements indicated in subsection (3), he shall cause the application to be examined as to whether the requirements of sections 3, 4 and 6 (3), (4) and (5), 7 and 9 and the Regulations pertaining thereto are fulfilled.

#### Grant of patent

11 (1) Where the Registrar of Patents finds that, subject to section 10 (5), the conditions referred to in section 10 (3) and (4) are fulfilled, he shall grant the patent, otherwise he shall refuse the application and notify the applicant of that decision.

#### Invalidation

14. (2) The Court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements for an invention in sections 3, 4 and 6 (3), (4) and (5) and the Regulations pertaining thereto are not fulfilled or if the owner of the patent is not the inventor or his successor in title.

*SWEDEN: Articles 8 (2) and (3), 8a and 25 (2) of the Patents Act No. 837 of 01/12/1967 as last amended by Law No. 161 of 01/04/2004*

8. (2) The application shall contain a description of the invention comprising also drawings if such are needed, and distinct statements about what is sought to be protected by the patent (patent claims). The fact that the invention relates to a chemical compound does not imply that a specified use has to be indicated in the patent claim. The application shall contain a statement as to how the invention can be industrially exploited, if that does not follow from the character of the invention. However, if the invention concerns a gene sequence or a partial gene sequence, the application shall always indicate how the invention can be applied industrially. The description shall be sufficiently clear so as to enable a person skilled in the art to carry out the invention with the guidance thereof. An invention that relates to a biological material or which implies the use of such material shall, in the cases referred to in Article 8 a, be deemed to be sufficiently clearly indicated only if also the conditions under that Article are fulfilled.

(3) The application shall also contain an abstract of the description and the patent claims. The abstract is intended only to give technical information about the contents of patent application and may not be taken into account for any other purpose.

8a. If an invention concerns a biological material which is neither available to the public nor can be described in the application documents in such a way as to enable a person skilled in the art to carry out the invention with the guidance of those, or if the invention implies the use of such a material, the biological material shall be deposited no later than the date of the filing of the application. The biological material shall thereafter be continuously kept on deposit so that anyone who under this Act is entitled to receive samples of the material can obtain the sample delivered in Sweden. The Government shall prescribe where deposits may be made.

If a deposited biological material ceased to be viable or if samples from of the material can not for other reasons be supplied, the material may be replaced by a new deposit of the same biological material within the time and in the manner specified by the Government. Where this has been done, the new deposit shall be deemed as having been made already on the date when the earlier deposit was made.

25. The Patent Authority shall revoke the patent after opposition if it  
2. relates to an invention which is not so clearly disclosed that a person skilled in the art can carry it out with the guidance thereof, or

*SWITZERLAND: Articles 26 (1) (b), 49 (2) (b) and (d), 49a, 50 and 50a of the Federal Patents Law of 25/06/1954 as last amended on 01/07 2009 and Article 67 of the Regulations thereto*

#### *Article 26*

1. Sur demande, le juge constate la nullité du brevet:

b. lorsque l'invention n'est pas exposée, dans le fascicule du brevet, de façon telle qu'un homme de métier puisse l'exécuter;

#### *Article 49*

2. La demande doit contenir: b. une description de l'invention et, dans le cas d'une revendication portant sur une séquence dérivée d'une séquence génique ou d'une séquence génique partielle, une description concrète de la fonction que remplit la séquence dérivée;;  
d. les dessins auxquels se réfèrent la description ou les revendications;

#### *Article 49a*

II. Indication de la source des ressources génétiques et des saviors traditionnels

La demande de brevet doit contenir des indications concernant la source:

- a. de la ressource génétique à laquelle l'inventeur ou le requérant a eu accès, pour autant que l'invention porte directement sur cette ressource;
- b. du savoir traditionnel des communautés indigènes ou locales relatif aux ressources génétiques auxquelles l'inventeur ou le requérant a eu accès, pour autant que l'invention porte directement sur ce savoir.

Si la source n'est connue ni de l'inventeur ni du requérant, ce dernier doit le confirmer par écrit.

#### *Article 50*

B. Exposé de l'invention I. En général

1. L'invention doit être exposée, dans la demande de brevet, de façon telle qu'un homme de métier puisse l'exécuter.
2. ...

#### *Article 50a*

II. Matière biologique

1. Lorsqu'une invention porte sur la fabrication ou l'utilisation de matière biologique et qu'elle ne peut être décrite de manière suffisante, l'exposé doit être complété par le dépôt d'un échantillon de la matière biologique et, dans la description, par des indications relatives aux caractéristiques essentielles de cette matière et par un renvoi à ce dépôt.
2. Lorsque, pour une invention qui porte sur de la matière biologique en tant que produit, la fabrication ne peut pas être décrite de manière suffisante, l'exposé doit être complété ou remplacé par le dépôt d'un échantillon de la matière et, dans la description, par un renvoi à ce dépôt.
3. L'invention n'est réputée exposée au sens de l'art. 50 que lorsque l'échantillon de la matière biologique a été déposé au plus tard à la date de dépôt de la demande auprès d'une institution de dépôt reconnue et que la demande de brevet telle que déposée initialement contient des données relatives à la matière biologique et le renvoi au dépôt.
- 4 Le Conseil fédéral règle les exigences liées au dépôt, aux indications relatives à la matière biologique et au renvoi au dépôt, et l'accès aux échantillons déposés.

#### *Regulations*

#### *Article 67*

Procédure

1. L'Institut examine d'abord si la demande de brevet doit faire l'objet d'une notification en vertu de l'art. 59, al. 1, de la loi. Si tel est le cas, il rejette la demande de brevet lorsque le demandeur ne parvient pas à infirmer les objections soulevées soit en modifiant les pièces techniques, soit d'une autre manière.
2. Si la demande de brevet ne satisfait pas aux dispositions des art. 49a, 50, 50a, 51, 52, 55 et 57 de la loi, ni à celles de la présente ordonnance, l'Institut impartit un délai au demandeur pour remédier aux défauts. Si les défauts ne sont que partiellement corrigés, il peut, s'il le juge opportun, faire d'autres notifications.

THAILAND: *Sections 17 3), 24 (1), 27 and 28 (1) of the Patent Act B.E. 2522 of 11/03/1979 as amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542*

Section 17(1) The application for the patent shall comply with the rules and procedures as prescribe in the Ministerial Regulations.

The application for a patent shall contain:

(3)a detailed description of the invention in such full, concise and clear and exact terms as to enable any person ordinarily skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention and setting forth the best mode contemplated by the inventor to carry out his invention;

Section 24

Before granting a patent to the applicant, the competent officer shall:

(1) examine the application as to its conformity with Section 17; and (2) examine the application as to its conformity with Section 5, in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulations.

Section 27

In the course of examination of an application, the competent officer may instruct the applicant to appear before him in order to answer any question, or to hand over to him any document or item. If the applicant has filed an application for a patent in any foreign country, he shall submit a report of the examination of the application in accordance with the rules and procedures prescribed by the Ministerial Regulations.

If any document to be filed is in a foreign language, the applicant shall file such document accompanied by translation in Thai.

If the applicant fails to comply with the instruction of the competent officer under the preceding paragraph, or fails to submit the examination report within ninety days in accordance with the second paragraph of this Section, he shall be deemed to have abandoned his application. In case of necessity, the Director-General may extend such period as he deems appropriate.

Section 28

Where the competent officer has submitted the examination report to the Director-General, (1) if it appears to the Director-General that the provisions of Section 17 have not been complied with, or the invention is not patentable under Section 9, the Director-General shall reject the application and the competent officer shall notify the applicant of the rejection by a return registered mail or by any other method prescribed by the Director-General within fifteen days from the date of rejection by the Director-General;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA: *Articles 43 (1) 2), 4) and 5), 45, 56 (1) 4) and 57 (1) and (3) of the Industrial Property Law of 12/01/2009*

Contents of the patent application

*Article 43*

(1) The patent application must include:

- 2) description of invention;
- 4) abstract concerning the essence of the invention;
- 5) drawing (if required) to which the description refers and a patent claim;

Description of the invention

*Article 45*

The description of the invention should be clear and precise, so that an expert in a certain field is able to apply it.

Examination of the application in procedure in the Office

*Article 56*

(1) When examining the patent application, the Office shall check whether:

- 4) the separate parts of the application comply with Articles 43, 44, 45, 46, and 47 of this Law; and

## Shortcomings of the application

### Article 57

(1) The Office shall notify the applicant by a letter, if after the examination it has been established that the requirements stipulated in Article 56, paragraph (1), items 1, 2, 3, and 4 of this Law are not fulfilled, and it shall invite the applicant to eliminate the identified shortcomings within 60 days from the receipt of the notification.

(3) The Office shall make a decision to reject the patent application, if the applicant fails to eliminate the shortcomings given in the notice referred to in paragraph (1) of this Article, within the specified period of time.

TONGA: Sections 7 (4), 10, 12 (1) and 16 (2) of the Industrial Property Act No. 19 of 09/11/1994

## 7 Applications

(4) The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be evaluated, and to be carried out by a person having ordinary skill in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

## 10 Information concerning corresponding foreign applications for patents or other titles of protection.

(1) The applicant shall, at the request of the Registrar, furnish him with the date and number of any application for a patent or other titles of protection filed by him abroad (herein referred to as "foreign applications"), relating to the same or essentially the same invention as that claimed in the application filed with the Registrar.

(2) The applicant shall, at the request of the Registrar, furnish him with the following documents relating to one of the foreign applications referred to in subsection (1):

- (a) a copy of the patent or other title of protection granted on the basis of the foreign application;
- (b) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;
- (c) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application; and
- (d) a copy of any final decision invalidating the patent or other title of protection granted on the basis of the foreign application referred to in subsection (1).

## 12 Grant of patent.

(1) Where the Registrar finds that the conditions referred to in section 11(5) are fulfilled, he shall grant the patent. Otherwise, he shall reject the application and notify the applicant of his decision.

## 16 Invalidation.

(2) The court shall invalidate the patent if the person requesting the invalidation proves that any of the requirements of sections 3, 4, 5, and 7(4), 7(5), 7(6) and 7(7) are not fulfilled or if the patentee is not the inventor or his successor in title.

TRINIDAD AND TOBAGO: Sections 18 (2) (b) and (3), 21, 22, 24 (1), 26 (2) and 60 (b) of the Patents Act No. 21 of 1996

(Making of application)

18.-(2) Every application for a patent shall contain-

(b) a specification containing a description of the invention, a claim or claims and any drawings referred to in the description or any claim;

(3) The specification of an application shall disclose the invention in a manner which is clear and complete enough for the invention to be performed by a person skilled in the art, and shall, in particular, indicate at least one mode known to the applicant for carrying out the invention.

(Information on corresponding foreign applications)

21.-(1) The applicant shall, at the request of the Controller, furnish the Controller with the date and number of any other application for a patent or other title of protection made in an industrial or intellectual property office of any other country, or within a regional industrial or intellectual property office (hereafter in this section referred to as a "foreign application"), relating to the same or essentially the same invention as that claimed in the application filed with the Controller.

(2) The applicant shall upon request furnish the Controller with the following documents relating to one of the foreign applications referred to in subsection (1):

(a) a copy of any communication received by the applicant concerning the result of any search or examination carried out in respect of the foreign application;

(b) copy of the patent or other title of protection granted on the basis of the foreign application;

(c) a copy of any final decision rejecting the foreign application or refusing the patent requested in the foreign application;

(d) a copy of any final decision invalidating the patent or other title of protection granted on the basis of the foreign application referred to in subsection (2).

(3) Documents furnished pursuant to subsections (1) and (2)

(a) shall, if not in English, be accompanied by a translation thereof in English verified by the translator that the translation is to the best of his knowledge complete and faithful; and

(b) may be used only for facilitating the evaluation of the novelty and inventive step of the invention for which the patent application is made.

(4) The applicant for a patent may submit comments on any documents furnished by him under subsections (1) and (2).

(Disclosure of matter, etc., between earlier and later applications)

22. Where an application is made for a patent under section 19 and a declaration is made in accordance with section 20(2) in or in connection with that application specifying an earlier application, the first-mentioned application and any patent granted in pursuance thereof shall not be invalidated by reason only of the fact that any subject matter disclosed in the earlier application was made available to the public at any time after the date of filing of the said earlier application.

Search and substantive examination

24.-(1) Where the Controller is of the opinion that the application complies with the requirements of section 23 he shall, upon payment by the applicant of the prescribed fee, cause the application to be examined as to whether there has been compliance with the requirements of sections 8 to 12 and 18(3) and (4) and the rules relating thereto.

26.- (2) No amendment of an application shall be allowed under section 23(3) or 25(I) or this section if such amendment extends the matter disclosed in the application as filed.

Grounds for revocation

60. An application for revocation of a patent may be made only on any of the following grounds, that is to say:

(b) the specification of the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;

TUNISIA: *Articles 21, 24 (3), 29 (1) and (2) and 55 of the Patents Law No.2000-84 of 24/08/2000*

21. The application shall comprise:

- a description of the invention in duplicate;

The description of the invention shall be sufficiently clear and complete for a person skilled in the corresponding field of technology to carry it out.

24. (3) The applicant is obliged, at the request of the entity responsible for industrial property, to provide it with any other document concerning the earlier application and, where applicable, concerning any other application filed in another country. Those documents shall include the following in particular:

- a copy of any document received by the applicant and pertaining to the findings of any search or examination carried out in relation to the application in which the publications or other documents establishing the state of the art are mentioned;
- a copy of any application other than the earlier application that relates to the same invention, or essentially to the same invention, and the priority of which is claimed;
- a copy of any final judgment rejecting the application.

29. (1) The entity responsible for industrial property shall examine whether the application is consistent in terms of form with the provisions of Articles 20, 21 and 22 of this Law.

(2) The entity responsible for industrial property shall reject the patent application if it finds that the provisions referred to in the first paragraph of this Article have not been respected after the applicant has been invited to remedy the shortcomings within a period of three months from the date of the notice served on him to that end.

55. The patent shall be declared null and void by judicial decision:

- where the invention cannot be described clearly and completely enough for a person skilled in the art to be able to carry it out;

*TURKEY: Articles 42 (1) (b), 46, and 129 (b) of the Decree-Law No. 551 on the Protection of Patent Rights of 27/06/1995 as last amended by Law No. 4128 of 7/11/1995*

42. (1) In order to obtain a patent, it is necessary to file an application, the form and content of which shall be determined by the Regulations and which shall comprise the following:

- (b) a description of the subject matter of the invention;

Explicitness of the Description

46. The description shall be written in sufficiently explicit and comprehensive terms for a person skilled in the technical field concerned to carry out the invention.

Where the invention relates to a microbiological process and the related microorganism is not accessible to interested parties, the description shall be deemed to meet the requirements specified in the first paragraph of this Article if the following conditions are fulfilled:

- (a) the description contains information regarding the characteristics of the microorganism;
- (b) the applicant has deposited, no later than on the filing date of the application, a culture of the microorganism with an authorized institution established in accordance with international conventions.

The said institution shall be mentioned in the publication provided for in the second paragraph of Article 55.

Invalidity

129. A patent shall be declared invalid by the court in the following situations:

- (b) where it is established that the subject matter of the invention has not been described in a sufficiently explicit and comprehensive manner for a person skilled in the technical field concerned to carry it out;

UGANDA: *Sections 13(2) (a), 17 and 36 (1) (c) of the Patents Act of 15/10/1993*

13. Application

(2) The application shall be accompanied by the following  
(a) a description disclosing the invention in a manner sufficiently clear and complete for the invention to be evaluated and to be carried out by a person skilled in the art and shall, in particular, indicate the best mode known to the applicant for carrying out the invention;

17. Information on corresponding foreign applications and grants

(1) The registrar may, within one year after the date of filing the application, request the applicant to furnish him or her with details of any foreign application for a patent or another title of protection filed by the applicant with a national industrial property office of another country, or with a regional industrial property office, relating to the same invention as that claimed in the application filed with the registrar.

(2) The applicant shall, at the request of the registrar, furnish him or her with the following particulars concerning any of the foreign applications referred to in subsection (1)

(a) copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;  
(b) a copy, if any, of the patent or other title of protection granted on the foreign application;  
(c) a copy, if any, of the final decision rejecting the foreign application or refusing the grant requested; and

(d) a copy, if any, of a decision invalidating the patent or other title of protection granted to the applicant on the basis of the foreign application.

(3) The particulars furnished under this section shall merely serve the purpose of facilitating the evaluation of novelty and inventive step with respect to the invention claimed in the application filed with the registrar or in the patent granted on the basis of that application.

36. Invalidation and revocation.

(1) The court may, at the request of a party to proceedings under this Act, invalidate and revoke a patent on any of the following grounds:

(c) that the description and claims accompanying the application for grant of a patent did not comply with the requirements of section 13(2); or

UKRAINE: *Section 12 (5) and (7) of the Law on the Protection of Rights to Inventions and Utility Models No. 3687-XII of 15/12/1993 as last amended in 2003*

Application

12.-(5) The application shall be presented in Ukrainian and shall contain:

a description of the invention (utility model);

(7) The description of an invention (utility model) shall be represented in the defined order and shall disclose the subject-matter of an invention (utility model) in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art.

UNITED KINGDOM: *Sections 14 (2) (b) and (3), 72 (1) (c) and 125A of the Patents Act of 1977, consolidated version of 01/01/2010*

Making of application

14.-(2) Every application for a patent shall contain

(b) a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim; and

(3) The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

Revocation of patents

#### Power to revoke patents on application

72.-(1) Subject to the following provisions of this Act, the court or the comptroller may by order revoke a patent for an invention on the application of any person (including the proprietor of the patent) on (but only on) any of the following grounds, that is to say -

(c) the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art;

#### Disclosure of invention by specification: availability of samples of biological material

125A.-(1) Provision may be made by rules prescribing the circumstances in which the specification of an application for a patent, or of a patent, for an invention which involves the use of or concerns biological material is to be treated as disclosing the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

(2) The rules may in particular require the applicant or patentee:

(a) to take such steps as may be prescribed for the purposes of making available to the public samples of the biological material, and

(b) not to impose or maintain restrictions on the uses to which such samples may be put, except as may be prescribed.

(3) The rules may provide that, in such cases as may be prescribed, samples need only be made available to such persons or descriptions of persons as may be prescribed; and the rules may identify a description of persons by reference to whether the comptroller has given his certificate as to any matter.

(4) An application for revocation of the patent under section 72(1)(c) above may be made if any of the requirements of the rules cease to be complied with.

#### UNITED REPUBLIC OF TANZANIA: *Sections 18 (1) (a) (ii) and (3), 22, 27 and 63 (2) (c) of the Patents Act No. 1 of 20/01/1987*

18.-(1) (a) Every application for the grant of a patent shall be made to the Registrar and shall contain.

(ii) a description:

(3) The description shall disclose the invention in a manner which is sufficiently clear and complete for the invention to be evaluated and to be carried out, by a person skilled in the art, and shall, in particular, indicate the best mode known to the person making the application for carrying out the invention, and shall include any drawing which is essential for the understanding of the invention.

#### Furnishing of information on corresponding foreign applications and grants

22.-(1) At the request of the Registrar, made within one year of the date of filing of the application, the person who is making an application shall furnish him with the date and number of any application for a patent or another title of protection filed by him with a national industrial property office of another country or with a regional industrial property office relating to the same invention as that claimed in the application filed with the Registrar.

(2) (a) The person making an application for registration of a patent shall, at the request of the Registrar, furnish the following documents relating to one of the foreign applications referred to in subsection (1):

(i) copies of any communication received by that person concerning the results of any search or examination carried out in respect of the foreign application;

(ii) a copy of the patent or other title of protection granted on the foreign application;

(iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(b) The person making an application for registration of a patent shall, at the request of the Registrar furnish him with a copy of any decision invalidating the patent or other title of protection granted to him on the basis of the foreign application referred to in paragraph (a).

(3) The person making the application shall, at the request of the Registrar, furnish him With copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of any foreign application other than the one referred to in subsection (2).

(4) The documents furnished under this section shall merely serve the purpose of facilitating the evaluation of novelty and inventive step with respect to the invention claimed in the application filed with the Registrar or in the patent granted on the basis of that application.

#### 27. Examination as to substance

(1) The Minister may by regulations direct that applications for patents relating to a specified technical field shall be the subject of an examination as to substance.

(2) If, in the opinion of the Registrar the subject matter of an invention for which a patent is sought falls within a technical field covered by the terms of a direction made under subsection (1), he shall cause an examination to be carried out as to whether the following conditions are fulfilled:

(i) the claimed invention is patentable within the meaning of sections 8 to 11;

(ii) the claimed invention is not excluded from protection under sections 12 to 13;

(iii) the description and the claims comply with the requirements prescribed by section 18 and the rules pertaining thereto;

(3(a) For the purposes of the examination under subsection (2), the Registrar may transmit the application together with all relevant documents to the authority designated in the Regulations for a preliminary examination as to the patentability of the claimed invention.

(b) The authority referred to in paragraph (a) shall establish a report on the conclusions of its examinations and shall transmit it to the Registrar and to the applicant.

(4) Where, taking due account of the conclusions of any report referred to in subsection (3)(b), the Registrar is of the opinion that any of the conditions referred to in subsection (2) are not fulfilled, he shall notify the applicant accordingly and invite him to submit his observations and where applicable, to amend his application.

(5) Where, despite any observation or amendment submitted by the person making the application, the Registrar finds that any of the conditions referred to in subsection (2) are not fulfilled, he shall refuse the grant of a patent and notify the applicant accordingly.

#### 63. Invalidation of patents

2) The court shall invalidate the patent on any of the following grounds

(c) that the description and the claims comply with the requirements prescribed by section 18(3) and (4) the rules pertaining thereto,

UNITED STATES OF AMERICA: *Sections 131-134 of the 35 U.S.C. as last amended on Sept. 2007 and § 1.105 and 1.1801 of the United States Code of Federal Regulations, as amended Dec. 2009, Title 37 Patents, Trademarks, and Copyrights*

#### 35 U.S.C. 131 Examination of application

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

#### 35 U.S.C. 132 Notice of rejection; reexamination

(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.

#### 35 U.S.C. 133 Time for prosecuting application

Upon failure of the applicant to prosecute the application within six months after any action therein, of which notice has been given or mailed to the applicant, or within such shorter time, not less than thirty days, as fixed by the Director in such action, the application shall be regarded as abandoned by the parties thereto, unless it be shown to the satisfaction of the Director that such delay was unavoidable.

#### 35 U.S.C. 134 Appeal to the Board of Patent Appeals and Interferences

(a) PATENT APPLICANT. - An applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Board of Patent Appeals and Interferences, having once paid the fee for such appeal.

(b) PATENT OWNER. - A patent owner in any reexamination proceeding may appeal from the final rejection of any claim by the primary examiner to the Board of Patent Appeals and Interferences, having once paid the fee for such appeal.

(c) THIRD-PARTY. - A third-party requester in an inter partes proceeding may appeal to the Board of Patent Appeals and Interferences from the final decision of the primary examiner favorable to the patentability of any original or proposed amended or new claim of a patent, having once paid the fee for such appeal.

### *Regulations*

#### § 1.105 Requirements for information

(a)(1) In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter, for example:

(i) Commercial databases: The existence of any particularly relevant commercial database known to any of the inventors that could be searched for a particular aspect of the invention.

(ii) Search: Whether a search of the prior art was made, and if so, what was searched.

(iii) Related information: A copy of any non-patent literature, published application, or patent (U.S. or foreign), by any of the inventors, that relates to the claimed invention.

(iv) Information used to draft application: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used to draft the application.

(v) Information used in invention process: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used in the invention process, such as by designing around or providing a solution to accomplish an invention result.

(vi) Improvements: Where the claimed invention is an improvement, identification of what is being improved.

(vii) In Use: Identification of any use of the claimed invention known to any of the inventors at the time the application was filed notwithstanding the date of the use.

(viii) Technical information known to applicant. Technical information known to applicant concerning the related art, the disclosure, the claimed subject matter, other factual information pertinent to examiner's stated interpretation of such items.

(2) Where an assignee has asserted its right to prosecute pursuant to § 3.71(a) of this chapter, matters such as paragraphs (a)(1)(i), (iii), and (vii) of this section may also be applied to such assignee.

(3) Requirements for factual information known to applicant may be presented in any appropriate manner, for example:

(i) A requirement for factual information;

(ii) Interrogatories in the form of specific questions seeking applicant's factual knowledge; or

(iii) Stipulations as to facts with which the applicant may agree or disagree.

(4) Any reply to a requirement for information pursuant to this section that states either that the information required to be submitted is unknown to or is not readily available to the party or parties from which it was requested may be accepted as a complete reply.

(b) The requirement for information of paragraph (a)(1) of this section may be included in an Office action, or sent separately.

(c) A reply, or a failure to reply, to a requirement for information under this section will be governed by §§ 1.135 and 1.136.

#### § 1.801 Biological material

For the purposes of these regulations pertaining to the deposit of biological material for purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.

URUGUAY: *Articles 22 (d), 25, 32 (a) and 44 (b) of the Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs No. 1.827\*R of 02/09/1999*

22. Patent applications shall contain the following:

(d) a clear and full description of the invention;

25. For applications relating to microorganisms, the biological material needed to describe their subject matter shall be deposited with the bodies approved by the National Industrial Property Directorate of the Ministry of Industry, Energy and Mining, until the relevant international agreements have been ratified.

32. The purpose of the substantive examination of applications shall be to determine whether the proposed invention meets the requirements and criteria for patentability laid down in this Law.

For this purpose, it shall be permissible:

(a) to request the applicant to furnish copies of the anticipation search, the substantive examinations and other documentation available to him;

44. Patents shall be invalid in the following cases:

(b) if the description was incomplete or inaccurate and did not allow the subject matter of the invention to be defined;

VIET NAM: *Article 102 (1) and (2) (a) of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005 as last amended by Order No. 12/2009/L-CTN of 29/06/2009 and Rule 15.2.(a) and (b) (i) of the Regulations thereto*

#### *Article 102*

Requirements on invention registration applications

1. Documents identifying an invention registered for protection in an invention registration application shall include a description of the invention and an abstract of the invention. The invention description consists of the description section and the scope of protection of the invention.

2. The description of invention must satisfy the following conditions:

a/ Fully and clearly disclosing the nature of the invention to the extent that such invention may be realized by a person with average knowledge in the art;

#### *Regulations*

15.2. Use of information search results

a/ In the course of substantive examination of invention/industrial design registration applications with claims for priority, the NOIP may use the results of information search and examination of those applications filed overseas.

b/ Applicants may supply (on their own initiative or upon the NOIP's request) the following documents for use in service of substantive examination of their applications:

(i) For an invention/industrial design registration application: Results of information search or examination of the application filed overseas for the object stated in the application; copies of the protection title granted on the basis of a similar application filed overseas; documents on technical conditions of the object stated in the invention registration application supplied by a competent foreign authority to the applicant and other documents;

ZAMBIA: Sections 14 (1), (2) and (3), 22 (1) (f) and (h) and 50 (1) of the Patent Act of 1958(Chapter 400) as last amended by Act No. 26 of 28/12/1987

#### Contents of specification

14. (1) Every specification shall indicate whether it is a provisional or a complete specification and shall commence with a title sufficiently indicating the subject to which the relevant invention relates.
- (2) A provisional specification shall fairly describe the invention.
- (3) A complete specification shall-
- (a) fully describe the invention and the manner in which it is to be performed;
  - (b) disclose the best method of performing the invention known to the applicant at the time when the specification is lodged at the Patent Office; and
  - (c) end with a claim or claims defining the subject-matter for which protection is claimed.

#### Opposition to grant a patent

22. (1) Any person interested. including the State, may. within three months from the date of the advertisement of the acceptance of a complete specification or within such further period as the Registrar. on application made to him within the said period of three months. may allow. or. with the consent of the applicant. at any time before the sealing of the patent. oppose the grant of a patent in accordance with the provisions of this section by giving written notice to the Registrar of opposition to such grant on any of the following grounds and no others. namely:

- f) that the complete specification does not fully describe and ascertain the invention and the manner in which it is to be performed;
- (h) that the complete specification does not disclose the best method of performing the invention known to the applicant at the time when the specification was lodged at the Patent Office;

#### Revocation of patents

50. (1) Application for revocation of a patent may be made to the High Court by any person interested. including the State, upon anyone or more of the grounds on which the grant of a patent might have been opposed, but subject to the provisions of subsection (2), of proviso (ii) to paragraph (b) of subsection (7) of section eight, and of paragraph (b) of subsection (1) of section ten, on no other grounds.

ZIMBABWE: Sections 9 (2) and (3) (a) and (b), 17 (1) (f) and (h) and 45 (1) of the Patents Act (Chapter 26:03) No. 26 of 1971 as last amended by Act 20/1994 (S.7)

#### Contents of specification

9.-(2) A provisional specification shall fairly describe the invention.

(3) A complete specification shall:

- (a) fully describe the invention and the manner in which it is to be performed; and
- (b) disclose the best method of performing the invention known to the applicant at the time when the specification is lodged at the Patent Office; and

#### Opposition to grant of patent

17.-(1) Any person interested, including the State, may within three months from the date of the advertisement of the acceptance of a complete specification which has not been cancelled in terms of subsection (5) of section sixteen or within such further period as the Registrar, on application made to him within the said period of three months, may allow, or, with the consent of the applicant, at any time before the sealing of the patent, oppose the grant of a patent in accordance with this section by giving written notice to the registrar of the Patents Tribunal of opposition to such grant on any of the following grounds and no others:

- (f) that the complete specification does not fully describe and ascertain the invention and the manner in which it is to be performed;

(h) that the complete specification does not disclose the best method of performing the invention known to the applicant at the time when the specification was lodged at the Patent Office;

#### Revocation of patents

45.-(1) An application for the revocation of a patent may be made to the Court or to the Patents Tribunal by any person interested, including the State, upon any one or more of the grounds on which the grant of a patent might have been opposed, but, subject to the provisions of subsection (2), of proviso (ii) to paragraph (b) of subsection (7) of section eighty and of paragraph (b) of subsection (1) of section eighty-three, on no other grounds.

*ANDEAN COMMUNITY: Articles 26 (b), (h) and (j), 28, 29, 46 and 75 (d) of the Decision No. 486 of 14/09/2000 of the Commission of the Andean Community - Common Industrial Property Regime*

26. The application for a patent shall be filed with the competent national office and shall contain the following:

(b) the description;

(h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin;

(j) where applicable, the certificate of deposit of biological material;

28. The description shall disclose the invention in a manner sufficiently clear and complete to be understood and for a person skilled in the corresponding technical field to be able to carry it out. The description of the invention shall state the name of the invention and include the following information:

(a) the technological sector to which the invention relates or applies;

(b) the previous technology known to the applicant that may be useful for understanding and examining the invention, and references to earlier documents and publications relating to the said technology;

(c) description of the invention in terms that allow the technical problem and the solution provided by the invention to be understood, with an explanation of the differences and possible advantages in relation to the earlier technology;

(d) an account of the drawings, if any have been filed;

(e) a description of the best method known to the applicant of carrying out the invention or putting it into practice, with the use of examples and references to the drawings where the latter are relevant; and

(f) a mention of the way in which the invention meets the condition of industrial applicability, if this is not clear from the description or the nature of the invention.

29. Where the invention relates to a product or process involving biological material, and the invention cannot be described in such a way as to be understood and carried out by a person skilled in the technical field, the description shall be completed with a deposit of the said material.

The deposit shall be made not later than on the filing date of the application in the member country or, where applicable, on the filing date of the application the priority of which is claimed. Deposits effected with an international depositary authority recognized under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure of 1977, or with another institution recognized by the national office competent in that connection, shall be considered valid. In such a case the description shall state the name and address of the depositary institution, the date of deposit and the deposit number assigned to it by the institution.

The deposit of biological material shall be valid for the purposes of the grant of a patent only if it is made in such a way that any interested party may obtain samples of the material not later than on the expiry of the period provided for in Article 40.

46. The competent national office may solicit reports from experts or from scientific technological bodies considered suitable, so as to have their opinion on the patentability of the invention. It may likewise, if it sees fit, solicit reports from other industrial property offices.

Where necessary for the purposes of the patentability examination the applicant shall, at the request of the competent national office, submit, within a period not exceeding three months, one or more of the following documents relating to one or more filed foreign applications relating wholly or partly to the same invention as that being examined:

- (a) a copy of the foreign application;
- (b) a copy of the findings of novelty or patentability examinations carried out in relation to that foreign application;
- (c) a copy of the patent or other protection title that has been granted on the basis of that foreign application;
- (d) a copy of any judgment or decision by which the foreign application has been rejected or denied;
- (e) a copy of any judgment or decision by which the patent or other protection title granted on the foreign application has been cancelled or invalidated.

The competent national office may recognize the results of examinations referred to under subparagraph (b) above as being sufficient to prove compliance with the conditions governing patentability of the invention.

Where the applicant fails to submit the documents requested within the period specified in this Article, the competent national office shall refuse the patent.

75. The competent national authority shall decree the absolute invalidity of a patent at any time, either ex officio or at the request of any person, where:

- (d) the patent does not disclose the invention as provided in Article 28 and where applicable in Article 29.

*ARIPO: Section 3 (1) (ii) and (1A) of the Harare Protocol of 10/12/1982 as last amended on 26/11/1999*

### Section 3

#### Patents

(1) A patent application shall:

(ii) contain, as prescribed, a description of the invention, a claim or claims, a drawing or drawings, where necessary, and an abstract;

(1A) Where the patent application describes or claims as an invention a microbiological process or a product thereof, and requires for the performance of the invention the use of a micro-organism which is not available to the public on the filing date of the application and which cannot be made or obtained on the basis of the description in the application, the microorganism shall before the acceptance of the application be dealt with in the manner prescribed in the Regulations.

*EUROPEAN UNION: Article 13 of the Directive 98/44/EC of 06/07/1998*

#### *Article 13*

1. Where an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in a patent application in such a manner as to enable the invention to be reproduced by a person skilled in the art, the description shall be considered inadequate for the purposes of patent law unless:

- (a) the biological material has been deposited no later than the date on which the patent application was filed with a recognised depositary institution. At least the international depositary authorities which acquired this status by virtue of Article 7 of the Budapest Treaty of 28 April 1977 on the international

recognition of the deposit of micro-organisms for the purposes of patent procedure, hereinafter referred to as the 'Budapest Treaty', shall be recognised;

(b) the application as filed contains such relevant information as is available to the applicant on the characteristics of the biological material deposited;

(c) the patent application states the name of the depository institution and the accession number.

2. Access to the deposited biological material shall be provided through the supply of a sample:

(a) up to the first publication of the patent application, only to those persons who are authorised under national patent law;

(b) between the first publication of the application and the granting of the patent, to anyone requesting it or, if the applicant so requests, only to an independent expert;

(c) after the patent has been granted, and notwithstanding revocation or cancellation of the patent, to anyone requesting it.

3. The sample shall be supplied only if the person requesting it undertakes, for the term during which the patent is in force:

(a) not to make it or any material derived from it available to third parties; and

(b) not to use it or any material derived from it except for experimental purposes, unless the applicant for or proprietor of the patent, as applicable, expressly waives such an undertaking.

4. At the applicant's request, where an application is refused or withdrawn, access to the deposited material shall be limited to an independent expert for 20 years from the date on which the patent application was filed.

In that case, paragraph 3 shall apply.

5. The applicant's requests referred to in point (b) of paragraph 2 and in paragraph 4 may only be made up to the date on which the technical preparations for publishing the patent application are deemed to have been completed.

*OAPI: Articles 14 (1) (d) (i) and (2), 24 (4) and (5) and 39 (1) (c), Annex I, of the Bangui Agreement of 02/03/1977, as revised on 24/02/1999*

#### *Article 14*

##### Filing of the Application

(1) Any person wishing to obtain a patent for an invention shall file with the Organization or with the Ministry responsible for industrial property, or send to it by registered mail with a request for acknowledgement of receipt,

(d) a sealed package containing in duplicate

(i) a specification of the invention for which the application has been made, set out clearly and completely so that a person having ordinary knowledge and skill in the art could carry it out,

(2) Where the invention involves a microorganism or the use of a microorganism, a receipt attesting the deposit of the microorganism, issued by a depository institution or an international depository authority specified in the Implementing Regulations, shall in addition be filed.

#### *Article 24*

##### Conditions Governing Rejection

(4) Any application for which the other requirements of Article 14, except for its subparagraph (b), and those of Article 15 have not been fulfilled is defective. The defect shall

be notified to the applicant or his agent, who shall be invited to correct the documents within a period of three months from the date of the notification. That period may be extended by 30 days, in cases of justifiable need, at the request of the applicant or his agent. The application so corrected within the said period shall retain the date of the initial application.

(5) In the event of the corrected documents not being provided within the prescribed period, the patent application shall be rejected.

#### *Article 39*

##### Invalidity

(1) Patents granted in the following cases shall be declared invalid:

(c) if the specification attached to the patent does not conform to the provisions of Article 14(d)(i) above, or if it does not state in a complete and honest manner the true methods of the inventor.

#### (4) PROVISIONS OF LAW ON SUBSTANTIVE EXAMINATION

*ALBANIA: Article 28 of the Industrial Property Law Nr. 9977 of 07/07/2008*

##### *Article 28*

Examination of the Application and Grant of the Patent

1. After verifying that the application filed is in conformity with articles 17, 18, 19, 20, 21, 22 and 24 of this Law, the GDPT shall grant the respective patent, subject to the payment of the relevant fee.

2. If the application does not meet, or partially meets, the requirements of paragraph 1 of this article, the GDPT shall notify the applicant, who, within a three months period, shall correct the deficiencies. If the deficiencies are not corrected in due time, the application shall be rejected and the GDPT shall notify the applicant of this decision.

3. A decision taken in conformity with paragraph 2 of this article may be appealed to the appeal board of the GDPT within a three months period from the date of receipt of notification, subject to the payment of a fee. The decision of the appeal board may be appealed to the court within a period of 30 days from the date of receipt of notification.

4. The GDPT shall not make a substantive examination of the invention, in conformity with articles 5, 6, 7, 9 and 10 of this Law. Therefore, the patent granted by GDPT shall have legal effect only if within 10 years from the filing date, the patent's owner files an examination report issued by an institution authorized in substantial examination of inventions, otherwise the patent shall be considered invalid.

5. Immediately after a decision to grant the patent, the GDPT shall publish it as provided in article 26 (4) of this Law.

*ALGERIA: Articles 27-31 of the Ordinance No. 03-07 of 19/07/2003*

##### Section 2

##### Examen

##### *Article 27*

- Après le dépôt, le service compétent vérifie si la demande répond aux conditions relatives aux formalités de dépôt fixées par la section 1 du titre III ci-dessus et des textes pris pour son application.

Lorsque la demande ne répond pas à ces conditions, le demandeur ou son mandataire est invité à régulariser le dossier dans un délai de deux (2) mois.

Ce délai peut être augmenté en cas de nécessité justifiée, sur requête du demandeur ou de son mandataire.

La demande régularisée dans ledit délai conserve la date de la demande initiale.

Dans le cas où le dossier n'est pas régularisé dans le délai imparti, la demande est réputée retirée.

##### *Article 28*

- Le service compétent vérifie également si l'objet de la demande n'entre pas dans les domaines visés à l'article 7 et s'il n'est pas de toute évidence exclu de la protection en vertu des articles 3 à 6 et 8.

Le cas échéant, il informe le demandeur que sa demande ne peut donner lieu à un brevet.

*Article 29*

- Toute demande qui, de toute évidence ne répond pas à la prescription de l'article 22 (alinéa 1) ci-dessus, peut, dans les délais fixés par voie réglementaire, être limitée ou divisée en un certain nombre de demandes bénéficiant de la date de dépôt de la demande initiale.

L'objet de chaque demande divisionnaire ne doit pas aller au-delà du contenu de la demande initiale.

*Article 30*

- Avant la délivrance d'un brevet d'invention, le service compétent peut exiger du demandeur, toute information relative à tout titre de protection qu'il aurait demandé ou obtenu dans d'autres pays et portant sur la même invention que celle qui a fait l'objet d'une demande déposée auprès du service compétent.

Section 3:  
Délivrance

*Article 31*

- Les brevets d'invention dont les demandes ont été régulièrement formées sont délivrés sans examen préalable aux risques et périls des demandeurs et sans garantie, soit de la réalité, de la nouveauté ou du mérite de l'invention, soit de la fidélité ou de l'exactitude de la description.

Une attestation établie par le service compétent, constatant la régularité de la demande, est délivrée au demandeur et constitue le brevet d'invention.

A l'attestation visée à l'alinéa ci-dessus, est joint un exemplaire de la description, des revendications et des dessins après que la conformité avec l'expédition originale en a été reconnue et établie au besoin.

ANDORRA: *Article 20 of the Patent Law of 10/06/1999*

*Article 20*

Examination of application and grant of patent

- (1) If an application has been accorded a filing date, the Patent Office shall examine whether the application complies with the requirements of Articles 9 and 10.
- (2) The Patent Office is under no obligation to examine whether the application and the invention to which it relates comply with the requirements under Articles 2 to 5, 12, 13, 15 and 18 (2).
- (3) Where the Patent Office finds that the application does not comply with the requirements referred to in paragraph (1), it shall indicate the deficiencies to the applicant and give him an opportunity to correct them in accordance with the Implementing Regulations. The application shall be rejected if the applicant fails to correct the deficiencies indicated by the Patent Office.
- (4) Where the application complies with the requirements referred to in paragraph (1), the Patent Office shall, on payment of the fees prescribed in the Patent Office Tax Law, grant a patent on the application. The Patent Office shall record the grant of the patent in the Patent Register and publish the patent specification as prescribed in the Implementing Regulations.
- (5) Where the applicant has filed a request for early publication of the application pursuant to Article 19(1)(b), he may request that the patent be granted immediately upon publication of the application.

ANTIGUA AND BARBUDA: *Section 9 of the Patents Act No. 23 of 29/12/2003*

9. (1) The Registrar shall accord as the filing date the date of receipt of the application, provided that, at the time of receipt, the application contains:

- (a) an express or implicit indication that the granting of a patent is sought;
- (b) indications allowing the identity of the applicant to be established;
- (c) a part which, on the face of it, appears to be a description of an invention.

(2) If the Registrar finds that the application did not, at the time of receipt, fulfill the requirements referred to in subsection (1), he shall invite the applicant to file the required correction and shall accord as the filing date the date of receipt of the required correction, but if no correction is made, the application shall be treated as if it had not been filed.

(3) Where the application refers to drawings which in fact are not included in the application, the Registrar shall invite the applicant to furnish the missing drawings. If the applicant complies with the said invitation, the Registrar shall accord as the filing date the date of receipt of the missing drawings. Otherwise, the Registrar shall accord as the filing date the date of receipt of the application and shall treat any reference to the said drawings as non-existent.

(4) After according a filing date, the Registrar shall examine whether the application complies with the requirements of section 5(1), (2), (3) and (4) and the Regulations pertaining thereto and those requirements of this Act and the Regulations which are designated by the Regulations as formal requirements for the purposes of this Act and whether information requested under section 8, if any, has been provided.

(5) Where the Registrar is of the opinion that the application complies with the requirements indicated in subsection (4), the Registrar shall take a decision as to whether the requirements of sections 2(I)(ii) and (2), 3, 5(5), (6), (7) and (8) and 6 and the Regulations pertaining thereto are fulfilled and for this purpose may, as provided for in the Regulations, cause the application to be examined.

(6) The Registrar shall take into account, for the purposes of subsection (5),  
(i) the results of any international search report and any international preliminary examination report established under the PCT in relation to the application; and/or  
(ii) a search and examination report submitted under section 8(2)(a) relating to, or a final decision submitted under Section 8(2)(c) on the refusal to grant a patent on, a corresponding foreign application; and/or  
(iii) a search and examination report which was carried out upon his request by an external search and examination authority.

*ARGENTINA: Articles 24 and 27 of the Law No. 24.481 of 23/05/1995 on Patents and Utility Models (as last amended by Law No. 24.572)*

24. The National Patent Administration shall conduct a preliminary examination of the documentation, and may ask to have points specified or clarified where it considers this necessary, or omissions to be made good. Where the applicant fails to comply with such a request within a period of 180 days, the application shall be considered abandoned.

27. On payment of the fee laid down in the implementing decree, the National Patent Administration shall undertake a substantive examination to determine compliance with the conditions set forth in Title II, Chapter I of this Law.

The National Patent Administration may request a copy of any substantive examination conducted by foreign examining offices according to the procedure laid down in the implementing decree, and may likewise seek expert opinions from researchers working in universities or science and technology institutes in the country, who in each case shall be rewarded as provided in the implementing decree.

If it is considered necessary, the patent applicant may request the Administration to conduct the examination on his premises.

Where three years have elapsed following the filing of the patent application and the applicant has not paid the fee for the substantive examination, the application shall be considered abandoned.

*ARMENIA: Articles 51 and 54 of the Industrial Property Law of 10/06/2008*

*Article 51*

Examination of an application (1) Where an application meets the requirements of Article 46 of this Law, the State Authorized Body shall examine the conformity of the content and form of the application, additional documents or evidence with the requirements under this Law and Rule. (2) The State Authorized Body shall also examine the conformity of invention with the requirements of Article 53 (2) and (4), and the conformity of paid state fees with the rates established by Law, including annual state fees under Articles 67(6) or 68(4) of this Law. (3) If during examination missing parts or missing documents are noted in the application, additional documents or evidence, the State Authorized Body shall invite the applicant to submit the corrected or missing parts or documents within three months from the receipt of the invitation. (4) If the applicant does not remedy all deficiencies in the established period, the application shall be deemed to be withdrawn, except in the cases referred to in Articles 73 and 74. (5) If the State Authorized Body establishes that all the documents to the application or supplements or evidence with their content and form meet the requirements under this Law and Rule then the proceedings shall continue in the order established by this Law.

*Article 54*

Examination of Requirements for the Grant of a Patent (1) In the process of examination for the grant of a patent, the State Authorized Body shall examine: (a) whether the subject of the claimed invention meets the requirements of patentability under Article 10 of this Law; (b) whether the claimed invention meets (obviously), at first sight, the requirements of patentability under Articles 11, 13 and 14, the state of the art being defined only based on the materials in the examiner's disposal. (2) In the process of examination for the grant of a patent on utility model, the State Authorized Body shall examine: (a) whether the subject of the claimed utility model meets the requirements of patentability under Article 10(1) and (2); (b) whether the claimed utility model meets the requirements of patentability under Articles 14, 15. (3) If the State Authorized Body establishes that the claims of the invention application meet all the requirements of paragraph (1) of this Article, or that the claims of the utility model application meet the requirements of paragraph (2) of this Article, it shall make a decision on publication of the application in the Official Bulletin and of granting the patent. (4) If the State Authorized Body establishes that the claims of the invention do not meet the requirements of paragraph (1) of this Article, or that the claims of the utility model do not meet the requirements of paragraph (2) of this Article, it shall make a decision on refusal of the application. (5) If the State Authorized Body establishes that the claims of the invention or the claims of the utility model do not meet the requirements of paragraphs (1) and (2) of this Article respectively, only in part, it shall make a decision on refusal of the application only with respect to that part.

*AUSTRALIA: Sections 44, 45, 47 and 48 of the Patents Act No. 83 of 1990 as last amended by Act No. 106 of 2006*

44 Request for examination

(1) Where a complete application for a standard patent has been made, the applicant may, within the prescribed period and in accordance with the regulations, ask for an examination of the patent request and specification relating to the application.

(2) Where a complete application has been made for a standard patent, the Commissioner may, on one or more of the prescribed grounds and in accordance with the regulations, direct the applicant to ask, within the prescribed period, for an examination of the patent request and complete specification relating to the application.

(3) Where the patent request and specification relating to a complete application for a standard patent are open to public inspection, a person may, in accordance with the regulations, require the Commissioner to direct the applicant to ask, within the prescribed period, for an examination of the request and specification.

(4) Where required under subsection (3), the Commissioner must give a direction accordingly, unless the applicant has already asked, or been directed to ask, for an examination of the patent request and specification.

45 Examination

(1) Where an applicant asks for an examination of a patent request and complete specification relating to an application for a standard patent, the Commissioner must examine the request and specification and report on:

- (a) whether the specification complies with section 40; and
- (b) whether, to the best of his or her knowledge, the invention, so far as claimed, satisfies the criterion mentioned in paragraph 18(1)(a); and
- (c) whether, to the best of his or her knowledge, the invention, so far as claimed in any claim and when compared with the prior art base as it existed before the priority date of that claim:
  - (i) is novel; and
  - (ii) involves an inventive step; and
- (d) such other matters (if any) as are prescribed.

(1A) For the purposes of paragraph (1)(c), the prior art base is to be taken not to include information made publicly available only through the doing of an act (whether in or out of the patent area).

(2) The examination must be carried out in accordance with the regulations.

(3) The applicant must inform the Commissioner, in accordance with the regulations, of the results of the following searches carried out for the purpose of assessing the patentability of an invention disclosed in the complete specification or a corresponding application filed outside Australia:

(a) any documentary searches by, or on behalf of, a foreign patent office, other than searches prescribed by the regulations;

(b) the documentary searches prescribed by the regulations.

(4) Subsection (3) only applies to searches completed before the grant of the patent.

(5) In subsection (4):

completed, in relation to a search, has the meaning prescribed by the regulations.

## Division 2 - Modified examination

### 47 Request for modified examination

(1) Where:

(a) a complete application for a standard patent has been made; and

(b) a patent has been granted in a prescribed foreign country in respect of a prescribed application made in that country;

the applicant may, instead of asking for an examination, ask for a modified examination of the patent request and specification relating to the application.

(2) The applicant may withdraw a request for a modified examination at any time before acceptance of the patent request and specification and ask for an examination under section 44 instead.

### 48 Modified examination

(1) When an applicant asks for a modified examination of a patent request and complete specification relating to an application for a standard patent, the Commissioner must examine the request and specification and report on:

(a) whether, to the best of his or her knowledge, the invention, so far as claimed, satisfies the criterion mentioned in paragraph 18(1)(a); and

(b) whether, to the best of his or her knowledge, the invention, so far as claimed in any claim and when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and

(ii) involves an inventive step; and

(c) such other matters (if any) as are prescribed.

(1A) For the purposes of paragraph (1)(b), the prior art base is to be taken not to include information made publicly available only through the doing of an act (whether in or out of the patent area).

(2) The modified examination must be carried out in accordance with the regulations.

*AUSTRIA: Sections 57a, 99 and 100 of the Patents Law BGBl. No. 259/1970 as last amended by BGBl. No. 143/2001*

### Section 57a. Services Rendered and Information Given by the Patent Office

The Patent Office shall, upon request, furnish expert opinions in writing

1. on the state of art concerning a concrete technical problem (searches) and

2. on the fact if there is an invention patentable according to the provisions of Sections 1 to 3 as compared with the state of art cited by the applicant or to be searched by the Patent Office.

#### Section 99. Preliminary Examination

- (1) A preliminary examination of the application shall be made by a member of the Technical Division. The examination shall not relate to the financial return to be expected from the invention.
- (2) If the application does not fulfill the requirements laid down, the applicant shall be requested to remedy the defects within a prescribed period.
- (3) Where the preliminary examination shows, if necessary after experts have been heard, that the invention is manifestly not patentable under Sections 1 to 3, applicant shall be informed accordingly, if necessary after having been questioned by the examiner. He shall be informed of the reasons and requested to state his case within a prescribed period.
- (4) The period (subsections (2) and (3)) may be extended on request. There shall be no remedy against rejection of a petition for extension of the period, but a statement of the case in reply to a preliminary decision may be submitted out of time within two weeks after the decision rejecting the petition has been served.
- (5) If, within the time limit laid down, neither a statement of the case in reply to the preliminary decision (subsections 2 and 3) nor a petition for an extension of the time limit is submitted, the application shall be deemed withdrawn. This legal consequence shall not take effect if, within four months of the expiry of the period (subsections 2 and 3), the statement of the case in reply to the preliminary decision is postfiled, if a fee equal to the application fee is paid (Section 166(1)) and if the payment of that fee is duly proved (Sec. 169). If timely payment has not been duly proved, a time limit of one month, which may not be extended, shall be prescribed for the applicant.
- (6) The President of the Patent Office may issue guidelines on the principles governing the preliminary examination and on the procedure for such examination to be observed by the members of the Technical Division. In particular, he may determine the periods to be laid down by the Office. In this connection, he shall take account of the need for as rational and careful a preliminary examination as possible and for uniformity in the treatment of applications.

#### Section 100. Rejection of an Application

- (1) Where the original or amended application does not fulfill the requirements laid down or where the invention is ex facie not patentable within the meaning of Sections 1 to 3 (Section 99), the application shall be rejected. Where the conditions referred to apply only in part, only the corresponding part of the application shall be rejected.
- (2) Where the application is to be rejected for a reason which was not already communicated to the applicant during the preliminary examination, he shall be given an opportunity to state his case in regard to that reason within a prescribed period.

*BAHARAIN: Article 19 of the Industrial Property Law as last amended by Law No. 14 of 28/05/2006*

#### *Article (19)*

- a. The competent administrative authority at the Ministry of Trade shall examine the patent application and the attachments thereof to verify that it meets the required conditions. It may request from the applicant - within thirty days as of date of receiving the application- to conduct further modifications and conditions as it sees appropriate to decide on it, provided it sets an appropriate appointment that must be communicated to the applicant. If the applicant failed to execute requests made by the competent administrative authority of industrial property on time, the application shall be considered void.
- b. The aforementioned authority shall issue a decision on the patent application within sixty days as of date of receipt a complete application, or as of date conducting the modifications and receipt of fees necessary for deciding on it.
- c. Upon issuing the decision of a patent registration it must be published in the official gazette. If granting the patent was rejected if must be a ground caused that must be communicated to the applicant immediately upon issuance by means of registered letter with receipt.
- d. Post to the publication of the acceptance, any person may examine the patent application, supporting attached documents, and related particulars that were entered in the patents register.

BARBADOS: *Sections 26 and 27 of the Patents Act No. 18 of 26/07/2001*

[Examination as to form.]

26.-(1) Where an application has been accorded a filing date, upon payment of the prescribed fee, the Director shall examine each application for a patent of invention to determine

- (a) whether subsection (4) of section 17, if applicable has been complied with;
- (b) whether the requirements concerning the petition in the application are in compliance with section 18 and the regulations;
- (c) whether the requirements of subsection (2) of section 18 have been complied with, if applicable;
- (d) whether the description, claims and, if applicable, drawings comply with the prescribed physical requirements for descriptions, claims and drawings; and
- (e) whether the application contains an abstract.

(2) If, the Director determines that any requirement mentioned in subsection (1) has not been complied with, he shall require the applicant to make such corrections in his application as are necessary to comply with that requirement; and, if an applicant fails to make the required corrections, the Director shall, subject to subsection (3), refuse to grant the patent requested by the application.

(3) Where the correction required by the Director is the filing of an abstract, the Director may, upon payment of the prescribed fee, prepare the abstract for the application; but if the prescribed fee for an abstract remains unpaid after the expiration of the time prescribed for its payment, the Director shall refuse the requested patent.

(4) When a patent is refused under this section, notice of the refusal and the reasons therefor shall be communicated to the applicant by the Director as soon as practicable.

[Examination as to substance.]

27.-(1) The Director shall examine each application for a patent of invention to determine

- (a) whether the invention is an invention within the meaning of this Act;
- (b) whether the invention is patentable within the meaning of sections 7 to 10;
- (c) whether the invention is excluded from patentability under section 11;
- (d) whether the description and the claims for the invention are in compliance with the requirements of subsection (2) of section 17, and the regulations;
- (e) whether any drawings necessary for the understanding of the invention have been furnished in accordance with subsection (2) of section 17;
- (f) whether the application complies with the requirements of this Act and the regulations regarding unity of invention;
- (g) whether, if applicable, any amendment or any divisional application goes beyond the disclosure in the prior application as provided in section 21;
- (h) whether the application has complied with any requirement made by the Director under section 22;
- (i) whether the description and the claims for the invention are in compliance with the requirements of subsection (2) of section 17, and the regulations.

(2) If the Director determines that any requirement mentioned in subsection (1) has not been complied with in respect of an application, the Director shall notify the applicant accordingly and invite the applicant to submit any comments the applicant wishes to make regarding his failure to comply with that requirement; and an invitation made to an applicant under this section may include an invitation to amend or divide the application.

(3) Where, notwithstanding any comment, amendment or division of the application submitted to the Director by the applicant, the Director is of the opinion that a requirement mentioned in subsection (1) has not been complied with, the Director may refuse to grant a patent on that application; but any refusal to grant a patent and the reasons therefor must be communicated to the applicant in writing by the Director as soon as practicable.

(4) For the purposes of examination under subsection (1), the Director shall take into account

- (a) the results of any international search and any International preliminary examination report submitted in accordance with the Patent Co-operation Treaty;

- (b) any document submitted under paragraph (i) or (iii) of section 23(1)(b); or
- (c) a search and examination report which was carried out upon the request of the Director by an external search and examination authority pursuant to subsection (5).

(5) For the purposes of the examination under this section the Director may transmit the application to a duly authorized authority with which an arrangement to that effect has been made by the Minister.

*BELARUS: Articles 18-21 of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/2002 as last amended on 24/12/2007*

#### *Article 18*

##### Expertise of the Application on Invention

1. The expertise of application on invention is conducted by the patent body in accordance with the present Law and other normative legal acts. The expertise of application on invention includes the preliminary and patent expertise.
2. If the applicant presents the additional materials for application on invention, it is checked whether or not they change the essence of the declared invention.  
The additional materials in the part changing the essence of the declared invention, at consideration of the application on invention are not taken into account at consideration of the application and can be registered by the applicant as independent application.
3. If the application on invention is submitted with violation of the requirement of the unity of the invention, the patent body offers to the applicant within 2 months from the date of reception of the relevant notification to report which of the inventions shall be considered and at necessity to introduce the clarifications to the documents on application. At violation of the requirement of unity of invention and also at presence in the first documents on application on other inventions the applicant has the right to submit the divisional application(s).  
In case, if the applicant within 2 months after reception of the notification of the patent body on violation of the requirement of unity of the invention does not report on which of the inventions should be considered and does not present the clarification documents the consideration of the invention first mentioned in the formula of invention shall be considered.
4. The application on invention can be recalled by the applicant before the date of publication of the information about the application but not later than the date of registration of the invention.

#### *Article 19*

##### Preliminary Expertise of the Applicant on Invention

1. Preliminary expertise of the application on invention is conducted in 3 months term from the date of its reception by the patent body.
2. At the course of conducting the preliminary expertise the presence of documents contained in application, the observance of the established requirements to them are checked and the question on whether or not the declared solution relates to the objects that can be recognized inventions.
3. The patent body directs to the applicant the notification in written form within 5 working days from the date of taking the decision about this decision taken under the results of preliminary expertise and also about the date of submitting the application to the patent body in accordance with the article 16 of the present Law.
4. If at the course of preliminary expertise it is established that the declared decision relates to the objects that are not considered inventions in accordance with the present Law the decision on refusal to issue the patent is taken.
5. If necessary, the applicant can be offered to introduce clarifications to the materials of the application within 2 months after reception of the relevant request by the patent body. In this case the term of conducting the expertise is prolonged for the term necessary for reception of the response of the applicant.  
If necessary clarifications are not submitted to the patent body in the established or the documents being absent on the date of reception of the application on invention are not presented or the petition on prolongation of the established term is not submitted, the application is considered recalled and the patent body notifies the applicant about it.

#### *Article 20*

##### Publication of the Information on Application on Invention

1. At expiration of 18 months from the date of submitting the application that has passed the preliminary expertise at the results of which the positive decision is taken, the patent body published the information about it in its official issue (further-official bulletin). The list of the published information is determined by the patent body.
2. At the petition of the applicant presented before expiration of 12 months from the date of submitting the application on invention the patent body can publish the information on application on invention earlier than the term established by point 1 of the present article.
3. After publication of information on invention any person has the right to get familiar with its materials being in patent body.

4. Information on application on invention are not published, if till the expiration of the term of publication it is recalled or partly recalled or the decision on issue of the patent is takes or its registration in the State Register of Inventions is made or the decision on refusal to issue the patent, the possibility of appealing which are limited, is taken.
5. The author of invention has the right to refuse to be mentioned as the author in the information published about the application on invention, if he is not an applicant.

#### *Article 21*

##### Patent Expertise of the Application on Invention

1. Within three years form the date of reception of the application on invention by the patent body the application or any interested person can submit the petition to the patent body on holding the patent expertise of the application. In case of not reception of the petition on holding the expertise in the mentioned period the application on invention is considered recalled.
2. At the course of patent expertise of application on invention the patentability of the invention is checked and the priority of the invention is established.
3. In the period of holding the patent expertise of application on invention the patent body has the right to request at the applicant the additional materials without which the fulfillment of expertise is impossible including the changed formula of invention.  
The applicant has the right within one months form the date of reception of the mentioned request of the patent body to inquire the patent body about the copies of the materials opposed at the course of the expertise to his application.  
The additional materials at the request of the patent body shall be presented without the change of the essence of the invention within two months from the date of reception by the application of the request or copies of the materials opposing the application.  
In case, if the applicant in the mentioned term does not present the materials requested by the patent body or petition on prolongation of the established term, the application is considered recalled.  
The additional materials in the part changing the essence of the declared invention at consideration of the application are not taken into consideration, the applicant is notified about it.
4. If as the result of conducted patent expertise it is established that the declared invention expressed in the formula on invention offered by the applicant complies with the terms of patentability, the patent body takes the decision on issue of the patent with such formula and indication of the established priority.
5. At establishing the non-compliance of the declared invention expressed by the formula offered by the applicant with the terms of patentability the patent body takes the decision to refuse to issue the patent.  
The decision on refusal to issue the patent is taken also in case, when the applicant does not change of the formula of invention after notifying him about the fact, that the offered formula characterizes the invention complying to the terms of patentability but does not contain the signs absent in the first description (formula) of invention.
6. The patent body sends the notification to the applicant in written form within 5 working days from the date of taking the decision taken at the results of the expertise of the application on invention and also on establishing the priority of invention.
7. The applicant has the right to request the copies of the materials opposing his application on invention as the result of conducting the expertise within one month from the date of reception of the decision on application on invention.
8. The decision on issue of the patent can be revised by the patent body before the registration of the invention in connection with reception of application on invention, industrial model enjoying earlier priority in accordance with points 3-6 of the article 16 of the present Law and also in connection with the revealed application or the patent issued on the identical inventions or industrial model with the same priority.
9. The patent body can revise the decision on the results of the patent expertise, if it has been taken with violation of the order of consideration of the application on invention established by the present Law. The decision on issue of the patent can be revised before the registration of the invention in the State Register of Inventions.
10. At non-agreement of the applicant with the decision of the patent body on refusal to issue the patent the applicant has the right in 3 months term from the day of reception of the decision or the copies of the materials requested by him opposing to the application on invention with the petition on holding the repeated expertise.
11. The repeated expertise is held within 6 months from the day of reception to the patent body of the relevant petition of the applicant.

12. If in the process of expertise it is established that the identical inventions have the same date of priority so with the agreement of the applicants one patent is issued to them. In case of non-agreement of the applicants they can turn to court for settlement of the matter on issue of the patent. The patent on invention is not issued by the patent body before the solving of the problem by court.

*BELGIUM: Articles 21 and 22 of the Patent Law of 28/03/1984 (Consolidated version as of 01/01/2010)*

#### *Article 21*

§ 1er. La demande de brevet donne lieu à l'établissement d'un rapport de recherche sur l'invention.

Il est assorti d'une opinion écrite sur la brevetabilité de l'invention au regard des documents cités, à titre d'information pour le demandeur. Cette opinion est accessible aux tiers dans le dossier du brevet délivré.

§ 2. Le rapport de recherche et l'opinion écrite sont établis par un organisme intergouvernemental désigné par le Roi.

Ce rapport et cette opinion écrite sont établis sur la base des revendications, en tenant compte de la description et, le cas échéant, des dessins. Ils citent les éléments de l'état de la technique qui peuvent être pris en considération pour apprécier la nouveauté de l'invention et l'activité inventive.

§ 3. Le demandeur est tenu d'acquitter une taxe de recherche, laquelle comprend le coût de la remise de l'opinion écrite mentionnée au § 1er, dans le délai et suivant les modalités fixés par le Roi.

La différence entre le montant de la redevance à verser à l'organisme intergouvernemental visé au § 2, alinéa 1er, pour la fourniture des rapports de recherche et la taxe de recherche est prise en charge par l'Etat.

La demande de brevet cesse de produire ses effets si la taxe de recherche n'est pas acquittée dans le délai visé à l'alinéa 1er.

§ 4. L'Office avertit le demandeur de l'approche du terme du délai dans lequel il doit acquitter la taxe de recherche et de la conséquence qui découlerait de l'absence de paiement de cette taxe. Une copie de l'avertissement est transmise par l'Office à l'usufruitier, au créancier gagiste ou saisissant et au licencié inscrits au Registre.

Une copie de l'avertissement est également transmise par l'Office à la personne dont l'action en revendication de la demande de brevet a été inscrite au Registre.

Par dérogation à la disposition du § 3 du présent article, le revendiquant peut acquitter la taxe de recherche dans le délai visé audit paragraphe. Si le titulaire de la demande de brevet acquitte également cette taxe, l'Office rembourse au revendiquant la taxe payée par ce dernier.

#### *Article 22*

§ 1er. Sous réserve des dispositions de l'article 39, § 3, l'accomplissement des formalités prescrites pour la délivrance du brevet est sanctionné par un arrêté ministériel. Cet arrêté constitue le brevet.

§ 2. L'arrêté est délivré aussitôt que possible après l'expiration d'un délai de dix-huit mois à compter de la date de dépôt de la demande de brevet ou, si le droit de priorité prévu par la Convention de Paris a été revendiqué conformément aux dispositions de l'article 19, à compter de la priorité la plus ancienne indiquée dans la déclaration de priorité.

Le demandeur peut requérir que l'arrêté soit délivré dès l'accomplissement des formalités prescrites pour l'octroi du brevet.

[...]

§ 3. La délivrance des brevets se fait sans examen préalable de la brevetabilité des inventions, sans garantie du mérite des inventions ou de l'exactitude de la description de celles-ci et aux risques et périls des demandeurs.

[L'opinion écrite visée à l'article 21, § 1er, ne lie aucunement l'Office et ne peut valoir à titre d'examen de la brevetabilité de l'invention.]

§ 4. Sans préjudice de l'application des dispositions des lois du 10 janvier 1955 et du 4 août 1955, mention de la délivrance des brevets est faite au Registre.

*BELIZE: Article 26 of the Patents Act (Ch. 253) No. 14 of 21/06/2000*

#### Examination

26. After according a filing date, and if the application is not withdrawn, the Registrar shall examine the application to determine whether:—

- (a) it complies with the requirements of section 17(1), (2), (3) and (10) and the Regulations pertaining thereto;
- (b) it complies with the requirements of this Act;
- (c) it complies with the requirements of the Regulations as have been designated by the Regulations to be formal requirements; and
- (d) information requested under section 23, if any, has been provided.

*BHUTAN: Section 11 (3), (4) and (5) of the Industrial Property Act of 2001*

#### Section 11

(3) After according a filing date, the Registrar shall examine whether the application complies with the requirements of Section 7(1) and 7(2) and the Rules pertaining thereto and those requirements of this Act and the Rules which are designated by the Rules as formal requirements for the purposes of this Act and whether information requested under Section 10, if any, has been provided.

(4) Where the Registrar is of the opinion that the application complies with the requirements of subsection (3), the Registrar shall take a decision as to whether the requirements of Sections 4(2) and (3), 5, 7(4), (5) and (6) and 8 and the Rules pertaining thereto are fulfilled and for this purpose may, as provided for in the Rules, cause the application to be examined.

(5) The Registrar shall take into account, for the purposes of subsection (4),

- (a) the results of any international search report and any international preliminary examination report established under the Patent Cooperation Treaty in relation to the application; and/or
- (b) a search and examination report submitted under Section 10(2)(a)(i) relating to, or a final decision submitted under Section 10(2)(a)(iii) on the refusal to grant a patent on, a corresponding foreign application; and/or
- (c) a search and examination report which was carried out upon his request by an external search and examination authority.

*BOTSWANA: Section 22 of the Industrial Property Act No. 14 of 21/08/1996*

22. (1) After according a filing date to an application, the Registrar Examination shall examine that application to determine whether such application of applications complies with the requirements of section 13(1) and (2) and the regulations pertaining thereto.

(2) The Minister may, by regulations, prescribe the categories of inventions in respect of which an examination under this section shall not cover the requirements of novelty and inventive step.

*BRAZIL: Articles 20 and 30-37 of the Industrial Property Law No. 9.279 of 14/05/1996 (as last amended by Law No.10.196, of 14/02/2001)*

20. Once the application has been submitted, it shall undergo a formal preliminary examination and, if found to be properly documented, shall be docketed, the date of submission shall be considered as the date of filing.

30. A patent application shall be kept secret for 18 (eighteen) months from the date of filing or of the oldest priority, if any, after which it shall be published, except as provided for in Article 75.

(1) The publication of the application may be anticipated at the request of the applicant.

(2) The publication shall contain data identifying the patent application, and a copy of the specifications, claims, abstract and drawings shall remain available to the public at the INPI.

(3) In the case referred to in the Sole Paragraph of Article 24, the biological material shall become available to the public upon the publication referred to in this Article.

31. After publication of the application and up to the end of the examination, interested parties may submit documents and data to assist the examination.

Sole Paragraph. The examination shall not begin before 60 (sixty) days from the publication of the application.

32. In order to better clarify or define a patent application, the applicant may make changes until the time of the request for examination, provided these are limited to the subject matter initially disclosed in the application.

33. The examination of a patent application must be requested by the applicant or by some other interested party, within a period of 36 (thirty six) months of the date of filing, under penalty of having the application dismissed.

Sole Paragraph. A patent application may be reinstated, if the applicant so requests, within 60 (sixty) days of the date it was dismissed, upon payment of a specific fee, under penalty of having the application definitively dismissed.

34. After the examination has been requested, the following must be submitted, within a period of 60 (sixty) days, whenever requested, under penalty of having the application dismissed:

I. objections, search for prior art and results of examination for granting of a corresponding application in other countries, when priority is claimed;

II. documents necessary to regularize the processing and examination of the application; and

III. free translation of the proper document referred to in Paragraph 2 of Article 16, if it was replaced by the statement referred to in Paragraph 5 of the same Article.

35. At the time of the technical examination, a report of search and an opinion shall be prepared with respect to:

I. patentability of the application;

II. appropriateness of the application given the nature claimed;

III. reformulation or division of the application; or

IV. technical requirements.

36. When the opinion ascertains the non-patentability of the application or the incompatibility of the application to the nature claimed, or makes some demand, the applicant shall be notified to submit comments within a period of 90 (ninety) days.

(1) If there is no response to the demand, the application shall be definitively dismissed.

(2) If there is response to the demand, even if it has not been satisfied, or its formulation is contested, and whether or not comments on patentability or compatibility have been submitted, the examination shall be continued.

37. Once the examination has been concluded, a decision shall be handed down, either approving or rejecting the patent application.

*BULGARIA: Articles 45a-46b and 47 of the Law on Patents and Utility Model Registration No. 27/2 of 1993 as last amended on 20/07/2007*

#### Examination as to the Availability of Classified Information

Art. 45a (1) Where the applicant is a Bulgarian citizen with a permanent address in the Republic of Bulgaria or a legal person with a principle place of business in the Republic of Bulgaria, the competent authorities referred to in Article 24(3) shall, within one month from the filing date of the application, examine it as to whether it contains classified information within the meaning of Article 25 of the Law on the Protection of Classified Information.

(2) Where the application is found to contain classified information, it shall be sent in due order to the competent authorities, and the latter shall, within three months from receipt thereof, determine the level of security classification.

(3) If, on expiry of the term referred to in paragraph (2), no information is received at the Patent Office concerning the security classification level, it shall be considered that the application is not a secret patent application.

(4) Where the application has been filed as a secret patent application and, after the examination referred to in paragraphs (1) to (3), no security classification level has been determined by the competent authorities, the Patent Office shall inform the applicant that the application contains no secret invention and shall ask for his express consent for the application to be examined in accordance with the ordinary provisions. In case no such consent is received within three months, the application shall be deemed to be withdrawn.

#### Examination of the Formal Requirements

Art. 46. (1) Within one month following the examination referred to in Article 45a (1) or (3) or from the date of filing of an application by a foreign applicant, any application bearing a filing date shall be subjected to examination as to its compliance with the requirements of Article 35, paragraph (1), items 1, 2 and 3, paragraph (4), and Article 36. If deficiencies are ascertained, the applicant shall be informed thereof and shall be given a three-month time limit to correct them. If the applicant fails to respond or to make the corrections within the above time limit, a decision shall be taken to terminate the procedure.

(2) Where the patent application is not accompanied by a document certifying payment of the fees referred to in Article 35(2), the applicant shall be given three months to pay them. If the applicant fails to do so, the application shall be deemed to be withdrawn.

(3) Where on expiration of the three-month time limit referred to in Article 35(3) it is established that no Bulgarian translation has been furnished, the application shall be deemed to be withdrawn and the applicant shall be informed thereof.

(4) Where priority is claimed according to Article 44(2) or (3), examination shall be carried out on expiry of the three-month time limit referred to in Article 44(2) as to whether the requirements of Article 44, Article 35, paragraph (1), item 4 and paragraph (2) are satisfied. If discrepancies are ascertained, the applicant shall be informed thereof and shall be given one month to submit his comments. If the applicant fails to respond or his arguments are groundless, the priority claim shall not be granted and the applicant shall be informed respectively.

#### Preliminary Examination and Examination as to Legal Protection Admissibility

Art. 46a Within three months following the examination referred to in Article 46, an examiner from the Examination Department shall carry out preliminary examination under Articles 37, 38 and 40. If deficiencies are ascertained, the applicant shall be informed thereof and shall be given three months to eliminate them. If the applicant fails to respond within this period or fails to remove the deficiencies, a decision shall be taken to terminate the procedure.

(2) Within the term referred to in paragraph (1), examination shall be performed also for compliance with the requirements of Article 6(2) and (4) and Article 7. If deficiencies are ascertained, the examiner from the Examination Department shall inform the applicant thereof and shall give him three months to submit his comments. If the applicant fails to respond or his arguments are groundless, a decision shall be taken to refuse grant of a patent.

#### Request for Search and Examination

Art. 46b Until the expiration of 13 months from the filing date of the application or the priority date, as appropriate, the applicant may file a search and examination request.

(2) Along with the request referred to in paragraph (1), the applicant shall pay a search and examination fee, as well as a publication fee for the application. In case of failure to pay the fees at the

time of filing the request, they may still be paid at twice the rate within one month following the filing date of the request referred to in paragraph (1).

(3) Where no request under paragraph (1) is filed with regard to the application, and/or the fees referred to in paragraph (2) are not paid, the application may be transformed into an application for utility model registration at the request of the applicant, which shall be filed prior to the expiration of 15 months from its priority date in accordance with a procedure as laid down in the Regulation referred to in Article 34(1). If no such request is filed, the application shall be deemed to be withdrawn and the applicant shall be informed thereof.

(4) A patent application relating to the subject matter referred to in Article 73(5) may not be transformed into an application for utility model registration according to paragraph (3). Where a transformation request is received with respect to such application, an examiner from the Examination Department shall inform the applicant of the transformation inadmissibility and shall give him one month comments and corrections. If the applicant fails to respond or his arguments are groundless, the transformation request shall not be granted and the patent application shall be deemed to be withdrawn.

#### Search and Examination

Art. 47 (1) In respect of each application, for which a request has been filed and the fees have been paid as referred to in Article 46b, an examiner from the Examination Department shall investigate the state of the art in accordance with Article 8 and shall draw up a search report and a written statement concerning the patentability of the invention in correspondence with Article 6(1) and Article 7a in connection with Articles 8, 9 and 10.

(2) The report, the statement referred to in paragraph (1) and the written objections referred to in Article 46d, if any, shall be sent to the applicant no later than six months upon expiration of the term referred to in Article 46d, except for the cases where as a result of the search a conflict application was found under Article 8 (3) or (4), and in such case the report and the statement shall be sent after its publication. The applicant shall dispose of three months to comment upon the statement and the objections received.

(3) Where it is determined in the statement referred to in paragraph (1) that the invention is not patentable within the meaning of Article 6(1) and Article 7a, for it does not satisfy the requirements of Article 8, 9 or 10, and the applicant fails to respond within the term referred to in paragraph (2), fails to remedy the deficiencies or his arguments are groundless, a decision shall be taken to refuse grant of a patent.

(4) Where the examiner from the Examination Department reveals that the invention applied for is patentable, but the specification and/or the patent claims do not comply with the requirements of Article 37(1) and/or Article 38, he shall invite the applicant to rectify them within a three-month time limit. If the applicant fails to make the necessary corrections within the prescribed time limit, or fails to reply or files a groundless objection, the examiner shall take a decision to terminate the proceedings in the application.

(5) Where, following the examination and the correspondence with the applicant, it is revealed that the invention is patentable and the requirements of Article 37(1) and Article 38 are satisfied, the examiner from the Examination Department shall invite the applicant in writing to pay the fees referred to in Article 33(4) and Article 53.

(6) The examiner from the Examination Department shall take a decision to grant a patent, provided that the fees referred to in paragraph (5) are paid. If the applicant fails to pay the fees, the application shall be deemed to be withdrawn.

#### BURUNDI: *Articles 40-43 of the Law No. 1/13 of 28/07/2009 on Industrial Property*

##### *Article 40*

Pour toute demande de brevet, il est effectué un examen visant à établir que:

1 ° L'invention qui fait l'objet de la demande de brevet n'est pas exclue de la protection conférée par le brevet, en vertu des articles 17 et 18 de la présente loi;

2° Les revendications sont conformes aux dispositions de l'article 19 de la présente loi ;

3° Les dispositions des articles 28, 29 et 30 sont respectées;

4 ° Au moment du dépôt de la demande de brevet, une demande de brevet déposée antérieurement ou bénéficiant d'une priorité antérieure valablement revendiquée et concernant la même invention n'est pas encore en instance de délivrance;

5° L'invention est nouvelle, résulte d'une activité inventive et est susceptible d'application industrielle.

*Article 41*

La délivrance des brevets se fait sans examen préalable de la brevetabilité des inventions, sans garantie du mérite des inventions ou de l'exactitude de la description de celles -ci et aux risques et périls des demandeurs.

*Article 42*

Le Directeur de la propriété industrielle décide si tout ou partie des dispositions de l'article 40 sont applicables à un ou plusieurs domaines techniques dont relèvent les inventions. Il détermine ces domaines par référence à la classification internationale des brevets.

*Article 43*

Pour toutes les demandes internationales, le Directeur de la propriété industrielle tient compte:

- 1 Des résultats de tout rapport de recherche internationale et de tout rapport d'examen préliminaire international établis selon le Traité de coopération en matière de brevets ;
- 2° D'un rapport de recherche et d'examen communiqué conformément à l'article 35 ou d'une décision définitive portant rejet de la demande étrangère ;
- 3° D'un rapport de recherche et d'examen qui a été établi sur sa demande par une administration extérieure chargée de la recherche et de l'examen ou par un organisme spécialisé du Burundi.

*CAMBODIA: Articles 35-37 of the Law on Patents, Utility Models and Industrial Designs of 22/01/2003*

*Article 35*

After according a filing date, the Registrar shall examine whether the application complies with the requirements of Articles 16 and 17 of this Law and other requirements which are designated as needed regulations of this Law. Where the foreign applications and patents filed in abroad, the registrar shall further examine whether information requested under Article 30, 31 and 32 of this Law, has been provided.

*Article 36*

Where the Registrar is of the opinion that the application complies with the requirements indicated in the Article 35, the Registrar shall take a decision as to whether the requirements of the 2nd and 3rd paragraph of Article 3, Articles 4 to 9, Articles 18 to 20 and Articles 23 to 26 of this Law and the Regulations pertaining thereto are fulfilled.

*Article 37*

The Registrar shall take into account, for the purposes of Article 36 of this Law, as following:

- (i) the results of any international search report and any international preliminary examination report established under the PCT in relation to the application; and/or
- (ii) a search and examination report submitted under item (i) of the 1<sup>st</sup> paragraph of Article 31 of this Law relating to, or a final decision submitted under item (iii) of the 1st paragraph of Article 31 of this Law on the refusal to grant a patent on, a corresponding foreign application; and/or
- (iii) a search and examination report which was carried out upon his request by an external search and examination authority.

*CANADA: Sections 27 and 35 of the Patent Act (R.S., 1985, c. P-4) as on 30/04/2010 and Rules 28-30 of the regulations thereto*

Commissioner may grant patents

27. (1) The Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met.

Examination

35. (1) The Commissioner shall, on the request of any person made in such manner as may be prescribed and on payment of a prescribed fee, cause an application for a patent to be examined by competent examiners to be employed in the Patent Office for that purpose.

(2) The Commissioner may by notice require an applicant for a patent to make a request for examination pursuant to subsection (1) or to pay the prescribed fee within the time specified in the notice, but the specified time may not exceed the time provided by the regulations for making the request and paying the fee.

(3) and (4) [Repealed, 1993, c. 15, s. 38]

## *Rules*

### Examination

28. (1) Subject to subsection (2), the Commissioner may advance an application for examination out of its routine order upon the request of any person who pays the fee set out in item 4 of Schedule II, where the Commissioner determines that failure to advance the application is likely to prejudice that person's rights.

(2) In respect of an application filed on or after October 1, 1989, subsection (1) only applies if the application is open to public inspection under section 10 of the Act and a request for examination has been made pursuant to subsection 35(1) of the Act.

29. (1) Where an examiner examining an application in accordance with section 35 of the Act or the Act as it read immediately before October 1, 1989 has reasonable grounds to believe that an application for a patent describing the same invention has been filed, in or for any country, on behalf of the applicant or on behalf of any other person claiming under an inventor named in the application being examined, the examiner may requisition from the applicant any of the following information and a copy of any related document:

- (a) an identification of any prior art cited in respect of the applications;
- (b) the application numbers, filing dates and, if granted, the patent numbers;
- (c) particulars of conflict, opposition, re-examination or similar proceedings; and
- (d) where a document is not in either English or French, a translation of the document, or a part of the document, into English or French.

(2) Where an examiner examining an application in accordance with section 35 of the Act or the Act as it read immediately before October 1, 1989 has reasonable grounds to believe that an invention disclosed in the application was, before the filing date of the application, published or the subject of a patent, the examiner may requisition the applicant to identify the first publication of or patent for that invention.

(3) Subsections (1) and (2) do not apply to any information or document that is not available or known to the applicant, provided that the applicant states the reasons why the information or document is not available or known.

30. (1) Where an examiner, after examining an application, has reasonable grounds to believe that the application complies with the Act and these Rules, the Commissioner shall notify the applicant that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice.

(2) Where an examiner examining an application in accordance with section 35 of the Act or the Act as it read immediately before October 1, 1989 has reasonable grounds to believe that an application does not comply with the Act or these Rules, the examiner shall inform the applicant of the application's defects and shall requisition the applicant to amend the application in order to comply or to provide arguments as to why the application does comply, within the six-month period after the requisition is made or, except in respect of Part V, within any shorter period established by the Commissioner in accordance with paragraph 73(1)(a) of the Act.

(3) Where an applicant has replied in good faith to a requisition referred to in subsection (2) within the time provided but the examiner has reasonable grounds to believe that the application still does not comply with the Act or these Rules in respect of one or more of the defects referred to in the requisition and that the applicant will not amend the application to comply with the Act and these Rules, the examiner may reject the application.

(4) Where an examiner rejects an application, the notice shall bear the notation "Final Action" or "Décision finale", shall indicate the outstanding defects and shall requisition the applicant to amend the application in order to comply with the Act and these Rules or to provide arguments as to why the application does comply, within the six-month period after the requisition is made or, except in respect of Part V, within any shorter period established by the Commissioner in accordance with paragraph 73(1)(a) of the Act.

(5) Where in accordance with subsection 30(4) the applicant amends the application or provides arguments and the examiner has reasonable grounds to believe that the application complies with the

Act and these Rules, the Commissioner shall notify the applicant that the rejection is withdrawn and that the application has been found allowable and shall requisition the payment of the applicable final fee set out in paragraph 6(a) or (b) of Schedule II within the six-month period after the date of the notice.

(6) Where the rejection is not withdrawn pursuant to subsection (5), the rejection shall be reviewed by the Commissioner and the applicant shall be given an opportunity to be heard.

(7) If after a notice is sent in accordance with subsection (1) or (5) but before a patent is issued the Commissioner has reasonable grounds to believe that the application does not comply with the Act or these Rules, the Commissioner shall

(a) notify the applicant of that fact;

(b) notify the applicant that the notice is withdrawn;

(c) return the application to the examiner for further examination; and

(d) if the final fee has been paid, refund it.

(8) Subsection (7) does not apply in respect of an application that has been deemed to be abandoned under section 73 of the Act unless the application has been reinstated in respect of each failure to take an action referred to in subsection 73(1) of the Act or section 97 or 151 of these Rules.

(9) After a notice is sent to the applicant in accordance with subsection (7),

(a) the notice that was sent in accordance with subsection (1) or (5) is deemed never to have been sent; and

(b) sections 32 and 33 do not apply unless a further notice is sent to the applicant in accordance with subsection (1) or (5).

(10) If an application has been abandoned under paragraph 73(1)(f) of the Act and reinstated,

(a) for the purposes of this section and section 32, any previous notice that was sent in accordance with subsection (1) or (5) is deemed never to have been sent; and

(b) if the final fee has already been paid and has not been refunded, any further notice sent in accordance with subsection (1) or (5) shall not requisition payment of the final fee.

(11) Subsection 26(1) does not apply in respect of the times set out in subsections (1) and (5).

*CHILE: Articles 45- 47 of the Industrial Property Law No. 19.039 of 24/01/1991 (consolidated version of 2005 as last amended on 2007) and Articles 17, 82 and 83 of the Regulations thereto*

#### *Article 45*

Once the application enters the Department, a preliminary examination shall be carried out to check that the documents stipulated in Article 43 have been attached. If any error or omission is detected in the preliminary examination, the interested party shall be informed so that he/she can make the corrections, clarifications or attach the relevant documents within 60 days, without losing the priority date. If the errors or omissions are not rectified within that time, the application shall be considered as not filed.

Applications that do not comply with any other processing requirement, within the periods established by this Law or its Regulations, shall be considered as abandoned and shall be shelved. Without prejudice to the foregoing, the applicant may request that the application be reopened, provided that he/she rectifies the processing requirements within the 125 days following the date of abandonment, without losing the right to priority. If this period ends without the errors or omissions having been rectified, the application shall be considered permanently abandoned.

When the examination of an application for an industrial property right reveals that the right claimed corresponds to another category, it shall be analyzed and processed as such, and the priority acquired conserved.

#### *Article 46*

Applicants for patents that have already been applied for abroad shall present the result of the search and the examination carried out by the foreign office, if they have been carried out, regardless of whether they resulted in the granting of the patent.

#### *Article 47*

All of the supporting material relating to a patent application shall be kept in the Department at the disposal of the public, following the publication referred to in Article 4.

## *Regulations*

### *Artículo 17*

El examen preliminar será realizado por el Departamento, debiendo verificar que la presentación cumpla con lo dispuesto en los artículos 14, 15, 43, 58, 64 y 80 de la Ley y artículos 11 y 12 de este reglamento, según corresponda.

Se evacuará un informe del examen preliminar en el que se indicará el tipo de solicitud de que se trate (patente de invención, modelo de utilidad, dibujo o diseño industrial y esquema de trazado o topografía de circuitos integrados), una clasificación técnica preliminar y las observaciones pertinentes a la presentación. Adicionalmente, los expertos del Departamento confeccionarán el extracto para publicar que, a su juicio, mejor interprete la materia solicitada.

En el examen preliminar, se deberá indicar cuál es el o los dibujos más representativos de la invención, modelo de utilidad, dibujo y diseño industrial, esquemas de trazados o topografías de circuitos integrados, a fin que una imagen de éstos sea incluida en la publicación a que se refiere el artículo 14 de este reglamento. Para tal efecto, la resolución respectiva señalará detalladamente cuál es el o los dibujos que se publicarán y ordenará la captación de éstos en soporte digital cuando no existan en este medio, en base a requerimientos y estándares compatibles con los sistemas correspondientes del Departamento.

### *Artículo 82*

La labor del Perito consistirá en lo siguiente:

- a) Pronunciarse sobre la concurrencia de los requisitos de fondo del derecho, señalados en los artículos 32, 56, 62 y 75 de la Ley.
- b) Calificar la suficiencia técnica del contenido de los documentos presentados por el solicitante.
- c) Verificar el estado del arte en el campo técnico a que se refiere la solicitud.
- d) Confeccionar y entregar al Departamento el informe pericial.

### *Artículo 83*

El informe pericial deberá contener, según la naturaleza del derecho en examen:

- a) Búsqueda del estado de la técnica.
- b) Análisis de la novedad.
- c) Análisis del nivel inventivo.
- d) Análisis de la aplicación industrial.
- e) Análisis técnico sobre la concurrencia de los demás requisitos establecidos en la Ley y en el reglamento.

## *CHINA: Articles 34-36 of the Patent Law of 27/12/2008*

### *Article 34*

Where, after receiving an application for a patent for invention, the patent administrative department under the State Council, upon preliminary examination, finds the application to be in conformity with the requirements of this Law, it shall publish the application promptly after the expiration of eighteen months from the date of filing. Upon the request of the applicant, the patent administrative department under the State Council may publish the application earlier.

### *Article 35*

Upon the applicant's request for an invention patent made at any time within three years from the filing date of an application, the patent administrative department under the State Council may carry out substantive examination of that application. If, without any justified reason, the applicant fails to meet the time limit for requesting such substantive examination, the application shall be deemed to have been withdrawn.

The Patent administrative department under the State Council may of its own accord carry out substantive examination of an application for an invention patent when it deems it necessary.

### *Article 36*

When requesting substantive examination of an invention patent application, the applicant shall furnish reference materials concerning the invention that were available prior to the filing date of the application.

For an patent application for an invention that has been already filed in a foreign country, the patent administrative department under the State Council may ask the applicant to furnish within a specified time limit documents concerning any search made for the purpose of examining that application, or concerning the results of any examination made, in that country. If, at the expiration of the specified time limit, without any justified reason, the said documents are not furnished, the application shall be deemed to have been withdrawn.

*COSTA RICA: Articles 9 and 13 of the Patents Law No. 6867 of 25/04/1983 (as last amended by Law No. 8039 of 12/10/2000)*

#### Examen de forma

9.- 1. El Registro de la Propiedad Industrial examinará si la solicitud cumple con los requisitos del artículo 6, párrafos 1, 2, 3 y 8, y con las disposiciones correspondientes al reglamento.  
2. En caso de observarse alguna omisión o deficiencia se le notificará al solicitante para que efectúe, dentro de los quince días hábiles siguientes, la corrección necesaria. Si el solicitante no efectuare la corrección en el plazo dicho, el Registro tendrá por desistida la solicitud.

#### Examen de fondo

13.-1. El Registro de la Propiedad Industrial examinará si la invención es patentable, de conformidad con los artículos 1 y 2, así como si la solicitud satisface el requisito de la unidad de la invención, según el artículo 7, y si en su caso, la modificación o la solicitud fraccionada están conformes con lo dispuesto en el artículo 8. También se examinará si la descripción, las reivindicaciones y los dibujos se ajustan a los requisitos señalados en el artículo 6, párrafos 2, 3, 4, y 5 y a las disposiciones correspondientes al reglamento.  
2. El Registro requerirá la opinión de centros oficiales, de educación superior, científicos, tecnológicos o profesionales, o en su defecto, de expertos independientes en la materia, sobre la novedad, el nivel inventivo y la aplicación industrial de la invención. Los centros referidos que sean dependientes o que estén financiados por el Estado, y los colegios profesionales estarán obligados a prestar el asesoramiento requerido. Quienes suscriban los informes responderán por su emisión, en su caso, conforme con lo dispuesto en el artículo 199 de la Ley General de la Administración Pública. Los informes presentados por los centros, entidades, o expertos consultados, deberán ser remitidos dentro del plazo que fije el Registro de la Propiedad Industrial, según la complejidad del asunto y contendrán una fundamentación detallada de sus conclusiones y su costo, fijado conforme con el reglamento, correrá a cargo del solicitante.

*CROATIA: Articles 29, 36 and 37 of the Patent Act No. 173/2003 of 31/10/2003 as last amended by Law OG No 76/2008 of 23/07/2007*

#### Article 29

(1) Upon receipt of a patent application, the Office shall examine whether:

1. the application complies with the requirements for the accordance of the filing date referred to in Article 21 of this Act,
2. the administrative fee and procedural charges for filing the application have been paid in compliance with Article 16 of this Act,
3. the translation of the application in the Croatian language is filed, if the application has been drafted in a foreign language,
4. the drawings referred to in Article 20, paragraph (1), item 4, of this Act have been filed, and
5. the applicant who is a natural or a legal person having domicile or principal place of business outside Croatia is represented by a patent representative entered in the Register of Representatives kept by the Office.

(2) If the application does not comply with the requirements for the acceptance of the filing date referred to in Article 21 of this Act, the Office shall invite the applicant to correct the deficiencies expressly indicated in the invitation, within a time limit of 2 months from the receipt of the invitation.

(3) If the applicant does not comply with the Office invitation within the time limit referred to in paragraph (2) of this Article, the patent application shall be rejected by a decision.

(4) If the applicant corrects the deficiencies within the time limit referred to in paragraph (2) of this Article, the Office shall issue a decision whereby the date of receipt of the required corrections shall be accorded as the filing date of the patent application.

(5) Where a patent application refers to drawings not included in the application, the Office shall invite the applicant to file such within a time limit of 2 months from the receipt of the invitation, and if the applicant complies with the Office invitation, it shall be considered that the filing date is the date of receipt of the drawings by the Office. If the drawings are not filed, it shall be considered that the applicant did not refer to them.

(6) The Office shall invite the applicant who has not paid the administrative fee and procedural charges, or has not submitted the translation of the patent application into the Croatian language, to correct the respective deficiencies within the time limit of 2 months from the receipt of the invitation.

(7) At the reasoned request of the applicant, the Office may extend the time limits set out in this Article, for a time period considered to be justified, but not exceeding 3 months.

(8) If the applicant does not comply with the invitation referred to in paragraph (6) of this Article, the patent application having the accorded filing date shall be considered to be withdrawn and the Office shall issue a decision on the suspension of the patent granting procedure.

#### *Article 36*

(1) Within 6 months from the date of publication of a patent application in the official gazette of the Office, the applicant may file:

1. a request for the grant of a patent on the basis of a substantive examination of the patent application, or
2. a request for the grant of a patent on the basis of the submitted results of the substantive examination of a patent application, or
3. a request for the grant of a patent not including a substantive examination of the patent application (a consensual patent).

(2) If, within the prescribed time limit, one of the requests referred to in paragraph (1) of this Article has not been filed, or the administrative fee and the procedural charges have not been paid in compliance with Article 16 of this Act, the patent application shall be considered to be withdrawn, and the Office shall issue a decision on the suspension of the procedure for the grant of the patent.

(3) The content of the request referred to in paragraph (1) shall be defined by the Regulations.

#### Grant of a Patent on the Basis of the Substantive Examination of a Patent Application

##### *Article 37*

(1) The substantive examination of a patent application shall establish whether the invention complies with all the requirements for the grant of the patent, i.e. whether the subject-matter of the application:

1. is an invention which is not excluded from patent protection in compliance with Article 5, paragraph (6) and Articles 6 and 7 of this Act;
2. is an invention which is disclosed in the application in compliance with Article 20, paragraph (4) of this Act;
3. is an invention which is in compliance with the rule of unity of invention referred to in Article 18 of this Act;
4. is an invention which is new in compliance with Articles 8 and 9 of this Act, which includes an inventive step in compliance with Article 10 of this Act, and which is industrially applicable in compliance with Article 11 of this Act.

(2) The Office may carry out the substantive examination of a patent application referred to in paragraph (1) of this Article, completely or in part, through one of the national patent offices of other countries with which it has concluded a cooperation agreement.

(3) The applicant who has also filed a patent application for the protection of the same invention with a national patent office of another country may file with the Office the results of substantive examination carried out by that office, translated into the Croatian language.

#### CYPRUS: *Articles 21 and 22 of the Patent Law N° 16(1) of 01/04/1998*

#### Examination as to Formalities

##### *Article 21*

(1) Where an application for a patent has a date of filing and is not withdrawn, the Registrar shall refer the application to an examiner to determine whether the application complies with those requirements of this Law and the rules which are designated by the rules as formal requirements for the purpose of this Law and to report the determination to the Registrar.

(2) If it is reported to the Registrar that not all the formal requirements are complied with, the applicant shall be given an opportunity to make observations on the report and to amend the application within a prescribed period so as to comply with those requirements, and if the applicant fails to do so the Registrar may refuse the application.

(3) If it is reported to the Registrar that the application, whether as originally filed or as amended pursuant to paragraph (2), complies with all the formal requirements at any time before the end of the prescribed period referred to in paragraph (2), the Registrar shall notify the applicant of that fact.

#### Submission of Search Report

##### *Article 22*

Where the applicant has been notified pursuant to Article 21(3) that his application complies with all the formal requirements, he shall, within the prescribed period, submit to the Office of the Registrar a search report drawn up by a prescribed authority quoting those elements of the state of the art that may be taken into consideration to assess, within the meaning of Articles 6 and 7, the patentability of the invention. If the applicant fails to do so within the prescribed period, the Registrar may refuse the application.

*CZEHK REPUBLIC: Sections 30-35 of the Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of November 27/11/1990 as last amended by Law No. 116 of 06/04/2000*

#### Preliminary Examination of Application for an Invention

30.- (1) All applications for an invention shall be subject to a preliminary examination carried out by the Office in order to ascertain that

(a) the application contains no element that is obviously contrary to the provisions of Section 3(1) or 26(2);

(b) the application contains no element referred to in the provisions of Section 3(2) or 4;

(c) the application contains no defect constituting a bar to publication;

(d) the applicant has paid the corresponding administrative fees.

(2) The Office shall reject an application for an invention if it contains an element contrary to the provisions of Sections 3(1) or 26(2) or on element referred to in the provisions of 3(2) or 4. The applicant shall be given an opportunity to make observations on the documents on the basis of which the decision has been taken, prior to rejection.

(3) If an application for an invention contains an element that constitutes a bar to its publication or if the applicant has not paid the corresponding administrative fee, the Office shall invite the applicant to submit his observations and to remedy any defects within the time limit it shall stipulate.

(4) If the applicant does not remedy the defects in an application for an invention constituting a bar for its publication or does not pay the corresponding administrative fee within the stipulated time limit, the Office shall terminate the procedure. The attention of the applicant shall be drawn to such consequence of failure to comply when the time limit is stipulated.

31.- (1) The Office shall publish an application for an invention after on expiry of a period of 18 months as from the date on which the priority right begins and shall give notice of the publication in the Official Bulletin.

(2) An application for an invention may be published before the expiry of the time limit laid down in subsection (1), on a request submitted by the applicant within 12 months from the date on which priority right begins and on payment of the administrative fee laid down in the relevant statutory provisions.

The Office shall publish an application for an invention before the expiry of the period referred to in subsection (1) if a patent has already been granted for the invention. However, if the owner of the patent does not give his consent, the Office shall not publish the application before expiry of 12 months as from the date on which the priority right begins.

(3) Together with the application for an invention, the Office may publish the report on the state of the art (search report) relating to an invention claimed in the application.

32.- (1) Following publication of an application for an invention, any person may submit observations on the patentability of the subject matter; the Office shall take such observations into consideration when carrying out the full examination of the application.

(2) Persons who have submitted observations under subsection (1) shall not become party to the procedure with respect to the application. However, the applicant shall inform of any observations submitted.

#### Full Examination of an Application for an Invention

33.- (1) The Office shall carry out a full examination of the application for an invention to ensure that that it meets the conditions for granting a patent laid down by this Law.

(2) The full examination of an application for an invention shall be carried out by the Office at the request of the applicant or of another person or may be carried out ex officio.

(3) The request for the full examination shall be filed a within 36 months as from the filing date of the application for an invention and may not be withdrawn. The person filing the request shall be required, on submitting the request, to pay an administrative fee in accordance with the relevant statutory provisions.

(4) The Office shall carry out the full examination immediately after the request has been filed.

(5) Where no request for full examination of an application for an invention has been duly filed or where the Office has not carried out an ex officio examination within the period laid down in subsection (3), the Office shall terminate the procedure concerning the application.

34.- (1) If the conditions for granting a patent have not been met, the Office shall reject the application for an invention. The applicant shall be given the possibility of submitting observations on the documents on the basis of which the decisions on the application is to be taken, before rejection.

(2) If the applicant does not remedy a defect constituting a bar to the granting of a patent within the given time limit, the Office shall terminate the procedure concerning the application. The attention of the applicant shall be drawn to such consequence of failure to comply when the time limit is stipulated.

(3) If the subject matter of the application for an invention satisfies the stipulated conditions and if the applicant has paid the fee laid down in the relevant statutory provisions, the Office shall grant a patent to the applicant who shall thereupon become the owner of the patent. The Office shall issue to the owner of the patent letters patent in which the name of the inventor shall be mentioned; the description of the invention and the claims shall form integral part of the letters patent; a notice of the grant of the patent shall be published in the Official Bulletin.

35.- If more than one application for an invention relating to the same subject matter is filed, only one patent can be granted.

*DENMARK: Sections 9, 15 and 19 of the Consolidated Patent Act No. 91 of 28/01/2009 and rules 37-43 of the Order on Patents and Supplementary Protection Certificates No. 93 of 29/01/2009*

9.- If the applicant so requests and pays the prescribed fee, the Patent Authority shall, in accordance with rules laid down by the Minister of Economic and Business Affairs, cause the application to be searched by an International Searching authority under the Cooperation Treaty, done at Washington on 19 June 1970.

15.-(1) If the applicant has not complied with the requirements prescribed for the application, or if the Patent Authority has other objections to the acceptance of the application, the applicant shall be notified accordingly and be invited to file his observations or to correct the application within a time limit to be specified. The Patent Authority may, however, make such amendments in the abstract as it finds necessary without consulting the applicant.

(2) If the applicant fails to file the required observations or to take steps to correct the application before the expiry of the time limit, the application shall be shelved. The notification referred to in subsection 1 shall contain information to that effect.

(3) The examination and other processing of the application shall, however, be resumed if the applicant submits his observations or takes steps to correct the application within 4 months after the expiry of the specified time limit and pays the prescribed resumption fee.

(4) If any renewal fee is not paid pursuant to sections 8, 41 and 42, the application shall be shelved without previous notification. The examination and other processing of an application shelved for that reason may not be resumed.

19.-(1) If the applicant complies with the requirements, and no objections have been found to the grant of a patent, and it has been established that the applicant approves the text in which the patent may

be granted, the Patent Authority shall send a notification to the applicant to the effect that the patent may be granted against payment of the prescribed fee for publication of the patent specification.

(2) After the Patent Authority has sent the notification referred to in subsection 1, the claims may not be amended in such a way as to extend the scope of the protection conferred by the patent.

(3) The patent specification may at the request of the applicant to that effect to be published in Danish or in English with claims in Danish.

(4) The fee for publication of the patent specification shall be paid within 2 months after the Patent Authority has sent the notification under subsection 1. Failure to pay shall cause the application to be shelved. The proceedings for grant shall, however, be resumed if the applicant pays the fee for publication of the patent specification and the prescribed fee within 4 months after the expiry of the time limit.

### *Regulations*

#### Examination as to patentability

37.-(1) In examining whether the conditions laid down in section 2 of the Patents Act for the grant of a patent are complied with, the Patent Authority shall consider everything that comes to its attention.

(2) If deemed necessary, the examination shall also be based on other available information.

38.-(1) If the applicant wishes the search referred to in section 9 of the Patents Act to be performed, he shall, within 3 months from the date of filing of the application, or from the date on which the application is deemed to have been filed, file a request to that effect and pay the fee prescribed by the Searching Authority and a fee for the handling of the application by the Patent and Trademark Office.

(2) If the applicant wishes the search to be performed by a specific international authority out of several possible authorities, he shall specify that in the request.

(3) If the patent application is not written in a language accepted by the Searching Authority, the request shall be accompanied by a translation of the application into a language approved by the Searching Authority. If the Nordic Patent Institute is stated in the request, the application shall be translated into Danish, English, Icelandic, Norwegian or Swedish. If the Swedish Patent Office is stated in the request, the application shall be translated into Danish, Swedish or English, and if the European Patent Office is stated in the request, the application shall be translated into English, French or German.

(4) If at the expiry of the time limit referred to in subsection 1 the patent application and the prescribed translation do not comply with the requirements as to form which apply to international applications, the request shall be deemed to be withdrawn.

39.-(1) If the Patent and Trademark Office has informed the applicant that an application relates to two or more mutually independent inventions in contravention of section 10 of the Patents Act, the application shall not be restricted to relate first to one invention and then, if that proves not to be patentable, be amended to relate to another of the inventions. Neither shall the application be related in parallel to several of the inventions.

(2) When the claims have been restricted due to lack of unity, the applicant shall be deemed in the application in question finally to have waived the invention or inventions deleted from the claims by the restriction.

40.- For the purpose of the examination and other processing of the application the Patent Authority may consult other experts.

41.- The Patent Authority may require the applicant to submit a model, sample or the like or to have investigations or experiments carried out.

42.-(1) If the applicant has also applied for a patent for the same invention abroad, the Patent Authority may, with the limitation specified in section 69(3), 2nd sentence, of the Patents Act, require the applicant to furnish information about any communication from the patent institution in question concerning the novelty of the invention or its patentability in other respects.

(2) The applicant shall, to the extent required by the Patent Authority, indicate the patent institutions with which he has applied for a patent for the invention and file a copy or a transcript of the communications with the said patent institutions as regards the novelty of the invention or its patentability in other respects. If the applicant has not received any such communication, the applicant shall submit a declaration to that effect.

43.- If, during the examination and other processing of a patent application, information of importance to the examination of the application is filed, the applicant shall be notified thereof. The person who has submitted such information shall, where relevant, be notified of the opportunity to file an opposition if and when a patent is granted.

DJIBOUTI. *Articles 46 and 47 of the Protection of Industrial Property Law No.50/AN/09/6th L of 21/06/2009*

*Article 46*

Les brevets sont délivrés après l'expiration du délai de trois mois qui suit la publication de la demande de brevet, s'il n'y a pas d'opposition conformément à l'article 44.

*Article 47*

Les brevets, dont la demande n'a pas été rejetée ni a fait l'objet d'une opposition, sont délivrés sans examen préalable, aux risques et périls des demandeurs et sans garantie, soit de la réalité de l'invention, soit de la fidélité ou de l'exactitude de la description, soit du mérite de l'invention.

DOMINICA: *Section 26 of the Patents Act No. 8 of 07/10/1999*

26. After according a filing date, and if the application is not withdrawn, the Registrar shall examine the application to determine whether -

- (a) it complies with the requirements of section 17(1), (2),(3) and (10) and the Regulations pertaining thereto;
- (b) it complies with the requirements of this Act;
- (c) it complies with the requirements of the Regulations as have been designated by the Regulations to be formal requirements; and
- (d) information requested under section 23, if any, has been provided.

DOMINICAN REPUBLIC: *Articles 19 and 22 of the Industrial Property Law No. 20-00 of 08/05/2000*

*Article 19*

Examination of Form

- 1) The General Agency for Industrial Property shall examine, within sixty (60) days of the date of the application, whether the application complies with the requirements of Articles 11 and 13 and the corresponding regulatory provisions.
  - 2) If any omission or deficiency is found, the applicant shall be notified so that he or she can make the necessary correction within a term of two months, or risk being considered abandoned and filed away on the initiative of the Agency. If the applicant does not comply in making the correction within the indicated time limit, the General Agency for Industrial Property shall confirm the abandonment through an official communication.
  - 3) If any of the elements indicated in Article 320 have been omitted, but the omission is remedied within the time limit stated in the preceding paragraph, the date on which the omission is remedied shall be assigned as the date of the application.
  - 4) If the description refers to drawings and these have not been included when the application was filed, the General Agency for Industrial Property shall notify the applicant so that he or she can file them. If the omission is remedied within the time limit indicated in numeral 2), the date the drawings are received shall be the filing date of the application.
- Otherwise it shall be deemed that reference to drawings has not been made.

*Article 22*

Examination of the Merits

- 1) The applicant must pay the fee for the examination of the merits of the patent application within a time limit of twelve months counted from the date of the appearance of the announcement of publication of the application. If this limit should expire without the fee having been paid, the application shall by full law fall into abandonment and shall be filed away automatically.

- 2) The patent application shall be examined to determine if its object constitutes an invention according to Articles 309 and 310.1, if the invention is patentable according to Articles 1 and 2 and Articles 3, 4, 5 and 6 if it fulfills the requirements of Articles 13, 14, 15, 16 and 17 and, when such is the case, Articles 18, numeral 1) and 135, and the corresponding regulatory provisions.
- 3) The examination shall be able to be carried out directly by the General Agency for Industrial Property or by means of independent experts or public or private entities, either local or foreign within the framework of international, regional or bilateral agreements. The cost of this examination shall be covered by the fee indicated in paragraph 1.
- 4) The examination may take into account documents relating to the examinations for novelty or patentability made by other industrial property offices or within the procedure indicated by the Patent Cooperation Treaty (PCT), which refer to the same item claimed in the application being examined. The General Agency for Industrial Property may recognize the results of such examinations as sufficient to certify the fulfillment of the conditions for patentability of the invention.
- 5) If any of the requirements for granting the patent are not fulfilled, the General Agency for Industrial Property shall notify the applicant so that he or she may, within a period of three months, complete the documentation filed, correct, modify or divide the application, or present such comments or documents as he may deem advisable.
- 6) If the applicant should not respond to the notification within the established time limit, or if, in spite of the reply, the General Agency for Industrial Property should find that the requirements for granting the patent are not satisfied, it shall be denied by means of a substantiated resolution.
- 7) For the purposes of the patentability examination the applicant shall provide, at the request of the General Agency for Industrial Property, the translation, when so required, of one or more of the following documents relating to one or more of the foreign applications referring to the invention being examined:
  - a) a copy of the foreign application.
  - b) a copy of the results of novelty or patentability examinations made with regard to the foreign application.
  - c) A copy of the patent or other protective title granted on the basis of the foreign application.
- 8) When necessary to better resolve a patent application or the validity of a granted patent, the General Agency for Industrial Property may at any time request the applicant or holder of a patent to present the following documents relating to a foreign application or protective title referring to the same invention:
  - a) a copy of any resolution or decision whereby the foreign application has been rejected or denied.
  - b) A copy of any resolution or decision whereby the patent or another protective title granted on the basis of the foreign application has been revoked, annulled or invalidated
- 9) If the applicant, having the information or document required available, should not comply with providing it within the time period indicated in the notification, which shall not be less than three months counted from the date of the notification, the patent shall be denied.
- 10) Upon the request by the applicant, or on its own initiative, the General Agency for Industrial Property may suspend the processing of the patent application when some document that should have been presented according to this article is still pending before a foreign authority.
- 11) The applicant may present observations and comments on any information or document he or she provides in compliance with this article.

*EGYPT: Article 16 of the Law on the Protection of Intellectual Property Rights No 82 of 03/06/2002*

*Article 16*

The Patent Office shall examine the patent application and its annexes in order to ascertain that the invention is new, involves an inventive step and is industrially applicable, in conformity with the provisions of Articles 1, 2 and 3 of this Law.

Where the invention satisfies the aforementioned conditions, and where the conditions provided for in Articles 12 and 13 are fulfilled in the patent application, the Patent Office shall publish the application acceptance, in the Patent Gazette, in the manner prescribed in the Regulations.

EL SALVADOR: *Articles 151-153 of the Intellectual Property Legislative Decree No. 604 of 15/07/1993 No. 604 as last amended by Legislative Decree No. 912 of 14/12/2005*

*Article 151*

In the case of patent applications, the Registry shall order a substantive examination of the invention or utility model, through a written request to the applicant. The application may be submitted at any time after the filing date has been assigned, but may not be submitted six months after the date that the publication of the patent application was announced in the Official Journal. The examination request shall be accompanied by the receipt for payment of the relevant examination duties. If the request for examination is not filed within the period specified in the foregoing paragraph, the application shall be considered abandoned and instructions shall be given for it to be shelved, whereupon it shall immediately become public property.

*Article 152*

The purpose of the substantive examination shall be to verify compliance with the conditions of patentability provided for in this Law, and also with the requirements relating to the description, claims, drawings and abstract and those relating to unity of invention.

To carry out the substantive examination, the Registry may request the technical support of research institutes, university teaching centres, international agencies and the opinion of external experts, in accordance with the provisions of the Regulations of this Law.

The Registry may accept or request reports on the prior art and patentability reports drafted by national or regional industrial property offices abroad, as well as using cooperation mechanisms that exist as part of bilateral or multilateral agreements to carry them out, in accordance with the provisions of the Regulations of this Law.

The Registry may recognize the results of such examinations as sufficient to certify that the conditions for the invention's patentability have been fulfilled.

*Article 153*

For the purposes of the substantive examination, the Registry may require the applicant to provide, duly translated into Spanish, one or more of the following documents relating to foreign applications mentioned in the application:

- (a) Copy of the foreign application and its accompanying documents;
- (b) Copy of any communication or report referring to the results of searches for anticipation or examinations carried out in relation to the foreign request;
- (c) Copy of the patent or other title of protection granted on the basis of the foreign application.

When the application filed in El Salvador includes inventions claimed in two or more foreign applications, in such a way that none of these totally includes what is claimed in the application filed, the Registry may ask the applicant to submit the documents mentioned in the above letters that relate to other foreign applications that correspond partially or totally to the application filed in El Salvador.

ESTONIA: *§ 23 of the Patent Act (RT I 1994, 25, 406) of 16/03/1994 as last amended by Law RT I 2004, 20, 141 of 10/03/2004*

§ 23. Examination of patent applications

(1) During an examination, the Patent Office shall verify the compliance of an invention with the criteria of patentability provided by § 8 of this Act.

(2) The Patent Office may request from an applicant oral or written explanations and correction or amendment of the patent claims, description of the invention, drawings and the abstract of the subject matter of the invention or translations of foreign language documents submitted by the applicant. The Patent Office shall set a term for the provision of explanations or submission of corrections, amendments and translations.

(3) The Patent Office has the right to request from an applicant copy of decisions of patent offices of other countries regarding the applicant's analogous patent applications and to exchange information regarding the patent application with patent offices of other countries.

(4) If the Patent Office finds that the subject of the invention can be protected by a patent pursuant to the provisions of §§ 6 and 7 of this Act and the subject matter of the invention as expressed in the patent claims complies, when compared to the state of the art, with the criteria of patentability established in § 8 of this Act and that the form and contents of the patent application documents

comply with the requirements relating to form and contents established on the basis of subsection 19 (4) of this Act, the Patent Office shall terminate the examination of the patent application, make a decision to issue the patent and shall notify the applicant thereof in writing.

(5) If the Patent Office finds that the subject of the invention cannot be protected by a patent pursuant to the provisions of §§ 6 and 7 of this Act or the subject matter of the invention as expressed in the patent claims does not comply, when compared to the state of the art, with the criteria of patentability established in § 8 of this Act or the applicant fails to separate an invention which violates the requirement of unity from the patent application by the due date set pursuant to subsection 9 (3) of this Act or that the form or contents of the patent application documents do not comply with the requirements relating to form and contents established on the basis of subsection 19 (2) of this Act or if the applicant fails to make the corrections or amendments or provide the explanations or submit the translations requested pursuant to subsection (2) or to submit the copies of decisions requested pursuant to subsection (3) of this section, the Patent Office shall terminate the examination of the patent application, make a decision to reject the patent application and shall notify the applicant thereof in writing.

(6) Any observations and opinions on a patent application submitted by a third person in the course of examination shall be communicated to the applicant who may comment on them. Third persons shall not be involved in processing.

*ETHIOPIA: Article 13 of the Proclamation concerning Inventions, Minor Inventions and Industrial Designs No. 123 of 10/05/1995*

### 13. Examination of Application

1. The Commission shall undertake a formal examination of the application.

2. When, upon formal examination, the application is not in conformity with the requirements laid down in this proclamation and in the regulations, the Commission shall call upon the applicant to amend the application. If the applicant fails to amend as required within a period of two months, the application shall be considered withdrawn.

3. Where the Commission determines that the application is acceptable, it shall undertake or cause to be undertaken a substantive examination of the invention.

*FINLAND: Sections 19 and 20 of the Patents Act No. 550 of 15/12/1967 as last amended by Act No. 684 of 21/07/2006*

Section 19 (21.3.1997/243) If the application satisfies the formal requirements and no obstacle is found to acceptance of the application, the patent authority shall notify the applicant that the application can be accepted.

Once the notice referred to in subsection (1) has been given to the applicant, no request may be filed under Section 11, nor may the patent claims be altered in such a way as to extend the scope of protection.

The applicant shall pay the prescribed printing fee within two months from the date on which he was given the notice pursuant to subsection (1). Failing that, the application shall be dismissed. However, examination may be resumed if, within four months of the expiration of the prescribed time limit, the applicant pays the printing fee together with the prescribed reinstatement fee.

If an application for a patent is filed by an inventor and if, within two months of the date on which he was given the notice pursuant to subsection (1), he requests exemption from payment of the printing fee, the Patent Authority may grant said exemption if the applicant is considered to have great difficulty in paying the fee. If the request is rejected, a fee paid within two months thereafter shall be deemed to have been paid on time.

Section 20 (21.3.1997/243) Once the applicant has done what is required of him under Section 19, the Patent Authority shall accept the application, provided that there is still no obstacle. The acceptance of the application shall be announced.

A patent has been granted on the day the acceptance of the application is announced. A granted patent shall be recorded in the Patent Register kept by the Patent Authority. Letters patent shall be issued to the proprietor of the patent.

FRANCE: *Articles L612-11-L612-15 of the Intellectual Property Code No. 92-597 of 01/07/1992 (Consolidated version of 2010) and Articles R612-56-1 and Article R612-57 of the Regulations thereto*

*Article L612-11* En savoir plus sur cet article...

Le directeur de l'Institut national de la propriété industrielle examine la conformité des demandes de brevet avec les dispositions législatives et réglementaires mentionnées à l'article L. 612-12.

*Article L612-12*

Est rejetée, en tout ou partie, toute demande de brevet :

1° Qui ne satisfait pas aux conditions visées à l'article L. 612-1 ;

2° Qui n'a pas été divisée conformément à l'article L. 612-4 ;

3° Qui porte sur une demande divisionnaire dont l'objet s'étend au-delà du contenu de la description de la demande initiale ;

4° Qui a pour objet une invention manifestement non brevetable en application des articles L. 611-16 à L. 611-19 ;

5° Dont l'objet ne peut manifestement être considéré comme une invention au sens de l'article L. 611-10, deuxième paragraphe.

6° Dont la description ou les revendications ne permettent pas d'appliquer les dispositions de l'article L. 612-14 ;

7° Qui n'a pas été modifiée, après mise en demeure, alors que l'absence de nouveauté résultait manifestement du rapport de recherche ;

8° Dont les revendications ne se fondent pas sur la description ;

9° Lorsque le demandeur n'a pas, s'il y a lieu, présenté d'observations ni déposé de nouvelles revendications au cours de la procédure d'établissement du rapport de recherche prévu à l'article L. 612-14.

Si les motifs de rejet n'affectent la demande de brevet qu'en partie, seules les revendications correspondantes sont rejetées.

En cas de non-conformité partielle de la demande aux dispositions des articles L. 611-17, L. 611-18, L. 611-19 (4° du I) ou L. 612-1, il est procédé d'office à la suppression des parties correspondantes de la description et des dessins.

*Article L612-13*

Du jour du dépôt de la demande et jusqu'au jour où la recherche documentaire préalable au rapport prévu à l'article L. 612-14 a été commencée, le demandeur peut déposer de nouvelles revendications.

La faculté de déposer de nouvelles revendications est ouverte au demandeur d'un certificat d'utilité jusqu'au jour de la délivrance de ce titre.

Du jour de la publication de la demande de brevet en application du 1° de l'article L. 612-21 et dans un délai fixé par voie réglementaire, tout tiers peut adresser à l'Institut national de la propriété industrielle des observations écrites sur la brevetabilité, au sens des articles L. 611-11 et L. 611-14, de l'invention objet de ladite demande. L'Institut national de la propriété industrielle notifie ces observations au demandeur qui, dans un délai fixé par voie réglementaire, peut présenter des observations en réponse et déposer de nouvelles revendications.

*Article L612-14*

Sous réserve des dispositions prévues à l'article L. 612-15 et si elle a reçu une date de dépôt, la demande de brevet donne lieu à l'établissement d'un rapport de recherche sur les éléments de l'état de la technique qui peuvent être pris en considération pour apprécier, au sens des articles L. 611-11 et L. 611-14, la brevetabilité de l'invention.

Ce rapport est établi dans des conditions fixées par décret.

*Article L612-15*

Le demandeur peut transformer sa demande de brevet en demande de certificat d'utilité dans des conditions fixées par voie réglementaire.

*Regulations*

*Article R612-56-1*

Dans le cas où ont été déposées d'autres demandes de brevet portant sur la même invention que celle qui fait l'objet de la demande de brevet français, l'Institut national de la propriété industrielle peut inviter le demandeur, avant l'établissement du rapport de recherche préliminaire, à lui communiquer, dans un délai qu'il lui impartit, les informations dont il dispose, au jour de la notification, sur l'état de la technique qui a été pris en considération lors de l'examen de ces autres demandes par les offices compétents.

L'Institut national de la propriété industrielle peut, en outre, exiger la production des documents cités autres que les brevets et les demandes de brevets publiés ainsi que l'indication des passages pertinents, traduits en français.

Si, à l'expiration du délai imparti et renouvelable une fois, le demandeur n'a ni satisfait aux demandes de l'Institut national de la propriété industrielle ni justifié être dans l'impossibilité de produire ces documents, la demande de brevet est rejetée conformément aux dispositions du 9° de l'article L. 612-12.

*Article R612-57*

Un rapport de recherche préliminaire est établi. Il cite les documents qui peuvent être pris en considération pour apprécier la brevetabilité de l'invention, objet de la demande de brevet. Il est assorti d'une opinion sur la brevetabilité de l'invention au regard des documents cités. Cette opinion est accessible aux tiers dans le dossier de la demande de brevet.

Le rapport de recherche préliminaire et l'opinion sont établis sur la base des revendications déposées, en tenant compte de la description et, le cas échéant, des dessins.

Chaque citation est faite en relation avec les revendications qu'elle concerne. Si nécessaire, les parties pertinentes du document cité sont identifiées en indiquant notamment la page, la colonne et les lignes ou les figures.

Le rapport de recherche préliminaire distingue entre les documents cités qui ont été publiés avant la date de priorité, entre la date de priorité et la date de dépôt, à la date de dépôt et postérieurement.

Tout document se référant à une divulgation orale, à un usage ou à toute autre divulgation ayant eu lieu antérieurement à la date du dépôt de la demande de brevet est cité dans le rapport de recherche préliminaire en précisant la date de publication du document et celle de la divulgation non écrite.

GEORGIA: *Sections 32-36 of the Patent Law of 05/02/1999*

32.-(1) Sakpatenti conducts patent examination on basis of which takes the decision about granting a patent.

(2) At examination Sakpatenti may demand from the applicant to present additional documents or make amendments in the application, without which it is impossible to continue the examination of the pending application.

33.-(1) Sakpatenti confirms the filing date of the application within one month in the case of presenting the document confirming the payment of the fee for the examination as to form.

(2) If it is revealed, that the application lacks for any application material provided for by the Article 27 of this Law, Sakpatenti asks the applicant to furnish the mentioned materials within one month from receipt of the notification.

(3) If the applicant fulfills the requirement of the paragraph (2) then as the application filing date shall be considered the date of fulfillment of this requirement. If the applicant fails to fulfill the requirement, the application shall not be considered filed.

(4) If in the description of the invention or utility model the drawings referred to are not presented in the application, Sakpatenti within the term provided for by paragraph (1) of this Article requires from the applicant to submit them. If the applicant satisfies the requirements, provided for by the paragraph (2) of this Article then the filing date of the application will be the day of receiving the said drawings. If the applicant fails to fulfill the requirement, the filing date of the application will be the receiving day of the application and any reference to the drawings will be considered withdrawn.

34.-(1) The examination as to form takes place within two months from the confirmation filing date of the application.

(2) The record-keeping on the application is terminated if it does not meet the requirements of examination as to form.

35.-(1) If it is proved that an application for an invention meets the requirements of the examination as to form, then Sakpatenti conducts the search to determine the state of the art for the invention described in the application, on basis of which conducts the examination on novelty and makes a documentary conclusion.

(2) Sakpatenti in respect to the approved rule provides for the search within six months in the case of payment of the established fee.

(3) The application for the invention for which the applicant has not paid the established fee, shall be regarded as application for the utility model.

36.-(1) Sakpatenti sends the applicant the documentary conclusion on state of the art. The applicant within two months from the receipt of the conclusion may present a new wording of claims, which must not exceed the essential scope of the patent description, or can send a written response.

(2) If within two months from the receipt of a documentary conclusion an applicant has not presented amendments or well-grounded response and requirements for novelty are fulfilled, Sakpatenti takes a preliminary decision on granting the patent for an invention.

*GERMANY: Sections 42, 43 and 44 of the Patent Act of 16/12/1980 as last amended by Act of 31/07/2009*

#### Section 42

(1) Should an application obviously not comply with the requirements of Sections 34, 36, 37 and 38, the Examining Section shall request the applicant to remedy the defects within a specified period. If an application does not comply with the provisions on form or other requirements for applications (Section 34(6)), the Examining Section may refrain from objecting to the defects until the start of the examination procedure (Section 44).

(2) Should the subject matter of an application obviously

1. not, by reason of its nature, constitute an invention;
2. not be susceptible of industrial application;

3. be excluded from grant as a patent under Section 2 or  
4. not be directed, in the case of the second sentence of Section 16(1), towards an improvement or further development of another invention,  
the Examining Section shall notify the applicant thereof, stating its reasons, and shall invite the applicant to submit observations within a specified period. The same shall apply if, in the case of the second sentence of Section 16(1), the application for a patent of addition has not been filed within the specified period.

(3) The Examining Section shall reject an application if the defects objected to in subsection (1) are not remedied or if the application is maintained although the invention is obviously not patentable (subsection (2), nos. 1 to 3) or if the requirements of the second sentence of Section 16(1) are obviously not met (subsection (2), first sentence, no. 4, second sentence). If rejection is to be based on facts that have not yet been communicated to the applicant, said applicant shall first be given an opportunity to submit observations thereon within a specified period.

#### Section 43

(1) The Patent Office shall, upon request, ascertain those publications available to the public to be taken into consideration when assessing the patentability of the invention for which an application has been filed (search). When the search for such publications has been transferred, in part or entirely, to an international institution (subsection (8), no. 1) for all or for certain technical fields, a request may be submitted that the search be conducted in such a way that the applicant can use the result of the search also for a European application.

(2) The request may be filed by the patent applicant, or by a third party who shall not thereby become a participant in the procedure. The request must be filed in writing. Section 25 shall be applied mutatis mutandis. If the request is filed in connection with an application for a patent of addition (Section 16(1), second sentence), the Patent Office shall invite the applicant to file a request as specified in subsection (1) before expiration of one month after the invitation in connection with the application for the main patent; if no request is filed, the application for the patent of addition shall be regarded as an application for an independent patent.

(3) The filing of the request shall be published in the Patent Gazette [Patentblatt], but not before publication of the notification pursuant to Section 32(5). If the request is filed by a third party, the applicant shall also be notified of the filing of the request. Any person shall be entitled to inform the Patent Office of publications which might prejudice the grant of a patent.

(4) The request shall be deemed not to have been filed if a request pursuant to Section 44 had already been filed. In such a case, the Patent Office shall notify the person making the request of the date of filing of the request pursuant to Section 44. The fee as prescribed by the Patent Cost Act paid for the search pursuant to Section 43 shall be refunded.

(5) When a request pursuant to subsection (1) has been filed, subsequent requests shall be deemed not to have been filed. The second and third sentences of subsection (4) shall apply mutatis mutandis.

(6) Where a request filed by a third party is found to be without effect after notification of the applicant (subsection (3), second sentence), the Patent Office shall also advise the applicant thereof in addition to said third party.

(7) The Patent Office shall notify the applicant regarding the publications ascertained in accordance with subsection (1) and, if the request has been filed by third party, said third party and the applicant, without a guarantee as to completeness, and shall publish in the Patent Gazette [Patentblatt] the fact that such notification has been made. If the publications have been ascertained by an international institution and if the applicant has so requested (subsection (1), second sentence), this shall be stated in the notification.

(8) To accelerate the patent granting procedure, the Federal Minister of Justice shall be empowered to direct by statutory order that

1. the search for the publications specified in subsection (1) be assigned to a division of the Patent Office other than the Examining Section (Section 27(1)) or to another national or international institution, either as a whole or for certain technical fields or certain languages, provided that the institution concerned appears competent to search for publications to be taken into consideration;
2. the Patent Office shall provide foreign or international authorities with data from the files of patent applications for reciprocal information on the results of examination procedures and searches of the state of the art when the applications concerned relate to inventions for which the grant of a patent has also been applied to such foreign or international authorities;
3. the examination of patent applications according to Section 42 and the supervision of fees and time limits shall be transferred in whole or in part to divisions of the Patent Office other than the Examining Sections or Patent Divisions (Section 27(1)).

Section 44

(1) The Patent Office shall examine on request whether an application complies with the requirements of Sections 34, 37 and 38 and whether the subject matter of said application is patentable under Sections 1 to 5.

(2) The request may be filed by the applicant, or by any third party who will not by this become a participant in the examination procedure, prior to the expiration of seven years after the filing of the application. The deadline for payment of the examination fee, as prescribed by the Patent Cost Act, shall be three months after the due date (Sec 3(1) Patent Cost Act). This deadline shall, however, end with expiry of the seven years following filing of the application.

(3) When a request pursuant to Section 43 has already been filed, the examination procedure shall begin only after disposal of the request pursuant to Section 43. In other respects, Section 43(2), second, third and fourth sentences, and subsections (3), (5) and (6) shall apply *mutatis mutandis*. If a request filed by a third party is without effect, the applicant may file a request within a period of three months from service of the notification, provided that such period expires later than the period specified in subsection (2). If the applicant does not file a request, a notice shall be published in the Patent Gazette [Patentblatt] referring to the publication of the request filed by the third party and stating that this request is without effect.

(4) The examination procedure shall be continued even if the request for examination is withdrawn. In the case given in the third sentence of subsection (3), the procedure shall be continued from the point which it had reached at the time the applicant's request for examination was filed.

*GHANA: Sections 18 and 20 of the Patent Law No. 305A of 30/12/1992*

Filing date and examination of application as to form

18.-(1) The Registrar shall accord as the filing date, the date of receipt of the application provided that at the time of receipt, the documents filed contain:

(a) the name of the applicant; and

(b) a part which on the face of it appears to be a claim or claims.

(2) If the Registrar finds that the application did not at the time of receipt fulfil the requirements referred to in subsection (1) of this section he shall invite the applicant to file the required correction and if the applicant complies with the invitation, the Registrar shall accord as the filing date the date of receipt of the correction but if the applicant does not comply with the invitation, the Registrar shall treat the application as if it had not been filed.

(3) Where the application refers to drawings which are not included in the application, the Registrar shall invite the applicant to furnish the missing drawings, and if the applicant complies with the said invitation the Registrar shall accord as the filing date the date of receipt of the missing drawings; otherwise he shall treat any reference to the said drawings as non-existent.

(4) Where no invitation under subsection (2) or (3) of the section has been sent to the applicant and the applicant nevertheless files a correction pertaining to any of the requirements under subsection (1) of this section, the Registrar shall accord as the filing date the date of the receipt of the correction, provided the correction was received within 30 days from the date of receipt of the application.

(5) Where the request is accompanied by the statement on the right to the patent referred to in section 12(4), the Registrar shall send a copy of the statement to the inventor, who shall have the right to inspect the application and receive, at his own expense, a copy thereof.

(6) The Registrar shall cause an examination of the application to be carried out as to whether

(a) the request complies with the requirements of section 12(3), 12(4) and 12(5) of this Law and rules pertaining thereto;

(b) the description, claims and, where applicable, the drawings comply with the physical requirements prescribed by the regulations;

(c) the application contains an abstract;

(d) the applicant has complied with a request made by the Registrar under section 19 of this Law; and

(e) the prescribed fees referred to in section 12(1) of this Law have been paid.

(7) Where the Registrar finds that the application is defective in respect of any of the matters referred to in this section, he shall invite the applicant to remedy the defect provided that any corrections made to the application shall not be such as would require a change of the filing date, and if the applicant does not comply with the said invitation, the application shall be rejected by the Registrar.

(8) Unless the application is to be the subject of an international-type search under section 19, the Registrar shall cause an examination to be carried out as to whether the application appears to comply with the requirement of unity of invention prescribed by section 13 of this Law and rules pertaining thereto.

(9) If the Registrar is of the opinion, that the requirement of unity of invention may not have been complied with he shall invite the applicant to restrict or divide the application and if the applicant does not comply with the invitation the application shall be rejected by the Registrar.

#### Search and examination as to substance

20.-(1) The Secretary may by legislative instrument direct the examination as to substance of applications for patent and may waive such examination where he deems it necessary in the national interest.

(2) The Secretary, on the advice of the Patent Policy Committee, may by legislative instrument, direct that applications for patent relating to a specified technical field shall not be the subject of an examination as to substance.

(3) Where the Secretary directs that an application for a patent be the subject of an examination as to substance he may by such instrument further designate the authority or agency by which the examination is to be carried out and the condition for the examination. The Secretary may add further technical fields to, or remove any technical field from, those covered by the direction under subsection (1) of this section.

(4) If, in the opinion of the Registrar, the subject matter of an invention for which a patent is sought does not fall within the terms of direction given under subsection (2) of this section, he shall cause a search and examination to be carried out as to whether—

(a) the claimed invention is patentable within the meaning of sections 2 to 5 of this Law;

(b) the claimed invention is not excluded from protection under section 6 or 7 of this Law;

(c) the description and the claims comply with the requirements prescribed by sections 12(1)(c) and 13 of this Law and rules pertaining thereto;

(d) any drawings which are necessary for the understanding of the claimed invention have been furnished.

(5) For the purposes of the examination under subsection (4) of this section, the Registrar may transmit the application together with all relevant documents, to the designated authority or agency for a preliminary examination as to the patentability of the claimed invention.

(6) The authority or agency to which the application is transmitted shall make a report on the conclusion of its examination and transmit it to the Registrar with a copy to the applicant.

(7) Where, after taking due account of the conclusions of any report referred to in subsection (6) of this section, the Registrar is of the opinion that any of the conditions referred to in subsection (4) of this section are not fulfilled, he shall notify the applicant accordingly and invite him to submit his observations and where applicable to amend his application.

(8) Where despite any observation or amendment submitted by the applicant the Registrar finds that any of the conditions referred to in subsection (4) of this section are not fulfilled he shall refuse the grant of a patent and notify the applicant accordingly.

(9) Where an applicant states in his application that an application covering the same invention has been submitted to and is to be examined as to substance by an authority or agency in accordance with an order of the Secretary, the Registrar shall have the power to postpone a decision on any examination as to substance until the results of the examination by the authority or agency specified are transmitted to the Registrar.

GREECE: *Article 8 (1)-(10) of the Law on "Technology transfer, inventions, and technological innovation" No. 1733/1987 (FEK 171, A' of 22/9/1987) as last amended by Law No. 2359 of 15/11/1995*

#### *Article 8*

##### Grant of the patent - Procedure

1. If after the lapse of the term stated in paragraph 9 of the preceding article O.B.I. discovers the orderly but not complete filing of the application, this shall be considered as not filed.
2. If the filing of the application is orderly and complete, O.B.I. shall examine:
  - a. whether the subject matter of the application relates to an invention which is obviously patentable within the meaning of paragraphs 6 and 8 of article 5;
  - b. whether the subject matter of the application cannot be obviously considered as invention within the meaning of article 5 paragraph 2.If either of the above cases occurs, O.B.I. shall reject the patent application in its entirety or in the part which falls under said cases.
3. If the application is not considered as non-filed or if it is not rejected, in accordance with the preceding paragraphs, O.B.I. shall draft a search, report based on the description of the invention, the claims, and the attached drawings which shall mention all data of the state of the art necessary for the assessment of the novelty and the inventive step of the invention (search report). The search report may be accompanied by comments or brief explanatory remarks made by O.B.I. which shall relate to the characteristics of the invention in accordance with article 5 par. 1.
4. The search report shall be drafted only if the applicant pays the search fee within four months from the filing date of the application. In case said fee is not paid in time, the patent application is automatically converted into an application for grant of a utility model certificate.
5. The search report, along with a copy of the documents accompanying it, shall be notified to the applicant who is entitled to present his/her comments within a period of three months from the date of the notification.
6. On the basis of the applicant's comments, O.B.I. shall draft a final search report including all data of the state of the art which have to be taken into consideration in appraising the patentability of the invention by granting a patent in accordance with the present law.
7. The search report shall be made available to the public along with the patent application or, if it has not yet been drawn-up, following its notification to the applicant.
8. The search report or the final search report have an informative character.
9. Upon drafting the search report, O.B.I. may request from the European Patent Office or from any other international or national organisation the supply of information or opinions which shall be freely evaluated. Furthermore, O.B.I. may request from the applicant additional information, clarifications or comments.
10. All other matters related to the procedure of drafting the search report or the final search report are regulated by decision of the Minister of Industry, Energy, and, Technology.

GRENADA: *Section 10 (5)-(7) of the Industrial Property Act of 2002*

- (5) After according a filing date, the Registrar must examine -
- (a) whether the application complies with the requirements of section [6] (1) to (3) and the relevant regulations and any requirements of this Act and the regulations which are designated by the regulations as formal requirements for the purposes of this Act;

(b) whether any information requested under section [9], has been provided.

(6) If the Registrar is of the opinion that the application complies with the requirements of subsection (5), the Registrar must take a decision as to whether the requirements of sections [3](2) and (3), [4], [6](4), (5) and (6) and [7] and the relevant regulations are fulfilled and for this purpose may, as provided for in the regulations, cause the application to be examined.

(7) The Registrar must take into account, for the purposes of subsection (6) -

(a) the results of any international search report and any international preliminary examination report established under the Paris Convention in relation to the application;

(b) any search and examination report submitted under section [9](2)(a) or a final decision submitted under section [9](2)(c) relating to the patent on a corresponding foreign application;

(c) any search and examination report which was carried out upon the Registrar's request by an external search and examination authority.

*GUATEMALA: Articles 113, 117 and 118 of the Industrial Property Law, Decree No. 57-2000 of 18/09/2000*

#### Examen de Forma

113. El Registro examinará si la solicitud cumple con los requisitos de los artículos 103 y 105 de esta ley. En caso de observarse alguna omisión o deficiencia, y dentro de un plazo que no exceda de un mes contado a partir de la fecha de presentación de la solicitud, el Registro deberá requerir al solicitante que efectúe la corrección necesaria o presente los documentos omitidos. Si el solicitante no cumple con lo requerido dentro de un plazo de dos meses contados a partir de la fecha de la notificación, se tendrá por abandonada la solicitud.

#### Examen de Fondo

117. Transcurridos tres meses después de la fecha de publicación del edicto, o de notificadas al solicitante de la patente las observaciones presentadas, si fuese el caso, el Registro procederá a fijar la tasa correspondiente para cubrir el examen de fondo, la cual deberá hacerse efectiva dentro del mes siguiente a la fecha de la notificación al solicitante de la orden de pago respectiva, pues de lo contrario la solicitud se tendrá por abandonada.

Posteriormente, procederá a efectuar el examen de fondo de la solicitud, previa presentación por el solicitante del comprobante del pago de la tasa fijada, el que tendrá por objeto determinar si la invención reivindicada se ajusta a lo que disponen los artículos 91, 92, 93, 94, 95, 96, 97, 98, 107, 108, 109, 110 y 111 de esta ley, así como lo que establece el artículo 104, cuando fuere pertinente.

El examen podrá ser realizado por el Registro directamente, mediante el concurso de técnicos independientes o con la colaboración de entidades públicas o privadas, nacionales o extranjeras. Al realizar el examen de fondo, se tomarán en cuenta las informaciones aportadas por el solicitante o, en su caso, por quien haya formulado observaciones, incluyendo lo relativo a exámenes de novedad o de patentabilidad efectuados por otras oficinas de propiedad industrial y referidos a la misma materia de la solicitud. El Registro podrá considerar los resultados de tales exámenes como suficientes para acreditar el cumplimiento de las condiciones de patentabilidad de la invención.

La cuestión de si una invención es o no patentable por falta de novedad o nivel inventivo, se resolverá caso por caso según corresponda, considerando los hechos pertinentes como por ejemplo, entre otros:

- a) El alcance y contenido del estado de la técnica;
- b) Las diferencias entre el estado de la técnica y la reivindicación;
- c) El nivel de destreza común en el arte pertinente; y
- d) Factores secundarios apropiados como el éxito comercial, necesidades largamente sentidas pero no resueltas, el fracaso de otros y resultados inesperados.

#### Otros Documentos

118. Para los efectos del examen de fondo, el Registro podrá requerir al solicitante que presente, dentro de un plazo de dos meses contados a partir de la notificación respectiva, prorrogable a un mes más en casos calificados por el Registro, una copia sin legalización y con traducción simple de cualquier material contenido en un expediente administrativo o judicial del extranjero, relacionado con la solicitud en trámite, incluyendo, entre otras:

- a) La propia solicitud;
- b) Los resultados de exámenes de novedad o de patentabilidad;
- c) La patente u otro título de protección que se hubiese concedido;
- d) Cualquier resolución o fallo por el cual se hubiese rechazado, denegado u otorgado la solicitud o patente; y
- e) Cualquier resolución o fallo por el cual se hubiese revocado, anulado, invalidado o cancelado la patente u otro título de protección concedido.

A pedido del solicitante o bien de oficio, el Registro podrá suspender la tramitación de la solicitud de patente cuando algún documento que deba presentarse por el solicitante, conforme a este artículo, no se hubiese emitido en el país de que se trate.

El solicitante podrá, respecto a la información o documentos que proporcione, formular las observaciones y comentarios que estime pertinentes.

Si del examen de fondo resultare que previo al otorgamiento de la patente es necesario completar la documentación presentada, corregir, modificar o dividir la solicitud, el Registro lo notificará al solicitante para que, dentro de los tres meses siguientes, cumpla con lo requerido o presente los comentarios o documentos que convinieran en sustento de la solicitud. Este procedimiento podrá realizarse cuantas veces lo estime necesario el Registro.

*HONDURAS: Article 54 of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

*Artículo 54*

El Registro de la Propiedad Industrial examinará, mediante o con la colaboración de las entidades públicas o privadas, nacionales o extranjeras, idóneas para estos fines y con las cuales tuviese convenio para esos efectos, si la invención es patentable de conformidad con los Artículos 4, 5, 6, 7, 8, 9 y 10 de la presente Ley, y si la descripción, las reivindicaciones, los dibujos y el resumen se adecuan a los requisitos señalados en los Artículos 35, 45, 50, 51, 52 y 53 de esta Ley. También se examinará si la solicitud satisface el requisito de unidad de la invención según el Artículo 26 de la misma.

Cuando fuese aplicable, el examen podrá realizarse con base en los documentos que proporcione el solicitante relativos a los exámenes de novedad o de patentabilidad efectuados por otras Oficinas de Propiedad Industrial, o dentro del procedimiento previsto por el Tratado de Cooperación en materia de Patentes (PCT) y referidos a la misma materia reivindicada en la solicitud que se examina. El Registro de la Propiedad Industrial podrá reconocer los resultados de tales exámenes, en su totalidad o en parte, como suficientes para acreditar el cumplimiento de las condiciones de patentabilidad de la invención previstas en esta Ley.

*HUNGARY: Articles 68, 69, 69A, 71 and 74-75 of the Act XXXIII of 1995 on the protection of inventions by patents (Consolidated text of 01.04.2010)*

Examination as to formal requirements

*Article 68*

(1) If a patent application satisfies the requirements examined under Article 65, the Hungarian Patent Office shall examine whether the formal requirements of Article 57(2) and (3) have been met.

(2) Where the application does not comply with the requirements examined under paragraph (1), the applicant shall be invited to rectify the irregularities.

(3) The patent application shall be rejected if, in spite of rectification or comments, it still does not comply with the requirements under examination. An application may be rejected only for grounds precisely and expressly stated in the invitation.

(4) Where the applicant does not reply to the invitation within the fixed time limit, the patent application shall be considered withdrawn.

#### Novelty search

##### *Article 69*

(1) If a patent application satisfies the requirements laid down in Article 65, the Hungarian Intellectual Property Office shall carry out a novelty search and shall draw up a search report on the basis of the claims, with due regard to the description and any drawings. (1a) If the patent application – with regard to all the claims or certain claims – is unsuitable for a proper novelty search, the search report shall only contain a statement to it and the reasons thereof. If the patent application also contains claims suitable for novelty search, the Hungarian Intellectual Property Office shall prepare a partial search report with regard to such claims. (1b) If the patent applications does not satisfy the requirements of unity of the invention (Article 59), the Hungarian Intellectual Property Office shall prepare a partial search report concerning the invention mentioned in the first place among the claims, or concerning the inventions constituting a uniform group with this invention as laid down in Article 59. The Hungarian Intellectual Property Office shall invite the applicant for the division of the patent application during the substantive examination (Article 76). (2) The search report shall mention those documents and data, which may be taken into consideration in deciding whether the invention to which the patent application relates is new and involves an inventive activity. (3) The search report together with copies of any cited document shall be transmitted to the applicant. (4) Information shall be published in the official journal of the Hungarian Intellectual Property Office on the search carried out simultaneously with the publication of the application, or separately if the search report is available at a later date.

##### *Article 69/A*

(1) At the request of the applicant, the Hungarian Intellectual Property Office shall draw up a search report supplemented with a written opinion.

(2) The written opinion – containing also reasons – is a preliminary establishment whether the invention, taking into account the documents and the information cited in the search report, appears to meet the requirements of novelty, inventive activity and industrial application. (3) The request for a search report supplemented with a written opinion shall be filed within two months from the accorded filing date. (4) A fee fixed by specific legislation shall be paid for a search report supplemented with a written opinion within one month from the filing of the request. (5) If the fee for the search report supplemented with a written opinion is not paid, the Hungarian Intellectual Property Office shall invite the applicant to rectify the irregularity within the time limit fixed in paragraph (4). Failing to comply with the said invitation, the request for a search report supplemented with a written opinion shall be considered withdrawn. (6) The request for a search report supplemented with a written opinion shall be rejected if it does not comply with the requirement under paragraph (3). (7) The Hungarian Intellectual Property Office shall draw up the search report supplemented with a written opinion on the basis of the description, claims and drawings at its disposal on the last day of the fourth month from the according filing date and shall send it to the applicant within six months from the accorded filing date. (8) On request, the Hungarian Intellectual Property Office shall refund the fee for the search report supplemented with a written opinion if (a) the applicant withdraws the patent application until the last day of the third month from the accorded filing date; (b) the Hungarian Intellectual Property Office rejects the patent application within the time limit in point (a); (c) the patent application is considered withdrawn for a reason occurring within the time limit in point (a); (d) the search report supplemented with a written opinion was not mailed after the last day of the sixth month from the accorded filing date because the Hungarian Intellectual Property Office admitted a request for restitutio in integrum concerning a failure to comply with a time limit in paragraph (3) or (4).

#### Observations

##### *Article 71*

(1) During the patent granting procedure any person may file an observation with the Hungarian Intellectual Property Office to the effect that the invention or the application does not comply with a requirement of patentability. (2) Such observation shall be taken into consideration when the requirement objected to in the observation is examined. (3) The person making the observation shall not be a party to the patent granting procedure. That person shall be notified of the outcome of his observation.

## Substantive examination

### *Article 74*

(1) The Hungarian Patent Office shall carry out a substantive examination of the published patent application at the request of the applicant.

(2) The substantive examination shall ascertain

(a) whether the invention meets the requirements of Articles 1 to 5/A and whether it is not excluded from patent protection under Article 6(2) to (4) and (10);

(b) whether the application complies with the requirements laid down by this Act.

### *Article 75*

(1) Substantive examination may be requested simultaneously with the filing of the patent application or within six months at the latest after the date of the official information on the performance of the novelty search [Article 69(4)]. Failing this, provisional patent protection shall be considered surrendered.

(2) Withdrawal of the request for substantive examination shall have no legal effect.

(3) An examination fee prescribed by specific legislation shall be payable within two months from the filing of the request.

(4) If the examination fee is not paid upon filing the request, the Hungarian Patent Office shall invite the applicant to rectify the irregularity within the time limit fixed in paragraph (3). Failing to comply with the said invitation, the application shall be considered withdrawn or the provisional patent protection shall be considered surrendered, as the case may be.

(5) The examination fee shall be refunded on request if before the date of the official information on the novelty search the applicant withdraws the application or surrenders provisional patent protection.

*ICELAND: Articles 15, 16 and 19 of the Patents Act No. 17/1991 as last amended by Law no. 167/2007 and Articles 26-28 of Regulations thereto*

### *Article 15*

If the applicant has not complied with the requirements regarding the application, or if the Patent Authority finds other obstacles to the allowance of the application, the applicant shall be notified thereof and be requested within a specified term to explain his case or make corrections to the application. The Patent Authority may, however, without consulting the applicant, make such changes in the abstract as it deems necessary.

If the applicant fails, within the stipulated term, to render a statement or to take measures to overcome the objections raised, the application shall be dismissed. Notice of this shall be given in accordance with Paragraph 1.

A dismissed application will be reinstated if, within four months from the expiration of the specified term, the applicant submits a statement or takes measures to overcome the objections and, within the same term, pays the prescribed resuming fee.

If renewal fees according to Articles 8, 41 and 42 are not paid, the application shall be dismissed without further notification. Applications which have been dismissed on these grounds shall not be reinstated.

### *Article 16*

If, after having received the applicant's statement, the Patent Authority still has objections to the allowance of the application, and the applicant has had an opportunity to submit a statement on the objections, the application shall be refused, unless there are found reasons to give the applicant another opportunity to state his case or amend his application according to Paragraph 1, Article 15.

### *Article 19*

If the application is in accordance with applicable rules and no obstacles to the grant of a patent are found, and the applicant has given his approval to the text of the forthcoming patent, the Patent Authority shall notify the applicant that the patent can be granted upon payment of the fee prescribed for the publication of the patent document.

After the Patent Authority has sent the notification provided for in the first paragraph, the patent claims may not be amended so as to broaden the scope of the protection stated by the patent.

The publication fee shall be paid within two months of the date of notification of the Patent Authority provided for in the first paragraph. In default thereof, the application shall be dismissed. The

processing of such application shall be resumed, however, if within four months after the expiration of this period of time the applicant pays the publication fee and the prescribed resumption fee.

An inventor applying for a patent himself may, within the time specified in the third paragraph, request exemption from payment of the publication fee. The Patent Authority may grant such exemption if the applicant may be regarded as having considerable difficulties in paying the fee. If such a request is refused, a fee paid within two months of the date of refusal shall be considered to have been paid within the proper time limit.

### *Regulations*

#### *Article 26*

Patent applications must be examined in respect of novelty and patentability, cf. Art. 2 of the Patents Act.

A novelty search must take everything that is known into consideration, including published patent applications that have been made available to the public, patents, and other available information and documents if thought necessary. It is permissible to rely on results from foreign institutions which have searched for novelty and patentability.

#### *Article 27*

The Patent Office may under Article 69 of the Patent Act come to an agreement with a foreign patent institution for assistance with novelty search and examination of patent applications.

The Patent Office may also consult external experts if this is considered necessary in order to come to a decision on a patent application.

#### *Article 28*

The Patent Office may require that an applicant submit a model, sample, or the like or that he carry out research or experiments, if this is considered necessary in order to come to a decision on a patent application.

*INDIA: Sections 11A, 11B, 12, 13 and 14 of the Patent Act No. 39 of 1970 as last amended by Act No. 15 of 2005*

#### Publication of applications

11A. "(1) Save as otherwise provided, no application for patent shall ordinarily be open to the public for such period as may be prescribed.

(2) The applicant may, in the prescribed manner, request the Controller to publish his application at any time before the expiry of the period prescribed under sub-section (1) and subject to the provisions of sub-section (3), the Controller shall publish such application as soon as possible.

(3) Every application for a patent shall, on the expiry of the period specified under sub-section (1), be published, except in cases where the application

(a) in which secrecy direction is imposed under section 35; or

(b) has been abandoned under sub-section (1) of section 9; or

(c) has been withdrawn three months prior to the period specified under sub-section (1).

(4) In case a secrecy direction has been given in respect of an application under section 35, then, it shall be published after the expiry of the period prescribed under sub-section (1) or when the secrecy direction has ceased to operate, whichever is later.

(5) The publication of every application, number of application, name and address of the applicant identifying the application and the abstract.

(6) Upon application of an application for a patent under this section

(a) the depository institution shall make the biological material mentioned in the specification available to the public;

(b) the patent office may, on payment of such fee as may be prescribed, make the specification and drawings, if any, of such application available to the public.

(7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted:

Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent: Provided also that after a patent is granted in respect of applications made under sub-section (2) of section 5, the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises.

Request for examination.

11B (1) No application for a patent shall be examined unless the applicant or any other interested person makes a request in the prescribed manner for such examination within the prescribed period. [(2) In case of an application filed before the commencement of the Patents (Amendment) Act, 2002, a request in the prescribed manner for examination shall be made by the applicant or any other interested person within a period of twelve months from the date of such commencement or within forty-eight months from the date of the application, whichever is later.] (omitted by Patents Amendment Act of 2005)

(3) In case of an application in respect of a claim for a patent filed under sub-section (2) of section 5 before the 1st day of January, 2005 a request for its examination shall be made in the prescribed manner and within the prescribed period by the applicant or any other interested person.

(4) In case the applicant or any other interested person does not make a request for examination of the application for a patent within the period as specified under sub-section (1) or sub-section (3), the application shall be treated as withdrawn by the applicant:

Provided that:

- (i) the applicant may, at any time after the filing of the application but before the grant of the patent, withdraw the application by making a request in the prescribed manner; and
- (ii) in a case a secrecy direction has been issued under section 35, the request for examination may be made within the prescribed period from the date of revocation of the secrecy direction.

## 12. Examination of application

(1) When a request for examination has been made in respect of an application for a patent in the prescribed manner under sub-section (1) or subsection (3) of section 11B, the application and specification and other documents related thereto shall be referred at the earliest by the Controller to an Examiner for making a report to him in respect of the following matters, namely:

- a) whether the application and the specification and other documents relating thereto are in accordance with the requirements of this Act and of any rules made thereunder;
- b) whether there is any lawful ground of objection to the grant of the patent under this Act in pursuance of the application;
- c) the result of investigations made under section 13; and
- d) any other matter which may be prescribed.

(2) The Examiner to whom the application and the specification and other documents relating thereto are referred under sub-section (1) shall ordinarily make the report to the Controller within such period as may be prescribed from the date of such reference.

## 13. Search for Anticipation by previous publication and by prior claim

(1) The Examiner to whom an application for a patent is referred under section 12 shall make investigation for the purpose of ascertaining whether the invention so far as claimed in any claim of the complete specification:

- a) has been anticipated by publication before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in India and dated on or after the 1st day of January, 1912;
- b) is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed in pursuance of an application for a patent made in India and dated before or claiming the priority date earlier than that date.

(2) The Examiner shall, in addition, make such investigation for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been anticipated by

publication in India or elsewhere in any document other than those mentioned in sub-section (1) before the date of filing of the applicant's complete specification.

(3) Where a complete specification is amended under the provisions of this Act before the grant of a patent, the amended specification shall be examined and investigated in like manner as the original specification.

(4) The examination and investigations required under section 12 and this section shall not be deemed in any way to warrant the validity of any patent, and no liability shall be incurred by the Central Government or any officer thereof by reason of, or in connection with, any such examination or investigation or any report or other proceedings consequent thereon.

#### 14. Consideration of the Report of examiner by Controller

Where, in respect of an application for a patent, the report of the examiner received by the Controller is adverse to the applicant or requires any amendment of the application, the specification or other documents to ensure compliance with the provisions of this Act or of the rules made thereunder, the Controller, before proceeding to dispose of the application in accordance with the provisions hereinafter appearing, shall communicate as expeditiously as possible the gist of the objections to the applicant and shall, if so required by the applicant within the prescribed period, give him an opportunity of being heard.

#### INDONESIA: *Articles 32 and 48-53 of the Law on Patents No. 14 of 01/08/2001*

##### *Article 32*

(1) Where the requirements as referred to in Article 30 have been fulfilled, however the Application does not fulfill the provisions of Article 24, the Directorate General may request that such deficiencies be fulfilled at the latest 3 (three) months commencing on the date of transmittal of the notification of deficiencies by the Directorate General.

(2) Based on reasons acceptable to the Directorate General, the period as referred to in paragraph (1) may be extended for a maximum of 2 (two) months upon the request of the Applicant.

(3) The period as referred to in paragraph (2) may be extended for a maximum of 1 (one) month as of the date of expiry of the period, provided that a fee has to be paid by the Applicant.

#### Part Two

#### Substantive Examination

##### *Article 48*

(1) A request for the examination of an Application must be filed in writing to the Directorate General with the payment of a fee.

(2) The procedure and requirements regarding the request for a substantive examination shall be further regulated by Presidential Decree.

##### *Article 49*

(1) A request for the substantive examination as referred to in Article 48 paragraph (1) shall be filed at the latest 36 (thirty six) months from the Filing Date.

(2) If a request for examination has not been filed within the period as referred to in paragraph (1), or the pertinent fee has not been paid, the Application shall be deemed withdrawn.

(3) The Directorate General shall notify the Applicant or his Proxy in writing regarding the withdrawal of the Application as referred to in paragraph (2).

(4) If the request for examination as referred to in paragraph (1) is filed before the end of the announcement period as referred to in Article 44 paragraph (1), the examination shall be conducted after the end of the announcement period.

(5) If the request for examination as referred to in paragraph (1) is filed after the end of the announcement period as referred to in Article 44 paragraph (1), the examination shall be conducted after the date of receipt of the request for substantive examination.

##### *Article 50*

(1) For purposes of the substantive examination, the Directorate General may request experts assistance and/or utilize appropriate facilities from other Government agencies or may request the assistance from Examiners of other Patent offices.

(2) The use of expert assistance, facilities, Examiners of other Patent offices as referred to in paragraph (1) shall be performed by observing the provisions concerning the obligation to preserve the confidentiality as referred to Article 40 and Article 41.

*Article 51*

- (1) A substantive examination shall be conducted by Examiners.
- (2) The Examiners at the Directorate General shall hold the position of a functional official and shall be appointed and dismissed by the Minister in accordance with the prevailing rules and regulations.
- (3) Upon the examiner as referred to in paragraph (2) shall be accorded a functional rank and allowances in addition to other rights in accordance with the prevailing regulations.

*Article 52*

- (1) Where the Examiner reports that an Invention for which a Patent has been requested evidently contains vague or other significant deficiencies, the Directorate General shall notify the Applicant or his Proxy and request comments or the completion of such deficiencies.
- (2) The notification as referred to in paragraph (1) shall clearly and specifically state the items considered to be vague or other significant deficiencies together with the reasons and standard or references used in the examination as well as the period for the completion of said deficiencies.

*Article 53*

If following the notification as referred to in Article 52 paragraph (1) the Applicant does not provide any clarification or complete the deficiencies, or does not make any changes or improvements on the Application within the period stipulated by the Directorate as referred to in Article 51 paragraph (2), the relevant Application shall be deemed withdrawn and the Directorate General shall notify the Applicant in writing.

*IRELAND: Articles 29, 30, 31, 34 and 35 of the Patent Act No. 1 of 1992 as last amended by Act No. 31 of 2006*

- 29.-(1) If a patent application under this Part has a date of filing, includes one or more claims and is not withdrawn or deemed to be withdrawn the Controller shall, on the request of the applicant made within the prescribed time, accompanied by the prescribed fee ("the search fee") cause a search to be undertaken in relation to the invention and a report (a "search report") of the results of the search to be prepared. The rules may specify by whom the search report shall be prepared and the scope thereof.
- (2) If it appears, in the course of the search, that an application discloses more than one invention the search shall be conducted in relation only to the first invention specified in the claims. A search may however be conducted in relation to the additional invention, or inventions, if the applicant, within the time allowed by the Controller, submits a request to that effect accompanied by the search fee.
- (3) The Controller shall send a copy of the search report to the applicant and, unless the application is withdrawn within a prescribed period, shall publish it.
- (4) If the application is not withdrawn, the Controller shall allow the applicant an opportunity to amend the application in the light of the search report or reports. Any amendments shall be submitted within the prescribed period. If the applicant fails, before the expiry of the prescribed period, either to submit amendments to the application or a statement that no amendment is considered necessary, the application may be refused by the Controller. In the case of an application to which subsection (2) applies, such application shall be amended so as to confine it to one invention only.

- 30.-(1) In lieu of making the request provided for in section 29(1), an applicant for a patent under this Part may, within the time prescribed for the purpose of section 29(1), submit a statement to the Controller that an application for a patent for the same invention has been made in a prescribed foreign state or under the provisions of any prescribed convention or treaty and where such a statement is submitted the applicant shall submit, within the prescribed period, such evidence as may be prescribed of either-
- (a) the results of the search carried out on the said application, or
  - (b) the grant of a patent in pursuance of the said application.
- (2) The applicant shall, if so required by the Controller, also furnish to the Controller within the prescribed time such information as may be prescribed with regard to the filing of foreign applications for protection of the invention for which a patent is sought.

(3) The evidence submitted under subsection (1) shall be accompanied by the prescribed fee. Unless the application is subsequently withdrawn within a prescribed period the evidence shall be published by the Controller.

(4) Where the evidence submitted is that referred to in subsection (1)(a) the Controller shall, unless the application is withdrawn, allow the applicant an opportunity to amend the application in the light of that evidence. Any amendments shall be submitted within the prescribed period. If the applicant fails, before the expiry of the prescribed period, either to submit amendments to the application or a statement that no amendment is considered necessary, the application may be refused by the Controller.

(5) Where the evidence submitted is that referred to in subsection (1)(b) the Controller shall, unless the application is withdrawn, allow the applicant an opportunity to amend the application in the light of that evidence. The applicant shall in particular submit such amendments as are required to the specification so that the subject-matter claimed therein does not extend beyond that of the evidence. Any amendments shall be submitted within the prescribed period. If the applicant fails, before the expiry of the prescribed period, either to submit amendments to the application or a statement that no amendment is considered necessary the application may be refused by the Controller.

(6) Any amendment or statement submitted in pursuance of subsections (4) and (5) or section 29(4) shall, where a duly authorized patent agent acts on behalf of the applicant, be submitted by such agent.

31.-(1) If it appears to the Controller that an application does not comply with a requirement of this Act or the rules made thereunder (other than the requirements of sections 9(1), 11, 13, 14, 19 and 20), the Controller shall so inform the applicant and if the applicant, within the time specified by the Controller, fails to satisfy the Controller that the said requirement is complied with or to amend the application so as to comply therewith the Controller may, subject to section 90, refuse the application.

(2) Nothing in subsection (1) shall preclude the Controller from refusing, or requiring amendment of, a patent application by reference to any requirement of a section mentioned in that subsection which may be specified in rules.

(3) A patent shall not be granted by the Controller until he has requested the applicant to pay the prescribed fee for the grant of a patent and the applicant has paid the said fee within the prescribed time. If the said fee is not so paid, the application shall be deemed to be withdrawn.

(4) The grant of a patent shall be notified to the applicant in the prescribed form.

(5) Where two or more patent applications for the same invention having the same date of filing or the same date of priority are filed by the same applicant or his successor in title, the Controller may on that ground refuse to grant a patent in respect of more than one of the applications.

34.-(1) The Controller shall as soon as practicable after a patent has been granted publish a notice of the grant in the Journal.

(2) At the same time as the publication of the notice of a grant, the Controller shall publish a specification of the patent containing the description and claims, and drawings (if any), and also such matters and information as appear to him to be useful or important.

35.-(1) A pending application shall lapse at the end of the period prescribed for the payment of any renewal fee if the fee is not paid within that period or within that period as extended under this section.

(2) The period prescribed for payment of any renewal fee shall be extended by such period, not being a period of more than six months, as may be specified in a request made in that behalf by the applicant to the Controller if the request is made and the prescribed additional fee paid before the expiration of the period of extension so specified.

(3) The provisions of section 37 shall apply to an application to which this section relates as if the references in that section to a patent and the proprietor of a patent were references to a patent application and the applicant for a patent, respectively.

ISRAEL: *Sections 17, 18, 18A and 18B of the Patents Law No. 5727 of 08/08/1967*

17.-(a) The Registrar or an examiner shall examine whether the application meets all the following conditions:

(1) the invention in it is patentable within the meaning of Chapter Two;

(2) the application complies with the provisions of Article One of this Chapter;

(3) the applicant paid the publication expenses under section 26.

(a1) The examiner shall accept the application if he is satisfied that the conditions of this section have been met; when he has accepted the application, he shall so notify the applicant; the notice shall state the acceptance date.

(b) Notwithstanding the provisions of subsection (a)(1), no examination shall be necessary if the invention is unpatentable by virtue of section 4(2).

(c) If the conditions specified below are met by an application, then it shall be deemed to have complied with the provisions of section 4, 5, 8, 12 and 13:

(1) the applicant submitted a patent application on the same invention (in this section: parallel application) and received a patent in a state, the name of which appears in the list published by the Registrar in Reshumot (in this section: parallel patent), and all the following hold true:

(a) priority right was lawfully claimed for the patent application in Israel under section 10, by virtue of the parallel application;

(b) priority right was claimed for the parallel application under the Law applicable to it, by virtue of the patent application in Israel;

(c) priority right was lawfully claimed for the patent application in Israel by virtue of another application for protection submitted in a Convention State, and by virtue of the other application priority right was claimed for the parallel application under the Law applicable to it;

(2) the applicant requested in writing that the provisions of this section be applied to his patent application;

(3) the applicant delivered to the Office the claims in the parallel patent, translated to the language in which his patent application was submitted in Israel;

(4) the claim or claims in the application are identical to the claims in the parallel patent, but the application can include fewer claims than those in the parallel patent;

(5) the applicant submitted a description and drawings identical to those in the parallel patent, or a description and drawings as said in section 12.

(d) The Registrar and also the Superintendent of Examiners or his deputy may refrain from accepting an application, if they determined on the basis of the material at their disposal or submitted to them in the course of the examination that the application does not comply with one of the provisions specified in subsection (c) or that there is some other special reason why the application should not be accepted.

(e) If proceedings for cancellation of the parallel patent are in progress, or if proceedings of opposition to the grant of the parallel patent outside of Israel are in progress, then the applicant shall so notify the Registrar not later than the date on which the patent is granted in Israel.

(f) For purposes of this section, "state"-including a group of states who maintain a joint system for the grant of patents.

[Additional means of examination]

18.-(a) The examiner shall use at least one of the following additional means of examination:

(1) the list of documents used by patent authorities in any foreign state in the examination of a patent application on the same patent application, submitted in a foreign country by the applicant or by his predecessor in title to the invention;

(2) a list of documents published before the application date, known to the applicant and directly connected with the invention;

(3) copies of publications and documents, a list of which the applicant must submit under this Article, if the examiner so demands;

(4) copies of publications and documents mentioned in publications and documents, a list of which the applicant must submit under this Article, if the examiner so demands;

(5) transmission of the specifications of the application-in order to search for material that will enable the Office make the examination-to an institution in Israel or abroad, with which the Office contracted under any Law by an agreement drawn up by the Registrar, including a section on keeping any patent application confidential and on nondisclosure under section 165;

and to that end he may do one or more of the following:

(1) require the applicant to submit to him all the documents specified in paragraphs (1) to (4);

(2) transmit the specification in the application for the search said in paragraph (5).

Applicant must keep Office informed

18A. Until the application is accepted the applicant must keep the Office informed of any change in the list of publications and documents said in section 18, if he or his representative was made aware of the said changes.

Notice of institutions that assist in the examination

18B. The Registrar shall publish a notice in Reshumot of the institutions with which the Office contracted under section 18(5), and of the categories of applications in respect of which he intends to use the means specified in the said section.

*ITALY: Article 170 (1) (b) and (3) of the Code of the Industrial Property, Legislative Decree No. 30 of 15/02/2005*

*Art. 170*

Esame delle domande

1. L'esame delle domande, delle quali sia stata riconosciuta la regolarità formale, e' rivolto ad accertare:

b) per le invenzioni ed i modelli di utilità che l'oggetto della domanda sia conforme a quello previsto dagli articoli 45, 50 e 82, esclusi i requisiti di validità, fino a quando non sarà disciplinata la ricerca delle anteriorità con decreto ministeriale a meno che la loro assenza risulti assolutamente evidente sulla base delle stesse dichiarazioni ed allegazioni del richiedente oppure sia certa alla stregua del notorio;

3. Qualora non si riscontrino le condizioni sopra indicate, l'Ufficio italiano brevetti e marchi provvede ai sensi dell'articolo 173, comma 7.

*JAPAN: Articles 47-49 of the Patent Act No. 121 of 1959 as last amended by Act No. 109 of 2006(Effective September 30, 2007)*

*Article 47 (Examination by examiner)*

(1) The Commissioner of the Patent Office shall direct the examination of patent applications by an examiner.

(2) The qualifications of examiners shall be as prescribed by Cabinet Order.

*Article 48 (Exclusion of examiners)*

Articles 139(i) to 139(v) and 139(vii) shall apply mutatis mutandis to examiners.

*Article 48-2 (Examination of patent applications)*

The examination of a patent application shall be initiated after the filing of a request for examination.

*Article 48-3 (Request for examination of application)*

(1) Where a patent application is filed, any person may, within 3 years from the filing date thereof, file with the Commissioner of the Patent Office a request for the examination of the said application.

(2) In the case of a new patent application arising from the division of a patent application under Article 44(1), or a patent application arising from the conversion of an application under Article 46(1) or 46(2), or a patent application based on a

utility model registration under Article 46-2(1), a request for the examination of the said patent application may be filed even after the lapse of the time limit prescribed in the preceding paragraph, but not later than 30 days following the division of a patent application, conversion of application or filing of patent application based on a utility model registration.

(3) A request for the examination of a patent application may not be withdrawn.

(4) Where a request for the examination of an application is not filed within the time limit as provided in paragraph (1) or (2), the said patent application shall be deemed to have been withdrawn.

*Article 48-4*

A person(s) filing a request for the examination of an application shall submit a written request to the Commissioner of the Patent Office stating the following :

(i) the name and domicile or residence of the demandant; and

(ii) the identification of the patent application for which the examination is requested.

*Article 48-5*

(1) Where a request for the examination of an application is filed, in the case where such request is filed prior to the laying open of the application, the Commissioner of the Patent Office shall publish the fact thereof in the patent gazette either at the time of laying open of the application or thereafter without delay, and in the case where such a request is filed after laying open of the application, without delay after laying open.

(2) Where a request for the examination of an application is filed by a person other than the applicant for a patent, the Commissioner of the Patent Office shall notify the applicant thereof.

*Article 48-6 (Preferential examination)*

Where it is recognized that a person other than the applicant is working the invention claimed in a patent application as a business after the laying open of the application, the Commissioner of the Patent Office may, where deemed necessary, cause the examiner to examine the patent application in preference to other patent applications.

*Article 48-7 Notice of ( statement of information concerning invention known to the public through publication)*

Where the examiner recognizes that a patent application does not comply with the requirements as provided in Article 36(4)(ii), the examiner may notify the applicant of the patent thereof and give the said applicant an opportunity to submit a written opinion, designating an adequate time limit for such purpose.

*Article 49 (Examiner's decision of refusal)*

The examiner shall render an examiner's decision to the effect that a patent application is to be refused where the patent application falls under any of the following:

(i) an amendment made to the description, scope of claims or drawings attached to the application of a patent application does not comply with the requirements as provided in Article 17-2(3) or (4);

(ii) the invention claimed in the patent application is not patentable under Article 25, 29, 29-2, 32, 38 or 39(1) to 39(4);

(iii) the invention claimed in the patent application is not patentable under the provisions of any relevant treaty;

(iv) the patent application does not comply with the requirements under Article 36(4)(i), 36(6), or 37;

- (v) where notice under the preceding Article has been given, following the amendment of the description or submission of the written opinion, the patent application does not comply with the requirements under Article 36(4)(ii);
- (vi) where the patent application is a foreign language written application, matters stated in the description, scope of claims or drawings attached to the application of the said patent application do not remain within the scope of matters stated in foreign language documents ; and
- (vii) where the applicant for the patent is not the inventor, the applicant has not succeeded to the right to obtain a patent for the said invention.

JORDAN: *Articles 13 and 16 of the Law on Patents of Invention No. 32 for the Year 1999(as last amended by Law No. 71 of 2001)*

*Article 13*

A. If the application meets the conditions prescribed in this law, the Registrar shall declare his acceptance of it and grant the applicant a preliminary acceptance. Then he shall publish a notice in the Official Gazette including the abstract of the invention or any drawings or particulars relating thereto, if any. The period in which publication should take place and the particulars to be published shall be determined in the regulations to be issued for this purpose.

B.1. Without prejudice to the provisions of Article 36 of this law, the applicant shall have a provisional protection during the period between the acceptance date and the grant date. In this case the applicant shall have the right to exploit the invention and to take measures to prove any infringement upon his invention during this period.

2. The applicant shall be entitled to take, after the patent grant, any legal measures to stop an infringement upon his patent and to claim damages if the infringement continues.

*Article 16*

The Registrar shall not be held answerable as regards the novelty, inventive step, industrial applicability, the standardization compliance, or the usefulness of the invention patent, and all those shall rest with the patentee.

KENYA: *Sections 41 (7), (8) and (9) and 44 of the Industrial Property Act No. 3 of 27/07/2001*

Filing date, examination as to form

41.-(7) The Managing Director shall cause an examination to be carried out as to whether there are any of the following defects with respect to the application:

- (a) the request does not comply with the requirements of section 34(3) and the rules pertaining thereto;
- (b) the description, the claims and, where applicable, the drawings do not comply with the physical requirements prescribed by the regulations;
- (c) the application does not contain an abstract;
- (d) the applicant has not complied with a request of the Managing Director under section 38; or
- (e) the fees referred to in section 39 have not been paid as provided for in the regulations or the payment of such fees has been waived under that section.

(8) If the Managing Director finds any of the defects referred to under subsection (7), he shall invite the applicant to remedy such defects provided that any corrections made to the application shall not be such that they would require a change of the filing date and if the applicant does not comply with the invitation, the application shall be rejected by the Managing Director.

(9) The details of the requirements and the procedure under this section shall be prescribed by the regulations.

Examination as to Substance

44.-(1) The Managing Director may, by notice in the Kenya Gazette or in the Industrial Property Journal

- (a) direct that applications for patents relating to a specified field or specified technical fields shall be the subject of an examination as to substance; or

(b) amend any direction issued pursuant to paragraph (a).

(2) Where an application for a patent satisfies the requirements specified in subparagraph (7) of section 41 and the subject matter thereof does not fall within a technical field specified under subsection (1) of this section, the Managing Director shall so notify the applicant who shall, within three years from the filing date of the application, submit a request in the prescribed form for the examination of the application pursuant to the provisions of subsection (3):

Provided that where no request is made within the prescribed period, the application shall be deemed to be abandoned.

(3) Where a request is filed under subsection (2), the Managing Director shall cause an examination of the application to be made as to whether

(a) the invention in respect of which the application is made is patentable within the meaning of this Act; and

(b) the application complies with the requirements of subsections (5) and (6) of section 34.

(4) For the purposes of the examination under subsection (3), the Managing Director may submit the application together with the relevant documents to an examiner or other competent authority for examination as to the patentability of the claimed invention and the examiner or other competent authority shall submit a report of the findings of the examination to the Managing Director who shall submit a copy thereof to the applicant.

(5) Save where an application is subject to an international-type search under section 43, the Managing Director shall cause an examination to be carried out as to whether the application complies with the requirements of unity of invention prescribed under section 35 and the rules pertaining thereto.

(6) If the Managing Director is of the opinion that the requirements of unity of invention have not been complied with, he shall invite the applicant to restrict or divide the application:

Provided that where the applicant fails to do so, the Managing Director shall reject the application.

(7) Where, taking due account of the conclusions of any report referred to in subsection (5), the Managing Director is of the opinion that any of the conditions referred to in subsection (2) are not fulfilled, he shall notify the applicant accordingly and invite him to submit his observations and, where applicable, to amend his application.

(8) Where, despite any observation or amendment submitted by the applicant, the Managing Director finds that any of the conditions referred to in subsection (2) are not fulfilled, he shall refuse the grant of a patent and notify the applicant accordingly.

(9) The details of the requirements and the procedure to be followed under this section shall be prescribed by the regulations.

*KYRGYZSTAN: Articles 23, 23-1, 23-2 and 24 of the Patent Law No. 8 of 14/01/1998, as last amended by Law No. 46 of 27/02/2003*

#### *Article 23*

##### Examination of the Application for an Invention

Kyrgyzpatent shall conduct formal and preliminary examination of an application.

At the petition of the applicant, which can be filed with Kyrgyzpatent simultaneously with application filing or within 30 months since the date of filing, consideration of the application can be made with or without examination on the essence. If petition is not submitted within said period, the application is considered as withdrawn.

*Article 23-1*

Formal Examination of the Application for an Invention

During the formal examination of the application for an invention within two-month-period the constitution and accuracy of required documents provided by Article 18 of this Law are checked as well as accordance of the claimed proposal to the objects for which the legal protection is provided. If after completion of formal examination it is determined that application is filed for proposal not related to the objects for which the legal protection is provided, the decision on refusal on patent grant is made.

If an application is filed with violations of requirements prescribed to registration and compilation, the applicant shall receive a request with proposal to submit corrected or absent materials within two-month-period since the date of receipt of the request.

If applicant shall not submit requested documents or petition for prolongation of effective terms, the application is considered as withdrawn.

If the application meets all the requirements of formal examination, a notification that the application is accepted for consideration shall be sent to the applicant.

*Article 23-2*

Preliminary Examination of the Application for an Invention

While conducting preliminary examination, Kyrgyzpatent within ten-month-period shall check compliance of the prescribed requirements to contents of the application documents, compliance of the claimed invention with the criteria of patentability of the materials of an application provided by the applicant, non-withdrawn applications with an earlier priority, the fund of issued protected documents of the Kyrgyz Republic, as well as published Eurasian applications and patents and shall establish the priority of the invention and check compliance of the application with requirements for the unity of the invention.

The applicant upon the payment of appropriate fee may submit a petition for conduct of rapid preliminary examination for the application for invention. In the event that before expiration of twelve-month-period since the date of filing of the application with Kyrgyzpatent or when priority is required since the date of priority, the decision on patent grant is made or patent is granted and similar application concerning vindication of earlier priority is filed, the decision on patent grant or patent is canceled.

If the applicant, in accordance with Article 22 of this Law, provided additional materials, in the course of the preliminary examination it shall be checked, that they do not change the essence of the claimed invention.

Additional materials shall change the essence of the claimed invention if they contain features that are supposed to be included into the formula of an invention which have been absent from the initial materials of an application. Additional materials of the part, which change the essence of the claimed invention, shall be taken into account in the course of consideration of an application and may be registered by the applicant as an independent application.

On applications, which had been filed with violations of the requirements of unity, an applicant shall be offered to inform, within two-month-period, which of the proposals must be considered, and clarify documents of the application.

Other decisions, included in the materials of the initial application, may be formalized as separate applications.

In the event, if the applicant within two months from the date of receipt of the notification on the violation of the requirement of the unity of an invention does not inform which of the proposals should be considered and does not submit specified documents, the first mentioned in the formula proposal shall be considered.

During the preliminary examination Kyrgyzpatent may request from the applicant any additional materials, which are necessary for examination conduct. The additional materials by the request of examination should be submitted within two-month-period since the date of receipt of the request.

In the event, if the applicant fails to provide required materials or the petition for extension of the established term, within the indicated term, the application shall be deemed withdrawn.

On the application, which has passed preliminary examination with a positive result, a decision to grant preliminary patent shall be made which is granted under responsibility of the applicant.

According to the results of preliminary examination in the presence of petition to conduct examination on the essence or in the absence of said petition or petition on patent grant without examination of the application on the essence, the applicant shall receive a notification.

If in the result of the preliminary examination it is established that the claimed proposal is not patentable, a decision on refusal to grant a patent shall be made.

The applicant may file an objection to this decision with the Appellate Council within two months after the receipt of refusal to grant a patent. The Appellate Council must consider the objection within two months as of the date of its receipt.

In the event the applicant does not agree with the decision of the Appellate Council he may appeal to court within six months as of the date of its receipt.

After expiration of 18 months since the date of application filing or if priority is required since the date of priority Kyrgyzpatent shall publish the information related to the application in Official Bulletin with the exception of cases when application is withdrawn or when decision on patent grant or refusal is made. Kyrgyzpatent shall determine the list and completeness of published information.

On the applicant's petition provided that appropriate fee is paid Kyrgyzpatent may publish the information related to application till 18 months since the date of its filing, or if priority is required since the date of priority.

While petition on patent grant without examination on essence is filed after preliminary examination completion, the decision on patent grant is made within two-month-period since the date of receipt of said petition.

#### *Article 24*

##### Examination of Application for Invention on Essence\Substance

Kyrgyzpatent within 18 months since the date of petition submission shall conduct examination of the application on the essence. An applicant shall be notified about petitions submitted by the third parties. During conduct of the examination on the essence compliance of the claimed invention to conditions of patentability specified in Article 5 of this Law.

During examination of an application on substance Kyrgyzpatent shall be entitled to request the applicant to submit materials without which examination procedure is not possible, including changed formula of the invention.

Additional documents on the request of examination shall be submitted without changing the essence of the invention during two months from the date of receipt of the request.

The order established by paragraphs 11 and 12 of this Article shall extent to additional documents in the part that changes the essence of an invention.

If in the result of scientific-technological examination of an application on essence Kyrgyzpatent finds that the claimed proposal, within the scope of legal protection required by an applicant, meets the requirements of patentability of the invention, the decision to grant a patent with the formula of an invention suggested and agreed with the applicant is made.

If the claimed proposal does not meet the requirements of patentability within the scope of legal protection required by an applicant, the decision on rejection to grant a patent shall be issued.

The applicant may file an objection against the decision on rejection to grant a patent with the Appellate Council during three months from the date of its receipt. The objection must be considered by the Appellate Council during four months from the date of its receipt.

Should the applicant not agree with the decision of the Appellate Council he may, within six months from the date of its receipt, appeal to court.

The applicant shall have the right to familiarize himself with all the materials indicated in the decision of examination or in the search report. Copies of the patent materials requested by the applicant shall be sent by Kyrgyzpatent during one month from receipt of the request.

The terms provided in Article 23-1, 23-2 and this Article, except for the terms established in paragraph 15 of Article 23-2 and paragraphs 9 of this Article, elapsed by the applicant, may be reinstated by Kyrgyzpatent in the presence of proof of excusable reasons and payment of the fee.

The petition to reinstate the term may be filed by an applicant not later than twelve months from the date of expiration of the elapsed term.

Both applicant and third parties may submit a petition on informational search conduct on the application for invention to determine technical level in comparison with which valuation of patentability of the invention is made. Kyrgyzpatent determine the order of informational search and information provision.

LAO PEOPLE'S DEMOCRATIC REPUBLIC: *Sections 37, 39 and 40 of the Intellectual Property Laws No. 08/NA of 24/12/2007*

Section 37: Preliminary Examination of Application Form for the Registration of Industrial Property  
Preliminary examination of application form for the registration of industrial property comprises the following steps:

1. Completeness of application form
  2. Conditions for protection
  3. Right of the applicant
- Page 13
4. Payment of fee

After preliminary examination, if it is deemed that the application form is not complete, the registration office shall inform the applicant to make amendment within 60 days from the date of issue of the notice.

Section 39: Request for Substantive Examination of the Application for Registration of Invention or Device

In case the applicant cannot submit substantive examination report on the invention or device for which a registration is requested, the applicant can request the registration office to perform substantive examination of said application. This can be done within 32 months for the invention and 12 months for the device from the application date or the priority date. The applicant shall bear the expenses for the request for the substantive examination for the registration of invention or device.

Section 40: Substantive Examination of the Application for the Registration of Industrial Property Right  
After preliminary examination by the registration office having been completed, the registration office shall perform the substantive examination of the application for registration of industrial design, trademark and source of origin

There will be no substantive examination on the integrated circuit design.

LATVIA: *Sections 34 and 37 of the Patent Law of 15/02/2007*

Section 34. Examination of the Formal Requirements of a Patent Application

(1) When a filing date of the patent application has been allocated, the Patent Office shall examine whether the filed application conforms with the requirements of Section 6, Paragraph two, Section 28, Paragraphs five, six and seven, Section 29, Paragraph three, Section 30, Paragraph three and Section 32 of this Law. The examination shall be carried out within three months from the filing date of the application to the Patent Office. Within this time period, the Patent Office shall prepare an abstract for publication.

(2) If the patent application conforms with the specified requirements, the Patent Office shall inform the applicant regarding the completion of the examination of the formal requirements and the date of the publication of the application.

(3) If the patent application does not conform or conforms partly with the specified requirements, the Patent Office shall notify the applicant thereof, explaining the non conformity, and shall determine a time period of three months for the elimination of the deficiencies and for the expression of their considerations.

(4) If the applicant has not eliminated the deficiencies indicated by the Patent Office, the application shall be rejected. The applicant shall be notified in writing thereof.

Section 37. Substantive Examination of the Patent Application

(1) The Patent Office shall examine whether the patent application conforms with the requirements of Section 8, Paragraph two, Section 9 and 10, Section 30, Paragraphs one and two and Section 36 of this Law. The Patent Office shall not carry out the patentability examination of an invention during the process of the substantive examination of a patent in conformity with the requirements of Sections 5 and 7 and Section 8, Paragraph one of this Law.

(2) If the applicant has not fulfilled the requirements of Section 31 of this Law regarding the unity of invention, the further record-keeping related to the patent application shall be maintained only in relation to the first claim of the application, unless the applicant, responding to the notification of the Patent Office regarding the non-observance of the requirements of the referred to Section, has informed the Patent Office regarding the division of the application or has requested to examine only

those claims which relate to the invention or group of inventions and conform with the requirements regarding the unity of invention. The procedures for the filing of the divisional patent application shall be determined by the Cabinet.

(3) If the patent application does not conform or partially conforms with the requirements of this Section, the Patent Office shall notify the applicant thereof, explaining the non-conformity, and shall determine a time period of three months for the elimination of the specified deficiencies.

(4) If the applicant has not eliminated the deficiencies specified by the Patent Office, the Patent Office shall take the decision regarding the rejection of the application. It shall be notified to the applicant in writing.

LEBANON: *Articles 12 and 16 of the Patent Law No. 240 of 14/08/2000*

*Article 12*

a. If the invention is among the inventions mentioned in Articles 3 and 4 of the Law herein stated the Head of the Intellectual Property Protection Authority shall inform the applicant of such findings within a period of thirty days from the date of the recording, otherwise the filing application shall be deemed accepted. The applicant may present his remarks of such findings within sixty days of being officially informed of such.

b. The Head of the Intellectual Property Protection Authority shall present a detailed report to the Minister of Economy and Trade together with the remarks of the applicant within thirty days of being notified of the remarks of the patent applicant.

c. The Minister of Economy and Trade shall issue a decision either to accept or reject the filing application within sixty days from the day of the detailed report is presented to him by the Head of the Intellectual Property Protection Authority. The decision of the Minister may be appealed against by the applicant before the Civil Court of Appeal of Lebanon within thirty days of notification of such decision.

d. If the filing application is rejected based upon stipulations of Articles 3 and 4 of the present Law, all fees paid shall be deemed to be revenues of the treasury.

*Article 16*

The patent is issued without guarantee as to the soundness, value, novelty, honesty or precision of description, industrial applicability or creativity of the invention.

LIBERIA: *Section 15 (3), (4) and (5) of the Industrial Property Act of 20/03/2003*

15.- (3) After according a filing date, the Director General shall examine whether the application complies with the requirements of Section 11 (1) and (2) and the Regulations pertaining thereto and those requirements of this Act and the Regulations which are designated by the Regulations as formal requirements for the purposes of this Act and whether information requested under Section 14, if any, has been provided.

(4) Where the Director General is of the opinion that the application complies with the requirements indicated in subsection (3), the Director General shall take a decision as to whether the requirements of Section 8(2) and (3), 31 (3) (4) and (5) and 12 and the Regulations pertaining thereto are fulfilled and for this purpose may, as provided for in the Regulations, cause the application to be examined.

(5) The Director General shall take into account, for the purposes of subsection (4):

(i) the results of any international search report and any International preliminary examination report established under the PACT in relation to the application, and/o:

(ii) any search and examination report submitted under Section 14(2)(i) relating to, or a final decision submitted under Section 14(2)(iii) on the refusal to grant a patent on, a corresponding foregoing application; and/or

(iii) any search and examination report which was carried out upon his request by an external search and examination authority.

LITHUANIA: *Article 19 of the Patent Law No. I-372 of 18/01/1994 as last amended by Law No. X-1119 of 10/05/2007*

*Article 19*

Examination

The State Patent Bureau shall make an examination of a patent application and establish whether the application complies with the requirements provided for in paragraphs 2 and 3 of Article 2, in Article 11, paragraphs 2 and 3 of Article 13, as well as in Articles 14 and 18.

After having found that the application does not meet the requirements of the Articles set out in paragraph 1 of this Article, the State Patent Bureau shall invite the applicant to meet such requirements within a period prescribed by the State Patent Bureau. If the applicant fails to do so, the application shall be deemed to be withdrawn.

After having determined that an invention is unpatentable on the grounds laid down in paragraphs 2, 3 and (or) 4 of Article 2 of this Law, the State Patent Bureau shall make a decision to refuse granting a patent.

LUXEMBOURG: *Articles 35, 36, 39 and 41 of the Patent Act of 20/07/1992*

*Article 35*

Recherche documentaire

1. Le demandeur d'un brevet doit, sous peine de voir considérer sa demande comme rejetée, présenter dans un délai de sept ans à partir de la date du dépôt de sa demande ou dans les conditions de l'article 31

a) soit une requête en vue de l'établissement, par un organisme international à désigner par arrêté grand-ducal, d'un rapport de recherche ;

b) soit un ou plusieurs rapports de recherche établis par un organisme international désigné par arrêté grand-ducal, pour autant que ces rapports sont basés sur une ou des demandes de brevet ou titre de propriété industrielle analogue

(i) dont la ou les priorités sont revendiquées par la demande de brevet luxembourgeois, ou

(ii) qui revendiquent la même ou les mêmes priorités que la demande de brevet luxembourgeois, ou

(iii) qui revendiquent la priorité de la demande de brevet luxembourgeois,

accompagnés d'une copie certifiée conforme desdites demandes de brevet ou titre de propriété industrielle analogue, s'il s'agit de demandes étrangères ou régionales, ainsi que d'une traduction de celles-ci dans les cas prévus par le règlement grand-ducal :

c) soit encore un rapport de recherche établi par un organisme international désigné par arrêté grand-ducal, pour autant que ce rapport est basé directement sur le contenu de la demande de brevet luxembourgeois, objet de la recherche.

2. Le rapport de recherche visé au paragraphe 1er litt. a) est établi sur la base des revendications, en leur dernier état, en tenant compte de la description et, le cas échéant, des dessins y annexés. Il énumère les éléments de l'état de la technique qui peuvent être pris en considération pour apprécier la nouveauté de l'invention, objet de la demande de brevet, et l'activité inventive.

3. Les rapports de recherche visés au paragraphe 1er sont acceptés en langue française, allemande ou anglaise ou doivent être accompagnés d'une traduction dans une de ces trois langues.

4. Le demandeur est dispensé de produire les pièces visées ci-dessus, si la demande a fait l'objet d'une intervention d'un tiers dans le sens de l'article 36.

5. La requête en vue de l'établissement du rapport de recherche n'est pas recevable si elle n'est pas accompagnée de la preuve de paiement des taxes de recherche, si elle ne satisfait pas aux autres exigences de la présente loi, ou si la demande de brevet est en instance de régularisation pour quelque motif que ce soit par application des dispositions de l'article 30.

6. L'organisme international établit le rapport de recherche sur la partie de la demande de brevet rattachée à l'objet principal des revendications et sur les parties de la demande de brevet pour lesquelles les taxes de recherche additionnelles requises ont été payées dans le délai prescrit. Les parties de la demande de brevet pour lesquelles les taxes de recherche additionnelles n'ont pas été payées dans le délai prescrit sont considérées comme retirées, si elles ne font pas l'objet de demandes divisionnaires dans les conditions de l'article 31. La requête en vue de l'établissement du

rapport de recherche doit mentionner les pièces visées au paragraphe 1er, litt. b) ou c), qui seraient produites par le titulaire de la demande de brevet, et spécifier les parties de la demande de brevet auxquelles les pièces ainsi mentionnées se réfèrent.

#### *Article 36*

Demande de recherche introduite par un tiers

1. A partir de la date de la mise à la disposition du public du dossier relatif à la demande de brevet et jusqu'à l'expiration d'un délai de sept ans à compter de la date de dépôt de la demande, les tiers sont habilités à introduire, dans les conditions à fixer par règlement grand-ducal, une requête en vue de l'établissement d'un rapport de recherche au sens de l'article précédent, tant que le demandeur ne s'est pas conformé à ce dernier.

2. L'intervention d'un tiers selon le paragraphe 1er est signalée au titulaire de la demande de brevet qui reçoit un exemplaire du rapport de recherche ainsi établi et qui reste le seul à pouvoir faire usage de la faculté prévue à l'article 37.

#### *Article 39*

1. Si l'instruction de la requête en vue de l'établissement d'un rapport de recherche ne peut avoir lieu au sein de l'organisme désigné par arrêté grand-ducal en raison de l'exclusion temporaire des activités de recherche de secteurs déterminés de la technique, et si l'organisme décide en l'espèce de ne pas procéder à la recherche, le service transmet au demandeur la décision y relative de l'organisme, laquelle se substitue au rapport de recherche aux fins de la délivrance du brevet.

2. Si l'organisme chargé de l'établissement du rapport de recherche estime

a) que la description, les revendications ou les dessins ne remplissent pas les conditions prescrites, dans une mesure telle qu'une recherche significative ne peut pas être effectuée, ou

b) que la demande de brevet concerne un objet ne répondant pas à la notion d'invention ou de matière brevetable ou à l'égard duquel il n'est pas tenu, pour d'autres raisons, de procéder à la recherche,

et déclare qu'un rapport de recherche ne sera pas établi, le service transmet la déclaration y relative au demandeur, auquel il impartit un délai de quatre mois pour corriger les éléments défectueux de la demande de brevet par application de l'article 37 et renouveler la requête en vue de l'établissement du rapport de recherche.

Si, après le renouvellement de la requête en vue de l'établissement du rapport de recherche, l'organisme estime ne pas être en mesure de modifier ses conclusions au regard de la demande de brevet, telle que corrigée une première fois, le demandeur peut introduire une pétition par laquelle il sollicite d'emblée la délivrance de son brevet, ainsi qu'une brève justification de cette pétition. La pétition n'est recevable que sous la condition qu'elle soit remise avant l'expiration du nouveau délai imparti par le service conformément à l'alinéa 1er, pour autant toutefois que ce nouveau délai expire postérieurement au terme d'un délai à fixer par règlement grand-ducal ou, à défaut, postérieurement au terme du délai qui est visé à l'article 35, paragraphe 1er.

Dans l'hypothèse de l'alinéa 2, le service peut proposer au ministre de ne pas délivrer le brevet, en émettant un avis motivé à cet effet. Les conditions d'application des dispositions du présent alinéa ainsi que les modalités de l'avis seront fixées par règlement grand-ducal.

3. Si les mêmes conclusions résultent des pièces visées à l'article 35, paragraphe 1er, litt. b) ou c), le service procède conformément aux dispositions des paragraphes 1er et 2 respectivement.

4. Si le service constate que la requête en vue de l'établissement du rapport de recherche visé à l'article 35, paragraphe 1er, litt. a) ne satisfait pas aux exigences du règlement d'exécution, il impartit au requérant un délai de quatre mois pour se conformer à ces exigences.

Si le service constate que les pièces produites en application de l'article 35, paragraphe 1er, litt. b) ou c) ne répondent pas aux exigences de la présente loi ou de son règlement d'exécution, il en informe le titulaire de la demande de brevet et lui impartit un délai de quatre mois pour régulariser les pièces

précitées ou pour présenter la requête en vue de l'établissement du rapport de recherche visée à l'article 35, paragraphe 1er, litt. a).

5. Le délai imparti par le service en vertu des paragraphes qui précèdent peut dépasser le terme du délai qui est prévu à l'article 35, paragraphe 1er. Si le titulaire de la demande de brevet ne se conforme pas à l'invitation du service dans le délai imparti, la délivrance du brevet est refusée par arrêté ministériel. Toutefois, si à la date d'expiration du délai imparti par le service, le délai de l'article 35, paragraphe 1er n'est pas encore venu à échéance, seules sont refusées la requête en vue de l'établissement du rapport de recherche et les pièces visées à l'article 35, paragraphe 1er, litt. b) ou c) respectivement. Le cas échéant, les taxes de recherche sont remboursées sous déduction des frais encourus à l'occasion du remboursement.

Délivrance du brevet

#### *Article 41*

1. Le titre constituant le brevet d'invention est délivré sous forme d'un arrêté du ministre.

2. Cet arrêté est pris dès l'accomplissement des formalités prévues pour la délivrance du brevet ou, le cas échéant, dès l'expiration du délai d'intervention accordé au titulaire de la demande de brevet conformément à l'article 37 et à condition que les annuités dues aient été valablement acquittées à cette date ou, le cas échéant, soient susceptibles de l'être à la date d'expiration du délai de grâce en cours.

3. Si, à la date de l'accomplissement des formalités susmentionnées ou à la date d'expiration du délai d'intervention précité il est constaté que la taxe annuelle échue ne peut plus être valablement payée compte tenu de l'expiration du délai de grâce, la demande est réputée retirée et le brevet n'est pas délivré.

4. La délivrance des brevets se fait sans examen préalable de la brevetabilité des inventions, sans garantie de l'exactitude de la description et aux risques et périls des demandeurs.

MADAGASCAR: *Articles 24-26 (1) of the Industrial Property Law, Ordinance No. 89 019 of 31/07/1989*

#### *Article 24*

1 L'examen administratif de la demande consiste à vérifier le paiement de la taxe prescrite et la régularité des principales pièces du dépôt:

- i) l'établissement de la demande;
- ii) la correcte présentation de la description et des revendications;
- iii) la présence des planches de dessins et leur bonne exécution aux fins de reproduction; le cas échéant :
- iv) le pouvoir du représentant ou du mandataire;
- v) les traductions réclamées;
- vi) les documents relatifs à la cession de priorité ainsi que tout autre document justificatif se rapportant aux droits du véritable inventeur.

2 L'examen administratif de la demande consiste également à y apposer les classes prescrites et à y déceler la multiplicité et non l'unité prescrite de l'invention.

#### *Article 25*

1 Tout dépôt de demande de brevet ou de certificat d'auteur d'invention fait l'objet d'un rapport de recherche documentaire sur l'état de la technique et d'un examen de brevetabilité.

2 Les rapports de recherche documentaire visés au paragraphe 1, établis selon les normes prescrites par le décret d'application sont, soit fournis par le déposant, soit établis conformément aux conditions prescrites par le décret d'application.

3 L'examen de brevetabilité s'effectue à partir du rapport de recherche documentaire en rapport avec la demande. Il a pour but de déterminer :

- i) si l'objet de la demande est brevetable selon les dispositions des articles 4 à 8;
- ii) si la description de l'invention et la ou les revendications contenues dans la demande satisfont aux exigences de l'article 18.

4 Par décret du Président de la République, l'application des paragraphes 1 et 3 peut être suspendue, en totalité ou en partie, soit pour toutes les catégories d'invention, soit pour des catégories déterminées.

*Article 26*

1 Si la demande satisfait aux conditions des articles 7, 23 et 24, l'Organisme enregistre le brevet ou, sous réserve des dispositions du paragraphe 2, le certificat d'auteur d'invention.

*MALAYSIA: Sections 29, 29A and 30 of the Patents Act No. 291 of 1983 as last amended by Act No. 1264 of 2006*

Section 29. Preliminary examination. (1) Where an application for a patent has a filing date and is not withdrawn, the Registrar shall examine the application and determine whether it complies with the requirements of this Act and the regulations made under this Act which are designated by such regulations as formal requirements for the purposes of this Act. (2) If the Registrar, as a result of the examination under subsection (1), finds that not all the formal requirements are complied with, he shall give an opportunity to the applicant to make any observation on such finding and to amend the application within the prescribed period so as to comply with those requirements, and if the applicant fails to do so the Registrar may refuse the application.

Section 29A. Request for substantive examination or modified substantive examination.

(1) If an application for a patent has been examined under section 29 and is not withdrawn or refused, the applicant shall file, within the prescribed period, a request for a substantive examination of the application. (2) If a patent or other title of industrial property protection has been granted to the applicant or his predecessor in title in a prescribed country outside Malaysia or under a prescribed treaty or Convention for an invention which is the same or essentially the same as the invention claimed in the application, the applicant may, instead of requesting for a substantive examination, request for a modified substantive examination. (3) A request for a substantive examination or a modified substantive examination shall be made in the prescribed form and shall not be deemed to have been filed until the prescribed fee has been paid to the Registrar and any other prescribed requirement has been complied with. (4) The Registrar may require the applicant to provide, at the time of filing a request for a substantive examination.

(a) any prescribed information or prescribed supporting document concerning the filing of any application for a patent or other title of industrial property protection filed outside Malaysia by such applicant or his predecessor in title with a national, regional or international industrial property office; (b) any prescribed information concerning the results of any search or examination carried out by an International Searching Authority under the Patent Cooperation Treaty, relating to the same or essentially the same invention as that claimed in the application for which the request for a substantive examination is being filed.

(5) If the applicant -

(a) fails to file either a request under subsection (1) for a substantive examination or a request under subsection (2) for a modified substantive examination; or (b) fails to provide the information or document referred to in subsection (4) as required by the Registrar, within the prescribed period, the application for a patent shall, subject to subsection (6), be deemed to be withdrawn at the end of that period. (6) Notwithstanding subsection (5), the Registrar may, upon the request of the applicant, grant a deferment of the filing of a request for examination referred to in subsection (1) or (2) or a deferment of the provision of the information or document referred to in subsection (4), and such deferment may be granted only on the grounds that -

(a) the patent or title referred to in subsection (2) has not been granted or is not available; or (b) the information or document referred to in subsection (4) would not be available, by the expiration of the prescribed period for the filing of a request under subsection (1) or (2). (7) No deferment shall be granted under subsection (6) unless the request for such deferment is filed before the expiration of the prescribed period for the filing of a request under subsection (1) or (2) and no deferment may be sought nor granted for a period greater than that prescribed in the regulations made under this Act. (8) Without prejudice to the power of the Registrar to grant a deferment, the period prescribed for the purposes of this section may not be extended under the provisions of section 82.

Section 30. Substantive examination and modified substantive examination. (1) Where a request for substantive examination has been filed under subsection 29A(1), the Registrar shall refer the application to an Examiner who shall -

(a) determine whether the application complies with those requirements of this Act and the regulations made under this Act which are designated by such regulations as substantive requirements for the purposes of this Act; and (b) report his determination to the Registrar.

(2) Where a request for a modified substantive examination has been filed under subsection 29A(2), the Registrar shall refer the application to an Examiner who shall -

(a) determine whether the application complies with those requirements of this Act and the regulations made under this Act which are designated by such regulations as modified substantive requirements for the purposes of this Act; and (b) report his determination to the Registrar.

(3) If the Examiner reports, in accordance with subsection (1) or (2), that any of the requirements referred to in subsection (1) or (2), as the case may be, are not complied with, the Registrar shall give the applicant an opportunity to make observations on the report and to amend the application so as to comply with those requirements, within the prescribed period, and if the applicant fails to satisfy the Registrar that those requirements are complied with, or to amend the application so as to comply with them, the Registrar may refuse the application.

(4) The Registrar may grant an extension of the prescribed period referred to in subsection (3) but such extension may be granted only once and no subsequent extension may be granted under the provisions of section 82.

(5) If the Examiner reports, in accordance with subsection (1) or (2), that the application, whether as originally filed or as amended, complies with the requirements referred to in subsection (1) or (2), as the case may be, the Registrar shall notify the applicant of that fact and, subject to subsection (6), shall process the application accordingly. (6) Where two or more applications for a patent for the same invention having the same priority date are filed by the same applicant or his successor in title, the Registrar may on that ground refuse to grant a patent in pursuance of more than one of the applications.

(7) The Registrar may waive, as he deems fit, the requirement of referring an application or any part of it for substantive examination under subsection (1):  
Provided that he shall notify in the Gazette his intention to waive such requirement and shall allow any party who would be aggrieved by such waiver to be heard on the matter.

*MALTA: Articles 23 and 24 (1) of the Patents and Designs Act, Chapter 417, of 01/06/2002 as last amended by Act XVIII of 2005*

23. (1) Where an application for a patent has been filed and is not withdrawn, the Comptroller shall refer the application to an officer in his department hereinafter referred to as "the examiner" to determine whether the application complies with such requirements of this Act and of any regulations made thereunder and which are designated by any regulations as may be prescribed as formal requirements. The examiner shall make a report thereon to the Comptroller.

(2) If the examiner reports to the Comptroller that not all the formal requirements are complied with, the applicant shall be given an opportunity to make observations on the report and to amend the application within such period as may be prescribed so as to comply with those requirements, and if the applicant fails to make such amendments the Comptroller may refuse the application.

(3) If the examiner reports to the Comptroller that the application, whether as originally filed or as amended pursuant to subarticle (2) complies with all the formal requirements at any time before the end of such prescribed period as is referred to in subarticle (2), the Comptroller shall notify the applicant accordingly.

Grant. 24. (1) Where the applicant has been notified pursuant to article 23(3) that his application complies with all the formal requirements, the Comptroller shall on payment of the prescribed fee, grant a patent on the application.

*MAURITIUS: Sections 19 and 20 (1) of the Patents, Industrial Designs and Trademarks Act No. 25 of 2002*

Examination

19.-(1) The Controller shall, after according a filing date, examine

(a) whether the application complies with section 14 and any other provisions of this Act; and

(b) whether any information requested under sections 16 and 17 has been provided.

(2) For the purposes of subsection (1), the Controller shall take into account

(a) the results of any international search reports, and any international preliminary reports, made in relation to the application;

(b) any search and examination report submitted under section 17(2)(a); and

(c) any final decision submitted under section 17(2)(c).

#### Grant of Patent

20.-(1) Where the Controller finds that the conditions referred to in section 19(1) have been fulfilled, he shall grant the patent.

*MEXICO: Articles 50, 52, 53, 54, 55 and 55bis of the Industrial Property Law of 25/06/1991 as last amended on 06/12/2005*

#### *Article 50*

Once the application has been filed, the Institute shall examine the form of the documents, and may require that further details or clarifications be provided wherever it considers this necessary, or that omissions be rectified. If the applicant fails to fulfill this requirement within two months, the application shall be considered abandoned.

#### *Article 52*

The publication of the pending patent application shall take place as soon as possible following the expiration of a period of 18 months from the filing date of the application or, where applicable, from the date of recognized priority. At the request of the applicant, the application shall be published prior to the expiration of said period.

#### *Article 53*

Once the patent application has been published and the appropriate fee has been paid, the Institute shall conduct an examination of the substance of the invention in order to determine whether the requirements specified in Article 16 of this Law are satisfied, or whether the invention is covered by any of the situations provided for in Articles 16 and 19 of this Law.

In order to conduct substantive examinations, the Institute may, where appropriate, request the technical support of national specialized agencies and institutions.

Article amended DOF August 2, 1994

#### *Article 54*

The Institute may accept or request the findings of substantive examinations or the equivalent thereof conducted by foreign patent offices or, where appropriate, a plain copy of the patent granted by any of said foreign offices.

#### *Article 55*

The Institute may call upon the applicant in writing to submit, within a period of two months, such additional or complementary information or documentation as may be necessary, including that which relates to searches or examinations undertaken by foreign offices, to alter the claims, description or drawings, or to make such clarifications as it considers relevant where:

I. in the opinion of the Institute this is necessary for the conduct of the substantive examination; and

II. during or as a result of the substantive examination it transpires that the invention, as identified in the application, does not meet the patentability requirements or falls into any of the cases provided for in Articles 16 and 19 of this Law.

If, within the period referred to in this Article, the applicant does not comply with the request served on him, his application shall be considered abandoned.

*Article 55 bis.*

Documents submitted either in compliance with any of the requests referred to in Articles 50 and 55 of this Law or, in the case of voluntary alterations, may not contain additional material or claims that give a scope greater than that contained in the original application considered as a whole.

Voluntary alterations shall be accepted only up to before the issue of the decision on the appropriateness or otherwise of the grant of a patent referred to in Articles 56 and 57 of this Law.

*MONGOLIA: Article 10 of the Patent Law of 25/06/1993, as last amended in 1999*

*Article 10*

Examination of patent application

1. After recording of the filing date, the [Intellectual Property Office shall examine the invention or industrial design to determine if it complies with the requirements of Article 4 of this law.

2. The applicant shall, on request, supply to the [Intellectual Property Office information on any application for a patent or other form of entitlement to protection which has been filed by the applicant in any other country and which relates to the same or essentially the same invention as that to which the application filed with the [Intellectual Property Office relates.

3. During the examination procedure the applicant may request that the application be corrected or amended, provided that the correction or amendment shall not go beyond the disclosure made in the initial application. If such a request is made the examination procedure may be postponed. The duration of any postponement shall be consistent with the time limits provided for in paragraph 5 of this article.

4. During the examination procedure, the applicant may divide the application into two or more applications, provided that each divided application shall not go beyond the disclosure made in the initial application.

Up to the time when the application is in order for grant, the application for a patent may be converted into the application for utility model, or the application for utility model into the application for a patent and the filing date shall be the date application first received.

5. The [Intellectual Property Office]\* shall, according to the examination report, reach a decision as to whether or not to grant a patent within 9 months from the filing date of the application. If required, the [Intellectual Property Office may extend this period for further 12 months.

6. If it is decided to grant the patent, the formulation of the invention or the drawing of the industrial design and the particulars concerned shall be published in the Patent Gazette.

7. If the invention or industrial design has not been recognized, a copy of the examination report shall be sent to the applicant within 30 days from the date of conclusion of the examination and the report shall be kept at the patent library.

8. The industrial design which is not different with previously disclosed designs or their peculiarity shall not be considered new and original.

*MOROCCO: Articles 41 and 47 of the Law No. 17-97 concerning Protection of Industrial Property as implemented by Law No. 31-05 of 02/03/2006*

*Article 41*

Est rejetée toute demande de brevet qui :

1) n'est pas considérée comme une invention au sens de l'article 23 ci-dessus;

2) n'est pas brevetable au sens de l'article 24 ci-dessus;

3) n'est pas considérée comme une invention susceptible d'application industrielle au sens de l'article 25 ci dessus;

4) n'a pas été régularisée dans le délai de trois mois prévu à l'article 32 ci-dessus;

5) ne satisfait pas aux dispositions de l'article 37 ci dessus;

6) concerne plusieurs inventions ou une pluralité d'inventions qui ne sont pas liées entre elles au sens de l'article 38 ci-dessus.

Le rejet de toute demande de brevet doit être motivé et notifié au déposant ou à son mandataire par lettre recommandée avec accusé de réception. La mention dudit rejet est inscrite au registre national des brevets visé au 1er alinéa de l'article 58 ci-dessous.

*Article 47*

Les brevets, dont la demande n'a pas été rejetée, sont délivrés sans examen préalable, aux risques et périls des demandeurs et sans garantie, soit de la réalité de l'invention, soit de la fidélité ou de l'exactitude de la description, soit du mérite de l'invention.

*NAMIBIA: Articles 15 (5), (6) and (7) and 16 of the Industrial Property Act of 1999*

15.- (5) After according a filing date the Registrar shall examine whether the application complies with the requirements of section 11 (1) and (2) and the regulations relating thereto and those requirements of this Act and the regulations which are designated as formal requirements for the purposes of this Act.

(6) Where the Registrar is of the opinion that the application complies with the requirements indicated in subsection 5, the Registrar shall cause the application to be examined as to whether the requirements of sections 7, 8, 9, 11(3), (4), (5), (6), (7), 12 and 14 and the regulations relating thereto are complied with.

(7) The regulations may prescribe that, in respect of some categories of inventions, the examination shall not cover the requirements of novelty and inventive step under section 9(2) and (3).

*Grant of patent, time limit for grant and changes in patents*

16. (1) Where the Registrar finds that, subject to section 14(5), the conditions referred to in section 15(5) and (6) are complied with, he or she shall grant the patent. Otherwise, he or she shall refuse the application and notify the applicant accordingly.

*NETHERLANDS: Articles 30, 32, 34 and 35 of the Patents Act of 15712/1995 (text as it applies on 03/09/2009)*

*Article 30*

1. If the provisions stipulated under and by virtue of Article 24 have not been complied with, the Office shall notify the applicant in that respect in writing within one month of the date of filing referred to in Article 29(1) or, in the case of a divisional application, within one month of the date on which the divisional application was filed, together with an indication of the provisions that have not been complied with.

2. If the defects are not remedied within three months after dispatch of the notice referred to in paragraph (1), or if the applicant gives notice before that time that he does not wish to remedy them, the Office shall decide not to process the application. The Office shall inform the applicant of its decision as quickly as possible.

*Article 32*

1. Within 13 months of:

a. the date of filing referred to in Article 29(1); or

b. if the application relates to one or more rights of priority that have been claimed, the first date of priority, the applicant shall request the Office to perform a search of the state of the art with respect to the subject matter of the patent application prior to the grant of the patent.

A fee in accordance with the rate stipulated under or by virtue of a general order in council for the Kingdom shall be paid together with the request submitted to the Office. The request shall not be handled until the Office has received that amount.

2. If a divisional application as provided for in Article 28 is involved, the request referred to in paragraph (1) shall be made within 13 months of the date of filing referred to in paragraph (1) or priority of the original application or within two months after the filing of the divisional application if that date is later.

3. If the applicant has not requested the search referred to in paragraph (1) or if the Office has not received the amount referred to in paragraph (1) in a timely manner, the Office shall decide not to process the application. The Office shall inform the applicant of its decision as quickly as possible.

*Article 34*

1. A search of the state of the art as provided for in Article 32(1) shall be conducted by the Office, if necessary with the assistance of the European Patent Office referred to in the European Patent Convention.
2. If the applicant so requests, the Office shall subject the application to an international search as provided for in Article 15(5)(a) of the Patent Cooperation Treaty. Such a search shall be deemed to be a search of the state of the art as referred to in Article 32(1).
3. If it appears from the search that the application filed is not in compliance with the provisions stipulated under or by virtue of Article 27, it shall be carried out with respect to the elements of the application relating to the invention or group of inventions referred to in Article 27 that is mentioned first in the claims.
4. The Office shall notify the applicant in writing of the results of the search of the state of the art.
5. If the provisions contained in paragraph (3) apply, the Office shall indicate that that is the case in the notification provided for in paragraph (4), specifying the invention or group of inventions with respect to which the search was conducted.

*Article 35*

1. If the Office is of the opinion that the search of the state of the art cannot be conducted owing to the application's lack of clarity, it shall so inform the applicant as quickly as possible in a substantiated, written notification.
2. If the defects are not remedied within two months of the dispatch of the notification referred to in paragraph (1), or if the applicant gives notice before that time that he does not wish to remedy them, the Office shall decide not to process the application. The Office shall inform the applicant of its decision as quickly as possible.

NEW ZEALAND: *Sections 12, 13, 14, 15 and 18 of the Patents Act No 64 of 1953 (as at 01/08/2008)*

12. Examination of application

(1) Subject to section 26G of this Act, when the complete specification has been filed in respect of an application for a patent, the application and specification or specifications shall be referred by the Commissioner to an examiner.

(2) If the examiner reports that the application or any specification filed in pursuance thereof does not comply with the requirements of this Act or of any regulations made thereunder, or that there is lawful ground of objection to the grant of a patent in pursuance of the application, the Commissioner *sic*: Commissioner may either:

(a) Refuse to proceed with the application; or

(b) Require the application or any such specification as aforesaid to be amended before he proceeds with the application.

(3) At any time after an application has been filed under this Act and before acceptance of the complete specification, the Commissioner may, at the request of the applicant and upon payment of the prescribed fee, direct that the application shall be post-dated to such date as may be specified in the request:

Provided that

(a) No application shall be post-dated under this subsection to a date later than 6 months from the date on which it was actually made or would, but for this subsection, be deemed to have been made; and

(b) A convention application shall not be post-dated under this subsection to a date later than the last date on which, under the foregoing provisions of this Act, the application could have been made.

(4) Where an application or specification filed under this Act is amended before acceptance of the complete specification, the Commissioner may direct that the application or specification shall be post-dated to the date on which the amendment is first filed.

(5) Regulations made under this Act may make provision for securing that where, at any time after an application or specification has been filed under this Act and before acceptance of the complete specification a fresh application or specification is filed in respect of any part of the subject-matter of the first-mentioned application or specification, the Commissioner may on request direct that the fresh application or specification shall be antedated to a date not earlier than the date of filing of the first-mentioned application or specification.

(6) An appeal to the Court shall lie from any decision of the Commissioner under subsection (2) or subsection (4) of this section.

### 13. Search for anticipation by previous publication

(1) Subject to the provisions of section 12 of this Act, the examiner to whom an application for a patent is referred under this Act shall make investigation for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been published before the date of filing of the applicant's complete specification in any specification filed in pursuance of an application for a patent made in New Zealand and dated within 50 years next before that date.

(2) The examiner shall, in addition, make such investigation as the Commissioner may direct for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, has been published in New Zealand before the date of filing of the applicant's complete specification in any other document (not being a document of any class described in subsection (1) of section 59 of this Act).

(3) If it appears to the Commissioner that the invention, so far as claimed in any claim of the complete specification, has been published as aforesaid, he may refuse to accept the specification unless the applicant either

(a) Shows to the satisfaction of the Commissioner that the priority date of the claim of his complete specification is not later than the date on which the relevant document was published; or

(b) Amends his complete specification to the satisfaction of the Commissioner.

(4) An appeal to the Court shall lie from any decision of the Commissioner under this section.

### 14. Search for anticipation by prior claim

(1) In addition to the investigation required by section 13 of this Act, the examiner shall make investigation for the purpose of ascertaining whether the invention, so far as claimed in any claim of the complete specification, is claimed in any claim of any other complete specification published on or after the date of filing of the applicant's complete specification, being a specification filed

(a) In pursuance of an application for a patent made in New Zealand and dated before that date; or

(b) In pursuance of a convention application founded upon an application for protection made in a convention country before that date.

(2) If it appears to the Commissioner that the said invention is claimed in a claim of any such other specification as aforesaid, he may, subject to the provisions of this section, direct that a reference to that other specification shall be inserted by way of notice to the public in the applicant's complete specification unless within such time as may be prescribed either

(a) The applicant shows to the satisfaction of the Commissioner that the priority date of his claim is not later than the priority date of the claim of the said other specification; or

(b) The complete specification is amended to the satisfaction of the Commissioner.

(3) If in consequence of the investigation under section 13 of this Act or otherwise it appears to the Commissioner

(a) That the invention, so far as claimed in any claim of the applicant's complete specification, has been claimed in any such specification as is mentioned in subsection (1) of that section; and

(b) That the other specification was published on or after the priority date of the applicant's claim,

then, unless it has been shown to the satisfaction of the Commissioner under that section that the priority date of the applicant's claim is not later than the priority date of claim of that other specification, the provisions of subsection (2) of this section shall apply as they apply in relation to a specification published on or after the date of filing of the applicant's complete specification.

(4) The powers of the Commissioner under this section to direct the insertion of a reference to another specification may be exercised either before or after a patent has been granted for the invention claimed in that other specification, but any directions given before the grant of such a patent shall be of no effect unless and until such a patent is granted.

(5) An appeal to the Court shall lie from any decision of the Commissioner under this section.

15 Commissioner may require information as to corresponding applications overseas

(1) Subject to subsection (2) of this section, for the purposes of the investigation required under this Act an applicant, if so required by the Commissioner shall,

(a) State whether a corresponding or substantially corresponding application has been filed in any of the following countries, namely,

(i) The United Kingdom, Canada, Australia, or the United States of America; or

(ii) Any other country for the time being declared by Order in Council to be a country to which this paragraph applies:

(b) With respect to any such application in any such country, furnish (so far as it is reasonably available to the applicant) the following information:

(i) The number and filing date of the application; and

(ii) Particulars sufficient to identify the prior art cited against the application; and

(iii) The number allotted to the patent when granted on the application and the form of the claims allowed; and

(iv) Particulars of any other application or patent with which the corresponding application is or has been involved in opposition, conflict, interference, or similar proceedings.

(2) This section shall not apply to Treaty applications.

18. Supplementary provisions as to examination, etc

(1) The powers of the Commissioner under section 14 or section 16 of this Act may be exercised either before or after the complete specification has been accepted or a patent granted to the applicant and references in those sections to the applicant shall accordingly be construed as including references to the patentee.

(2) Where a complete specification is amended under the foregoing provisions of this Act before it has been accepted, the amended specification shall be examined and investigated in like manner as the original specification.

(3) The examination and investigations required by the foregoing provisions of this Act shall not be deemed to warrant the validity of any patent, and no liability shall be incurred by the Patent Office or any officer thereof by reason of or in connection with any such examination or investigation or any report or other proceedings consequent thereon.

NICARAGUA: *Articles 30, 34 and 35 of the Law on Patents, Utility Models and Industrial Designs No. 354 of 19/09/2000 as last amended by Law No. 634 of 13/09/2007*

#### Examination as to Form

30. The Intellectual Property Registry shall examine the application to determine whether it complies with the requirements of Article 19 of this Law and with the corresponding regulatory provisions. Where any deficiency is noted, the applicant shall be notified so that he may make the correction within a period of two months counted from the date of notification, and warned that the application will otherwise be considered abandoned and be shelved *ex officio*. Where the applicant does not make the correction in the period specified, the Intellectual Property Registry shall enforce the warning in the form of a resolution with a statement of reasons.

#### Substantive Examination

34. The applicant shall prove payment of the amount payable for the substantive examination of the patent application within a period of six months counted from the publication date of the notice of application. Where that period expires without the amount having been paid, the application shall be considered abandoned and the file shelved *ex officio*. Where any of the requirements or conditions for the patenting of the invention are not complied with, the Intellectual Property Registry shall notify the applicant so that, within a period of three months, he may complete the documentation, correct, amend or divide the application or make such comments in support of it as he sees fit. Should the opposite be the case, the application shall be rejected in a decision with a statement of reasons.

The examination may be conducted by the Intellectual Property Registry direct or through the agency of independent experts or public or private bodies, either national or foreign, or under regional or international agreements.

Where applicable, the examination shall be conducted on the basis of documents supplied by the applicant relating to novelty or patentability examinations conducted by other intellectual property offices or under the procedure provided for in the Patent Cooperation Treaty (PCT) that relate to the same subject matter as is claimed in the application under examination. The Intellectual Property Registry may recognize the findings of such examinations as being sufficient to prove compliance with the conditions of patentability of the invention.

The examination shall be conducted by the Intellectual Property Registry according to the procedure laid down in the regulations under this Law.

#### Documents Relating to Foreign Applications

35. For the purposes of the patentability examination, the applicant shall, at the request of the Intellectual Property Registry, provide the following, with the corresponding translation:

- (a) a single copy of the foreign application and the results of the novelty and patentability examination conducted in relation to that application;
- (b) a single copy of the patent or other title of protection granted by the patent office of the issuing country.

Where necessary for a better decision on a patent application or on the validity of a granted patent, the Intellectual Property Registry may at any time request the applicant or patent owner to submit a copy of any decision or ruling that has rejected, refused, revoked, cancelled or invalidated the foreign application or the patent or other title of protection granted thereon.

Where the applicant who has the required information or document at his disposal does not comply with the request that he submit it within the period specified in the request, which shall be three months from the date thereof, the patent applied for shall be refused. At the request of the applicant or *ex officio*, the Intellectual Property Registry may suspend the processing of the patent application where any document that should be submitted under this provision is still pending before a foreign authority.

The applicant may submit observations and comments on any information or document supplied pursuant to this Article. Where necessary or where there is reasonable doubt as to the legitimacy of a document, the Intellectual Property Registry may request that it be legalized or authenticated.

*NIGERIA: Section 4 of the Industrial Property Act (Chapter 344) No. 60 of 1970 (version of 1990)*

4. (1) The Registrar shall examine every patent application as to its conformity with section 3 (1), (3) and (4) of this Act, and-

(a) if section 3(1) of this Act has not been complied with, the Registrar shall reject the application;

(b) if section 3(3) of this Act has not been complied with, the Registrar shall-

(i) invite the applicant to restrict the application so that it relates to only one invention, and  
(ii) notify the applicant that he may within, three months file in respect of the other inventions dealt with in the original application subsidiary applications which shall benefit from the date of filing of the original application and, if relevant, from the date of any foreign priority claimed under section 3(4) of this Act, and, if the applicant does not comply with the invitation mentioned in sub-paragraph (i) of this subsection, shall reject the application, and

(c) if section 3(4) of this Act has not been complied with, the Registrar shall disregard any claim for foreign priority.

(2) Where the examination mentioned in subsection (1) of this subsection shows that a patent application satisfies the requirements of section 3(1) and (3) of this Act, the patent shall be granted as applied for without further examination and, in particular, without examination of the questions:

(a) whether the subject of the application is patentable under section 1 of this Act;

(b) whether the description and claims satisfy the requirements of section 3(2) of this Act; and

(c) whether a prior application, or an application benefiting from a foreign priority, has been made in Nigeria in respect of the same invention, and whether a patent has been granted as a result of such an application.

(3) Where the said examination shows that section 3(4) of this Act has been complied with as respects a claim for a foreign priority, the foreign priority claimed shall be mentioned in the patent.

(4) Patents are granted at the risk of the patentee and without guarantee of their validity.

*NORWAY: Sections 9, 15, 15 a and 19 of the Patents Acts No.9 of 15/12/1967 as last amended by Act No.80 of 29/06/2007*

Section 9. If the applicant so requests and pays the prescribed fee, the Norwegian Industrial Property Office shall, on conditions laid down by the King, allow the application to be subjected to a novelty search by an International Searching Authority as referred to in Article 15(5) of the Patent Cooperation Treaty, done at Washington on June 19,1970.

Section 15. If the applicant has not complied with the prescribed requirements with respect to the application, or if the Norwegian Industrial Property Office finds other obstacles to the acceptance of the application, the applicant shall be notified to that effect and be invited to submit observations or to correct the application within a specified time limit. However, the Norwegian Industrial Property Office may make such amendments in the abstract as found necessary without consulting the applicant. If the applicant fails, within the time limit, to submit observations or to take steps to correct a defect which has been pointed out, the application shall be shelved. Information to that effect shall be given in the notification from the Norwegian Industrial Property Office referred to in the first paragraph. However, the processing of the application shall be resumed if the applicant submits observations or takes steps to make corrections for resumption of the processing within four months from the expiration of the said time limit. The prescribed fee shall be paid.

If the annual fee referred to in sections 8, 41 and 42 is not paid, the application shall be shelved without prior notification. The processing of an application which has been shelved for this reason cannot be resumed.

Section 15 a. If the Norwegian Industrial Property Office is in doubt whether a patent should be granted or refused based on section 1 b, the Norwegian Industrial Property Office shall obtain an advisory statement from an ethics committee appointed by the King, before making a decision. The ethics committee shall give their advisory statement within three months of receiving the request. The King may, by regulation, determine specific rules for the committee's procedures.

Section 19. If the application complies with the prescribed requirements and there are no obstacles to the grant of a patent, the applicant shall be notified that a patent may be granted. Subsequent to the applicant having been notified that a patent may be granted, the patent claims may not be amended so as to extend the scope of the patent protection.

OMAN: *Article 9 of the Law on Industrial Property Rights (Royal decree No. 67/2008)*

*Article (9)*

A) The Registrar shall accord as the filing date the date of receipt of the application, provided that the application contains all of the following elements:

- 1 - An express or implicit indication, written in the Arabic language, to the effect that the elements are intended to be an application;
- 2 - Indications, written in Arabic language, allowing the identity of the applicant to be established and information allowing the applicant to be contacted by the Office;
- 3 - A part which, on the face of it, appears to be a description, written in any language, of an invention;
- 4 - A reference, written in Arabic language, to the previously filed application if appropriate.

B) If the Registrar finds that the application did not fulfill the requirements he shall notify the applicant to file the required correction and shall accord as the filing date the date of receipt of the required correction, but if no correction is made, the application shall be treated as if it had not been filed.

C) 1 - Where, in establishing the filing date, the Registrar notices that the application refers to drawings which are not included in the application, the Registrar shall promptly invite the applicant to furnish the missing drawings. The Registrar shall accord as the filing date the date of receipt of the missing drawings. Otherwise, the Registrar shall accord as the filing date the date of receipt of the application and shall treat any reference to the said drawings as non-existent.

2 - Where, in establishing the filing date, the Registrar notices that a part of the description appears to be missing; the Registrar shall promptly invite the applicant to furnish the missing part of the description. The Registrar shall accord as the filing date the date of receipt of the missing part. Otherwise, the Registrar shall accord as the filing date the date of receipt of the application and shall treat any reference to the said part as non-existent.

3 - After according a filing date, and having the invention classified according to the International Classification, the Registrar shall examine whether the application complies with the requirements prescribed in this law and its executive regulations.

4 - A - Immediately after eighteen months from the filing date, the Registrar shall open the patent application for public inspection. Public notice of that act shall be given by means of the publication in the Official Gazette of the following elements:

- 1) the number and the filing date of the application;
- 2) the title of the invention;
- 3) the name of the applicant(s) and of the inventor(s);
- 4) the priority date;
- 5) the international classification;
- 6) one drawing, if any, that depicts the main element(s) of the invention;
- 7) the abstract.

B - Any interested person shall receive a copy of the full contents of patent applications opened for public inspection, provided the prescribed fees are paid.

C - The Registrar shall not give access to or information about the contents of the patent application to third persons until the notice is published in the official gazette.

D - Upon payment of the prescribed fee, at any time between the filing date and the end of the eighteen-month period, the applicant may request the Registrar to open the application for public inspection and to publish the notice in the official gazette.

5 - A - Within (36) thirty six months from the filing date, the patent applicant or any other interested person may request the Registrar that the patent application be examined as to its compliance with the conditions under this law, provided that the request be accompanied by payment of the prescribed fee which shall take into account the number of claims. The Registrar shall publish in the Official Gazette the request for examination.

B - If the request that the previous paragraph refers to is not submitted within the prescribed term the application shall be deemed abandoned.

C - Within one hundred twenty (120) days from the publication in the Official Gazette of the notice of the request for substantive examination any interested party may file with the Registrar information relevant to patentability as well as relevant evidences.

6 - For the purposes of the examination of the patent application under the previous paragraph, the Registrar shall take into account

A) the results of any international search report and any international preliminary examination report established under the Patent Cooperation Treaty in relation to the application; and/or

B) any search and examination report or a final decision submitted under Article 8(2) and 8(4) on the refusal to grant a patent on, a corresponding foreign application; and/or

C) any search and examination report which was carried out upon his request by an external search and examination authority or by a specialized agency of the Government of Oman.

PAKISTAN: *Sections 16, 17, 19, 20, 21 and 22 of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

16. Examination of application.- (1) The Controller shall refer to an examiner every application in respect of which a complete specification has been filed, for making a report to the Controller after detail scrutiny of the application, specification, claims and drawing, if any, to the effect whether the invention is new and involves an inventive step, and to also determine whether other requirements of this Ordinance and rules has e been complied with

(2) The examiner shall make the report to the Controller as soon as is reasonably possible, but before the period of eighteen months from the date of filing of the application in Pakistan.

(3) If the examiner reports that any of the requirements of this Ordinance and rules are not complied with, the Controller shall give the applicant an opportunity, or more than one opportunity, to comply with such requirements as may be mentioned in the said report and to amend the application, if necessary, within such time as may be prescribed, failing which the Controller may refuse to proceed with the application.

(4) If the Controller considers, at any time, before the acceptance of the application, that the invention claimed therein has been wholly or in part claimed in a specification published on or after the date which the patent applied for would bear, if granted appertaining to an application for grant of a patent which, if granted, will be prior date to the patent applied for, he may require that the applicant's specification be amended by the insertion of a reference to such other specification by way of notice to the public.

(5) The investigation required under this section shall not be held in any way to guarantee the validity of any patent, and no liability shall be incurred by the Federal Government or any officer by reason of, or in connection with, any such investigation or any proceeding consequent thereon.

(6) Unless an application is accepted within eighteen months from the date of the application, the application shall, except where an appeal has been lodged, be deemed to have been refused: Provided that where, before, or within three months after the expiration of the said period of eighteen months, a request is made to the Controller for an extension of time, the application shall, on payment of the prescribed fee, be continued for any period so requested not exceeding in all three months from the expiration of the said period of eighteen months:

Provided further that the Controller may upon a written request made by an applicant in the prescribed manner postpone the formal acceptance of the application until such date, not later than twenty-one months from tile date of filing of the complete specification, as may be requested by the applicant.

17. Reference to other patent.- (1) If, in consequence of the investigation under Section 16, it appears to the Controller that an invention in respect of which application for a patent has been made cannot be performed without substantial risk of infringement of a claim of any other patent, he may direct that a reference to that other patent shall be inserted in the applicant's complete specification by way of notice to the public unless, within such time as may be prescribed, either-

(a) the applicant shows to the satisfaction of the Controller that there are reasonable grounds for contesting the validity of the said claim of the other patent; or

(b) the complete specification is amended to the satisfaction of the Controller

(2) Where, after a reference to another patent has been inserted in a complete specification in pursuance of a direction under sub-Section (1).-

(a) that other patent is revoked or otherwise ceases to be in force;

(b) the Specification of that other patent is amended by the deletion of the relevant claim; or

(c) it is found, in proceedings before the court or the Controller, that the relevant claim of that other patent is invalid or is not infringed by any working of the applicant's invention,

the Controller may, on the application of the applicant, delete the reference to that other patent.

19. Time for putting application in order of acceptance.- (1) If on the expiration of the period of eighteen months specified in sub-section (6) of section 16 or the extended period-

(a) an appeal to the High Court is pending in respect of an application for a patent for an invention; or

(b) in the case of an application for a patent of addition, an appeal to the High Court is pending in respect either of that application or the application for the main invention,

the time within which the requirements of the Controller shall be complied with shall, on an application made by the applicant before the expiration of the said period of eighteen months or the extended period, as the case may be, be extended until such date as the High Court may determine.

(2) If the time within which the appeal mentioned in sub-section (1) may be instituted has not expired, the Controller may extend the period of eighteen months or, as the case may be, the extended period, until the expiration of such further period as he may determine:

Provided that, if an appeal has been filed during the said further period and the High Court has granted any extension of time for complying with the requirements of the Controller, then the requirements may be complied with within the time granted by the High Court.

20. Power of Controller to require certain information and documents relating to foreign application.

(1) The applicant shall, when required by the Controller, furnish him with the date and number of any application for a patent filed by him abroad, hereinafter referred to as foreign application, relating to the same or essentially the same invention as that claimed in the application filed in Pakistan.

(2) The applicant shall, when required by the Controller, furnish him with the following documents relating to one of the foreign applications referred to in sub-section (1), namely:

(i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application;

(ii) a copy of the patent granted on the basis of the foreign application; and

(iii) a copy of any final decision rejecting the foreign application.

(3) The applicant shall, when required by the Controller, furnish him with a copy of any final decision invalidating the patent granted on the basis of foreign application referred to in sub-section (1).

21. Acceptance of complete specification.- On the acceptance of a complete specification, the Controller shall give notice thereof to the applicant and shall advertise in the official Gazette the fact that specification has been accepted and thereupon the application and the specification, and the priority documents, if any, filed in pursuance thereof shall be open to public inspection.

22. Effect of acceptance of complete specification.

After the acceptance of an application and until the date of sealing a patent in respect thereof, or the expiration of the time for sealing, the applicant shall have the like privileges and rights as if a patent for the invention had been sealed on the date of the acceptance of the application:

Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been sealed.

*PANAMA: Articles 40, 45-49 and 52 of the Law No. 35 of 10/05/1996 Enacting Provisions on Industrial Property*

40. Where the application does not comply with the provisions of the foregoing Article, DIGERPI shall notify the applicant accordingly so that within a period of six months, which shall be renewable for another two months on just grounds, he may divide it into two or more applications, which shall retain the date of the initial application and where appropriate of the recognized priority as the date for each one of them. If, on expiration of the said period, the applicant has not made the division, the application shall be considered abandoned and its consignment to the archives shall be ordered.

45. On receiving the application, DIGERPI shall undertake an examination of the documentation as to form, and may request further information or clarification where necessary, or the rectification of omissions. It shall also examine whether the subject matter of the patent application meets the patentability requirements laid down in this Law, with the exception of the novelty and inventive step requirements. Nevertheless, DIGERPI shall refuse the grant of a patent in a reasoned decision, after having heard the person concerned, when the invention to which the application relates is found to be clearly and overtly lacking in novelty.

Where the applicant fails to comply with the request made to him by DIGERPI to rectify defects in the application within a period of six months, which period shall be renewable for another six months at the request of the applicant, the application shall be considered abandoned and its consignment to the archives shall be ordered. The documents filed shall on no account contain additional claims or claims of greater scope than those of the original application, which would necessitate the filing of a new application.

46. DIGERPI shall reject the application totally or partly if it considers that the subject matter thereof is not patentable or that it has defects that have still not been rectified.

Where the examination by DIGERPI does not reveal defects that would prevent the grant of the patent, or where such defects have been duly rectified, it shall be made known to the applicant that, for the consideration of his application to proceed, he must request the production of a report on the state of the art within the periods laid down in this Law if he has not already done so.

47. On the expiration of 18 months following the filing date of the application, or the date of any priority claimed, if the examination finding referred to in the foregoing Article has been favorable and the applicant has filed the request for a report on the state of the art, DIGERPI shall order the publication of the patent application in BORPI. At any time prior to the expiration of the period referred to, the applicant may, in writing, request publication of his application if he has complied with the provisions of Article 46.

48. Within the 14 months following the filing date, the applicant may request DIGERPI to produce the report on the state of the art, and pay the prescribed fee for the purpose. Where priority has been claimed, the 14 months shall be counted from the priority date.

Where the applicant has to rectify defects as a result of the examination of his application, the period for rectification shall be that laid down in Article 45 of this Law. Once the notification referred to in the final paragraph of the said Article has been made, the applicant shall request the production of the report on the state of the art within the month following the said notification.

Where the applicant fails to comply with the provisions of this Article, his application shall be deemed abandoned.

The production of the report on the state of the art may not be requested with reference to an addition if it has not, either previously or at the same time, been requested for the main patent and for any earlier additions.

49. Once the examination of the application provided for in Article 45 has been completed and the applicant has requested the production of the report on the state of the art, DIGERPI shall proceed to draw up the said report with reference to the subject matter of the patent application within a period not exceeding eight months.

For the production of the report, DIGERPI may avail itself of the services of national and international bodies or counterpart offices.

DIGERPI may accept a report on the state of the art submitted by the applicant that has been drawn up by a national or international body.

That report shall mention the elements of prior art that may be taken into consideration for the assessment of the novelty and inventive step of the subject matter of the application, and it shall be evaluated on the basis of the claims of the application, due account being taken of the description and any drawings filed.

Once the report on the state of the art has been drawn up, DIGERPI shall forward it to the patent applicant and publish it in BORPI.

52. Regardless of the contents of the report on the state of the art and of any comments made by third parties, DIGERPI shall, on the expiration of the period for comments by the applicant, proceed to grant the patent applied for against payment of the corresponding fees.

Where the claims are amended, DIGERPI shall send a copy thereof to third parties who have made comments on the report on the state of the art.

The grant of the patent shall be made without prejudice to the rights of third parties and without any State guarantee of the effectiveness of the patent, of the invention itself or of the usefulness of the subject matter to which it relates.

The applicant shall pay the grant fees within a period of two months. Where that period expires without payment having been made, the application shall be considered abandoned and its consignment to the archives shall be ordered.

*PAPUA NEW GUINEA: Section 26 of the Industrial Property Act No. 30 of 19/07/2000*

26. Examination of patent

After recording a filing date under Section 25 for an application under Section 19 -

(a) the Registrar shall examine whether -

(i) the application complies with the requirements of Section 19 (2) and (4) and any Regulations pertaining thereto; and

(ii) the application complies with those requirements of this Act, and the Regulations which are designated by the Regulations as formal requirements for the purposes of this Act; and

(iii) information requested under Section 24, if any, has been provided; and

(b) where the Registrar is of the opinion that the application does not comply with the requirements of Paragraph (a) he may invite the applicant to file, within a time limit specified by the Registrar and in a manner directed by the Registrar, -

(i) a correction or amendment; or

(ii) a submission as to whether the application complies with the requirements of Paragraph (a); or

(iii) both (i) and (ii),

and where after the expiration of the time limit specified by the Registrar, whether or not the applicant has responded to the invitation of the Registrar under this paragraph, the Registrar is still of the opinion that the application does not comply with the requirements of Paragraph (a) the Registrar shall refuse the application and notify the applicant in writing of his decision.

*PARAGUAY: Articles 22- 26 of the Patents Law No. 1630 of 29/11/2000*

*Artículo 22*

Del examen de forma. La Dirección de la Propiedad Industrial examinará si la solicitud cumple con los requisitos de forma previstos en esta ley y otorgará un plazo de hasta sesenta días hábiles para efectuar la corrección de cualquier omisión o deficiencia, bajo apercibimiento de considerar abandonada la solicitud de pleno derecho y archivarla de oficio. La Dirección Industrial hará efectivo el apercibimiento mediante resolución.

#### *Artículo 23*

De la publicidad de la solicitud. Al cumplirse el plazo de dieciocho meses contado desde la fecha de presentación de la solicitud de patente, o desde la fecha de presentación de la solicitud prioritaria si se hubiese invocado un derecho de prioridad, la Dirección de la Propiedad Industrial dispondrá de oficio que la solicitud se haga pública y ordenará su publicación.

El solicitante podrá pedir que se haga pública la solicitud antes de cumplirse el plazo indicado, en cuyo caso se ordenará la publicación conforme al párrafo anterior.

Toda solicitud de patente se mantendrá en secreto hasta la publicación. Esta confidencialidad será aplicable igualmente a la solicitud que antes de su publicación hubiese sido objeto de desistimiento o abandono. Una vez publicada, cualquier persona podrá consultar en la Dirección de Propiedad Industrial el expediente y obtener copias de todo o parte del mismo o muestras del material biológico que se hubiese depositado.

#### *Artículo 24*

De las observaciones de terceros a la solicitud. Cualquier persona interesada podrá presentar a la Dirección de la Propiedad Industrial, hasta antes del examen de fondo, observaciones fundamentadas, incluyendo informaciones o documentos, que fuesen útiles para determinar la patentabilidad de la invención objeto de la solicitud. El solicitante una vez notificado de las mismas, podrá presentar los descargos y comentarios o documentos que le convinieran en relación con las observaciones.

La presentación de observaciones no suspenderá la tramitación y los plazos de la solicitud. Quien las hiciera no pasará a ser parte en el procedimiento.

#### *Artículo 25*

Del examen de fondo. La Dirección de la Propiedad Industrial realizará el examen de fondo de la presentación a fin de determinar si la invención reúne el requisito de novedad y demás exigencias de patentabilidad establecidos en esta ley para el otorgamiento de la patente. También se verificará si la solicitud satisface el requisito de unidad de la invención. El examen de fondo se hará previo pago de la tasa establecida y si transcurridos tres años de la solicitud de patente, el peticionante no la abonase, la presentación se considerará desistida.

El examen será realizado por la Dirección de la Propiedad Industrial, institución que podrá requerir el concurso de expertos independientes, de entidades públicas o privadas nacionales o de los medios admitidos en el marco de los acuerdos internacionales o regionales de los cuales el Paraguay sea parte.

Cuando fuese aplicable, la Dirección de la Propiedad Industrial podrá requerir al solicitante los documentos relativos a los exámenes de novedad o de patentabilidad efectuados por otras oficinas de propiedad industrial o dentro del procedimiento previsto en algún tratado internacional del que el Paraguay sea parte. La Dirección de la Propiedad Industrial podrá reconocer los resultados de tales exámenes como suficientes para acreditar el cumplimiento de las condiciones de patentabilidad.

#### *Artículo 26*

De las solicitudes extranjeras correspondientes. A efectos de verificar el cumplimiento de los requisitos de patentabilidad, el solicitante proporcionará a la Dirección de la Propiedad Industrial, junto con la traducción correspondiente, los siguientes documentos de las solicitudes extranjeras relativas a la misma invención que se examina:

- a) copia de la solicitud extranjera y de sus documentos acompañantes;
- b) copia de los resultados de exámenes de novedad o de patentabilidad efectuados respecto a la solicitud extranjera; y,
- c) copia de la patente u otro título de protección que se hubiese concedido con base en la solicitud extranjera.

El solicitante podrá presentar observaciones y comentarios adicionales sobre cualquier información o documento en cumplimiento del presente artículo.

PHILIPPINES: *Sections 42-44 and 48 – 49 of the Intellectual Property Code, Act No. 8293 of 06/06/1997 as last amended by Act No. 9502 of 2008*

Formality Examination

42.-1. After the patent application has been accorded a filing date and the required fees have been paid on time in accordance with the Regulations, the applicant shall comply with the formal requirements specified by Section 32 and the Regulations within the prescribed period, otherwise the application shall be considered withdrawn.

2. The Regulations shall determine the procedure for the re-examination and revival of an application as well as the appeal to the Director of Patents from any final action by the examiner. (Sec. 16, R.A. No. 165a)

#### Classification and Search

43. An application that has complied with the formal requirement shall be classified and a search conducted to determine the prior art. (n)

#### Publication of Patent Application

44.-1. The patent application shall be published in the IPO Gazette together with a search document established by or on behalf of the Office citing any documents that reflect prior art, after the expiration of eighteen (18) months from the filing date or priority date.

2. After publication of a patent application, any interested party may inspect the application documents filed with the Office.

3. The Director General, subject to the approval of the Secretary of Trade and Industry, may prohibit or restrict the publication of an application, if in his opinion, to do so would be prejudicial to the national security and interests of the Republic of the Philippines. (n)

#### Request for Substantive Examination

48.-1. The application shall be deemed withdrawn unless within six (6) months from the date of publication under Section 41, a written request to determine whether a patent application meets the requirements of Sections 21 to 27 and Sections 32 to 39 and the fees have been paid on time.

2. Withdrawal of the request for examination shall be irrevocable and shall not authorize the refund of any fee. (n)

#### Amendment of Application

49. An applicant may amend the patent application during examination: Provided, That such amendment shall not include new matter outside the scope of the disclosure contained in the application as filed. (n)

*POLAND: Articles 44-47 of the Industrial Property Law of 30/06/2000, as last amended by Act of 29/06/2007 and Articles 34 and 35 of the Regulations thereto*

#### *Article 44*

1. As from the date of publication of the particulars of the patent application third parties may inspect the application specification. Until a decision on the grant of a patent is taken, such parties may submit to the Patent Office any observations as to the existence of grounds that may cause a patent to be denied.

2. Any amendments to the patent claims received by the Patent Office at least one month before the publication of the particulars of the patent application shall be introduced in the specification together with the indication of the date of making thereof.

#### *Article 45*

1. During a period preceding the publication of the particulars of a patent application filed, the files relating to the application may not be disclosed or made available to unauthorised parties without the applicant's consent.

2. Where in the request for a patent the applicant gives his consent, the Patent Office may only make available to third parties the information on the filing of the application, while disclosing its number, the filing date, the title of the invention and the applicant's name.

3. In the course of examination of the patent application the Patent Office may, without the applicant's consent, seek opinions, as necessary. Anyone involved in the preparation and the issue of such opinions shall be bound not to disclose the data concerning the application.

#### *Article 46*

1. When reasonable, the Patent Office, when having established that the statutory requirements for the grant of a patent have been satisfied, may invite the applicant in an order to furnish, within a fixed time limit and under pain of discontinuance of the proceedings, documents and explanations relating to the application, as well as to make specified corrections or additions in the documents making up the application and to furnish drawings which, although not essential for a better understanding of the invention, however are needed for the purpose of the proper presentation of the invention or are for other reasons necessary.

2. Paragraph (1) shall apply accordingly, where after the start of patent granting proceedings the applicant has made additions or corrections in the application documentation that are prohibited by this Law.

3. Subject to paragraph (4), the Patent Office may make corrections in the documents making up the application only to the extent as necessary to rectify obvious mistakes or language errors.

4. The Patent Office may also make corrections in the abstract other than those specified in paragraph (3).

#### *Article 47*

1. For each patent application, the particulars of which are to be published, the Patent Office shall draw up a search report containing the citations of the documents which may be taken into consideration in evaluating the invention claimed in the application.

2. Immediately after it has been drawn up, the search report referred to in paragraph (1) shall be communicated by the Patent Office to the applicant.

#### *Regulations*

34.-After having carried out the examination, the Patent Office shall:

- i) not consider the subject matter of the invention as a technical solution, especially where it finds that it does not relate to any material product described by means of technical features of its structure or composition, or to a definite technical method of influence the substance.
- ii) not consider the subject matter of the invention as a new solution, if it may produce evidences, in light of which all substantial features of that solution, taken together, cover entirely the solution already known,
- iii) consider the invention claimed and complying with the requirement of novelty as an obvious solution, if it may evidence the state of the art to the extent which justify the ascertainment that the implementation or application of the invention results, when considering the average knowledge of a person skilled in the art, directly from that state of the art,
- iv) not consider the subject matter of the application as susceptible of application, especially where it finds that it is impossible to use it when considering generally adopted and recognized scientific principles or if it is only susceptible of a single application.

35.-1) The Patent Office shall decide on the refusal to grant a patent in cases referred to in para 34, as well as in the event where it finds that:

- i) the invention claimed is excluded from the patent protection (Article 12),
- ii) the solution has not been presented in a manner which sufficiently discloses all substantive features necessary for it to be carried out or the applicant has not determined in the claims the scope of protection sought through the indication of at least one technical feature relating to the subject matter of the application (Article 26),

- iii) a person seeking for a patent is not entitled to a patent,
  - iv) the applicant is not entitled to obtain a patent pursuant to Article 4, or
  - v) a patent has been granted to a patentee enjoying the right of priority.
- 2) The Patent Office shall, before taking the decision referred to in section 1), fix for the applicant a time limit for reacting on proofs and documents which may evidence the lack of statutory requirements for granting a patent.
- 3) In the case, where the lack of statutory requirements for granting a patent relates only to a part of the application and the applicant has not restricted the scope of protection sought, the provisions of sections 1) and 2) shall apply accordingly.

PORTUGAL: *Articles 65, 65A, 66 and 68 of the Industrial Property Code, Decree-Law No. 36 of 05/03/2003 as last amended by Law No. 16 of 01/04/2008*

#### *Article 65*

##### Examination of form and limitations

- 1 After a patent application has been submitted to the National Industrial Property Institute, an examination of the form and limitations of the object or patent shall be performed within one month to check that it meets the requirements of Articles 52, 53 and 61 to 63
- 2 If the National Industrial Property Institute finds that the application contains formal irregularities or that there are limitations regarding the object or patent, the applicant shall be given two months to correct them.
- 3 If he does not do so within the specified time, the application shall be refused and the decision shall be published in the Industrial Property Bulletin, in which case the publication set forth in Article 66 will not be made.

#### *Article 65-A*

##### Search Report

- 1 After the examination set forth in the previous article, there shall be a search of the state of the art based on all the elements in the case file in order to assess whether the novelty and inventive step requirements have been met.
- 2 The search report, which is not binding, shall be sent to the applicant immediately.

#### *Article 66*

##### Publication of the application

- 1 If the application is in order or has been regularised under Article 65(2), it shall be published in the Industrial Property Bulletin with a copy of the summary and the international patent classification.
- 2 The publication referred to in the previous paragraph shall be made 18 months after the date of submission of the patent application at the National Industrial Property Institute or of the priority claim.
- 3 The publication may be brought forward at the applicant's express request.
- 4 After publication, anyone may request a copy of the elements in the file.
- 5 Without prejudice to the previous articles, any claims or expressions violating Article 61(2) shall be ex officio deleted in the patent and in any publications resulting from the application.

#### *Article 68*

##### Examination of invention

- 1 The National Industrial Property Institute shall promote the examination of an invention, considering all elements in the file.
- 2 If no opposition has been filed within the time limit the examination report shall be drafted within one month.
- 3 If an opposition has been filed, the report shall be drafted within one month of the submission of the last part of the procedure referred to in Article 17.
- 4 If the examination shows that the patent can be granted, the respective notice shall be published in the Industrial Property Bulletin.
- 5 If the examination shows that the patent cannot be granted, the report and copies of all the elements mentioned in it shall be sent to the applicant, who shall be given two months to respond to the remarks made.
- 6 If, after the applicant's response, it is found that there are still objections to the grant of the patent, the applicant shall be given one month to clarify the points on which doubts persist.

7 If, as a result of the applicant's response, it is found that the patent can be granted, the respective notice shall be published in the Industrial Property Bulletin.

8 If the response to notifications is not considered sufficient, a notice of refusal or partial grant shall be published, in keeping with the examination report.

9 If the applicant does not respond to the notification, the patent shall be refused and the respective notice shall be published in the Industrial Property Bulletin.

REPUBLIC OF KOREA: : *Articles 57-61 of the Patent Act No. 950 on 28/11/1949, as last amended by Act No. 9381 of 30/01/2009*

*Article 57*

Examination by Examiner

(1) The Commissioner of the KIPO shall have patent applications examined by an examiner.

(2) Necessary matters concerning the qualifications for examiners are prescribed by Presidential Decree.

*Article 58*

Search for Prior Art etc.

(1) If considered necessary for examination of a patent application (including an international search or international preliminary examination), the Commissioner of the KIPO may designate a specialized organization and request it to search for prior art, make an international patent classification, and conduct other tasks prescribed by Presidential Decree.

(2) If considered necessary for the examination process, the Commissioner of the KIPO may request the cooperation and advice of a government agency, an organization specialized in the technology concerned or an expert with profound knowledge and experience in patent matters, and may pay them allowances or expenses for their cooperation or advice within the limits of the budget of the KIPO.

(3) Necessary matters concerning the designation of specialized organizations, such as the standards for designation, and assigning procedures, such as those related to prior art searches and the making of international patent classifications, under paragraph (1) are prescribed by Presidential Decree.

*Article 59*

Request for an Examination of a Patent Application

(1) A patent application is examined only when a request for an examination is filed.

(2) Where a patent application has been filed, any person may request the Commissioner of the KIPO for an examination of the patent application within five years from the filing date of the application.

However, a patent applicant may request an examination of a patent application only when a description with the scope of claims is attached to the written application.

(3) For a divisional application under Article 52(2) or a converted application under Article 53(2), a person may request an examination within thirty days from the filing date of the divisional application or the converted application, even after the expiry of the period prescribed in paragraph (2).

(4) A request for an examination may not be withdrawn.

(5) Where a request for an examination has not been made within the periods prescribed in paragraphs (2) or (3), the patent application concerned is deemed to have been withdrawn.

*Article 60*

Procedure for Requesting an Examination

(1) A person requesting an examination of an application shall submit a written request to the Commissioner of the KIPO, stating the following:

(i) the name and residential address of the person making the request (and, if the person is a juridical person, the name and business address);

(ii) deleted; and

(iii) the indication of the patent application for which the request for an examination is made.

(2) Where a request for an examination has been made before the laying open of the application, the Commissioner of the KIPO shall notify the indication of the request in the Patent Gazette when the application is laid open. Where a request for an examination has been made after the laying open of the application, the Commissioner shall immediately notify the indication of the request in the Patent Gazette.

(3) Where a request for an examination has been made by a person other than the applicant, the Commissioner of the KIPO shall notify the patent applicant accordingly.

#### *Article 61*

##### Accelerated Examination

The Commissioner of the KIPO may have an examiner examine an application in preference to others if the former falls under either of the following subparagraphs:

- (i) where a person other than the applicant is considered to work the invention claimed in the patent application as a business after the laying open of the application; or
- (ii) where urgent processing of the patent application is considered necessary as prescribed by Presidential Decree.

REPUBLIC OF MOLDOVA: *Articles 46- 51 of the Law on the protection of Inventions No. 50-XVI of 07/03/2008*

#### *Article 46*

##### Examination of Patent Application

(1) AGEPI shall examine, in accordance with the Regulations, whether the patent application and the invention which forms its subject-matter meet the requirements of the law. For that purpose AGEPI shall undertake a formal and a preliminary examination and, upon request, a substantive examination of the patent application.

(2) AGEPI may invite the applicant to furnish additional elements that are considered to be essential for identification of the applicant or inventor, the constituted regular national filing or compliance with the patentability requirements.

#### *Article 47*

##### Formal Examination

(1) In the formal examination, AGEPI shall check whether the patent application meets the formal requirements laid down in the Regulations and the conditions for accordance of a filing date under Article 34.

(2) If the patent application does not comply with one or more requirements prescribed in Article 34, AGEPI shall give the applicant an opportunity to correct the deficiencies within the term prescribed in the Regulations.

(3) If the applicant fails to furnish the required information or fails to meet the requirements referred to Article 34 within the prescribed time limit, the application shall be deemed not to have been filed; the applicant shall be notified of the fact.

(4) If a date of filing has been accorded to the patent application, the Agency shall enter it in the National Register of Patent Applications. The data shall be treated as confidential prior to the publication of the patent application.

#### *Article 48*

##### Preliminary Examination

(1) If a patent application has been accorded a date of filing, AGEPI shall undertake a preliminary examination.

(2) In the preliminary examination AGEPI shall examine whether:

- a) the patent application meets the requirements laid down in Article 33;
- b) the subject-matter of the invention is patentable within the meaning of Article 6 and Article 7 and, in case of short-term patents, of Article 12 paragraph (3);
- c) the patent application meets at the first examination the requirements of Article 35;
- d) the requirements of Article 40 paragraph (8) - (11) concerning the priority claim have been satisfied and, where appropriate, the claimed priority is acknowledged;
- e) the requirements of Article 86 paragraph (2) have been satisfied.

(3) Where AGEPI notes that there are deficiencies which may be corrected, it shall give the applicant an opportunity to correct them in accordance with the Regulations.

(4) Where the examination undertaken under paragraph (2) above finds that the requirements of Article 32 paragraph (3) and Article 33 paragraph (9) and (10) have not been satisfied, the patent application shall be refused. If the applicant disregards the provisions of Article 40 concerning the priority right, the deficiency shall lead to the loss of this right for the application.

(5) If the designation of the inventor has not been made in the patent application in accordance with Article 33 paragraph (6) and the omission of the designation of the inventor is not corrected within 16 months from the date of filing of the patent application or, if priority is claimed, from the date of priority, the patent application shall be deemed to be withdrawn.

(6) If the claimed invention is not patentable within the meaning of Article 6, Article 7 and, as the case may be, Article 12 paragraph (3), AGEPI shall take a decision to refuse the application, which is notified to the applicant. The notice concerning the refusal shall be published in BOPI.

#### *Article 49*

##### Publication of Patent Application

(1) A patent application shall be published after the expiry of a period of eighteen months from the date of filing or, if priority has been claimed, as from the date of priority. The particulars to be published in BOPI shall be determined by the AGEPI.

(2) At the request of the applicant and on payment of the prescribed fee, the patent application may be published before the expiry of the period referred to in paragraph (1) above.

(3) The patent application shall be published simultaneously with the publication of the decision to grant a patent when the grant of the patent has become effective before the expiry of the period referred to in paragraph (1) above.

(4) International patent applications shall be published before the expiry of a time limit of 6 months from the date on which the national phase was initiated, subject to the compliance with the requirements of Article 43 paragraph (1).

(5) The publication referred to in paragraph (1) above shall contain the description, the claims and, where appropriate, any drawings as filed and, in an annex, the search report and the abstract, in so far as the latter is available before the termination of the technical preparations for publication. If the search report has not been published at the same time as the application, it shall be published subsequently separately.

(6) Patent applications withdrawn or rejected prior to the termination of the technical preparations for publication shall not be published.

(7) For short-term patents, a patent application shall be published simultaneously with the publication of the decision to grant a patent, and the search report shall be published immediately after it has been drawn up on the basis of the patent search undertaken under Article 18 paragraph (2) or Article 50 paragraph (1).

#### *Article 50*

##### Patent Search

(1) The applicant or any interested person may request, subject to payment of the prescribed fee, a prior art research, of which results will enable the patentability of the invention to be assessed. Based on the search results, the AGEPI shall draw up the search report on the basis of the claims, with due regard to the description and, where appropriate, any drawings, in the form prescribed in the Regulations.

(2) The conditions governing the search and communication of information obtained shall be determined by the Regulations.

#### *Article 51*

##### Substantive Examination of Patent Application

(1) The AGEPI shall examine, on written request, whether the patent application and the invention which forms its subject-matter meet the requirements of this law.

(2) The substantive examination of the patent application shall be carried out within 18 months, excluding the time limits for correspondence and subject to the compliance with the provisions of art. 48. A request for substantive examination may be filed prior to the expiry of 30 months following the filing date of the patent application. The request shall only be deemed to be filed on payment of the examination fee and may not be withdrawn.

(3) If the request for substantive examination is not submitted prior to the expiry of the time limit specified in paragraph (2), the patent application shall be deemed to be withdrawn.

(4) In the substantive examination, the AGEPI shall check whether the application meets, in particular, the requirements set out in Article 6-11, Article 36 and Article 37.

(5) If the examination of a patent application reveals that the application or the invention which makes its subject-matter does not meet the requirements of this law, the AGEPI shall invite the applicant, as

often as necessary, to file his observations and, subject to Article 87, to amend the application within a period to be fixed.

(6) If the applicant fails to reply in due time to any communication from the Agency under paragraph (5), the patent application shall be deemed to be withdrawn.

(7) Upon completion of the substantive examination of the patent application and based on the examination report, the AGEPI shall decide either to grant a patent or to refuse the patent application.

(8) The provisions of this article shall not apply to short-term patents.

ROMANIA: *Articles 24-27 of the Patent Law No. 64/1991 as republished in the OJ, Part I, No. 638/18.IX.2007*

#### *Article 24*

At the request of the applicant, OSIM shall draw up a search report which may be accompanied by a written opinion concerning the patentability, where appropriate, and shall publish the search report under the provisions of the Implementing Regulations to this Law.

If the search report is not published at the same time as the patent application, it shall be published subsequently.

#### *Article 25*

Examination of the patent application may be requested on the filing date of the patent application or, as the case may be, upon the opening of the national phase or within 30 months from one of these dates.

For the patents applications containing information classified as secret of State, examination may be requested on the filing date of the patent application or within 3 months from the date on which such secrecy has been lifted, but no later than 30 months before the expiry of the patent duration prescribed under Art. 31.

#### *Article 26*

OSIM shall examine whether:

A. the patent application satisfies:

- a) the provisions of Art. 6;
- b) the requirements concerning filing, prescribed under Art. 14 - 16;
- c) the requirements for recognizing the priority, prescribed under Art. 20, 21 and 22;
- d) the requirement of unity of invention, prescribed under Art. 19, paragraph 1;

B. the invention which is the object of the application:

- a) is disclosed in accordance with Art. 18;
- b) is not excluded from patentability under Art. 8, paragraph 1, or does not fail to comply with the requirements under Art. 9;
- c) satisfies the patentability conditions under Art. 7 and Art. 10 - 13.

#### *Article 27*

OSIM is authorized to request the applicant to provide explanations and documents considered necessary in connection with the identity of the applicant or the inventor, with the regular national filing effected or in order to meet the conditions of patentability.

In all the procedures related to the patent application or the patent, OSIM may send notifications to the applicant, the patent owner or the interested person, and they may send communications to OSIM, observing the time limits prescribed by the Implementing Regulations to this Law, time-limits that may be extended by OSIM upon request, against payment of the prescribed fee.

The absence of notifications shall not absolve the applicant, patent owner or interested person from the obligation to meet the requirements of this Law.

The applicant shall file with OSIM all public documents connected to his invention, including copies of patents granted in other States.

At the request of OSIM or on his own initiative, the applicant or his successor in title may, until such time as a decision is made, modify the patent application, provided that the disclosure of the invention do not extend beyond the content of the patent application on the filing date.

RUSSIAN FEDERATION: *Articles 1384- 1386 of the Patent Act (Chapter 72)*

*Article 1384*

Formal Examination of an Application for an Invention

1. Formal examination of an application for an invention that has been filed with the federal executive authority for intellectual property shall be carried out. In the process of such examination the presence of the documents provided for by Paragraph 2 of the 1375 of the present Code and their conformity to prescribed requirements shall be verified.

2. In the case when the applicant has presented supplementary materials to the application for an invention under Paragraph 1 of Article 1378 of the present Code it shall be ascertained whether they change the essence of the claimed invention.

Supplementary materials that change the essence of the claimed invention shall not be taken into account for the purposes of examination of the application for the invention, but may be filed by the applicant as separate application. The federal executive authority for intellectual property shall inform it to the applicant.

3. The federal executive authority for intellectual property shall notify the applicant of a favorable result of formal examination and of the filing date of the application for the invention, promptly after the completion of formal examination.

4. If an application for an invention fails to meet the prescribed requirements for documents of the application, the federal executive authority for intellectual property, shall invite the applicant to furnish corrected or missing documents within two months from the date of the receipt by him of such invitation. If the applicant fails to furnish the documents in question or to file a request for extending this period within the prescribed time limit, the application shall be considered as withdrawn. This time limit may be extended by the federal executive authority, but by no more than ten months.

5. If an application for an invention has been filed with non-fulfillment of the requirement of unity of invention (Paragraph 1 of Article 1375), the federal executive authority for intellectual property shall invite of the applicant to communicate, within two months from the date of receipt by him of the respective notification, which of the claimed inventions should be examined, and if necessary, to correct the documents of the application. Other inventions claimed in the original application may be submitted as divisional applications. If the applicant fails to communicate within the prescribed time limit which of the claimed inventions should be examined or fails to furnish, if necessary, the appropriate documents, the examination of the invention shall carried out in respect of the invention that is indicated first in the claims.

*Article 1385*

Publication of Information on the Application for an Invention

1. The federal executive authority for intellectual property, upon the expiration of eighteen months from the filing date of an application for an invention, in respect of which the formal examination finding is favorable, shall publish information on the application for the invention in the official gazette. The list of the published data shall be determined by the federal executive authority responsible for normative and legal regulation in the area of intellectual property.

The author of the invention may waive his right to be indicated as such in the published information on the application for an invention.

At the request of an applicant filed before the expiration of twelve months from the filing date of the application for an invention, the federal executive authority for intellectual property may publish information on the application for an invention before the expiration of eighteen months from the day of its filing.

Publication shall not be made if before the expiration of twelve months from the day of filing the application for the invention it was withdrawn or recognized as withdrawn or if on its basis the registration of the invention was effected.

2. Any person after publication of the information on the application for the invention shall have the right to learn the documents of the application unless the application has been withdrawn or recognized as withdrawn on the date of publication of information on invention. The procedure governing access to the documents of the application and making copies of such documents shall be established by the federal of executive authority responsible for normative and legal regulation in the area of intellectual property.

3. In case of publication of information on an application for an invention, which application on the date of publication had been withdrawn or recognized as withdrawn, such information shall not be included in the prior art in the processing of subsequent applications of the same applicant filed with the federal

executive authority for intellectual property before the expiration of twelve months from the date of publication of information on the application for an invention.

*Article 1386*

Substantive Examination of an Application for an Invention

1. At the request of the applicant or of third parties, which may be filed with the federal executive authority for intellectual property when filing of the application for an invention or within three years from the filing date of this application, and on the condition of successful completion of formal examination of this application, substantive examination of the application for an invention shall be conducted. The federal executive authority for intellectual property shall notify the applicant of request received from third parties.

The time period for filing the request for the conduct of substantive examination of an invention may be extended by the federal executive authority for intellectual property at the request of the applicant filed before the expiration of this time period, but for not more than two months, provided that the request be accompanied by a document confirming payment of the patent fee.

If the request for the conduct of a substantive examination of an invention has not been filed within the prescribed time limit, the application shall be considered as withdrawn.

2. Substantive examination of an invention shall include:

a prior art search with respect to the claimed invention to check the novelty and inventive step of the invention;

checking the fulfillment of the claimed invention to the criteria of patentability stipulated by Article 1350 of the present Code.

A search with respect to the claimed invention, relating to the objects indicated in Paragraph 4 of Article 1349 and in Paragraphs 5 and 6 of Article 1350 of the present Code, shall not be conducted.

The federal executive authority for intellectual property shall notify it to the applicant before the expiration of six months from the date of the start of substantive examination of the invention.

The procedure for conduct of the search and the presentation of the search report shall be established by the federal executive authority responsible for normative and legal regulation in the area of intellectual property.

3. Upon the expiration of six months from the date of the start of the substantive examination of the application for an invention, the federal executive authority for intellectual property shall send to the applicant a search report, unless the application claims a priority earlier than the filing date of the application and if the request for the conduct of substantive examination of the application for the invention was filed on the filing date of the application.

The time period for sending the applicant a search report may be extended by the federal executive authority for intellectual property if the necessary information source has to be obtained from other organizations in case when information is missing in the collections of the said federal authority or the characterization of the claimed invention is such as to make a search impossible under the established procedure. The said federal authority shall notify the applicant of the extension of the time period for sending the search report and of the reasons for of extension.

4. The applicant and third persons shall have the right to request for the conduct for an application for an invention that has passed formal examination with a favorable result, of an prior-art search in order to determine whether the claimed invention meets the criteria of novelty and inventive step. The procedure and modalities for the conduct of such a search and communication of its results shall be established by the federal authority responsible for normative and legal regulation in the area of intellectual property.

5. In the process of substantive examination of an application for an invention the federal executive authority for intellectual property may request the applicant furnishing supplementary materials (including amended claims for the invention) without which the conduct of examination is impossible. In this case supplementary materials without changing the essence of the invention shall be presented within two months from the day of receipt by the applicant of the request or copy of materials cited in request, provided that the applicant has requested the aforesaid copies within one month from the day of receipt by him of the request from the said federal authority. If within the established time limit the applicant fails to present the requested materials or a request on the extension of this time limit, the application shall be considered as withdrawn. The time limit established for presentation by the applicant of the requested materials may be extended by the said federal authority not for more than ten months.

*RWANDA: Article 33 of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property*

*Article 33*

**Examination**

After according a filing date, and having the invention classified according to the International Classification, the empowered authority shall examine whether the application complies with the requirements of articles 23 and 24, and the provisions of the administrative regulations pertaining thereto, as well as the other requirements of this Law and relevant administrative regulations which, under this Law, constitute formal requirements, and shall examine whether information specifically requested under articles 30 and 31 if any, has been provided.

If the empowered authority finds that the requirements of paragraph (1) of this article have not been satisfied, he shall invite the applicant to make the required corrections; if the applicant does not comply with the invitation, the application shall be considered withdrawn; if the correction relates to the declaration of priority, the right of priority shall be lost.

Where the empowered authority is of the opinion that the application complies with the formal requirements of the paragraph (1) of this article, he shall take a decision as to whether the requirements of articles 14 to 18, 25 and 26 and the administrative regulations pertaining thereto and cause, if appropriate, the application to be examined as to substance. For the purposes of examination as to substance, the empowered authority shall take into account:

- 1° the results of any international search report and any international preliminary examination report established under the Patent Cooperation Treaty in relation to the application filed in Rwanda; and/or
- 2° the results of any search and examination report and any decision submitted under article 31 of this Law; and/ or
- 3° the results of any search and examination report which was carried out upon his request by an external search and examination authority or by a specialized agency of the Government of Rwanda.

*SAINT LUCIA: Sections 24 and 25 of the Patents Act No. 16 of 27/08/2001*

**Examination as to form**

24.- (1) Where an application for a patent has a date of filing and is not withdrawn or treated as having been abandoned, the Registrar shall, as soon as practicable after the end of the prescribed period, examine the application so as to determine whether the application complies with those requirements pursuant to this Act which are designated by the Regulations as formal requirements for the purposes of this Act.

(2) Where, after an examination under subsection (1), it is determined that not all the formal requirements are complied with, the Registrar shall give the applicant an opportunity to make observations and to amend the application within such period as the Registrar may specify so as to comply with those requirements, subject, however, to section 80, and if the applicant fails to do so, the Registrar may refuse the application

**Search and examination and corresponding international applications**

25.- (1) Where an application for a patent complies with all the formal requirements referred to in section 24(1), the Registrar shall notify the applicant who shall

- (a) file a request in the prescribed form and pay the prescribed fee for a search report within the prescribed period;
- (b) file a request in the prescribed form and pay the prescribed fee for a search and examination report within the prescribed period; or
- (c) where the applicant has filed, alone or jointly with any other person, a corresponding international application for a patent, not designating Saint Lucia, or a corresponding application for a patent at any prescribed patent office, furnish such detail as prescribed and within the prescribed period, of all the corresponding international applications and the other corresponding applications filed by him or her;

and if the applicant fails to make such request, pay the prescribed fee or furnish the prescribed detail within the prescribed period, the application shall be treated as having been abandoned at the end of the period prescribed under paragraph (a), (b) or (c), whichever is the latest.

(2) Where the applicant has filed a request and paid the fee under subsection (1) (a), the Registrar shall cause the application to be subject to a search by an examiner to discover the relevant prior art contained in such documentation as may be prescribed.

(3) Upon receipt of the report of the search carried out under subsection (2), the Registrar shall send to the applicant a copy of the report, and the applicant may, within the prescribed period, file a request and pay the prescribed fee for an examination report on the application so as to determine whether the conditions specified in sections 9 and 21(4) and (5) have been complied with, taking into consideration all the relevant prior art, if any, referred to in the search report; and upon receipt of the report, the Registrar shall send to the applicant a copy of the report.

(4) Where the applicant has furnished the prescribed details under subsection (1) (c), he or she shall, subject to subsection (5), within the prescribed period, file the prescribed information in or translated into the English Language relating to any one of the corresponding international applications or other corresponding applications referred to in subsection (1) (c).

(5) The applicant may, instead of filing the prescribed information referred to in subsection (4), within the prescribed period, either:

(a) file a copy of a search report in respect of any one of the corresponding international applications or other corresponding applications referred to in subsection (1) (c), together with a request in the prescribed form and the prescribed fee, for an examination report; or

(b) file a request in the prescribed form and pay the prescribed fee for a search and examination report.

(6) Where the applicant has filed a request and paid the fee under subsection (1) (b) or (5) (b), the Registrar shall cause the application to be subject to:

(a) a search by an examiner to discover the relevant prior art contained in such documentation as may be prescribed;

(b) an examination by an examiner so as to determine whether the conditions specified in sections 9 and 21 (4) and (5) have been complied with, taking into consideration all the relevant prior art, if any, discovered in the search, and upon receipt of the search and examination report, the Registrar shall send to the applicant a copy of the report.

(7) Where the applicant has filed a request and paid the fee under subsection (5) (a), the Registrar shall cause the application to be subject to an examination by an examiner so as to determine whether the conditions specified in sections 9 and 21 (4) and (5) have been complied with, taking into consideration all the relevant prior art, if any, referred to in the search report and upon receipt of the examination report, the Registrar shall send to the applicant a copy of the report.

(8) Where an international application for a patent (Saint Lucia) has been filed by the applicant and the international preliminary examination report is not established, the applicant may, within the prescribed period file a request in the prescribed form and pay the prescribed fee, for an examination report on the application so as to determine whether the conditions specified in sections 9 and 21 (4) and (5) have been complied with, taking into consideration all the relevant prior art, if any, referred to in the international search report, and upon receipt of the examination report, the Registrar shall send to the applicant a copy of the report.

(9) For the purposes of this Part, "corresponding international application" and "corresponding application", in relation to an invention, mean an application for protection filed, respectively, under the Patent Co-operation Treaty or with any prescribed patent office in respect of the same or substantially the same invention as that which is the subject of the application in suit, the application filed under the Patent Co-operation Treaty or with the prescribed patent office being

(a) the basis for a priority claim pursuant to section 13 in the application in suit; or

(b) subject to a priority claim based on the application in suit or an application which is also the basis for a priority claim pursuant to section 13 in the application in suit.

*SAN MARINO: Article 23 of the Law on Industrial Property No. 79 of 25/05/2005*

#### *Art. 23*

*(Esame della domanda e rilievi)*

1. L'esame della domanda è rivolto ad accertare se l'invenzione sia conforme alle disposizioni di questo Testo Unico. Esso è rivolto a verificare in primo luogo la regolarità formale della domanda di brevetto e non riguarda in ogni caso il valore tecnico od economico dell'invenzione.

2. L'Ufficio di Stato Brevetti e Marchi esamina se l'invenzione soddisfa i requisiti degli articoli 1 e 2, commi 2 a 5, articoli 10, 11, 12, 13, 14, 15, 16 e 18 precedenti tuttavia l'Ufficio di Stato Brevetti e Marchi non esamina in quanto al merito la conformità con i requisiti degli articoli 3, 4 e 5 precedenti.

3. Per l'applicazione del precedente comma 2, l'Ufficio di Stato Brevetti e Marchi può utilizzare rapporti di ricerca documentale o rapporti di esame di merito preparati da un'altra autorità, in particolare da autorità di ricerca e/o di esame ai sensi del Trattato di Cooperazione sui Brevetti (PCT).

4. L'esame della domanda non viene iniziato da parte dell'Ufficio di Stato Brevetti e Marchi prima della pubblicazione della domanda di brevetto. Su istanza del richiedente, l'esame può essere accelerato, compatibilmente con le risorse disponibili da parte dell'Ufficio di Stato Brevetti e Marchi, così da arrivare nel più breve tempo possibile ad una conclusione di tale esame. In caso venga presentata una istanza di esame accelerato senza che sia disponibile uno dei rapporti di cui al precedente comma 3, il richiedente dovrà necessariamente fornire tale rapporto all'Ufficio di Stato Brevetti e Marchi.

5. Il richiedente deve fornire, su richiesta dell'Ufficio di Stato Brevetti e Marchi, copia di qualsiasi comunicazione ricevuta dal richiedente concernente i risultati di ricerche o esami condotti nei riguardi della domanda di brevetto o di altro titolo di protezione depositato dal richiedente all'estero relativo alla stessa o sostanzialmente alla stessa invenzione rivendicata nella domanda depositata presso l'Ufficio medesimo.

6. Salve le disposizioni dei precedenti commi 1 e 2, se l'Ufficio di Stato Brevetti e Marchi rileva che la domanda non soddisfa alcuni dei requisiti previsti da questo Testo Unico, i rilievi, ai quali dia luogo l'esame della domanda, debbono essere comunicati per iscritto, all'interessato, con l'assegnazione di un termine, prorogabile su richiesta motivata, ai sensi di questo Testo Unico. Se il richiedente non risponde, nei termini prescritti, ai rilievi o obiezioni dell'Ufficio di Stato Brevetti e Marchi, la domanda verrà rifiutata.

*SAUDI ARABIA: Articles 12 and 13 of the Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs of 2004 and Articles 34, 35 and 36 of the Regulations thereto*

*Article Twelve*

The Directorate shall examine the registered applications in terms of formalities. If it appears, from the examination, that some of the legally prescribed conditions are not satisfied it may instruct the applicant to satisfy them within a maximum of ninety days from the date of notification. If he did not fulfill what was requested within the said period, his application would be considered as if it had never been filed.

*Article Thirteen*

Once the application for patent or plant patent has been examined in terms of formalities, it shall be examined in terms of substance, in accordance with what is stated in the Regulations.

*Regulations*

*Article (34)*

Registered applications shall be examined to ensure that they satisfy the formal conditions provided for in Articles 8 and 10 of the Law and the articles of Part Two of these Regulations for each subject of protection. If it is found from the formal examination that some of the prescribed conditions are not satisfied, the applicant shall be requested to satisfy them within a period not exceeding ninety days from the date of notifying him thereof. If he fails to perform what is requested from him within the said period, his application shall be deemed null and void.

*Article (35)*

(1) If it is found from the formal examination of the application for a patent or a plant patent that the application satisfies formal requirements, the Directorate shall notify the applicant to pay the prescribed publication fees within a grace period of three months. If he does not pay within the specified period, the application and publication thereof shall be rejected, and this shall be recorded in the Register and published in the Gazette.

(2) The Directorate shall assess the necessary expenses for the examination of the substance of the application for a patent or a plant patent. The assessments shall be in accordance with the actual cost of examination, and the applicant shall be required to pay it within three months from the date of his notification thereof. If he fails to pay, the application shall be rejected and this shall be recorded in the Register and published in the Gazette.

(3) Upon payment of the costs assessed above, the Directorate shall examine the substance of the application.

*Article (36)*

The Directorate shall examine the substance of the application for the patent to ensure that the application satisfies the conditions provided for in Articles (4), (43), (44), (45) and (46) of the Law and the provisions stipulated in these Regulations. For that purpose, it may perform the following:

- Classify the application in accordance with the International Classification of Patents.
- Examine the protection elements, the description and the illustrations.
- Search the data bases at the Directorate, or on the Internet or at other patent offices.
- Compare available documents with the invention.

The Directorate shall prepare the report of the substantial examination which shall include its opinion as to whether the application satisfies the conditions provided for and the required explanations and amendments.

SERBIA: *Articles 40-45 of the Patent Law of 10/07/2004*

Examination as to Form

*Article 40*

Once the application has been accorded a date of filing, the competent authority shall examine whether it meets all requirements for publication, particularly taking into account whether:

- 1) the filing fee for the application has been paid;
- 2) a valid authorisation for the representative or a statement on the appointment of a common representative has been filed, where appropriate;
- 3) the application contains designation of the inventor or a statement to the effect that he does not wish to be mentioned in the application;
- 4) a claim for a grant of priority, satisfying all formal requirements, has been filed;
- 5) a statement specifying the grounds for the filing of the application has been submitted;
- 6) the application has been filed through a representative, pursuant to Article 4 of this Law, in the event that the applicant is a foreign national;
- 7) the application contains all documents prescribed by Article 23 of this Law and they satisfy all requirements as to form;
- 8) a separate application has been filed for each invention, where, at first glance, the application fails to meet the requirements concerning unity of invention referred to in Article 22 of this Law.

If the examination stipulated in paragraph 1 of this Article shows that the application is not in conformity with the provisions of that paragraph, the competent authority shall set out the reasons thereof in a communication to the applicant, inviting him to correct the deficiencies within an appropriate time limit. Such time limit shall not be less than 60 or more than 90 days.

On a reasoned request by the applicant, the competent authority may extend the time limit specified in paragraph 2 of this Article, for a period it deems appropriate, but not exceeding 90 days.

If the applicant fails to remedy the defects referred to in paragraph 2 of this Article, the competent authority shall take a decision to reject the application.

Publication of Patent Application

*Article 41*

A patent application that satisfies all the requirements laid down in Article 40, paragraph 1 of this Law shall be published in the Official Bulletin of the competent authority, as soon as possible upon the expiry of eighteen months from the filing date of the application or from the claimed date of priority.

At the request of the applicant, the patent application may be published earlier, but not before the expiry of three months from the filing date.

The content of the publication shall be defined by a regulation under this Law.

Request for Substantive Examination as to Patentability

*Article 42*

The request for substantive examination of a patent application shall be filed by the applicant after the publication of the application in the Official Bulletin within a period of six months from the date of publication.

In the event of failure to observe the time limit specified in the previous paragraph, the applicant may file the request referred to in paragraph 1 of this Article within an extended period of 30 days from the date of the receipt of a notification of the expiry.

The request referred to in paragraph 1 of this Article may not be withdrawn.

If the applicant fails to file a request under paragraph 1 of this Article within the prescribed time limit, the patent application shall be deemed withdrawn and a decision to that effect shall be given.

#### Substantive Examination Procedure

##### *Article 43*

In the course of the substantive examination of an application, the competent authority shall examine whether the subject matter of the application:

- 1) constitutes an invention within the meaning of Articles 5 and 6 of this Law;
- 2) constitutes an invention patentable within the terms of Article 7 of this Law;
- 3) constitutes an invention that is in accordance with Article 22 of this Law relating to unity of invention;
- 4) is disclosed in a manner sufficiently clear and complete pursuant to Article 25 of this Law;
- 5) constitutes a technical solution of a specific problem, is new in accordance with Articles 8 and 9 of this Law, involves an inventive step as set out by Article 10 and is susceptible to industrial application as laid down in Article 11 of this Law;

The substantive examination of a patent application shall be conducted within the limits set by the content of the patent claims.

The utility of the invention shall not be examined during the substantive examination procedure.

##### *Article 44*

If the competent authority establishes that the subject matter of an application does not meet the requirements laid down in Article 43 of this Law, the applicant shall be informed thereof in the examination report and shall be invited to comment on the reasons preventing the grant of a patent or to rectify any deficiencies identified, within an appropriate time limit. This time limit shall be not be less than 60 days nor more than 90 days.

On a reasoned request from the applicant, the competent authority shall extend the time limit under paragraph 1 of this Article for such a period as it deems appropriate, but not exceeding 90 days.

##### *Article 45*

An applicant, who has filed an application for the same invention in any other state, may furnish the competent authority with a certified translation of the examination report issued in the said state.

SINGAPORE: *Sections 28, 29 and 38A of the Patents Act No. 21 of 25/11/1994 as of 01/12/2008*

#### Preliminary examination

28.-(1) The Registrar shall conduct a preliminary examination of an application for a patent if

- (a) the application has a date of filing;
  - (b) the application has not been withdrawn or treated as abandoned;
  - (c) the filing fee under section 25 (1) (b) has been paid;
  - (d) one or more claims for the purposes of the application have been filed under section 26 (12) (a); and
  - (e) where the application has a date of filing under section 26 (1) by reason only that the documents filed at the Registry to initiate the application satisfy the conditions in section 26 (1) (a), (b) and (c) (ii), the documents referred to in section 26 (7) (a), (b) and (c) have been filed at the Registry.
- (2) If, after the Registrar has conducted a preliminary examination of an application for a patent under subsection (1), the applicant files at the Registry, and does not withdraw, any missing part of the application in accordance with section 26 (8), then the Registrar shall conduct another preliminary examination of the application, with the missing part treated as included in the application.
- (3) On a preliminary examination of an application, the Registrar shall determine
- (a) whether the application complies with all the formal requirements; and
  - (b) whether
    - (i) any drawing referred to in the application; or
    - (ii) any part of the description of the invention for which the patent is sought, is missing from the application.
- (4) If the Registrar determines under subsection (3) (a) that not all the formal requirements have been complied with, then the Registrar shall notify the applicant accordingly and shall specify in the notification a period during which the applicant shall have the opportunity
- (a) to make observations on the Registrar's determination; and
  - (b) subject to section 84, to amend the application so as to comply with all the formal requirements.

- (5) Where subsection (4) applies, the Registrar may refuse the application if the applicant fails to amend the application as mentioned in paragraph (b) of that subsection before the end of the period specified by the Registrar under that subsection.
- (6) Subsection (5) does not apply if
- (a) the applicant makes observations as mentioned in subsection (4) (a) before the end of the period specified by the Registrar under subsection (4); and
  - (b) as a result of the observations, the Registrar is satisfied that all the formal requirements have been complied with.
- (7) If the Registrar determines under subsection (3) (b) that a drawing or part of the description of the invention is missing from the application, then the Registrar shall notify the applicant accordingly.
- (8) Where subsection (7) applies, if the applicant files the drawing or part of the description of the invention that is missing from the application within such period and in such manner as may be prescribed, and the applicant does not withdraw that drawing or part of the description of the invention before the end of that period, then
- (a) that drawing or part of the description of the invention shall be treated as included in the application; and
  - (b) the date of filing of the application shall be the date on which that drawing or part of the description of the invention is filed at the Registry.
- (9) Subsection (8) (b) does not apply if
- (a) on or before the date which is the date of filing of the application by virtue of section 26 (1), a declaration is made under section 17 (2), in or in connection with the application, specifying an earlier relevant application; and
  - (b) within such period as may be prescribed, the applicant
    - (i) makes a request to the Registrar for subsection (8) (b) not to apply to the application;
    - (ii) files a statement that the drawing or part of the description of the invention referred to in subsection (8) is incorporated in the application by reference to, and is completely contained in, the earlier relevant application, as filed;
    - (iii) furnishes such information on the earlier relevant application as may be prescribed; and
    - (iv) files such other documents as may be prescribed.
- (10) In subsection (9), "relevant application" has the same meaning as in section 17 (5).

#### Search and examination

29.-(1) Where an application for a patent complies with all the formal requirements, the Registrar shall send a notification to the applicant.

(2) The applicant shall comply with any of the following paragraphs which is applicable within the period prescribed for that paragraph:

- (a) where the application is not an international application for a patent (Singapore) that has entered the national phase in Singapore under section 86 (3), file a request in the prescribed form and pay the prescribed fee for a search report;
- (b) file a request in the prescribed form and pay the prescribed fee for a search and examination report;
- (c) where a corresponding application for a patent has been filed at any prescribed patent office
  - (i) file
    - (A) a copy of the search report in respect of the corresponding application;
    - (B) where the search report is not in English, an English translation of the search report;
    - (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
    - (D) a request in the prescribed form for an examination report,and pay the prescribed fee for an examination report; or
- (ii) file
  - (A) in the prescribed form, the prescribed information relating to the corresponding application; and
  - (B) where the prescribed information includes any document that is not in English, an English translation of such document;
- (d) where a corresponding international application for a patent has been filed
  - (i) file
    - (A) a copy of the international search report in respect of the corresponding international application;
    - (B) where the international search report is not in English, an English translation of the international search report;

- (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
  - (D) a request in the prescribed form for an examination report,
- and pay the prescribed fee for an examination report; or

(ii) file

- (A) in the prescribed form, the prescribed information relating to the corresponding international application; and
- (B) where the prescribed information includes any document that is not in English, an English translation of such document;

(e) where the application is an international application for a patent (Singapore) that has entered the national phase in Singapore under section 86 (3)

(i) file

- (A) a copy of the international search report issued in respect of the application;
  - (B) where the international search report is not in English, an English translation of the international search report;
  - (C) a copy of each prescribed document and, where required by the rules, an English translation of the document if it is not in English; and
  - (D) a request in the prescribed form for an examination report,
- and pay the prescribed fee for an examination report; or

(ii) file a notice in the prescribed form of the applicant's intention to rely on the international preliminary report on patentability in respect of that application.

[19/2004]

(3) Where the applicant has filed a request and paid the prescribed fee for a search report under subsection (2) (a), the Registrar shall

(a) cause the application to be subjected to a search by an Examiner to discover the relevant prior art contained in

- (i) such documentation as may be prescribed; and
  - (ii) any additional documentation that the Examiner is aware of and considers to be relevant;
- and

(b) upon receiving the search report prepared by the Examiner, send the applicant a notification and a copy of the search report.

(4) Upon receiving the search report under subsection (3) (b) from the Registrar, the applicant shall, within the prescribed period, file a request in the prescribed form and pay the prescribed fee for an examination report.

(5) Where the applicant has filed a request and paid the fee for an examination report under subsection (2) (c) (i), (d) (i) or (e) (i) or (4), the Registrar shall

- (a) cause the application to be subjected to an examination by an Examiner to determine
- (i) whether the conditions specified in sections 13 and 25 (4) and (5) have been complied with;
  - (ii) whether the application discloses any additional matter referred to in section 84 (1); and
  - (iii) whether the application discloses any matter extending beyond that disclosed in the application as filed,

taking into consideration all the relevant prior art, if any, that the Examiner is aware of or that has been referred to in the search report or international search report, as the case may be; and

(b) upon receiving the examination report prepared by the Examiner, send the applicant a notification and a copy of the examination report.

(6) Where the applicant has filed a request and paid the fee for a search and examination report under subsection (2) (b), the Registrar shall

(a) cause the application to be subjected to

- (i) a search by an Examiner to discover the relevant prior art contained in
  - (A) such documentation as may be prescribed; and
  - (B) any additional documentation that the Examiner is aware of and considers to be relevant; and

(ii) an examination by an Examiner to determine

- (A) whether the conditions specified in sections 13 and 25 (4) and (5) have been complied with;
- (B) whether the application discloses any additional matter referred to in section 84 (1); and
- (C) whether the application discloses any matter extending beyond that disclosed in the application as filed,

taking into consideration all the relevant prior art, if any, that the Examiner is aware of or that has been discovered in the search; and

- (b) upon receiving the search and examination report prepared by the Examiner, send the applicant a notification and a copy of the search and examination report.

[19/2004]

- (7) If, within the prescribed period under

- (a) paragraph (b), (c) (i) or (ii), (d) (i) or (ii) or (e) (i) or (ii) of subsection (2); or
- (b) subsection (4),

an applicant files a request in the prescribed form and pays the prescribed fee for that period to be extended, the applicant shall perform the acts set out in that provision within the prescribed extended period for performing those acts.

#### Search and examination after grant

38A.-(1) Subject to subsection (2), any person may request for a search and examination report in respect of any claim or claims in the specification of a patent on any of the following grounds:

- (a) where the patent was granted on the basis of any examination report or search and examination report referred to in section 29, any international preliminary report on patentability referred to in section 30 (2) (b) (vi) or any international preliminary examination report, that
  - (i) at least one claim in the application for the patent at the time the prescribed documents for the grant of the patent were filed and the prescribed fee for the grant of the patent was paid was not related to any claim in the application at the time the report was issued

- (A) which has been examined; and

- (B) which is referred to in the report; or

- (ii) the Examiner of the application did not consider all the relevant prior art before preparing the report;

- (b) where the patent was granted on the basis of any prescribed information relating to a corresponding application or corresponding international application referred to in section 29, that

- (i) at the time the prescribed documents for the grant of the patent were filed and the prescribed fee for the grant of the patent was paid, at least one claim in the application for the patent did not relate to any claim

- (A) which is set out in the prescribed information relating to the corresponding application or corresponding international application, as the case may be; and

- (B) which has been examined to determine whether the claim appears to satisfy the criteria of novelty, inventive step (or non-obviousness) and industrial applicability (or utility); or

- (ii) the Examiner of the corresponding application or corresponding international application, as the case may be, did not consider all the relevant prior art before preparing his report on the examination of the corresponding application or corresponding international application, as the case may be.

[19/2004]

- (2) The Registrar shall not grant a request under subsection (1) unless

- (a) the request is filed in the prescribed manner;
- (b) the prescribed fee for the search and examination report has been paid; and
- (c) in a case to which subsections (3) and (4) apply, subsection (4) has been complied with.

[19/2004]

- (3) Subject to subsection (4), any person who files a request under subsection (1) may, at the time he files the request, also file

- (a) any observation which he wishes to make in relation to the patent; and
- (b) any document which he considers to be relevant for the purposes of the examination.

- (4) Where any document referred to in subsection (3) (b) is not in English, the person who files the request under subsection (1) shall also file an English translation of the document.

[19/2004]

(5) The Registrar shall not grant a request under subsection (1) if he is of the view that the request is frivolous, vexatious or an abuse of the process.

[19/2004]

(6) No request under subsection (1) shall be filed or granted where there are pending before the court or the Registrar proceedings in which the validity of the patent may be put in issue.

[19/2004]

(7) Where the Registrar grants a request under subsection (1), the Registrar shall cause the claim or claims to be subjected to

- (a) a search by an Examiner to discover the relevant prior art contained in
  - (i) such documentation as may be prescribed; and
  - (ii) any additional documentation that the Examiner is aware of and considers to be relevant;and
- (b) an examination by an Examiner to determine
  - (i) whether the conditions specified in sections 13 and 25 (4) and (5) have been complied with;
  - (ii) whether the specification of the patent discloses any additional matter referred to in section 84 (1); and
  - (iii) whether the specification of the patent discloses any matter extending beyond that disclosed in the application for the patent as filed,

taking into consideration all the relevant prior art, if any, that the Examiner is aware of or that has been discovered in the search.

(8) If it appears to the Examiner during the examination of the specification of the patent that

- (a) the conditions specified in sections 13 and 25 (4) and (5) have not been complied with; or
- (b) the specification of the patent discloses

- (i) any additional matter referred to in section 84 (1); or
- (ii) any matter extending beyond that disclosed in the application for the patent as filed,

the Examiner shall give the proprietor of the patent a written opinion to that effect, and the proprietor of the patent shall, before the examination report is issued, have the right to respond in the prescribed manner to the written opinion within the prescribed period.

(9) Upon receiving the search and examination report prepared by the Examiner, the Registrar shall

- (a) send a copy of the report to the proprietor of the patent; and
- (b) where the request under subsection (1) is not filed by the proprietor of the patent, send a copy

- each of
  - (i) the report;
  - (ii) any written opinion given by the Examiner; and
  - (iii) any response given in the prescribed manner by the proprietor of the patent to any such written opinion,

to the person who filed the request.

*SLOVAKIA: Articles 40- 44 of the Patent Act No. 435/2001as last amended by Act No. 202/ 2009 Coll.*

Preliminary examination of application

*Article 40*

(1) Within preliminary examination the Office shall ascertain whether

- a) conditions to determine filing date of an application pursuant to Article 35 have been met,
- b) conditions to confer priority right pursuant to Article 36 have been met,
- c) application meets conditions pursuant to Articles 37, 38 and 59,
- d) application meets conditions pursuant to a generally binding regulation (Article 80),
- e) applicant has paid an appropriate administrative fee pursuant to Article 79(9),
- f) applicant is being represented by an authorised representative pursuant to Article 79(1),
- g) application does not contain a subject-matter which clearly fails to meet conditions pursuant to Article 5(1) or is not being considered to be an invention pursuant to Article 5(3), or which is a subject to exclusion from patentability pursuant to Article 6.

(2) In case of doubts the Office may invite an applicant to prove utility of a subject matter of an application by its demonstrating or in another suitable manner. If an applicant fails to prove utility or fails to comply with an invitation, subject-matter of an application shall be deemed not to be utilisable.

(3) In case that irregularities have been ascertained pursuant to paragraph 1(e) and (f) or Article 35(2), or Article 37(3) and (5), or Article 79(9), or pursuant to implementing regulation (Article (80)), the Office shall invite an applicant to correct these irregularities within the prescribed time limit or to respond to

the invitation. If an applicant fails to comply with the invitation within the prescribed time limit or his response fails to rebut validity of the invitation, the Office shall suspend application proceedings. An applicant shall be notified in an invitation about this consequence.

(4) If an application fails to meet conditions pursuant to Article 37(1) and (4) or Article 38(1) to (3) or a subject-matter of an application evidently fails to meet conditions pursuant to Article 5(1), or it is not being considered to be an invention pursuant to Article 5(3), or is subject to exclusion from patentability pursuant to Article 6, or an assumption pursuant to paragraph 2 applies, the Office shall refuse an application. Before an application is refused, the Office shall enable an applicant to respond to ascertained reasons for refusal of an application.

(5) If conditions for claiming priority right pursuant to Article 36(2) to (9) and pursuant to generally binding regulation (Article 80) have not been met, the Office shall grant to an applicant priority right pursuant to Article 36(1)(a).

#### *Article 41*

(1) The Office shall publish an application after expiry of 18 months from rise of priority right without delay and shall communicate this publication in the Journal.

(2) An application may be published before expiry of the time limit prescribed in paragraph 1, if an applicant requests it no later than within 12 months from rise of priority right and if he pays administrative fee (Article 79(9)). The Office shall publish an application before expiry of the time limit prescribed in paragraph 1, if a patent has already been granted for an invention; the Office shall not publish an application before expiry of 12 months from rise of priority right without consent of an applicant.

(3) The Office may publish, together with an application, a search report on a state of the art related to an invention applied in an application.

#### *Article 42*

(1) Any person may file oppositions on patentability of a subject-matter of an application with the Office after publication of an application; the Office shall take them into consideration during substantive examination of an application.

(2) Persons who have filed oppositions pursuant to paragraph 1 shall not become parties to application proceedings. However, an applicant shall be notified about oppositions and shall have right to respond to them.

#### Substantive examination of an application

##### *Article 43*

(1) On request of an applicant, third party or ex officio, the Office shall conduct without delay substantive examination of an application, in which it shall ascertain whether an application meets conditions for granting a patent prescribed by this Act.

(2) Request for conducting substantive examination has to be filed no later than within 36 months from filing an application (Article 35) and it cannot be withdrawn. Requesting person shall be obliged to pay administrative fee (Article 79(9)) together with a request.

(3) If a request for conducting substantive examination has not been filed properly within the time limit prescribed in paragraph 2, or if within the same time limit the Office failed to start substantive examination of an application ex officio, the Office shall suspend application proceedings.

(4) The Office shall notify an applicant without delay about starting of substantive examination on request of a third party or ex officio.

##### *Article 44*

(1) If conditions stipulated for granting patent are not met (Articles 5, 7, 8 and 9), the Office shall refuse an application. Before an application is refused, the Office shall enable an applicant to respond to ascertained reasons on basis of which an application shall be refused.

(2) If the Office additionally ascertains irregularities in an application or failure to meet conditions, which are subject-matter of preliminary examination of an application, it shall proceed according to Article 40(2) to (5).

(3) If several applications with an identical subject-matter have been filed, only one patent shall be granted to one applicant.

(4) If a subject-matter of an application meets stipulated conditions and an applicant pays an appropriate administrative fee (Article 79(9)), the Office shall grant a patent to an applicant and an applicant shall become an owner of a patent. The Office shall issue a patent document to an owner and granting of a patent shall be published in the Journal.

(5) Owner of a patent shall be obliged to pay an maintenance fee under special regulation 13a).

SLOVENIA: *Articles 85 and 88 of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

*Article 85*

Examination of an application as to formal requirements

(1) When an application contains all items referred to in Article 79, the Office shall examine whether the items of the application or supplements or evidence, if any, are, as to their contents and form, drawn up as prescribed by this Act and the regulations issued pursuant to this Act.

(2) In the case of a patent application, the Office shall also examine whether the invention meets the requirements of Article 87(2) and (4), and whether all fees have been paid, including any renewal fees under Articles 109(4) or 110(4).

(3) If, in the case of a mark application, the Office establishes that the list of goods and services contains a good or service which is not classified according to the international classification established by the Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks of 15 June 1957, as revised on 14 July 1967 (Official Gazette SFRJ-MP No 51/74, Official Gazette RS-MP No 9/92), hereinafter referred as "the Nice Classification", or is classified in the wrong class, the Office may, in the case of minor irregularities, on its own motion, classify the good or service according to the Nice Classification, or correct the classification, and inform the applicant accordingly. Where the Office groups or corrects more than five classifications of goods or services according to the Nice Classification, it shall invite the applicant to pay, within one month from the receipt of the invitation, the fee for classification. If the applicant fails to pay the fee in due time, the application for the goods or services which the Office classified according to the Nice Classification or corrected the classification thereof, shall be deemed to be withdrawn.

(4) If, in the case of a mark application, the Office establishes that a good or service in the list of goods and services is indicated by a term that is too vague for the purposes of a correct classification according to the Nice Classification, or if the Office does not act according to paragraph (3), it shall invite the applicant to remedy irregularity within three months from the receipt of the invitation. If the applicant fails to remedy the irregularity in due time, the application for the goods or services which were not clearly indicated or correctly classified according to the Nice Classification shall be deemed to be withdrawn.

(5) If any deficiencies are noted in the application or in supplements or evidence, the Office shall invite the applicant to remedy deficiencies within three months from the receipt of the invitation.

(6) If the applicant does not remedy all deficiencies in due time, the application shall be deemed to be withdrawn, except in the cases referred to in paragraphs (3) and (4), and in Articles 128(4) and 129(5).

(7) If the Office establishes that all the items of the application or supplements or evidence, if any, comply, as to their contents and form, with the provisions of this Act and the regulations issued pursuant to this Act, the proceedings shall continue:

- (a) for patent applications, under Article 88 and subsequent articles;
- (b) for industrial design applications, under Article 96;
- (c) for mark applications, under Article 99 and subsequent articles.

*Article 88*

Examination of requirements for the grant of a patent

(1) In the examination preceding the grant of a patent, the Office shall examine:

- (a) whether, subject to Article 11, the subject-matter of the claimed invention is patentable;
- (b) whether the claimed invention meets, at first sight, the requirements of Articles 12, 14 and 15.

(2) In the examination preceding the grant of a short-term patent, the Office shall examine:

- (a) whether, subject to Article 11(1) and (2)(a), the subject-matter of the invention to which the application relates may be protected by a short-term patent;
- (b) whether the claimed invention meets, at first sight, the requirements of Articles 12, 15 and 16.

(3) If the Office establishes that the claims of the patent application meet all the requirements of paragraph (1), or that the claims of the short-term patent application meet all the requirements of paragraph (2), it shall decide to publish the application in the Official Journal.

(4) If the Office establishes that the claims of the patent application do not meet all the requirements of paragraph (1), or that the claims of the short-term patent application do not meet all the requirements of paragraph (2), it shall refuse the application.

(5) If the Office establishes that the claims of the patent application do not meet the requirements of paragraphs (1) and (2) only in part, it shall refuse the application only in that part.

*SOUTH AFRICA: Sections 34, 35, 42 and 43 of the Patents Act No. 37 of 1952 as last amended by Act No. 20 of 2005*

34. Examinations of applications and specifications.

The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he shall accept it.

35. Procedure if result of examination of application is adverse to applicant.

(1) If the result of an examination in connection with an application for a patent, or in connection with the specification which accompanied that application, is adverse to the applicant, the registrar may refuse to accept the application or require the application or the specification which accompanied it to be amended in such manner as may be necessary.

(2) If in the case of a convention application the prescribed documents do not accompany the application or are not furnished within the prescribed period, the registrar may deal with the application as an ordinary application.

42. Notice and publication of acceptance of complete specification.

(1) When a complete specification has been accepted, the registrar shall give written notice of that fact to the applicant.

(2) Such notice shall contain

(a) the date of acceptance of the specification; and

(b) a statement that on publication by the applicant in the journal of the acceptance of the specification, the patent concerned shall be deemed to have been sealed and granted as from the date of such publication.

(3) Unless the acceptance is so published in the journal within the prescribed period or within such further period as the registrar may, on application to him and on good cause shown and on payment of the prescribed fee, allow, the application shall lapse.

43. Inspection by public.

(1) After the publication contemplated in section 42, or after being open for public inspection in terms of subsection (3) of this section, the patent and the application and all documents lodged in support thereof shall on payment of the prescribed fee be open to public inspection in the patent office.

(2) When an application which claims a priority date in terms of section 31 (1) is so open to public inspection, any other application from which it claims a priority date and any documents lodged in support of such an application shall simultaneously be open likewise to public inspection.

(3) If the acceptance of an application which claims priority in terms of section 31 (1) (c) is not published in terms of section 42 within 18 months from the earliest priority date claimed from the relevant application in a convention country, it shall be open to public inspection as provided in subsection (1).

(4) (a) After the expiry of five years following the date of application for a patent, any person may apply to the registrar for the patentee to supply the applicant with the prescribed particulars of any search report issued in another country in respect of an application for a patent relating to the same subject-matter which has been lodged in that country.

(b) On receipt of the application, the registrar shall forward a copy thereof to the patentee at the patentee's address for service.

(c) If the patentee fails to comply with the application within three months of receipt of the copy of the application at the patentee's address for service, the applicant may apply to the commissioner for an order requiring compliance with the application.

(d) Upon an application for compliance, the commissioner may order such compliance and, if the order is not complied with, the commissioner may make the further order that he or she thinks fit.

SPAIN: *Articles 31-34 and 39 of the Law about Patents of Invention and Utility Models No. 11 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

#### *Artículo 31*

1. Admitida a trámite la solicitud, el Registro de la Propiedad Industrial examinará si reúne los requisitos formales establecidos en el capítulo anterior, tal como hubieren sido desarrollados reglamentariamente. No será objeto de examen la suficiencia de la descripción.
2. El Registro de la Propiedad Industrial examinará igualmente si el objeto de la solicitud reúne los requisitos de patentabilidad establecidos en el título segundo de la presente Ley, salvo los de novedad y actividad inventiva. Esto no obstante, el Registro de la Propiedad Industrial denegará, previa audiencia del interesado, la concesión de la patente mediante resolución debidamente motivada cuando resulte que la invención objeto de la solicitud carezca de novedad de manera manifiesta y notoria.
3. Si como resultado del examen apareciera que la solicitud presenta defectos de forma o que su objeto no es patentable, se declarará la suspensión del expediente y se otorgará al solicitante el plazo reglamentariamente establecido para que subsane, en su caso, los defectos que hubieren sido señalados y para que formule las alegaciones pertinentes. A los efectos mencionados, el solicitante podrá modificar las reivindicaciones o dividir la solicitud.
4. El Registro de la Propiedad Industrial denegará total o parcialmente la solicitud si estima que su objeto no es patentable o que subsisten en ella defectos que no hubieren sido debidamente subsanados.
5. Cuando el examen del Registro de la Propiedad Industrial no resulten defectos que impidan la concesión de la patente o cuando tales defectos hubieren sido debidamente subsanados, el Registro de la Propiedad Industrial hará saber al solicitante que, para que el procedimiento de concesión continúe, deberá pedir la realización del informe sobre el estado de la técnica, dentro de los plazos establecidos en la presente Ley, si no lo hubiere hecho ya anteriormente.

#### *Artículo 32*

1. Transcurridos dieciocho meses desde la fecha de presentación de la solicitud o desde la fecha de prioridad que se hubiera reivindicado, una vez superado el examen de oficio y hecha por el solicitante la petición del informe sobre el estado de la técnica a que se refiere el artículo 33, el Registro procederá a poner a disposición del público la solicitud de patente, haciendo la correspondiente publicación en el «Boletín Oficial de la Propiedad Industrial» de los elementos de la misma que se determinen reglamentariamente.
2. Al mismo tiempo se publicará un folleto de la solicitud de patente que contendrá la descripción, las reivindicaciones y, en su caso, los dibujos y los demás elementos que se determinen reglamentariamente.
3. A petición del solicitante podrá publicarse la solicitud de patente, en los términos establecidos en el presente artículo, aun cuando no hubiera transcurrido el plazo de dieciocho meses mencionado en el apartado 1.

#### Procedimiento general de concesión

#### *Artículo 33*

1. Dentro de los quince meses siguientes a la fecha de presentación, el solicitante deberá pedir al Registro la realización del informe sobre el estado de la técnica, abonando la tasa establecida al efecto. En el caso de que una prioridad hubiere sido reivindicada, los quince meses se computarán desde la fecha de prioridad.
2. Cuando el plazo establecido en el apartado anterior hubiere transcurrido ya en el momento de efectuarse la notificación prevista en el artículo 31, apartado 5, el solicitante podrá pedir la realización del informe sobre el estado de la técnica dentro del mes siguiente a dicha notificación.
3. Si el solicitante no cumple lo dispuesto en el presente artículo, se reputará que su solicitud ha sido retirada.

4. No podrá solicitarse la realización del informe sobre el estado de la técnica con referencia a una adición si previa o simultáneamente no se pide para la patente principal y, en su caso, para las anteriores adiciones.
5. Cuando el informe sobre el estado de la técnica pueda basarse parcial o totalmente en el informe de búsqueda internacional realizado en aplicación del Tratado de Cooperación en materia de Patentes, se reembolsará al solicitante el 25 %, el 50%, el 75% o el 100% de la tasa en función del alcance de dicho informe.
6. No serán objeto del informe sobre el estado de la técnica las solicitudes cuyo informe de búsqueda internacional haya sido realizado por la Administración española encargada de la búsqueda internacional.

#### *Artículo 34*

1. Una vez superado el examen de la solicitud previsto en el artículo 31, y recibida la petición del solicitante para que se realice el informe sobre el estado de la técnica, el Registro procederá a la elaboración de dicho informe con referencia al objeto de la solicitud de patente, dentro del plazo que reglamentariamente se establezca.
2. No podrá iniciarse la elaboración del informe hasta que quede definitivamente fijada, dentro del procedimiento de concesión, la fecha de presentación de la solicitud.
3. El informe sobre el estado de la técnica mencionará los elementos del estado de la técnica que puedan ser tomados en consideración para apreciar la novedad y la actividad inventiva de la invención objeto de la solicitud.  
Se elaborará sobre la base de las reivindicaciones de la solicitud y teniendo en cuenta la descripción y, en su caso, los dibujos que hubieren sido presentados.
4. Para la realización del informe, el Registro, además de efectuar la búsqueda con la documentación de que disponga, podrá utilizar los servicios de los organismos nacionales e internacionales cuya colaboración hubiera sido previamente aprobada con carácter general por medio de Real Decreto.
5. Una vez elaborado el informe sobre el estado de la técnica, el Registro dará traslado del mismo al solicitante de la patente y publicará un folleto con dicho informe, haciendo el correspondiente anuncio en el «Boletín Oficial de la Propiedad Industrial».
6. Al mismo tiempo que el informe sobre el estado de la técnica, deberá publicarse la solicitud de patente si ésta no hubiera sido todavía publicada.

#### *Artículo 39*

1. En los casos en que resulte aplicable, según lo dispuesto en la disposición transitoria quinta, el procedimiento de concesión será el mismo que se establece con carácter general en el capítulo anterior de la presente Ley hasta que se formule la petición de examen a que se refiere el apartado siguiente.
2. Dentro de los tres meses siguientes a la publicación del Informe sobre el estado de la técnica, el solicitante podrá pedir que se proceda a examinar la suficiencia de la descripción, la novedad y la actividad inventiva objeto de la solicitud de patente. La petición de examen previo sólo se considerará válidamente formulada tras el pago de la tasa de examen, será irrevocable y se publicará en el Boletín Oficial de la Propiedad Industrial.
3. Cuando el examen previo pueda basarse parcial o totalmente en el informe de examen preliminar internacional realizado por la Administración Encargada del Examen Preliminar internacional competente, se reembolsará al solicitante el 25%, el 50%, el 75% o el 100% de dicha tasa, en función del alcance de dicho informe.
4. En los dos meses siguientes a la publicación de la petición de examen, cualquier interesado podrá oponerse a la concesión de la patente, alegando la falta de cualquiera de los requisitos exigidos para

esa concesión. El escrito de oposición habrá de ir acompañado de los correspondientes documentos probatorios.

5. No podrá alegarse, sin embargo, que el peticionario carece de derecho para solicitar la patente, lo cual deberá hacerse valer ante los tribunales ordinarios.

(Redacción de los apartados 1, 3, 4 y 5 según el Real Decreto-Ley 8/1998, de 31 de julio, de medidas urgentes en materia de Propiedad Industrial.)

6. Concluido el examen, el Registro notificará al solicitante el resultado y le dará traslado de las oposiciones presentadas.

7. Cuando no se hubieren presentado oposiciones y del examen realizado no resulte la falta de ningún requisito que lo impida, el Registro concederá la patente solicitada.

8. En los casos en que no sea aplicable lo establecido en el apartado anterior, el solicitante podrá subsanar los defectos formales imputados a la solicitud, modificar las reivindicaciones, si así lo estima oportuno, y contestar formulando las alegaciones que estime pertinentes.

9. Cuando el solicitante no realice ningún acto para obviar las objeciones formuladas por el Registro o por los terceros, la patente deberá ser denegada total o parcialmente. En los demás casos, el Registro, mediante resolución motivada, decidirá sobre la concesión total o parcial, una vez recibida la contestación del solicitante.

10. Cuando la resolución declare que falta alguno de los requisitos de forma o que la invención no es patentable, el Registro otorgará al solicitante un nuevo plazo para que subsane el defecto o formule las alegaciones que estime pertinentes y resolverá con carácter definitivo sobre la concesión de la patente.

11. Reglamentariamente se establecerán los plazos correspondientes al procedimiento establecido en el presente artículo.

*SRI LANKA: Sections 73 and 78 of the Intellectual Property Act No. 36 of 2003*

73. (1) Every applicant shall furnish, within the prescribed period, a report, which if not in English shall be accompanied by a translation thereof in English, of a search which shall conform such type as may be prescribed :

Provided, however, that in lieu of the said search an applicant may request the Director-General to refer the application to a local examiner who shall examine the application on the basis of any claim with due regard to the description and the drawings, if any, and furnish a report to the Director-General within the prescribed period, on the relevant prior art, after making the required effort to discover as much of the relevant prior art as facilities permit ; and for the purposes of the search the local examiner shall make reference to every documentation on prior art available to him.

(2) The applicant shall, when requiring the Director- General to refer his application to a local examiner, forward such application with the prescribed fee to Director-General.

(3) (a) The applicant shall, at the request of the Director- General, furnish him with the following documents in respect of any foreign application for a patent filed by him abroad relating to the same or essentially the same invention as that claimed in the application filed under this Act

(i) a copy of any communication received by the applicant concerning the results of any search or examination carried out in respect of the foreign application ;

(ii) a copy of the patent granted on the basis of the foreign application ; and

(iii) a copy of any final decision rejecting the foreign application or refusing the grant of a patent requested in the foreign application.

(b) The applicant shall, at the request of the Director-General, furnish him with a copy of any final decision invalidating the patent granted on the basis of the foreign application referred to in paragraph (a).

(4) For this purposes of the section "local examiner" means any skilled person to whom the Director-General may refer questions concerning patents.

Examination of applications &c.

78. (1) The Director-General shall examine the application and shall satisfy himself as to the fulfilment of the following :

- (a) where applicable, the requirements of paragraph (b) of subsection (1) of section 71 ;
- (b) the requirements of paragraph (a) of subsection (2) of section 71 ;
- (c) where applicable, the requirements of paragraph (b) of subsection (2) of section 71 ;
- (d) the description, the claims and where applicable, the drawings, which comply with the prescribed requirements ;
- (e) the essential elements of the invention claimed in the application have not been unlawfully derived from a patent already granted in Sri Lanka ;
- (f) the application contains an abstract ;
- (g) the search report referred to in section 73 has been submitted.

(2) Where the Director-General finds that the conditions referred to in subsection (1) are not fulfilled he shall request the applicant to file the required correction within a period of three months from the date of such request ; where the applicant fails to so comply the application shall, subject to the provisions of subsection (3), be rejected.

(3) Where no correction is provided in response to a request under subsection (2), the Director-General shall, on payment of the prescribed fee within the prescribed period, include the corrections into the application and if the prescribed fee is not paid within the prescribed period the application shall be rejected.

(4) Where the Director-General finds that the essential elements of an invention claimed in an application are unlawfully derived from a patent already granted in Sri Lanka, such application shall be rejected.

(5) The Director-General shall notify the applicant of any decision under subsections (2), (3) and (4) and any decision taken to reject the application shall be in writing stating the reasons for such rejection.

*SWAZILAND: Section 10 (3), (4) and (5) of the Industrial Property Law No. 6 of 04/09/1997*

Filing date, Examination.

10-(3) After according a filing date, the Registrar of Patents shall "examine whether the application complies with the requirements of section 6 (1) and (2) and the Regulations pertaining thereto and those requirements of this Act and the Regulations which are designated as formal requirements for the purpose of this Act.

(4) Where the Registrar of Patents is of the opinion that the application complies with the requirements indicated in subsection (3), he shall cause the application to be examined as to whether the requirements of sections 3, 4 and 6 (3), (4) and (5), 7 and 9 and the Regulations pertaining thereto are fulfilled .

(5) The Regulations may prescribe that, in respect of some categories of inventions, the examination shall not cover the requirements of novelty and inventive step under section 4 (2) and (3).

*SWEDEN: Articles 19 and 20 of the Patents Act No. 837 of 01/12/1967 as last amended by Law No. 161 of 01/04/2004*

19. If the application is complete and no obstacles to a patent are found, the Patent Authority shall notify the applicant that a patent can be granted.

Within two months of the date of notification, the applicant shall pay a fixed grant fee. In default of this, the application shall be dismissed. The processing of a dismissed application shall be resumed if, within four months after the expiration of the two months, the applicant pays the grant fee and a fixed resuming fee.

If a patent is sought by an inventor who has considerable difficulty in paying the grant fee, the Patent Authority may exempt him from this obligation if he makes a written request to that effect within two months of the date of notification. If the Patent Authority rejects the inventor's request, a fee paid within two months thereafter shall be considered as being paid within the proper time limit.

20. If the applicant has fulfilled the requirements of Section 19 and there is still no obstacle to a patent, the Patent Authority shall grant the application. The decision shall be announced.

When the decision to grant the patent application has been announced, a patent has been granted. A granted patent shall be recorded in the Register of Patents kept by the Patent Authority. Letters patent shall also be issued.

After the patent has been granted, the claims may not be amended so that the scope of the patent protection is broadened.

SWITZERLAND: *Articles 59 and 59a of the Federal Patents Law of 25/06/1954 as last amended on 01/07 2009 and Articles 47, 53, 61a, 63 and 67 of the Regulations thereto*

#### A - Objet de l'invention

##### *Article 59*

1. Si l'objet d'une demande de brevet n'est pas ou n'est que partiellement conforme aux art. 1, 1a, 1b et 2 l'Institut en informe le requérant en lui indiquant les raisons et lui impartit un délai pour répondre.
2. Si la demande de brevet ne répond pas à d'autres prescriptions de la présente loi ou de l'ordonnance, l'Institut impartit au requérant un délai pour en corriger les défauts.
- 3 ...
4. L'Institut n'examine pas si l'invention est nouvelle ni si elle découle d'une manière évidente de l'état de la technique.
5. Le requérant peut, moyennant le paiement d'une taxe:
  - a. demander, dans le délai de quatorze mois à compter de la date de dépôt ou, lorsqu'une priorité est revendiquée, à compter de la date de priorité, que l'Institut établisse un rapport sur l'état de la technique;
  - b. demander, dans le délai de six mois à compter de la date de dépôt d'une première demande, que l'Institut réalise une recherche de type international.
6. Si aucun rapport au sens de l'al. 5, let. a n'a été établi ni aucune recherche au sens de l'al. 5, let. b réalisée, toute personne habilitée à demander la consultation du dossier conformément à l'art. 65 peut, moyennant le paiement d'une taxe, demander l'établissement par l'Institut d'un rapport sur l'état de la technique.

#### B - Fin de l'examen

##### *Article 59a*

1. Si les conditions de la délivrance du brevet sont remplies, l'Institut communique au requérant que la procédure d'examen a pris fin.
- 2 ...
3. L'Institut rejette la demande si:
  - a. elle n'est pas retirée, bien qu'un brevet ne puisse pas être délivré pour les raisons mentionnées à l'art. 59, al. 1, ou
  - b. les défauts signalés conformément à l'art. 59, al. 2 ne sont pas corrigés.

#### *Regulations*

##### *Article 47*

#### Examen quant à la forme

Parallèlement à l'examen des conditions pour l'attribution de la date de dépôt, l'Institut vérifie:

- a. si un mandataire doit être institué (art. 48);
- b. si une requête en délivrance d'un brevet, si au moins une revendication et un abrégé ont été déposés et s'ils satisfont aux prescriptions (art. 48a à 48c);
- c. si la mention de l'inventeur a été déposée (art. 48d);
- d. si la taxe de dépôt a été payée (art. 49);
- e. si les pièces techniques satisfont aux prescriptions qui ne concernent pas leur contenu (art. 50).

##### *Article 53*

#### Requête et paiement de la taxe de recherche

1. Contre paiement de la taxe de recherche, le demandeur peut requérir, dans les quatorze mois à compter de la date de dépôt ou, s'il a revendiqué une priorité, suivant la date de priorité, que l'Institut établisse un rapport sur l'état de la technique.

L'inobservation de ce délai entraîne l'extinction de son droit.

2. Si la taxe de recherche n'a pas été versée au moment où la requête a été présentée, le demandeur doit la payer dans les deux mois suivant l'invitation de l'Institut ou dans les quatorze mois à compter de la date de dépôt ou de priorité si ce délai expire avant. La requête est réputée présentée seulement lorsque la taxe de recherche a été payée.

#### *Article 61a*

##### Taxe d'examen et taxes de revendication

1. Avant le début de l'examen quant au fond, le demandeur doit, sur l'invitation de l'Institut, payer la taxe d'examen dans le délai imparti.
2. Si les pièces techniques contiennent plus de dix revendications et si le demandeur n'a pas versé les taxes de revendication pour les revendications surnuméraires (art. 31a) ou ne les a versées qu'en partie (art. 53a, il doit payer les taxes de revendication dues dans les deux mois suivant l'invitation de l'Institut.
3. En cas de non-paiement ou de paiement partiel, les revendications surnuméraires sont biffées à partir de la dernière.

#### *Article 63*

##### Procédure accélérée

1. Le demandeur peut requérir que l'examen quant au fond soit entrepris selon une procédure accélérée. Jusqu'à l'expiration de 18 mois à compter de la date de dépôt ou de priorité, cette requête ne peut être présentée que si les pièces techniques satisfont aux exigences énoncées aux art. 46 à 52. 123
2. La demande n'est réputée présentée que lorsque la taxe facturée à cet effet par l'Institut a été payée.

#### *Article 67*

##### Procédure

1. L'Institut examine d'abord si la demande de brevet doit faire l'objet d'une notification en vertu de l'art. 59, al. 1, de la loi. Si tel est le cas, il rejette la demande de brevet lorsque le demandeur ne parvient pas à infirmer les objections soulevées soit en modifiant les pièces techniques, soit d'une autre manière.
2. Si la demande de brevet ne satisfait pas aux dispositions des art. 49a, 50, 50a, 51, 52, 55 et 57 de la loi, ni à celles de la présente ordonnance, l'Institut impartit un délai au demandeur pour remédier aux défauts. Si les défauts ne sont que partiellement corrigés, il peut, s'il le juge opportun, faire d'autres notifications.

THAILAND: *Sections 24-29 of the Patent Act B.E. 2522 of 11/03/1979 as amended by the Patent Act (No.2) B.E 2535 and the Patent Act (No.3) B.E. 2542*

Section 24 - Before granting a patent to the applicant, the competent officer shall:

- (1) examine the application as to its conformity with Section 17; and
- (2) examine the application as to its conformity with Section 5, in accordance with the rules, procedures and conditions prescribed in the Ministerial Regulations.

Section 25 - In order to facilitate the examination of a patent application, the Director-General may request any government department, unit or organization or any foreign or international patent office of organization, to examine the application as to its conformity with Section 5, 6, 7, 8, and 9, or the detailed description of the invention as to its conformity with Section 17 (3). The Director-General may treat such examination as having been done by the competent officer.

Section 26 - In the examination of an application if it appears that the application relates to several distinct inventions which are not so linked as to form a single inventive concept, the competent officer shall give a notice to the applicant requiring him to separate the application into a number of applications, each of which relates to a single invention.

If the applicant files any of the separated applications within one hundred and eighty days following the receipt of such notice under the preceding paragraph, he shall be deemed to have filed that application on the filing date of his first application.

The application shall be separated in accordance with the rules and procedures provided by the Ministerial Regulations.

If the applicant does not agree with the requirement to separate the application, he shall appeal to the Director-General within one hundred and twenty days. The decision of the Director-General shall be final.

Section 27 - In the course of examination of an application, the competent officer may instruct the applicant to appear before him in order to answer any question, or to hand over to him any document or item.

If the applicant has filed an application for a patent in any foreign country, he shall submit a report of the examination of the application in accordance with the rules and procedures prescribed by the Ministerial Regulations.

If any document to be filed is in a foreign language, the applicant shall file such document accompanied by translation in Thai.

If the applicant fails to comply with the instruction of the competent officer under the preceding paragraph, or fails to submit the examination report within ninety days in accordance with the second paragraph of this Section, he shall be deemed to have abandoned his application. In case of necessity, the Director-General may extend such period as he deems appropriate.

Section 28(1) - Where the competent officer has submitted the examination report to the Director-General,

(1) if it appears to the Director-General that the provisions of Section 17 have not been complied with, or the invention is not patentable under Section 9, the Director-General shall reject the application and the competent officer shall notify the applicant of the rejection by a return registered mail or by any other method prescribed by the Director-General within fifteen days from the date of rejection by the Director-General; or

(2) if it appears to the Director-General that the provisions of Section 17 have been complied with and it is not an unpatentable invention under Section 9, the Director-General shall, in accordance with the rules and procedures in the Ministerial Regulations, order the application to be published. Before the publication is made, the competent officer shall, by any method prescribed by the Director-General or by a return registered mail, notify the applicant to pay the publication fee. If the applicant fails to pay the fee within sixty days from the date of receipt of the notice, the competent officer shall once again notify the applicant by a return registered mail. If the applicant fails to pay the publication fee within sixty days from the date of receipt of such notice, he shall be deemed to have abandoned his application.

Section 29 - After the publication of the application under Section 28, the applicant may request the competent officer to proceed with the examination as to its conformity with Section 5 either within five years after the publication of such application or, in cases where there is an opposition and an appeal is taken, within one year after the final decision has been made, depending on which period expires last. If the applicant fails to make such a request within said period, he shall be deemed to have abandoned his application.

If the Director-General requests any governmental department, unit or organization or any foreign or international patent office or organization to examine the application under Section 25, and there is some expense derived from such examination, such expense shall be paid by the applicant within sixty days after he has been notified by the competent officer. If the applicant fails to pay the expense within the said period, he shall be deemed to have abandoned his application.

THE FORMER REPUBLIC OF MACEDONIA: *Articles 56, 60, 61, 62, 63, 64, 65 and 66 of the Industrial Property Law of 12/01/2009*

Examination of the application in procedure in the Office

*Article 56*

(1) When examining the patent application, the Office shall check whether:

- 1) the inventor has been indicated;
- 2) the priority right recognition has been requested in compliance with Articles 37 and 38 of this Law;
- 3) the application is in conformity with the unity rule of invention stipulated in Article 35 of this Law;
- 4) the separate parts of the application comply with Articles 43, 44, 45, 46, and 47 of this Law; and
- 5) the subject of the application is an invention, which at first may be protected by a patent in terms of Article 25, paragraph (3), Articles 26, 27, paragraph (3), and Article 30 of this Law.

(2) When examining the application, the Office shall not examine whether the requirement stipulated in Article 29 of this Law has been fulfilled.

#### Decision for grant of patent

##### *Article 60*

(1) If the requirements referred to in Article 56 are fulfilled and if the applicant pays the costs and fees stipulated in Article 59, paragraph (1) of this Law within the specified period of time, the Office shall make a decision for grant of patent.

(2) The data from the decision for grant of patent shall be entered in the patent register on the date of making the decision and shall be published in the official newsletter of the Office within 90 days from the date of making the decision.

#### Examination of the application on the basis of a substantive examination

##### *Article 61*

(1) Articles 54, 55, and 56, paragraph (1), items from 1, 2, 3 and 4 of this Law shall apply to the applications for which the applicant requested procedure for substantive examination.

#### Evidence and procedure concerning the evidence of the substantive examination

##### *Article 62*

(1) The patent applicant who has stated to implement the procedure in compliance with Article 52, paragraph (1) items 1 and 2 of this Law, shall submit a request for substantive examination in one of the examining institutions referred to in Article 63 of this Law, two years at the latest from the date of submitting the patent application to the Office.

(2) The person referred to in paragraph (1) of this Article shall submit a copy of the submitted request to the Office.

(3) The applicant referred to in paragraph (1) of this Article shall be bound, within a period of six months from the date on which it has received the evidence of the examination referred to in Article 64 of this Law, to submit to the Office the evidence and the translation of the evidence in Macedonian language.

(4) In case that the patent applicant fails to proceed in compliance with paragraphs (1), (2), and (3) of this Article, the Office shall make a decision to reject the application.

(5) The Office may not make the decision referred to in paragraph (4) of this Article if it previously had not notified in writing the applicant about the reasons for which it rejected the application and if it previously failed to invite the applicant in a reasonable time limit to explain those reasons.

(6) The applicant or the owner of the exclusive right shall also be bound to present the evidence from the substantive examination when a third party lawsuits due to the infringement of the right to a patent.

(7) In case of paragraph (6) of this Article, the Office shall issue one of the decisions referred to in Article 66 of this Law by urgent procedure.

(8) The contents of the evidence of the substantive examination shall be determined by a regulation adopted by the director of the Office.

#### Institutions for substantive examination

##### *Article 63*

The substantive examination of the patent application referred to in Article 64 of this Law shall be conducted in:

- 1) one of the selected institutions, which by rule are national and international offices and which on the basis of PCT have a status of authorised institutions for international search i.e. preliminary international examination of international patent applications, or
- 2) some of the institutions with which a special agreement is signed for the purpose of searching and substantive examination.

#### Contents of the evidence from substantive examination

##### *Article 64*

1) The evidence of the substantive examination shall determine if the invention fully meets the conditions for acknowledgement of the patent right i.e. if the subject of the application is:

- an invention that may be patent granted in accordance with Articles 25 and 26 of this Law;
  - the invention described in a manner that an expert in the field may apply in accordance with Article 27, paragraph (2) of this Law;
  - invention which is in accordance with the rule of unity of invention referred to in Article 35 of this Law;
- and

- invention which is new in accordance with Articles 27 and 28 of this Law, which has inventive step in accordance with Article 29 of this Law, and is applicable in industry in accordance with Article 30 of this Law.

#### Additional examination

##### *Article 65*

(1) The Office shall make the decision laid down in Article 66 of this Law on the basis of the presented evidences from the substantive examination referred to in Article 64 of this Law and on the basis of the additional examinations of this Article.

(2) The additional examination of patent application shall determine whether the requirements for grant of patent have been satisfied i.e. whether the subject of application is in compliance with Article 56, paragraph (1) item 5 of this Law.

(3) The Office may not make the decision referred to in Article 66 paragraph (1) item 2 or of this Law if it previously had not notified in writing the applicant about the reasons for which it cannot accept the requested right as a whole or partially and if it previously failed to invite the applicant in a reasonable time limit to explain those reasons.

(4) Upon an elaborated request by the applicant, the time limit referred to in paragraph (3) of this Article may be extended up to six (6) months.

#### Decisions based on the evidence from the substantive examination

##### *Article 66*

(1) On the basis of the presented evidence, the Office shall determine to what extent the contents and scope of the patent claims regarding the relevant invention meet the conditions of Articles 27, 29, and 30 of this Law and shall issue one of the following decisions:

1) a decision that the invention related to the required patent meets all the conditions referred to in Articles 27, 29, and 30 of this Law and that the patent claim or patent claims are fully in compliance with those conditions.

2) decision that the invention only partially meets the conditions referred to in Articles 27, 29, and 30 of this Law, and a decision which provides limited further validity of the patent claim or patent claims in a scope that fulfils the conditions; and

3) decision to announce nullity at the time when the patent as of the date of filing the patent application does not fulfill the conditions referred to in Articles 27, 29, and 30 of this Law.

#### TONGA: *Section 11 of the Industrial Property Act No. 19 of 09/11/1994*

##### 11- Filing Date; Examination.

(1) The Registrar shall accord as the filing date, the date of receipt of the application, provided that, at the time of receipt, the application fee is paid and the application contains —

(a) the name of the applicant;

(b) a part which on the face of it appears to be a description;

(c) a part which on the face of it appears to be a claim or claims;

(d) an express or implicit indication that the grant of a patent is sought.

(2) If the Registrar finds that the application did not, at the time of receipt, fulfil the requirements referred to in subsection (1), he shall invite the applicant to file the required correction and shall accord as the filing date the date of receipt of the required correction, but if no correction is made, the application shall be treated as if it had not been filed.

(3) Where the application refers to drawings which in fact are not included in the application, the Registrar shall invite the applicant to furnish the missing drawings.

(4) If the applicant complies with the invitation referred to in subsection (3), the Registrar shall accord, as the filing date, the date of receipt of the missing drawings. Otherwise the Registrar shall accord, as the filing date, the date of receipt of the application and shall treat any references to the said drawings as non-existent.

(5) After according a filing date, the Registrar shall examine whether the application complies with the requirements of section 7(1), (2), (3) and (4).

TRINIDAD AND TOBAGO: *Sections 23 and 24 of the Patents Act No. 21 of 1996*

(Examination as to form)

23.-(1) Where an application for a patent has a date of filing and is not withdrawn, upon the payment by the applicant of the prescribed fee, the Controller shall conduct a formalities examination.

(2) On such formalities examination the Controller shall determine whether the application complies with the provisions of this Act and rules made thereunder relating to such examination.

(3) If the Controller determines that all the formal requirements have not been complied with, he shall give the applicant an opportunity to make observations on the report and to amend the application within a specified period so as to comply with those requirements and if the applicant fails to do so the Controller may refuse the application.

(4) If the Controller refuses the application under subsection (3), he shall inform the applicant in writing of his decision and the reason therefor.

(Search and substantive examination)

24.-(1) Where the Controller is of the opinion that the application complies with the requirements of section 23 he shall, upon payment by the applicant of the prescribed fee, cause the application to be examined as to whether there has been compliance with the requirements of sections 8 to 12 and 18(3) and (4) and the rules relating thereto.

(2) For the purposes of the examination under this section the Controller may transmit the application to a duly authorized authority with which an arrangement to that effect has been made.

TUNISIA: *Articles 29-31 of the Patents Law No.2000-84 of 24/08/2000*

Section 2

Examination of the Application

29. The entity responsible for industrial property shall examine whether the application is consistent in terms of form with the provisions of Articles 20, 21 and 22 of this Law.

The entity responsible for industrial property shall reject the patent application if it finds that the provisions referred to in the first paragraph of this Article have not been respected after the applicant has been invited to remedy the shortcomings within a period of three months from the date of the notice served on him to that end.

The rejection decision shall be accompanied by a statement of reasons, and shall be notified to the applicant or his agent by registered letter with advice of receipt.

30. The entity responsible for industrial property shall ascertain whether, in terms of substance:

- the subject matter claimed is not manifestly excluded from patentability under the second paragraph of Article 2 and Article 3 of this Law;
- the subject matter claimed corresponds to the definition given in Article 6 of this Law;
- the description satisfies the requirements specified in the third paragraph of Article 21 of this Law;
- the claims meet the requirements specified in the fourth paragraph of Article 21 of this Law;
- the application meets the requirements specified in Article 23 of this Law;
- the divisional application does not extend beyond the disclosure of the initial application;
- all the documents required under the third paragraph of Article 24 of this Law have been supplied.

Where the entity responsible for industrial property considers that the conditions set forth in the first paragraph of this Article have not been met, it shall inform the applicant or his agent accordingly and invite him to amend his application or to make comments within a period of three months of the notice served on him to that end.

If in the course of that period the applicant rectifies his application in accordance with the notice from the entity responsible for industrial property, the examination of the application shall resume on payment of a fee the amount of which shall be fixed by decree, failing which the entity responsible for industrial property shall reject the application.

Where the entity responsible for industrial property considers, in the light of either the comments or the amendments made by the applicant under the second paragraph of this Article, that the conditions set forth in the first paragraph have been met, the application shall be entertained. Otherwise the entity responsible for industrial property shall inform the applicant and invite him to meet the said conditions within three months of notice having been served on him to that end.

If at the end of the period set the entity responsible for industrial property considers that the said conditions have still not been met, it shall reject the application.

Any rejection decision shall be accompanied by a statement of reasons and be notified in writing to the applicant or his agent by registered letter with advice of receipt.

31. Where the application conforms to the provisions of this Section, a mention of its filing shall be published in the official bulletin of the entity responsible for industrial property within 18 months of the filing date.

*TURKEY: Articles 54-59, 62 and 63 of the Decree-Law No. 551 on the Protection of Patent Rights of 27/06/1995 as last amended by Law No. 4128 of 7/11/1995*

Examination as to Form

54. When the filing date of an application has become definite, the Institute shall examine the application for compliance with the requirements of form set forth in Articles 42 to 52 and in the Regulations.

The compliance of the specification, claims and drawing with the patentability requirements shall not fall within the scope of this examination. The Institute shall examine the subject matter of the application, in the light of Articles 6 and 10 of this Decree-Law, to determine whether or not it constitutes a patentable invention and is applicable in industry. The Institute shall, after having heard the applicant, reject the application, stating the reasons for its decision, when the invention in respect of which it is filed obviously and indisputably lacks novelty and industrial applicability.

Where the examination finding is that the application has defects of form within the meaning of Article 53, or that its subject matter is not a patentable invention, the examination procedure shall be suspended and the applicant requested to remedy the defects or communicate his objections to the Institute within the period prescribed by the Regulations.

In the course of this procedure, the applicant may amend the claims or divide the application into two or more divisional applications.

The Institute shall reject the application entirely or in part when it does not find acceptable the objections raised against its decision that the subject matter of the application is not a patentable invention, or when a reported deficiency has not been remedied pursuant to the conditions and requirements of form laid down in the Regulations.

Where the examination conducted by the Institute under this Article shows that there is no deficiency as to form, or when any such deficiency has been duly remedied and completed pursuant to the requirements of this Decree-Law, the Institute shall inform the applicant that the request for the conduct of a state-of-the-art search, if not filed earlier, is to be filed within the time limit specified in Article 56.

#### Publication of the Application

55. The application shall be open to public inspection on publication as provided in the Regulations after 18 months have elapsed from the filing date of the application, or from the date of any priority claimed. The application shall be published after the completion by the Institute of the examination for compliance with formal requirements under Article 54 and after the filing under Article 56 of the request for the conduct of a state-of-the-art search.

Applications shall be published periodically in the relevant Bulletin, with all their particulars, in the form and subject to the conditions laid down in the Regulations.

At the request of the applicant, the application shall be published as provided in this Article even when the period of 18 months mentioned in the first paragraph thereof has not expired.

#### Request for the Conduct of the State-of-the-Art Search and Payment of the Search Fee

56. Within 15 months from the filing date of the application, the applicant shall file a request with the Institute for the conduct of a search of the state of the art and shall pay the appropriate fee.

Where priority is claimed, the said period shall be calculated from the date of priority.

Where the period prescribed in the first paragraph of this Article has already expired when the notification under the sixth paragraph of Article 54 is made, the applicant shall file the request for the conduct of the state-of-the-art search within the month following such notification.

Where the applicant does not file the request for the conduct of the state-of-the-art search as provided in this Article, the application shall be deemed withdrawn.

The conduct of the state-of-the-art search in respect of an application for a patent of addition may only be requested when the request is filed together with the application for the main patent, or when a search has already been conducted or requested in relation to previous applications for patents of addition. The provisions of the first and fourth paragraphs of this Article shall apply also to patents of addition.

#### Drawing up, Notification and Publication of the State-of-the-Art Search Report

57. The Institute shall conduct the state-of-the-art search after having examined the application in accordance with the provisions of Article 54, and on receipt of the request, filed by the applicant under Article 56, for the conduct of the state-of-the-art search.

The search report shall include the elements of the state of the art to be considered in the assessment of the novelty and inventive step characteristics of the invention forming the subject matter of the application.

The search report shall be drawn up, in the light of the specification, the drawings if any and the claims by the Institute or by the search authority designated by the Institute from among internationally recognized search authorities.

The search report shall be notified to the applicant after it has been drawn up. The copies of the reference patents and publications cited in the search report shall be sent to the applicant together with the report.

Following its notification to the applicant, the search report shall be published by the Institute after the three-month period accorded to the applicant under Article 59 has elapsed.

Of the systems for the grant of patents with or without substantive examination, the one that the applicant has chosen shall be published in the Bulletin in which the state-of-the-art search report is published.

If, when the search report is drawn up, the patent application has not yet been published, the search report shall be published together with the patent application.

#### Impossibility of Drawing up Search Report for Reasons of Deficiency

58. Where lack of sufficient explicitness in the description or claims prevents the drawing up of the search report on the state of the art either in full or in part, the Institute shall ask the applicant to remedy the deficiency. Where the deficiency is not remedied by the applicant by the time limit laid down in the Regulations, the Institute shall notify the applicant of its decision that the search report cannot be drawn up, and shall inform him of his right to object. In the case of partial deficiency, the search report shall be drawn up for those claims that are sufficiently explicit.

#### Choice of the Substantive Examination System

59. The applicant shall declare to the Institute, within three months following the notification to him of the search report, that he has opted for the system of patent grant with substantive examination, in order that the Institute may examine the application in relation to the patentability requirements pursuant to the provisions of Article 62. Where no such declaration is made by the said time limit, the system of patent grant without substantive examination shall be deemed to have been chosen.

#### Section IV

##### System of Patent Grant with Substantive Examination

##### Patent Grant with Substantive Examination

62. The provisions of Articles 42 to 58 on the filing of the patent application and the requirements therefor and on the examination of the application as to form shall apply also to the system of patent grant with substantive examination.

Within six months following the publication of the state-of-the-art search report, third parties may, in the form laid down in the Regulations, file objections to the grant of the patent, alleging non-compliance with the patentability requirements, including lack of novelty or inventive step, or the inadequacy of the description. Documentary evidence in support of the allegation shall be enclosed with the objections, which shall be made in writing.

Within six months following the publication of the state-of-the-art search report, the applicant wishing to obtain a patent with substantive examination shall request the Institute to conduct the examination to determine whether the subject matter of the invention is comprehensively described and whether the invention is novel and involves an inventive step. The conduct of the examination shall be subject to prior expiry of the period of six months for third-party objections and payment of the examination fee provided for in the Regulations. The examination fee may be paid at any time during the period specified in the second paragraph of this Article.

When objections are raised by third parties under the second paragraph of this Article, all such objections and the evidence in support of them shall be immediately notified to the applicant. The applicant may respond to the objections raised within three months following the expiry of the period allowed for raising objections, or within the period extending such term for three additional months if requested, or may submit reasons in support of his response with a view to removing the objections raised, or again if he deems it necessary, may amend the description, the drawings and the claims.

The Institute shall initiate the examination for compliance with the patentability requirements after the expiry of the time limit specified in the fourth paragraph of this Article. Failure by the applicant to respond to the objections raised within the prescribed time limit shall not delay the initiation of the examination.

After having examined the application, the Institute shall decide on whether the application has deficiencies or meets the patentability requirements. It shall substantiate its decision by citing the grounds therefor. The Institute shall confine its examination to the content of the claims.

The Institute shall communicate to the applicant the examination report that it has drawn up on whether the application has deficiencies or does not meet the patentability requirements, citing the grounds on which it is based, and shall allow the applicant six months within which to rectify the deficiency, amend the claims or object to the report.

The applicant may submit substantiated observations with a view to removing the unfavorable opinions expressed by the Institute in its examination report, and may amend the application if he deems it necessary.

The Institute shall examine the observations made by the applicant and any amendments made to the application. Where the Institute decides that the adverse findings of the examination report are to be upheld, it shall notify the applicant accordingly, stating the grounds therefor, and shall allow the applicant a period of three months within which to submit his opinions to the contrary.

The applicant may, at that stage of the examination, submit his observations with a view to overcoming the adverse findings, and may amend the application if he deems it necessary.

The Institute shall reach its final decision after examining the applicant's observations and amendments made to the application. The decision of the Institute may be to grant the patent for all or part of the claims.

Where, on examination, the Institute finds that the application meets the patentability requirements and that no objections have been raised, it shall decide to grant the patent and shall notify the applicant accordingly.

On payment of the prescribed fees according to the decision reached, the Institute shall issue the patent applied for.

Under the system of patent grant with substantive examination, the State shall not guarantee the validity and usefulness of the subject matter of the patent granted.

#### Publication and Printing of a Patent Granted with Substantive Examination

63. The grant of a patent shall be published in the relevant Bulletin. This publication shall include the following particulars:

- (a) the patent number;
- (b) the classification code or codes of the invention;
- (c) the title describing the subject matter of the invention;
- (d) the name, nationality and domicile of the patentee
- (e) the abstract;
- (f) the number and date of the issue or issues of the Bulletin in which the patent application and any amendments to the application were published;
- (g) the date of issue of the patent;
- (h) the possibility of inspecting the documentation concerning the patent, the search report and the decision of the Institute on the substantive examination, showing its findings on the novelty and inventive step characteristics and on the adequacy of the description and any objections raised in the course of the examination;
- (i) a mention that the patent has been granted following a substantive examination of novelty and inventive step.

Every patent shall be printed by the Institute in the form of a pamphlet and distributed on request. Printing may be carried out by reprographic means where necessary.

In addition to the particulars mentioned in the first paragraph of this Article, every pamphlet shall contain the description, the claims and drawings in their entirety, and also the full text of the state-of-the-art search report and the issue number of the Bulletin in which the decision to grant the patent was published.

UGANDA: *Sections 19 (4) and 20 of the Patents Act of 15/10/1993*

19. Filing date and formal examination.

(4) After according a filing date, the registrar shall examine whether the application complies with the requirements of section 13 and the regulations pertaining to them and those requirements of this Act and the regulations which are designated as formal requirements for the purposes of this Act.

20. Search and substantive examination.

(1) The Minister may, by statutory instrument

(a) direct that applications for patents relating to a specified technical field or fields or that all applications relating to any technical field shall be the subject of an examination as to substance; or  
(b) add further technical fields to those covered by a direction under paragraph (a) of this subsection or remove any technical field from the scope of the direction.

(2) If, in the registrar's opinion, the subject matter of an invention for which a patent is sought falls within a technical field covered by the terms of a direction made under subsection (1), he or she shall cause an examination to be carried out as to patentability under Part III of this Act.

(3) For the purposes of the examination under subsection (2), the registrar may transmit the application, with all accompanying documents, to the ARIPO Office or some other examining authority designated in the statutory instrument for a preliminary examination as to the patentability of the invention claimed, and the examining authority shall furnish a report on the conclusions of its examination and shall transmit it to the registrar and to the applicant.

(4) Where, taking due account of the conclusions of any report referred to in subsection (3), the registrar is of the opinion that any of the conditions as to patentability have not been fulfilled, he or she shall notify the applicant accordingly and invite him or her to amend his or her application.

(5) Where the applicant fails to amend his or her application, within the specified period of time, to the satisfaction of the registrar, the latter shall refuse the grant of a patent and notify the applicant accordingly.

UKRAINE: *Section 16 of the Law on the Protection of Rights to Inventions and Utility Models No. 3687-XII of 15/12/1993 as last amended in 2003*

Examination of Application

16.-(1) Examination of the application has the status of scientific and technical examination and consists of the preliminary examination, formal examination and, by the application for a patent for an invention (secret invention), qualifying examination. The examination shall be made by the examination institute according to this Law and regulations issued by the Office in compliance with this Law.

(2) The examination institute carries out information activity required for examination of applications and is the center for the international exchange of information communications according to the Convention on International Information Communication that was adopted on December 3, 1958, by the United Nation General Conference for Education, Science, and Culture.

(3) The final results of the examination of the application that is not considered withdrawn or was not withdrawn shall be presented in the grounded conclusion of examination, which shall be valid after its approving by the Office. Based on such a conclusion, the Office shall make a decision on the granting a patent or on refusing the patent. The applicant shall be notified on the Office decision.

The applicant shall have the right to require the copies of the materials, which were opposed to the application, within a month after receiving the Office decision. These copies shall be sent to the applicant within a month.

(4) The applicant shall have the right, on his own initiative or on the examination institute invitation, to participate personally or via his representative in discussion of the matters arising in the course of examination under the procedure specified by the Office.

(5) The applicant shall have the right to correct errors in the application, change his name and his address, address for service and name and address of his representative.

The applicant may make changes in the application that are connected with the change of the person of the applicant by the consent of all other applicants mentioned in the application. The person, who wishes to be the applicant, may also make these changes by the consent of all other applicants.

The said corrections and changes are taken into consideration, provided that the examination institute has received them not later than the document on the payment of the state fee for granting a patent had been received.

The said corrections and changes shall be taken into consideration while publishing the information on the application for granting a patent for an invention if the examination institute has received them within 6 months before the date of publication.

The filing of the request for correction of a mistake or making of any of the mentioned changes is subject to the payment of the respective fee, provided that a mistake is not obvious or technical, and the change is caused by reasons depended on the applicant.

(6) The examination institute may demand from the applicant to submit additional materials if the examination is impossible without these materials or if the examination institute reasonable doubts the veracity of the information or elements presented in the application documents.

The applicant shall have the right to request the copies of the materials, which were opposed to the application, within a month after receiving the examination institute notification or conclusion with the demand to submit the additional materials.

The applicant shall submit the additional materials within 2 months from the date of receiving the notification or conclusion of the examination institute or the copies of the materials, which were opposed the application. The period for submitting the additional materials may be extended, but for no more than 6 months, provided that the relevant request has been submitted and the fee has been paid before expiry of the said period. This period defaulted due to important reasons shall be renewed provided that the relevant request is submitted and the fee is paid within 6 months after the expiry of the period. If the applicant failed to submit the additional materials within the fixed period, the application shall be considered withdrawn, and the applicant shall be notified accordingly.

(7) If the applicant has submitted the additional materials, it shall be determined in the course of examination, whether these materials do not go beyond the subject-matter of an invention (utility model), disclosed in the application.

The additional materials shall go beyond the subject-matter of an invention (utility model) disclosed in the application if they contain features that should be included to invention (utility model) claims.

The additional materials in a part, that goes beyond the subject-matter of invention (utility model) disclosed in the application, shall not be taken into consideration in the course of the examination and may be presented by the applicant as an individual application after receiving the relevant notification of the examination institute.

(8) In the course of the preliminary examination, the application without the proposition of the applicant for referring an invention (utility model) to the state secret shall be examined for detecting information that may be referred to the state secret according to the Corpus of Data that constitute the state secret of Ukraine.

If such information is available in the application, and if the application contains the proposition of an applicant to refer an invention (utility model) to the state secret, the application documents shall be transferred to the relevant State Expert on Secret Matters (hereinafter - "the State Expert") for making the decision on referring an invention (utility model) to the state secret.

The State Expert shall submit his decision, together with the application documents, to the examination institute within a month from the date of receiving the application documents.

The period, within which the decision on referring an invention (utility model) to the state secret shall be valid, shall be determined by the State Expert in dependence on a degree of the information secrecy.

If the State Expert has made the decision to refer an invention (utility model) to the state secret, the State Expert shall determine the persons, who have the right to access it, and the following processing of the application shall be accomplished in the secret regime.

The examination institute shall immediately notify the applicant on the State Expert decision. If the application did not contain the proposition of an applicant to refer an invention (utility model) to the state secret, and the State Expert has referred an invention (utility model) to the state secret, the applicant, in case of disagreement, may submit to the examination institute a grounded request to declassify the application documents or appeal to the court against the State Expert decision.

(9) In the course of the formal examination:

the date of filing of the application shall be determined according to Article 13 of this Law;

it shall be determined whether the claimed object belongs to the technology objects specified in Paragraph 2 of Article 6 of this Law as well as to the technology objects specified in Paragraph 3 of Article 6 of this Law;

the application shall be examined for conformity with the formal requirements of Article 12 of this Law and the regulations issued by the Office in compliance with this Law;

the document on the payment of the respective fee for filing of the application shall be examined for conformity with established requirements.

(10) If the application materials meet the requirements of Article 13 of this Law and the document on the payment of the respective fee for filing of the application is presented, the applicant shall be notified on the determined date of filing of the application.

(11) If the application materials do not meet the requirements of Article 13 of this Law, the applicant shall be immediately notified. If the applicant removes the nonconformity within 2 months from the date of receiving the notification, the date on which the examination institute has received the corrected application materials shall be considered to be the date of filing of the application. Otherwise, the application shall be considered not filed, and the applicant shall be notified accordingly.

(12) If in the materials of the application, which meets the requirements of Article 13 of this Law, there is a reference to a drawing, but the drawing is not available in the application, the applicant shall be notified accordingly with the proposition to submit the drawing or to remove the relevant reference from the application. If an applicant submits the drawing within 2 months from the date of receiving the notification, the date of filing of an application shall be the date when the examination institute receives the drawing. If the applicant does not react to the proposition, the application shall be considered not filed, and the applicant shall be notified accordingly.

(13) If the requirements of Paragraph 11 of Article 12 of this Law are not met, the application shall be considered withdrawn, and the applicant shall be notified accordingly.

(14) If the claimed object belongs to the technology objects specified in Paragraph 2 of Article 6 of this Law and if the application materials meet the formal requirements of Article 12 of this Law and the regulations issued by the Office in compliance with this Law, and the document on the payment of the respective fee for filing of an application meets the specified requirements, the applicant shall receive:

with respect to a patent for an invention - a notification that the formal examination was completed and that it is possible to carry out the qualifying examination;

with respect to a declarative patent for an invention (utility model) - the decision of the Office for granting a declarative patent for an invention (utility model).

(15) If there are reasons to consider that the claimed object does not belong to the technology objects mentioned in Paragraph 2 of Article 6 of this Law, or if the application materials do not meet the formal requirements of Article 12 of this Law and the regulations issued by the Office in compliance with this Law, or the document on the payment of the respective fee for filing of the application does not meet the specified requirements, the examination institute shall send to the applicant the grounded preliminary conclusion with the proposition to present a grounded answer and to remedy, if necessary, the irregularities specified in the conclusion.

The applicant shall give the answer within the period fixed in Paragraph 6 of this Article, and this answer shall be taken into consideration when the conclusion of the examination on the application is being prepared.

If the requirement of unity of invention that is specified in Paragraph 4 of Article 12 of this Law is not fulfilled, the applicant shall indicate in the answer an invention (utility model), with respect to which the examination of the application should be carried out, and make clarifications in the application if necessary. With respect to other inventions (utility models) individual applications shall be filed.

If the requirement of unity of invention is not fulfilled on the proposition of the examination institute, the examination of the application shall be accomplished with respect to an invention (utility model) that is indicated as the first in its invention claims.

(16) After the expiry of 18 months from the date of filing of the application for granting a patent for an invention or, if the priority has been claimed, from its priority date, the Office shall publish in its official bulletin the defined data on the application, provided that the application was not withdrawn, is not considered withdrawn or the decision on the refusal of a patent was not made.

On the request of the applicant, the Office shall publish the data on the application before the expiry of the said period. The filing of the request is subject to the payment of the respective fee.

After publication of the information on the application, any person shall have the right to access to this data under the established procedure. The access to the application materials is subject to the payment of respective fee.

In the case of detecting obvious errors in the published data, the applicant shall have the right to file a request for correcting the errors.

Data on the application for granting a declarative patent for an invention (utility model) shall not be published.

Data on applications, for which the State Expert has taken the decision to refer them to the state secret, shall not be published.

(17) In the course of the qualifying examination a claimed invention shall be examined on the conformity with the patentability requirements defined by Article 7 of this Law.

The examination institute shall carry out the qualifying examination after the receipt of the relevant request of any person and the document on the payment of respective fee for the examination.

The applicant may file the said request and the document on the payment within 3 years from the date of filing of the application. Another person may file the said request and document after publication of the data on the application for an invention but not later than 3 years from the date of filing of the application. This person shall not make decisions with respect to the application, and shall only receive the conclusion of the examination on the application approved by the Office.

The period for filing of the said request and document shall be extended but for no more than 6 months provided that the relevant request has been filed and the fee for filing of the request has been paid before the expiry of this period. This period defaulted due to important reasons shall be renewed provided that the relevant request is filed and the fee is paid within 12 months after the expiry of this period. If the applicant fails to file the said request and document within the specified period, the application shall be considered withdrawn, and the applicant shall be notified accordingly.

(18) If there are reasons to consider that the claimed invention does not meet the patentability requirements, the examination institute shall send to the applicant the grounded preliminary conclusion with the proposition to give a motivated answer and, if necessary, to remedy the irregularities specified in the conclusion.

The applicant shall give the answer within the period determined in Paragraph 6 of this Article for additional materials, and this answer shall be taken into consideration when the conclusion of the examination on the application is being prepared. The matters on the fulfillment of the requirement of unity of invention shall be considered according to Paragraph 15 of this Article.

UNITED KINGDOM: *Sections 15A-18 of the Patents Act of 1977, consolidated version of 01/01/2010*

#### Preliminary examination

15A.-(1) The comptroller shall refer an application for a patent to an examiner for a preliminary examination if -

- (a) the application has a date of filing;
- (b) the application has not been withdrawn or treated as withdrawn; and
- (c) the application fee has been paid.

(2) On a preliminary examination of an application the examiner shall -

- (a) determine whether the application complies with those requirements of this Act and the rules which are designated by the rules as formal requirements for the purposes of this Act; and
- (b) determine whether any requirements under section 13(2) or 15(10) above remain to be complied with.

(3) The examiner shall report to the comptroller his determinations under subsection (2) above.

(4) If on the preliminary examination of an application it is found that -

- (a) any drawing referred to in the application, or
- (b) part of the description of the invention for which the patent is sought, is missing from the application, then the examiner shall include this finding in his report under subsection (3) above.

(5) Subsections (6) to (8) below apply if a report is made to the comptroller under subsection (3) above that not all the formal requirements have been complied with.

(6) The comptroller shall specify a period during which the applicant shall have the opportunity

- (a) to make observations on the report, and
- (b) to amend the application so as to comply with those requirements (subject to section 76 below).

(7) The comptroller may refuse the application if the applicant fails to amend the application as mentioned in subsection (6)(b) above before the end of the period specified by the comptroller under that subsection.

(8) Subsection (7) above does not apply if

- (a) the applicant makes observations as mentioned in subsection (6)(a) above before the end of the period specified by the comptroller under that subsection, and
- (b) as a result of the observations, the comptroller is satisfied that the formal requirements have been complied with.

(9) If a report is made to the comptroller under subsection (3) above

- (a) that any requirement of section 13(2) or 15(10) above has not been complied with; or
- (b) that a drawing or part of the description of the invention has been found to be missing, then the comptroller shall notify the applicant accordingly.

#### Publication of application

16.-(1) Subject to section 22 below and to any prescribed restrictions, where an application has a date of filing, then, as soon as possible after the end of the prescribed period, the comptroller shall, unless the application is withdrawn or refused before preparations for its publication have been completed by the Patent Office, publish it as filed (including not only the original claims but also any amendments of those claims and new claims subsisting immediately before the completion of those preparations) and he may, if so requested by the applicant, publish it as aforesaid during that period, and in either event shall advertise the fact and date of its publication in the journal.

(2) The comptroller may omit from the specification of a published application for a patent any matter

- (a) which in his opinion disparages any person in a way likely to damage him, or
- (b) the publication or exploitation of which would in his opinion be generally expected to encourage offensive, immoral or antisocial behaviour.

## Search

17.-(1) The comptroller shall refer an application for a patent to an examiner for a search if, and only if (a) the comptroller has referred the application to an examiner for a preliminary examination under section 15A(1) above;

(b) the application has not been withdrawn or treated as withdrawn;

(c) before the end of the prescribed period -

(i) the applicant makes a request to the Patent Office in the prescribed form for a search; and

(ii) the fee prescribed for the search ("the search fee") is paid;

(d) the application includes

(i) a description of the invention for which a patent is sought; and

(ii) one or more claims; and

(e) the description and each of the claims comply with the requirements of rules as to language.

(2) [repealed]

(3) [repealed]

(4) Subject to subsections (5) and (6) below, on a search requested under this section, the examiner shall make such investigation as in his opinion is reasonably practicable and necessary for him to identify the documents which he thinks will be needed to decide, on a substantive examination under section 18 below, whether the invention for which a patent is sought is new and involves an inventive step.

(5) On any such search the examiner shall determine whether or not the search would serve any useful purpose on the application as for the time being constituted and -

(a) if he determines that it would serve such a purpose in relation to the whole or part of the application, he shall proceed to conduct the search so far as it would serve such a purpose and shall report on the results of the search to the comptroller; and

(b) if he determines that the search would not serve such a purpose in relation to the whole or part of the application, he shall report accordingly to the comptroller;

and in either event the applicant shall be informed of the examiner's report.

(6) If it appears to the examiner, either before or on conducting a search under this section, that an application relates to two or more inventions, but that they are not so linked as to form a single inventive concept, he shall initially only conduct a search in relation to the first invention specified in the claims of the application, but may proceed to conduct a search in relation to another invention so specified if the applicant pays the search fee in respect of the application so far as it relates to that other invention.

(7) After a search has been requested under this section for an application the comptroller may at any time refer the application to an examiner for a supplementary search, and subsections (4) and (5) above shall apply in relation to a supplementary search as they apply in relation to any other search under this section.

(8) A reference for a supplementary search in consequence of

(a) an amendment of the application made by the applicant under section 18(3) or 19(1) below, or

(b) a correction of the application, or of a document filed in connection with the application, under section 117 below, shall be made only on payment of the prescribed fee, unless the comptroller directs otherwise.

## Substantive examination and grant or refusal of patent

18.-(1) Where the conditions imposed by section 17(1) above for the comptroller to refer an application to an examiner for a search are satisfied and at the time of the request under that subsection or within the prescribed period

(a) a request is made by the applicant to the Patent Office in the prescribed form for a substantive examination; and

(b) the prescribed fee is paid for the examination;

the comptroller shall refer the application to an examiner for a substantive examination; and if no such request is made or the prescribed fee is not paid within that period, the application shall be treated as having been withdrawn at the end of that period.

(1A) If the examiner forms the view that a supplementary search under section 17 above is required for which a fee is payable, he shall inform the comptroller, who may decide that the substantive examination should not proceed until the fee is paid;

and if he so decides, then unless within such period as he may allow

(a) the fee is paid, or

(b) the application is amended so as to render the supplementary search unnecessary, he may refuse the application.

(2) On a substantive examination of an application the examiner shall investigate, to such extent as he considers necessary in view of any examination carried out under section 15A above and search carried out under section 17 above, whether the application complies with the requirements of this Act and the rules and shall determine that question and report his determination to the comptroller.

(3) If the examiner reports that any of those requirements are not complied with, the comptroller shall give the applicant an opportunity within a specified period to make observations on the report and to amend the application so as to comply with those requirements (subject, however, to section 76 below), and if the applicant fails to satisfy the comptroller that those requirements are complied with, or to amend the application so as to comply with them, the comptroller may refuse the application.

(4) If the examiner reports that the application, whether as originally filed or as amended in pursuance of section 15A above, this section or section 19 below, complies with those requirements at any time before the end of the prescribed period, the comptroller shall notify the applicant of that fact and, subject to subsection (5) and sections 19 and 22 below and on payment within the prescribed period of any fee prescribed for the grant, grant him a patent.

(5) Where two or more applications for a patent for the same invention having the same priority date are filed by the same applicant or his successor in title, the comptroller may on that ground refuse to grant a patent in pursuance of more than one of the applications.

UNITED REPUBLIC OF TANZANIA: *Sections 22, 25 and 27 of the Patents Act No. 1 of 20/01/1987*

Furnishing of information on corresponding foreign applications and grants

22.-(1) At the request of the Registrar, made within one year of the date of filing of the application, the person who is making an application shall furnish him with the date and number of any application for a patent or another title of protection filed by him with a national industrial property office of another country or with a regional industrial property office relating to the same invention as that claimed in the application filed with the Registrar. .

(2) (a) The person making an application for registration of a patent shall, at the request of the Registrar, furnish the following documents relating to one of the foreign applications referred to in subsection (1):

(i) copies of any communication received by that person concerning the results of any search or examination carried out in respect of the foreign application;

(ii) a copy of the patent or other title of protection granted on the foreign application;

(iii) a copy of any final decision rejecting the foreign application or refusing the grant requested in the foreign application.

(b) The person making an application for registration of a patent shall, at the request of the Registrar furnish him with a copy of any decision invalidating the patent or other title of protection granted to him on the basis of the foreign application referred to in paragraph (a).

(3) The person making the application shall, at the request of the Registrar, furnish him with copies of any communication received by the applicant concerning the results of any search or examination carried out in respect of any foreign application other than the one referred to in subsection (2).

(4) The documents furnished under this section shall merely serve the purpose of facilitating the evaluation of novelty and inventive step with respect to the invention claimed in the application filed with the Registrar or in the patent granted on the basis of that application.

(5) The person making an application for registration of a patent shall have the right to submit comments on the documents furnished under this section.

Examination application

25.-(1) (a) The Registrar shall record as a filing date the date of receipt of the application, provided that, at the time of receipt, the documents filed contain-

(i) the name of the applicant;

(ii) a part which on the face of it appears to be a description;

(iii) a part which on the face of it appears to be a claim.

(b) If the registrar finds that the application did not, at the time of receipt, fulfill the requirements referred to in paragraph (a), he shall require the person making the application to file the required correction.

(c) If the person making the application complies with the invitation referred to paragraph (b), the Registrar shall accord as filing date, the date of receipt of the required correction; otherwise he shall treat the application as if it has not been filed.

(d) Where the application refers to drawings which in fact are not included in the application, the Registrar shall require the person making the application to furnish the missing drawings and if he complies with the said requirement, the Registrar shall record as a filing date the date of receipt of the correction, provided that the correction was received within thirty days from the date of receipt of the application.

(e) Where no requirement under paragraph (b) or (d) was sent to the person making an application and that person nevertheless files a correction, pertaining to any of the requirements under paragraph (a), to his application, the Registrar shall record as filing date the date of receipt of the correction provided that the correction was received within thirty days from the date of receipt of the application.

(2) Where the request is accompanied by the statement on the right to the patent referred to in section 18 (2)(b), the Registrar shall send a copy of the statement to the inventor who shall have the right to inspect the application and to receive, at his own expense, a copy of the application.

(3) (a) The Registrar shall cause an examination to be carried out as to whether there are any of the following defects with respect to the application:

(i) the request does not comply with the requirements of section 18(2) and the rules pertaining thereto;

(ii) the description, the claims and, where applicable, the drawings do not comply with the physical requirements prescribed by the Regulations;

(iii) the application does not contain an abstract;

(iv) the applicant has not complied with a request made by the Registrar under section 22;

(v) the fees referred to in section 23 are not paid as provided in the Regulations.

(b) If the Registrar finds any of the defects referred under paragraph (a) he shall require the person making the application to remedy such defects provided that any corrections made to the application shall not be such that they would require a change of the filing date and if the applicant does not comply with the said invitation, the Registrar shall reject the application.

(4) (a) Unless the application is to be the subject of an international type search under section 26, the Registrar shall cause an examination to be carried out as to whether the application appears to comply with the requirement of unity of invention prescribed by section 19 and the rules pertaining thereto.

(b) If the Registrar is of the opinion that the requirement of unity of invention may not have been complied with, he shall invite the applicant to restrict or divide the application.

(c) If the person making the application does not comply with the requirement made under paragraph (b), the application shall be rejected by the Registrar,

(5) The details of the requirements and the procedure under this section shall be prescribed by the Regulations.

#### Examination as to substance

27.-(1) The Minister may by regulations direct that applications for patents relating to a specified technical field shall be the subject of an examination as to substance.

(2) If, in the opinion of the Registrar the subject matter of an invention for which a patent is sought falls within a technical field covered by the terms of a direction made under subsection (1), he shall cause an examination to be carried out as to whether the following conditions are fulfilled:

(i) the claimed invention is patentable within the meaning of sections 8 to 11;

(ii) the claimed invention is not excluded from protection under sections 12 to 13;

(iii) the description and the claims comply with the requirements prescribed by section 18 and the rules pertaining thereto;

(3)(a) For the purposes of the examination under subsection (2), the Registrar may transmit the application together with all relevant documents to the authority designated in the Regulations for a preliminary examination as to the patentability of the claimed invention.

(b) The authority referred to in paragraph (a) shall establish a report on the conclusions of its examinations and shall transmit it to the Registrar and to the applicant.

(4) Where, taking due account of the conclusions of any report referred to in subsection (3)(b), the Registrar is of the opinion that any of the conditions referred to in subsection (2) are not fulfilled, he shall notify the applicant accordingly and invite him to submit his observations and where applicable, to amend his application.

(5) Where, despite any observation or amendment submitted by the person making the application, the Registrar finds that any of the conditions referred to in subsection (2) are not fulfilled, he shall refuse the grant of a patent and notify the applicant accordingly.

(6) The details of the requirements and the procedure under this section shall be prescribed by the Regulations.

UNITED STATES OF AMERICA: *Section 131 of the 35 U.S.C, as last amended on 01/11/2005 and § 1.56, 1.98 (a) (1) and (2), § 1.104 (a) and (b) and § 1.105 of the United States Code of Federal Regulations, as amended Dec. 2009, Title 37 - Patents, Trademarks, and Copyrights*

35 U.S.C. 131 Examination of application.

The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Director shall issue a patent therefor.

35 U.S.C. 132 Notice of rejection; reexamination.

(a) Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1) of this title.

### *Regulations*

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and  
(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
  - (2) Each attorney or agent who prepares or prosecutes the application; and
  - (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.
- (d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.
- (e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

§ 1.98 Content of information disclosure statement.

(a) Any information disclosure statement filed under § 1.97 shall include the items listed in paragraphs (a)(1), (a)(2) and (a)(3) of this section.

(1) A list of all patents, publications, applications, or other information submitted for consideration by the Office. U.S. patents and U.S. patent application publications must be listed in a section separately from citations of other documents. Each page of the list must include:

- (i) The application number of the application in which the information disclosure statement is being submitted;
- (ii) A column that provides a space, next to each document to be considered, for the examiner's initials; and
- (iii) A heading that clearly indicates that the list is an information disclosure statement.

(2) A legible copy of:

- (i) Each foreign patent;
- (ii) Each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office;
- (iii) For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion; and
- (iv) All other information or that portion which caused it to be listed.

§ 1.104 Nature of examination.

(a) Examiner's action.

(1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

(2) The applicant, or in the case of a reexamination proceeding, both the patent owner and the requester, will be notified of the examiner's action. The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant, or in the case of a reexamination proceeding the patent owner, to judge the propriety of continuing the prosecution.

(3) An international-type search will be made in all national applications filed on and after June 1, 1978.

(4) Any national application may also have an international-type search report prepared thereon at the time of the national examination on the merits, upon specific written request therefor and payment of the international-type search report fee set forth in § 1.21(e). The Patent and Trademark Office does not require that a formal report of an international-type search be prepared in order to obtain a search fee refund in a later filed international application.

(b) Completeness of examiner's action. The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

§ 1.105 Requirements for information.

- (a)(1) In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter, for example:
- (i) Commercial databases: The existence of any particularly relevant commercial database known to any of the inventors that could be searched for a particular aspect of the invention.
  - (ii) Search: Whether a search of the prior art was made, and if so, what was searched.
  - (iii) Related information: A copy of any non-patent literature, published application, or patent (U.S. or foreign), by any of the inventors, that relates to the claimed invention.
  - (iv) Information used to draft application: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used to draft the application.
  - (v) Information used in invention process: A copy of any non-patent literature, published application, or patent (U.S. or foreign) that was used in the invention process, such as by designing around or providing a solution to accomplish an invention result.
  - (vi) Improvements: Where the claimed invention is an improvement, identification of what is being improved.
  - (vii) In Use: Identification of any use of the claimed invention known to any of the inventors at the time the application was filed notwithstanding the date of the use.
  - (viii) Technical information known to applicant. Technical information known to applicant concerning the related art, the disclosure, the claimed subject matter, other factual information pertinent to patentability, or concerning the accuracy of the examiner's stated interpretation of such items.
- (2) Where an assignee has asserted its right to prosecute pursuant to § 3.71(a) of this chapter, matters such as paragraphs (a)(1)(i), (iii), and (vii) of this section may also be applied to such assignee.
- (3) Requirements for factual information known to applicant may be presented in any appropriate manner, for example:
- (i) A requirement for factual information;
  - (ii) Interrogatories in the form of specific questions seeking applicant's factual knowledge; or
  - (iii) Stipulations as to facts with which the applicant may agree or disagree.
- (4) Any reply to a requirement for information pursuant to this section that states either that the information required to be submitted is unknown to or is not readily available to the party or parties from which it was requested may be accepted as a complete reply.
- (b) The requirement for information of paragraph (a)(1) of this section may be included in an Office action, or sent separately.
- (c) A reply, or a failure to reply, to a requirement for information under this section will be governed by §§ 1.135 and 1.136.

*URUGUAY: Articles 23, 31 and 32 of the Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs No. 1.827\*R of 02/09/1999*

23. Where the preliminary formal examination of a patent application shows that it does not meet the requirements prescribed in the preceding Article, but that it identifies the applicant, contains a description of the subject matter and the claims, the applicant shall be given the period laid down in the regulations but not exceeding 90 days to meet the requirements. The application shall retain the date of filing if the requirements are met within this time limit; if they are not, the application is deemed to have been abandoned.

31. Any interested party may put forward comments based on the patent application within the period prescribed in the regulations, as of the date of publication. The submission of comments shall not suspend the application process and the person making the comments shall not become a party to the procedure.

32. The purpose of the substantive examination of applications shall be to determine whether the proposed invention meets the requirements and criteria for patentability laid down in this Law.

For this purpose, it shall be permissible:

(a) to request the applicant to furnish copies of the anticipation search, the substantive examinations and other documentation available to him;

(b) to seek the advice of bodies which carry out scientific and technological activities;

(c) to utilize patent documents, search and examination reports or similar documents prepared by other patent offices.

All the comments resulting from the substantive examination shall be contained in a single act, unless there are new or supervenient elements that might affect patentability.

The comments made shall be shown to the applicant within the time limit fixed in the regulations.

*UZBEKISTAN: Articles 20, 21 and 23 of the Law on Inventions, Utility Models and Industrial Designs of 29/08/2002*

*Article 20*

State examination of an application for the grant of a patent

The Patent Office shall conduct a State examination on an application for the grant of a patent, consisting of a formal examination, an examination of the application for a utility model, and a scientific and technical examination of the substance of the application for an invention or industrial model (hereinafter – substantive examination).

Within two months of the filing date of an application for the grant of a patent, the applicant shall be entitled to make amendments or clarifications thereto, or to include additional documents, without changing the essential features of the claimed industrial property subject matter.

In the case of an application for the grant of a patent, compiled in violation of the established requirements, the applicant shall be requested to provide, within three months of the date of dispatch, corrected or missing documents.

Where an applicant does not provide, within the period indicated, the requested documents or does not submit a request to extend the established period, an application for the grant of a patent shall be considered to have been withdrawn.

Corrections, clarifications or additional documents relating to an application for the grant of a patent may be submitted after the period in question has expired, but not once a decision has been taken to grant a patent, provided that the patent fee has been paid.

In the case of an application for the grant of a patent, filed in violation of the requirements of unity of industrial property subject matter, the applicant shall be invited, within three months of the date of dispatch to him of the corresponding request, to state which subject matter should be examined, and to clarify the application documents accordingly. The other subject matter forming part of the original application documents may be separated into individual applications. If an applicant does not state which subject matter should be examined, and does not provide clarified documents, a State examination shall be conducted of the subject matter indicated first in the claims for the invention or utility model, or in the description of the industrial design.

Deadlines missed by an applicant for the submission of materials following a State examination request may be re-established by the Patent Office, provided that the causes of the unavoidable postponement of the established deadline are confirmed and the patent fee is paid. A request to re-establish a missed deadline may be filed by the applicant not later than 12 months from the day on which the missed deadline expires.

Up to the time of State registration of industrial property subject matter in the appropriate State register, an applicant may withdraw an application for the grant of a patent at any stage of the State examination.

The information contained in documents for applications for the grant of a patent shall be kept secret by the Patent Office, and details thereof shall not be supplied without the consent of the applicant or patent owner. The dissemination of the information contained in application documents, prior to official publication of information on the registration of industrial property subject matter, shall give rise to liability in accordance with the law.

Applications for the grant of a patent, accepted for consideration by the Patent Office, shall not be returned to applicants.

#### *Article 21*

##### Formal examination

A formal examination shall be carried out by the Patent Office after a period of two months from the filing date of an application for the grant of a patent. At the applicant's request, a formal examination may be undertaken before the period in question expires. In this case, from the time the request is filed the applicant shall be deprived of the rights to add to, correct and refine the application documents at his own initiative, without the payment of an additional patent fee.

During a formal examination, it shall be examined whether the claimed proposal complies with the industrial property subject matter for which legal protection is granted. Based on the results of the formal examination, the Patent Office shall inform the applicant of the decision.

An applicant may lodge an appeal with the Appeal Board concerning a decision of the Patent Office, within three months of the date on which the decision is dispatched. The appeal shall be examined by the Appeal Board within two months of the date of its receipt.

An Appeal Board decision may be appealed in the courts within six months of the date of its adoption.

#### *Article 23*

##### Substantive examination

The Patent Office shall conduct a substantive examination provided that the patent fee has been paid. The patent fee may be paid within three months of the date of dispatch to the applicant of the decision for a formal examination concerning the acceptance of an application for the grant of a patent for consideration. Where the deadline in question is not respected, an application shall be considered to have been withdrawn.

If, as a result of a substantive examination, it is established that subject matter claimed as an invention, expressed as a formula proposed by the applicant and subject matter claimed as an industrial design, expressed in terms of all its essential features, as proposed by the applicant, meet the established requirements, the Patent Office shall decide to grant a patent.

In establishing that subject matter claimed as an invention or an industrial design fails to comply with the requirements of patentability, a decision shall be taken to refuse to grant a patent.

An applicant may lodge with the Appeal Board an appeal concerning a decision of the Patent Office within three months of the date of its dispatch. The appeal shall be examined by the Appeal Board within four months of the date of its receipt.

An Appeal Board decision may be appealed in the courts within six months of the date of its adoption.

VIET NAM: *Articles 109, 113 and 114 of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005 as last amended by Order No. 12/2009/L-CTN of 29/06/2009*

#### *Article 109*

##### Formal examination of industrial property registration applications

1. Industrial property registration applications shall be subject to formal examination for evaluating their validity.
2. An industrial property registration application shall be considered invalid in the following cases:

- a/ It does not fulfill the formal requirements;
  - b/ The subject matter stated in the application is ineligible for protection;
  - c/ The applicant does not have the registration right, including where the registration right belongs to more than one organizations or individuals but one or several of them do not agree with the filing;
  - d/ It is filed in contravention of regulations on the filing mode provided for in Article 89 of this Law;
  - e/ The applicant fails to pay fees and charges.
3. For industrial property registration applications falling into the cases specified in Clause 2 of this Article, the state management agency in charge of industrial property rights shall carry out the following procedures:
- a/ Issuing a notice of intended refusal to accept valid applications, clearly stating reasons and setting a time limit for the applicant to correct errors or to object such intended refusal;
  - b/ Issuing a notice of refusal to accept valid applications if the applicant fails to correct errors, improperly corrects errors or fails to make a justifiable objection to such intended refusal mentioned at Point a of this Clause;
  - c/ Issuing a notice of refusal to grant a certificate of registered semiconductor integrated circuit layout-design in case of an integrated circuit registration application;
  - d/ Carrying out procedures specified in Clause 4 of this Article if the applicant properly corrects errors or makes justifiable objection to the intended refusal to accept valid application mentioned at Point a of this Clause.
4. For industrial property registration applications not falling into the cases specified in Clause 2 of this Article, or in the cases specified at Point d, Clause 3 of this Article, the state management agency in charge of industrial property rights shall issue notices of acceptance of valid applications or carry out procedures for granting protection titles and recording them in the national register of industrial property as provided for in Article 118 of this Law, for layout-design registration applications.
5. Mark registration applications rejected according to the provisions of Clause 3 of this Article shall be considered having not been filed, except where they serve as grounds for claims for priority right.

#### *Article 113*

Request for substantive examination of invention registration applications

1. Within 42 months after the filing date or the priority date, as applicable, an applicant or any third party may request the concerned state management agency in charge of industrial property rights to substantively examine the application, provided that the substantive examination fee is paid.
2. The time limit for making request for substantive examination of an invention registration application involving a request for a utility solution patent shall be 36 months counting from the filing date or the priority date, as applicable.
3. Where no request for substantive examination is filed within the time limit specified in Clauses 1 and 2 of this Article, the invention registration application shall be considered having been withdrawn at the expiration of that time limit.

#### *Article 114*

Substantive examination of industrial property registration applications

1. The following industrial property registration applications shall be substantively examined for evaluation of the eligibility for grant of protection titles for subject matters stated in such applications under protection conditions and for determination of the respective scope of protection:
  - a/ Invention registration applications which have already been accepted as being valid and involve requests for substantive examination filed according to regulations;
  - b/ Industrial design registration applications, mark registration applications or geographical indication registration applications which have been accepted as being valid.
2. Layout-design registration applications shall not be substantively examined.

*ZAMBIA: Section 16 of the Patent Act of 1958(Chapter 400) as last amended by Act No. 26 of 28/12/1987*

Examination of applications and specifications

16. (I) The Registrar shall examine every application for a patent and every specification accompanying such application or lodged at the Patent Office in pursuance of such application, in order to ascertain-
  - (a) whether such application or specification complies with the requirements of this Act;

(b) in the case of a complete specification lodged after a provisional specification, or of a convention application, whether the invention claimed is substantially the same as that disclosed in the provisional specification or in the application lodged in the convention country, as the case may be.

(2) Any examination or investigation required in terms of subsection

(1) may, on the direction of the Registrar, be undertaken by an examiner who shall report his findings on any such examination or investigation to the Registrar.

(3) An examination or investigation required by the provisions of this Act shall not be deemed to warrant the validity of any patent, and no liability shall be incurred by the Government, the Minister, the Registrar or any officer of the Patent Office by reason of or in connection with any such examination or investigation or report or other proceeding consequent thereon.

*ZIMBABWE: Section 11 of the Patents Act (Chapter 26:03) No. 26 of 1971 as last amended by Act 20/1994 (S.7)*

#### Examination of applications and specifications

11.-(1) An application for a patent, including any specification and other document accompanying such application or subsequently lodged within such time as may be prescribed at the Patent Office in pursuance of such application, shall be examined by an examiner for the purpose of ascertaining

(a) whether the application, specification and accompanying documents comply with the requirements of this Act, including whether any of the grounds of opposition specified in subsection (1) of section seventeen are applicable; and

(b) in the case of a complete specification lodged after a provisional specification or of a Convention application, whether the matter claimed is substantially the same as that disclosed in the provisional specification or in the application lodged in the Convention country, as the case may be.

(2) An examination or investigation required by this Act shall not be deemed to warrant the validity of any patent and no liability shall be incurred by the State, the Minister, the Registrar or any examiner or other officer of the Patent Office by reason of or in connection with any such examination or investigation or report or other proceeding consequent thereon.

*ANDEAN COMMUNITY: Articles 44-48 of the Decision No. 486 of 14/09/2000 of the Commission of the Andean Community - Common Industrial Property Regime*

44. Within a period of six months following the publication of the application, regardless of whether or not oppositions have been filed, the applicant shall request that the invention be examined for patentability. Member countries may charge a fee for the conduct of that examination. Where the said period expires without the applicant having requested examination, the application shall lapse.

45. If the competent national office finds that the invention is not patentable or does not comply with one of the requirements laid down in this Decision for the grant of a patent, it shall notify the applicant accordingly. The applicant shall respond to such notification within a period of 60 days from the date thereof. That period may be extended once for a period of 30 additional days.

The competent national office may notify the applicant two or more times under the foregoing paragraph if it considers such action necessary.

Where the applicant fails to respond to the notification within the periods specified, or where in spite of the response there are still obstacles to grant, the competent national office shall refuse the patent.

46. The competent national office may solicit reports from experts or from scientific technological bodies considered suitable, so as to have their opinion on the patentability of the invention. It may likewise, if it sees fit, solicit reports from other industrial property offices.

Where necessary for the purposes of the patentability examination the applicant shall, at the request of the competent national office, submit, within a period not exceeding three months, one or more of

the following documents relating to one or more filed foreign applications relating wholly or partly to the same invention as that being examined:

- (a) a copy of the foreign application;
- (b) a copy of the findings of novelty or patentability examinations carried out in relation to that foreign application;
- (c) a copy of the patent or other protection title that has been granted on the basis of that foreign application;
- (d) a copy of any judgment or decision by which the foreign application has been rejected or denied;
- (e) a copy of any judgment or decision by which the patent or other protection title granted on the foreign application has been cancelled or invalidated.

The competent national office may recognize the results of examinations referred to under subparagraph (b) above as being sufficient to prove compliance with the conditions governing patentability of the invention.

Where the applicant fails to submit the documents requested within the period specified in this Article, the competent national office shall refuse the patent.

47. At the request of the applicant, the competent national office may suspend the processing of the patent application where any document that should be filed under subparagraphs (b) and (c) of Article 46 has yet to be received or is pending for a foreign authority.

48. If the final examination is favorable, the patent shall be granted. If it is only partly favorable, the title shall be granted only in respect of those claims that have been accepted. If it is unfavorable the grant of a patent shall be refused.

*ARIPO: Section 3, (2), (3), (4), (5), (6), (7) and (8) of the Harare Protocol of 10/12/1982 as last amended on 26/11/1999*

#### Section 3 - Patents

(2)(a) The Office shall examine whether the formal requirements for applications have been complied with and shall accord the appropriate filing date to the application.

(b) If the Office finds that the application does not comply with the formal requirements, it shall notify the applicant accordingly, inviting him to comply with the requirements within the prescribed period. If the applicant does not comply with the requirements within the said period, the Office shall refuse the application.

(c) The Office shall notify each designated State of the fact that a patent application has been filed which complies with the prescribed formal requirements.

(3) The Office shall undertake, or arrange for, the substantive examination of the patent application. If it finds that the invention claimed in the application does not comply with the requirements of patentability referred to in subsection (9), it shall refuse the application.

(4) Where under:

- (a) subsection (2)(b) or (3) of this Section;
- (b) any other Protocol within the framework of ARIPO;

the Office refuses any application, the applicant may, within the prescribed period, request the Office to reconsider the matter.

(5) If after the Office has reconsidered the application, the Office is still of the view that the application shall be refused, the applicant may lodge an appeal against the decision of the Office to the Board of Appeal established in terms of Section 4bis of the Protocol.

(6) Before the expiration of six months from the date of the notification referred to in subsection (5), a designated State may make a written communication to the Office that, if a patent is granted by the Office, that patent shall have no effect in its territory for the reason

(i) that the invention is not patentable in accordance with the provisions of this Protocol, or

(ii) that, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State.

(7) After the expiration of the said six months, the Office shall grant the patent, which shall have effect in those designated States which have not made the communication referred to in subsection (6). The Office shall publish the patent granted.

(8) If the Office refuses the application notwithstanding a request for reconsideration under subsection (4), the applicant may, within three months from being notified of such refusal, request that his application be treated, in any designated State, as an application according to the national law of that State.

*OAPI: Articles 18 and 20, Annex I; of the Bangui Agreement of 02/03/1977, as revised on 24/02/1999*

#### *Article 18*

##### Filing Date

(1) The Organization shall grant as the filing date the date of receipt of the application, written in one of its working languages, by the Ministry responsible for industrial property or by the Organization, provided that, at the time of receipt, the application contains

(a) an express or implicit indication that the grant of a patent is requested;

(b) information whereby the identity of the applicant may be established;

(c) a part which, at first sight, purports to be the description of an invention and one or more claims;

(d) proof of payment of the prescribed fees.

(2) The filing date of an international application shall be that assigned to it by the receiving Office.

#### *Article 20*

##### Examination of Applications

(1) Any application for a patent shall undergo examination to ensure that

(a) the invention mentioned in the application is not excluded from the protection afforded by the patent under the provisions of Article 6 of this Annex;

(b) the claim or claims conform to the provisions of Article 14(1)(d)(iii) of this Annex;

(c) the provisions of Article 15 of this Annex have been respected.

(2) Subject to the provisions of paragraph (3) below, a search shall also be conducted to ensure that

(a) at the time of the filing of the patent application, an application for a patent filed earlier, or benefiting from a validly claimed earlier priority and concerning the same invention, was not in the process of being granted;

(b) the invention

(i) is new,

(ii) involves an inventive step,

(iii) is industrially applicable.

(3) The Administrative Council shall decide whether, and to what extent, the provisions of paragraph (2)(a) and (b) above shall be applied; in particular, it may decide whether all or some of the said provisions are applicable to one or several fields of technology covered by the inventions; it shall determine such fields by reference to the International Patent Classification.

(4) Where the invention relates to the use of a microorganism, the Organization shall reserve the right to require the applicant to deposit a sample of the microorganism as issued by the depositary institution or the international depositary authority.

(5) For international applications under the Patent Cooperation Treaty, the Organization may avail itself of the provisions of Articles 20 and 36 of the said Treaty, which relate to the international search report and the international preliminary examination report, respectively.

#### (5) PROVISIONS OF LAW ON EX-OFFICIO IP OFFICE CONTROL OF ANTI-COMPETITIVE CLAUSES IN LICENSING AGREEMENTS

*ALGERIA: Article 37 of the Ordinance No. 03-07 of 19/07/2003*

##### *Article 37*

- Le titulaire ou le demandeur du brevet d'invention peut, par contrat, donner à une autre personne licence d'exploiter son invention.

Sont réputées nulles les clauses contenues dans les contrats de licence dans la mesure où elles imposent au preneur de licence sur le plan industriel ou commercial, des limitations constituant un usage abusif des droits conférés par le brevet d'invention ayant un effet préjudiciable sur la concurrence sur le marché national.

*ARGENTINA: Sections 37, 38 and 41 of the Law No. 24.481 of 23/05/1995 on Patents and Utility Models (as last amended by Law No. 24.572)*

37. Patents and utility model certificates shall be transferable and may be licensed, either fully or in part, in the manner and subject to the formalities laid down by law. In order to be binding on third parties, any transfer shall be registered with the National Institute of Industrial Property.

38. License agreements shall not contain restrictive trade clauses that would affect the production, marketing or technological development of the licensee, restrict competition or impose any other procedure such as exclusive transfer-back conditions, conditions preventing any challenge to validity, those that impose mandatory joint licenses or any other of the practices specified in Law No. 22.262 or such legislation as may amend or replace it.

41. The National Institute of Industrial Property may, at the reasoned request of a competent authority, introduce limited exceptions to the rights conferred by a patent. Such exceptions shall not unjustifiably prejudice the exploitation of the patent or do unjustified harm to the legitimate interests of the owner thereof, due account being taken of the legitimate interests of third parties.

*AUSTRALIA: Section 144 of the Patens Act No. 83 of 1990 as amended by Act No. 106 of 2006*

##### 144. Void conditions

(1) A condition in a contract relating to the sale or lease of, or a licence to exploit, a patented invention is void if the effect of the condition would be:

- (a) to prohibit or restrict the buyer, lessee or licensee from using a product or process (whether patented or not) supplied or owned by a person other than the seller, lessor or licensor, or a nominee of the seller, lessor or licensor; or
- (b) to require the buyer, lessee or licensee to acquire a product not protected by the patent from the seller, lessor or licensor, or a nominee of the seller, lessor or licensor.

(1A) A condition in a contract relating to the sale or lease of, or a licence to exploit, an invention the subject of an innovation patent is void if the effect of the condition would be to:

- (a) prohibit the buyer, lessee or licensee from applying for examination of the patent; or
- (b) impose restrictions on the circumstances in which the buyer, lessee or licensee may apply for examination of the patent.

(2) Subsection (1) does not apply if:

(a) the seller, lessor or licensor proves that, at the time the contract was made, the buyer, lessee or licensee had the option of buying the product, or obtaining a lease or licence, on reasonable terms without the condition; and

(b) the contract entitles the buyer, lessee or licensee to be relieved of the liability to comply with the condition on giving the other party 3 months' notice in writing and paying, in compensation for the relief:

- (i) in the case of a sale - such sum as is fixed by an arbitrator appointed by the Minister; or
- (ii) in the case of a lease or licence - such rent or royalty as is so fixed for the rest of the term of the contract.

(3) A person is not stopped from applying for or obtaining relief in any proceedings under this Act merely because of an admission made by the person about the reasonableness of terms offered to the person as mentioned in paragraph (2)(a).

(4) It is a defence to proceedings for infringement of a patent that the patented invention is, or was when the proceedings were started, the subject of a contract containing a provision, inserted by the patentee, that is void under this section.

(5) If the patentee offers the other parties to a contract mentioned in subsection (4) a new contract that does not contain the void condition but that otherwise gives the parties the same rights as the existing contract, then, whether or not the other parties accept the new contract in place of the existing contract, subsection (4) ceases to apply, but the patentee is not entitled to damages or an account of profit for an infringement of the patent committed before the offer of the new contract.

DOMINICAN REPUBLIC: *Article 33 of the Industrial Property Law No. 20-00 of 08/05/2000*

### *Article 33*

#### Contractual licenses

1) The holder or applicant of a patent may grant to third parties one or more licenses for exploitation of the invention that is the object of the patent or application.

2) Every contract for a license to exploit an invention must be confirmed in writing and recorded in the General Agency for Industrial Property. The license will have legal effect for third parties only after being recorded. The established fee shall be paid for the recording.

3) In the absence of a stipulation to the contrary in the contract for an exploitation license, the following standards are applicable:

a) the license covers all acts indicated in Article 29, numeral 1), during the entire life of the patent, in all of the territory of this country and with regard to any application of the invention.

b) the licensee cannot assign the license or grant sublicenses.

c) the license is not exclusive and the licensor can give other licenses for the exploitation of the patent in this country, and as well may himself or herself exploit the patent in this country.

d) When the license is granted as exclusive, the licensor can neither give other licenses for the exploitation of the patent in this country nor himself or herself exploit the patent in this country.

4) Licensing contracts must not contain restrictive commercial clauses affecting the production, marketing or technological development of the licensee and restricting competition, such as exclusive conditions for reciprocity, those which prevent challenge to validity, and those which impose compulsory joint licenses, or any other conduct which is anti-competitive or restrictive to competition.

GHANA: *Section 41 of the Patent Law No. 305A of 30/12/1992*

## Prohibited terms in licence contracts

41. The Registrar may refuse to register a licence contract if the effect of any of its terms is

(a) to permit or require the importation of technology from abroad when substantially similar or equivalent technology may be obtained on the same or more favourable conditions without importation from abroad;

(b) to require payment of a price, royalty or other consideration which is disproportionate to the value of the technology to which the contract relates;

(c) to require the licensee to acquire any materials from the licensor or from sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(d) to prohibit the licensee from acquiring, or to restrict his acquisition of, any materials from any source, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(e) to prohibit the licensee from using, or to restrict his use of any materials which are not supplied by the licensor or by a source designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(f) to require the licensee to sell products produced by him under the contract exclusively or principally to persons designated by the licensor;

(g) to require the licensee to make available to the licensor without appropriate consideration any improvements made by the licensee with respect to the technology to which the contract relates;

(h) to limit the volume of the product produced by the licensee with the help of the technology to which the contract relates;

(i) to prohibit or restrict the export of products produced by the licensee;

(j) to require the licensee to employ on a permanent basis persons designated by the licensor;

(k) to impose restrictions on research or technological development carried out by the licensee;

(l) to prohibit or restrict the use by the licensee of any technology to which the contract relates;

(m) to extend the coverage of the contract to technology not required for the use of the technology which is the main subject of the contract and to require consideration for such additional technology;

(n) to fix prices for the sale or resale of the products produced by the licensee with the help of the technology to which the contract relates;

(o) to exempt the licensor from any liability consequent upon any defect inherent in the technology to which the contract relates or restrict such liability;

(p) to prohibit or restrict the use by the licensee, after the expiration of the contract, of the technology acquired as a result of the contract, subject to any right of the licensor under the patent;

(q) to require that disputes arising from the interpretation or performance of the contract be governed by a law other than laws of Ghana or that such disputes be brought before courts located in a country other than Ghana;

(r) to require the licensee to pay royalties or other consideration beyond the period of the patent which is the subject of the contract; or

(s) to require the licensee to pay royalties or other consideration for patents not granted or registered in Ghana.

GREECE: *Articles 21 and 22 of the Law on "Technology transfer, inventions, and technological innovation" No. 1733/1987 (FEK 171, A' of 22/9/1987) as last amended by Law No. 2359 of 15/11/1995*

#### *Article 21*

Meaning - Nullity of terms of the contract

1. By the contract on technology transfer the supplier of technology is called upon to supply technology to the recipient of technology, and the recipient is called upon to pay the value agreed upon. In particular, the following are conceived within the meaning of this article as technology supply:
  - a. The licence for exploitation of patents and utility model certificates;
  - b. The assignment of patents and of utility model certificates;
  - c. The supplying of technical constructing instructions, drawings or services;
  - d. The supplying of organisational and management services, as well as of specialised consulting services or services for follow-up and control;
  - e. The disclosure of industrial secrets with drawings, diagrams, specimens, models, instructions, proportions, conditions, processes, prescriptions and methods of production of products referring to the productive exploitation. Such industrial secrets are mainly technical information, data or knowledge which relate to processes, expertise or skills, that have practical application particularly to the production of goods and the rendering of services, provided that they have not become widely known;
  - f. The joint research or development of new technology, demonstrative or experimental programs or works;
  - g. Providing technical assistance in the form of briefing, instruction, and formation of personnel.
2. The following terms shall be null and void:
  - a. Terms in patent licences that include dispositions which are contrary to those of article 3 of Regulation number 2349/1984 of the Commission of European Communities (Official Journal No. L 219/15) concerning the implementation of article 85 par. 3 of the EEC Convention, to classes of agreements relating to the licence for exploitation of patents;
  - b. Terms in contracts on technology transfer including ban of exportation. The Minister of Industry, Energy, and Technology may, by his decision, permit the conclusion of a contract containing a clause banning exportation, if this is imposed by serious reasons of economic development and public interest and provided that the ban is not contrary to international obligations of the country.

#### *Article 22*

Registration of the contract on technology transfer

1. The contract on technology transfer shall be submitted to O.B.I. by the contracting parties which have their domicile or seat in Greece, within one month from its conclusion and at the same time the dispositions of law No 1360/83 (Official Journal No. 65) apply.
2. The contract shall be registered in the register of technology transfer. The registered contracts on technology transfer or the information contained in the form provided in paragraph 5 of the present article shall be kept secret. Whoever shall violate the present disposition shall be punished according to article 17 of Law No 146/1914 on Unfair Competition.
3. Contracts with the following subject shall not be subject to the obligation of being registered:
  - a. Isolated use of foreign engineers and technicians for installation and repair of factories or machinery;
  - b. Advice, drawings or similar provisions usually accompanying machinery or equipment, provided that they do not entail any special surcharge for the one whom they are destined to;
  - c. Urgent technical assistance or repair, provided that they are carried out by reason of an earlier registered agreement.
  - d. Technical training given by educational organisations or enterprises to their personnel;
  - e. Defense systems.
4. The party responsible for registering the contract on technology transfer may either submit a copy of the contract or complete the special form in accordance with paragraph 5. Suit or petition to the Court which concerns any difference between the contracting parties and which relates to a contract on technology transfer cannot be discussed before the court without a written confirmation of O.B.I. indicating that the parties have complied with the requirements of this paragraph.

5. The process of compiling, drafting, and granting of the special form regarding contracts on technology transfer and the relevant prerequisites to be completed for statistical use are determined by decision of the Minister of Industry, Energy, and Technology.

6. The registration of the contract on technology transfer with O.B.I. may entail for the contracting party(-ies) submitting the agreement a deduction from the sum of the fees due to O.B.I.. The percentage of the deduction shall be determined by decision of the Administrative Council of O.B.I.

GUATEMALA: *Articles 132 and 133 of the Industrial Property Law, Decree No. 57-2000 of 18/09/2000*

#### Licencias Contractuales

132. El titular de una patente podrá conceder licencia para la explotación de la invención patentada. La inscripción de la licencia contractual en el Registro no es obligatoria, pero la misma sólo tendrá efectos legales frente a terceros desde la inscripción. La explotación de la patente por el licenciario cuya licencia esté inscrita en el Registro, se considerará para todos los efectos legales como efectuada por el propio titular.

La solicitud de inscripción de la licencia contendrá:

- a) El nombre, razón social o denominación del titular registrado y del licenciario y sus direcciones;
- b) Identificación de la patente objeto de la licencia e indicación de su registro; y
- c) Plazo, exclusividad, territorio y demás estipulaciones esenciales.

A la solicitud deberá acompañarse una copia del contrato de licencia o un resumen del mismo, firmado por las partes, que contenga la información a que se refiere el párrafo anterior, y el comprobante de pago de la tasa correspondiente. Si el contrato de licencia o el resumen del mismo no hubiere sido otorgado en Guatemala, el documento deberá estar debidamente legalizado y con traducción jurada al español, si fuere el caso.

Si la solicitud cumpliera con lo establecido en esta ley, la licencia se anotará sin más trámite en cada una de las patentes objeto de la misma y el Registro extenderá el certificado correspondiente.

#### Régimen

133. Salvo estipulación en contrario, serán aplicables a las licencias de patente las siguientes normas:

- a) La licencia se extenderá a todos los actos de explotación de la invención, durante toda la vigencia de la patente, en todo el territorio del país y con respecto a cualquier aplicación de la invención;
- b) El licenciario no podrá transferir la licencia ni otorgar sublicencias;
- c) La licencia no será exclusiva, pudiendo el licenciante otorgar otras licencias para la explotación de la patente en el país, así como explotar la patente por sí mismo en el país;
- d) Cuando la licencia se hubiese concedido como exclusiva, el licenciante no podrá otorgar otras licencias para la explotación de la patente en el país, ni podrá explotar la patente por sí mismo en el país; y
- e) El licenciario exclusivo podrá ejercer por sí mismo las acciones legales de protección de la patente, como si fuera el titular de la misma, si la licencia está registrada.

Serán nulas las cláusulas de un contrato de licencia cuando tuvieran el propósito o el efecto de restringir indebidamente la competencia o implicaran un abuso de la patente.

INDONESIA: *Articles 71-73 of the Law on Patents No. 14 of 01/08/2001*

*Article 71*

- (1) A licensing agreement shall not contain any provisions that may directly or indirectly damage the Indonesian economy. or to contain restrictions. which obstruct the ability of the Indonesian people to master and develop technology in general and in connection with the Patented Invention in particular.
- (2) The Directorate General shall refuse any request for registration of a licensing agreement containing provisions as referred to in paragraph (1).

*Article 72*

- (1) A licensing agreement shall be recorded and announced, with the payment of a fee.
- (2) Where a licensing agreement is not recorded at the Directorate General as referred to in paragraph (1). said licensing agreement will not have legal effects on a third party.

*Article 73*

Provisions concerning licensing agreements shall be further regulated by Government Regulation.

IRELAND: *Section 83 of the Patent Act No. 1 of 1992 as last amended by Act no. 31 of 2006*

83. (1) It shall not be lawful to include in any contract in relation to the sale or lease of, or licence to use or work, any product or process which is the subject of a patent application or patent a condition which, directly or indirectly, would-

(a) prevent or restrict a party to the contract from using any product or process, whether or not the subject of a patent application or patent, which in either case is supplied or owned by any person other than a party to the contract or his nominee;

(b) require any such party to acquire from any other such party, or his nominee, any product which is not the subject of a patent application or a patent;

and any such condition, if so included, shall be null and void; provided that this subsection shall not apply if:

(i) the party seeking to rely on the condition proves that at the time the contract was entered into the party which the condition purports to bind had the option of purchasing the relevant product or obtaining a lease or licence in relation thereto on reasonable terms, without the conditions described in paragraphs (a) and (b) of this subsection; and

(ii) the contract entitles the party to the contract which the condition purports to bind to relieve himself of his liability to observe the condition on giving to the other party three months notice in writing and on the payment of compensation for such relief, in the case of a purchase, of such sum, or in the case of a lease or licence, of such rent or royalty for the residue of the term of the contract, as may be fixed by an arbitrator appointed by the Minister.

(2) In any proceedings under this Act no person shall be estopped from applying for or obtaining relief by reason only of any admission made by him as to the reasonableness of the terms offered to him under paragraph (i) of the proviso to subsection (1).

(3) Any contract for or relating to a lease of or a licence to use or work any product or process which, at the time when the contract is made, is the subject of one or more patent applications or one or more patents may, at any time after the patent or all of the patents, as may be appropriate, by which the product or process was protected or the patent or patents, as may be appropriate, resulting from such application or applications, has or have ceased to be in force, be determined by either party to the contract on giving three months notice in writing to the other party to the contract notwithstanding anything to the contrary contained in that or in any other contract.

(4) The inclusion by the proprietor of or applicant for a patent in a contract of any condition which by virtue of this section is null and void shall be available as a defence to an action for infringement of the patent or application to which the contract relates brought while that contract is in force.

(5) Nothing in this section shall-

(a) affect any condition in a contract whereby a person is prohibited from selling any goods other than those of a particular person; or

- (b) be construed as validating any contract which would, apart from this section, be invalid; or
- (c) affect any right of determining a contract or conditions in a contract exercisable independently of this section; or
- (d) affect any condition in a contract for the lease of or licence to use a product which is the subject of a patent application or patent, whereby a party to the contract reserves to himself or his nominees the right to supply such new parts of the product as may be required to put or keep it in repair.

KENYA: *Section 69 of the Industrial Property Act No. 3 of 27/07/2001*

#### Prohibited Terms in Licence Contracts

69. The Managing Director may refuse to register a licence contract if he is of the opinion that any clause in a licence contract imposes unjustified restrictions on the licensee with the consequence that the contract, taken as a whole, is harmful to the economic interests of Kenya, and that the effect of any such term contained in the contract is;

(i) to permit or require the importation of technology from outside Kenya when substantially similar or equivalent technology may be obtained on the same or more favourable conditions, without importation from abroad;

(ii) to require payment of a price, royalty or other consideration which is disproportionate to the value of the technology to which the contract relates;

(iii) to require the licensee to acquire any materials from the licensor or from sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(iv) to prohibit the licensee from acquiring, or to restrict his acquisition of, any materials from any source, unless it is otherwise impossible, for all ' practical purposes, to ensure the quality of the products to be produced;

(v) to prohibit the licensee from using, or to restrict his or her use of any materials which are not supplied by the licensor or by sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(vi) to require the licensee to sell products produced by him under the contract exclusively or principally to persons designated by the licensor;

(vii) to require the licensee to make available to the licensor, without appropriate consideration any improvements made by the licensee with respect to the technology to which the contract relates;

(viii) to limit the volume of the products produced by the licensee with the help of the technology to which the contract relates;

(ix) to restrict or prohibit the export of the products produced by the licensee;

(x) to oblige the licensee to employ persons designated by the transferor not needed for the efficient transfer of the technology to which the contract relates, provided that, for persons so needed, the contract shall provide for training of persons to replace them within a reasonable period;

(xi) to impose restrictions on research or technological development carried out by the licensee to absorb or adapt the technology in connection with new products, processes or equipment;

(xii) to prohibit or restrict the use by the licensee of any technology other than the technology to which the contract relates;

(xiii) to extend the coverage of the contract to technology not required for the use of the technology which is the main subject of the contract and to require consideration for such additional technology;

- (xiv) to fix prices for the sale or resale of the products produced by the licensee with the help of the technology to which the contract relates;
- (xv) to exempt the licensor from any liability consequent upon any defect inherent in the technology to which the contract relates or restrict such liability;
- (xvi) to prohibit or restrict the use by the licensee, after the expiration of the contract, of the technology acquired as a result of the contract, subject, however, to any right of the licensor under the patent;
- (xvii) to require that disputes arising from the interpretation or performance of the contract be governed by a law other than the law of Kenya or that such disputes be brought before courts located in a country other than Kenya;
- (xviii) to establish the duration of the contract for a period which is unreasonably long in relation to the economic function of the contract, provided that any period which does not exceed the duration of the patent to which the contract relates shall not be regarded as unreasonably long;
- (xix) to restrict the licensee from entering into sales, representation or manufacturing agreements relating to similar or competing technologies, when such restrictions are not needed for protecting the legitimate interests of the licensor, including, in particular, protecting the licensor's industrial or intellectual property rights or ensuring that the licensee exercises his best efforts in respect of any manufacturing, distribution or promotional obligations;
- (xx) to prevent the licensee from adapting the technology to local conditions or introducing innovations in it or change to alternative inputs, or which require the licensee to introduce unnecessary designs or specification changes, if the licensee makes adaptations on his own responsibility and without using the licensor's name, trade or service marks or trade names, and except to the extent that this adaptation unsuitably affects those products, or the process for their manufacture, to be supplied by the licensor, his designates, or his other licensees, or to be used as a component or spare part in a product to be supplied to his customer;
- (xxi) to impose acceptance of additional technology, future inventions and improvements, goods or services not wanted by the licensee;
- (xxii) to impose restrictions on territories, quantities, prices, customers or markets arising out of patent pool or cross-licensing agreements or other international technology transfer interchange arrangements which unduly limit access to new technological developments or which would result in an abusing domination of an industry or market with adverse effects on the licensee, except for those restrictions appropriate and ancillary to co-operative arrangements such as co-operative research arrangements;
- (xxiii) to impose restrictions which regulate advertising or publicity by the licensee except where restriction of such publicity may be required to prevent injury to the licensor's goodwill or reputation where the advertising or publicity makes reference to the licensor's name, trade or service marks, trade names or other identifying items;
- (xxiv) to impose confidentiality after the expiry of the licence agreement or to impose unreasonably long periods for secrecy following the commissioning of manufacturing facilities using the licensed technology, or to impose measures which limit technological learning and mastery, except those which relate to industrial property rights;
- (xxv) to impose requirements for payments even under conditions of force majeure;
- (xxvi) to impose restrictions which prevent or hinder export by means of territorial or quantitative limitations or prior approval for export or export prices of products or increase rates of payments for exportable products resulting from the technology licensed;
- (xxvii) to impose quality control methods or standards not needed by licensee, except to meet the requirement of a guarantee or when the product bears a trade mark, service mark or trade name of the licensor;

(xxviii) to allow the licensor to participate permanently in the management of the licensee's business as a condition for obtaining the technology;

(xxix) to restrict the licensee from taking measures that will enhance local technological capability and which are not prejudicial to the licensor's industrial property rights;

(xxx) to restrict the use of local expertise in management and consultancy or in any other positions;

(xxxi) to require payment of royalty for patents granted outside Kenya;

(xxxii) to apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing the licensee at a competitive disadvantage; or

(xxxiii) to make the contract subject to acceptance of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

*NICARAGUA: Article 50 of the Law on Patents, Utility Models and Industrial Designs No. 354 of 19/09/2000 as last amended by Law No. 634 of 13/09/2007*

#### Contractual Licenses

50. The patent owner or applicant may grant a license for the exploitation of the invention, which shall be binding on third parties as from the filing and recording thereof at the Intellectual Property Registry. The request for the recording of a license shall give rise to payment of the prescribed fee.

Unless otherwise provided, the following provisions shall be applicable to patent licenses:

(a) the license shall cover all acts of exploitation of the invention throughout the term of the patent, throughout the territory of the country and for any application of the invention;

(b) the licensee may not transfer the license or grant sublicenses;

(c) the license shall not be exclusive, and the owner of the patent may grant other licenses for the working of the patent within the country, and also work the patent himself;

(d) where the license has been granted with exclusive rights, the licensor may not grant other licenses for the working of the patent or work the patent himself within the country.

The clauses of a license contract shall be null and void where their purpose or effect is to restrict competition unduly or where they constitute abuse of the patent.

*PAKISTAN: Section 37 of the Patent Ordinance No. LXI of 2000 as last amended by Patent Ordinance No. 2(1)/2002*

37. Avoidance of restrictive condition in contracts.-

(1) Subject to the provisions of this section, any condition of a contract for the sale or lease of a patented article or of an article made by a patented process or for license to exploit a patented article or process, or relating to any such sale, lease or license, shall be void so far as it purports-

(a) to require the purchaser, lessee or licensee to acquire from the vendor, lessor or licensor, or his nominees, or prohibit him from acquiring from any specified person, or from acquiring except from the vendor, lessor or licensor, or his nominees, any article other than the patented article or an article made by the patented process; or

(b) to prohibit the purchaser, lessee or licensee from using articles, whether patented or not, which are not supplied by, or any patented process which does not belong to, the vendor, lessor or licensor, or

his nominees, or to restrict the right of the purchaser, lessee or licensee to use any such article or process.

(2) In proceedings against any person for infringement of a patent, it shall be a defence to prove that at the time of the infringement there was in force a contract relating to the patent made by or with the consent of the plaintiff and containing a condition void by virtue of this section.

(3) A condition of a contract shall not be void by virtue of this section if-

(a) at the time of the making of the contract the vendor, lessor or licensor was willing to sell or lease the article, or grant a license to use or exploit the article or process, as the case may be, to the purchaser, lessee or licensee, on reasonable terms specified in the contract and without any such condition as is mentioned in sub-section (1); and

(b) the purchaser, lessee or licensee is entitled under the contract to relieve himself of his liability to observe the condition upon giving to the other party three months notice in writing and subject to payment to him of a just compensation.

PARAGUAY: *Article 36 of the Patents Law No. 1630 of 29/11/2000*

#### *Artículo 36*

De la licencia convencional de patentes. El titular o el solicitante de una patente podrá conceder licencia para la explotación de la invención.

La licencia para la explotación de una invención tendrá efectos legales frente a terceros desde su inscripción en la Dirección de la Propiedad Industrial.

Queda prohibido establecer condiciones o cláusulas comerciales que produzcan un efecto negativo en la competencia, constituyan una competencia desleal, haga posible un abuso por el titular del derecho patentado o de su posición dominante en el mercado, entre ellas las que produzcan:

- a) efectos perjudiciales para el comercio;
- b) condiciones exclusivas de retrocesión;
- c) impedimentos a la impugnación de la validez de las patentes o licencias dependientes;
- d) limitaciones al licenciatarío en el plano comercial o industrial, cuando ello no se derive de los derechos conferidos por la patente; y,
- e) limitaciones a la exportación del producto protegido por la patente hacia los países con los que existiera un acuerdo para establecer una zona de integración económica o comercial.

PHILIPPINES: *Sections 86, 87, 91 and 92 of the Intellectual Property Code, Act No. 8293 of 06/06/1997 as last amended by Act No. 9502 of 2008*

#### Jurisdiction to Settle Disputes on Royalties

86. The Director of the Documentation, Information and Technology Transfer Bureau shall exercise quasi-judicial jurisdiction in the settlement of disputes between parties to a technology transfer arrangement arising from technology transfer payments, including the fixing of appropriate amount or rate of the royalty. (n)

#### Prohibited Clauses

87. Except in cases under Section 91, the following provisions shall be deemed prima facie to have an adverse on competition and trade:

1. Those which impose upon the licensee the obligation to acquire from a specific source capital goods, intermediate products, raw materials, and other technologies, or of permanently employing personnel indicated by the licensor;
2. Those pursuant to which the licensor reserves the right to fix the sale or resale prices of the products manufactured on the basis of the license;
3. Those that contain restrictions regarding the volume and structure of production;
4. Those that prohibit the use of competitive technologies in a non-exclusive technology transfer agreement;

5. Those that establish a full or partial purchase option in favor of the licensor;
6. Those that obligate the licensee to transfer for free to the licensor the inventions or improvements that may be obtained through the use of the licensed technology;
7. Those that require payment of royalties to the owners of patents for patents which are not used;
8. Those that prohibit the licensee to export the licensed product unless justified for the protection of the legitimate interest of the licensor such as exports to countries where exclusive licenses to manufacture and/or distribute the licensed product(s) have already been granted;
9. Those which restrict the use of the technology supplied after the expiration of the technology transfer arrangement, except in cases of early termination of the technology transfer arrangement due to reason(s) attributable to the licensee;
10. Those which require payments for patents and other industrial property rights after their expiration, termination arrangement;
11. Those which require that the technology recipient shall not contest the validity of any of the patents of the technology supplier;
12. Those which restrict the research and development activities of the licensee designed to absorb and adapt the transferred technology to local conditions or to initiate research and development programs in connection with new products, processes or equipment;
13. Those which prevent the licensee from adapting the imported technology to local conditions, or introducing innovation to it, as long as it does not impair the quality standards prescribed by the licensor;
14. Those which exempt the licensor for liability for non-fulfillment of his responsibilities under the technology transfer arrangement and/or liability arising from third party suits brought about by the use of the licensed product or the licensed technology; and
15. Other clauses with equivalent effects. (Sec. 33-C(2), R.A. No. 165a)

#### Exceptional Cases

91. In exceptional or meritorious cases where substantial benefits will accrue to the economy, such as high technology content, increase in foreign exchange earnings, employment generation, regional dispersal of industries and/or substitution with or use of local raw materials, or in the case of Board of Investments, registered companies with pioneer status, exemption from any of the above requirements may be allowed by the Documentation, Information and Technology Transfer Bureau after evaluation thereof on a case-by- case basis. (n)

#### Non-Registration with the Documentation, Information and Technology Transfer Bureau

92. Technology transfer arrangements that conform with the provisions of Sections 86 and 87 need not be registered with the Documentation, Information and Technology Transfer Bureau. Non-conformance with any of the provisions of Sections 87 and 88, however, shall automatically render the technology transfer arrangement unenforceable, unless said technology transfer arrangement is approved and registered with the Documentation, Information and Technology Transfer Bureau under the provisions of Section 91 on exceptional cases. (n)

REPUBLIC OF MOLDOVA: *Article 26 (7) of the Law on the protection of Inventions No. 50-XVI of 07/03/2008*

#### *Article 26*

##### Transfer and Constitution of Rights

- (1) A patent application and a patent may be transferred or give rise to any rights.
- (2) The right to a patent, the right to grant of a patent and the rights deriving from a patent

application or a patent may be transferred in whole or in part.

(3) Rights may be transferred under an assignment contract, contract on exclusive or nonexclusive license, or by hereditary or testamentary succession.

(4) A patent application or a patent possessed by a business may be transferred independently of the transfer of business.

(5) The transfer of a business in its totality shall imply the transfer of a patent application and/or patent except where the applicable legislation provides otherwise or where it is obvious from the circumstances. This provision shall apply to the contractual obligation concerning the transfer of a business.

(6) Under a licensing contract, the patent owner (licensor) shall afford to any other person (licensee) the right to exploit a patent application or a patent, maintaining his right of property in it. Where there is more than one licensee for a patent application or a patent, the licenses may be solely nonexclusive or limited exclusive. The license contract may contain provisions concerning the payment of royalty by the licensee.

(7) Any provisions containing exclusive grant back conditions, conditions containing challenges to validity and coercive package licensing as well as any other conditions limiting fair competition based on professional principles shall not be included in license contracts.

(8) Any transfer of rights under an assignment or license contract must be in writing and signed by the contracting parties except where the transfer is adjudicated by a court decision; otherwise the transfer shall not be registered with the AGEPI.

(9) Without prejudice to the cases referred to in Article 16 or Article 63 paragraph (1), the transfer of rights shall not affect the rights obtained by any third party prior to the date of transfer.

(10) Any transfer or change made by the applicant or patent owner in a patent application or a patent shall be entered, on request of any of the parties, in the National Register of Patent Applications or the National Register of Patents and published in BOPI.

(11) Any transfer of rights in a patent application or a patent shall solely have effect for third parties as from the date of publication in BOPI of the notice of transfer registered with the AGEPI.

*RWANDA: Article 45 of the Law No. 31/2009 of 26/10/2009 on the protection of intellectual property*

#### *Article 45*

Control of anti-competitive practices in contractual licenses

In order to guarantee free and honest practices in the exercise of industrial and commercial activities, the empowered authority shall examine, at the time the license contracts are registered, whether certain practices or conditions limit competition or may have prejudicial effects on trade and hamper the transfer and dissemination of technology.

The empowered authority may adopt appropriate measures to prevent or control license issue practices which may include exclusive reassignment clauses, conditions preventing the dispute of validity and a coercive grouped licenses regime.

The empowered authority shall examine in particular whether the clauses of the contract do not oblige the licensee to pay fees for an invention not used or not patented, or to pay enormous sums in fees, even before the invention is used.

The empowered authority shall examine whether the license contract does not oblige the licensee to import raw materials, intermediate goods or equipment from the licensor, even without the guarantee of quality and profitability of the goods to be produced.

The empowered authority shall verify the clauses of the contract license, the effect of which is to prevent by excessive means the export of the goods made by the licensee, and which authorize the export in return for enormous fees or limit the licensee's competitive opportunities on the domestic and foreign market.

Consequently, the empowered authority may refuse to record a license contract when he decides that the contract concerning the right in question contains one or more clauses that are abusive, or anti-competitive or in any manner restrain trade, or limit access to technology or are likely to have any of those effects. The empowered authority shall hear the allegations of the parties to the contract, if one or both so request. Those allegations shall take into account evidence that is pertinent. Any decision to refuse to record the contract may be subject to appeal to the appeal committee provided by this Law within a period of thirty (30) days from the date on which the owner was notified the empowered authority's decision.

Where the appellant is not satisfied by the appealing committee's decision, he may appeal to the competent tribunal within a period of thirty (30) days from the date on which he was notified the appealing committee's decision.

For the purposes of the provisions of this article, any limitations imposed on the licensee that do not derive from the rights conferred by the registration of the licensed right, and that are not necessary for the safeguard of that right shall be deemed abusive or, in the event that they have anti-competitive effects, anti-competitive.

*SAINT LUCIA: Section 47 of the Patents Act No. 16 of 27/08/2001*

*Avoidance of certain restrictive conditions*

47.- (1) Subject to this section, any condition or term of a contract for the supply of a patented product or of a licence to work a patented invention, or of a contract relating to any such supply or licence, shall be void in so far as it purports —

(a) in the case of a contract for supply, to require the person supplied to acquire from the supplier, or his or her nominee, or prohibit him or her from acquiring from any specified person, or from acquiring except from the supplier or his or her nominee, anything other than the patented product;

(b) in the case of a licence to work a patented invention, to require the licensee to acquire from the licensor or his or her nominee, or prohibit him or her from acquiring from any specified person, or from acquiring except from the licensor or his or her nominee, anything other than the product which is the patented invention or, if it is a process, other than any product obtained directly by means of the process or to which the process has been applied;

(c) in either case, to prohibit the person supplied or the licensee from using articles, whether patented products or not, which are not supplied by, or any patented process which does not belong to, the supplier or licensor, or his or her nominee, or to restrict the right of the person supplied or the licensee to use any such articles or process.

(2) In proceedings against any person for infringement of a patent, it shall be a defence to prove that at the time of the infringement there was in force a contract relating to the patent made by or with the consent of the plaintiff or a licence under the patent granted by the plaintiff or with his or her consent and containing in either case a condition or term void by virtue of this section.

(3) A condition or term of a contract or licence shall not be void by virtue of this section if:

(a) at the time of the making of the contract or granting of the licence, the supplier or licensor was willing to supply the product, or grant a licence to work the invention, as the case may be, to the person supplied or the licensee, on reasonable terms specified in the contract or licence and without any such condition or term as is mentioned in subsection (1); and

(b) the person supplied or the licensee is entitled under the contract or licence to relieve himself or herself of his or her liability to observe the condition or term on giving to the other party three months notice in writing, and subject to payment to that other party of such compensation, being, in the case of a contract to supply, a lump sum or rent for the residue of the term of the contract and, in the case of a licence, a royalty for the residue of the term of the licence, as may be determined by an arbitrator appointed by the Minister.

(4) If in any proceedings it is alleged that any condition or term of a contract or licence is void by virtue of this section, it shall lie on the supplier or licensor to prove the matters set out in subsection (3) (a).

(5) A condition or term of a contract or licence shall not be void by virtue of this section by reason only that it prohibits any person from selling goods other than those supplied by a specific person or, in the case of a contract for the hiring of or licence to use a patented product, that it reserves to the bailor or licensor, or his or her nominee, the right to supply such new parts of the patented product as may be required to put or keep it in repair.

*SAUDI ARABIA: Article 22 of the Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs of 2004*

*Article Twenty Two*

The Directorate may instruct the parties to the license contract to amend it in order to prevent abusing the right in the protection document or any other negative effect on competition or the acquisition of technology and its dissemination.

SINGAPORE: *Section 51 of the Patents Act No. 21 of 25/11/1994 as of 01/12/2008*

Avoidance of certain restrictive conditions

51.-(1) Subject to this section, any condition or term of a contract for the supply of a patented product or of a licence to work a patented invention, or of a contract relating to any such supply or licence, shall be void in so far as it purports

(a) in the case of a contract for supply, to require the person supplied to acquire from the supplier, or his nominee, or prohibit him from acquiring from any specified person, or from acquiring except from the supplier or his nominee, anything other than the patented product;

(b) in the case of a licence to work a patented invention, to require the licensee to acquire from the licensor or his nominee, or prohibit him from acquiring from any specified person, or from acquiring except from the licensor or his nominee, anything other than the product which is the patented invention or (if it is a process) other than any product obtained directly by means of the process or to which the process has been applied; or

(c) in either case, to prohibit the person supplied or the licensee from using articles (whether patented products or not) which are not supplied by, or any patented process which does not belong to, the supplier or licensor, or his nominee, or to restrict the right of the person supplied or the licensee to use any such articles or process.

(2) In proceedings against any person for infringement of a patent, it shall be a defence to prove that at the time of the infringement there was in force a contract relating to the patent made by or with the consent of the plaintiff or a licence under the patent granted by him or with his consent and containing in either case a condition or term void by virtue of this section.

(3) A condition or term of a contract or licence shall not be void by virtue of this section if:

(a) at the time of the making of the contract or granting of the licence, the supplier or licensor was willing to supply the product, or grant a licence to work the invention, as the case may be, to the person supplied or the licensee, on reasonable terms specified in the contract or licence and without any such condition or term as is mentioned in subsection (1); and

(b) the person supplied or the licensee is entitled under the contract or licence to relieve himself of his liability to observe the condition or term on giving to the other party 3 months' notice in writing, and subject to payment to that other party of such compensation (being, in the case of a contract to supply, a lump sum or rent for the residue of the term of the contract and, in the case of a licence, a royalty for the residue of the term of the licence) as may be determined by an arbitrator appointed by the Minister.

(4) If in any proceedings it is alleged that any condition or term of a contract or licence is void by virtue of this section, it shall lie on the supplier or licensor to prove the matters set out in subsection (3) (a).

(5) A condition or term of a contract or licence shall not be void by virtue of this section by reason only that it prohibits any person from selling goods other than those supplied by a specific person or, in the case of a contract for the hiring of or licence to use a patented product, that it reserves to the bailor or licensor, or his nominee, the right to supply such new parts of the patented product as may be required to put or keep it in repair.

SOUTH AFRICA: *Section 90 of the Intellectual Property Law, Act No. 57 of 1978*

90. Certain conditions excluded from contracts.

(1) Any condition in a contract relating to the sale of a patented article or to a licence under a patent of which the effect will be

(a) to prohibit or restrict the purchaser or licensee from purchasing or using any article or class of articles, whether patented or not, supplied or owned by any person other than the seller or licensor or his nominee;

(b) to prohibit or restrict the licensee from using any article or process not protected by the patent;

(c) to require the purchaser or licensee to acquire from the seller, licensor or his nominee any article or class of articles not protected by the patent;

(d) to require or induce the purchaser to observe a specified minimum resale price in respect of any article or class of articles protected by the patent; or

(e) to prohibit or restrict the making, using, exercising or disposing of the invention concerned in any country in which the invention is not patented,

shall be null and void.

(2) Nothing in this section shall

- (a) affect any condition in a contract whereby a person is prohibited from selling any goods other than those of a particular person; or
- (b) affect any condition in a contract for the lease of or a licence to use a patented article, whereby the lessor or licensor reserves to himself or his nominee the right to supply such new parts of the patented article, other than ordinary articles of commerce, as may be required to put or keep it in repair.

*SRI LANKA: Section 94 of the Intellectual Property Act No. 36 of 2003*

Invalid clauses in licence contracts

94. Any term or condition in a licence contract shall be null and void in so far as it imposes upon the licensee, in the industrial or commercial field, restrictions not derived from the rights conferred by this Part on the owner of the patent, or unnecessary for the safeguarding of such rights :

Provided that

- (a) restrictions concerning the scope, extent or duration of exploitation of the patented invention, or the geographical area in or the quality or quantity of the products in connection with, which the patented invention may be exploited ; and
- (b) obligations imposed upon the licensee to abstain from all acts capable of prejudicing the validity of the patent, shall not be deemed to constitute such restrictions.

*THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA: Articles 272 and 273 of the Law on Industrial Property No. 07-1006/1 of 12/02/2009*

License agreement

*Article 272*

- (1) The applicant of an industrial property right and the holder of the right may, by licence agreement, assign that right under the stipulations provided for in this Law or other regulations.
- (2) The licence agreement must be composed in writing.
- (3) If more persons have submitted a patent application or if the patent holders are more entities, the consent of all these persons shall be necessary for concluding the licence agreement
- (4) If there is no consent for concluding a licence agreement referred to in paragraph (3) of this Article, the rules of property shall apply for assigning the right to usage.
- (5) The licence agreement which is not composed in writing shall not provide legal effect.
- (6) The licence agreement on request of one of the contracting parties shall be registered in an appropriate register kept in the Office.
- (7) The licence agreement not registered in the appropriate register of the Office shall not provide effect against third parties.

Void license agreement

*Article 273*

Each provision of the licence agreement that sets limitations to the licence user which do not result from the right being subject of the agreement or which is not necessary for keeping that right, or if it is contrary to the regulations for limiting the competition shall be void.

*UGANDA: Sections 39 and 40 of the Patents Act of 15/10/1993*

39. Prohibited terms in licence contracts.

- (1) The registrar shall examine the contract to ascertain whether it contains terms which impose unjustified restrictions on the licensee and whether, as a consequence, the contract taken as a whole, is harmful to the economic interests of Uganda, and he or she may refuse to register the licence contract if after taking into consideration, in such examination, in particular, any term contained in the contract he or she is satisfied that the effect of that term would be—
  - (a) to permit or require the importation of technology from abroad when substantially similar or equivalent technology may be obtained on the same or more favourable conditions without importation from abroad;
  - (b) to require payment of a price, royalty or other consideration which is disproportionate to the value of the technology to which the contract relates;

- (c) to require the licensee to acquire any materials from the licensor or from the sources designated or approved by him or her, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;
  - (d) to prohibit the licensee from acquiring, or to restrict his or her acquisition of, any materials from any source, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;
  - (e) to prohibit the licensee from using, or to restrict his or her use of, any materials which are not supplied by the licensor or by sources designated or approved by him or her, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;
  - (f) to require the licensee to sell products produced by him or her under the contract exclusively or principally to persons designated by the licensor;
  - (g) to require the licensee to make available to the licensor without appropriate consideration any improvements made by the licensee with respect to the technology to which the contract relates;
  - (h) to limit the volume of the products produced by the licensee with the help of the technology to which the contract relates;
  - (i) to prohibit or restrict the export of the products produced by the licensee;
  - (j) to require the licensee to employ on a permanent basis persons designated by the licensor;
  - (k) to impose restrictions on research or technological development carried out by the licensee;
  - (l) to prohibit or restrict the use by the licensee of any technology other than the technology to which the contract relates;
  - (m) to extend the coverage of the contract to technology not required for the use of the main subject of the contract and to require consideration for such additional technology;
  - (n) to fix prices for the sale or resale of the products produced by the licensee with the help of the technology to which the contract relates;
  - (o) to exempt the licensor from any liability consequent upon any defect inherent in the technology to which the contract relates or to restrict the liability;
  - (p) to prohibit or restrict the use by the licensee, after the expiration of the contract, of technology acquired as a result of the contract, subject, however, to any right of the licensor under the patent;
  - (q) to require that disputes arising from the interpretation or performance of the contract be governed by a law other than the laws applicable in Uganda or that those disputes be brought before courts outside the territory of Uganda;
  - (r) to establish the duration of the contract for a period which is unreasonably long in relation to the economic function of the contract, so however that any period which does not exceed the duration of the patent to which the contract relates shall not be regarded as unreasonably long.
- (2) Where the registrar is of the opinion that the contract contains one or more terms which impose unjustified restrictions on the licensee and that, as a consequence, the contract, taken as a whole, is harmful to the economic interests of Uganda, he or she shall notify the petitioners accordingly and invite them to modify the contract so that it does not contain any such term.

#### 40. Registration and certificates.

- (1) If the registrar finds the licence contract in order, he or she shall register the contract and issue a certificate of registration to the petitioners.
- (2) The certificate of registration shall state:
  - (a) the names of the parties to the contract;
  - (b) the date of the petition;
  - (c) the date of registration; and
  - (d) the registration number.
- (3) All the particulars specified in subsection (2)(a), (b) and (c) shall be published by the registrar in the Gazette.

#### UNITED ARAB EMIRATES: *Article 59 of the Federal Law No (31) of 2006 pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs*

##### *Article ( 59 )*

Licensing agreements, assignments, or transfer of the right of the subject under protection, with any amendments or validation made thereon shall all be subject to supervision of the administration in respect to conditions, securities, and rights being afforded by the deeds of protection. The administration may request the competent parties to amend those agreements involving misuse of an

intellectual property right or conflicting with the trade competition associated with the said agreement in the State.

Should the agreement not be amended, the administration shall then have the right to deny approval and registration of the agreement in the record as provided for in the implementing regulations of this law.

UNITED REPUBLIC OF TANZANIA: *Sections 47 and 48 of the Patents Act No. 1 of 20/01/1987*

Petition for registration

47.-(1) All licence contracts, including modifications thereof, shall be submitted to the Registrar for registration in the patent register.

(2) A petition for registration may be made by any party to the contract.

(3) The petition shall be accompanied by the documents prescribed by the Regulations.

(4) The petition shall be subject to the payment of a prescribed fee.

(5) The Registrar shall issue to the applicant a receipt, which shall be proof of the fact of filing the petition and of the date on which it was filed; if no receipt is issued within 14 days from the date of the petition, the petitioner may rely on other evidence to prove the said fact and date,

(6) Where-

(i) section 46 or subsections (2) to (4) of this section, and the rules relating thereto, have not been complied with, or

(ii) the licence contract is unregistrable under section 48, the Registrar shall refuse to register the licence contract, stating the reasons for such refusal-

(7) Before he refuses to register the licence contract, the Registrar shall notify the petitioner and allow the parties-

(i) to submit any observations;

(ii) to correct any defect in the petition;

(iii) to amend any term, or to correct any defect, in the licence contract that has been declared by the Registrar to be a term or defect precluding registration, within 45 days from the date of the notification referred to herein.

(8) A licence contract shall be void if the registration has been refused by the Registrar in accordance with the provisions of this Act.

Prohibited terms in licence contracts

48. The Registrar may, with the approved of and after consultation with other competent government authorities' refuse to register a licence contract if the effect of its terms is-

(a) to permit or require the importation of technology from abroad when substantially similar or equivalent technology may be obtained on the same or more favourable conditions without importation from abroad;

(b) to require payment of a price, royalty or other consideration which is disproportionate to the value of the technology to which the contract relates;

(c) to require the licensee to acquire any materials from the licensor or from sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(d) to prohibit the licensee from acquiring, or to restrict his acquisition of, any materials from any source, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(e) to prohibit the licensee from using, or to restrict his use of, any materials which are not supplied by the licensor or by sources designated or approved by him, unless it is otherwise impossible, for all practical purposes, to ensure the quality of the products to be produced;

(f) to require the licensee to sell products produced by him under the contract exclusively or principally to persons designated by the licensor;

(g) to require the licensee to make available to the licensor without appropriate consideration any improvements made by the licensee with respect to the technology to which the contract relates;

(h) to limit the volume of the products produced by the licensee with the help of the technology to which the contract relates;

(i) to prohibit or restrict the export of the products produced by the licensee;

(j) to require the licensee, to employ on permanent basis persons designated by the licensor;

(k) to impose restrictions on research or technological development carried out by the licensee;

- (l) to prohibit or restrict the use by the licensee of any technology other than the technology to which the contract relates;
- (m) to extend the coverage of the contract to technology not required for the use of the technology which is the main subject of the contract and to require consideration for such additional technology;
- (n) to fix prices for the sale or resale of the products produced by the licensee with the help of the technology to which the contract relates;
- (o) to exempt the licensor from any liability consequent upon any defect inherent in the technology to which the contract relates or to restrict such liability;
- (p) to prohibit or restrict the use by the licensee, after the expiration of the contract, of the technology acquired as a result of the contract, subject, however, to any right of the licensor under the patent;
- (q) to require the disputes arising from the interpretation or performance of the contract be governed by a law other than the law of the United Republic or that such disputes be brought before courts located in the United Republic other than the country;
- (r) to establish the duration of the contract for a period which is unreasonably long in relation to the economic function of the contract, provides that any period which does not exceed the duration of the patent to which the contract relates shall not be regarded as unreasonably long.

URUGUAY: *Article 52 of the Law No. 17.164 Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs No. 1.827\*R of 02/09/1999*

52. Contractual licenses may not contain clauses or terms that have an adverse impact on competition, constitute unfair competition, lead to possible abuse by the owner of the patented right or of his dominant position on the market.

In particular, clauses or terms that have the following effects shall not be included:

- (a) cause a prejudicial impact on trade;
- (b) impose exclusive grant back conditions;
- (c) prevent contestation of the validity of dependent patents or licenses;
- (d) place restrictions on the licensee at the commercial or industrial levels when they are not derived from the rights conferred by the patent;
- (e) place restrictions on exporting the product protected by the patent to countries with which there is an agreement on establishing an economic and trade integration area.

UNITED KINGDOM: *Section 50 A. of the Patents Act of 1977, consolidated version of 01/01/2010*

Powers exercisable following merger and market investigations

50A.-(1) Subsection (2) below applies where

- (a) section 41(2), 55(2), 66(6), 75(2), 83(2), 138(2), 147(2) or 160(2) of, or paragraph 5(2) or 10(2) of Schedule 7 to, the Enterprise Act 2002 (powers to take remedial action following merger or market investigations) applies;
  - (b) the Competition Commission or (as the case may be) the Secretary of State considers that it would be appropriate to make an application under this section for the purpose of remedying, mitigating or preventing a matter which cannot be dealt with under the enactment concerned; and
  - (c) the matter concerned involves
    - (i) conditions in licences granted under a patent by its proprietor restricting the use of the invention by the licensee or the right of the proprietor to grant other licences; or
    - (ii) a refusal by the proprietor of a patent to grant licences on reasonable terms.
- (2) The Competition Commission or (as the case may be) the Secretary of State may apply to the comptroller to take action under this section.
- (3) Before making an application the Competition Commission or (as the case may be) the Secretary of State shall publish, in such manner as it or he thinks appropriate, a notice describing the nature of the proposed application and shall consider any

representations which may be made within 30 days of such publication by persons whose interests appear to it or him to be affected.

(4) The comptroller may, if it appears to him on an application under this section that the application is made in accordance with this section, by order cancel or modify any condition concerned of the kind mentioned in subsection (1)(c)(i) above or may, instead or in addition, make an entry in the register to the effect that licences under the patent are to be available as of right.

(5) References in this section to the Competition Commission shall, in cases where section 75(2) of the Enterprise Act 2002 applies, be read as references to the Office of Fair Trading.

(6) References in section 35, 36, 47, 63, 134 or 141 of the Enterprise Act 2002 (questions to be decided by the Competition Commission in its reports) to taking action under section 41(2), 55, 66, 138 or 147 shall include references to taking action under subsection (2) above.

(7) Action taken by virtue of subsection (4) above in consequence of an application under subsection (2) above where an enactment mentioned in subsection (1)(a) above applies shall be treated, for the purposes of sections 91(3), 92(1)(a), 162(1) and 166(3) of the Enterprise Act 2002 (duties to register and keep under review enforcement orders etc.), as if it were the making of an enforcement order (within the meaning of the Part concerned) under the relevant power in Part 3 or (as the case may be) 4 of that Act.

*VIET NAM: Article 144 of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005 as last amended by Order No. 12/2009/L-CTN of 29/06/2009*

*Article 144*

Contents of industrial property object license contracts

1. An industrial property object license contract must have the following principal contents:

- a/ Full names and addresses of the licensor and the licensee;
- b/ Licensing bases;
- c/ Contract type;
- d/ Licensing scope of, covering limitations on use right and territorial limitations;
- e/ Contract term;
- f/ Licensing price;
- g/ Rights and obligations of the licensor and the licensee.

2. An industrial property object license contract must not have provisions which unreasonably restrict the right of the licensee, particularly the following provisions which do not derive from the rights of the licensor:

- a/ Prohibiting the licensee to improve the industrial property object other than marks; compelling the licensee to transfer free of charge to the licensor improvements of the industrial property object made by the licensee or the right of industrial property registration or industrial property rights to such improvements;
- b/ Directly or indirectly restricting the licensee to export goods produced or services provided under the industrial property object license contract to the territories where the licensor neither holds the respective industrial property rights nor has the exclusive right to import such goods;
- c/ Compelling the licensee to buy all or a certain percentage of raw materials, components or equipment from the licensor or a third party designated by the licensor not for the purpose of ensuring the quality of goods produced or services provided by the licensee;
- d/ Forbidding the licensee to complain about or initiate lawsuits with regard to the validity of the industrial property rights or the licensor's right to license.

3. Any clauses in the contract falling into the cases specified in Clause 2 of this Article shall be ex-officio invalid.

*ZAMBIA: Section 49 of the Patent Act of 1958(Chapter 400) as last amended by Act No. 26 of 28/12/1987*

Avoidance of certain restrictive conditions in contracts

49. (1) It shall not be lawful in any contract made after the commencement of this Act in relation to the sale or lease of or a licence to use or work any article or process protected by a patent to insert a condition the effect of which will be-

(a) to prohibit or restrict the purchaser, lessee or licensee from using any article or class of articles, whether patented or not, or any patented process, supplied or owned by any person other than the seller, lessor or licensor or his nominee; or

(b) to require the purchaser, lessee or licensee to acquire from the seller, lessor or licensor or his nominee any article or class of articles not protected by the patent; and any such condition shall be null and void, as being in restraint of trade and contrary to public policy:

Provided that this subsection shall not apply if-

(i) the seller, lessor or licensor proves that at the time the contract was entered into, the purchaser, lessee or licensee had the option of purchasing the article or obtaining a lease or licence on reasonable terms without such conditions as aforesaid; and

(ii) the contract entitles the purchaser, lessee or licensee to relieve himself of his liability to observe any such condition on giving the other party three months' notice in writing and on payment, if the Registrar so directs, of compensation for such relief, in the case of a purchase of such sum, or in case of a lease or licence of such rent or royalty for the residue of the term of the contract, as may be fixed by the Registrar.

An appeal shall lie from any decision of the Registrar under proviso (ii).

(2) Any contract relating to the lease of or licence to use or work any patented article or patented process may, at any time after the patent or all the patents by which the article or process was protected in Zambia at the time of the making of the contract has or have ceased to be in force, and notwithstanding anything to the contrary in the same or in any other contract, be determined by either party on giving three months' notice in writing to the other party.

(3) Nothing in this section shall-

(a) affect any condition in a contract whereby any person is prohibited from selling any goods other than those of a particular person;

(b) be construed as validating any contract which would, apart from this section, be invalid;

(c) affect any right of determining a contract or condition in a contract exercisable independently of this section;

(d) affect any condition in a contract for the lease of or a licence to use a patented article, whereby the lessor or licensor reserves to himself or his nominee the right to supply such new parts of the patented article as may be required to put or keep it in repair.

ZIMBABWE: *Section 44 of the Patent Act (Chapter 26:03) No. 26 of 1971 as last amended by Act 20/1994 (S.7)*

Avoidance of certain restrictive conditions in contracts

44.-(1) Subject to subsection (2), it shall not be lawful in any contract made after the appointed day in relation to the sale or lease of or a licence to use or work any article or process protected by a patent to insert a condition the effect of which will be:

(a) to prohibit or restrict the purchaser, lessee or licensee from using any article or class of articles, whether patented or not, or any patented process supplied or owned by any person other than the seller, lessor or licensor or his nominee; or

(b) to require the purchaser, lessee or licensee to acquire from the seller, lessor or licensor or his nominee any article or class of articles not protected by the patent;

and any such condition shall be null and void, as being in restraint of trade and contrary to public policy.

(2) Subsection (1) shall not apply if

(a) the seller, lessor or licensor proves that at the time the contract was entered into the purchaser, lessee or licensee had the option of purchasing the article or obtaining a lease or licence on reasonable terms without the conditions referred to in subsection (1); and

(b) the contract entitles the purchaser, lessee or licensee to relieve himself of his liability to observe any such condition on giving the other party three months' notice in writing and on payment, if the

Patents Tribunal so directs, of compensation for such relief, in the case of a purchase of such sum, or in case of a lease or licence of such rent or royalty, for the residue of the term of the contract, as may be fixed by the Patents Tribunal.

(3) Any contract relating to the lease of or licence to use or work any patented article or patented process may, at any time after the patent or all the patents by which the article or process was protected in Zimbabwe at the time of the making of the contract has or have ceased to be in force, and notwithstanding anything to the contrary in the same or in any other contract, be determined by either party on giving three months' notice in writing to the other party.

(4) Nothing in this section shall

(a) affect any condition in a contract whereby any person is prohibited from selling any goods other than those of a particular person;

(b) be construed as validating any contract which would, apart from this section, be invalid;

(c) affect any right of determining a contract or condition in a contract exercisable independently of this section;

(d) affect any condition in a contract for the lease of or a licence to use a patented article whereby the lessor or licensor reserves to himself or his nominee the right to supply such new parts of the patented article as may be required to put or keep it in repair.

*ANDEAN COMMUNITY: Article 58 of the decision No. 486 of 14/09/2000 of the Commission of the Andean Community- Common Industrial Property Regime*

58. The competent national authority shall not register license contracts for the working of patents that do not conform to the Common Provisions on the Treatment of Foreign Capital and on Trademarks, Patents, Licenses and Royalties, or do not conform to Community or national provisions on business practices that restrict free competition.

*OAPI: Articles 37 and 38 of the Bangui Agreement of 02/03/1977, as revised on 24/02/1999*

*Article 37*

Invalid Clauses

(1) Clauses in license contracts or relating to such contracts shall be invalid in so far as they impose on the licensee, in the industrial or commercial sphere, restrictions not deriving from the rights conferred by the patent or not necessary for the upholding of such rights.

(2) The following shall not be considered restrictions within the meaning of paragraph (1) above:

(i) limitations relating to the extent, the scope or the duration of exploitation of the patented invention;

(ii) the obligation on the licensee to abstain from any act liable to harm the validity of the patent.

(3) In the absence of provisions to the contrary in the license contract, the license shall not be assignable to third parties and the licensee shall not be authorized to grant sublicenses.

*Article 38*

Recognition of Invalid Clauses

Recognition of the invalid clauses referred to in Article 37 above shall be done by the civil court at the request of any interested party.

[Annex II follows]