

ANNEX I

PROVISION OF LAW

(1) PROVISIONS OF LAW ON COMPULSORY LICENSING

ALBANIA : *Articles 50 and 51 of the Law on Industrial Property No. 9977 of 07/07/2008*

Article 50 - Compulsory Licenses

1. On request, the court is entitled to grant a compulsory license to any Person who can demonstrate the capability to exploit the invention which is the subject-matter of the granted patent in the Republic of Albania when he meets all the requirements defined in the implementing regulation of this Law, provided that:

- a) four years have expired from the filing of the application and three years have expired from the grant of the patent;
- b) the patent owner has not exploited the patent on reasonable terms or has not made effective and serious preparations to do so, unless he provides legitimate reasons to justify his inaction.
- c) the Person requesting the compulsory license has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions, and if such efforts have not been successful within a reasonable period of time.

2. On request, the court is entitled to grant a compulsory license in respect of a first patent to the owner of a subsequent patent who cannot use his patent without infringing the first patent, provided that the invention in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. In the case of a compulsory license in respect of a dependent patent, the owner of the first patent shall be entitled to use the subsequent patented invention on reasonable terms.

3. On request, the court is entitled to grant a compulsory license in respect of patents and supplementary protection certificates relating to the manufacture and sell of pharmaceutical products, when such products are intended for export to importing countries in need of such products in order to address public health problems, subject to the implementing regulation.

4. The type of use covered and the conditions to be met shall be specified by the court. The following conditions shall apply:

- a) The scope and duration of the exploitation shall be limited to the purpose for which it was authorized;
- b) The exploitation shall be non-exclusive;
- c) The exploitation shall be non-assignable. In the case of a compulsory license in respect of a dependent patent, the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.
- d) The amount of products manufactured under the license shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of products manufactured under other compulsory licenses granted elsewhere.

5. The exploitation shall be authorized, above all, to supply the market of the Republic of Albania, except in the case provided in paragraph 3 of this article.
6. A compulsory license shall be valid until the end of the time period designated by the court or until the end of the term of the patent. However, the court may, on reasoned request, decide to cancel the authorization, subject to adequate protection of the legitimate interests of the Persons so authorized, if and when the circumstances which led to it cease to exist and are unlikely to recur.
7. Compulsory licenses shall be registered in the patent register.
8. The owner of the patent shall be entitled to adequate compensation for a compulsory license, taking into account the economic value of the authorization. When the parties do not agree, the amount of this compensation shall be set by the court.
9. The holder of a compulsory license may renounce at it at any time. If the holder does not begin exploitation within one year from the final grant of the compulsory license, the owner of the patent may claim for the compulsory license to be modified or annulled.
10. The requirements of paragraphs 1(c) and 5 of this article shall not be applicable when such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account of in determining the amount of remuneration in such cases. The court shall have the authority to refuse termination of an authorization if the conditions that led to such authorization are likely to recur.

Article 51

Exploitation by the Government or Third Parties Authorized by the Government

1. When the interests of essential defense or national security require it, the Minister of Defense or the Minister of Health may, even without the approval of the owner of the patent or the applicant, by a notification in the GDPT Gazette, authorize a governmental agency or a specific Person to make, use or sell the invention for which the patent application was submitted, or the patent was granted, subject to payment of equitable remuneration to the owner of the patent or to the patent applicant. The owner of the patent or the patent applicant shall be notified as soon as possible.
2. An appeal to the court can be taken against the decision of the Minister of Defense or the Minister of Health.

ALGERIA : Articles 38 and 47-49 of the Ordinance No. 03-07 of 19/07/2003 - 1424

38. Toute personne peut, à tout moment après l'expiration d'un délai de quatre (4) années à compter de la date de dépôt de la demande d'un brevet ou de trois (3) années à compter de la date de délivrance du brevet d'invention, obtenir auprès du service compétent, une licence d'exploitation pour cause de défaut ou d'insuffisance d'exploitation.
Pour l'appréciation du délai cité à l'alinéa ci-dessus, le service compétent appliquera celui qui expire le plus tard.
La licence obligatoire ne peut être accordée par le service compétent, qu'après vérification de la réalité du défaut ou de l'insuffisance d'exploitation et s'il n'existe pas de circonstances qui justifient ce défaut ou cette insuffisance d'exploitation de l'invention brevetée.

47. Si une invention protégée par un brevet d'invention ne peut être exploitée sans qu'il soit porté atteinte aux droits découlant d'un brevet d'invention antérieur, il peut être accordé, sur demande, une licence obligatoire au titulaire du brevet d'invention ultérieur.

Une telle licence sera accordée dans la mesure nécessaire à l'exploitation de l'invention, pour autant que celle-ci présente un progrès technique notable et soit d'un intérêt économique important, par rapport à l'invention objet du brevet antérieur.

Le titulaire du brevet antérieur a droit à une licence réciproque, à des conditions raisonnables, pour utiliser l'invention objet du brevet ultérieur.

48. La licence obligatoire visée à l'article 38 ci-dessus sera non exclusive et aura principalement pour objet l'approvisionnement du marché national.

49. Une licence obligatoire peut être accordée à tout moment par le ministre chargé de la propriété industrielle à un service de l'État ou à un tiers désigné par le ministre, pour une demande de brevet ou pour un brevet d'invention, dans l'un des cas suivants :

- 1) Lorsque l'intérêt public, en particulier la sécurité nationale, la nutrition, la santé ou le développement d'autres secteurs de l'économie nationale l'exige, et notamment lorsque la fixation, pour les produits pharmaceutiques brevetés, de prix excessifs ou discriminatoires par rapport aux prix moyens du marché;
- 2) Lorsqu'un organe judiciaire ou administratif juge que la manière dont le titulaire du brevet ou son preneur de licence exploite l'invention est anticoncurrentielle et lorsque le ministre chargé de la propriété industrielle est convaincu que l'exploitation de l'invention en application du présent alinéa, permettra de remédier à cette pratique.

ANDORRA : *Article 34 of the Patent Act of 10/06/1999*

Article 34 - Compulsory licenses

(1) Any person who proves his ability to work the patented invention in Andorra, after the expiration of a period of four years from the filing date of the application or three years from the grant of the patent, whichever is later, may institute legal proceedings in front of the Civil Court to request a the grant of a compulsory license to exploit the patented invention if it is not worked or is insufficiently worked in Andorra .

(2) The scope and duration of any compulsory license shall be limited to the purpose for which it is granted, and such license shall be

- (a) non-exclusive,
- (b) non-assignable, except with that part of the enterprise or goodwill which enjoys such authorization,
- (c) granted exclusively for the supply of the domestic market.

(3) The grant of a compulsory license shall be subject to the payment of adequate remuneration to the proprietor of the patent. Such license may only be granted if, prior, the person requesting it has made efforts to obtain authorization from the proprietor on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

(4) A compulsory license shall not be granted if the Judicial Authority determines that circumstances exist which justify the non-working or insufficient working of the patented invention in Andorra, and in particular if the product covered by the patent is put on the market in Andorra in sufficient quantity to satisfy the needs in Andorra.

ANTIGUA AND BARBUDA : *Sections 13-14 of the Patent Act No. 23 of 2003*

13. Exploitation by Government or person thereby authorized

(1) Where:

(a) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, or

(b) the Registrar has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice,

(c) The Minister may decide that, even without the agreement of the owner of the patent, a Government

agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the patented invention shall be limited to the purposes for which it was authorized and shall be subject to the payment to the owner of an adequate remuneration therefor,

taking into account the economic value of the Minister's authorization, as determined in the decision, and, where a decision has been taken under paragraph (b) of subsection (1), the need to correct anti-competitive practices.

(3) A request for the Minister's authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(4) Subsection (3) shall not apply in cases of:

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable;

(b) public non-commercial use, and

(c) anti-competitive practices determined as such by a judicial or administrative body in accordance with subsection (1) b).

(3) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anticompetitive and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy such practice.

(4) The authorization shall not exclude:

(a) the conclusion of licence contracts by the owner of the patent; or

(b) the continued exercise, by the owner of the patent, of his rights under section 11(2);

or

(c) the issuance of a non-voluntary licence under section 14.

- (5) Where a third person has been designated by the Minister, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.
- (6) The exploitation of the invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market in Antigua and Barbuda.
- (7) Upon request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.
- (8) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.
- (9) Notwithstanding subsection (10), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.
- (10) The decisions of the Minister under subsections (1) to (11) may be the subject of an appeal before the High Court.

14. Non-Voluntary Licences.

- (1) On request, made to the Registrar after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Registrar may issue a non-voluntary licence if he is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importation, in Antigua and Barbuda.
- (2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Registrar that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Antigua and Barbuda.
- (3) The decision issuing the non-voluntary licence shall fix
- (a) the scope and function of the licence,
 - (b) the time limit within which the licensee must begin to exploit the patented invention,
- and
- (c) the amount of the remuneration to be paid to the owner of the patent and the conditions of payment.
- (4) The beneficiary of the non-voluntary licence shall have the right to exploit the patented invention in Antigua and Barbuda according to the terms set out in the decision issuing the licence, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention sufficiently.

(5) If the invention claimed in a patent (“later patent”) cannot be exploited in the country without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date (“earlier patent”), and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Registrar, upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is issued under subsection (9), the Registrar, upon the request of the owner of the earlier patent, shall issue a non-voluntary licence in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary licence under subsections (5) and (6), subsection (2) shall apply mutatis mutandis with the proviso that no time limit needs to be fixed.

(8) In the case of a non-voluntary-licence issued under subsection (9), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary licence shall be subject to payment of the prescribed fee.

(10) Section 13 (2) to (10) shall apply mutatis mutandis.

ARGENTINA : *Articles 42- 47 of the Patents Act No. 24.481 of 1996 as amended by Law 24.572 T.O. 1996 - B.O. 22/3/96*

Artículo 42 - Cuando un potencial usuario haya intentado obtener la concesión de una licencia del titular de una patente en términos y condiciones comerciales razonables en los términos del artículo 43 y tales intentos no hayan surtido efecto luego de transcurrido un plazo de ciento cincuenta (150) días corridos contados desde la fecha en que se solicitó la respectiva licencia, el Instituto Nacional de la Propiedad Industrial, podrá permitir otros usos de esa patente sin autorización de su titular. Sin perjuicio de lo mencionado precedentemente, se deberá dar comunicación a las autoridades creadas por la Ley N 22.262 o la que la modifique o sustituya, que tutela la libre competencia a los efectos que correspondiere.

Artículo 43 - Transcurridos tres (3) años desde la concesión de la patente, o cuatro (4) desde la presentación de la solicitud, si la invención no ha sido explotada, salvo fuerza mayor o no se hayan realizado preparativos efectivos y serios para explotar la invención objeto de la patente o cuando la explotación de ésta haya sido interrumpida durante más de UN (1) año, cualquier persona podrá solicitar autorización para usar la invención sin autorización de su titular.

Se considerarán como fuerza mayor, además de las legalmente reconocidas como tales, las dificultades objetivas de carácter técnico legal, tales como la demora en obtener el registro en Organismos Públicos para la autorización para la comercialización, ajenas a la voluntad del titular de la patente, que hagan imposible la explotación del invento. La falta de recursos

ecónomicos o la falta de viabilidad económica de la explotación no constituirán por sí solos circunstancias justificativas.

El Instituto Nacional de la Propiedad Industrial notificará al titular de la patente el incumplimiento de lo prescrito en el primer párrafo antes de otorgar el uso de la patente sin su autorización.

La autoridad de aplicación previa audiencia de las partes y si ellas no se pusieran de acuerdo, fijará una remuneración razonable que percibirá el titular de la patente, la que será establecida según circunstancias propias de cada caso y habida cuenta del valor económico de la autorización, teniendo presente la tasa de regalías promedio para el sector de que se trate en contratos de licencias comerciales entre partes independientes. Las decisiones referentes a la concesión de estos usos deberán ser adoptadas dentro de los noventa (90) días hábiles de presentada la solicitud y ellas serán apelables por ante la Justicia Federal en lo Civil y Comercial. La sustanciación del recurso no tendrá efectos suspensivos.

Artículo 44 - Será otorgado el derecho de explotación conferido por una patente, sin autorización de su titular, cuando la autoridad competente haya determinado que el titular de la patente ha incurrido en prácticas anticompetitivas. En estos casos, sin perjuicio de los recursos que le competan al titular de la patente, la concesión se efectuará sin necesidad de aplicar el procedimiento establecido en el artículo 42.

A los fines de la presente ley, se considerarán prácticas anticompetitivas, entre otras, las siguientes:

- a) La fijación de precios comparativamente excesivos, respecto de la media del mercado o discriminatorios de los productos patentados; en particular cuando existan ofertas de abastecimiento del mercado a precios significativamente inferiores a los ofrecidos por el titular de la patente para el mismo producto;
- b) La negativa de abastecer al mercado local en condiciones comerciales razonables;
- c) El entorpecimiento de actividades comerciales o productivas;
- d) Todo otro acto que se encuadre en las conductas consideradas punibles por la Ley N 22.262 o la que la reemplace o sustituya.

Artículo 45 - El poder ejecutivo nacional podrá por motivos de emergencia sanitaria o seguridad nacional disponer la explotación de ciertas patentes mediante el otorgamiento del derecho de explotación conferido por una patente; su alcance y duración se limitará a los fines de la concesión.

Artículo 46 - Se concederá el uso sin autorización del titular de la patente para permitir la explotación de una patente -segunda patente- que no pueda ser explotada sin infringir otra patente -primera patente- siempre que se cumplan las siguientes condiciones:

- a) Que la invención reivindicada en la segunda patente suponga un avance técnico significativo de una importancia económica considerable, con respecto a la invención reivindicada en la primera patente;
- b) Que el titular de la primera patente tenga derecho a obtener una licencia cruzada en condiciones razonables para explotar la invención reivindicada en la segunda patente, y
- c) Que no pueda cederse el uso autorizado de la primera patente sin la cesión de la segunda patente.

Artículo 47 - Cuando se permitan otros usos sin autorización del titular de la patente, se observarán las siguientes disposiciones:

- a) La autorización de dichos usos la efectuará el Instituto Nacional de la Propiedad Industrial;
- b) La autorización de dichos usos será considerada en función de las circunstancias propias de cada caso;
- c) Para los usos contemplados en el artículo 43 y/o 46 previo a su concesión el potencial usuario deberá haber intentado obtener la autorización del titular de los derechos en término y condiciones comerciales conforme al artículo 43 y esos intentos no hubieren surtido efectos en el plazo dispuesto por el artículo 42. En el caso de uso público no comercial, cuando el gobierno o el contratista, sin hacer una búsqueda de patentes, sepa o tenga motivos demostrables para saber que una patente válida es o será utilizada por o para el gobierno, se informará sin demoras a su titular;
- d) La autorización se extenderá a las patentes relativas a los componentes y procesos de fabricación que permitan su explotación;
- e) Esos usos serán de carácter no exclusivo;
- f) No podrán cederse, salvo con aquella parte de la empresa o de su activo intangible que la integre;
- g) Se autorizarán para abastecer principalmente al mercado interno, salvo en los casos dispuestos en los artículos 44 y 45;
- h) El titular de los derechos percibirá una remuneración razonable según las circunstancias propias de cada caso, habida cuenta del valor económico de la autorización, siguiendo el procedimiento del artículo 43; al determinar el importe de las remuneraciones en los casos en que los usos se hubieran autorizado para poner remedio a prácticas anticompetitivas se tendrá en cuenta la necesidad de corregir dichas prácticas y se podrá negar la revocación de la autorización si se estima que es probable que en las condiciones que dieron lugar a la licencia se repitan;
- i) Para los usos establecidos en el artículo 45 y para todo otro uso no contemplado, su alcance y duración se limitará a los fines para los que hayan sido autorizados y podrán retirarse si las circunstancias que dieron origen a esa autorización se han extinguido y no sea probable que vuelvan a surgir, estando el Instituto nacional de la propiedad Industrial facultado para examinar, previa petición fundada, si dichas circunstancias siguen existiendo. Al dejarse sin efecto estos usos se deberán tener en cuenta los intereses legítimos de las personas que hubieran recibido dicha autorización. Si se tratara de tecnología de semiconductores, sólo podrá hacerse de ella un uso público no comercial o utilizarse para rectificar una práctica declarada contraria a la competencia tras un procedimiento judicial o administrativo.

ARMENIA : Articles 69-70 of the Patent Law of 10/06/2008

Article 69. Compulsory License

(1) Any person or the Republic of Armenia may, without the consent of the patent owner (rightholder), use the protected invention, utility model or industrial design (compulsory license) by court decision where:

(a) the public interest demands, in particular, national security, nutrition, health or the development of other vital sectors so requires;

(b) it is determined that the owner of the patent or his licensee abuses the patent rights, in particular where the manner of exploitation, contrary to the adopted regulations, restrains competition;

(c) the invention, utility model, industrial design has not been used or has been used unconscientiously during the period of 4 years from filing the application or 3 years from granting patent (certificate) (the later filing date shall be applied).

(2) The court shall grant compulsory licenses under paragraph (1) of this Article with regard to given circumstances and after hearing the right holder.

(3) Compulsory licenses under paragraph (1) of this Article shall be granted provided that the person filing the request proves that he has made efforts to conclude a license contract with the rightholder on reasonable commercial terms and that such efforts failed to succeed within a reasonable period of time.

(4) Paragraph (3) of this Article shall not apply if a state of war or emergency has been declared.

Article 70. Conditions for Granting Compulsory Licenses

(1) Compulsory licenses under Article 69 shall be granted under the following conditions:

- (a) scope and duration shall be limited with regard to their purposes;
- (b) they shall be only non-exclusive;
- (c) they may not be transferred to third parties, with the exception of the licensee enterprise or business;
- (d) they shall be granted primarily for the suffice of the internal market demand.

(2) Where a patent, hereinafter referred to as “the second patent”, cannot be exploited without infringing another patent, hereinafter referred to as “the first patent”, the following conditions, in addition to paragraph (1) above, for the grant of compulsory license in respect of the first patent it is necessary that:

- (a) the invention protected by the second patent shall involve a technical advance of considerable economic significance compared to the invention protected by the first patent;
- (b) the owner of the first patent shall, under reasonable conditions, be entitled to a cross-license to use the invention protected by the second patent;
- (c) the use authorized in respect of the first patent shall be transferred by the person having the compulsory license only with the simultaneous transfer of the company’s part, where the use of the mentioned subject matter is realized.

(3) The compulsory license is recognized as expired by the court decision:

- (a) if the circumstances which led to it have been eliminated and are unlikely to recur;
- (b) after receiving compulsory license the license-holder didn’t undertake the necessary preparatory work to use it during one-year period.

(4) In the case of semiconductor technologies a compulsory license may be granted only by the State for exclusively non-commercial use as well by judicial or administrative authorities for prevention of unfair competition.

AUSTRALIA : *Sections 133, 135 and 163, 167 and 168 of the Patent Act No. 83 of 30/10/1990 as last amended by Law No. 106 of 2006*

133 - Compulsory licences

(1) Subject to subsection (1A), a person may apply to the Federal Court, after the end of the prescribed period, for an order requiring the patentee to grant the applicant a licence to work the patented invention.

(1A) A person cannot apply for an order in respect of an innovation patent unless the patent has been certified.

(2) After hearing the application, the court may, subject to this section, make the order if satisfied that:

(a) all the following conditions exist:

(i) the applicant has tried for a reasonable period, but without success, to obtain from the patentee an authorisation to work the invention on reasonable terms and conditions;

(ii) the reasonable requirements of the public with respect to the patented invention have not been satisfied;

(iii) the patentee has given no satisfactory reason for failing to exploit the patent;

or

(b) the patentee has contravened, or is contravening, Part IV of the Trade Practices Act 1974 or an application law (as defined in section 150A of that Act) in connection with the patent.

(3) An order must direct that the licence:

(a) is not to give the licensee, or a person authorised by the licensee, the exclusive right to work the patented invention; and

(b) is to be assignable only in connection with an enterprise or goodwill in connection with which the licence is used;

and may direct that the licence is to be granted on any other terms specified in the order.

(3B) If the patented invention cannot be worked by the applicant without his or her infringing another patent:

(a) the court is to make the order only if the court is further satisfied that the patented invention involves an important technical advance of considerable economic significance on the invention (other invention) to which the other patent relates; and

(b) the court must further order that the patentee of the other invention:

(i) must grant to the applicant a licence to work the other invention insofar as is necessary to work the patented invention; and

(ii) is to be granted, if he or she so requires, a cross-licence on reasonable terms to work the patented invention; and

(c) the court must direct that the licence granted by the patentee of the other invention may be assigned by the applicant:

(i) only if he or she assigns the licence granted in respect of the patented invention; and

(ii) only to the assignee of that licence.

(4) An order operates, without prejudice to any other method of enforcement, as if it were embodied in a deed granting a licence and executed by the patentee and all other necessary parties.

- (5) The patentee is to be paid in respect of a licence granted to the applicant under an order:
- (a) such amount as is agreed between the patentee and the applicant; or
 - (b) if paragraph (a) does not apply - such amount as is determined by the Federal Court to be just and reasonable having regard to the economic value of the licence and the desirability of discouraging contraventions of Part IV of the Trade Practices Act 1974 or an application law (as defined in section 150A of that Act).
- (6) The patentee or the Federal Court may revoke the licence if:
- (a) the patentee and the licensee are agreed, or the court on application made by either party finds, that the circumstances that justified the grant of the licence have ceased to exist and are unlikely to recur; and
 - (b) the legitimate interests of the licensee are not likely to be adversely affected by the revocation.

135 - Reasonable requirements of the public

- (1) For the purposes of sections 133 and 134, the reasonable requirements of the public with respect to a patented invention are to be taken not to have been satisfied if:
- (a) an existing trade or industry in Australia, or the establishment of a new trade or industry in Australia, is unfairly prejudiced, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure:
 - (i) to manufacture the patented product to an adequate extent, and supply it on reasonable terms; or
 - (ii) to manufacture, to an adequate extent, a part of the patented product that is necessary for the efficient working of the product, and supply the part on reasonable terms; or
 - (iii) to carry on the patented process to a reasonable extent; or
 - (iv) to grant licences on reasonable terms; or
 - (b) a trade or industry in Australia is unfairly prejudiced by the conditions attached by the patentee (whether before or after the commencing day) to the purchase, hire or use of the patented product, the use or working of the patented process; or
 - (c) if the patented invention is not being worked in Australia on a commercial scale, but is capable of being worked in Australia.

- (2) If, where paragraph (1)(c) applies, the court is satisfied that the time that has elapsed since the patent was sealed has, because of the nature of the invention or some other cause, been insufficient to enable the invention to be worked in Australia on a commercial scale, the court may adjourn the hearing of the application for the period that the court thinks sufficient for that purpose.

163 - Exploitation of inventions by Crown

- (1) Where, at any time after a patent application has been made, the invention concerned is exploited by the Commonwealth or a State (or by a person authorised in writing by the Commonwealth or a State) for the services of the Commonwealth or the State, the exploitation is not an infringement:
- (a) if the application is pending - of the nominated person's rights in the invention; or
 - (b) if a patent has been granted for the invention - of the patent.
- (2) A person may be authorised for the purposes of subsection (1):
- (a) before or after any act for which the authorisation is given has been done; and

(b) before or after a patent has been granted for the invention; and
(c) even if the person is directly or indirectly authorised by the nominated person or patentee to exploit the invention.

(3) Subject to section 168, an invention is taken for the purposes of this Part to be exploited for services of the Commonwealth or of a State if the exploitation of the invention is necessary for the proper provision of those services within Australia.

167 - Sale of products

(1) The right to exploit an invention under subsection 163(1) includes the right to sell products made in exercise of that right.

(2) Where under subsection 163(1) the sale of products is not an infringement of:

- (a) a patent; or
- (b) a nominated person's rights in the products;

the buyer, and any person claiming through the buyer, is entitled to deal with the products as if the relevant authority were the patentee or the nominated person.

168 - Supply of products by Commonwealth to foreign countries

Where the Commonwealth has made an agreement with a foreign country to supply to that country products required for the defence of the country:

(a) the use of a product or process by the Commonwealth, or by a person authorised in writing by the Commonwealth, for the supply of that product is to be taken, for the purposes of this Chapter, to be use of the product or process by the Commonwealth for the services of the Commonwealth; and

(b) the Commonwealth or the authorised person may sell those products to the country under the agreement; and

(c) the Commonwealth or the authorised person may sell to any person any of the products that are not required for the purpose for which they were made.

AUSTRIA (EU) : *Section 36 of the Patents Law 1970 (BGBl. No. 259/1970), as last amended by Act No. 143/2001 (last amended version of 2010 not available in English)*

Section 36. Compulsory Licenses

(1) If a patented invention cannot be worked without infringing an invention patented earlier (older patent), the holder of the later patent may apply for a non-exclusive license to work the earlier patent if the invention protected by the later patent involves an important technical advance of considerable economic significance. If a license is granted, also the holder of the earlier patent may apply for a non-exclusive license to work the later patent.

(2) Where a patented invention is not worked to a reasonable extent in Austria, the working being possible also by imports, and where the patentee has not taken all steps required for such working, any person may apply for a non-exclusive license to work the patent for the purposes of his business, unless the patentee proves that the invention could not reasonably have been worked, or could not reasonably have been worked to a greater extent, in Austria owing to the difficulties of exploitation.

(3) If a license for a patented invention is required in the public interest, any person may apply for a non-exclusive license to work the invention for the purposes of his business. The respective title of the federal administrative authorities, however, shall not be bound to a business.

(4) If the person entitled to grant a license in accordance with subsections 1 to 3 refuses to do so although the applicant for the license has made efforts to obtain within a reasonable period of time on reasonable, commercial terms and conditions, the Patent Office shall at the request of the applicant for the license decide the matter under the procedure relating to the contesting of patents. If a license is granted, an adequate remuneration shall be fixed, taking into account the economic value of the license. The security which may be required and any other terms governing use shall be fixed having regard to the nature of the invention and the circumstances of the case. The scope and duration of the license in accordance with subsections 1 to 3 shall be authorised predominantly for the supply of the domestic market and shall be limited to the purpose requiring the license. In the case of semiconductor technology the license shall only be granted for public noncommercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

(5) A license in accordance with subsection 2 may not be applied for until four years after the filing of the application, or three years after the publication of the grant relating to the patent for which the license is sought, whichever period expires last.

(6) The requirement to obtain the authorization of the person entitled to grant a license can be waived in the case of subsection 3 in the case of national emergency or other circumstances of extreme urgency. In this case a temporary permission for the use of the invention shall be granted by an interim decision.

(7) A license granted in accordance with subsection 4 shall be canceled upon request subject to adequate protection of the legitimate interests of the entitled person, if and when the circumstances having brought about such permission have ceased to exist and are unlikely to crop up again. The Patent Office shall decide on request under the procedure relating to the contesting.

BARBADOS : *Articles 49 and 50 of the Patent Act No. 18 of 26/07/2001*

Use by Government or Third Party
[Exploitation by Crown, government agency or person named.]

49.-(1) Where:

(a) the exploitation within Barbados of an invention protected by patent is, in the opinion of the Minister, necessary

- (i) in the interests of national security;
- (ii) in the interests of national health;
- (iii) in the interests of national nutrition;
- (iv) in the interests of the development of an essential sector of the economy of Barbados; or
- (v) for other public interests;

(b) the High Court has determined that the manner of exploitation by the owner of a patent or his licensee is anti-competitive,

the Minister may, without the consent of the owner of the patent, but subject to the payment of a reasonable amount for its exploitation, authorize by order the exploitation of the invention in Barbados by the Crown, by a government agency or by any person named in the order.

(7) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either for public non-commercial use or where the High Court has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Minister is satisfied that the grant of the authorization would remedy such practice.

(10) The exploitation of the invention by the Crown, government agency or third person referred to in subsection (1), shall be predominantly for the supply of the market in Barbados and shall be limited to the purposes for which it was authorized.

50. (1) After the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, any person interested may apply to the High Court for the grant of a non-voluntary licence under a patent, on the ground that the patented invention is not exploited or is insufficiently exploited by working the invention locally or by importation in Barbados.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the High Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Barbados.

(3) The High Court shall make an order setting out
(a) the scope and function of the licence;
(b) the time limit within which the licensee shall begin to exploit the patented invention;
and
(c) the amount to be paid to the owner of the patent and the conditions of payment.

(4) Any person to whom a licence is granted under this section, shall exploit the patented invention in Barbados in accordance with the terms of the order under subsection (3), and shall exploit the patented invention sufficiently.

(5) Where:
(a) the invention claimed in a patent, (in this section referred to as the “later patent”) cannot be exploited in Barbados without infringing a patent granted on the basis of an application benefiting from an earlier application, in this section referred to as the “earlier patent”; and
(b) the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent,

the High Court may, upon the request of the owner of the later patent, issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is granted under subsection (5), the High Court shall, upon the request of the owner of the earlier patent, issue a non-voluntary licence in respect of the later patent.

(7) In the case of the grant of a non-voluntary licence under subsection (5), subsection (3) applies, *mutatis mutandis*, with the exception that no time limit need be fixed.

(8) In the case of a non-voluntary licence issued under subsection (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence granted under subsection (6), only with the earlier patent.

(9) A licence granted under this section:

- (a) is not exclusive;
- (b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and
- (c) is limited to the supply of the patented invention predominantly in Barbados.

BELARUS : *Article 38 of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/2002*

Compulsory Licensing

38. Where the owner of a patent has failed to use or has insufficiently used an invention within five years or a utility model or an industrial design within three years following the date of the grant of the patent, any person who wishes to use the patented invention, utility model or industrial design and is in a position to do so, but with whom the owner of the patent has refused to conclude a licensing agreement, may apply to the courts for the grant of a non-exclusive compulsory license. The court shall grant a compulsory license and shall lay down the limits on the use of the invention, utility model or industrial design, as also the amount, dates and procedure for the payment of royalties, unless the owner of the patent is able to prove that the failure to use or the insufficient use of the invention, utility model or industrial design is justified by legitimate reasons.

BELGIUM (EU) : *Articles 31-38 of the Patent Law of 28/03/1984 (Official Consolidation of 01/01/2010)*

Article 31

§ 1er. Le Ministre peut octroyer, conformément aux articles 32 à 34, une licence d'exploitation d'une invention couverte par un brevet :

1. Lorsqu'un délai de quatre années à compter de la date de dépôt de la demande de brevet, ou de trois années à compter de la délivrance du brevet, le délai qui expire le plus tard devant être appliqué, s'est écoulé sans que l'invention brevetée soit exploitée par [importation ou] une fabrication sérieuse et continue en Belgique et sans que le titulaire du brevet justifie son inaction par des excuses légitimes.

Dans le cas d'un brevet ayant pour objet une machine, la fabrication sérieuse et continue en Belgique par le titulaire du brevet de produits obtenus à l'aide de cette machine peut être considérée comme valant exploitation de l'invention brevetée en Belgique lorsque cette fabrication apparaît comme plus importante pour l'économie du pays que celle de la machine elle-même.

[Une licence obligatoire pour défaut ou insuffisance d'exploitation ne sera accordée qu'à condition que la licence soit octroyée principalement pour l'approvisionnement du marché national.]

2. Lorsqu'une invention, couverte par un brevet appartenant au demandeur de la licence, ne peut être exploitée sans porter atteinte aux droits attachés à un brevet issu d'un dépôt antérieur et pour autant que le brevet dépendant [permette un progrès technique important, d'un intérêt économique considérable, par rapport à l'invention revendiquée dans le brevet dominant] [et à condition que la licence soit octroyée principalement pour l'approvisionnement du marché national ;]

3. Lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété représente un progrès technique important d'un intérêt économique considérable par rapport à l'invention revendiquée dans le brevet et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national;

4. Au titulaire d'un droit d'obtention végétale, lorsque le titulaire d'un brevet concernant une invention biotechnologique a, conformément aux dispositions de la loi sur la protection des obtentions végétales, obtenu une licence obligatoire pour l'exploitation non-exclusive de la variété végétale protégée par ce droit d'obtention végétale parce qu'il ne peut exploiter l'invention biotechnologique sans porter atteinte à ce droit d'obtention végétale antérieur et à condition que cette licence soit octroyée principalement pour l'approvisionnement du marché national.]

[Dans le cas de la technologie des semi-conducteurs telle que définie dans la directive 87/54 du Conseil du 16 décembre 1986, les licences visées au 1° et au 2° du présent paragraphe ne peuvent être accordées que si elles sont destinées à remédier à une pratique dont il a été déterminé, à l'issue d'une procédure judiciaire ou administrative, qu'elle est anticoncurrentielle.]

§ 2. Le demandeur de la licence doit établir :

1) Dans les cas visés au paragraphe précédent :

a) que le titulaire du brevet tombe sous l'application de l'une de ces dispositions;
b) qu'il s'est vainement adressé au titulaire du brevet pour obtenir une licence à l'amiable;

2) En outre, si la licence est réclamée par application du 1° du paragraphe précédent, qu'il disposerait, dans l'hypothèse où la licence lui serait octroyée, des moyens nécessaires pour assurer une fabrication sérieuse et continue en Belgique d'après l'invention brevetée.

§ 3. Toute action en contrefaçon d'une invention couverte par un brevet dont une licence obligatoire est demandée et intentée contre le demandeur d'une telle licence suspend la procédure d'octroi de la licence jusqu'au moment où le jugement ou l'arrêt acquiert force de chose jugée. Si la contrefaçon est établie, la demande de licence obligatoire est rejetée.

§ 4. Est réservée l'application des lois prévoyant l'octroi de licences d'exploitation d'inventions brevetées en des matières spéciales, notamment la défense nationale et l'énergie nucléaire.

Article 31bis

§ 1er. Dans l'intérêt de la santé publique, le Roi peut, par arrêté délibéré en Conseil des ministres, octroyer une licence d'exploitation et d'application d'une invention couverte par un brevet pour :

- a) un médicament, un dispositif médical, un dispositif médical ou un produit de diagnostic, un produit thérapeutique dérivé ou à combiner;
- b) la méthode ou le produit nécessaire pour la production d'un ou plusieurs produits mentionnés sous a);
- c) une méthode de diagnostic appliquée en dehors du corps humain ou animal.

§ 2. Le demandeur de la licence obligatoire doit établir qu'il dispose, dans le cas où la licence obligatoire lui serait octroyée, des moyens ou de l'intention loyale d'obtenir les moyens qui sont nécessaires pour la fabrication et/ou l'application sérieuse et continue en Belgique de l'invention brevetée.

§ 3. Toute procédure concernant une action en contrefaçon d'une invention couverte par un brevet pour lequel une licence obligatoire pour des raisons de santé publique a été demandée et qui est intentée contre le demandeur d'une telle licence, est suspendue en ce qui concerne la question de la contrefaçon jusqu'au moment où une décision concernant la licence obligatoire est prise par le Roi conformément au § 1er.

§ 4. Les licences octroyées en application du présent article ne sont pas exclusives.

§ 5. La licence obligatoire peut être limitée dans le temps ou en ce qui concerne son champ d'application.

Article 31ter

§ 1er. Sans préjudice du § 2, le Roi est l'autorité compétente au sens de l'article 2.4. du Règlement (CE) N° 816/2006 du Parlement européen et du Conseil du 17 mai 2006 concernant l'octroi de licences obligatoires pour des brevets visant la fabrication de produits pharmaceutiques destinés à l'exportation vers des pays connaissant des problèmes de santé publique.

Les décisions relatives à l'octroi, à la révision, au rejet et au retrait d'une licence obligatoire sont prises par arrêté délibéré en Conseil des ministres.

BELIZE : *Article 38 of the Patent Act, Chapter 253, of 21/06/2000*

Non-Voluntary Licences

38. (1) At any time after the expiration of four years from the date of filing of a patent application or three years from the date of the grant of a patent, whichever happens later, any interested person may apply to the Court for the grant of a non-voluntary licence under the patent on the grounds that the patented invention is not being exploited or is being insufficiently exploited by working the invention in Belize, or by importation into Belize.

- (2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Court that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Belize.
- (3) The Court shall, where it grants a non-voluntary licence, fix:-
(a) the scope and function of the licence;
(b) the time limit within which the licensee must begin to exploit the patented invention;
and
(c) the amount of the remuneration to be paid to the owner of the patent, and the conditions of the payment thereof.
- (4) The beneficiary of the non-voluntary licence shall:-
(a) have the right to exploit the patented invention in Belize in accordance with the Court's order;
(b) commence the exploitation of the patented invention within the time stipulated in the said order; and
(c) thereafter, exploit the patented invention sufficiently.
- (5) Where the invention claimed in a patent (referred to in this section as a "later patent") cannot be exploited in Belize without infringing a patent granted on the basis of an application benefiting from an earlier filing, or, where appropriate, priority date (referred to in this section as an "earlier patent"), and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Court may, upon the application of the owner of the later patent, issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.
- (6) Where a non-voluntary licence is issued in accordance with subsection (5), the Court shall, upon the application of the owner of the earlier patent, issue a non-voluntary licence in respect of the later patent.
- (7) In the case of an application for the issuance of a non-voluntary licence in accordance with subsections (5) and (6), subsection (3) shall apply mutatis mutandis, except that no time limit need be fixed by the Court.
- (8) In the case of a non-voluntary licence issued under subsection (1), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (5), only with the earlier patent.
- (9) An application for a non-voluntary licence shall be subject to payment of the prescribed fee.
- (10) No licence shall be granted under this section in respect of a patented invention in the field of semi-conductor technology.
- (11) Section 35(2) to (12), and 62 (2) shall apply mutatis mutandis.

BHUTAN : *Section 15 of the Industrial Property Act of the Kingdom of Bhutan of 2001*

Exploitation by Government or Person thereby Authorized

15. (1) Where:

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (ii) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Minister is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice:
the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention. The exploitation of the invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the invention, as determined in the said decision, and, where a decision has been taken under paragraph (ii), the need to correct anti-competitive practices. The Minister shall take his decision after hearing the owner of the patent and any interested person if they wish to be heard.

(2) Upon request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(3) (a) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

BOTSWANA : *Section 31 of Industrial Property Act, Act No. 14 of 1996*

31. (1) At any time after the expiration of three years from the date of the grant of a patent or four years from the date of the application therefor, whichever happens later, any interested party may apply to the High Court for the grant of a licence under the patent upon any of the grounds specified in subsection (2) of this section.

(2) The grounds upon which a licence may be granted under this section are that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Botswana.

(3) Subject to the provisions of subsections (4), (5), (6) and (7) of this section, if the High Court is satisfied that either of the grounds specified in subsection (2) of the section have been

established, the Court may make an order for the grant of a licence in accordance with the application upon such terms as the Court thinks fit.

- (4) A licence granted under this section:
 - (a) shall not be exclusive;
 - (b) shall not be assigned otherwise that in connection with the good will of the business in which the patented invention is used; and
 - (c) shall be authorized by the court for the supply of the patented invention predominantly in Botswana.
- (5) A licence granted under this section may, on the application of any interested party, be terminated by the Court where the Court is satisfied that the grounds on which the licence was granted have ceased to exist and are unlikely to recur.
- (6) Where a licence is granted under this section to any person, that person shall pay, to the patentee, such remuneration as may be agreed, or as may be determined by a method agreed, between that person and the patentee, or, in default of the agreement, as is determined by the Court on the application of that person or the patentee.
- (7) No licence shall be granted under this section unless the person applying for the licence, having taken all reasonable steps to do so, has been unable to obtain a licence, or to obtain a licence on reasonable terms, from the owner of the patent.
- (8) No licence shall be granted under this section in respect of a patent relating to an integrated circuit.

BRAZIL : Articles 68-74 of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001

68. The titleholder shall be subject to having the patent licensed on a compulsory basis if he exercises his rights derived therefrom in an abusive manner, or by means thereof engages in abuse of economic power, proven pursuant to law in an administrative or judicial decision.

- (1) The following also occasion a compulsory license:

I. non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product, or also failure to make full use of the patented process, except cases where this is not economically feasible, when importation shall be permitted; or

II. commercialization that does not satisfy the needs of the market.

- (2) A license may be requested only by a person having a legitimate interest and having technical and economic capacity to effectively exploit the object of the patent, that shall be destined predominantly for the domestic market, in which case the exception contained in Item I of the previous Paragraph shall be extinguished.

- (3) In the case that a compulsory license is granted on the grounds of abuse of economic power, the licensee who proposes local manufacture shall be assured a period, limited to the

provisions of Article 74, to import the object of the license, provided that it was introduced onto the market directly by the titleholder or with his consent.

(4) In the case of importation to exploit a patent and in the case of importation as provided for in the preceding Paragraph, third parties shall also be allowed to import a product manufactured according to a process or product patent, provided that it has been introduced onto the market by the titleholder or with his consent.

(5) The compulsory license that is the subject of Paragraph 1 shall only be required when 3 (three) years have elapsed since the patent was granted.

69. A compulsory license shall not be granted if, on the date of the application, the titleholder:

- I. justifies the non-use based on legitimate reasons;
- II. proves that serious and effective preparations for exploitation have been made;
- III. justifies the failure to manufacture or to market on grounds of an obstacle of legal nature;

70. The compulsory license shall also be granted when all the following circumstances apply:

- I. there is a situation of dependency of one patent with regard to another;
- II. the object of the dependent patent constitutes a substantial technical progress with regard to the earlier patent; and
- III. the titleholder fails to reach agreement with the patentholder of the dependent patent on the exploitation of the earlier patent.

(1) For the purposes of this Article, a dependent patent is considered to be a patent whose exploitation necessarily depends on the use of the object of an earlier patent.

(2) For purposes of this Article, a process patent may be considered dependent on the respective product patent, and likewise, a product patent may be dependent on a process patent.

(3) The patentholder licensed pursuant to the provisions of this Article shall have the right to a crossed compulsory license on the dependent patent.

71. In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patentholder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, *ex officio*, without prejudice to the rights of the respective titleholder.

Sole Paragraph. The act of granting the license shall establish its term and the possibility of extension.

72. Compulsory licenses shall always be granted on a non-exclusive basis, and sublicensing shall not be permitted.

BRUNEI DARUSSALAM : *Sections 55-65 of the Patents Order No. S42/99 of 1999*

55. (1) At any time after the expiration of 3 years from the date of the grant of a patent or 4 years from the date of filing of the patent application, whichever is the later, any person interested may apply to the court for the grant of a licence under the patent upon any of the grounds specified in subsection (2).

(2) The grounds upon which a licence may be granted under this section are that the market in Brunei Darussalam for the patented invention is not being supplied –

- (a) due to the failure to work or, to work to a sufficient extent, the patented invention; or
- (b) on reasonable terms,

by the proprietor of the patent.

(3) Subject to this section, if the court is satisfied that either of the grounds referred to in subsection (2) is established, the court may make an order for the grant of a licence in accordance with the application upon such terms as the court thinks fit.

(4) A licence granted under this section –

- (a) shall be non-exclusive;
- (b) may not be assigned otherwise than in connection with that part of the enterprise or the goodwill of the business in which the patented invention is used;
- (c) may only authorize use of the patented invention predominantly for the supply of the market in Brunei Darussalam; and
- (d) shall be limited in the scope and duration of the use of the patented invention to the purpose for which it is to be authorized.

(5) Any licence granted under this section may, on the application of any interested party, be terminated by the court where the court is satisfied that the ground upon which the licence was granted has ceased to exist and is, in the opinion of the court, unlikely to recur, provided that the legitimate interests of the licensee are not likely to be adversely affected by the revocation.

(6) Where a licence is granted under this section to any person, that person shall pay such remuneration to the proprietor of the patent as may be agreed, or as may be determined by a method agreed, between that person and the proprietor or the patent or, in default of agreement, as is determined by the court on the application of that person or the proprietor of the patent.

(7) No licence shall be granted under this section –

- (a) Unless it is established that within a reasonable period of time, the applicant for the grant of the licence has been unable after reasonable efforts to obtain a licence on reasonable terms and conditions from the proprietor of the patent; or
- (b) If the application for a licence under this section is in connection with a patented invention which deals with a layout design, except to remedy a practice which is determined by the court to be anti-competitive.

(8) The proprietor of a patent (“the second patent”) may apply to the court for the grant of a licence under another patent (“the first patent”) on the ground that the second patent cannot be worked without his infringing the first patent, and if the court is satisfied that –

- (a) The ground is established; and
- (b) The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent,

The court may make an order for the grant of a licence in accordance with the application, upon such terms as it thinks fit and insofar as it is necessary to work the invention claimed in the second patent.

- (9) Where the court makes an order under subsection (8) the proprietor of the first patent shall be entitled to an order, if he so requires, for the grant of a cross-licence on reasonable terms to work the invention claimed in the second patent.
- (10) The licence granted under subsection (8) may not be assigned except with the assignment of the second patent.
- (11) Subsections (4)c and (7)a shall not prevent the court from making an order for the grant of a licence to work an invention claimed in a patent against the wishes of the proprietor of the patent if the court is satisfied that the grant of the licence is for the purpose of remedying a practice which it considers to be anti-competitive.
- (12) For the purposes of this Part,
 - (a) “layout design” means the three-dimensional disposition, however expressed of the elements, at least one of which is an active element, and some or all of the interconnections, of an integrated circuit; and includes a three-dimensional disposition prepared for an integrated circuit intended for manufacture; and
 - (b) “integrated circuit” means a circuit, in its final or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in or on a piece of material and that is intended to perform an electronic function.

PART XII

USE OF PATENTED INVENTIONS FOR SERVICES OF GOVERNMENT

58. (1) Subject to this Part, notwithstanding anything in this Order, any Government department and any person authorized in writing by a Government department may, for the services of the Government and in accordance with this section do any of the following acts in Brunei Darussalam for the services of the Government –

(a) where the patented invention is a product, may make, use, import, obtain or keep the product;

(b) where the patented invention is a process, may use it or, in relation to any product obtained directly by means of the process, do anything mentioned in paragraph (a); and

(c) may dispose or offer to dispose of anything which was made, used, imported, obtained or kept in exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported, obtained or kept, as the case may be,

and anything done by virtue of this section shall not amount to an infringement of the patent.

(2) any act done in relation to an invention by virtue of this section is in this section referred to as use of the invention; and “use”, in relation to an invention, in sections 59 to 63 shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a Government department otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) A person acquiring anything disposed of in the exercise of the powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Government.

(5) In this section, “relevant communication”, in relation to a patented invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

59. (1) Any reference in this Part to a patented invention, in relation to any time, is a reference to an invention for which a patent has before that time been, or is subsequently, granted.

- (2) In this Part, unless the context otherwise requires, “the services of the government” shall be deemed to include –
- (a) The sale or supply of anything for foreign defence purposes;
 - (b) The supply of anything to avoid prejudice to the security or defence of Brunei Darussalam; and
 - (c) The supply of anything to assist in the exercise of powers and the implementation of measures during a period of national emergency or other circumstances of extreme urgency,

And “use for the services of the Government” shall be construed accordingly and is limited to public non-commercial use.

- (3) In subsection (2) a references to a sale or supply of anything for foreign defence purposes are references to a sale or supply of the thing –
- (a) To the government of any country outside Brunei Darussalam in pursuance of an agreement or arrangement between the Government and the government of that country, where the thing is required for the defence of that country or of any other country whose government is party to any agreement or arrangement with the Government in respect of defence matters;
 - (b) To the United Nations, or to the government of any country belonging to that organization, in pursuance of an agreement or arrangement between

the Government and that organization or government, where the thing is required for any armed forces operating in pursuance of a resolution of that organization or any organ of that organization.

60. (1) The right to use a patented invention under section 58 –
- (a) shall be non-exclusive;
 - (b) may not be assigned otherwise than in connection with that part of the enterprise or the goodwill of the business in which the patented invention is used;
 - (c) is, notwithstanding subsection (2) of section 59, limited to the supply of the patented invention in Brunei Darussalam by a Government department or a person authorized by a Government department under that section.

(2) The right to use a patented invention under section 58 may, on the application of any interested party, be terminated by the court, where the court is satisfied that the circumstances that gave rise to the right to use the patented invention have ceased to exist and are unlikely to recur.

(3) Except in a case to which section 64 applies, the right to use a patented invention under section 58 is subject to the Government department or the person authorized by a Government department under section 58 having first taken all reasonable steps to obtain the consent of the proprietor of the patent to the use of the patented invention on reasonable commercial terms and conditions, and having failed to obtain such consent within a reasonable period of time.

64. (1) Subject to this Part, the powers exercisable in relation to an invention by a Government department or a person authorized by a Government department under section 58 shall include power to use the patented invention for any purpose which appears to the department necessary or expedient –

- (a) to avoid prejudice to the security or defence of Brunei Darussalam or for the efficient prosecution of any war in which Brunei Darussalam may be engaged;
- (b) to assist in the exercise of powers and the implementation of measures during a period of national emergency or other circumstances of extreme urgency; or
- (c) for public non-commercial purposes,

and any reference in this Order to the services of the Government shall, as respects any period of national emergency, include a reference to those purposes.

(2) In this section, the use of a patented invention includes, in addition to any act constituting such use by virtue of section 58, any act which would, apart from that section and this section, amount to an infringement of the patent or, as the case may be, give rise to a right under section 76 to bring proceedings in respect of the application, and any reference in this Order to “use for the services of the Government” shall, as respects any period of national emergency, be construed accordingly.

BULGARIA (EU) : *Articles 32, 32a, 66 and 74c of the Patent Law No. 27/2 of 1993 as last amended by Law No. 59/20 of July 2007*

Article 32

- (1) Any person concerned, who has unsuccessfully tried to get a contractual license from the holder under fair conditions, may request the Patent Office to grant him a compulsory license to use the invention, provided that at least one of the following conditions is met:
 1. failure to use the invention for a period of four years from filing of the patent application or three years from the grant of a patent, the time limit which expires later being applicable;
 2. insufficient working of the invention to satisfy the needs of the national market, within the time limits set out in item 1 above, unless the patent owner gives valid reasons therefor.
- (2) The person requesting a license under the preceding paragraph shall be required to prove that he is in a position to work the invention within the limits of the compulsory license requested.
- (3) Beyond the cases referred to in paragraph (1), a compulsory license may be granted, where demanded by the public interest, without negotiating with the holder of the right in the invention enjoying patent protection.
- (4) A compulsory license may be granted to a holder, whose invention is the subject matter of a later patent and is included in the scope of another, earlier patent, if the owner of the earlier patent refuses to grant a license under fair conditions, where the subject matter of the later patent represents significant technical progress of great economic importance compared to the subject matter of the earlier patent.
The owner of the earlier patent shall be entitled to a cross license under reasonable conditions for working the invention claimed in the later patent.
- (5) A compulsory license may only be non-exclusive. It may only be assigned together with the enterprise in which the licensed invention is being worked.
- (6) A compulsory license may be terminated if within one year of its grant the licensee has made no preparation for working the invention. A compulsory license shall be terminated in all cases if the licensee fails to start working the invention within two years of grant.
- (7) The scope of a compulsory license shall be determined by the purpose it was granted for.
- (8) A compulsory license shall not be granted to an infringer of the patent.
- (9) Bilateral and multilateral treaties to which the Republic of Bulgaria is a party may lay down further conditions for the grant of a compulsory license to patent owners from States party to such treaties.
- (10) The compulsory licensee shall owe the patent owner remuneration.
- (11) A compulsory license shall be terminated as soon as the ground therefore no longer exists.

(12) The procedure of granting and terminating compulsory licenses shall be specified in the Regulation referred to in Article 55(3).

Compulsory Cross-License

Article 32a

(1) Where a breeder cannot obtain or use the right in a plant variety without infringing an earlier patent, he may apply for a compulsory license for non-exclusive use of the invention enjoying patent protection, in so far as the license is required for using the plant variety for the purposes of its legal protection, subject to the payment of a respective remuneration. Where such a license is granted, the patent owner shall be entitled to a cross-license for using the protected plant variety under fair conditions.

(2) Where the owner of a patent for a biotechnological invention cannot use it without infringing an earlier plant variety right, he may apply for a compulsory license for non-exclusive use of the protected plant variety, subject to the payment of a respective remuneration. Where such a license is granted, the protected variety owner shall be entitled to get a cross-license for using the invention under fair conditions.

(3) The person applying for the grant of a compulsory license according to paragraphs (1) and (2) shall prove that:

1. he has tried unsuccessfully to get a contractual license from the patent or plant variety owner;
2. the plant variety or the invention represents significant technical progress of great economic importance compared to the patented invention or the protected plant variety.

Compulsory License

Article 74c

(1) A compulsory license shall be granted to a utility model owner, where the utility model cannot be used without infringing the right in another utility model the owner of which refuses to grant a license under fair conditions.

(2) A compulsory license shall be granted to a patent owner, where the invention according to the patent cannot be used without infringing the right in a utility model the owner of which refuses to grant a license under fair conditions.

(3) The compulsory license treatment under Article 32 shall equally apply to registered utility models.

CANADA : Sections 19, 21 and 65 of the Patent Act (R.S., 1985, c. P-4, Act current to 21/01/2010)

Government may apply to use patented invention

19. (1) Subject to section 19.1, the Commissioner may, on application by the Government of Canada or the government of a province, authorize the use of a patented invention by that government.

Terms of use:

(2) Subject to section 19.1, the use of the patented invention may be authorized for such purpose, for such period and on such other terms as the Commissioner considers expedient but the Commissioner shall settle those terms in accordance with the following principles:

- (a) the scope and duration of the use shall be limited to the purpose for which the use is authorized;
- (b) the use authorized shall be non-exclusive; and
- (c) any use shall be authorized predominantly to supply the domestic market.

Conditions for authorizing use:

19.1 (1) The Commissioner may not authorize the use of a patented invention under section 19 unless the applicant establishes that:

(a) it has made efforts to obtain from the patentee on reasonable commercial terms and conditions the authority to use the patented invention; and

(b) its efforts have not been successful within a reasonable period.

Exception:

(2) Subsection (1) does not apply in cases of national emergency or extreme urgency or where the use for which the authorization is sought is a public non-commercial use.

Prescribed uses:

(3) The Commissioner may not, under section 19, authorize any use that is a prescribed use unless the proposed user complies with the prescribed conditions.

Limitation on use of semi-conductor technology:

(4) The Commissioner may not, under section 19, authorize any use of semi-conductor technology other than a public non-commercial use.

Section 21

Use of patents for international humanitarian purposes to address public health problems
Purpose

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

Amending Schedules:

21.03 (1) The Governor in Council may, by order,

- (a) on the recommendation of the Minister and the Minister of Health, amend Schedule 1
 - (i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration, and

(ii) by removing any entry listed in it;

(b) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 2 by adding the name of any country recognized by the United Nations as being a least-developed country that has,

(i) if it is a WTO Member, provided the TRIPS Council with a notice in writing stating that the country intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, and

(ii) if it is not a WTO Member, provided the Government of Canada with a notice in writing through diplomatic channels stating that the country intends to import pharmaceutical products, as defined in paragraph 1(a) of the General Council Decision, that it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of that decision;

(c) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 3 by adding the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision; and

(d) on the recommendation of the Minister of Foreign Affairs, the Minister for International Trade and the Minister for International Cooperation, amend Schedule 4 by adding the name of

(i) any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO Member intends to import, in accordance with the General Council Decision, pharmaceutical products, as defined in paragraph 1(a) of that decision, or

(ii) any country that is not a WTO Member and that is named on the Organization for Economic Co-operation and Development's list of countries that are eligible for official development assistance and that has provided the Government of Canada with a notice in writing through diplomatic channels

(A) stating that it is faced with a national emergency or other circumstances of extreme urgency,

(B) specifying the name of the pharmaceutical product, as defined in paragraph 1(a) of the General Council Decision, and the quantity of that product, needed by the country to deal with the emergency or other urgency,

(C) stating that it has no, or insufficient, pharmaceutical capacity to manufacture that product, and

(D) stating that it agrees that that product will not be used for commercial purposes and that it undertakes to adopt the measures referred to in Article 4 of the General Council Decision.

Authorization:

21.04 (1) Subject to subsection (3), the Commissioner shall, on the application of any person and on the payment of the prescribed fee, authorize the person to make, construct and use a patented invention solely for purposes directly related to the manufacture of the pharmaceutical product named in the application and to sell it for export to a country or WTO Member that is listed in any of Schedules 2 to 4 and that is named in the application.

Abuse of rights under patents:

65. (1) The Attorney General of Canada or any person interested may, at any time after the expiration of three years from the date of the grant of a patent, apply to the Commissioner alleging in the case of that patent that there has been an abuse of the exclusive rights thereunder and asking for relief under this Act.

What amounts to abuse

(2) The exclusive rights under a patent shall be deemed to have been abused in any of the following circumstances:

(a) and (b) [Repealed, 1993, c. 44, s. 196]

(c) if the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms;

(d) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms, the trade or industry of Canada or the trade of any person or class of persons trading in Canada, or the establishment of any new trade or industry in Canada, is prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Canada, or any person or class of persons engaged therein, is unfairly prejudiced by the conditions attached by the patentee, whether before or after the passing of this Act, to the purchase, hire, licence or use of the patented article or to the using or working of the patented process; or

(f) if it is shown that the existence of the patent, being a patent for an invention relating to a process involving the use of materials not protected by the patent or for an invention relating to a substance produced by such a process, has been utilized by the patentee so as unfairly to prejudice in Canada the manufacture, use or sale of any materials.

(3) and (4) [Repealed, 1993, c. 44, s. 196]

Definition of “patented article”:

(5) For the purposes of this section, the expression “patented article” includes articles made by a patented process.

R.S., 1985, c. P-4, s. 65; 1993, c. 2, s. 5, c. 15, s. 51, c. 44, s. 196.

CHILE : *Article 51 of the Industrial Property Law No. 19.039 of 24/01/1991 as last revised in 2005*

Artículo 51.- Procederá pronunciarse respecto de una solicitud de licencia no voluntaria en los siguientes casos:

1) Cuando el titular de la patente haya incurrido en conductas o prácticas declaradas contrarias a la libre competencia, en relación directa con la utilización o explotación de la patente de que se trate, según decisión firme o ejecutoriada del Tribunal de Defensa de la Libre Competencia.

2) Cuando por razones de salud pública, seguridad nacional, uso público no comercial, o de emergencia nacional u otras de extrema urgencia, declaradas por la autoridad competente, se justifique el otorgamiento de dichas licencias.

3) Cuando la licencia no voluntaria tenga por objeto la explotación de una patente posterior que no pudiera ser explotada sin infringir una patente anterior. La concesión de licencias no voluntarias por patentes dependientes quedará sometida a las siguientes normas:

a) La invención reivindicada en la patente posterior debe comprender un avance técnico de significación económica considerable respecto a la invención reivindicada en la primera patente.

b) La licencia no voluntaria para explotar la patente anterior sólo podrá transferirse con la patente posterior.

c) El titular de la patente anterior podrá, en las mismas circunstancias, obtener una licencia no voluntaria en condiciones razonables para explotar la invención reivindicada en la patente posterior.

Tratándose de tecnología de semiconductores, la licencia sólo se podrá otorgar para fines públicos no comerciales o para rectificar la práctica declarada contraria a la competencia.

CHINA : Articles 48-58 of the Patent Law of 12/03/1984 as last amended on 27/12/2008 and State intellectual Property Office Order # 37 of November 2005

Chapter VI Compulsory License for Patent Exploitation

Article 48 - In any of the following cases, the patent administrative department under the State Council may, upon the application of that entity or individual, grant a compulsory license to exploit the patent for the invention or utility model.

(1) where the patentee after the expiration of three years from the date of granting the patent right, and the expiration of four years from the date of filing, has not exploited the patent or has not sufficiently exploited the patent without any justified reasons;

(2) where it has been legally determined that the enforcement of the patent right by the patentee is an act of monopoly, to avoid or to eliminate the adverse effects caused to competition.

Article 49 - Where a national emergency or an extraordinary state of affairs occurs, or where the public interest so requires, the patent administrative department under the State Council may grant a compulsory license to exploit the patent for invention or utility model.

Article 50 - For the purpose of public health, the patent administrative department under the State Council may grant a compulsory license to manufacture a drug which has been granted a patent right in China and to export it to the countries or regions specified in related international conventions in which China is a contracting member.

Article 51 - Where the invention or utility model for which the patent right has been granted constitutes important technical advance of considerable economic significance compared with another invention or utility model for which a patent right has been granted earlier and the exploitation of the later invention or utility model depends on the exploitation of the earlier invention or utility model, the patent administrative department under the State Council may, upon the request of the later patentee, grant a compulsory license to exploit the earlier invention or utility model.

Where, according to the preceding paragraph, a compulsory license is granted, the patent administrative department under the State Council may, upon the request of the earlier patentee, also grant a compulsory license to exploit the later invention or utility model.

Article 52 - Where the invention-creation covered by the compulsory license relates to semiconductor technology, the exploitation under the compulsory license is limited to the use for the purpose of public interest and the conditions specified in Article 48(2).

Article 53 - Except as otherwise provided for in Article 48(2) and 50 of this Law, the compulsory license is used mainly for the supply of the domestic market.

Article 54 - Any entity or individual applying a compulsory license in accordance with the provisions of Article 48(1) or Article 51 of this Law, shall provide proof that it or he has made requests for a license to the patentee to exploit the patent on reasonable conditions but was not licensed within a reasonable period of time.

Article 1 of the State Intellectual Property Office Order # 37 of November 2005

In order to deal with public health problems facing our country (editor's note: hereinafter called China), to help countries and districts concerned to deal with public health problems they face, and to implement the "Declaration on the TRIPS Agreement and Public Health" of the WTO Ministerial Conference in Doha (hereinafter called "Doha Declaration") and the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" of the WTO General Council (hereinafter called "General Council Decision"), SIPO formulated these measures in accordance with the Patent Law of the PRC (hereinafter called "Patent Law").

COSTA RICA : *Articles 18-20 of the Law on Patents, Industrial Designs and Utility Models No. 6867 of 25/04/1983 as last amended on 12/10/2000*

Falta o insuficiencia de explotación industrial

18. - 1. La concesión de una patente conlleva la obligación de explotarla en Costa Rica, en forma permanente y estable, de modo que el mercado sea abastecido conveniente y razonablemente dentro del plazo de tres años, contados a partir de la concesión de la patente o de cuatro años, contados a partir de la solicitud de la patente, según sea el plazo más largo. Tampoco podrá interrumpirse la explotación por más de un año.

(Así reformado por el artículo 2.e) de la Ley 7979 del 6 de enero del 2000)

2. El titular de una patente está obligado, mediante declaración jurada otorgada ante un notario público, a comunicar en forma detallada el comienzo de la explotación al Registro de la Propiedad Industrial.

3. Para efectos del primer párrafo del presente artículo, se considerarán formas de explotación, entre otras, la producción local y la importación lícita de productos.

(Así reformado por el artículo 2.e) de la Ley 7979 del 6 de enero del 2000)

4. La falta de comunicación del comienzo de la explotación dentro del plazo establecido en este artículo, hará presumir la no explotación de la patente.

5. Vencidos los plazos a que se refiere el párrafo 1 de este artículo, cualquier persona podrá solicitar la concesión de una licencia obligatoria por falta de explotación, durante el año siguiente. Si transcurridos los términos la patente no se ha explotado, ésta caducará, salvo caso fortuito o de fuerza mayor comprobada por el titular de la patente.

6. La autorización de las licencias obligatorias será considerada en función de sus circunstancias propias y se extenderán a las patentes relativas a los componentes y procesos que permitan su explotación. Previamente a que se le otorgue una licencia obligatoria, el solicitante deberá probar que tiene la capacidad suficiente para explotar la invención patentada y que ha intentado obtener la autorización del titular de los derechos, en términos y condiciones comerciales razonables y estos intentos no han surtido efectos dentro del plazo fijado en el primer párrafo de este artículo.

Licencia obligatoria en caso de patentes dependientes

19. A. Licencia obligatoria en caso de patentes dependientes

1. Si la invención reivindicada en una patente no puede explotarse industrialmente en el país sin infringir una patente anterior, el Registro de la Propiedad Industrial, a petición del titular de la segunda patente, de su licenciatario o el beneficiario de una licencia obligatoria sobre la patente posterior, otorgará una licencia obligatoria en tanto sea necesaria para evitar la infracción de la patente anterior, con sujeción en lo pertinente a las disposiciones del artículo 18 de la presente ley y a las condiciones siguientes:

a) La invención reivindicada en la segunda patente ha de suponer un avance técnico relevante, de importancia económica considerable con respecto a la invención reivindicada en la primera patente.

b) El titular de la primera patente tendrá derecho a una licencia cruzada en condiciones razonables, para explotar la invención reivindicada en la segunda patente.

c) No podrá cederse el uso autorizado de la primera patente sin la cesión de la segunda patente.

2. El Registro de la Propiedad Industrial deberá conceder, en las mismas circunstancias, licencia obligatoria con respecto a la patente posterior, si lo solicita el titular de la patente anterior, su licenciatario o el beneficiario de una licencia obligatoria sobre esa patente.

B. Licencias obligatorias por prácticas anticompetitivas

1. Serán otorgadas licencias obligatorias cuando la Comisión para Promover la Competencia determine que el titular de la patente ha incurrido en prácticas anticompetitivas.

En estos casos, sin perjuicio de los recursos y audiencias que le competan al titular de la patente, la concesión se efectuará sin necesidad de que:

- a) El potencial licenciataria haya intentado obtener la autorización del titular según el párrafo 6) del artículo 18 de la presente ley.
 - b) Sea para abastecer el mercado interno.
2. No obstante lo dispuesto en el inciso a) del párrafo 1 de este artículo, el titular de la patente objeto de la licencia deberá ser notificado cuando sea razonablemente posible.
3. Para los fines de la presente ley, se considerarán prácticas anticompetitivas, entre otras, las siguientes:
- a) La fijación de precios excesivos o discriminatorios de los productos patentados.
 - b) La falta de abastecimiento del mercado en condiciones comerciales razonables.

El entorpecimiento de actividades comerciales o productivas.

Licencias de utilidad pública

20. - 1. Cuando lo exijan razones calificadas de extrema urgencia, interés público, emergencia o seguridad nacional, el Poder Ejecutivo, mediante decreto, podrá someter la patente o la solicitud de la patente a licencia obligatoria en cualquier momento, aun sin acuerdo de su titular, para que la invención sea explotada por una entidad estatal o por terceros autorizados por el Gobierno. El titular de la patente objeto de la licencia será notificado cuando sea razonablemente posible. Para otorgar estas licencias, deberán observarse, en lo procedente, las disposiciones contenidas en el artículo 18 de la presente ley.

2. Para las licencias de utilidad pública, el Estado deberá compensar al titular de la patente. El titular podrá acudir a la vía contencioso-administrativa a fin de que el tribunal competente establezca la respectiva remuneración económica. Para ello, la autoridad judicial considerará las circunstancias de cada caso y el valor económico de la autorización, teniendo presente la tasa de regalías promedio para el sector de que se trate, en los contratos de licencias comerciales entre partes independientes.

3. Cuando el Gobierno haya otorgado una licencia de utilidad pública a un tercero, este deberá retribuirle al Estado, total o parcialmente, la compensación que corresponda al titular.

(Así reformado por el artículo 2.f) de la Ley 7979 del 6 de enero del 2000).

CROATIA : *Articles 68-69b of the Patents Law No. 173/2003as last amended by Act No. 76/2007*

Article 68 - Grant of a compulsory licence

(1) The competent court in the Republic of Croatia may grant a compulsory license for lack or insufficiency of exploitation of a patent to any person filing a request for the grant of a compulsory license, or to the Government of the Republic of Croatia, if the patent owner has not exploited the invention protected by a patent in the territory of the Republic of Croatia on reasonable terms or has not made effective and serious preparations for its exploitation.

- (2) A request for the grant of a compulsory license based on paragraph (1) of this Article can be filed after the expiration of a period of four years from the filing date of a patent application, or after the expiration of three years from the date the patent was granted.
- (3) A compulsory license cannot be granted if the patent owner provides legitimate reasons to justify non-exploitation or insufficiency of exploitation of the protected invention.
- (4) Upon a reasoned request, the court may grant a compulsory license in respect of a first patent to the owner of a patent or to the owner of a plant variety right who cannot use his patent (second patent) or his plant variety right without infringing the first patent, provided that the invention claimed in the second patent or a protected plant variety involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The competent court may take any measure it regards as useful to verify the existence of such a situation.
- (5) In the case of a compulsory license as provided in paragraph (4) of this Article, the owner of the first patent shall be entitled to a cross license on reasonable terms to use the invention protected by the second patent or protected plant variety.
- (6) The court may grant a compulsory license if the exploitation of the patented invention is necessary in situations of extreme urgency (national security, public interest protection in the field of health, food supply, environmental protection and improvement, specific commercial interest) or when it is necessary to remedy a practice determined by a judicial or administrative process to be anti-competitive.
- (7) In the case of semi-conductor technology, a compulsory license may be granted only in the cases set out in paragraph 6 of this Article.
- (8) A compulsory license may be granted only if the person filing the request has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time. The court may derogate from these conditions in the situations set out in paragraph (6) of this Article. The right holder shall be informed of the granting of a compulsory license as soon as is reasonably possible.

Article 69 - Conditions applicable to the grant of a compulsory license

- (1) A compulsory license shall be non-exclusive, and its scope and duration shall be exclusively limited to the purpose for which it was authorized.
- (2) A compulsory license shall be transferred only with the production plant or the part thereof respectively, in which the invention it is granted for has been exploited.
- (3) A compulsory license shall be granted predominantly for the purposes of supplying the domestic market unless it is necessary to correct a practice determined by judicial or administrative process to be anti-competitive.
- (4) The competent authority shall, upon reasoned request by an interested person, cancel a compulsory license, subject to adequate protection of the legitimate interests of the persons so authorized, if and when the circumstances which led to its authorization cease to exist and are unlikely to recur.
- (5) The patent owner has the right to remuneration, taking into account the economic value of the authorization and need to correct anti-competitive practice.
- (6) A compulsory license according to Article 68 paragraph (4) of this Act shall be non-transferable except with a transfer of the second patent or the protected plant variety.

3. Compulsory licences for patents relating to the manufacture of pharmaceutical products intended for export to countries having public health problems”, and headings and Articles 69a to 69h are added to read:

Article 69a - Granting of a compulsory license

(1) The court may grant to any person filing an application pursuant to the provisions of this Act, a compulsory licence for a patent and/or issue a Supplementary Protection Certificate required for the manufacture and sale of pharmaceutical products, when such products are intended for export to importing countries having public health problems. When deciding on the grant of a compulsory licence the court shall take into consideration in particular, the need to implement the Decision adopted by the WTO General Council on 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (hereinafter: the Decision) of 14 November 2001.

(2) The pharmaceutical product referred to in paragraph (1) of this Article shall be any product of the pharmaceutical industry, including medicinal products for human use, comprising any substance or combination of substances intended for treating or preventing disease in human beings, and any substance or combination of substances, which may be administered to human beings with a view to restoring, correcting or modifying physiological functions in humans, by exerting a pharmacological, immunological or metabolic action, or to making a medicinal diagnosis, including active ingredients and diagnostic kits *ex vivo*.

(3) The importing country referred to in paragraph (1) of this Article shall be any country to which the pharmaceutical product is to be exported. The importing country may be:

(a) any least-developed country appearing as such in the United Nations list;

(b) any member of the WTO, other than the least-developed country members referred to in item (a) of this paragraph that has made a notification to the Council for TRIPS of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way;

(c) any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee’s list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Office of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

(4) Any WTO member that has made a declaration that it will not use the system as an importing WTO member is not an eligible importing country.

(5) Importing countries, which are not WTO members, and are least developed or developing countries, eligible under paragraph (3) of this Article shall comply with additional requirements:

(a) the importing country shall make the notification pursuant to the Decision directly to the Office;

(b) the importing country shall state in the notification that it will use the system to address public health problems, and not as an instrument to pursue industrial or commercial policy objectives, and that it will adopt the measures referred to in paragraph 4 of the Decision;

(c) the court may, upon a legal action instituted by a right holder or by the Office, terminate a compulsory license, if the importing country has failed to comply with its obligations referred to in item (b).

(6) A legal action containing an application for the grant of a compulsory license shall be instituted before the court pursuant to the provisions of Article 67a of this Act, if in the territory of the Republic of Croatia there is a patent or a Supplementary Protection Certificate the effects of which cover the intended manufacturing and sale activity for export purposes.

(7) A legal action shall contain:

(a) information concerning the applications for compulsory licences filed in other countries for the same product with details of the quantities and importing countries concerned;

(b) information concerning the applicant for a compulsory licence and of her/his representative, if any;

(c) the non-proprietary name of the pharmaceutical product, which the applicant intends to manufacture under the compulsory licence;

(d) the quantity of the pharmaceutical product, which the applicant intends to manufacture under the compulsory licence;

(e) the importing country;

(f) evidence of prior negotiations with the right holder pursuant to the provisions of paragraph (10) of this Article;

(g) evidence of a specific request from an authorized representative of the importing country, or a non-governmental organization acting with the formal authorization of one or more importing countries, or UN bodies or other international health organization acting with the formal authorization of one or more importing countries, indicating the quantity of the product required.

(8) When deciding on an application for the grant of a compulsory license, the court shall verify in particular the following:

(a) whether each importing country cited in the application, which is a WTO member, has made a notification to the WTO pursuant to the Decision, or whether each importing country cited in the application, which is not a WTO member, has made a notification to the Office pursuant to the provisions of this Article in respect of each of the products covered by the application. This shall be without prejudice to the possibility, which the least-developed countries have pursuant to the Decision of the TRIPS Council of 27 July 2002;

(b) that the quantity of the product cited in the application does not exceed that notified to the WTO and the Office, respectively, by an importing country, which is a WTO member;

(c) that, taking into account other compulsory licenses granted elsewhere, the total amount of the product authorized to be produced for any importing country does not significantly exceed the amount notified by that country to the WTO, and the Office, respectively.

(9) The information referred to in paragraph (8) of this Article shall be provided and presented in a legal action by the applicant for the grant of a compulsory licence.

(10) A compulsory license may be granted only if the applicant has made efforts to obtain authorization from the patent owner for the exploitation of the protected invention on reasonable commercial terms and conditions, and if such efforts have not been successful within thirty days prior to a legal action. This provision shall not apply in situations of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use, pursuant to Article 31, item (b) of the TRIPS Agreement.

Article 69b

(1) A compulsory license shall be granted as a non-exclusive license, and its scope and duration, which shall be cited in a decision on its grant, shall be exclusively limited to the purpose for which it has been granted. The quantity of products to be manufactured under such licence shall not exceed the quantity necessary to satisfy the needs of the importing country, or importing countries cited in a legal action, taking into account the quantity of the products manufactured under compulsory licenses granted elsewhere.

(2) A compulsory license shall be transferred only with the production plant in which the invention, it is granted for, has been exploited.

(3) In its decision the court shall specify the acts, which the applicant is entitled to perform, and which are necessary for the purpose of manufacturing the products intended for export and distribution in the country or countries cited in the application. No product made or imported under a compulsory license shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question.

(4) In its decision the court shall order that the products made under such license shall be clearly identified, through specific labeling or marking, as being produced under a compulsory licence. The products shall be distinguished from those made by the right holder through special packaging and/or special coloring or shaping, provided that such distinction is feasible, and does not have a significant impact on price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory license, giving the name of the competent court which granted it, the file number and specifying clearly that the product is intended exclusively for export to and distribution in the importing country or countries. Details of the product characteristics shall be made available to the customs authorities in the Republic of Croatia and the Member States of the European Union.

(5) In its decision the court shall order that before shipment to the importing country the licensee shall post on a web site, the address of which shall be communicated to the Office, the following information:

(a) the quantities of products being supplied under the licence to the importing countries;

(b) the distinguishing features of the product concerned.

(6) If a product covered by a compulsory licence granted in the Republic of Croatia, is patented in the importing country cited in the application, the product shall only be exported if

those countries have issued a compulsory licence for the import, sale and/or distribution of the product concerned.

(7) In its decision the court shall order the applicant to pay remuneration to the right holder, as determined by the court as follows:

(a) in the cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31 item (b) of the TRIPS Agreement, the remuneration shall be a maximum of 4% of the total price to be paid by the importing country or on its behalf;

(b) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorized under the license to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the license.

(8) When the court decision on the grant of a compulsory license has become final, the court may, upon a claim for the preservation of evidence filed by the right holder, inspect books and other records kept by the licensee, for the sole purpose of checking whether all the obligations contained in the court decision on the grant of a compulsory license, and in particular those relating to the final destination of the products, have been complied with. The books and records shall contain a proof of exportation of the product, in the form of a declaration of exportation certified by the customs authority, and a proof of importation.

(9) The license conditions shall be without prejudice to the method of distribution in the importing country.

CUBA : *Articles 69-73 of the Law No. 68 of 14/05/1983*

Artículo 69

El Director de la Oficina, a instancia de un tercero, tiene derecho a otorgar la concesión de una licencia obligatoria para la explotación de una invención protegida por un Certificado de Patente de Invención o por un Certificado de Patentes de Invención de Adición si no se encuentra en explotación, si es de importancia para la economía nacional y si no se ha podido llegar a un acuerdo con su titular.

Artículo 70

No se hará uso de la licencia obligatoria antes de los tres años siguientes a la fecha de concesión o antes de los cuatro años siguientes a la presentación de la solicitud. De ambos términos, se aplica siempre el que expire último.

Artículo 71

De no llegarse a un acuerdo entre el titular y el poseedor de una licencia obligatoria sobre el monto y los términos de pago, el Director de la Oficina decide definitivamente sobre los mismos.

En cuanto al procedimiento a seguir, así como el monto y los términos del pago se regulan en el Reglamento del presente Decreto-Ley.

Artículo 72

Si la explotación de una invención protegida por un Certificado de Patente de Invención de Adición o por un Certificado de Autor de Invención de Adición no puede efectuarse sin que se cometa una violación de un Certificado de Patente de Invención anterior, la Oficina, a petición del titular del Certificado de Patente de Invención de Adición o del Certificado de Autor de Invención de Adición, puede conceder una licencia obligatoria para la explotación de la invención protegida por el Certificado de Patente de Invención anterior, siempre que dicha invención represente un progreso tecnológico importante.

Artículo 73

El Director de la Oficina puede modificar las condiciones de concesión de una licencia obligatoria o de oficio, cuando nuevas situaciones lo justifiquen, a petición del titular o del beneficiario de la licencia obligatoria o de oficio.

CYPRUS (EU) : *Articles 49-56 of the Patent Law of 01/04/1998, No. 16(1) (Amended in 2000, 2002 and 2006 but no text available in English)*

Non-Voluntary Licenses

Article 49.-(1) At any time after the expiration of four years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the Registrar on one or more of the grounds specified in paragraph (2) below

(a) for a non-voluntary license under the patent,

(b) where the applicant is a government department, for the grant to any person specified in the application of a license under the patent.

(2) The grounds for the submission for non-voluntary license are:

(a) where the patented invention is capable of being commercially worked in Cyprus but it is not being so worked or is not being so worked to the fullest extent that is reasonable practicable;

(b) where the patented invention is a product for which demand in Cyprus

(a) is not being met or

(b) is not being met on reasonable terms or

(c) that by reason of the refusal of the proprietor of the patent to grant a license or licenses on reasonable terms:

(i) a market for the export of any patented product made in Cyprus is not being supplied or

(ii) the working or efficient working in Cyprus of any other patented invention which makes a substantial contribution to the art is prevented or hindered or

(iii) the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced;

(d) that by reason of conditions imposed by the proprietor of the patent on the grant of licenses under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in Cyprus is unfairly prejudiced.

(3) Subject to the provisions of paragraphs (4) and (6) below, if the Registrar is satisfied that any of the therein mentioned grounds are established, he may-

(a) where the application is under paragraph (1)(a) above, order the grant of a license to the applicant on such terms as the Registrar thinks fit;

(b) where the application is under paragraph (1)(b) above, order the grant of a license to the person specified in the application on such terms as the Registrar thinks fit.

(4) Where the application is made on the ground that the patented invention is not being commercially worked in Cyprus or is not being so worked to the fullest extent that is reasonably practicable, and it appears to the Registrar that the time which has elapsed since the publication in the Official Gazette of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, the Registrar may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

(5) No entry shall be made in the register under this Article on the ground mentioned in paragraph (2)(c)(i) above, and any license granted under this Article on that ground shall contain such provisions as appear to the Registrar to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(6) No order or entry shall be made under this Article in respect of a patent (the patent concerned) on the ground mentioned in paragraph (2)(c)(ii) above unless the Registrar is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a license under the patent for the other invention on reasonable terms.

(7) An application may be made under this Article in respect of a patent notwithstanding that the applicant is already the holder of a license under the patent; and no person shall be stopped or barred from alleging any of the matters specified in paragraph (2) above by reason of any admission made by him, whether in such a license or otherwise, or by reason of his having accepted such a license.

Provisions about Licenses under Article 49

Article 50.-(1) Where the Registrar is satisfied, on an application made under Article 49 above in respect of a patent, that the manufacture, use or disposal of materials not protected by the patent is unfairly prejudiced by reason of conditions imposed by the proprietor of the patent on the grant of licenses under the patent, or on the disposal or use of the patented

product or the use of the patented process, he may (subject to the provisions of that Article) order the grant of licenses under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

(2) Where an application under Article 49 above is made in respect of a patent by a person who holds a license under the patent, the Registrar-

(a) may, if he orders the grant of a license to the applicant, order the existing license to be canceled or

(b) may, instead of ordering the grant of a license to the applicant, order the existing license to be amended.

(3) Where, on an application under Article 49 above in respect of a patent, the Registrar orders the grant of a license, he may direct that the license shall operate-

(a) to deprive the proprietor of the patent of any right he has to work the invention concerned or grant licenses under the patent;

(b) to revoke all existing licenses granted under the patent.

Exercise of Powers on Applications under Article 49

Article 51.-(1) The powers of the Registrar on an application under Article 49 above in respect of a patent shall be exercised with a view to securing the following general purposes:

(a) that inventions which can be worked on a commercial scale in Cyprus and which should in the public interest be so worked shall be worked there without undue delay and to the fullest extent that is reasonably practicable;

(b) that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention;

(c) that the interests of any person for the time being working or developing an invention in Cyprus under the protection of a patent shall not be unfairly prejudiced.

(2) Subject to paragraph (1) above, the Registrar shall, in determining whether to make an order or entry in pursuance of such an application, take account of the following matters, that is to say-

(a) the nature of the invention, the time which has elapsed since the publication in the Official Gazette of the Republic of a notice of the grant of the patent and the measures already taken by the proprietor of the patent or any licensee to make full use of the invention;

(b) the ability of any person to whom a license would be granted under the order concerned to work the invention to the public advantage; and

(c) the risks to be undertaken by that person in providing capital and working the invention if the application for an order is granted,

but shall not be required to take account of matters subsequent to the making of the application.

Opposition and Arbitration

Article 52.-(1) The proprietor of the patent concerned or any other person wishing to oppose an application under Articles 49 to 51 above may, in accordance with the rules, give to the Registrar notice of opposition and the Registrar shall consider the opposition in deciding whether to grant the application.

(2) Where an application under Articles 49 to 51 above is opposed under paragraph (1) above and either-

(a) the parties consent or

(b) the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot in the opinion of the Registrar conveniently be made before him,

the Registrar may at any time order the whole proceedings, or any question or issue of fact arising in them, to be referred to an arbitrator or mediator agreed upon by the parties, or in default of agreement, appointed by the Registrar.

(3) Where a question or issue of fact is so referred, the arbitrator or arbiter shall report his findings to the Registrar and the Registrar shall proceed to issue a decision.

Supplementary Provisions

Article 53. In any proceedings on an application made in relation to a patent under Articles 49 to 51 above, any statement with respect to any activity in relation to the patented invention, or with respect to the grant or refusal of licenses under the patent, contained in a report of the Commission for Protection against Unfair Competition shall be prima facie evidence of the matters stated.

Special Provisions where Patented Invention Is Being Worked Abroad

Article 54. The import into Cyprus of any product protected by a patent granted by any country member of the World Trade Organization shall be considered as use in Cyprus.

Exploitation by Government or by Third Parties Authorized by Government

Article 55. Where the national security or public safety so requires, the Council of Ministers may authorize, even without the agreement of the proprietor of the patent or the patent application, by notice published in the Official Gazette, a government agency or a person designated in such notice to make, use or sell an invention to which a patent or an application for a patent relates, subject to payment of equitable remuneration to the proprietor of the patent or the application for the patent. The decision of the Council of Ministers with regard to remuneration may be the subject of a recourse to the Court.

Provisions for Non-Voluntary License

Article 56. Where according to Articles 50, 51 and 55 of the present Law a license is given for use of the subject-matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

- (a) authorization of such use shall be considered on its individual merits;
- (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement is waived in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semiconductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market;
- (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The Registrar shall have the authority to review, upon motivated request, the continued existence of these circumstances;
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
- (i) the legal validity of any decision relating to the authorization of such use shall be subject to review by the Court.

CZECH REPUBLIC (EU) : *Section 20 of the Law on Inventions, Industrial Designs and Rationalization Proposals No. 527 of 27/11/1990 as last amended by Act No. 207/2000 Coll. and Act No. 378/2007*

Compulsory License

20.-

- (1) If no agreement is reached on the conclusion of a license contract, the Office may grant a compulsory license:
 - (a) if the owner of the patent does not work his patent at all or works it insufficiently and cannot give legitimate reasons for his failure to act; a compulsory license may not be granted prior to the expiration of four years as from the filing date of the patent application or three years as from the date of grant of the patent, whichever period expires last;
 - (b) If an important public interest is endangered.
- (2) The grant of a compulsory license shall not affect the right of the owner to obtain compensation in respect of the value of the license.

DENMARK (EU) : *Sections 45-50 of the Consolidate Patent Act No. 91 of 28/01/2009*

45.-(1) If a patent invention is not worked to a reasonable extent in this country when 3 years have elapsed from the grant of the patent and 4 years have elapsed from the filing of the patent application, any person wishing to work the invention in this country may obtain a compulsory license to do so, unless there are legitimate reasons for failure to work the invention.

(2) The Minister for Trade and Industry may direct that for the purposes of subsection 1 hereof working of the invention in another country shall be equivalent to working in this country. Such a provision may be made subject to reciprocity.

46.-(1) The proprietor of a patent for an invention, the use of which is dependent on a patent or a registered utility model which belongs to another person may obtain compulsory license for use of the protected invention of the latter patent or the protected model on utility model registration if the former invention makes up an essential technical progress of substantial economic importance.

(2) The proprietor of the patent of the invention or of the registered utility model for which use compulsory license has been granted pursuant to the provision in (1) shall on reasonable terms be able to obtain compulsory license for use of the other invention.

46a.-(1) An owner of a variety who cannot acquire or exploit a plant variety right without infringing a prior patent may apply for a compulsory license for use of the invention, if the compulsory license is necessary for the exploitation of the plant variety to be protected, against payment of an appropriate royalty. Compulsory license will only be granted provided that the owner of the variety proves that the variety constitutes essential technical progress of substantial economic importance in relation to the invention.

(2) Where, under the Danish Plant Variety Protection Act, a proprietor of a patent has obtained a compulsory license to exploit a protected plant variety, the owner of the plant variety has the right, on reasonable terms, to obtain cross-license for use of the invention.

47. When required by important public interests, any person who wishes to exploit an invention commercially for which another person holds a patent may obtain a compulsory license to do so.

48.-(1) Any person who, in this country, at the time when a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for, may, if the application results in a patent, obtain a compulsory license to exploit the invention, if very special circumstances make it desirable, and he had no knowledge and could not reasonably have obtained any knowledge of the application. Such a right shall also, under similar conditions, be enjoyed by any person who had made substantial preparations for commercial exploitation of the invention in this country.

(2) Such a compulsory license may include the time preceding the grant of the patent.

(3) The Minister for Business and Industry may direct that for the purposes of subsection 1 hereof exploitation of the invention in another country shall be equivalent to exploitation in this country. Such a provision may be made subject to reciprocity.

49.-(1) Compulsory license shall only be granted to persons who by agreement have not been able to obtain license on reasonable terms and who may be regarded as being able to make use of the invention in a reasonable and proper manner and in compliance with the license.

(2) A compulsory license shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licenses to others.

(3) Compulsory license can only be transferred to others together with the establishment in which it is used or in which the utilisation was intended. For compulsory license filed in accordance with Section 46(1) it shall moreover be applicable that transfer of compulsory license shall take place together with the patent the use of which is dependent on a patent or a registered utility model which belongs to another person.

(4) Compulsory license concerning semiconductor technology can only be filed for public, non-commercial use or for terminating an anti-competitive practice, which has been established by decree or administrative decision.

DOMINICA : *Sections 35, 38 and 39 of the Patent Act No. 8 of 07/10/1999*

35. (1) Where:

(a) the public interest, in particular national security, nutrition, health, or the development of other vital sectors of the national economy so requires; or

(b) the Minister has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and he is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practise,

The Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Minister's authorisation, as determined in the said decision, and, where a decision has been taken under subsection 1 (b), the need to correct anti-competitive practises.

(3) The Minister shall make his decision after hearing the owner of the patent and any interested person.

(4) A request for the Minister's authorisation to exploit a patented invention shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorisation, a request for contractual license, but that that person has been unable to obtain such a license on reasonable commercial terms and conditions within a reasonable time.

(5) Subsection (4) shall not apply in cases of:

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as reasonably practicable;

(b) public non-commercial use, and

(c) anti-competitive practices determined as such by the Minister in accordance with subsection (1) (b).

(6) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorised for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive, and if the Minister is satisfied that the issuance of the non-voluntary license would remedy such practice.

(7) The authorisation shall not exclude –

- (i) the conclusion of license contracts by the owner of the patent; or
- (ii) the continued exercise, by the owner of the patent, of his rights under section 33(2); or
- (iii) the grant of a non-voluntary license under section 38.

(8) Where a third person has been designated by the Minister, the authorisation may only be transferred with the enterprise or business of that person or with the part of enterprise or business within which the patented invention is being exploited.

(9) The exploitation of the patented invention by the Government agency or third person designated by the Minister shall be predominantly for the supply of the market of Dominica.

(10) Upon the request of the owner of the patent, of the Government agency or of the third person authorised to exploit the patented invention, the Minister may, after hearing the parties, vary the terms of the decision authorising the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(11) Upon the request of the owner of the patent, the Minister shall terminate the authorisation if he is satisfied, after hearing the parties, that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the Government agency or third person designated by him has failed to comply with the terms of the decision.

(12) Notwithstanding subsection (11), the Minister shall not terminate the authorisation if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by him justifies the maintenance of the decision.

38. (1) (a) At any time after the expiration of four years from the date of filing of a patent application or three years from the date of grant of the patent, whichever happens later, any interested person may apply to the Court for the grant of a non-voluntary licence under the patent on the grounds that the patented invention is not being exploited or is being

insufficiently exploited by working the invention in Dominica, or by importation into Dominica.

(b) Notwithstanding paragraph (a), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Court that circumstances exist which justify the exploitation or insufficient exploitation of the patented invention in Dominica.

(2) The Court shall, where it grants a non-voluntary licence, fix –

(a) the scope and function of the licence;

(b) the time limit within which the licensee must begin to exploit the patented invention; and

(c) the amount of the remuneration to be paid to the owner of the patent, and the conditions of the payment thereof.

The beneficiary of the non-voluntary licence shall:

(a) have the right to exploit the patented invention in Dominica in accordance with the Court's order;

39. The powers of the Court on an application under section 38 shall be exercised with a view to ensuring that the inventor or other person beneficially entitled to a patent receives adequate remuneration having regard to the economic value of the licence.

DOMINICAN REPUBLIC : *Articles 39-42 and 44-48 of the Law on Industrial Property No. 20-00 of 18/04/2000*

Article 39.- Exploitation of the Patent

For the effects of Article 41 of this law, exploitation of a patent is understood as follows:

a) When the patent has been granted for a product or for a procedure for the obtaining of a product, supply to the internal market in reasonable quantity, quality and price, through production in this country and importation.

b) When the patent has been granted for a procedure not included in subparagraph a), the use of the procedure on a commercial scale in this country.

Article 40.- Compulsory licenses

When a potential user has attempted to obtain the granting of a license from the patent holder under reasonable commercial terms and conditions and such attempts have not been effective after a period of two hundred and ten (210) days, counted from the date on which the respective license was applied for, the General Agency for Industrial Property, after prior hearing of the holder, shall be able to issue compulsory licenses relating to that patent. In all cases that merit it, the National Agency for Industrial Property shall concede compulsory licenses when the interested party demonstrates:

a) That he/she possesses the technical and economic capacity to confront the exploitation in question. Technical capacity shall be evaluated by the competent authority, in compliance with the specific regulations in the country that exist in each field of

activity. Economic capacity shall be understood as the possibility to fulfill the obligation that derive from the exploitation that is to be undertaken.

b) When the patent refers to raw material from which a final product is to be developed, that the applicant is able to develop the final product independently or through third parties in the country, save cases in which production is impossible in national territory.

2) To determine what is understood by reasonable commercial terms and conditions, the particular circumstances of each case and the economic value of the authorization must be taken into account, keeping in mind the average rate of royalties for the sector in question in contracts for commercial licenses between independent parties.

Article 41.- Compulsory License for lack of Exploitation

1) After three (3) years from the granting of the patent, or four (4) years from the filing of the application, applying whichever term expires later, if the invention has not been exploited or when the exploitation of the same has been interrupted for more than one (1) year without justifiable cause, any person with the ability to exploit the invention may apply to the General Agency for Industrial Property to grant him or her an compulsory license for the patent in question.

2) A compulsory license shall not be granted when it is demonstrated that the lack or insufficiency of exploitation is due to fortuitous circumstances or *force majeure*, or to circumstances beyond the will or control of the patent holder and which justify the lack or insufficiency of exploitation. The lack of economic resources and the lack of economic viability of the exploitation are not considered justifying circumstances.

Article 42.- Compulsory Licenses for Anti-competitive Practices

Compulsory licenses shall be granted when the General Agency for Industrial Property has determined that the patent holder has indulged in anti-competitive practices. In such cases, without prejudice to the appeals available to the patent holder, the concession shall be carried out without the need to apply the procedure set forth in numeral 2 of Article 43. For the purposes of this law, the following practices, among others, are considered to be anti-competitive:

a) Setting excessive or discriminatory prices for the patented products. In particular, when there are offers of supply to the market at prices significantly lower than those offered by the patent holder for the same product.

b) Failure to supply the market under reasonable commercial conditions.

c) Hindrance of commercial or productive activities

d) The other actions set forth as such by this code and every other action which national legislation typifies as anti-competitive, limiting or restrictive to competition.

Article 44.- Conditions for the Granting of Compulsory Licenses

1) To grant compulsory licenses, the following provisions must be observed:

a) The granting of same must be by the General Agency for Industrial Property.

b) The circumstances of each case shall be considered.

c) The compulsory licenses shall be extended to patents relating to the components and processes permitting their exploitation

d) The granting of these licenses shall not be exclusive.

e) They may not be assigned, except for that part of the company or of its intangible asset that forms part of it.

f) They shall be granted principally to supply the internal market, except in the cases established in Articles 41 and 46.

g) The patent holder shall receive a reasonable remuneration according to the circumstances of each case, taking into account the economic value of the authorization. In determining the amount of the remuneration in cases in which the compulsory licenses have been granted to remedy anti-competitive practices, the necessity of correcting such practices shall be taken into account and the revocation of the grant may be denied if it is considered probable that the conditions that caused that granting have been repeated.

- 2) The person to whom the compulsory license is granted must begin its exploitation within two years of the granting of the license to him.
- 3) When the patent protects any semiconductor technology, compulsory licenses shall be granted only for non-commercial public use, or to rectify a practice declared to be contrary to competition.
- 4) A compulsory license may be completely or partially revoked by the court created by this Code, upon request by the holder, if the circumstances that gave rise to the license have ceased to exist and it is improbable that they will again arise, so long as such revocation does not affect the legitimate interests of the licensee.
- 5) A compulsory license can be modified by the court created by this Code, upon application by an interested party, when so justified by new facts or circumstances.

Article 45.- Compulsory License in the Case of Dependent Patents

- 1) When an invention claimed in a subsequent patent cannot be exploited in this country without infringing an earlier patent, the General Agency for Industrial Property, upon the request of the holder of the first mentioned patent or of his licensee, or of the beneficiary of a compulsory license for that patent, may grant a compulsory license with regard to the earlier patent insofar as may be necessary to avoid the infringement.
- 2) The compulsory license shall be granted only when the invention claimed in the subsequent patent implies an important technical advance of considerable economic significance with regard to the invention claimed in the earlier patent.
- 3) When a compulsory license is granted in conformity with numeral 1, a compulsory license may be granted in the same circumstances with regard to the later patent, if the holder of the earlier patent, his licensee or the beneficiary of a compulsory license for said earlier patent applies for it.
- 4) A compulsory license of those set forth in this article cannot be granted as exclusive. This compulsory license can only be the object of transfer simultaneously with the dependent patent the industrial exploitation of which requires the license. The transfer of the compulsory license shall be subject to the provisions of Article 32, numeral 2, insofar as is appropriate.
- 5) The provisions of Articles 43 and 44, insofar as they are appropriate, are applicable to the licenses set forth in this article.

Article 46.- Public Interest licenses

For reasons of public interest, and in particular for reasons of emergency or national security declared by the Executive Power, the General Agency for Industrial Property, at the request of any interested person or competent authority, or on its own initiative, shall at any time order the following:

a) that an invention which is the object of a patent or patent application being processed be exploited by a government agency or by one or more public or private persons designated for the purpose.

b) that an invention that is the object of a patent or of a patent application being processed be open for the granting of licenses in the public interest, in which case the General Agency for Industrial Property shall grant a license for exploitation to any person who applies for it and has the ability to carry out such exploitation in this country.

Article 47.- Conditions for Public Interest Licenses

1) Every public interest license implies the corresponding payment to the patent holder. After prior hearing of the parties, and in the absence of an agreement, the amount and method of payment shall be set by the General Agency for Industrial Property, according to Articles 44, literal g).

2) A public interest license can refer to the execution of any of the actions referred to in Article 29, numeral 1.

3) The provisions of Articles 43 and 44, insofar as appropriate, are applicable to the granting of public interest licenses.

4) The granting of a compulsory license by reason of public interest shall not diminish the right of the patent holder to continue exploiting it.

Article 48.- Revocation of the Patent in Case of Abuse

1) At the request of any interested person or of any competent authority, the General Agency for Industrial Property can revoke a patent when the rights conferred by the patent are abused with regard to anti-competitive practices or abuse of a dominant market position in such a way that the national economy is unduly affected.

2) The request for revocation may not be presented until two years have passed counting from the date of granting of the first compulsory license.

EGYPT : Articles 23 and 24 of the Law on the Protection of Intellectual Property Rights No. 82 of 2002

Article 23

The Patent Office may, subject to the approval of a ministerial committee to be established by a decision of the Prime Minister, grant non-voluntary licenses for the exploitation of an invention. The committee decides the financial rights of the patent owner when such licenses are issued, in any of the following cases:

(1) Where the competent Minister finds — under the circumstances — that the exploitation of the patent will benefit the following:

(a) Public non-commercial interest. This includes the preservation of national security, health, environment and food safety.

(b) Cases of emergency or circumstances of extreme urgency.

A non-voluntary license to counter the conditions mentioned in items 1 and 2 is granted without prior negotiations with the patent owner or after a certain period of negotiations with the patent owner or offering reasonable conditions to acquire his agreement to the exploitation.

(c) Support of national efforts in vital sectors for economic, social and technological development, without unreasonable prejudice to the rights of the patent owner and taking into consideration the legitimate interests of third parties.

In cases stated in items 1 and 3, the owner of the patent shall be notified promptly of the decision of non-voluntary exploitation, and as soon as reasonably practicable in cases stated in item 2 .

(2) Upon the request of the Minister of Health, when the quantity of patented medicines made available fail to adequately meet the national needs, due to their poor quality or if they are offered at a prohibitive price, or if the patent is related to medicines addressing critical cases, incurable or endemic diseases or products used in the prevention of these diseases, or where the invention is related to the medicines, their manufacturing process, the raw materials necessary for their preparation or the process of manufacturing of those materials.

In all these cases, the decision of granting non-voluntary license shall be notified promptly to the owner of the patent.

(3) Where the patent owner refuses to grant license to a third party seeking the exploitation of the invention, whatever the purpose of the exploitation, and despite the offer of suitable terms and the lapse of reasonable negotiation time.

In this case, the party requesting the non-voluntary license shall provide evidence that he has made serious efforts to obtain a voluntary license from the patent owner.

(4) If the owner of the patent fails to exploit the invention in Egypt, himself or through his consent; or if the patent was not sufficiently exploited after the lapse of four years since the date of the application or three years since the grant of the patent, whichever comes later; or if the patent owner suspended, without a valid reason, the exploitation of the patent for more than one year.

The exploitation of a patent shall be through the manufacturing of the patented product or the use of the patented process in Egypt.

Nevertheless, where the Patent Office finds that, despite the expiration of either of the above mentioned time limits, failure to exploit the invention was due to legal, technical or economic reasons beyond the power of the owner of the patent, it may decide to allow him a sufficient period of grace for the exploitation of the invention.

(5) If it is determined that the patent owner has abused of or exercised the rights conferred by the patent in a manner that is contrary to fair competition, such as:

(a) Fixing exorbitant prices for the patented products or preferential treatment of agents with regards to prices and sales conditions.

(b) Failure to supply the local market with the patented product, or supplying it under prohibitive terms.

(c) Stopping the production of the patented item or its production in a disproportionate manner, given the production capacity and the market needs.

(d) Undertaking acts or practices which have adverse effect on the free competition, according to the prescribed legal norms.

(e) Exercising of the rights conferred by the this Law in a manner that adversely affects the transfer of technology.

In all above cases, the non-voluntary license is granted without recourse to negotiation or the expiry of a time limit thereto, even if the non-voluntary license is not intended to satisfy the needs of the domestic market.

The Patent Office may refuse to terminate the non-voluntary license, where the conditions that called for it are likely to remain or to reoccur.

The compensation due to the owner of the patent shall take into account the prejudice caused by his arbitrary or unfair competition practices.

The Patent Office may revoke the patent if, two years after the grant of a non-voluntary license, it became clear that the grant of that license was not adequate to remedy the adverse effects caused to the national economy by the r the patent owner's abuse of his rights or his unfair competition practices.

Any concerned party may challenge the revocation of a patent before the Committee provided for in Article 36, and in accordance with the conditions and procedures prescribed in the Regulations.

(6) Where the exploitation of an invention by the legitimate patent holder requires inevitably the use of another invention, underlying concrete technical advance as well as technical and economical significance compared to the other, he shall be entitled to obtain a non-voluntary license for the exploitation of the other invention, in which case the other patent holder shall equally have the same right.

The licensed exploitation of one patent may not be assigned without the corresponding assignment of the other.

(7) The grant of a non-voluntary license in the field of semi-conductor technology shall be authorized for public non-commercial purposes only, or to remedy the consequences of any unfair competition practices.

The grant of non-voluntary licenses in the cases provided for in this Article, shall be in accordance with the rules and procedures prescribed in the Regulations.

Article 24

Where a non-voluntary license is to be issued, the following elements shall be taken into account:

(1) A request for the grant of the non-voluntary license shall be considered on the merits of each case. The license shall mainly seek to satisfy the needs of the domestic market.

(2) The requesting party shall prove that he has made serious attempts during a reasonable period of time to obtain a voluntary license from the patent holder against fair compensation, and that he failed.

- (3) The patent owner may, within one month from his notification of the grant of the license, appeal to the Committee provided for in Article 36 and in accordance with the conditions and procedures stipulated by the Regulations, against the decision to grant the non-voluntary license to a third party.
- (4) The party requesting the grant of a non-voluntary license, or the party to whom a non-voluntary license is granted, must have the capacity to efficiently exploit the invention in Egypt.
- (5) The licensee must abide by the scope, terms and period prescribed by the decision granting the such a license. The Patent Office may extend the duration of the license if it expires without achieving its purpose.
- (6) The use of the non-voluntary license shall be limited to the applicant; the Patent Office may however grant it to a third party.
- (7) The beneficiary shall not assign the rights of a non-voluntary license to a third party except with the enterprise or the part related to the exploitation of the patent.
- (8) The patent owner shall be entitled to a fair compensation for the exploitation of his invention. The amount of the compensation shall be fixed on the basis of the economic value of the invention. He shall have the right to appeal against the compensation assessment, within 30 days of being notified the decision, before the Committee provided for in Article 36, in accordance with the rules and procedures prescribed by the Regulations.
- (9) The non-voluntary license shall lapse on the expiry of its duration. Nonetheless, the Patent Office may decide to terminate the non-voluntary license if the reasons which led to its grant cease to exist and are unlikely to reoccur; in which case, the procedure prescribed by the Regulations shall apply.
- (10) The patent owner may request the termination of the non-voluntary license before its expiry, if the reasons which led to its grant cease to exist and are unlikely to reoccur.
- (11) Where a non-voluntary license is terminated before its term, the legitimate interests of the licensee shall be taken into account.
- (12) The non-voluntary license may be terminated or its terms amended by the Patent Office, or upon a request from any interested party, if within two years after the grant of the non-voluntary license, the licensee fails to exploit the subject matter of the license or to meet his obligations as prescribed by the license.

EL SALVADOR : *Articles 133 and 134 of the Intellectual Property Legislative Decree No. 604 of 15/07/1993, as last amended by the Intellectual Property Legislative Decree Amendment No. 912 of 14/12/2005*

Article 133. When reasons of emergency or national security have been declared and for as long as they persist, compulsory licenses may be granted for the exploitation of patents, provided that such grant is necessary to satisfy the basic needs of the population.

Licenses granted under the foregoing paragraph shall be neither transferable nor exclusive.

Article 134. Compulsory licenses shall be granted by the competent jurisdiction, and they shall specify the remuneration payable according to the particular circumstances of each case, due account being taken of the economic value of the authorization; the remuneration shall be awarded to the owner of the patent by virtue of the license granted; the manner in which payment is to be made to the owner shall likewise be specified.

Article 134-A.- A solicitud del titular de la patente, el tribunal competente podrá revocar la licencia obligatoria si las circunstancias que dieron lugar a su otorgamiento han desaparecido, para lo cual se tomarán las previsiones necesarias para proteger los intereses legítimos de los licenciatarios. Para tal efecto, además de las pruebas aportadas por el titular de la patente, se recabará la información que se estime necesaria para verificar esos hechos.

ESTONIA (EU) : *Section 47 of the Patent Act of 16/03/1994, as last amended by the Act of 10/03/2004*

Compulsory licence 47.-(1) Each person interested in using a patented invention and able to use it in the Republic of Estonia may, upon refusal from the patentee to grant a licence, bring action for obtaining a compulsory licence, if:

1. the patentee has not used the invention in the Republic of Estonia within three years from the publication date of a notice of the grant of the patent or within four years from filing the patent application, whereby the term with a later expiration date is taken into account;
2. the extent of the use of the invention by the patentee does not comply with the needs of Estonian domestic market;
3. the patent hinders the use of another invention which is technologically progressive and essential for Estonian economy;
4. the use of the invention is required by State defence, environment protection, public health or other important State interests of the Republic of Estonia, including an urgent necessity to use the invention in connection with natural catastrophes or other emergencies;
5. the patent prevents the grant of protection to a plant variety under the Plant Variety Rights Act (RT I, 1998, 36/37, 553) or the use of a plant variety that has been granted legal protection.

(1¹) A compulsory licence shall not be granted if the patentee imports, from any member State of the World Trade Organization, a product protected by a patent in the extent meeting the needs of Estonian domestic market.

(2) In cases specified in clause 3 of subsection (1) of this Section, the patentee shall be entitled to obtain a compulsory licence for another invention if no agreement is reached about exchanging licences (reciprocal licence).

(3) Upon granting a compulsory licence, the court shall prescribe the terms of the compulsory licence, including the extent and duration of the use of invention as well as the amount and payment procedure of the licence fee. The extent and duration of the use of the invention are determined on the basis of the needs of Estonian domestic market.

- (4) The right to use the invention under a compulsory licence may transfer to another person solely with the enterprise using the compulsory licence or planning to use it pursuant to the terms of the compulsory licence.
- (5) The grant of a compulsory licence shall not prevent the patentee from using the invention or from granting licences to other persons.
- (6) A compulsory licence is valid as of the date of making an entry in the register. A request for the making of a register entry together with a copy of the court judgment and information certifying payment of the state fee shall be filed with the Patent Office within one month after entry into force of the court judgment.
- (7) If circumstances change, both the licensor and the licensee may file an action in court for amendment of the terms of a compulsory licence.

ETHIOPIA : *Sections 29-33 of the Proclamation of the Industrial Property Law No. 123 of 10/05/1995*

29. Application for a Compulsory License

1. The patentee whose invention cannot be worked effectively without the invention patented earlier may apply for a compulsory license to use the earlier invention.
2. The earlier patentee whose invention cannot be worked effectively without the later invention may apply for a compulsory license to use the later invention.
- 3.-Any person who is capable of working a patented invention may apply for a compulsory license, where the patentee fails, without legitimate reason to justify his inaction, to work his invention in Ethiopia, after the expiration of a period of three years from the date of grant of the patent or four years from the date of filing of the patent application which ever expires last.

30. Grant of Compulsory License

1. Where the Commission finds the request to be satisfactory, it shall grant a compulsory license.
2. The grant of a compulsory license shall not exclude the exploitation of the invention, the conclusion of license contracts by the owner of the patent or the grant of other compulsory licenses.
3. The decision made by the compulsory license shall be in the official gazette.
Commission to grant a registered and announced

31. Proof Required of the Applicant

The person requesting for a compulsory license to exploit an invention shall furnish proof that he has not been able to conclude a license contract with the patentee for the exploitation of the invention on reasonable terms.

32. Limitation of Rights of Licensee

1. Any person who is granted compulsory license for the exploitation of a patented invention shall not have an exclusive right of over the invention and shall not have a right to authorize exploitation by any other person.

2. The licensee shall have the right to exploit the patented invention in Ethiopia according to the terms set out in the decision- granting the license, and shall commence the working of the patented invention within the time limit fixed in the said decision.

33. *Exploitation Fee*

1. Any person who is granted a compulsory license shall pay the patentee a reasonable exploitation fee, the amount of which shall be fixed by both parties.

2. Where the parties disagree on the amount of fee, it shall be fixed by the Commission.

FINLAND (EU) : *Sections 45-50 of the Patents Act No. 550 of 15/12/1967 as last amended by Act 684/2006 of 21/07/2006.*

Section 45 - Where three years have elapsed since the grant of the patent and four years have elapsed from the filing of the application, and if the invention is not worked or brought into use to a reasonable extent in Finland, any person who wishes to work the invention in Finland may obtain a compulsory licence to do so unless legitimate grounds for failing to work the invention may be shown. (22.12.1995/1695)

Subject to reciprocity, the Government may decree that, for the purposes of subsection (1) of this Section, the working of an invention in a foreign State shall be deemed equivalent to working in this country.

Section 46 - The proprietor of a patent for an invention whose exploitation is dependent on a patent held by another person may obtain a compulsory licence to exploit the invention protected by such patent if deemed reasonable in view of the importance of the first-mentioned invention or for other special reasons.

The proprietor of a patent in respect of which a compulsory licence is granted under subsection (1) of this Section may obtain a compulsory licence to exploit the other invention unless there are special reasons to the contrary.

Section 46 a (30.6.2000/650) - Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety.

Applicants for the licence referred to in subsection 1 above must demonstrate that they have applied unsuccessfully to the holder of the patent to obtain a contractual licence and that the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

Provisions concerning the right of a patent holder to obtain a compulsory licence for the exploitation of a plant variety protected by plant breeder's right are laid down by the Act on Plant Breeders' Rights (No. 789/1992).

Section 47 - In the event of considerable public interest, a person who wishes to exploit commercially an invention for which another person holds a patent may obtain a compulsory licence to do so.

Section 48 - Any person who was commercially exploiting in this country an invention which is the subject of a patent application, at the time the application documents were made available under Section 22, shall, if the application results in a patent, be entitled to a

compulsory licence for such exploitation, provided there are special reasons for this and also provided that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such a right shall also be enjoyed, under corresponding conditions, by any person who has made substantial preparations for commercial exploitation of the invention in this country. Compulsory licences may also relate to the period of time preceding the grant of the patent.

Section 49 (22.12.1995/1695) - A compulsory licence may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner and in accordance with the terms of the licence who, before filing a claim for a compulsory licence, has made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention. A compulsory licence shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. A compulsory licence may only be transferred to a third party together with the business in which it is exploited or was intended to be exploited.

Section 50 - Compulsory licences shall be granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid and any other conditions under the licence. In the event of a substantial change in the circumstances, the court may, on request, revoke the licence or lay down new conditions.

FRANCE (EU) : *Articles L. 613-11 – L. 613-20 of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 (as last amended by Law No. 2007-1544) and sections R613-4 to R613-42 of the regulation part*

Article L613-11

Modifié par Loi n°96-1106 du 18 décembre 1996 - art. 5 JORF 19 décembre 1996

Toute personne de droit public ou privé peut, à l'expiration d'un délai de trois ans après la délivrance d'un brevet, ou de quatre ans à compter de la date du dépôt de la demande, obtenir une licence obligatoire de ce brevet, dans les conditions prévues aux articles suivants, si au moment de la requête, et sauf excuses légitimes le propriétaire du brevet ou son ayant cause :

a) N'a pas commencé à exploiter ou fait des préparatifs effectifs et sérieux pour exploiter l'invention objet du brevet sur le territoire d'un Etat membre de la Communauté économique européenne ou d'un autre Etat partie à l'accord sur l'Espace économique européen.

b) N'a pas commercialisé le produit objet du brevet en quantité suffisante pour satisfaire aux besoins du marché français.

Il en est de même lorsque l'exploitation prévue au a) ci-dessus ou la commercialisation prévue au b) ci-dessus a été abandonnée depuis plus de trois ans.

Pour l'application du présent article, l'importation de produits objets de brevets fabriqués dans un Etat partie à l'accord instituant l'Organisation mondiale du commerce est considérée comme une exploitation de ce brevet.

Article L613-12

Modifié par Loi n°96-1106 du 18 décembre 1996 - art. 7 JORF 19 décembre 1996

La demande de licence obligatoire est formée auprès du tribunal de grande instance : elle doit être accompagnée de la justification que le demandeur n'a pu obtenir du propriétaire du brevet

une licence d'exploitation et qu'il est en état d'exploiter l'invention de manière sérieuse et effective.

La licence obligatoire est accordée à des conditions déterminées, notamment quant à sa durée, son champ d'application et le montant des redevances auxquelles elle donne lieu.

Ces conditions peuvent être modifiées par décision du tribunal, à la requête du propriétaire ou du licencié.

Article L613-13 En savoir plus sur cet article...

Modifié par Loi n°96-1106 du 18 décembre 1996 - art. 6 JORF 19 décembre 1996

Les licences obligatoires et les licences d'office sont non exclusives. Les droits attachés à ces licences ne peuvent être transmis qu'avec le fonds de commerce, l'entreprise ou la partie de l'entreprise auquel ils sont attachés [*cession indissociable*].

Article L613-14

Si le titulaire d'une licence obligatoire ne satisfait pas aux conditions auxquelles cette licence a été accordée, le propriétaire du brevet et, le cas échéant, les autres licenciés peuvent obtenir du tribunal le retrait de cette licence.

Article L613-15

Modifié par Loi n°2004-1338 du 8 décembre 2004 - art. 9 JORF 9 décembre 2004

Le titulaire d'un brevet portant atteinte à un brevet antérieur ne peut exploiter son brevet sans l'autorisation du titulaire du brevet antérieur ; ledit titulaire ne peut exploiter le brevet postérieur sans l'autorisation du titulaire du brevet postérieur.

Lorsque le titulaire d'un brevet ne peut l'exploiter sans porter atteinte à un brevet antérieur dont un tiers est titulaire, le tribunal de grande instance peut lui accorder une licence d'exploitation du brevet antérieur dans la mesure nécessaire à l'exploitation du brevet dont il est titulaire et pour autant que cette invention constitue à l'égard du brevet antérieur un progrès technique important et présente un intérêt économique considérable.

La licence accordée au titulaire du brevet postérieur ne peut être transmise qu'avec ledit brevet.

Le titulaire du brevet antérieur obtient, sur demande présentée au tribunal, la concession d'une licence réciproque sur le brevet postérieur.

Les dispositions des articles L. 613-12 à L. 613-14 sont applicables.

Article L613-15-1

Créé par Loi n°2004-1338 du 8 décembre 2004 - art. 7 JORF 9 décembre 2004

Lorsqu'un obtenteur ne peut obtenir ou exploiter un droit d'obtention végétale sans porter atteinte à un brevet antérieur, il peut demander la concession d'une licence de ce brevet dans la mesure où cette licence est nécessaire pour l'exploitation de la variété végétale à protéger et pour autant que la variété constitue à l'égard de l'invention revendiquée dans ce brevet un progrès technique important et présente un intérêt économique considérable.

Lorsqu'une telle licence est accordée, le titulaire du brevet obtient à des conditions équitables, sur demande présentée au tribunal, la concession d'une licence réciproque pour utiliser la variété protégée.

Les dispositions des articles L. 613-12 à L. 613-14 sont applicables.

Article L613-16

Modifié par Loi n°2004-1338 du 8 décembre 2004 - art. 10 JORF 9 décembre 2004

Si l'intérêt de la santé publique l'exige et à défaut d'accord amiable avec le titulaire du brevet, le ministre chargé de la propriété industrielle peut, sur la demande du ministre chargé de la

santé publique, soumettre par arrêté au régime de la licence d'office, dans les conditions prévues à l'article L. 613-17, tout brevet délivré pour :

- a) Un médicament, un dispositif médical, un dispositif médical de diagnostic in vitro, un produit thérapeutique annexe ;
- b) Leur procédé d'obtention, un produit nécessaire à leur obtention ou un procédé de fabrication d'un tel produit ;
- c) Une méthode de diagnostic ex vivo.

Les brevets de ces produits, procédés ou méthodes de diagnostic ne peuvent être soumis au régime de la licence d'office dans l'intérêt de la santé publique que lorsque ces produits, ou des produits issus de ces procédés, ou ces méthodes sont mis à la disposition du public en quantité ou qualité insuffisantes ou à des prix anormalement élevés, ou lorsque le brevet est exploité dans des conditions contraires à l'intérêt de la santé publique ou constitutives de pratiques déclarées anticoncurrentielles à la suite d'une décision administrative ou juridictionnelle devenue définitive.

Lorsque la licence a pour but de remédier à une pratique déclarée anticoncurrentielle ou en cas d'urgence, le ministre chargé de la propriété industrielle n'est pas tenu de rechercher un accord amiable.

Article L613-17-1

Créé par Loi n°2007-1544 du 29 octobre 2007 - art. 8 JORF 30 octobre 2007

La demande d'une licence obligatoire, présentée en application du règlement (CE) n° 816/2006 du Parlement européen et du Conseil, du 17 mai 2006, concernant l'octroi de licences obligatoires pour des brevets visant la fabrication de produits pharmaceutiques destinés à l'exportation vers des pays connaissant des problèmes de santé publique, est adressée à l'autorité administrative. La licence est délivrée conformément aux conditions déterminées par l'article 10 de ce règlement. L'arrêté d'octroi de la licence fixe le montant des redevances dues.

La licence prend effet à la date la plus tardive à laquelle l'arrêté est notifié au demandeur et au titulaire du droit.

Article L613-18

Modifié par Loi n°96-1106 du 18 décembre 1996 - art. 7 JORF 19 décembre 1996

Le ministre chargé de la propriété industrielle peut mettre en demeure les propriétaires de brevets d'invention autres que ceux visés à l'article L. 613-16 d'en entreprendre l'exploitation de manière à satisfaire aux besoins de l'économie nationale.

Si la mise en demeure n'a pas été suivie d'effet dans le délai d'un an et si l'absence d'exploitation ou l'insuffisance en qualité ou en quantité de l'exploitation entreprise porte gravement préjudice au développement économique et à l'intérêt public, les brevets, objets de la mise en demeure, peuvent être soumis au régime de licence d'office par décret en Conseil d'Etat.

Le ministre chargé de la propriété industrielle peut prolonger le délai d'un an prévu ci-dessus lorsque le titulaire du brevet justifie d'excuses légitimes et compatibles avec les exigences de l'économie nationale.

Du jour de la publication du décret qui soumet le brevet au régime de la licence d'office, toute personne qualifiée peut demander au ministre chargé de la propriété industrielle l'octroi d'une licence d'exploitation.

Cette licence est accordée par arrêté dudit ministre à des conditions déterminées quant à sa durée et son champ d'application, mais à l'exclusion des redevances auxquelles elle donne lieu. Elle prend effet à la date de notification de l'arrêté aux parties.

A défaut d'accord amiable, le montant des redevances est fixé par le tribunal de grande instance.

Article L613-19

L'Etat peut obtenir d'office, à tout moment, pour les besoins de la défense nationale, une licence pour l'exploitation d'une invention, objet d'une demande de brevet ou d'un brevet, que cette exploitation soit faite par lui-même ou pour son compte.

La licence d'office est accordée à la demande du ministre chargé de la défense par arrêté du ministre chargé de la propriété industrielle. Cet arrêté fixe les conditions de la licence à l'exclusion de celles relatives aux redevances auxquelles elle donne lieu.

La licence prend effet à la date de la demande de licence d'office.

A défaut d'accord amiable, le montant des redevances est fixé par le tribunal de grande instance. A tous les degrés de juridiction, les débats ont lieu en chambre du conseil.

Article L613-19-1

Créé par Loi n°96-1106 du 18 décembre 1996 - art. 9 JORF 19 décembre 1996

Si le brevet a pour objet une invention dans le domaine de la technologie des semi-conducteurs, une licence obligatoire ou d'office ne peut être accordée que pour une utilisation à des fins publiques non commerciales ou pour remédier à une pratique déclarée anticoncurrentielle à la suite d'une procédure juridictionnelle ou administrative.

GEORGIA : Sections 61-62 of the Patent Law of 05/02/1999

61.—(1) The compulsory or official license can be granted for an invention, utility model. The compulsory or official license is granted under the decision of the Compulsory Licensing Committee at the Ministry of Economy of Georgia.

(2) The compulsory license may be only simple. It is granted at the request of any party concerned after four years from the date the patent was granted.

(3) The compulsory license necessary for public requirements is claimed, if within the above mentioned term an invention, utility model has not been used within the territory of Georgia, or whether they have been used insufficiently, also if their usage is impossible without infringing the earlier patent.

(4) The compulsory license can be issued only in the case, if prior to this the interested party tried to obtain the permission from the patent owner or his assignee on basis of reasonable conditions and term, but his efforts have not been successful.

(5) The official license is a kind of compulsory license and is granted only in case of demand from the State Bodies, if the necessity of a patent use for the national defense, humane health protection, or the economic interests of the country is proved. An official license is granted before expiration of the four years period stated in the paragraph (2) of this Article.

- (6) The granting of the official license at the request of a patent owner can be postponed, under the condition that the patent owner shall take the responsibility to satisfy government and public requirements by his own production.
- (7) The use of a patent on the basis of the official license can be conducted by the State, as well as the private person, which shall be named by the competent body demanding a license or Court.
- (8) The decision on granting of the compulsory or official license sets spheres of its application, validity term, rights and duties of a licensor and licensee and the amount of remuneration.
- 62.—(1) The license shall be concluded in a written form. Upon agreement the contract shall be registered within no later than two months from the date of its conclusion.
- (2) The substantial changes in the license, if there is a wish of the parties, can be registered at Sakpatenti regarding the established rule no later than a month after the amendments are made.
- (3) The data of granted license and amendments are published in the Official Bulletin.

GERMANY (EU) : *Sections 13, 24 and 81-85a of the Patent Law of 16/12/1980 (as last amended by the Act on Improvement of Enforcement of Intellectual Property Rights of 31/07/2009)*

Section 13

- (1) A patent shall have no effect should the Federal Government order that the invention is to be used in the interest of public welfare. Nor shall the effect of a patent extend to any use of the invention ordered in the interests of the security of the Federal Republic by the competent highest federal authority or, on the latter's instructions, by a subordinate agency.
- (2) Should an order under subsection (1) be challenged, the Federal Administrative Court [Bundesverwaltungsgericht] shall have jurisdiction if said order was issued by the Federal Government or the competent highest federal authority.
- (3) In those cases referred to in subsection (1), the patentee shall have a claim against the Federal Republic for reasonable compensation. In the event of dispute as to the amount, legal action may be brought before the ordinary civil courts. Any order by the Federal Government under the first sentence of subsection (1) shall be communicated to the person recorded as patentee in the Register (Section 30(1)) before the invention is used. If the highest federal authority that has issued an order or an instruction under the second sentence of subsection (1) becomes aware that a claim for compensation has arisen under the first sentence, said highest federal authority shall communicate this to the person recorded in the Register as patentee.

Section 24

- (1) A non-exclusive authorization to commercially use an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory license) if
1. the person seeking a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to use the invention under reasonable conditions usual in trade; and
 2. public interest commands the grant of a compulsory license.

(2) When the person seeking a license is unable to exploit an invention for which he holds protection under a patent of later date without infringing the patent of earlier date, said person shall be entitled to the grant of a compulsory license from the owner of the patent of earlier date if

1. the condition stipulated in subsection (1), no. 1, is fulfilled and

2. the invention of said person includes, in comparison with the invention under the patent of earlier date, an important technical progress of considerable commercial significance.

The patentee may request the grant of a counter-license under reasonable conditions by the person seeking a license for the use of the patented invention of later date.

(3) Subsection (2) shall apply *mutatis mutandis* if a plant breeder cannot obtain or exploit a plant variety patent without infringing an earlier patent.

(4) A compulsory license under the provisions of subsection (1) may only be granted for a patented invention in the field of semiconductor technology if said grant is necessary to remove an anti-competitive practice on the part of the patentee that has been established in judicial or administrative proceedings.

(5) When a patentee does not work the patented invention or does not work it predominantly in Germany, compulsory licenses under the provisions of subsection (1) may be granted to ensure an adequate supply of the patented product to the domestic market. Importing shall insofar be deemed to constitute working of the patent in Germany.

(6) The grant of a compulsory license to a patent shall become permissible only after the patent has been granted. The license may be granted subject to restrictions and made dependent upon conditions. The scope and duration of use shall be restricted to the purpose for which said license has been granted. The patentee shall be entitled to remuneration from the holder of a compulsory license commensurate with the circumstances and taking into consideration the commercial value of the compulsory license. With regard to the recurring remuneration due in the future, should there be a significant change in the circumstances decisive for the determination of the amount of this remuneration, each party shall be entitled to demand a corresponding adjustment. If the circumstances on which the grant of a compulsory license was based no longer apply and if it is unlikely that they will reoccur, the patentee may demand that the compulsory license be revoked.

(7) A compulsory license to a patent may only be transferred together with the business concerned with the exploitation of the invention. A compulsory license to an invention that is the subject matter of a patent of earlier date may only be transferred together with the patent of later date.

GHANA : Sections 45- 50 of the Patents Law No. 305A of 30/12/1992

Compulsory licences for non-working and similar reasons

45.—(1) At any time after four years from the filing date of an application or three years from the grant of a patent whichever period last expires, any person may, in proceedings instituted by him against the owner of the patent or in proceedings instituted against him by the said owner, request the court to grant a compulsory licence on any of the following grounds—

(a) that a patented invention, which is capable of being worked in the country has not been so worked;

(b) that the existing degree of working of the patented invention in the country does not meet on reasonable terms the demand for the patented product on the domestic market or for purposes of exportation;

(c) that the working of the patented invention in the country is being hindered or prevented by the importation of the patented product; or

(d) that, by reason of the refusal by the owner of the patent to grant licences on reasonable terms, the establishment or development of industrial or commercial activity in the country, or the possibilities of exportation from the country, are unfairly and substantially prejudiced.

(2) Where the patented invention is a process, “patented product” in subsection (1) of this section means a product obtained directly by means of the process.

(3) A compulsory licence shall not be granted in respect of a patent if the owner of the patent satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances.

Compulsory licences based upon the interdependence of patents

46.—(1) Where a patented invention cannot be worked without infringing rights derived from an earlier patent, the owner of the later patent may, in proceedings instituted by him against the owner of the earlier patent or in proceedings instituted against him, request the Tribunal at any time to grant a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention if the invention—

(a) serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or

(b) constitutes substantial technical progress in relation to the later invention.

(2) Where the two inventions mentioned in subsection (1) serve the same industrial purpose, a compulsory licence may be granted under that subsection only on condition that a compulsory licence shall also be granted in respect of the later patent to the owner of the earlier patent if he so requests.

(3) In this section, “earlier patent” means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and “later patent” shall be construed accordingly.

Compulsory licences for products and processes declared to be of vital importance

47.—(1) The Secretary may by legislative instrument direct that, for patented inventions concerning certain kinds of products, or processes for the manufacture of such products declared to be of vital importance to the defence, economic or public health interests of Ghana, compulsory licences may be granted.

(2) Compulsory licences with respect to any product or process specified in subsection (1) of this section may be granted at any time after the grant of the relevant patent by the Tribunal in proceedings instituted against or by the owner of patent.

Preconditions to grant of compulsory licences

48. A compulsory licence shall not be granted unless the person requesting the compulsory licence—

(a) satisfies the Tribunal that he has asked the owner of the patent for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time; and

(b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies, or to satisfy the requirements, which gave rise to his request.

Grant and terms of compulsory licences

49.—(1) In considering a request for a compulsory licence, the court shall first decide whether a compulsory licence may be granted and, if it decides in favour of a grant, shall then proceed to determine the terms, taking into account any terms agreed by the parties.

(2) In determining the terms under subsection (1) of this section, the court shall ensure that the compulsory licence—

(a) entitles the licensee to do any act specified in section 28 of this Law, except importation, unless the application was made under section 47;

(b) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;

(c) is non-exclusive; and

(d) provides for the payment to the owner of the patent of remuneration which is equitable having regard to all the circumstances of the case.

(3) The terms determined by the court shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of Part VIII of this Law.

(4) A representative of the Secretary shall have the right to appear and be heard by the court at the hearing of an application for a compulsory licence.

Transfer of compulsory licences

50. A compulsory licence may be transferred only with the industrial undertaking in which the relevant invention is used and no such transfer shall be valid except with the approval of the Tribunal.

GREECE (EU) : *Articles 13- 14 of the Law on “Technology transfer, inventions and technological innovation” No. 1733 of 1987*

Article 13 - Non-contractual licence

1. The competent court mentioned in paragraph 10 of the present article may grant to a third party, without prior consent of the patentee, a licence for exploitation of the patent in case that the following prerequisites concur accumulatively:

a. A period of three years has elapsed since the grant of the patent or a period of four years has elapsed since the filing date of the patent application;

b. The relevant invention has not been exploited in Greece or, in case it has, the production of the products thereof is insufficient to cover local demand;

c. The third party is in a position to exploit productively the invention covered by the patent;

d. The third party notified the patentee, one month prior to the initiation of the judicial proceedings, regarding his intention to request a non-contractual licence.

2. The non-contractual licence shall not be granted in case the patentee justifies lack of exploitation or insufficient exploitation in the country. The importation of the product does not constitute an excuse for the invocation and application of this paragraph. The regulation of item 1 above shall not apply to products imported from Member States of the European Union and the Member States of the World Trade Organization(1).

3. The grant of a non-contractual licence may not exclude other contractual or non-contractual licences. The non-contractual licence may be assigned only along with the part of the enterprise which exploits the invention.

4. The owner of the patent may request from the competent court mentioned in paragraph 10 the grant of a non-contractual licence on an earlier patent, provided that his invention relates to the invention of the earlier patent, the productive exploitation of said invention is not possible without offending the rights of the owners of the earlier patent and his invention constitutes a significant progress in comparison with the invention of the prior patent. When the aforementioned non-contractual licence has been granted, the owner of the earlier patent may request the granting of a non-contractual licence for the subsequent invention.

5. The non-contractual licence shall be granted following petition of the interested party before the competent court mentioned in paragraph 10. The petition is accompanied by the opinion of the Industrial Property Organisation regarding the existence of the prerequisites for granting the non-contractual licence in accordance with the preceding paragraphs, the amount, the terms of the compensation to be given to the owner of the patent, and the exclusive or non exclusive character of the exploitation of the invention. The Industrial Property Organisation states its opinion following petition of the party interested in exploiting the patent. The opinion of O.B.I. is granted within one month from the date the relevant petition is filed and is not binding for the competent court. Copy of the application for granting a non-contractual licence along with the relevant opinion of O.B.I. and the note fixing the day of the trial shall be notified to the owner of the patent and to the beneficiaries of other contractual or non-contractual licences.

6. In case the petition is approved, the competent court grants a non-contractual licence. The licence pertains to the extent of the exploitation rights of the invention, the duration of its validity, the date of commencement of the productive exploitation of the invention in Greece

and the amount and terms of compensation to be paid to the patentee by the beneficiary of the licence. The amount and the terms of the compensation are determined in accordance with the extent of the industrial exploitation of the protected invention.

7. The decision of the court in accordance with paragraph 6 shall be recorded to the Patents Register of O.B.I., published in the Industrial Property Bulletin and notified to the persons mentioned in paragraph 5.

8. Following petition of the owner of the patent or the beneficiary of the non-contractual licence, the competent court mentioned in paragraph 10 may amend the terms of granting of the licence if new data justify the amendment or revoke the non contractual licence if its beneficiary does not respect the terms of the licence or if the prerequisites for its granting have ceased existing. If the immediate revocation brings about a significant damage to the beneficiary of the non-contractual licence, the court may allow the continuation of the exploitation for a reasonable period of time.

9. The non-contractual licence does not grant the right for importation of the products covered by the invention.

10. The competent court for the grant, assignment, amendment or revocation of a non-contractual licence is the three member court of first instance at the place of residence of the petitioner, which judges in accordance with the proceeding of article 741 to 781 of the Code of Civil Procedure Law.

Article 14

Licence to the Public Sector

1. For imperative reason of serving public health and national defence after justified decision of the Minister of Industry, Energy, and Technology and, according to the case, any competent Ministers, a licence for exploitation of an invention can be granted to bodies of the public sector which may exploit the invention in Greece, provided that the relevant invention has not been productively exploited in Greece or the production of the products thereof is insufficient to cover local needs.

2. Prior to the issue of the relevant decision, the patentee and anyone who is in position to give useful advice, are called upon to express their views.

3. By the same decision, following the opinion of O.B.I., the amount and the terms of the compensation to the owner or the patent are determined. The amount of the compensation is determined in accordance with the extent of the industrial exploitation of the invention. In case of disagreement of the patentee as regards the amount of the compensation, the compensation is determined by the relevant one-member court of first instance of the jurisdiction, in the injunction proceedings.

GRENADA : Sections 14 and 14 A of the Industrial Property Bill of 2002

Exploitation by Government or authorised persons

14. (1) If –

(a) the public interest (in particular, national security, nutrition, person health or the development of other vital sectors of the national economy) so requires; or

(b) the [Minister of Finance] has determined that the manner of exploitation by the owner of the patent or a licensee is anticompetitive, and the Minister [for Legal Affairs] is satisfied that the exploitation of the invention in accordance with this subsection would remedy such practice,

the Minister [for Legal Affairs] may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit the invention.

(2) The exploitation of the invention under this section is limited to the purpose for which it was authorized and is subject to the payment to the owner of adequate remuneration, taking into account the economic value of the Minister's decision, as determined in the said decision, and, where a decision has been taken under paragraph (b) of subsection (1), the need to correct anti-competitive practices.

(3) The Minister [of Finance] and the Minister [of Legal Affairs] must take a decision under subsection (1) only after hearing the owner of the patent and any interested person who wishes to be heard.

(4) Upon the request of the owner of the patent, of the Government agency or of the third person authorized to exploit the patented invention, the Minister [of Legal Affairs] may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(5) (a) Upon the request of the owner of the patent, the Minister [of Legal Affairs] must terminate the authorization if the Minister is satisfied, after hearing the parties, (if either or both wish to be heard) that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated has failed to comply with the terms of the decision.

(b) Notwithstanding paragraph (a), the Minister must not terminate the authorization if he or she is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated justifies the maintenance of the decision.

(6) If a third person has been designated by the Minister under subsection (1), the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(7) The authorization must not exclude –

(a) the conclusion of licence contracts by the owner of the patent;

(b) the continued exercise, by the owner of the patent, of the rights under section [12](2); or

(c) the issue of a non-voluntary licence under subsections (1) and (2) of section [14 A.]

(8) (a) A request for the Minister's authorization must be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a

contractual licence, but that that person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(b) Paragraph (a) of this subsection does not apply in cases of national emergency or other circumstances of extreme urgency, but in such cases the owner of the patent must be notified of the Minister's decision as soon as reasonably practicable.

(9) The exploitation of the invention by the Government agency or third person designated by the Minister must be predominantly for the supply of the market in Grenada.

(10) The exploitation of an invention in the field of semi-conductor technology can only be authorized for public non-commercial use or if a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or the owner's licensee, is anti-competitive and if the Minister is satisfied that the issuance of the non-voluntary licence would remedy such practice.

(11) Decisions of a Minister under any of subsections (1) to (10) may be the subject of an appeal to the High Court.

Non-voluntary licences

[14A. (1) If the invention claimed in a patent ("later patent") cannot be exploited in Grenada without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date ("earlier patent"), and if the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the [Registrar] [Court], upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(2) If a non-voluntary licence is issued under subsection (1), the [Registrar] [Court], upon the request of the owner of the earlier patent, must issue a non-voluntary licence in respect of the later patent.

(3) If a non-voluntary licence is issued under subsection (1) or (2), the issuing authority must fix the scope and function of the licence, the amount of the remuneration to be paid to the owner of the patent and the conditions of payment.

(4) In the case of a non-voluntary licence issued under subsection (1), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (2), only with the earlier patent.

(5) The issue of a non-voluntary licence is subject to payment of the prescribed fee.

(6) If a non-voluntary licence is issued under subsection (1) or (2), subsections (2) to (8) and (10) of section [14] apply with necessary modifications.]

GUATEMALA : *Sections 134- 137 of the Industrial Property Law, Decree No. 57 of 18/09/2000*

Licencia Obligatorias

134. Por razón de interés público y en particular por razones de emergencia nacional, salud pública, seguridad nacional o uso público no comercial, o bien, para remediar alguna práctica anticompetitiva, previa audiencia al interesado, el Registro podrá, a petición de la autoridad o de una persona interesada, disponer en cualquier tiempo:

a) Que la invención objeto de una patente o de una solicitud de patente en trámite sea usada o explotada industrial o comercialmente por una entidad estatal o por una o más personas de derecho público o privado designadas al efecto; o

b) Que la invención objeto de una patente o de una solicitud de patente en trámite quede abierta a la concesión de una o más licencias obligatorias, en cuyo caso la autoridad nacional competente podrá conceder tal licencia a quien la solicite, con sujeción a las condiciones establecidas.

Cuando la patente protegiera alguna tecnología de semiconductores, sólo se otorgará licencias obligatorias para un uso público no comercial, o para rectificar una práctica declarada contraria a la competencia en el procedimiento aplicable.

Solicitud de Licencia Obligatoria

135. La persona que solicite una licencia obligatoria deberá acreditar haber pedido previamente al titular de la patente una licencia contractual, que no ha podido obtenerla en términos y condiciones comerciales razonables y que esos intentos no surtieron efecto en un plazo que no podrá ser menor de los noventa días siguientes al primer requerimiento. No será necesario cumplir este requisito tratándose de una licencia obligatoria en casos de emergencia nacional, de extrema urgencia o de un uso no comercial de la invención por una entidad pública. En ambos casos el titular de la patente será informado sin demora de la concesión de la licencia.

La solicitud de licencia obligatoria deberá indicar las condiciones bajo las cuales se pretende obtener la licencia y, junto con la misma, deberá acompañarse la documentación que justifique el otorgamiento de la licencia y la capacidad técnica y económica del solicitante para explotar adecuadamente la patente. Esta prueba no será necesaria en los casos y situaciones señalados en la segunda parte del párrafo que antecede.

De la solicitud se dará audiencia al titular de la patente por el plazo de un mes y, con su contestación o sin ella, el Registro resolverá sobre la procedencia o no de conceder la licencia. La resolución del Registro que otorgue una licencia obligatoria contendrá:

a) El alcance de la licencia, incluyendo su vigencia y los actos para los cuales se concede, que se limitarán a los fines que la motivaron;

b) El monto y la forma de pago de la remuneración debida al titular de la patente; y

c) Las condiciones necesarias para que la licencia cumpla su propósito.

Condiciones Relativas a la Licencia Obligatoria

136. Son condiciones necesarias relativas al otorgamiento de la licencia obligatoria, entre otras, las siguientes:

a) La licencia obligatoria se concederá principalmente para abastecer el mercado interno;

b) El titular de la patente objeto de una licencia obligatoria recibirá una remuneración adecuada, según las circunstancias del caso y el valor económico de la licencia. A falta de acuerdo entre las partes, el Registro fijará el monto y la forma de pago de la remuneración,

para lo cual podrá tomar en cuenta además información que recabe sobre el promedio de regalías que en el mismo sector se haya establecido en contratos de licencia celebrados entre terceras partes; y

c) Una licencia obligatoria no podrá concederse con carácter exclusivo, no podrá ser objeto de cesión, ni de sub licencia y sólo podrá transferirse con la empresa o el establecimiento, o con aquella parte del mismo, que explota la licencia.

A solicitud del titular de la patente, el Registro podrá cancelar la licencia obligatoria si las circunstancias que dieron lugar a su otorgamiento han desaparecido y no es probable que vuelvan a ocurrir, para lo cual tomará las previsiones necesarias para proteger los intereses legítimos de los licenciarios. Para tal efecto, además de las pruebas aportadas por el titular de la patente, el Registro recabará la información que estime necesaria para verificar esos hechos.

Contra las resoluciones que dicte el Registro relativas al otorgamiento o revocación de una licencia obligatoria y las condiciones de la misma, incluyendo la remuneración que deba pagarse al titular de la patente y cualquier modificación de tales condiciones, se podrán interponer los recursos a que se refiere el artículo 13 de esta Ley, los que deben tramitarse y resolverse con absoluta prioridad.

Si la licencia obligatoria se otorga para remediar o eliminar prácticas que a resultas de un proceso judicial o administrativo se ha determinado que son anticompetitivas, no serán aplicables las normas contenidas en el párrafo uno del artículo 134 de esta ley. En este caso, para determinar la remuneración del titular de la patente se tendrá en cuenta que el objeto de la licencia es poner fin a prácticas anticompetitivas. Asimismo, podrá denegarse la revocación de la licencia si resulta probable que las condiciones que dieron lugar al otorgamiento de la misma se repitan.

Licencia Obligatoria por Dependencia de Patentes

137. Cuando una licencia obligatoria fuera solicitada para permitir la explotación de una patente posterior (“segunda patente”), que no pudiera ser explotada sin infringir otra patente anterior (“primera patente”), se observarán las siguientes condiciones adicionales:

a) La invención reivindicada en la segunda patente debe suponer un avance técnico relevante de una importancia económica considerable, con respecto a la invención reivindicada en la primera patente;

b) La licencia obligatoria para explotar la primera patente sólo podrá transferirse con la segunda patente; y

c) El titular de la primera patente tendrá derecho a una licencia sobre la segunda patente, en condiciones razonables para explotar la invención objeto de la segunda patente.

HONDURAS : *Articles 65-70 of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

Artículo 65. - A los efectos de la presente Ley, se entenderá por explotación de una patente lo siguiente:

Cuando la patente se haya concedido para un producto, el abastecimiento de mercado interno conforme a la demanda del producto, sea mediante producción local, importación, o ambos;

Cuando la patente se haya concedido para un procedimiento no comprendido en el numeral 3) del presente Artículo, el empleo de ese procedimiento en escala comercial en Honduras; y,

Cuando la patente se haya concedido para un procedimiento obtención de un producto, el abastecimiento del mercado interno conforme a la demanda del producto obtenido por ese sistema, mediante el empleo del procedimiento en el país o en el extranjero.

Artículo 66. - A solicitud de cualquier persona que acredite su capacidad para explotar la invención patentada, presentada después de cuatro (4) años contados desde la fecha de presentación de la solicitud de patente o de tres (3) años contados desde la fecha de concesión de la patente, aplicándose el plazo que expire más tarde, el Registro de la Propiedad Industrial podrá previa audiencia del titular de la patente, conceder una licencia obligatoria para la explotación conforme al Artículo 65 de esta Ley.

No se concederá una licencia obligatoria cuando se demuestra que la falta o insuficiencia de explotación se debe a un caso fortuito o de fuerza mayor, o a circunstancias que escapan a la voluntad o al control del titular de la patente y que justifican la falta o insuficiencia de explotación Industrial de la invención patentada. No serán consideradas circunstancias justificativas la falta de recursos económicos ni la falta de viabilidad económica de la explotación.

Antes de conceder una licencia obligatoria, la Oficina de Registro dará oportunidad al titular de la patente para que dentro del plazo de dos (2) años contados a partir de la notificación que se haga a éste proceda a su explotación.

Artículo 67. - La persona que solicite una licencia obligatoria de conformidad con el artículo 62 de esta Ley, deberá acreditar fehacientemente haber pedido previamente al titular de la patente, una licencia contractual y que no ha podido obtenerla en condiciones y plazos razonables. La Solicitud de licencia obligatoria indicará las condiciones bajo las cuales pretende obtenerse la licencia.

Cuando la licencia obligatoria se solicitara para una patente en la cual se reivindicara alguna tecnología de semiconductores, la licencia sólo se concederá para un uso público no comercial a favor de una autoridad pública o de otra persona que actúe por cuenta de ella o para rectificar una práctica declarada contraria a la competencia mediante el procedimiento administrativo o judicial correspondiente.

La resolución de concesión de la licencia obligatoria establecerá:

El alcance o extensión de la licencia, especificando en particular el período y los actos, que será principalmente para abastecer el mercado interno del país;

La cuantía y la forma del pago que deberá efectuar el licenciataria, debiendo determinarse dicho pago sobre la base de la amplitud de la explotación de la invención objeto de la licencia, y el valor económico de la licencia; y,

Otras condiciones que el Registro de la Propiedad Industrial estime necesarias o convenientes para la mejor explotación de la patente.

Artículo 68. - Una licencia obligatoria concedida de conformidad con el Artículo 66 de esta Ley, podrá ser revocada por el Registro de la Propiedad Industrial, a solicitud de la persona interesada, si el beneficiario de la licencia incumpliere las obligaciones que le incumben, o si las circunstancias que dieron origen a la licencia hubiesen desaparecido y no fuese probable que vuelvan a surgir. La licencia obligatoria podrá ser modificada por el Registro, a solicitud de alguna de las partes, cuando nuevos hechos o circunstancias lo justifiquen, en particular

cuando el titular de la patente hubiese otorgado licencias contractuales en condiciones más favorables que las acordadas al beneficiario de la licencia obligatoria.

La licencia obligatoria prevista en el Artículo 66 de la presente Ley no podrá concederse con carácter de exclusiva. Tal licencia no podrá ser objeto de cesión ni de sub.-licencia y solo podrá transferirse con el establecimiento, o con aquella parte de la empresa o del establecimiento, en que se explota industrialmente la invención. La transferencia se sujetará a las disposiciones del Artículo 20, párrafo segundo de la misma, en cuanto corresponda.

Artículo 69. - Cuando una invención reivindicada en una patente no pudiera explotarse industrialmente en el país sin que ello infrinja una patente anterior, el Registro de la Propiedad Industrial, a petición del titular de aquella patente o de su licenciataria, o del beneficiario de una licencia obligatoria sobre esa patente, podrá conceder una licencia obligatoria respecto de la patente anterior, en la medida que fuese necesario para evitar la infracción de esa patente anterior.

Tal licencia solo se concederá cuando la invención reivindicada en la patente posterior suponga un avance técnico de una importancia económica considerable con respecto a la invención que es objeto de la patente anterior.

Cuando se concediere una licencia obligatoria de acuerdo con el párrafo anterior, el Registro de la Propiedad Industrial podrá en las mismas circunstancias conceder una licencia obligatoria con respecto a la patente posterior, si lo solicitare el titular de la patente anterior, su licenciataria, o el beneficiario de una licencia obligatoria sobre dicha patente anterior.

Una licencia obligatoria de las previstas en este Artículo no podrá concederse con carácter de exclusiva.

Esta licencia obligatoria sólo podrá ser objeto de cesión, transferencia o sublicencia cuando simultáneamente fuese objeto de cesión, transferencia o licencia la patente dependiente cuya explotación industrial requiere de la licencia. La cesión, transferencia o sublicencia de la licencia obligatoria se sujetará a las disposiciones del párrafo segundo de la presente Ley, en cuanto corresponda.

Serán aplicables a las licencias previstas en el presente Artículo, las disposiciones de los artículos 67 y 68 de esta Ley, en cuanto corresponda.

Artículo 70. - Por razones de interés público, y en particular en casos de emergencia o por razones de seguridad nacional, nutrición o salud pública, la Secretaría de Estado en los Despachos de Industria y Comercio podrá, a petición de cualquier persona natural o jurídica, entidad del Estado, o de oficio, disponer en cualquier tiempo lo siguiente:

Que una invención objeto de una patente o de solicitud de patente en trámite sea explotada por una entidad estatal o por una o más personas de derecho público o privado designada al efecto; y,

Que una invención objeto de una patente o de una solicitud de patente en trámite quede abierta a la concesión de licencias de interés público, en cuyo caso el Registro de la Propiedad Industrial otorgará una licencia de explotación a cualquier persona que lo solicite y tuviera capacidad para efectuar tal explotación en el país.

HUNGARY (EU): *Articles 31, 32,33A of the Law on the Protection of Inventions by Patents
No. XXXIII of 1995 (Consolidated text of 01/10/2009)*

Compulsory licenses for lack of exploitation

Article 31

If within four years from the date of filing of the patent application or within three years from the grant of the patent, whichever period expires last, the patentee has not exploited the invention in the territory of the country to satisfy the domestic demand or if he has not undertaken serious preparations or has not granted a license for such purpose, a compulsory license shall be granted to the applicant for the license, unless the patentee justifies the lack of exploitation.

Compulsory licenses in respect of dependent patents

Article 32

(1) If the patented invention cannot be exploited without infringing another patent (hereinafter referred to as “the dominant patent”), a compulsory license shall be granted, on request and to the extent necessary for the exploitation of the dominant patent, to the holder of the dependent patent, provided that the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the dominant patent.

(2) Where a compulsory license has been granted under paragraph (1) with respect to a dominant patent, the holder of such a patent shall be entitled on reasonable terms to a license to exploit the invention claimed in the dependent patent according to the common provisions on compulsory licenses.

(3) The provisions of Article 33(1) and (2) shall also apply *mutatis mutandis* if the subject matter of a plant variety protection provided for in Chapter XIII cannot be exploited without infringing a patent.

Compulsory licenses to address public health problems

Article 33/A

(1) The Hungarian Patent Office shall grant a compulsory license for the exploitation of an invention in the cases and on the terms laid down in Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2007 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (hereinafter referred to as “Regulation 816/2006/EC”).

(2) The licensee may not grant a license of exploitation on the basis of the compulsory license under paragraph (1).

(3) The licensee may relinquish his compulsory license under paragraph (1) at any time.

Unless relinquished or cancelled, a compulsory license under paragraph (1) shall have effect until expiration of the term of validity fixed by the Hungarian Patent Office or until the lapse of patent protection.

ICELAND : *Articles 45-49 of the Patent Act No. 17 of 1991 as last amended by Act No. 167/2007*

Article 45

If a patented invention is not worked to a reasonable extent in this country when three years have elapsed from the grant of the patent and four years have elapsed from the filing of the patent application, any person wishing to work the invention in this country may obtain a compulsory license to do so unless there are shown legitimate reasons for the failure to work the invention.

Subject to reciprocity [the Minister of Business Affairs] may direct that, for the purposes of Paragraph 1, working of the invention in another country shall be equivalent to working in this country.

Article 46

The proprietor of a patent for an invention, the exploitation of which is dependent on a patent held by another person, may obtain a compulsory license to exploit the invention protected by the latter patent if the former invention is considered to represent an important technical advance, which has considerable economic significance.

In the event of a compulsory license being granted to exploit a patented invention in pursuance of Paragraph 1, the proprietor of that invention shall be entitled to obtain, upon reasonable terms, a compulsory license to exploit the other invention.

Article 46 a)

A holder of a plant variety who can neither acquire nor exploit a plant variety right without infringing a prior patent may request a compulsory licence for a reasonable payment to exploit the invention if the licence is necessary to exploit the variety to be protected. A compulsory licence shall be granted only if the plant variety holder demonstrates that the variety involves technically important progress and leads to considerable financial benefit in comparison to the invention in the patent.

If a patent holder has obtained a compulsory licence on the basis of the Act on Plant Variety Rights, No. 58/2000, to exploit a protected plant variety, the holder of the plant variety is entitled to a compulsory cross-licence on reasonable terms to exploit the invention.

Article 47

When required by important public interests, any person who wishes to exploit an invention commercially for which another person holds a patent may obtain a compulsory license to do so.

Article 48

Any person who, in this country, at the time when a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for, may, if the application results in a patent, obtain a compulsory license to exploit the invention if very special circumstances make it desirable and he had no knowledge and could not reasonably have obtained any knowledge of the application. Such a right shall also, under similar conditions, be enjoyed by any person who had made substantial preparations for commercial exploitation of the invention in this country.

A compulsory license in accordance with Paragraph 1 may include the time preceding the grant of the patent.

Article 49

A compulsory license may only be granted to a person who has not been able to reach agreement to obtain a license on reasonable terms and may be presumed to be capable of exploiting the invention in a reasonable and acceptable way and in accordance with the terms of the license. [In the event of a national emergency or other circumstances of extreme urgency, it is permissible to waive the requirement for prior negotiations, though the patent holder shall in such cases be notified of this use as soon as reasonably practicable. Further provisions may be made through regulations.

A compulsory license shall not prevent the proprietor of the patent from exploiting the invention himself or from granting licenses to others.

A compulsory license may only be transferred to others together with the business in which it is exploited or in which the exploitation was intended. Furthermore, where a compulsory license has been granted as provided for in Paragraph 1 of Article 46, transfer of a compulsory license may only occur concurrent with transfer of the patent which was dependent upon a patent held by another party.

A compulsory license concerning semi-conductor technology may only be granted for public exploitation which is not of a commercial nature, or to prevent behaviour which a court or government authority has regarded as anti-competitive.]²⁾

A compulsory licence may be granted for exporting medicines to developing countries and countries which are struggling with a severe public health problem, in accordance with the decision of the World Trade Organisation's General Council of 30 August 2003 on the TRIPS agreement and public health. The party requesting a compulsory license must show that they have, for a period of thirty days, made unsuccessful efforts to obtain authorisation for manufacture from the patent holder. However, the above-mentioned requirement for negotiations does not apply in the event of an emergency or other circumstances of extreme urgency. Compulsory licenses, under the terms of this paragraph, will only be granted upon the fulfilment of conditions further specified in regulations³⁾ that are in compliance with the aforementioned decision of the World Trade Organisation's General Council, for instance regarding quantities and drug labelling.

INDIA : Sections 82-85, 88-94 and 99-101 of the Patent Act No. 39 of 1970 as last amended by the Patents Amendment Act No. 15 of 2005.

82. In this Chapter, unless the context otherwise requires,-

- (a) "patented article" includes any article made by a patented process; and
- (b) "patentee" includes an exclusive licensee.

83. Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely,-

(a) that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;

(b) that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;

(c) that the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economical welfare, and to a balance of rights and obligations;

(d) that patents granted do not impede protection of public health and nutrition and should act as instruments to promote public interest specially in sectors of vital importance for socio-economic and technological development of India;

(e) that patents granted do not in any way prohibit central Government in taking measures to protect public health;

(f) that the patent right is not abused by the patentee or person deriving title or interest on patent from the patentee, and the patentee or a person deriving title or interest on patent from the patentee does not resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology; and

(g) that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public.

84.-(1) At any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant on compulsory license on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

(b) that the patented invention is not available to the public at a reasonable price, or

(c) that the patented invention is not worked in the territory of India.

(2) Any application under this section may be made by any person notwithstanding that he is already the holder of a licence under the patent and no person shall be stopped from alleging that the reasonable requirements of the public with respect to the patented invention are not satisfied or that the patented invention is not available to the public at a reasonably affordable price by reason of any admission made by him, whether in such a licence or otherwise or by reason of his having accepted such a licence.

(3) Every application under sub-section (1) shall contain a statement setting out the nature of the applicant's interest together with such particulars as may be prescribed and the facts upon which the application is based.

(4) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention is not worked in the territory of India or that the patented invention is not available to the public at a reasonable price, may grant a licence upon such terms as he may deem fit.

(5) Where the Controller directs the patentee to grant a licence he may, as incidental thereto, exercise the powers set out in section 88.

(6) In considering the application filed under this section, the controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention;

- (ii) the ability of the applicant to work the invention to the public advantage;
- (iii) the capacity of the applicant to undertake the risk in providing capital and working the invention, if the application were granted;
- (iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit:

Provided that this clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on establishment of a ground of anti-competitive practices adopted by the patentee,

But shall not be required to take into account matters subsequent to the making of application.

Explanation.- For the purposes of clause (iv), “reasonable period” shall be construed as a period not ordinarily exceeding a period of six months”.

(7) For the purposes of this Chapter, the reasonable requirements of the public shall be deemed not to have been satisfied-

(a) if, by reason of the refusal of the patentee to grant a licence or licences on reasonable terms,-

- (i) an existing trade or industry or the development thereof or the establishment of any new trade or industry in India or the trade or industry of any person or class of persons trading or manufacturing in India is prejudiced; or
- (ii) the demand for the patented article has not been met to an adequate extent or on reasonable terms; or
- (iii) a market for export of the patented article manufactured in India is not being supplied or developed; or
- (iv) the establishment or development of commercial activities in India is prejudiced; or

(b) if, by reason of conditions imposed by the patentee upon the grant of licenses under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of materials not protected by the patent, or the establishment or development of any trade or industry in India, is prejudiced; or

(c) if the patentee imposes a condition upon the grant of licences under the patent to provide exclusive grant back, preventions to challenges to the validity of patent or coercive package licensing, or

(d) if the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practicable, or

(e) if the working of the patented invention in the territory of India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article by-

- (i) the patentee or person claiming under him, or
- (ii) persons directly or indirectly purchasing from him; or

(iii) other persons against whom the patentee is not taking or has not taken proceeding for infringement.

85. (1) Where, in respect of a patent, a compulsory licence has been granted, the Central Government or person interested may, after the expiration of two years from the date of the order granting the first compulsory licence, apply to the Controller for an order revoking the patent on the ground that the patented invention has not been worked in the territory of India or that reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price.

(2) Every application under sub-section (1) shall contain such particulars as may be prescribed, the facts upon which the application is based, and, in the case of an application other than by the central Government, shall also set out the nature of the applicant's interest.

(3) The Controller, if satisfied that the reasonable requirements of the public with respect to the patented invention have not been satisfied or that the patented invention has not been worked in the territory of India or that the patented invention is not available to the public at a reasonably affordable price, may make an order revoking the patent.

(4) Every application under sub-section (1) shall ordinarily be decided within one year of its being presented to the Controller.

88. (1) Where the Controller is satisfied on application made under section 84 that the manufacture, use or sale of materials not protected by the patent is prejudiced by reason of conditions imposed by the patentee upon the grant of licences under the patent, or upon the purchase, hire or use of the patented article or process, he may, subject to the provisions of that section, order the grant of licences under the patent to such customers of the applicant as he thinks fit as well as to the applicant.

(2) Where an application under section 84 is made by a person being the holder of a licence under the patent, the Controller may, if he makes an order for the grant of a licence to the applicant, order the existing licence to be cancelled, or may, if he thinks fit, instead of making an order for the grant of a licence to the applicant, order the existing licence to be amended.

(3) Where two or more patents are held by the same patentee and an applicant for a compulsory licence establishes that the reasonable requirements of the public have not been satisfied with respect to some only of the said patents, then, if the Controller is satisfied that the applicant cannot efficiently or satisfactorily work the licence granted to him under those patents without infringing the other patents held by the patentee and if those patents involve important technical advancement of considerable economic significance in relation to the other patents, he may, by order, direct the grant of a licence in respect of the other patents also to enable the licensee to work the patent or patents in regard to which a licence is granted under section 84.

(4) Where the terms and conditions of a licence have been settled by the Controller, the licensee may, at any time after he has worked the invention on a commercial scale for a period of not less than twelve months, make an application to the Controller for the revision of the terms and conditions on the ground that the terms and conditions settled have proved to

be more onerous than originally expected and that in consequence thereof the licensee is unable to work the invention except at a loss:

Provided that no such application shall be entertained a second time.

89. The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,-

(a) that patented inventions are worked on a commercial scale in India without undue delay and to the fullest extent that is reasonably practicable;

(b) that the interests of any person for the time being working or developing an invention in India under the protection of a patent are not unfairly prejudiced.

90.-(1) In settling the terms and conditions of a licence under section 84, the Controller shall endeavour to secure-

- (i) that the royalty and other remuneration, if any, reserved to the patentee or other person beneficially entitled to the patent, is reasonable, having regard to the nature of the invention, the expenditure incurred by the patentee in making the invention or in developing it and obtaining a patent and keeping it in force and other relevant factors;
- (ii) that the patented invention is worked to the fullest extent by the person to whom the licence is granted and with reasonable profit to him;
- (iii) that the patented articles are made available to the public at reasonably affordable prices.
- (iv) that the licence granted is a non-exclusive licence;
- (v) that the right of the licensee is non-assignable;
- (vi) that the licence is for the balance term of the patent unless a shorter term is consistent with public interest;
- (vii) that the licence is granted with a predominant purpose of supplying in the Indian market and that the licensee may also export the patented product, if need be in accordance with the provisions of sub-clause (iii) of clause (a) of subsection (7) of section 84;
- (viii) that in the case of semi-conductor technology, the licence granted is to work the invention for public non-commercial use;
- (ix) that in the case the licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive, licensee shall be permitted to export the patented product, if need be.”

(2) No licence granted by the Controller shall authorise the licensee to import the patented article or an article or substance made by a patented process from abroad where such importation would, but for such authorisation, constitute an infringement of the rights of the patentee.

(3) Notwithstanding anything contained in sub-section (2), the Central Government may, if in its opinion it is necessary so to do, in the public interest, direct the Controller at any time to authorise any licensee in respect of a patent to import the patented article or an article or substance made by a patented process from abroad (subject to such conditions as it considers necessary to impose relating among other matters to the royalty and other remuneration, if

any, payable to the patentee, the quantum of import, the sale price of the imported article, and the period of importation), and thereupon the Controller shall give effect to the directions.

91. -(1) Notwithstanding anything contained in the other provisions of this Chapter, at any time after the sealing of a patent, any person who has the right to work any other patented invention either as patentee or as licensee thereof, exclusive or otherwise, may apply to the Controller for the grant of a licence of the first mentioned patent on the ground that he is prevented or hindered without such licence from working the other invention efficiently, or to the best advantage possible.

(2) No order under sub-section (1) shall be made unless the Controller is satisfied-

(i) that the applicant is able and willing to grant, or procure the grant to the patentee and his licensees if they so desire, of a licence in respect of the other invention on reasonable terms; and

(ii) that the other invention has made a substantial contribution to the establishment or development of commercial or industrial activities in India.

(3) When the Controller is satisfied that the conditions mentioned in sub-section (1) have been established by the applicant, he may make an order on such terms as he thinks fit granting a licence under the first mentioned patent and a similar order under the other patent if so requested by the proprietor of the first mentioned patent or his licensee: Provided that the licence granted by the controller shall be non assignable except with the assignment of the respective patents.

(4) The provisions of sections 87, 88 and 89 shall apply to licences granted under this section as they apply to licences granted under section 84.

92. -(1) If the Central Government is satisfied in respect of any patent or class of patents in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary or expedient in the public interest that compulsory licences should be granted at any time after the sealing thereof to work the invention or inventions, it may make a declaration to that effect in the Official Gazette, and thereupon the following provisions shall have effect, that is to say-

(i) the Controller shall, on application made at any time after the notification by any person interested, grant to the applicant a licence under the patent on such terms as he thinks fit;

(ii) in settling the terms of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(2) The provisions of sections 83, 87, 88, 89 and 90 shall apply in relation to the grant of licences under this section as they apply in relation to the grant of licences under section 84.

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section (1) that is necessary in-

- (i) a circumstance of national emergency; or
- (ii) a circumstance of extreme urgency; or
- (iii) a cause of public non-commercial use,

Which may arise or is required, as the case may be, including public health crises, related to Acquired Immune deficiency Syndrome, human immunodeficiency virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section:

Provided that the Controller shall, as soon as may be practicable, inform the patentee of the patent relating to the application for such non-application of section 87.

92A. (1) Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory licence has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India.

(2) The controller shall, on receipt of an application in the prescribed manner, grant a compulsory licence solely for manufacture and export of the concerned product to such country under such terms and conditions as may be specified and published by him.

(3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under any other provision of this Act.

Explanation:- for the purposes of this section, “pharmaceutical products” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use”.

93. Any order for the grant of a licence under this Chapter shall operate as if it were a deed granting a licence executed by the patentee and all other necessary parties embodying the terms and conditions, if any, settled by the Controller.

94. (1) On an application made by the patentee or any other person deriving title or interest in the patent, a compulsory licence granted under section 84 may be terminated by the Controller, if and when the circumstances that gave rise to the grant thereof no longer exist and such circumstances are unlikely to recur.

Provided that the holder of the compulsory licence shall have the right to object to such termination.

(2) While considering an application under sub-section (1), the controller shall take into account that the interest of the person who had previously been granted the licence is not unduly prejudiced.

99.-(1) For the purposes of this Chapter, an invention is said to be used for the purposes of Government if it is made, used, exercised or vended for the purposes of the Central Government, a State Government or a Government undertaking.

(2) (omitted)

(3) Nothing contained in this Chapter shall apply in respect of any such importation, making or using of any machine, apparatus or other article or of any such using of any process, or of any such importation, using or distribution of any medicine or drug, as may be made by virtue of one or more of the conditions specified in section 47.

100.-(1) Notwithstanding anything contained in this Act, at any time after an application for a patent has been filed at the patent office or a patent has been granted, the Central Government and any person authorised in writing by it, may use the invention for the purposes of Government in accordance with the provisions of this Chapter.

(2) Where an invention has, before the priority date of the relevant claim of the complete specification, been duly recorded in a document, or tested or tried, by or on behalf of the Government or a Government undertaking, otherwise than in consequence of the communication of the invention directly or indirectly by the patentee or by a person from whom he derives title, any use of the invention by the Central Government or any person authorised in writing by it for the purposes of Government may be made free of any royalty or other remuneration to the patentee.

(3) If and so far as the invention has not been so recorded or tried or tested as aforesaid, any use of the invention made by the Central Government or any person authorised by it under sub-section (1), at any time after grant of the patent or in consequence of any such communication as aforesaid, shall be made upon terms as may be agreed upon either before or after the use, between the Central Government or any person authorised under sub-section (1) and the patentee, or, as may in default of agreement be determined by the High Court on a reference under section 103:

Provided that in case of any such use of any patent, the patentee shall be paid not more than adequate remuneration in the circumstances of each case, taking into account the economic value of the use of the patent.

(4) The authorisation by the Central Government in respect of an invention may be given under this section, either before or after the patent is granted and either before or after the acts in respect of which such authorisation is given are done, and may be given to any person, whether or not he is authorised directly or indirectly by the applicant or the patentee to make, use, exercise or vend the invention or import the machine, apparatus or other article or medicine or drug covered by such patent.

(5) Where an invention has been used by or with the authority of the Central Government for the purposes of Government under this section, then, except in case of national emergency or other circumstances of extreme urgency or for non-commercial use, the Government shall notify the patentee as soon as practicable of the fact and furnish him with such information as to the extent of the use of the invention as he may, from time to time, reasonably require; and where the invention has been used for the purposes of a Government undertaking, the Central

Government may call for such information as may be necessary for this purpose from such undertaking.

(6) The right to make, use, exercise and vend an invention for the purposes of Government under sub-section (1) shall include the right to sell, on non-commercial basis, the goods which have been made in exercise of that right, and a purchaser of goods so sold, and a person claiming through him, shall have the power to deal with the goods as if the Central Government or the person authorised under sub-section (1) were the patentee of the invention.

(7) Where in respect of a patent which has been the subject of an authorisation under this section, there is an exclusive licensee as is referred to in sub-section (3) of section 101, or where such patent has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention (including payments by way of minimum royalty), the notice directed to be given under sub-section (5) shall also be given to such exclusive licensee or assignor, as the case may be, and the reference to the patentee in sub-section (3) shall be deemed to include a reference to such assignor or exclusive licensee.

101.-(1) In relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the purposes of Government-

(a) by the Central Government or any person authorised by the Central Government under section 100; or

(b) by the patentee or applicant for the patent to the order made by the Central Government,

the provisions of any licence, assignment or agreement granted or made between the patentee or applicant for the patent (or any person who derives title from him or from whom he derives title) and any person other than the Central Government shall be of no effect so far as those provisions-

(i) restrict or regulate the use for the purposes of Government of the invention, or of any model, document or information relating thereto, or

(ii) provide for the making of payments in respect of any use of the invention or of the model, document or information relating thereto for the purposes of Government,

and the reproduction or publication of any model or document in connection with the said use for the purposes of Government shall not be deemed to be an infringement of any copyright subsisting in the model or document.

(2) Where the patent, or the right to apply for or obtain the patent, has been assigned to the patentee in consideration of royalties or other benefits determined by reference to the use of the invention, then, in relation to any use of the invention made for the purposes of Government by the patentee to the order of the Central Government, sub-section (3) of section 100 shall have effect as if that use were made by virtue of an authority given under that section; and any use of the invention for the purposes of Government by virtue of sub-section 3) of that section shall have effect as if the reference to the patentee included a reference to the assignor of the patent, and any sum payable by virtue of that sub-section shall be divided

between the patentee and the assignor in such proportion as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103.

(3) Where by virtue of sub-section (3) of section 100, payments are required to be made by the Central Government or persons authorised under sub-section (1) of that section in respect of the use of an invention for the purposes of Government and where in respect of such patent there is an exclusive licensee authorised under his licence to use the invention for the purposes of Government, such sum shall be shared by the patentee and such licensee in such proportions, if any, as may be agreed upon between them or as may in default of agreement be determined by the High Court on a reference under section 103 to be just, having regard to any expenditure incurred by the licensee-

- (a) in developing the said invention; or
- (b) in making payments to the patentees other than royalties or other benefits determined by reference to the use of the invention.

INDONESIA : *Articles 74-77, 79 and 99-103 of the Patent Law No. 14 of 01/08/2001*

Article 74

A compulsory license shall mean a License to implement a Patent that is granted based on a decision of the Directorate General based on an Application.

Article 75

(1) Any party, after the expiration of a period of 36 (thirty six) months commencing from the date of grant of a Patent, may file a request for a Compulsory License at the Directorate General, with the payment of a fee.

(2) A request for a Compulsory License as referred to in paragraph (1) shall only be made on the grounds that the relevant Patent has not been implemented or only partially implemented by the Patent holder.

(3) A request for a Compulsory License may also be filed at any time after the grant of Patent on the grounds that the relevant Patent has been implemented by the Patent Holder or the licensee in a form and manner that contravenes the public interest.

Article 76

(1) In addition to the truth of grounds as referred to in Article 75 paragraph (2), a Compulsory License may only be granted if:

a) the person filing the request can provide convincing evidence that he:

1. has the ability to personally and fully implement the relevant Patent;
2. has his own facilities to readily implement of the relevant Patent;
3. has made efforts in a sufficient period of time to acquire a License from the Patent Holder on the basis of normal terms and conditions but did not succeed.

b) the Directorate General is of the opinion that relevant Patent can be implemented in Indonesia on a feasible economic scale and can be of benefit to the majority of the society.

(2) The examination of a request for a compulsory license shall be carried out by the Directorate General by hearing the opinion of other related government agencies and parties, as well as the relevant 'Patent Holder.

(3) A Compulsory License shall be granted for a period no longer than the period of Patent protection.

Article 77

If, based on the evidence and opinions as referred to in Article 76, the Directorate General is convinced that the period as referred to in Article 75 paragraph (1) is insufficient for the Patent Holder to commercially implement the Patent in Indonesia, or within a regional scope as referred to in Article 17 paragraph (2), it may stipulate to temporarily postpone the decision to grant a Compulsory License or to refuse to grant one.

Article 79

The decision of the Directorate General regarding the grant of a Compulsory License shall include the followings:

- a) that the Compulsory License shall be non-exclusive;
- b) the grounds for granting of the Compulsory License;
- c) evidence, including convincing information or explanations, which form the basis for the granting of the Compulsory License;
- d) the period of the Compulsory License;
- e) the amount of royalties to be paid by the compulsory licensee to the Patent Holder and the method of payment therefore;
- f) conditions on the termination of the Compulsory License and matters, which may cause revocation of the Compulsory License;
- g) that the Compulsory License will be primarily used to supply the demand in the national market.
- h) other matters necessary to fairly protect the interest of the parties concerned.

Article 99

(1) If the Government is of the opinion that a Patent in Indonesia is very important for the conduct of defense and security of the State and for an urgent need for the sake of public interest, the Government may itself exploit the relevant Patent.

(2) The decision to self-exploit a Patent shall be regulated by Presidential Decree after hearing the consideration from the Minister and from the minister or head of the agencies responsible in the relevant field.

Article 100

(1) The provisions of Article 99 shall apply *mutatis mutandis* to any Invention for which a Patent has been requested but which has not been announced as referred to in Article 46.

(2) Where the Government does not or has not yet intended to self-exploit a Patent as referred to in paragraph (1), the exploitation of such a Patent may only be undertaken with an approval from the Government.

(3) The Patent Holder as referred to in paragraph (2) shall be released from the obligation to pay the annual fees until the relevant Patent is exploited.

Article 101

(1) Where the Government intends to self-exploit a Patent that is important to the conduct of defense and security of the State and for an urgent need for the sake of public interest, the Government shall notify the Patent Holder in writing of this fact by setting forth:

- a) the title and number of the relevant Patent as well as the name of Patent Holder;
- b) reasoning;
- c) the period of exploitation;
- d) other matters that are deemed significant.

(2) The exploitation of a Patent by the Government shall be carried out with the provision of reasonable compensation to the Patent Holder.

Article 102

(1) The decision of the Government to self-exploit a Patent shall be final.

(2) Where the Patent Holder does not agree with the amount of compensation stipulated by the Government, he may file objections as a lawsuit to the Commercial Court.

(3) The process of examining the lawsuit as referred to in paragraph (2) shall not stop the exploitation of the relevant Patent by the Government.

Article 103

Provisions regarding the procedure of exploitation of Patent by the Government shall be further regulated by Government Regulation.

IRAQ : Articles 27-30b of the Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law No. 65 of 1970 as last amended by Coalition Provisional Authority Order Number 81

Article 2 - "The Registrar may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively:

A) If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible.

B) 1. If the patentee does not exploit it or exploits it insufficiently before the elapse of four years as of the application date or three years as of the granting date, the period to be applied is the one that elapses later. However, the Registrar may grant the patentee an additional grace period if it is deemed that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the relevant International Conventions, the importation of the subject goods of the patent to Iraq shall be deemed utilization of the patent.

C. If rights are exercised by the patentee in such a way as to prevent others from competing fairly.”

Article 28 - “The following shall be taken into consideration when compulsory licenses are granted:

A) Each application for a license shall be decided separately for its specific conditions and circumstances.

B) The applicant shall have tried to obtain a license from the patentee under reasonable remuneration and conditions but did not reach an agreement during a reasonable period of time in the case provided for in paragraph (B) of Article 27 of this Law.

C) The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for noncommercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive.

D) The license to exploit shall not be exclusive.

E) The license shall not be assignable to third parties.

F) The license shall only be granted for meeting the demand in the local market except in cases where practices have been deemed by the competent judicial or administrative authority to be anticompetitive.

G) The patentee shall receive an equitable remuneration which takes into account the economic value of the patent.”

Article 29 - “The Registrar may cancel the compulsory license sua sponte or on the strength of an application from the patentee if the reasons for its grant lapsed. This license cancellation shall, however, preserve the rights of those involved in the compulsory license.”

Article 30 - “The provisions and procedures related to licensing of patent utilization shall be prescribed pursuant to regulations to be issued to this aim.”

Article 30b - “The Registrar’s compulsory license decision shall be appealable to the Minister within 60 days of its notification.”

IRELAND (EU) : *Sections 70-78 of the Patent Act No. 1 of 27/02/1992, as last amended by Law No. 31 of 2006*

70.— (1) At any time after the expiration of the period of three years, or such other period as may be prescribed, beginning on the date of the publication of notice of grant of a patent any person may apply to the Controller for a licence under the patent, or for an entry in the register to the effect that licences under the patent are to be available as of right, on any or all of the following grounds:

(a) that—

- (i) a demand in the State for the subject matter of the patent is not being met or is not being met on reasonable terms, or
- (ii) a demand in the State for a product which is protected by the patent is being met by importation other than from a member of the World Trade Organisation;

(b) that the establishment or development of commercial or industrial activities in the State is unfairly prejudiced.

(2) If an invention protected by a patent (in this section referred to as ‘the second patent’) cannot be exploited in the State without infringing rights deriving from another patent (in this section referred to as ‘the first patent’) the proprietor of the second patent may apply to the Controller for a licence under the first patent to the extent necessary for the exploitation of the invention concerned, provided that such invention involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.

(3) Where an application is made under this section, if the Controller is satisfied:

- (a) that any of the grounds specified in subsection (1) are established, or
- (b) that an invention protected by a patent cannot be exploited without infringing rights deriving from the first patent as referred to in subsection (2),

the Controller may make an order in accordance with the application and, where the order is for the grant of a licence, the order may require the licence to be granted upon such terms as the Controller thinks fit, provided that:

- (i) any licence granted shall be non-exclusive;
- (ii) any licence granted shall be predominantly for the supply of the market in the State;
- (iii) any licence granted may only be assigned with the prior authorisation of the Controller and with that part of the enterprise or goodwill which uses the patented invention and, in the case of a licence granted on an application under subsection (2) in respect of the first patent, the licence may only be assigned by the proprietor of the second patent in conjunction with the assignment of the second patent;
- (iv) a licence shall only be granted subject to the payment to the proprietor of the patent of adequate remuneration in the circumstances of the case, taking into account the economic value of the licence;
- (v) the scope and duration of the licence shall be limited to the purpose for which it is granted;
- (vi) any licence granted on an application under subsection (1) in respect of a patent which relates to semi-conductor technology shall only be for public non-commercial use;
- (vii) no order shall be made on an application under subsection (2) unless the proprietor of the second patent is able and willing to grant the proprietor of the first patent and the licensee of that proprietor a cross-licence, on reasonable terms, to use the invention claimed in the second patent.

(4) The Controller shall, in determining whether to make an order pursuant to an application under this section, take account of the following matters, namely—

(a) the nature of the relevant invention, the time which has elapsed since the grant of the patent and the measures already taken by the proprietor or any licensee to make full use of the invention,

(b) the ability of any person to whom a licence would be granted under the order to exploit the patent to the public advantage, and

(c) the risks to be undertaken by that person in providing capital and exploiting the patent if the application is granted.

(5) Section 68(3) shall apply to a licence granted pursuant to an order under this section as it applies to a licence granted by virtue of section 68.”

71.— (1) Where an order for the grant of a licence or for an entry in the register has been made pursuant to an application under section 70, any person may apply to the Controller to amend or cancel the order on the grounds that the circumstances which led to the order have changed or have ceased to exist and are unlikely to recur.

(2) Where the Controller is satisfied that the circumstances referred to in subsection (1) have changed or have ceased to exist and are unlikely to recur, the Controller may order the amendment or cancellation of the existing order upon such terms as the Controller thinks fit, including, in particular, terms which provide for the protection of the interests of the licensee concerned.

(3) Section 73 shall, in so far as it is applicable, apply in relation to an application under subsection (1).

(4) Where, following an application under subsection (1), an order is amended, subsections (1), (2) and (3) shall, in so far as they are applicable, apply in relation to the order so amended.

72.-

(1) At any time after the expiration of the period of three years beginning on the date of the publication of notice of grant of a patent, or such other period as may be prescribed under section 70(1), any Minister of the Government may apply to the Controller upon any one or more of the grounds specified in section 70 for an entry in the register to the effect that licences under the patent are to be available as of right, or for the grant to any person specified in the application of a licence under the patent, and the Controller may, if satisfied that any of those grounds are established, make an order in accordance with the application.

(2) Sections 70(3) and 71 shall, so far as applicable, apply in relation to an application and an order made under this section as they apply in relation to an application and an order under section 70.

73.-

(1) Every application under section 70 or 72 shall specify the nature of the order sought by the applicant and shall contain a statement (to be verified in such manner as may be

prescribed) setting out the nature of the applicant's interest (if any) and the facts upon which the application is based and shall be accompanied by evidence indicating that the applicant sought to obtain a licence from the proprietor of the patent but has been unable to obtain such a licence on reasonable terms and within a reasonable time.

(1A) The Controller may, when so requested by the applicant, dispense with the evidence referred to in subsection (1)—

(a) where there exists a national emergency or other circumstances of extreme urgency, or

(b) in the case of an application for a licence for public non-commercial use:

Provided that the proprietor of the relevant patent has been informed as soon as reasonably practicable of the intention of the applicant to apply to the Controller for a licence under the patent.

(2) Where the Controller is satisfied, upon consideration of any application referred to in subsection (1), that a prima facie case has been made out for the making of an order, he shall direct the applicant to serve copies of the application upon the proprietor of the relevant patent and any other persons appearing from the register to be interested in the patent in respect of which the application is made, and shall advertise the application in the Journal.

(3) The proprietor of the relevant patent or any other person desiring to oppose an application referred to in subsection (1) may, within such time as may be prescribed, give to the Controller notice of opposition.

(4) A notice of opposition given under this section shall contain a statement (to be verified in such manner as may be prescribed) setting out the grounds on which the relevant application is opposed.

(5) Where a notice of opposition is duly given under this section, the Controller shall notify the applicant and shall, subject to the provisions of section 74 with respect to arbitration, determine the question.

74.-

(1) On any appeal from any order made by the Controller in pursuance of an application under section 70, 71 or 72 the Attorney General shall be entitled to appear and be represented.

(2) Where an application is opposed and either:

(a) the parties consent; or

(b) the proceedings require a prolonged examination of documents or any scientific or local investigation which cannot, in the opinion of the Controller, conveniently be made before him,

the Controller may at any time order the whole proceedings, or any question or issue of fact arising therein, to be referred to an arbitrator agreed on by the parties, or, in default of agreement, appointed by the Controller.

(3) Where the whole proceedings are referred under this section, section 35 of the Arbitration Act, 1954 (which relates to the statement of cases by arbitrators for the decision of the Court), shall not apply to the arbitration; but unless the parties otherwise agree before the award of the arbitrator is made, an appeal to the Court shall lie from the award.

(4) Where a question or issue of fact is referred under this section, the arbitrator shall report his findings to the Controller.

75.-

(1) Any order under this Act for the grant of a licence shall, without prejudice to any other method of enforcement, have effect as if it were a deed, executed by the proprietor of the patent and all other necessary parties, granting a licence in accordance with the order.

(2) An order may be made on an application under section 70 or 72 for an entry in the register to the effect that licences under the relevant patent are to be available as of right notwithstanding any contract which would have precluded the making of such an entry in respect of the patent on the application of the proprietor of the patent under section 68, and any such order shall for all purposes have the same effect as an entry made in pursuance of an application under section 68.

(3) No order shall be made in pursuance of any application under section 70, 71 or 72 which would be at variance with the Treaty establishing the European Economic Community or with the TRIPs Agreement.

PART V

Use of Inventions for the Service of the State

76.-

(1) Any inventor, or any applicant for or proprietor of a patent, may (either for or without valuable consideration) make to a Minister of the Government, and such Minister may take on behalf of the State, an assignment of the whole of or any share or interest in the benefit of an invention, of a patent application therefor, or of any patent obtained or to be obtained therefor, and where a Minister of the Government takes any such assignment, such Minister may do, or, as may be appropriate, join in doing, on behalf of the State, all or any of the following things, that is to say-

- (a) develop and perfect such invention,
- (b) form or promote an incorporated company or an unincorporated association of persons to develop and perfect such invention,
- (c) sell or lease any such patent application or patent or grant licences under any such application or patent on such terms as he shall, with the agreement of the Minister for Finance, think proper,
- (d) form or promote an incorporated company or an unincorporated association of persons to work commercially any such invention,
- (e) do all such things as may be necessary for the maintenance or preservation of any such application or patent or be otherwise incidental to the ownership thereof.

(2) Every Minister of the Government shall, before the 1st day of April in every year, lay before each House of the Oireachtas a report of every (if any) exercise by him during the year ending on the previous 31st day of December of the several powers conferred on him by paragraph (c) or (d) of subsection (1) and also, if and so far as he considers it to be in the

public interest, of any or all of the powers conferred by paragraph (a), (b) or (e) of subsection (1).

(3) All expenses incurred by a Minister of the Government under this section shall, to such extent as may be sanctioned by the Minister for Finance, be paid out of moneys provided by the Oireachtas.

77.-

(1) A patent and a patent application shall have to all intents the like effect as against the State as it has against an individual; provided that any Minister of the Government may, by himself or by such of his officers, servants or agents as may be authorized in writing by him or by any other person acting on his behalf at any time after the making of an application for a patent, do for the service of the State any of the following acts in the State in relation to an invention which is the subject of the application or patent, without the consent of the applicant for or the proprietor of the patent, that is to say-

(a) where the invention is a product, make, use, import or stock the product or dispose of or sell or offer to dispose of or sell it to any person;

(b) where the invention is a process, use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a);

(c) supply or offer to supply to any person any of the means, relating to an essential element of that invention, for putting the invention into effect.

(2) Anything done by virtue of subsection (1) in relation to an invention which is the subject of an application or a patent, is subsequently in this section and in section 78 referred to as "use of the invention" and the doing of any such thing shall not amount to an infringement of the application or patent concerned.

(3) Use of an invention under this section shall be subject to such terms as may, either before or after the use thereof, be agreed on, with the approval of the Minister for Finance, by any Minister of the Government and the applicant for or the proprietor of the patent relating to the invention, or, in default of agreement, as may be settled in the manner hereinafter provided, and the terms of any agreement or licence concluded between such applicant or proprietor and any person other than a Minister of the Government shall not operate to prevent or regulate the use of the invention for the service of the State.

(4) Where an invention which is the subject of any patent or application for a patent has, before the date of filing, or, where priority is claimed, the priority date of the application, been duly recorded in a document by, or been tried by or on behalf of any Minister of the Government (such invention not having been communicated directly or indirectly by the applicant for or the proprietor of the relevant patent), any Minister of the Government or such of his officers, servants or agents as may be authorized in writing by him, may use the invention so recorded or tried for the service of the State free of any royalty or other payment to the applicant for or the proprietor of the patent, notwithstanding the existence of the application or patent, and, if in the opinion of such Minister the disclosure to the applicant or the proprietor, as the case may be, of the document recording the invention or the evidence of the trial thereof would be detrimental to the public interest, such disclosure may be made confidentially to counsel on behalf of such applicant or proprietor or to any independent expert mutually agreed upon.

(5) Where any use of an invention is made by or with the authority of a Minister of the Government under this section, then, unless it appears to such Minister that it would be contrary to the public interest so to do, the Minister shall notify the applicant for or the proprietor of a patent (if any) relating to the invention as soon as practicable after the use is begun and furnish him with such information as to the extent of the use as he may from time to time reasonably require.

(6) In the case of any dispute as to or in connection with the use of an invention under this section or the terms therefor, or as to the existence or scope of any record or trial referred to in subsection (4), the matter shall be referred to the Court for decision, and the Court shall have the power to refer the whole matter or any question or issue of fact arising thereon to be heard by an arbitrator upon such conditions as it may direct; the Court or arbitrator in settling the dispute shall be entitled to take into consideration any benefit or compensation which the applicant for or proprietor of a patent (if any) relating to the invention or any other person interested in such application or in such patent may have received directly or indirectly from the State in respect of such application or patent.

(7) In any proceedings under this section the Minister of the Government who is a party to the proceedings may-

- (a) put in issue the validity of the relevant patent without applying for its revocation;
- (b) if the proprietor of a patent is a party to the proceedings, apply for revocation of the patent upon any ground upon which a patent may be revoked under section 58.

(8) The right to use an invention for the service of the State under the provisions of this section shall include a power to dispose of or sell, or offer to dispose of or sell, any products made in pursuance of such right which are no longer required for the service of the State.

(9) Any person who acquires products disposed of or sold in the exercise of powers conferred by this section and any person claiming through him shall have power to deal with the products in the same manner as if they had been made pursuant to a patent held on behalf of the State.

(10) In this section "service of the State" means a service financed out of moneys charged on or advanced out of the Central Fund or moneys provided by the Oireachtas or by a local authority for the purposes of the Local Government Act, 1941.

78.-

(1) During any period when an order under subsection (2)(a) is in force the power exercisable in relation to an invention by a Minister of the Government, or a person authorized by a Minister of the Government under section 77, shall include power to use the invention for any purpose which appears to such Minister to be necessary or expedient-

- (a) for the maintenance of supplies and services essential to the life of the community;
- (b) for securing a sufficiency of supplies and services essential to the well-being of the community;

- (c) for promoting the productivity of commerce and industry, including agriculture;
- (d) generally for ensuring that the whole resources of the community are available for use and are used, in a manner best calculated to serve the interests of the community;

- (e) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory other than the State that is in grave distress;

or

- (f) for ensuring the public safety and the preservation of the State.

(2)

(a) Where the Government are of opinion that, owing to the existence of exceptional circumstances, it is desirable in the interests of the community that a power conferred by subsection (1) shall be available, they may by order declare that the power shall be available.

(b) Where an order under paragraph (a) of this subsection is for the time being in force and the Government are of the opinion that the exceptional circumstances referred to in that paragraph no longer exist, they shall by order revoke the first-mentioned order.

ISRAEL : *Sections 104-107 and 116-126 of the Patent Law no. 5727 of 08/08/1967*

Right of State to exploit invention

104. The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.

Right of State to permit exploitation of invention

105. The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract and for the requirements of the State only.

Notice of Grant of exploitation permit

106. When a permit has been granted under this Article, the Minister shall notify the owner of the invention or the patent holder and the holder of the exclusive license that the permit was granted and the scope of the permitted use, unless National security requires otherwise.

Compensation for restriction of activities

107. If an order was made under section 94 or 99 or if a permit was not granted under section 98 or 103, then the Treasury shall pay to the owner of the invention compensation at the rate set by agreement between the parties or-in the absence of agreement-by the compensation and royalties committee established under section 109.

116. In this Article-"patented product"-a product for which, or for the production process of which a patent was granted;

"patent holder" includes the holder of an exclusive license under the patent.

Power to grant compulsory license

117.-(a) If the Registrar is satisfied that a patent holder abuses his monopoly, then he may grant a license to exploit the invention that is the subject of the patent to a person who applied therefor in the prescribed manner and paid the prescribed fee.

(b) The Registrar shall not entertain an application under this section, unless it was submitted later than three years after the date on which the patent was granted or four years after the date on which the patent application was submitted, whichever is later.

Power to require notification concerning exploitation of patent

118.-(a) At the end of the time said in section 117, the Registrar may demand that a patent holder notify him, within sixty days of the date of the demand, whether he exploits the patented invention in Israel by way of production, and if so, what the extent and the location of the production are.

(b) The Registrar shall demand the notification under this section if he was requested to do so by use of the prescribed form and if the prescribed fee was paid.

(c) If the patent holder does not respond to the demand within 60 days after the date of the demand or within an additional period prescribed by the Registrar, then that shall be deemed an admission on the part of the patent holder that he abuses the monopoly conferred on him by the patent for the invention, in respect of which the notice was sent.

Abuse of monopoly defined

119. The exercise of a monopoly conferred by a patent shall be deemed abusive, if one of the following circumstances exists in respect of the invention, the product or the process which is the subject of the patent, and if the patent holder did not provide a reasonable justification for its existence:

- (1) all the demand for the product is not satisfied in Israel on reasonable terms;
- (2) the conditions attached by the patent holder to the supply of the product or to the grant of a license for its production or use are not fair under the circumstances of the case, do not take account of the public interest and arise essentially out of the existence of the patent;
- (3) exploitation of the invention by way of production in Israel is impossible or restricted by the importation of the product;
- (4) the product is not produced in Israel and the patent holder refuses to grant to a local producer a license for its production or use on reasonable terms, neither for the requirements of the local market nor for export purposes;
- (5) the patent holder refuses to grant a license for the production of the product or for the use of the process in Israel on reasonable terms and because of that refusal-
 - (a) the export of a product from Israel is prevented or adversely affected; or
 - (b) the launching or development in Israel of a commercial or industrial activity is prevented.

Compulsory license for medical purposes

120.-(a) Subject to the provisions of section 122, the Registrar may-if he was requested to do so and if that is necessary in order to give the public a reasonable quantity of medical supplies-grant a license for-

- (1) a patented product that can be used as a medicament or for the production of a medicament;
- (2) a patented process for the production of a product said in paragraph (1);
- (3) a patented device that can be used as a device for medical purposes or as part thereof.
 - (b) This section shall add to, and not derogate from the powers of the Registrar under section 117.

Compulsory license to exploit earlier patent on which the fate of a later patent depends

121.-(a) If a patented invention (hereafter: later invention) cannot be exploited without infringing an invention, for which the patent application date was earlier (hereafter: earlier invention), then the Registrar may, if so requested by the patent holder of the later invention, grant him a license to exploit the earlier invention to the extent necessary for the exploitation of the later invention, on condition that the later invention serves a different industrial purpose than the earlier one or that it makes a considerable advance over the earlier one.

(b) If the earlier and the later invention serve the same industrial purpose, then a license under subsection (a) shall be granted on condition that the owner of the later invention grant a similar license to the owner of the earlier invention if he so requests.

(c) In the case of a patent application for which priority was claimed under section 10(a), the date of the previous application, within the meaning of section 10(a), shall be deemed the patent application date for purposes of this section.

Factors to be taken into account in granting compulsory license

122. In dealing with an application for a license under section 117 or 120, the Registrar shall also take the following factors into account:

(1) the applicant's ability to remedy the fault, because of which the license was applied for;

(2) the public interest, which generally requires that inventions that can be exploited in Israel by way of production should be so exploited to the greatest extent possible under existing circumstances and without delay;

(3) the right to reasonable remuneration, taking the nature of the invention into account, for exploitation of the patented invention;

(4) protection of the rights of any person who exploits in Israel, by way of production, the invention to which the application for the license relates and of persons engaged in developing that invention;

(5) the nature of the invention, the time elapsed since the patent was granted, and the steps taken by the patent holder or by his representative for the exploitation of the invention in Israel by way of production.

Restriction of scope of compulsory license

123.-(a) A license under this Chapter shall only be granted for exploitation of an invention in Israel in the course of production.

(b) A license under this Chapter shall only be granted to a person who is capable of exploiting the invention as said in subsection (a) to a reasonable extent.

(c) Notwithstanding the provisions of this section, when the Registrar grants a license under section 120 he may permit exploitation of the invention also in some other manner, if it is not possible to exploit it by way of production in Israel, or if it is not possible to supply the patented product in this manner to an extent that satisfies demand for it, and if it is necessary to grant the license, so that the public will have a reasonable quantity of medical supplies at reasonable prices.

Invitation to join proceedings on application for compulsory license

124.-(a) As soon as possible after an application for a license under this Chapter was submitted, the Registrar shall-at the applicant's expense-publish a notice in Reshumot that the application was submitted, and in it he shall invite all persons with an interest in the

application or likely to be adversely affected by the grant of the license to join the proceedings.

(b) If a person wishes to join the proceeding, then he shall give notice thereof in the prescribed manner and at the prescribed time, and he shall pay the prescribed fee, and when he has done so he shall be deemed an applicant or a respondent in the proceeding, as the case may be.

(c) This section shall add to and not derogate from the provision of section 159.

Effect of compulsory license

125. A compulsory license under this Chapter shall go into effect thirty days after the day of the Registrar's decision or on a later date prescribed by the Registrar; if an appeal was submitted against the decision, then the Court may delay its going into effect or it may attach conditions to its going into effect or to its delay.

Conditions of license

126. A license under this Chapter shall be a non-exclusive license, and the Registrar shall prescribe its conditions when he grants it, including the royalties or other consideration which the licensee shall pay to the patent holder, all as is reasonable and appropriate in the circumstances of the case, and the Registrar shall also prescribe-

- (1) circumstances under which the license shall be deemed void or shall be cancelled or its conditions shall be changed;
- (2) the ways of determining the amount of the royalties or of the other consideration, when and how they shall be paid;
- (3) the ways of marking the product produced under the license.

ITALY (EU): *Articles 70- 72 of the Industrial Property Code, Legislative Decree No. 30 of 15/02/2005*

Art. 70

Licenza obbligatoria per mancata attuazione

1. Trascorsi tre anni dalla data di rilascio del brevetto o quattro anni dalla data di deposito della domanda se questo termine scade successivamente al precedente, qualora il titolare del brevetto o il suo avente causa, direttamente o a mezzo di uno o più licenziatari, non abbia attuato l'invenzione brevettata, producendo nel territorio dello Stato o importando oggetti prodotti in uno Stato membro della Unione europea o dello Spazio economico europeo ovvero in uno Stato membro dell'Organizzazione mondiale del commercio, ovvero l'abbia attuata in misura tale da risultare in grave sproporzione con i bisogni del Paese, può essere concessa licenza obbligatoria per l'uso non esclusivo dell'invenzione medesima, a favore di ogni interessato che ne faccia richiesta.

2. La licenza obbligatoria di cui al comma 1 può ugualmente venire concessa, qualora l'attuazione dell'invenzione sia stata, per oltre tre anni, sospesa o ridotta in misura tale da risultare in grave sproporzione con i bisogni del Paese.

3. La licenza obbligatoria non viene concessa se la mancata o insufficiente attuazione e' dovuta a cause indipendenti dalla volontà del titolare del brevetto o del suo avente causa. Non sono comprese fra tali cause la mancanza di mezzi finanziari e, qualora il prodotto stesso sia

diffuso all'estero, la mancanza di richiesta nel mercato interno del prodotto brevettato od ottenuto con il procedimento brevettato.

4. La concessione della licenza obbligatoria non esonera il titolare del brevetto o il suo avente causa dall'onere di attuare l'invenzione. Il brevetto decade, qualora l'invenzione non sia stata attuata entro due anni dalla data di concessione della prima licenza obbligatoria o lo sia stata in misura tale da risultare in grave sproporzione con i bisogni del Paese.

Art. 71

Brevetto dipendente

1. Può essere concessa licenza obbligatoria se l'invenzione protetta dal brevetto non possa essere utilizzata senza pregiudizio dei diritti relativi ad un brevetto concesso in base a domanda precedente. In tale caso, la licenza può essere concessa al titolare del brevetto posteriore nella misura necessaria a sfruttare l'invenzione, purché questa rappresenti, rispetto all'oggetto del precedente brevetto, un importante progresso tecnico di considerevole rilevanza economica.

2. La licenza così ottenuta non è cedibile se non unitamente al brevetto sull'invenzione dipendente. Il titolare del brevetto sull'invenzione principale ha diritto, a sua volta, alla concessione di una licenza obbligatoria a condizioni ragionevoli sul brevetto dell'invenzione dipendente.

Art. 72.

Disposizioni comuni

1. Chiunque domandi la concessione di una licenza obbligatoria ai sensi degli articoli 70 e 71, deve provare di essersi preventivamente rivolto al titolare del brevetto e di non avere potuto ottenere da questi una licenza contrattuale ad eque condizioni.

2. La licenza obbligatoria può essere concessa soltanto contro corresponsione, da parte del licenziatario ed a favore del titolare del brevetto o dei suoi aventi causa, di un equo compenso e purché il richiedente la licenza fornisca le necessarie garanzie in ordine ad una soddisfacente attuazione dell'invenzione a norma delle condizioni fissate nella licenza medesima.

3. La licenza obbligatoria non può essere concessa quando risulti che il richiedente abbia contraffatto il brevetto, a meno che non dimostri la sua buona fede.

4. La licenza obbligatoria può essere concessa per uno sfruttamento dell'invenzione diretto prevalentemente all'approvvigionamento del mercato interno.

5. La licenza obbligatoria è concessa per durata non superiore alla rimanente durata del brevetto e, salvo che vi sia il consenso del titolare del brevetto o del suo avente causa, può essere trasferita soltanto con l'azienda del licenziatario o con il ramo particolare di questa nel quale la licenza stessa viene utilizzata.

6. La concessione della licenza obbligatoria non pregiudica l'esercizio, anche da parte del licenziatario, dell'azione giudiziaria circa la validità del brevetto o l'estensione dei diritti che ne derivano.

7. Nel decreto di concessione della licenza vengono determinati l'ambito la durata, le modalità per l'attuazione, le garanzie e le altre condizioni alle quali è subordinata la

concessione in relazione allo scopo della stessa, la misura e le modalità di pagamento del compenso. In caso di opposizione, la misura e le modalità di pagamento del compenso sono determinate a norma dell'articolo 80.

8. Le condizioni della licenza possono, con decreto del Ministero delle attività produttive, essere variate su richiesta di ognuna delle parti interessate, qualora sussistano validi motivi al riguardo.

9. Per la modificazione del compenso si applica l'articolo 80.

10. Nel caso in cui il titolare del brevetto per il quale sia stata concessa licenza obbligatoria o il suo avente causa conceda a terzi l'uso del brevetto medesimo a condizioni più vantaggiose di quelle stabilite per la licenza obbligatoria, le condizioni stesse sono estese alla licenza obbligatoria, su istanza del licenziatario.

JAPAN : Articles 72, 79-83 and 92-97 of the Patent Law No. 121 of 13/04/1959, as last amended by Act No. 109 of 2006

Article 72 (Related to patented inventions, etc., by others)

Where a patented invention uses another person's patented invention, registered utility model, registered design or design similar thereto for which an application was filed prior to the date of filing of the said patent application, or where the patent right is in conflict with another person's design right or trademark right obtained based on an application filed prior to the date of filing of the said patent application, the patentee, exclusive licensee or non-exclusive licensees may not work the patented invention as a business.

Article 79 (Non-exclusive license based on prior use)

A person who, without knowledge of the content of an invention claimed in a patent application, made an invention identical to the said invention, or a person who, without knowledge of the content of an invention claimed in a patent application, learned the invention from a person who made an invention identical to the said invention and has been working the invention or preparing for the working of the invention in Japan at the time of the filing of the patent application, shall have a non-exclusive license on the patent right, only to the extent of the invention and the purpose of such business worked or prepared.

Article 80 (Non-exclusive license due to the working of the invention prior to the registration of the request for a trial for patent invalidation)

(1) A person falling under any of the following items, who is doing a business working an invention in Japan or preparing such business, before the registration of a request for a trial for patent invalidation, without knowledge that the patent falls under any of the paragraphs of Article 123(1), shall have a non-exclusive license regarding the invalidated patent right or the exclusive license existing at the time of the invalidation, only to the extent of the invention and the purpose of such business worked or prepared:

- (i) the original patentee in the case where one of two or more patents granted for the same invention has been invalidated;

- (ii) the original patentee in the case where, after a patent has been invalidated, a patent is granted to the person who is entitled to obtain a patent for the same invention; and
- iii) in the case referred to in items () (i) and (ii), a person that, at the time of the registration of the request for a trial for patent invalidation, has an exclusive license regarding the patent right to be invalidated, or a non-exclusive license effective under Article 99(1) regarding the patent right or an exclusive license on the patent right.

(2) The patentee or the exclusive licensee shall have a right to receive reasonable consideration from the non-exclusive licensee under the preceding paragraph.

Article 81 (Non-exclusive license after expiration of duration of design right)

Where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, the original holder of design right shall, upon expiration of the duration of the design right, have a non-exclusive license on the said patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original design right.

Article 82

(1) Where a design right with regard to an application for a design registration filed on or before the date of filing of a patent application is in conflict with the patent right with regard to the patent application, a person who, at the time of expiration of the duration of the design right, actually owns the exclusive license on the design right, or a non-exclusive license having effect under Article 99(1) of the Patent Act as applied under Article 28(3) of the Design Act on the design right or on the exclusive license shall, upon expiration of the duration of the design right, have a non-exclusive license on the patent right or on the exclusive license actually existing at the time of expiration of the duration of the design right, limited to the extent of the original right.

(2) The patentee or the exclusive licensee shall have a right to receive reasonable consideration from the non-exclusive licensee under the preceding paragraph.

Article 83 (Award granting non-exclusive license where invention is not worked)

(1) Where a patented invention is not sufficiently and continuously worked for 3 years or longer in Japan, a person intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license; provided, however, that this shall not apply unless 4 years have lapsed from the filing date of the patent application in which the patented invention was filed.

(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Commissioner of the Patent Office for an award.

Article 92 (Award granting non-exclusive license to work own patented invention)

(1) Where a patented invention falls under any of the cases as provided in Article 72, the patentee or exclusive licensee may request the other person under the said Article to hold consultations to discuss granting a non-exclusive license to work the patented invention or a non-exclusive license on the utility model right or the design right.

(2) The other person under Article 72 who is requested to hold consultations under the preceding paragraph may request the patentee or exclusive licensee requesting such consultations to hold consultations to discuss granting a non-exclusive license to the extent of the patented invention that the said patentee or exclusive licensee intend to work with a non-exclusive license on the patent right, on the utility model right or on the design right granted through consultations.

(3) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (1), the patentee or the exclusive licensee may request the Commissioner of the Patent Office for an award.

(4) Where no agreement is reached by consultations or no consultations are able to be held as provided in paragraph (2) and where a request for an award is filed under the preceding paragraph, the other person under Article 72 may request the Commissioner of the Patent Office for an award only within the time limit for the submission of a written answer by the said other person designated by the Commissioner of the Patent Office under Article 84 as applied *mutatis mutandis* under paragraph (7).

(5) In the case of paragraph (3) or (4), the Commissioner of the Patent Office shall not render an award to the effect that a non-exclusive license is to be granted where the granting of the non-exclusive license will be unreasonably prejudicial to interest of the other person under Article 72, the patentee or the exclusive licensee.

(6) In the case of paragraph (4), in addition to the case provided for in the preceding paragraph, the Commissioner of the Patent Office shall not render an award ordering a non-exclusive license to be granted if an award ordering a non-exclusive license to be granted is not rendered with respect to the request for an award under paragraph (3).

(7) Articles 84, 85(1) and 86 through 91-2 shall apply *mutatis mutandis* to the award under paragraph (3) or (4).

Article 93 (Award granting non-exclusive license for public interest)

(1) Where the working of a patented invention is particularly necessary for the public interest, a person(s) intending to work the patented invention may request the patentee or the exclusive licensee to hold consultations to discuss granting a non-exclusive license.

(2) Where no agreement is reached by consultations or no consultations are able to be held as provided in the preceding paragraph, the person intending to work the patented invention may request the Minister of Economy, Trade and Industry for an award.

3 Articles 84, 85 () (1) and 86 through 91-2 shall apply *mutatis mutandis* to the award under the preceding paragraph.

Article 94 (Transfer, etc. of non-exclusive license)

(1) Except for a non-exclusive license granted by an award under Article 83(2), 92(3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive license may be transferred only where the business involving the working of the relevant invention is also transferred, where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is

obtained and where the transfer occurs as a result of general succession including inheritance.

(2) Except for a non-exclusive license granted by an award under Article 83(2), 92(3), 92(4) or 93(2) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, a non-exclusive licensee may establish a right of pledge on the non-exclusive right only where the consent of the patentee (or, in the case of non-exclusive license on the exclusive license, the patentee and the exclusive licensee) is obtained.

(3) A non-exclusive license granted by an award under Article 83(2) or 93(2) may be transferred only where the business involving the working of the relevant invention is also transferred.

(4) Where a non-exclusive license is granted by an award under Article 92(3) of the Patent Act, Article 22(3) of the Utility Model Act or Article 33(3) of the Design Act, the said non-exclusive license shall be transferred together with the patent right, utility model right or design right of the non-exclusive licensee on which the non-exclusive license is granted and the business involving the working of the relevant invention in the case where each right is transferred together with the said business, and shall be extinguished in the case where each right of the said non-exclusive licensee is extinguished or transferred independently of the said business.

(5) A non-exclusive license granted by an award under Article 92(4) shall be transferred together with the patent right, utility model right or design right of the non-exclusive licensee on which the non-exclusive license is granted, and shall be extinguished in the case where the said patent right, utility model right or design right is extinguished.

(6) Article 73(1) shall apply *mutatis mutandis* to non-exclusive licenses.

Article 95 (Right of pledge)

Unless otherwise agreed upon by contract, where a right of pledge is established on a patent right, exclusive license or non-exclusive license, the pledgee may not work the patented invention.

Article 96

A right of pledge on a patent right, exclusive license or non-exclusive license may be exercised against any consideration to be paid for the patent right, exclusive license or non-exclusive license or any money or goods to be received by the patentee or the exclusive licensee for the working of the patented invention; provided, however, that the pledgee have to attach the consideration, money or goods prior to the payment of money or delivery of goods.

Article 97 (Waiver of patent right, etc.)

(1) Where there is an exclusive licensee, pledgee or non-exclusive licensee as provided in Article 35(1), 77(4) or 78(1), a patentee may waive the patent right, only where the consent of the said exclusive licensee, pledgee or non-exclusive licensee is obtained.

(2) Where there is a pledgee or non-exclusive licensee as provided in Article 77(4), an exclusive licensee may waive the exclusive license, only where the consent of the said pledgee or non-exclusive licensee is obtained.

(3) Where there is a pledgee, a non-exclusive licensee may waive the non-exclusive license, only where the consent of the said pledgee is obtained.

JORDAN : *Articles 22-26 of the Law on Patents No. 32 of 1999, as last amended by Law No. 71 of 2001*

Article 22

The Minister may grant a license to use a patent to third parties without obtaining the patentee's consent in any of the following cases exclusively:

A) If the use of the patent by the state authorities or licensed third parties is a necessity for national defense or emergency or for noncommercial public good provided that the patentee is notified as soon as it becomes possible.

B)1. If the patentee doesn't exploit it or exploits it insufficiently before the elapse of 4 years as of the application date or 3 years as of the granting date, the period to be applied is the one that elapses later. However, the Minister may grant the patentee an additional grace period if he deems that reasons beyond the control of the patentee have prevented exploitation.

2. For the purposes of item (1) of this paragraph, and without prejudice to the provisions of the related International Conventions, the importation of the subject goods of the patent to the kingdom shall be deemed utilization of the patent.

C) If the patentee exercises his rights in such a way as to prevent others from competing fairly.

Article 23

The following shall be taken into consideration when compulsory licenses are granted:

A) Each application for a license shall be decided separately for its specific conditions and circumstances.

B) The applicant shall have tried to obtain a license from the patentee under reasonable remuneration and conditions but did not reach an agreement during a reasonable period of time in the case provided for in paragraph (B) of Article 22 of this law.

C) The scope and duration of the license shall be limited to the purpose for which it is granted. If the license application relates to semiconductor technology, then it shall only be granted for noncommercial public good or to rectify practices deemed by the competent judicial or administrative authority to be anticompetitive.

D) The license to exploit shall not be exclusive.

E) The license shall not be assignable to third parties.

F) The license shall only be granted for meeting the demand in the local market other than for the case provided for in paragraph (C) of Article 22 of this law.

G) The patentee shall receive an equitable remuneration which takes into account the economic value of the patent.

Article 24

The Minister may cancel the compulsory license by himself or on the strength of an application from the patentee if the reasons for its grant disappeared. This license cancellation shall however preserve the rights of those involved in the compulsory license.

Article 25

The provisions and procedures related to licensing of patent utilization shall be prescribed pursuant to regulations to be issued to this aim.

Article 26

The Minister's compulsory-license decision shall be appealable to the High Court of Justice within 60 days of its notification.

KAZAKHSTAN : *Articles 4 (4-5) and Section 14 (6) of the Patent Law No. 427 of 16/07/1999*

Article 4

4) Where the patent owner has failed to continuously use the invention within four years following the date of first publication of the particulars of the patent grant and has declined an offer to conclude a license contract on commercially acceptable terms, any person may file an appeal with the court requesting the grant of a compulsory nonexclusive license.

If the patent owner fails to furnish proof to the effect that non-use of the invention is justified by reasonable grounds, the court shall grant the said license and shall determine the time limits of the use, the amount and terms of payment. The amount of payment shall not be lower than the market value of the license to be determined in accordance with the established practice.

Any compulsory license shall be primarily granted in order to satisfy the requirements of internal market in the Republic of Kazakhstan.

The person to whom a compulsory license was granted may assign the right to use the invention to another person only together with the enterprise that uses the invention.

The court may decide to revoke a compulsory license if the grounds leading to the grant thereof no longer exist.

5) The patent owner who cannot use the industrial property subject matter without infringing the rights of the owner of another title of protection for the industrial property subject matter who has declined an offer to conclude a license contract on commercially acceptable terms, shall have the right to file an appeal with the court requesting the grant of a compulsory non-exclusive license to use the industrial property subject matter in the territory of the Republic of Kazakhstan.

When the said compulsory license is granted, the court shall determine the scope of use of the industrial property subject matter the title of protection for which belongs to another person, the time limits of the use, the amount and terms of payment. The amount of payment shall not be lower than the market value of the license to be determined in accordance with the established practice.

The right to use the industrial property subject matter acquired on the basis of this provision may be assigned only together with the title of protection granted for that industrial property subject matter.

Article 14

(...)(6) The Government of the Republic of Kazakhstan may authorize the use of the protected industrial property subject matter without the consent of the patent owner in cases of national emergency and other force majeure situations provided that the owner is immediately informed and is paid a commensurate compensation.

Any dispute relating to the amount of compensation shall be settled by court.

KENYA : *Sections 72- 75 and 80 of the Industrial Property Act No. 3 of 27/07/2001*

Compulsory Licences for Non-Working and Similar Reasons

72.—(1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may apply to the Tribunal for a licence to exploit the patented invention on the grounds that a market for the patented invention is not being supplied on reasonable terms in Kenya.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies the Tribunal that circumstances exist which justify the fact that the market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in Kenya.

Compulsory Licences Based Upon Interdependence of Patents

73.—(1) Where a patented invention cannot be worked without infringing the rights derived from an earlier patent, the owner of the latter patent may request the Tribunal at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention, if the invention constitutes an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent.

(2) The owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent.

(3) The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(4) In this section, “earlier patent” or “first patent” means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and “latter patent” or “second patent” shall be construed accordingly.

Preconditions for Grant of Compulsory Licences

74.—(1) A compulsory licence shall not be granted unless the person requesting the licence—

(a) satisfies the Tribunal that he has asked the owner of the patent for a contractual licence but has been unable to obtain the licence on reasonable commercial terms and within a reasonable time; and

(b) offers guarantees satisfactory to the Tribunal to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements which gave rise to his request.

(2) The requirement under subsection (1)(a) shall be waived in the case of a national emergency or other circumstances of extreme urgency, provided the owner of the patent shall be so notified as soon as is reasonably practicable.

Grant and Terms of Compulsory Licences

75.—(1) In considering a request for a compulsory licence, the Tribunal shall decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant taking into account any terms agreed by the parties, proceed to fix the terms which shall be deemed to constitute a valid contract between the parties and shall be governed by the provisions of contractual licences.

(2) In fixing the terms under subsection (1), the Tribunal shall ensure that the compulsory licence—

(a) is limited, in scope and duration, to the purpose for which it was authorized, and in the case of semi-conductor technology, shall only be for public non-commercial use or to remedy a practice determined after a judicial or administrative process to be anti-competitive;

(b) is limited predominantly for the supply of the domestic market;

(c) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;

(d) is non-exclusive; and

(e) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case, including the economic value of the licence.

(3) A representative of the Institute and of the Government shall have the right to appear and be heard at the hearing of an application for a compulsory licence, before the Tribunal.

Exploitation of the Patented Inventions by the Government or by Third Persons Authorised by the Government

80.—(1) Subject to this section, where—

(a) the public interest, in particular, national security, nutrition, health, environmental conservation, or the development of other vital sector of the national economy so requires; or

(b) the Managing Director determines that the manner of exploitation of an invention by the owner of the patent or his licensee is not competitive,

the Minister may, upon application to him in the prescribed form and after consultation with the Institute and the owner of the patent, order that the protected invention shall be exploited by a Government Ministry, Department, agency or other person as the Minister may designate in the order subject to the payment of adequate compensation to the owner of the patent in accordance with this section.

(1A) Upon exercising the powers conferred upon him under subsection (1), the Minister may, notwithstanding any of the measures set out in this section, authorize by written order the importation, manufacture or supply, or authorize the utilization of any molecule or substance whatsoever by any individual, corporation or society as named or described by any individual, corporation or society as named or described in the order without notice to the patent holder or any other notifiable party, and such order shall remain in force until revoked by the Minister in writing, after giving six months' prior notice of his intention of such revocation to the party named or described in the order.

(1B) An order made under the subsection (1A) shall not require the payment of compensation to the owner of the patent or licence holder or any other party so interested.

(1C) The Minister shall, notwithstanding any of the measures set out in this section, authorise the utilisation of any process for the manufacture, sale or supply of any molecule or substance whatsoever by any individual, corporation or society as named or described in the order, and such order shall remain in force until revoked by the Minister in writing, giving six months prior notice of intention of such revocation to the party named or described in the order.

(2) No application shall be made under subsection (1) unless the applicant has unsuccessfully sought a contractual licence from the owner of the patent:

Provided that the provisions of this subsection shall not apply in cases of national emergency or other extreme urgency in which case the Minister shall cause the contents of the order to be communicated to the owner of the patent as soon as reasonably practicable.

(3) An order under this section shall be subject to such conditions as the Minister may deem necessary.

(4) Where an order under this section is made, the Managing Director shall fix the amount of the compensation to be paid to the owner of the patent, such compensation being equitable with due regard to all the circumstances of the case and in particular, the economic value of the patent.

(5) An order under this section shall not preclude the owner of the patent from concluding a licence contract or from exercising the powers conferred by section 54 of this Act.

(6) The Minister may, upon the request of the owner of the patent or the Government Ministry, Department, agency or other person designated by the Minister for the purposes of any order under this section and after hearing all interested parties, vary the terms of the order to the extent that changed circumstances justify such variation.

(7) The Minister may, upon the request of the owner of a patent and after hearing all interested parties, revoke an order under this section—

(a) if satisfied that the circumstances necessitating the order have ceased and are unlikely to recur; or

(b) where the Government Ministry, Department, agency or other person designated for the purposes of the order is in breach of any condition imposed under subsection (3).

(8) The authorization of any person in an order under this subsection shall not be transferable except to a business or enterprise owned or operated by that person.

(9) The exploitation of the invention pursuant to an order under this section shall be primarily for the supply of the market in Kenya.

(10) An order relating to the exploitation of an invention in the field of semi-conductor technology shall only be made where the Tribunal has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is not competitive and the Minister is satisfied that the issuance of such order would remedy such practice.

(11) Any person aggrieved by any decision of the Minister under this section may appeal to the Tribunal.

KYRGYZSTAN : *Article 12 of the Patent Law of 14/01/1998 as last amended in 2003*

Article 12. Obligations of the Patent Owner and Compulsory Licenses

If the object of industrial property is not used or insufficiently used by the patent owner or persons to whom the rights for it has been transferred, within three years as of the date of granting a patent, that leads to insufficient supply of the appropriate goods or services at the market of goods and services, any person wishing and ready to use patent of an industrial property, in the event of refusal of the patent owner to conclude licensing agreement with this person on the conditions pursuant to the common practice, has the right to apply to court with an action to provide him a compulsory license for the use of this object.

If the patent owner fails to prove that the non-use or insufficient use of an object of industrial property is conditioned by excusable reasons, the court shall grant the indicated license specifying the scope of use, the amount, time limits and procedures of payment. The amount of payment must not be lower than the price of the license, which is determined in compliance with the established practice.

The patent owner that can not use an invention without infringing the rights of the other owner of a patent for an invention or for a utility model, who has refused to conclude a licensing agreement based on the conditions that are in compliance with the common practice, has the right to apply to court with an appeal to grant him a compulsory license for the exploitation of an invention or utility model under condition that his invention presents an important technological achievement of the significant economic value with respect to the invention or utility model patent for which belongs to the other person.

If the indicated license is provided, the court must establish the limits for the use of an invention or utility model, patent for which belongs to the other person, in the scope necessary to exploit an invention patented by the person requiring to provide him a compulsory license, as well as the amount, terms and payment order. The amount of payment must be established not less than the price for a license, which is determined in compliance with the common practice.

In the emergency situations (disasters, catastrophes, big accidents), as well as in the interests of the national security, the Government of the Kyrgyz Republic shall have the right to grant a compulsory license coupled to payment of an applicable compensation to a patent owner, in this case the volume and time of exploitation of the patented object of industrial property shall be restricted by the purposes for which it was allowed. Disputes arising due to such exploitation shall be decided by court.

The compulsory license shall always be non-exclusive license, it cannot be reassigned to another person.

LAO PEOPLE'S DEMOCRATIC REPUBLIC: *Sections 53-54 of the Intellectual Property Law of 14/01/2008*

Section 53: Compulsory license of Patent or Petty Patent

In case of necessity in protection of the country, protection of peace, food supply, safety concerning health of the people of Lao, without the purpose of trade, the Government may permit a person and other organization to exploit the patent or petty patent without the consent of the owner of said patent or petty patent. However, the exploitation must be based on the scope of permission of the government. The owner of the patent or petty patent must be informed and be paid a suitable royalty. The owner of the patent or petty patent can submit an argument on the unsuitable order or royalty within 60 days from the date of having been informed of such order.

In case the country is in emergency status due to natural causes or war, the Prime Minister can order a person or organization to exploit the patent or petty patent and to proceed as stated earlier.

Section 54: Exploitation of Patent or Petty Patent

In case of the invention or device which has been granted a patent or petty patent has not been exploited or not fully exploited 3 years after grant of the patent or petty patent, the government shall inform the owner of the rights to submit an explanation in writing within 90 days. If there is no response or the response is not satisfactory, the government shall allow others who apply for exploitation to exploit same.

LATVIA (EU) : *Section 54 of the Patent Law of 15/02/2007*

Section 54. Compulsory Licence

(1) If within four years after filing date of application or within three years after the date when the notification regarding the grant of a patent was published, the patented invention has not been used or has been used in an insufficient amount in the Republic of Latvia, any person may submit to the administrative court an application with a request to provide a permit (compulsory licence) to it to use the patented invention in conformity with this Law and court judgement. This provision shall not be applied if the proprietor of the patent proves to the

court that there have been substantiated reasons for the failure to use or insufficient use of the invention.

(2) If the proprietor of the patent of a biotechnological invention is not able to use it without violating the prior rights to the plant variety, he or she may apply for a compulsory licence for the use of such plant variety, which is protected by the referred to rights, and pay a compensation to the proprietor, determined by the court. In the case of a grant of such licence, the proprietor of the plant variety is entitled to qualify for a cross-licence with substantiated requirements for the use of the protected invention.

(3) The compulsory licence of the patented invention may be obtained in conformity with Paragraphs one and two of this Section, if:

1) the patented subject or the product acquired with a patented method is of vital importance for ensuring of the welfare, protection or economic interests of Latvian citizens; or

2) an invention which is of a significant economic importance may not be used without the use of another earlier patented invention.

(4) The compulsory licence shall be granted by the court if the submitter of the claim within a reasonable time period has made an effort to acquire, but has not acquired the licence from the proprietor of the patent with acceptable commercial terms.

(5) If an emergency situation has been declared in the State, a compulsory licence may be granted by the Cabinet.

(6) The court, in the case provided for in Paragraph three, Clause 1 of this Section, reviewing the facts of the case regarding the grant of a compulsory licence, in addition shall observe the following requirements:

1) the amount of and the time period for use of the patent may be restricted, depending on the purpose for which the compulsory licence has been granted;

2) the compulsory licence shall be regarded as equal to a non-exclusive licence;

3) a compulsory licence may not be transferred to another person, except for the case when it is transferred together with an undertaking, which is directly related to the use of the relevant patent or a part of such undertaking; and

4) the compulsory licence shall be granted for use in the internal market of Latvia.

(7) The court, in the case provided for in Paragraph three, Clause 2 of this Section, upon reviewing the facts of the case regarding the grant of a compulsory licence shall, in addition, observe the following requirements:

1) the proprietor of the patent granted earlier (first) may request a cross-licence with reasonable terms for the use of an invention from the proprietor of later granted patent; and

2) the licence to the first patent shall not be transferred further unless it is transferred together with the rights to the later patent.

(8) The court may decide regarding the termination of the time period for a compulsory licence, if the facts referred to in Paragraph one or Paragraph three, Clause 1 of this Section no longer exist and a repeated commencement thereof is hardly credible.

(9) The holder of a compulsory licence shall pay to the proprietor of the patent a compensation, the amount of which shall be determined by the court, observing the economic value of the licence, the extent of use of an invention and other circumstances.

LEBANON : *Articles 32-39 of the Patents Law No. 240 of 07/08/2000*

Article 32

In compliance with Article 5 of the Paris Union Convention of 1883 (as amended), every person, subject to public or private laws, is entitled after three years from the date of the patent grant, to present an official request for a compulsory license to exploit the invention in Lebanon, according to the conditions hereinafter stated, if the patent owner or his successors did not exploit the patent or actually and practically prepare to exploit the invention being the subject of the patent in the Lebanese Territory.

Compulsory license may also be requested if the patent owner or his successors started the exploitation, then seized to do so for a period not less than three years for no legitimate reason.

Article 33

The request for a compulsory license is presented by serving the patent owner before the First Instance Civil Court of Beirut and evidence that the plaintiff:

1. Has exerted efforts to acquire the patent owner's approval to exploit such, according to appropriate commercial conditions, and that such efforts were unsuccessful within a proper period of time.

In case of national emergencies or force majeure or public utilization for non commercial purposes provided that the patent owner is notified urgently.

2. Should have the needed qualifications and capacities in order to seriously and effectively exploit the invention.

Each request for a compulsory license shall be considered separately according to stipulations defined by the judicial decision so as the scope and period of such license be restricted to the purpose of the utilization so as to fulfill the needs of the local market in the majority of cases and so as the compensations due to the patent owner be equivalent to the economic value of the invention.

Compulsory licensing may not be exclusive.

The patent owner or the licensees may refer to the Court to amend conditions of the license or terminate such, provided that new circumstances impose such action.

The Court may insure the presence and validity of circumstances that justified principally granting the license such an action shall be based upon the request of a beneficiary.

Article 34

The compulsory license may not be transferred to third parties without the Court permission, otherwise it shall be void and null. The exception from the Court permission is the case where the investing enterprise transfers it or is joined, merged or split.

Article 35

If the compulsory license owner does not comply to the conditions as stipulated in the Court decision, then the patent owner or any of the other licensees may resort to the court to issue a decision to repeal such compulsory license.

Article 36

Upon the request of the Minister in charge and for purposes of protecting the public health, food safety and safeguarding the public interest in areas of vital importance in the economic, social and technological development the Cabinet of Ministers may subject the invention patents granted in Lebanon to Compulsory Administrative licensing if the products produced as a result of such patents are offered to the public in quantities or qualities that does not fulfill the market requirements or are offered at exaggerated prices.

Once the decision is published in the public gazette, any person qualified to work the patent invention in a serious and practical manner is entitled to request a non-exclusive license to the patent in Lebanon from the Minister of Economy and Trade.

Such license is granted by issuing a conditioned decision by the Minister of Economy and Trade, such conditions shall include its period and scope of application in Lebanon. Exceptionally the annual compensation is to be agreed upon between the patent owner and the licensee, otherwise the civil court of Appeal of Beirut shall determine such compensation the economic value of the license.

The Compulsory Administrative License shall come into effect from the date serving such decision to the patent owner, Intellectual Property Protection Authority and the right owners of the patent whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 37

The State, for National Security reasons may acquire a license to an invention patent based on a decision issued by the Minister of Economy and Trade upon the request of the Minister of National Defense.

Such Compulsory Administrative License is granted by a decision issued by the Minister of Economy and Trade stipulating the conditions but excluding the related compensation.

If the annual compensation is not amicably agreed upon, it shall be determined by Beirut Civil Court of Appeal.

Such license shall come into effect from the date of the request of the Minister of National Defense and shall be notified to the patent owner, the Intellectual Property Protection Authority and the patent rights owners whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 38

The State may, for National Security reasons own in part or in whole any invention patent by issuing a decree that also states a fair compensation for such proprietary and to be served to

the patent owner, the Intellectual Property Protection Authority and to patent rights owners whose titles are registered in the patents register at the Authority hereinbefore mentioned.

Article 39

3. The administrative decisions hereby mentioned may be appealed before Beirut Civil Court of Appeal within thirty days of the decisions being served.

4. The stipulations mentioned do not prevent resorting to arbitration in matters where conciliation is possible.

LIBYAN ARAB JAMAHIRIYA : *Articles 23, 28, 29 and 30 of the Law on Patents and Industrial Designs and Models No. 8 of 1959*

Article No. 23

If the Office of Industrial & Commercial Property Protection noticed that the invention is related to defense affairs or it has an actual military value, it shall brief the Ministry of Defense immediately on the patent application and on the attached documents.

The Minister of Defense has the right to challenge granting the patent to the applicant within three months as of patent application date, in return for purchasing the invention from him or making a deal with him to exploit it.

Article No. 28

If the invention has not been utilized in Libya or in the country of origin within three years as of granting date of the patent, it becomes cancelled.

Article No. 29

If the Office of Industrial & Commercial Protection found, despite of expiry of stated deadlines mentioned in the previous article, that non exploitation of the invention was due to compelling circumstances, he may be granted an extended period of not more than two years in order to utilize it perfectly.

Article No. 30

Competent government departments may be granted a compulsory license through a decision issued by the Minister of National Economy to utilize the invention due to reasons related to pro bono publico or national defense.

In such circumstances, the owner of the patent has the right to get a fair compensation, which shall be estimated with the knowledge of the stated committee in article No.20, and grievances against its decisions are made before the Supreme Federal Court within sixty days as of committee's date of declaration of decision to the grievant.

LITHUANIA (EU) : *Articles 38-39 of the Patent Law No. I-372 of 18/01/1994 as last amended by Law No. X-1119 of 10/05/2007*

Article 38. Compulsory Cross-licensing when an Invention is Related to the Protected Plant Variety

Where a breeder cannot acquire or exploit a plant variety right without infringing the exclusive rights protected by a prior patent, he may apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty. Where such a licence is granted, the patent owner will be entitled to a cross-licence on reasonable terms to use the protected variety.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention.

Applicants for the licences referred to in paragraphs 1 and 2 of this Article must demonstrate that:

- 1) they have applied unsuccessfully to the owner of the patent of a biological invention or the holder of the plant variety right to obtain a contractual licence;
- 2) the plant variety or the biological invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

The court shall make a decision regarding the granting of licences referred to in paragraphs 1 and 2 of this Article, the amount of royalty and other conditions and extent of a compulsory licence. If the conditions of granting of a compulsory licence change or disappear, at the request of the owner of the patent of a biological invention or the holder of the plant variety right, the court may revoke a compulsory licence or change its conditions.

Offices keeping a list of protectable plant varieties and the Patent Register of the Republic of Lithuania shall be responsible for the registration, in the manner prescribed by legal acts, of the licences referred to paragraphs 1 and 2 of this Article.

Where a licence for a plant variety can be granted only by the Community Plant Variety Office, Article 29 of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights shall apply.

Article 38.1. Compulsory Licence for Pharmaceutical Products

A competent institution authorised by the Government shall grant mandatory licences in compliance with Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Article 39. Exploitation of an Invention with the Authorisation of the Government of the Republic of Lithuania

The Government of the Republic of Lithuania may adopt a resolution to permit a State or municipal institution, natural or legal persons to market, without the consent of the owner of a patent, a patented invention within the territory of the Republic of Lithuania, if:

- 1) an invention protected by a patent is related to public needs, national security and public health protection, development of economically important sectors;
- 2) the court determines that a method of the exploitation of an invention employed by the owner of a patent or licensee is anti-competitive.

An invention may be exploited only for the purpose in respect of which the resolution has been adopted. The owner of a patent must, for the exploitation of the invention, be remunerated fairly, taking into consideration economic value of the invention.

If the owner of a patent or a person who has authorisation to use an invention, requests, the Government of the Republic of Lithuania may, taking into consideration their reasons, change the conditions of the use of a patented invention, and time limits of the validity of permission. When authorisation to use a patented invention is issued to the owner of a patent which improves a previously patented invention (second invention) and that may infringe the exclusive rights of the owner of the first patent, the Government of the Republic of Lithuania shall, before the adoption of this resolution, take into consideration the following additional conditions:

- 1) the claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
- 2) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.
- 3) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.

The Government of the Republic of Lithuania may declare the resolution null and void, if the circumstances which led to the authorisation to use a patented invention cease to exist, or if a State or municipal institution, natural or legal persons use a patented invention for the purpose other than that in respect of which the resolution has been adopted.

Authorisation to exploit an invention must be non-exclusive, i.e. the owner of a patent shall not lose the right to use a patented invention himself, and it shall not prohibit the owner of a patent to conclude license agreements related to the use of a patented invention as well as to further exploit a patented invention or to implement his rights in other ways.

Authorisation to use a patented invention may not be transferred, except when the enterprise (or a part thereof) in which a patented invention is used, is transferred in a manner prescribed by law.

Attached to a request to permit the exploitation of a patented invention must be evidences confirming that the person seeking authorisation has requested, but has not received authorisation of the owner of a patent to use the patented invention. This provision shall not apply in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use of a patented invention. The owner of a patent must be

informed in writing about a resolution, which is being drawn up, concerning the authorisation to use a patented invention, and about an intention to use a patented invention for the purposes provided for in subparagraph 1 of paragraph 1 of this Article.

Resolutions of the Government of the Republic of Lithuania concerning the authorisation to use a patented invention without the consent of the owner of a patent may be appealed against in court in a manner prescribed by law.

Upon the receipt of the resolution of the Government of the Republic of Lithuania concerning the authorisation to exploit an invention, the State Patent Bureau shall publish information on the authorisation in the next issue of its Official Bulletin.

LUXEMBOURG (EU) : *Articles 59-60 and 62-63 bis of the Patent Act of 20/07/1992*

Art. 59. Licence obligatoire

1. Toute personne de droit public ou privé peut, à l'expiration d'un délai de trois ans après la délivrance d'un brevet, ou de quatre ans à compter de la date de dépôt de la demande de brevet, le délai qui expire le plus tard devant être pris en considération, obtenir une licence obligatoire de ce brevet, dans les conditions prévues aux articles suivants, si, au moment de la requête, et sauf excuses légitimes, le propriétaire du brevet ou son ayant cause :

a) n'a pas commencé à exploiter ou fait des préparatifs effectifs et sérieux pour exploiter l'invention objet du brevet sur le territoire du Grand-Duché ou d'un autre Etat partie à l'Accord instituant l'OMC ;

b) n'a pas exploité l'invention objet du brevet de manière suffisante pour approvisionner le marché luxembourgeois.

2. Il en est de même lorsque l'exploitation au Grand-Duché ou dans un autre Etat partie à l'accord instituant l'OMC a été abandonnée depuis plus de trois ans.

Art. 60. Procédure d'octroi et conditions d'une licence obligatoire

1. La demande de licence obligatoire est formée auprès du tribunal ; elle doit être accompagnée de la justification que le demandeur n'a pas pu obtenir du propriétaire du brevet une licence d'exploitation et qu'il est en état d'exploiter l'invention de manière effective et sérieuse.

2. La licence ne peut être que non exclusive ; elle est accordée à des conditions déterminées, notamment quant à sa durée, son champ d'application et le montant des redevances auxquelles elle donne lieu. Ces conditions peuvent être modifiées par décision du tribunal, à la requête du propriétaire du brevet ou du licencié.

3. La licence est accordée principalement pour l'approvisionnement du marché luxembourgeois. Dans la fixation du montant des redevances, le tribunal tient compte de la valeur économique de la licence.

4. Les jugements rendus conformément aux dispositions qui précèdent sont sujets à appel, quelle que soit la valeur du litige.

Art. 62. Brevets interdépendants

1. Le propriétaire d'un brevet portant sur un perfectionnement à une invention déjà brevetée au profit d'un tiers ne peut exploiter son invention sans l'autorisation du titulaire du brevet antérieur ; ledit titulaire ne peut exploiter le perfectionnement breveté sans l'autorisation du titulaire du brevet de perfectionnement.

2. Le tribunal peut, le ministère public entendu, dans l'intérêt public, accorder sur sa demande, qui ne peut être antérieure à l'expiration du délai prévu à l'article 59, une licence non exclusive au titulaire du brevet de perfectionnement dans la mesure nécessaire à l'exploitation de l'invention qui fait l'objet de ce brevet et pour autant que l'invention, objet du brevet de perfectionnement, présente à l'égard du brevet antérieur un progrès technique important et un intérêt économique considérable. Le propriétaire du premier brevet obtient, sur requête présentée au tribunal, la concession d'une licence sur le brevet de perfectionnement.

3. Les dispositions des articles 59, 60, 61 et 65 sont applicables.

Art. 63. Licence d'office

1. Le brevet est soumis à un régime de licence d'office pour autant qu'un arrêté grand-ducal, sur avis obligatoire du Conseil d'Etat, a déclaré d'intérêt public la mise en oeuvre de l'invention. Sauf en cas d'urgence, cet arrêté ne peut être pris que s'il est établi que le titulaire du brevet n'est pas disposé à accorder de licence volontairement et à des conditions et modalités commerciales raisonnables.

2. Du jour de la publication de l'arrêté soumettant le brevet au régime de la licence d'office toute personne qualifiée peut demander au ministre l'octroi d'une licence d'exploitation. Cette licence, qui ne peut être que non exclusive, est accordée par arrêté du ministre à des conditions déterminées, en particulier quant à sa durée et son champ d'application, mais non quant aux redevances auxquelles elle donne lieu. La licence est accordée principalement pour l'approvisionnement du marché luxembourgeois. Elle prend effet à la date de la notification de l'arrêté aux parties.

3. A défaut d'accord amiable entre les parties intéressées, le montant des redevances est fixé judiciairement. Dans la fixation du montant des redevances, le tribunal tient compte de la valeur économique de la licence.

4. La licence d'office peut être retirée par arrêté motivé du ministre à l'expiration d'un délai fixé dans l'arrêté d'octroi de la licence, si l'invention brevetée n'est pas exploitée d'une manière sérieuse ou si l'exploitation ne se fait pas aux conditions imposées ou convenues. Elle peut également être retirée lorsque les circonstances ayant conduit à son octroi cessent d'exister et ne se reproduiront vraisemblablement pas.

Art. 63bis. Licences obligatoires ou d'office dans le domaine des semi-conducteurs

Si le brevet a pour objet une invention dans le domaine de la technologie des semi-conducteurs, une licence obligatoire ou d'office ne peut être accordée que pour une utilisation destinée à remédier à une pratique déclarée anticoncurrentielle à la suite d'une procédure judiciaire ou administrative.

MADAGASCAR : *Sections 36 of the Industrial Property Law, Ordinance No. 89—019 of 31/07/1989*

36.—(1) Any interested natural or legal person may request, on the expiry of a period of four years as from the filing date of the patent application or three years as from the date of grant of the patent, the period of time that expires last being applied, from the competent court the grant of a compulsory license, against fair and equitable remuneration, on one or more of the following grounds:

- (i) the patented invention has not been worked or has been insufficiently worked within the country;
- (ii) the patentee refuses to grant licenses under reasonable conditions;
- (iii) working of the patented invention within the country does not satisfy, under reasonable conditions, demand for the product.

(2) When applying paragraph (1), a compulsory license shall be granted only if the patentee is unable to give legitimate grounds for the lack of working or insufficient working within the country.

(3) The compulsory license shall be non-exclusive and may only be transferred, even in the form of the granting of a sublicense, together with the establishment of the beneficiary of the license or with that part of the establishment within which the patented invention is being worked.

(4) A compulsory license may only be withdrawn as the result of a court decision.

37.—(1) Any owner of a patent who is not prevented by the conditions of an earlier license may request the Agency to enter in the special register, with respect to his patent, the notice “license of right.” Such notice shall afford to any interested person the right to obtain a license to work that patent under conditions which, failing agreement between the parties, shall be laid down by the competent court.

(2) The State may obtain *ex officio*, at any time for reasons of public interest, a license to work an invention that is covered by a patent application or a patent whether such exploitation be carried out by the State itself or on its behalf. The royalties due under an *ex officio* license shall be determined by agreement between the State and the applicant or owner of the patent or the successor in title of the applicant or owner. Failing amicable agreement, the royalties shall be laid down by the competent court within the meaning of Article 135.

MALAYSIA : *Sections 49-51 and 84 of the Patents Act No. 291 of 1983 as last amended on 2006*

Section 49. Application for compulsory licences. (1) At any time after the expiration of three years from the grant of a patent, or four years from the filing date of the patent application, whichever is the later, any person may apply to the Registrar for a compulsory licence under any of the following circumstances:

(a) where there is no production of the patented product or application of the patented process in Malaysia without any legitimate reason;

(b) where there is no product produced in Malaysia under the patent for sale in any domestic market, or there are some but they are sold at unreasonably high prices or do not meet public demand without any legitimate reason.

(2) A compulsory licence shall not be applied for unless the person making the application has made efforts to obtain authorization from the owner of the patent on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

(3) The application for a compulsory licence shall be in compliance with such regulations as may be prescribed by the Minister.

Section 49A. Application for compulsory licence based on interdependence of patents. (1) If the invention claimed in a patent (“later patent”) cannot be worked in Malaysia without infringing a patent granted on the basis of an application benefiting from an earlier priority date (“earlier patent”), and if the invention claimed in the later patent constitutes, in the opinion of the Corporation, an important technical advance of considerable economic significance in relation to the invention claimed in the earlier patent, the Corporation, upon the request of the owner of the later patent, the licensee of a licence contract under the later patent or the beneficiary of a compulsory licence under the later patent, may grant a compulsory licence to the extent necessary to avoid infringement of the earlier patent.

(2) If a compulsory licence is granted under subsection (1), the Corporation, upon the request of the owner of the earlier patent, the licensee of a licence contract under the earlier patent or the beneficiary of a compulsory licence under the earlier patent, may grant a compulsory licence under the later patent.

Section 50. Request for grant of compulsory licence. (1) In an application for a compulsory licence under section 49 or section 49A, the applicant shall set forth the amount of royalty, the conditions of the exploitation of the patent and the restrictions of the rights of the licensor or the licensee, as the case may be, and a request for the said licence.

(2) Where an application for a compulsory licence is filed pursuant to section 49 or section 49A, and this section, the Registrar shall notify the applicant, the licensor or the licensee, as the case may be, of the date the application shall be considered by the Corporation.

(3) The licensor or the licensee, as the case may be, shall be furnished with a copy of the application as mentioned in subsection (1).

Section 51. Decision by the Corporation. (1) In considering the application for a compulsory licence under section 49 or section 49A, the Corporation may require the applicant, the licensor or the licensee, as the case may be, to appear before the Corporation to give a statement or to hand to the Corporation any document or any other item.

(2) When the application has been considered by the Corporation and a decision has been made, the applicant, the licensor or the licensee, as the case may be, shall be notified of the decision.

Section 84. Rights of Government. (1) Notwithstanding anything contained in this Act-

(a) where there is national emergency or where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the Government, so requires; or

(b) where a judicial or relevant authority has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive, the Minister may decide that, even without the agreement of the owner of the patent, a Government agency or a third person designated by the Minister may exploit a patented invention.

(2) The owner of the patent shall be notified of the decision of the Minister as soon as is reasonably practicable.

(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the owner of the patent of an adequate remuneration for such exploitation, taking into account-

(a) the economic value of the Minister's authorization as determined in the decision; and

(b) where a decision has been taken under paragraph (1)(b), the need to correct anti-competitive practices.

(4) The Minister shall make his decision under subsection (3) after hearing the owner of the patent and any other interested person if they wished to be heard.

(5) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either-

(a) for public non-commercial use; or

(b) where a judicial or relevant authority has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Minister is satisfied that the authorization would remedy such anti-competitive practice.

(6) The authorization shall not exclude-

(a) the continued exercise by the owner of the patent of his rights under subsection 36(1); or

(b) the issuance of compulsory licences under Part X.

(7) Where a third person has been designated by the Minister, the authorization may only be transferred with the goodwill or business of that person or with that part of the goodwill or business in which the patented invention is being exploited.

(8) The exploitation of the invention by the Government agency or the third person designated by the Minister shall be predominantly for the supply of the market in Malaysia.

(9) Upon the request of-

(a) the owner of the patent; or (b) the Government agency or the third person authorized to exploit the patented invention,

the Minister may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(10) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances mentioned in subsection (1) which led to his decision have ceased to exist and are unlikely to recur or that the Government agency or the third person designated by him has failed to comply with the terms of the decision.

(11) Notwithstanding subsection (10), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or the third person designated by him justifies the maintenance of the decision.

(12) The owner of a patent, a Government agency or the third person authorized to exploit a patented invention may appeal to the Court against the decision of the Minister under this section.

(13) In this section “Government agency” means the Federal Government or the Government of a State and includes a Ministry or Department of that Government.

MALTA (EU): Articles 39-40 of the Patents and Designs Act, Chapter 417, of 01/06/2002, as amended by Acts IX of 2003 and XVIII of 2005

Non-voluntary licences.

39. (1) The Civil Court, First Hall, may, on a writ of summons filed by any person who proves his ability to work the patented invention in Malta, made after the expiration of a period of four years from the date of filing the application for the patent or three years from the grant of the patent, whichever is later, direct the Controller to grant a non-exclusive, non-voluntary licence if the patented invention is not worked or is insufficiently worked in Malta.

(2) The grant of the non-voluntary licence shall be subject to the payment of such equitable remuneration to the proprietor of the patent as may be determined by the Civil Court, First Hall, and may be permitted if, prior to the institution of such proceedings, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and if such efforts have not been successful within a reasonable period of time.

(3) Notwithstanding subarticle (1), a non-voluntary licence shall not be granted if the Court is convinced that circumstances exist which justify the non-working or insufficient working of the patented invention in Malta.

(4) In deciding whether to grant a non-voluntary licence, the Court shall give both the proprietor of the patent and the person requesting the non-voluntary licence an adequate opportunity to present arguments according to the provisions of the Code of Organization and Civil Procedure.

- (5) Any non-voluntary licence shall be revoked when the circumstances which led to its granting cease to exist, taking into account the legitimate interests of the proprietor of the patent and of the licensee. The continued existence of these circumstances shall be reviewed upon the request of the proprietor of the patent by writ of summons before the Civil Court, First Hall.
- (6) Article 27(3)(a) of this Act shall be interpreted in the sense that if the patented product is put on the market by a licensee pursuant to a non-voluntary licence, it will not be deemed to have been put on the market with the express consent of the proprietor of the patent.
- (7) The scope and duration of a non-voluntary licence shall be limited to the purpose for which it was authorised and shall be:
- (a) non-exclusive,
 - (b) non-assignable, except with that part of the enterprise or goodwill which enjoys such authorisation,
 - (c) terminated if and when the circumstances which led to it cease to exist, and
 - (d) predominantly for the supply of the domestic market.
- (8) The Civil Court, First Hall, may on a writ of summons filed by the owner of a patent (the second patent) which cannot be exploited without infringing an earlier patent (the first patent), direct the Comptroller to grant a non-exclusive, non-voluntary licence provided that:
- (i) the invention claimed in the second patent shall involved an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (i) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to sue the invention claimed in the second patent; and
 - (ii) the use authorised in respect of the first patent shall be non-assignable except with the assignment of the second patent.
- (9) Where a breeder cannot acquire plant variety protection or exploit a plant variety without infringing a prior patent, he may apply to the Civil Court, First Hall, for a compulsory licence for non-exclusive use of the invention protected by the patent in so far as the licence is necessary for the exploitation of the plant variety to be protected, subject to payment of an appropriate royalty.
- Where such a licence is granted, the holder of the patent will be entitled to a cross-licence on reasonable terms to use the protected variety:
- Provided that an applicant for a licence referred to in above shall demonstrate that:
- (a) he had applied unsuccessfully to the holder of the prior patent to obtain a contractual licence;
 - (b) the plant variety constitutes significant technical progress of considerable economic interest compared with the invention claimed in the prior patent.
- (10) Where the holder of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may apply for a compulsory licence for non-exclusive use of the plant variety protected by that right, subject to payment of an appropriate

royalty. Where such a licence is granted, the holder of the variety right will be entitled to a cross-licence on reasonable terms to use the protected invention:

Provided that an applicant for a licence referred to in above shall demonstrate that:

(a) he had applied unsuccessfully to the holder of the prior plant variety right to obtain a contractual licence;

(b) the invention constitutes significant technical progress of considerable economic interest compared with the plant variety protected by the prior plant variety right.

(11) With regard to plant variety protection subarticles (9) and (10) shall only come into force when the relevant form of plant variety protection comes into force as provided in article 4(5)(e).

Exploitation by Government or by third parties authorised by Government.

40. (1) Where the national security or public safety so requires, the Minister may authorise, even without the agreement of the proprietor of the patent or the patent application, by notice published in the prescribed form, a Government agency or a person designated in the said notice to make, use or sell an invention to which a patent or an application for a patent relates, subject to payment of equitable remuneration to the proprietor of the patent or the application for the patent.

(2) The conditions set out in article 39(7) and (8) shall also apply in respect of an authorisation issued by the Minister under this article.

(3) Any decision taken by the Minister under this article may be the subject of an appeal in an action by writ of summons before the Civil Court, First Hall.

MAURITIUS : *Sections 23-24 of the Patents, Industrial Designs and Trademarks Act No. 25 of 2002*

Exploitation by Government or Person Thereby Authorized

23.—(1) Where the competent authority—

(a) is satisfied that the public interest including, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or

(b) has, on the application of any party, determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive and that it is necessary to remedy such anti-competitive practice;

it may, upon a request being made, authorise, even without the agreement of the owner of the patent, authorise a Government agency or a third person to exploit the patented invention.

(2) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment, to the owner, of an adequate compensation.

(3) For the purposes of a decision under subsection (1) the competent authority shall take—

(a) into account the economic value of the authorization, as determined in the said decision, and where a decision has been taken under subsection (1)(b), the need to correct anti-competitive practices; and

(b) his decision after hearing the owner of the patent and any interested person, whenever necessary.

(4) A request for the authorization under subsection (1) shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual licence, but that the latter has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(5) Subsection (4) shall not apply in cases of—

(a) national emergency or other circumstances of extreme urgency provided, however, that in such cases the owner of the patent shall be notified of the competent authority's decision as soon as reasonably practicable;

(b) public non-commercial use; and

(c) anti-competitive practices determined as such by the competent authority in accordance with subsection (1)(b).

(6) The exploitation of a patented invention in the field of semi-conductor technology by a person other than the owner, shall only be authorized—

(a) where the competent authority has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and is satisfied that the issuance of the non-voluntary licence would remedy such practice; or

(b) for public non-commercial use.

(7) The authorization shall not exclude—

(a) the conclusion of licence contracts by the owner of the patent; or

(b) the continued exercise, by the owner of the patent, of his rights under section 21; or

(c) the issuance of a non-voluntary licence under section 24.

(8) Where a third person has been authorised by the competent authority, the authorization may only be transferred with the enterprise or business of that person or with the part of the enterprise or business within which the patented invention is being exploited.

(9) Upon a request of the owner of the patent, or the Government agency or of the third person authorized to exploit the patented invention, the competent authority may, after hearing the parties, whenever necessary, vary the terms of the decision authorizing the

exploitation of the patented invention to the extent that any change in circumstances justifies such variation.

(10) Upon the request of the owner of the patent, the competent authority shall terminate the authorization if he is satisfied, after hearing the parties, whenever necessary, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person authorised has failed to comply with the terms of the decision.

(11) Notwithstanding subsection (10), the competent authority shall not terminate the authorization where he is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person authorised, justifies the maintenance of the decision.

(12) The decision of the competent authority under this section shall be subject to review by the Supreme Court.

Non-Voluntary Licences

24.—(1) Upon request made to the Controller after the expiration of a period of 4 years from the date of filing of the patent application or 3 years from the date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary licence if he is satisfied that the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importation, in Mauritius.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the non-exploitation or insufficient exploitation of the patented invention in Mauritius.

(3) The decision issuing the non-voluntary licence shall fix—

(a) the scope and the function of the licence;

(b) the time limit within which the licensee must begin to exploit the patented invention;
and

(c) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The holder of the non-voluntary licence shall—

(a) have the right to exploit the patented invention in Mauritius according to the terms set out in the decision issuing the licence;

(b) commence the exploitation of the patented invention within the time limit fixed in the said decision; and

(c) thereafter, exploit the patented invention sufficiently.

(5) Where—

(a) the invention claimed in a patent (later patent) cannot be exploited in the country without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date (earlier patent); and

(b) the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent;

the Controller, upon the request of the owner of the later patent, may issue a non-voluntary licence to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary licence is issued under subsection (5), the Controller, upon the request of the owner of the earlier patent, shall issue a non-voluntary licence in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary licence under subsections (5) and (6), subsection (3) shall apply mutatis mutandis with the proviso that no time limit needs to be fixed.

(8) In the case of a non-voluntary licence issued under subsection (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary licence issued under subsection (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary licence shall be subject to payment of a prescribed fee.

(11) Sections 23(2) to 23(12) shall apply mutatis mutandis to a non-voluntary licence issued under this section.

MEXICO : Articles 70, 73 and 77 of the Industrial Property Law of 25/06/1991, last amended version of 06/12/2005

Article 70. In the case of inventions, after three years from the date of grant of the patent, or four years from the filing of the application, whichever period elapses later, any person may apply to the Institute for the grant of a compulsory license to use said invention, where it has not been used, unless there are duly justified reasons for such non-use.

A compulsory license shall not be granted when the patent owner or the holder of a contractual license has been importing the patented product or a product obtained using the patented process.

Article 73. On expiration of the period of two years following the date of grant of the first compulsory license, the Institute may for administrative purposes declare the patent lapsed if the grant of the compulsory license has not remedied the non-working thereof, or if the patent owner has not proved the working thereof or the existence of reasons that are justified in the opinion of the Institute.

The payment of royalties under a compulsory license shall end when the patent lapses or is invalidated, or for any other reason provided for in this Law.

Article 77. For reasons of national emergency or security, and for as long as those reasons obtain, including the outbreak of serious diseases declared as requiring priority attention by

the General Health Council, the Institute shall, in a declaration published in the Official Journal, determine that use may be made of certain patents by means of the grant of licenses of public utility in cases where, if such use were not made, the production, supply or distribution to the public of staple goods and services or medicines would be prevented, hindered or made more expensive.

In cases of serious disease causing an emergency situation or threatening national security, the General Health Council shall issue the declaration of priority attention either on its own initiative or in response to a written request by the national institutions specialized in disease which are accredited by the General Health Council, in which it justifies the need for priority attention. Once the Council's declaration has been published in the Official Journal, pharmaceutical firms may request that the Institute grant a license of public utility, and the Institute shall grant said license after hearing the parties, for as short a period as justified by the case in accordance with the opinion of the Council, within 90 days, starting from the date on which the request is submitted to the Institute. The Ministry of Health shall determine the conditions of production and quality, duration and scope of application of said license, as well as the classification of the applicant's technical ability. After listening to both parties, the Institute shall establish a reasonable total in royalties for the owner of the patent. The grant may cover one or all of the prerogatives referred to in subparagraphs I or II of Article 25 of this Law. With the exception of the grant of licenses of public utility as referred to in paragraphs two and three of this Article, other licenses shall be granted in accordance with the terms contained in paragraph two of Article 72. None of the licenses referred to in this Article may be exclusive or transferable.

MONGOLIA : *Article 20 of the Patent Law of 25/06/1993, as last amended in 1997*

Article 20. Compulsory licences

1. In the following cases, on the request of any interested person, a compulsory licence in respect of a patented invention may be granted by the [Intellectual Property Office]:

1) if the invention must be used for a purpose associated with the public interest and in particular with national security, food supply or health

2) if the invention has not been used or has been insufficiently used for a period of four years from the filing date of the patent application or three years from the date of the grant of the patent (whichever period expires last) and the patent owner does not satisfy the [Intellectual Property Office] that circumstances exist which justify the lack of use of the invention in Mongolia;

3) if the patent owner sets unacceptable terms for the exploitation of the invention.

2. If the patent owner disagrees with a decision of the [Intellectual Property Office] to grant a compulsory licence he or she may appeal to the Court.

MOROCCO : *Articles 25, 31, 38-39, 60, 62, 66-67 and 75 of the Law No. 17-97 of 15/02/2000 concerning Protection of Industrial Property as implemented by the Decree No. 2-00-368 of 07/06/2004*

Chapitre III : Des licences d'office

Section 1: Des licences d'office octroyées dans l'intérêt de la sante publique

Article 25 : Pour l'application des dispositions du 2^e alinéa de l'article 67 de la loi 17-97 précitée, l'autorité gouvernementale chargée de la santé transmet la demande d'exploitation d'office d'un brevet d'invention dans l'intérêt de la santé publique à l'autorité gouvernementale chargée de l'industrie et du commerce.

L'autorité gouvernementale chargée de l'industrie et du commerce notifie la demande d'exploitation d'office visée au 1^{er} alinéa ci-dessus, par lettre recommandée avec accusé de réception, au(x) titulaire(s) du brevet d'invention concerné, et, le cas échéant, au(x) titulaire(s) de licence sur ce brevet inscrite au registre national des brevets, ou à leur mandataire, aux fins de présenter par écrit, par lettre recommandée avec accusé de réception, leurs observations dans un délai de 15 jours à compter de la réception de ladite notification.

À l'expiration du délai de 15 jours prévu au 2^e alinéa ci-dessus, l'autorité gouvernementale chargée de l'industrie et du commerce soumet, pour avis, la demande d'exploitation d'office visée au 1^{er} alinéa ci-dessus, accompagnée, le cas échéant, des observations susmentionnées, à une commission technique dont la composition et les modalités de fonctionnement sont fixées par arrêté conjoint de l'autorité gouvernementale chargée de l'industrie et du commerce et de l'autorité gouvernementale chargée de la santé.

Cette commission technique doit donner son avis dans un délai de deux mois à compter de la date de sa saisine.

Article 31: Pour l'application des dispositions de l'article 71 de la loi no.17-97 précitée, la mise en demeure des propriétaires des brevets d'invention, d'en entreprendre l'exploitation de manière à satisfaire aux besoins de l'économie nationale, est faite par décision motivée de l'autorité gouvernementale chargée de l'industrie et du commerce à la demande de l'autorité gouvernementale directement concernée par l'objet du brevet d'invention.

Cette décision précise les besoins de l'économie nationale qui n'ont pas été satisfaits.

Cette décision est notifiée par l'autorité gouvernementale chargée de l'industrie et du commerce, par lettre recommandée avec accusé de réception, au(x) propriétaire(s) du brevet d'invention et, le cas échéant, au(x) titulaire(s) de licence sur ce brevet inscrite au registre national des brevets, ou à leur mandataire, ainsi qu'à l'Office.

Article 38: Pour l'application des dispositions du 2^e alinéa de l'article 75 de la loi no.17-97 précitée, la licence d'office pour les besoins de la défense nationale est accordée par décret sur proposition de l'autorité gouvernementale chargée de l'industrie et du commerce à la demande de l'autorité chargée de la défense nationale.

Ce décret est publié au « Bulletin Officiel ».

Il est immédiatement notifié à l'autorité chargée de la défense nationale, au(x) propriétaire(s) de la demande de brevet d'invention ou du brevet d'invention et, le cas échéant, au(x) titulaire(s) de licence sur ladite demande ou ledit brevet inscrite au registre national des brevets, ainsi qu'à l'Office qui inscrit ce décret d'office audit registre.

Article 39: Les dispositions du présent chapitre III sont applicables aux certificats d'addition et aux certificats de schémas de configuration (topographies) de circuits intégrés, en application respectivement des dispositions des articles 29 et 93 de la loi no.17-97 précitée.

60. Toute personne de droit public ou privé peut, trois ans après la délivrance du brevet ou quatre ans après la date de dépôt de la demande de brevet, obtenir du tribunal une licence obligatoire de ce brevet, dans les conditions prévues aux articles 61 et 62 ci-dessus, si au moment de la requête, et sauf excuses légitimes, le propriétaire du brevet ou son ayant cause :

a) n'a pas commencé à exploiter ou fait des préparatifs effectifs et sérieux pour exploiter l'invention objet du brevet sur le territoire du Royaume du Maroc;

b) n'a pas commercialisé le produit objet du brevet en quantité suffisante pour satisfaire aux besoins du marché marocain; ou

c) lorsque l'exploitation ou la commercialisation du brevet au Maroc a été abandonnée depuis plus de trois ans.

62. La licence obligatoire ne peut être que non exclusive.

Toute licence obligatoire doit être octroyée principalement pour l'approvisionnement du marché marocain.

Elle est accordée à des conditions déterminées par le tribunal, notamment quant à sa durée et à son champ d'application, qui seront limités aux fins auxquelles la licence est accordée, ainsi que le montant des redevances auxquelles elle donne lieu. Ces redevances sont fixées selon le cas d'espèce, compte tenu de la valeur économique de la licence.

Ces conditions peuvent être modifiées par le tribunal à la requête du propriétaire ou du licencié.

66. Lorsqu'une invention protégée par un brevet ne peut être exploitée sans qu'il soit porté atteinte aux droits attachés à un brevet antérieur dont le propriétaire refuse la licence d'exploitation à des conditions et modalités commerciales raisonnables, le propriétaire du brevet ultérieur peut obtenir du tribunal une licence obligatoire, dans les mêmes conditions que celles prévues aux articles 60 à 62 ci-dessus, sous réserve :

a) que l'invention revendiquée dans le brevet ultérieur suppose un progrès technique important, d'un intérêt économique considérable par rapport à l'invention revendiquée dans le brevet antérieur;

b) que le titulaire du brevet antérieur ait droit à une licence réciproque à des conditions raisonnables pour utiliser l'invention revendiquée dans le brevet ultérieur; et

c) que la licence en rapport avec le brevet antérieur soit incessible sauf si le brevet ultérieur est également cédé.

67. Si l'intérêt de la santé publique l'exige, les brevets délivrés pour des médicaments, pour des procédés d'obtention de médicaments, pour des produits nécessaires à l'obtention de ces médicaments ou pour des procédés de fabrication de tels produits, peuvent, au cas où ces médicaments ne sont mis à la disposition du public qu'en quantité ou qualité insuffisante ou à des prix anormalement élevés, être exploités d'office.

L'exploitation d'office est édictée par un acte administratif à la demande de l'administration chargée de la santé publique.

75. L'État peut obtenir d'office, à tout moment, pour les besoins de la défense nationale, une licence pour l'exploitation d'une invention, objet d'une demande de brevet ou d'un brevet, que cette exploitation soit faite par lui-même ou pour son compte.

La licence d'office est accordée à la demande de l'administration chargée de la défense nationale par un acte administratif.

Cet acte fixe les conditions de la licence à l'exclusion de celles relatives aux redevances auxquelles elle donne lieu. La licence prend effet à la date de la demande de licence d'office.

À défaut d'accord amiable entre le propriétaire du brevet et l'administration intéressée, le montant des redevances est fixé par le tribunal administratif de Rabat.

MOZAMBIQUE : *Articles 83, 85-88 of the Industrial Property Code, Decree No. 4 of 12/04/2006*

Article 83 Compulsory working

1. The proprietor of a patent shall be required to work the patented invention, either directly or indirectly.
2. Working shall commence within three years after the date on which the patent was granted, or within four years after the application was filed, whichever period is longer.
3. If the proprietor fails to work the invention within the stipulated periods, he may be compelled to grant a licence to a third party.
4. The proprietor of the patent may also be compelled to grant a licence to a third party to work the patent if the use of another patent depends on it.
5. A compulsory licence will only be granted, as envisaged in the preceding paragraphs, when the potential user has made efforts to obtain the patent proprietor's agreement on reasonable conditions and the negotiations have not been successful.

Article 85 Compulsory licence

1. The invention may be worked under authorisation given by the responsible Ministry, without the consent of the proprietor of the patent, for reasons of public interest.
2. For the purposes of this article, an invention is of public interest if it is of fundamental importance to public health, national defence and economic and technological development.
3. The application for a compulsory licence shall be addressed to the IPI, accompanied by evidence that the applicant sought a contractual licence from the proprietor of the patent but did not obtain one on reasonable commercial conditions and within a reasonable time.
4. The provisions of the preceding paragraph shall not apply to cases of national emergency or other circumstances of extreme urgency.
5. In all cases referred to in this article, the IPI shall immediately inform the proprietor of the patent of the grounds for the grant of a compulsory licence.
6. The proprietor of the patent shall be given adequate remuneration, adjusted according to each particular case, taking into account the economic value of the patent.
7. The extent and duration of the use shall be limited to the purposes for which it was authorised.
8. The use provided for under the terms of this article shall not be exclusive.
9. The use provided for under the terms of this article cannot be assigned.
10. The use provided for under the terms of this article may only be transferred together with the enterprise or the goodwill of the enterprise that works the patented invention.
11. The working of the invention by a third party or a legal entity designated by the Government shall be aimed predominantly at supplying the market in Mozambique.

Article 86 Opposition against the compulsory licence

The proprietor of the patent may at any time oppose an application by a third party for a compulsory licence, on grounds that show that the failure to observe the law was not attributable to him.

Article 87 Proof of working

1. Proof that a patent is being worked may be supplied by means of an official certificate issued by a competent body in the area of work in question.

2. The certificate of working shall certify that the invention is being used in manufacturing processes at the industrial establishment where it is claimed the invention is being worked, or that the subject matter of the invention is actually being marketed.

Article 88 Dependent patents

1. For the purposes of compulsory licences, a dependent patent shall be one the working of which relies necessarily on using the subject matter of a previous patent.
2. A process patent may be considered dependent upon a patent for the respective process [sic], and a product patent may be considered dependent upon a process patent.
3. When the above circumstances occur, there shall be no right to obtain a crossed compulsory license on the dependent patent.

NAMIBIA : Section 19 of the Industrial Property Bill of 1999

Non-voluntary licences

19. (1) On the request of any person who proves his or her ability to work a patented invention in Namibia, made to the Registrar after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Registrar may grant a non-voluntary licence if the patented invention is not worked or is insufficiently worked in Namibia.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the owner of the patent satisfies the Registrar that circumstances exist which justify the non-working or insufficient working of the patented invention in Namibia. Importation shall not constitute such a circumstance.

(3) The beneficiary of the non-voluntary licence shall have the right to exploit, other than to import the patented invention in Namibia according to the terms set down in the decision granting the licence, shall commence the working of the patented invention in Namibia within the time limit fixed in the said decision and, thereafter, shall work the patented invention sufficiently in Namibia, subject to the payment of an equitable remuneration therefor as determined in the said decision.

- (4) The grant of the non-voluntary licence shall not exclude –
- (a) the conclusion of licence contracts by the owner of the patent or the grant of other non-voluntary licences; or
 - (b) the exploitation of the patented invention under section 17(5).

NETHERLANDS (EU) : Articles 57-59 of the Patent Act of 15/12/1994, (Text as it applies on 03/06/2009) and Policy Rules on issuing compulsory licenses pursuant to WTO decision WT/L/540 on the implementation of paragraph 6 of the Doha declaration on the TRIPS Agreement and public health, under section 57 of the Act on Patent of 1995, of 23/12/2004

Article 57

1. If Our Minister considers it in the public interest he may grant a licence under a patent to a party that he designates, provided that he precisely indicates the relevant content. Before

rendering his decision, unless it is incompatible with the urgency of the matter Our Minister shall ascertain whether the patent holder is willing to grant the licence voluntarily and on reasonable terms. To this end, he shall give the patent holder an opportunity to express his opinions on the matter in writing and, at his request, also orally. The patent holder and the licensee shall be notified of the decision. In his decision Our Minister may impose upon the licensee the obligation to provide security within a certain term. The lodging of an objection and an appeal shall have a suspensive effect, unless the decision of Our Minister provides otherwise in view of the urgency of the matter.

2. If, after three years have elapsed since the grant of the patent, neither the patent holder nor any other party who has been granted a licence operates an industrial establishment in the Kingdom or in another State to be designated by general order in council for the Kingdom in which the product concerned is being made or where the process concerned is being applied in good faith and on a sufficient scale, the patent holder shall be obliged to grant the licence needed for operating such an establishment unless valid reasons are shown to exist for the absence of such an establishment. This obligation shall apply in respect of the holder of a European patent if, after three years have elapsed since the date on which the notification of the grant of the European patent was published in accordance with Article 97(4) of the European Patent Convention, an industrial establishment as referred to above is not in operation in the Netherlands or in the Netherlands Antilles or in another State to be designated by general order in council for the Kingdom.

3. Paragraph (2) shall not apply if the patent holder or any other party who has been granted a licence has an industrial establishment in operation in that part of the continental shelf contiguous to the Netherlands or Netherlands Antilles in which the Kingdom has sovereign rights, in which those acts referred to in that paragraph are performed in good faith and on a sufficient scale, provided that such acts are associated with and performed during the exploration for or recovery of natural resources.

4. The patent holder is obliged at all times to grant a licence required for the use of a patent granted in respect of an application that has the same or a later date of filing or, if a right of priority exists in respect of the application, the same or later date of priority, insofar as the patent for which the licence is requested represents a considerable technical advance involving a considerable economic value; however the patent holder will be obliged to grant a licence required for the use of a European patent only after the term for filing an opposition to the European patent has expired or after opposition proceedings thus instituted have ended. The scope of such a licence shall not extend further than is necessary for the use of the licensee's patent. The latter will be obliged to grant a reciprocal licence under his patent to the holder of the other patent.

5. The patent holder shall grant a plant breeder a licence in exchange for a reasonable fee if the plant breeder cannot obtain or exploit a plant breeder's right in respect of the plant variety without infringing the patent that was granted earlier and the licence is necessary for the exploitation of the plant variety to be protected, which represents a significant technical advance involving a considerable economic value in respect of the invention protected by the patent.

6. If a patent holder is granted a licence on the ground of Article 42(2) of the Dutch Seeds and Planting Materials Act (*Zaaizaad- en Plantgoedwet*), the patent holder shall grant the holder

of the plant breeder's right a reciprocal licence, at the latter's request, to use the protected invention subject to reasonable conditions.

Article 57a

Notwithstanding the provisions contained in Article 57, a compulsory patent licence in the field of semiconductor technology may be granted only for non-commercial use by the government or in order to combat an act that has been determined to be restrictive of competition after judicial or administrative proceedings.

Article 58

1. If the licence referred to in Article 57(2), (4), (5) or (6) is unjustifiably withheld, the licence shall be granted by the court on the basis of a claim brought by the interested party. At the claimant's request the Office shall enter the writ of summons in the patent register.

2. If a patent is granted on the basis of this Kingdom Act, the claimant's claim shall be inadmissible if he does not attach to his writ of summons the results of a report by the Office or the European Patent Office as referred to in the European Patent Convention concerning the state of the art with regard to the subject matter of the patent for which the licence is being claimed.

3. The grant of a licence claimed pursuant to the first sentence of Article 57(4) may be suspended, subject to a term or subject to no term, if a claim to have the patent for which the licence is being claimed invalidated has been submitted within two months after service of the writ of summons in which the licence is claimed.

4. In the description of the licence granted the court may derogate from the licensee's claims and may also require that the licensee furnish security within a certain term. A licence granted pursuant to the first sentence of Article 57(4) may be transferred only together with the licence holder's patent. A licence granted pursuant to the first or third sentence of Article 57(4) shall not expire because the patent on which the licence is granted has lapsed upon the expiry of the period referred to in Article 36(6) or has been successfully claimed, but such a licence shall expire insofar as the patent is invalidated in whole or in part as a result of the claim referred to in paragraph (3).

5. A decision within the meaning of Article 57(1) or a court decision that has become final and has acquired the force of res judicata shall be entered in the patent register by the Office. If an obligation to furnish security has been imposed, the entry shall not be made before that obligation has been met. A fee, the amount of which shall be fixed by general order in council for the Kingdom, shall be due for the entry. The licence shall enter into effect only after the entry, but shall subsequently also have effect with regard to parties who became entitled to the patent after the entry in the register of the writ of summons referred to in paragraph (1). However, a registered licence granted on the ground of Article 57(4) shall have retroactive effect to the date on which the writ of summons was entered.

6. On the ground of a claim brought by the initiating party, in the absence of agreement the court shall fix the fee that the licensee must pay to the patent holder. In that context the court may also require that the licensee furnish security within a certain term or confirm or change the security stipulated by virtue of Article 57(1) or paragraph (5) of this Article.

Article 58a

1. A licence granted on the ground of Article 57 is not exclusive.
2. A licence granted on the ground of Article 57 may be transferred only together with the part of the business or the goodwill of the part of the business in which the licence is exercised.
3. A licence granted on the ground of Article 57 may be revoked if, taking into consideration a reasonable protection of the licensee's justified interests, the circumstances that led to the licence being granted have ceased to exist and it is unlikely that they will be revived. On the ground of a substantiated request the authority that granted the licence shall investigate whether the aforementioned circumstances continue to apply.

Article 59

1. In the interest of the defence of the Kingdom, and on a joint recommendation by Our Minister and Our Minister who is directly concerned, it may be provided by Royal Decree that the State shall be authorised to perform or cause others to perform acts, to be described precisely in that Decree, that the patent holder to be specified in that Decree has the exclusive right to perform pursuant to Articles 53 and 53a. The authorisation shall apply as long as the patent is in effect, unless a shorter term has been specified in the Decree.
2. Upon the entry into force of a Decree as referred to in paragraph (1), Our Minister who is directly concerned shall determine, by agreement with the patent holder, the fee to be paid to the patent holder by the State. If Our Minister who is directly concerned has not reached an agreement with the patent holder within six months from the date of the entry into force of that Decree, Article 58(6) shall apply mutatis mutandis, with the exception of the provisions concerning the furnishing of security.

Article 2 of the Policy Rules on issuing compulsory licenses pursuant to WTO decision WT/L/540

1. In the interests of solving public health problems in an importing state or group of states, the Minister shall, upon receiving an application that satisfies the requirements of articles 3 and 4 of these policy rules, issue a compulsory licence as referred to in section 57, subsection 1 of the Patents Act 1995 for the pharmaceutical product that is needed to address the public health problems in question.
2. The compulsory licence shall at a minimum state the type and amount of the pharmaceutical product to which the compulsory licence issued for the purposes of the order applies.
3. The compulsory licence shall relate only to pharmaceutical products intended for the national market or markets of the importing state or group of states.

NEW ZEALAND : *Sections 46, 55-56 and 58-58A of the Patents Act No. 64 of 1953 (as at 01/08/2008)*

46 Compulsory licence

- (1) At any time after the expiration of 3 years from the date of the sealing of a patent or 4 years from the date of the patent, whichever is the later, any person interested may apply to

the Court for the grant of a licence under the patent upon any of the grounds specified in subsection (2) of this section.

(2) The grounds upon which a licence may be granted under this section are that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms, in New Zealand.

(3) Subject to subsections (4), (5), (6), and (7) of this section, if the Court is satisfied that either of the grounds referred to in subsection (2) of this section are established, the Court may make an order for the grant of a licence in accordance with the application upon such terms as the Court thinks fit.

(4) A licence granted under this section -

(a) Is not exclusive:

(b) Must not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used:

(c) Is limited to the supply of the patented invention predominantly in New Zealand.

(5) Any licence granted under this section may, on the application of any interested party, be terminated by the Court, where the Court is satisfied that the grounds on which the licence was granted have ceased to exist.

(6) Where a licence is granted under this section to any person, that person shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed, between that person and the patentee or, in default of agreement, as is determined by the Court on the application of that person or the patentee.

(7) No licence shall be granted under this section unless the person applying for the licence, having taken all reasonable steps to do so, has been unable to obtain a licence, or to obtain a licence on reasonable terms, from the patentee.

(8) No licence shall be granted under this section in respect of a patent relating to an integrated circuit.

55 Use of patented inventions for services of the Crown

(1) Subject to sections 58A to 58C of this Act, but notwithstanding any other provision of this Act, any Government Department, and any person authorized in writing by a Government Department, may make, use, exercise, and vend any patented invention for the services of the Crown and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

(2) For the purposes of this section and section 56 of this Act, -

(a) Any use of an invention for the supply to the Government of any country outside New Zealand, in pursuance of any agreement or arrangement between the Government of New Zealand and the Government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention for the services of the Crown:

- (b) The power of a Government Department or a person authorized by a Government Department under this section to make, use, exercise, and vend a patented invention shall include power to sell to any person any articles made in the exercise of the powers conferred by this section that are no longer required for the purpose for which they were made:
 - (c) The power of a Government Department or a person authorized by a Government Department under this section to vend a patented invention shall not, in the case of a patent relating to an integrated circuit, extend to sale of the invention to the public.
- (3) Where the Governor-General, by Order in Council, declares that the use of any patented invention by any person or by any class of persons engaged in a particular industry is necessary or desirable enable full benefit to be derived by the members of the public in New Zealand of any enterprise or undertaking in which the Crown or any Government Department has a complete or almost complete monopoly, any such use of the invention or inventions shall for the purposes of this section and sections 56 and 57 of this Act be deemed to be a use for the services of the Crown.
- (4) The purchaser of any articles sold in the exercise of powers conferred by this section, and any person claiming through the purchaser, shall have power to deal with them in the same manner as if the patent were held on behalf of the Crown.

56 Rights of third parties in respect of the Crown use

- (1) In relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the services of the Crown –
- (a) By a Government Department or a person authorized by a Government Department under section 55 of this Act; or
 - (b) By the patentee or applicant for the patent to the order of a Government Department, -
- the provision of any licence, assignment, or agreement made, whether before or after the commencement of this Act, between the patentee or applicant for the patent, or any person who derives title from him or from whom he derives title, and any person other than a Government Department shall, subject to sections 58A and 58C of this Act, be of no effect so far as those provisions restrict or regulate the use of the invention, or any mode, document, or information, relating thereto, or provide for making of payments in respect of any such use, or calculated by reference thereto; and the reproduction or publication of any model or document in connection with the said use shall not be deemed to be an infringement of any copyright subsisting in the model or document.

- (2) [Repealed]
- (3) [Repealed]
- (4) [Repealed]

58 Special provisions as to Crown use during emergency

Subject to sections 58A to 58C of this Act, the powers exercisable in relation to an invention by a Government Department or a person authorized by a Government Department under section 55 of this Act, shall include power to make, use, exercise, and vend the patented invention for any purpose which appears to the Department necessary or expedient –

- (a) to avoid prejudice to the security or defence of the New Zealand; or

- (b) to assist in the exercise of powers and the implementation of civil defence emergency management during a state of emergency declared under the Civil Defence Emergency Management Act 2002.

58A Nature and scope of rights under section 55

- (1) The right to use a patented invention under section 55 of this Act -
 - (a) Is not exclusive:
 - (b) Must not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used:
 - (c) Is, notwithstanding subsection (2)(a) of that section, limited to the supply of the patented invention predominantly in New Zealand by a government Department or a person authorized by a Government Department under that section.
- (2) The right to use a patented invention under section 55 of this Act may, on the application of any interested party, be terminated by the Court, where the Court is satisfied that the circumstances that gave rise to the right to use the patented invention have ceased to exist and are unlikely to recur.
- (3) Except in a case to which section 58 of this Act applies, the right to use a patented invention under section 55 of this Act is subject to the Government Department or person authorized by a Government Department under section 55 of this Act having first taken all reasonable steps to obtain the consent of the patentee to the use of the patented invention on reasonable terms and conditions, and having failed to obtain such consent within a reasonable period of time.

NICARAGUA : *Sections 51, 53 and 54 of the Industrial Property Law No. 354 of 19/09/2000*

Compulsory Licenses

51. At the request of an interested party or competent authority, the Intellectual Property Registry may, after having heard the owner of the patent, grant compulsory licenses for reasons of public interest or national emergency, or to control any anti-competitive practice. The Intellectual Property Registry shall order that:

(a) the invention for which a patent has been granted or for which a patent application is pending be used or exploited industrially or commercially by a State body or by one or more persons under public or private law designated for the purpose;

(b) the invention for which a patent has been granted or a patent application is pending remain open for the grant of one or more compulsory licenses, in which case the Registry may grant such a license to whoever may apply for one, subject to established conditions.

Those acts that unduly affect free competition or constitute an abuse of a dominant market position are included among those that are not consistent with the proper exercise of patent rights.

Where the patent protects any kind of semiconductor technology, the compulsory license shall be granted only for non-commercial public use, or to control a practice declared anti-competitive in an appropriate procedure.

Conditions Governing Compulsory Licenses

53. The compulsory license shall be granted mainly to supply the domestic market, and its owner shall receive adequate remuneration according to the circumstances of the case and the

economic value of the license. In the absence of agreement the Intellectual Property Registry shall set the amount of the remuneration and the manner of its payment.

The compulsory license may not be granted with exclusive rights, or be the subject of assignment or sublicensing, and it may only be transferred together with the business or establishment or part thereof that exploits the license.

Compulsory License in the Case of Patent Dependency

54. Where a compulsory license is requested to permit the working of a later patent that cannot be worked without infringing an earlier patent, the following additional conditions shall be observed:

(a) the invention claimed in the later patent must represent a substantial technical advance of considerable economic importance in relation to the invention claimed in the earlier patent;

(b) the compulsory license for working the earlier patent may only be assigned together with the later patent;

(c) the owner of the earlier patent may under the same circumstances obtain a compulsory license on reasonable terms for the exploitation of the invention claimed in the later patent.

NIGERIA : Section 11 of the Industrial Property Act (Chapter 344) No. 60 of 1970 (amended law of 1990 not available)

1. Subject to this Part, at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of a patent, whichever period last expires, a person may apply to the court for the grant of a compulsory licence on one or more of the following grounds—

(a) that the patented invention, being capable of being worked in Nigeria, has not been so worked;

(b) that the existing degree of working of the patented invention in Nigeria does not meet on reasonable terms the demand for the product;

(c) that the working of the patented invention in Nigeria is being hindered or prevented by the importation of the patented article; and

(d) that, by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly and substantially prejudiced.

2. If an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority, a compulsory licence may be granted to the patentee of the later patent to the extent necessary for the working of his invention if the invention—

(a) serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or

(b) constitutes substantial technical progress in relation to that last mentioned invention.

3. If the two inventions mentioned in paragraph 2 of this Schedule serve the same industrial purposes, a compulsory licence may be granted under that paragraph only on condition that a compulsory licence shall also be granted in respect of the later patent to the patentee of the earlier patent, if he so requests.
4. A compulsory licence shall not be granted in respect of a patent if the patentee satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances, but he shall not be held to have so satisfied the court if he merely shows that the patented article is freely available for importation.
5. A compulsory licence shall not be granted unless the applicant—
 - (a) satisfies the court that he has asked the patentee for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time; and
 - (b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies (or to satisfy the requirements) which gave rise to his application.
6. A compulsory licence—
 - (a) entitles the licensee to do any act mentioned in section 6 of this Act except importation;
 - (b) does not entitle the licensee to grant further licences;
 - (c) shall be non-exclusive, and
 - (d) may contain additional obligations and restrictions as regards both the licensee and the patentee.
7. A compulsory licence may be transferred only with the industrial undertaking in which the relevant invention is used, and no such transfer shall be valid until the consent of the court has been obtained.
8. On hearing an application for a compulsory licence, the court shall first decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant and the parties cannot agree on the terms, proceed to fix the terms (including adequate royalties having regard to the extent to which the relevant invention is to be worked) which shall be deemed to constitute a valid contract between the parties.
9. On the application of the patentee, the court may cancel a compulsory licence if—
 - (a) the licensee fails to comply with the terms of the licence; or
 - (b) the conditions which justified the grant of the licence have ceased to exist,so however that in the latter case a reasonable time shall be given to the licensee to cease working the relevant invention if an immediate cessation would cause him to suffer substantial damage.

10. On the application of the patentee or licensee, the court may vary the terms of a compulsory licence if new facts justify the variation, and in particular (without prejudice to the generality of the foregoing) if the patentee has granted contractual licences on more favourable terms.
11. Where the court grants, cancels or varies the terms of a compulsory licence—
 - (a) the proper officer of the court shall inform the Registrar, who shall register the grant, cancellation or variation without fee; and
 - (b) the grant, cancellation or variation shall have no effect as against third parties until it has been registered.
12. A representative of the Minister shall have the right to appear and be heard at the hearing of an application for a compulsory licence.
13. The Minister by order in the Federal Gazette may provide that, for certain patented products and processes (or for certain categories thereof) declared by the order to be of vital importance for the defence or the economy of Nigeria or for public health, compulsory licences may be granted before the expiration of the period mentioned in paragraph 1 above and may permit importation.
14. For the purposes of this Part, references to the working of a patented invention are to be construed as references to—
 - (a) the manufacture of a patented article; or
 - (b) the application of a patented process; or
 - (c) the use in manufacture of a patented machine,by an effective and serious establishment existing in Nigeria on a scale which is adequate and reasonable in the circumstances.
15. Notwithstanding anything in this Act, where a Minister is satisfied that it is in the public interest to do so, he may authorise any person to purchase, make, exercise or vend any patented article or invention for the service of a government agency in the Federal Republic.
16. The authority of a Minister under paragraph 15 of this Schedule may be given—
 - (a) before or after the relevant patent has been granted;
 - (b) before or after the doing of the acts in respect of which the authority is given; and
 - (c) to any person whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the relevant article or invention.
17. Paragraphs 15 and 16 of this Schedule shall have effect so as to exempt—
 - (a) the Government;
 - (b) any person authorised under those paragraphs;

- (c) any supplier of the Government or of any such person; and
- (d) any agent of any such supplier,

from liability for the infringement of any patent relating to the relevant article or invention and from liability to make any payment to the patentee by way of royalty or otherwise.

18. Where any act is done in respect of an article on the authority of a Minister under paragraph 15 of this Schedule, then, unless it appears to the Minister that it would be contrary to the public interest to do so, the Ministry concerned with the act shall furnish the patentee with such information as to the extent of the act as the patentee may from time to time require.

19. The provisions of any licence, assignment or agreement made before or after the commencement of this Act between a patentee and any person other than the Government or a Ministry shall be of no effect in so far as those provisions restrict or regulate the use of a patented article or invention or provide for the making of payments in respect of any such use, or are calculated by reference thereto.

20. During any period of emergency the powers exercisable in relation to a patented article or invention on the authority of a Minister under paragraph 15 of this Schedule shall include power to purchase, make, use, exercise and vend the article or invention for any purpose which appears to the Minister necessary or expedient—

- (a) for the efficient prosecution of any war in which the Federal Republic may be engaged; or
- (b) for the maintenance of supplies and services essential to the life of the community; or
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community; or
- (d) for promoting the productivity of industry, commerce and agriculture; or
- (e) for fostering and directing exports and reducing imports (or any class or classes of imports) from all or any countries and for redressing the balance of trade; or
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community.

21. Where a patented article is purchased, made, used, exercised or vended by or on behalf of a government agency, the benefit of this Part shall extend to the agency and to persons acting in any capacity on its behalf.

22. This Part shall apply to a patented article forfeited under any law relating to customs and excise; and, on any such forfeiture, the Government may use or sell the article as if it had been imported for the use of a government agency in Nigeria.

NORWAY : Sections 45-50a and 107 of the Patent Act No. 9 of 15/12/1967 (as last amended by Act No.80 of 29/06/2007) and Sections 107-108 of the Patent Regulations No. 1162 of 20/12/1996 (as last amended by Royal Decree of 14/05/2004)

Section 45. Where three years have elapsed from the grant of the patent and four years from the filing of the patent application without the invention being worked in this country to a reasonable extent, anyone who wishes to work the invention in this country may obtain a

compulsory licence for that purpose, provided there is no legitimate reason for the failure to work the invention.

For the purpose of the first paragraph, utilization of the invention shall, in contracting states in the WTO treaty or the EEA, be given equal status as utilization within this country, provided that the patent rights do not prevent national imports. The same applies for utilization in other states, to the extent it complies with a reciprocal duty following an international treaty.

Section 46. The holder of a patent for an invention, the use of which is dependent on a patent owned by someone else, may obtain a compulsory licence to use the invention protected by the latter patent provided that the former invention involves an important technical advance of considerable economic significance in relation to the latter invention.

The holder of the patent for the invention to which the compulsory licence applies shall be entitled to obtain a compulsory licence on reasonable terms to use the other invention.

Section 46 a. Where a breeder cannot acquire or exploit a plant variety right without infringing a prior patent, he may, subject to payment of an appropriate royalty, apply for a compulsory licence for non-exclusive use of the invention protected by the patent inasmuch as the licence is necessary for exploitation of the plant variety to be protected. A compulsory licence will only be granted where the applicant can demonstrate that the plant variety constitutes significant technical progress of considerable financial interest in relation to the invention.

If a patent holder has been granted a compulsory licence for the exploitation of a protected plant variety according to Act No 32, March 12, 1993 about Plant variety protection Section 28 second paragraph, the holder of the plant variety right is entitled to a compulsory licences of the patented invention on reasonable terms.

Section 47. Any person who wants to exploit an invention commercially, which has been patented by someone else, may be given a compulsory licence

- when required by important public interests.
- when the patent rights are exploited in a way that significantly limits competition.

Section 48. Anyone who, at the time a patent application was made available to the public, was commercially exploiting the invention for which a patent is applied for in this country, may, if the application results in a patent, obtain a compulsory licence for the exploitation of the invention, provided that special circumstances make it desirable, and that he had no knowledge of the application and could not reasonably have obtained such knowledge. Such right shall also, on similar conditions, be enjoyed by anyone who has made substantial preparations for commercial exploitation of the invention in this country. The compulsory licence may also comprise the time preceding the grant of the patent.

Section 49. A compulsory licence may only be granted to someone who has made efforts to obtain a licence on reasonable business terms by agreement, without achieving it in reasonable time, and may be presumed able to exploit the invention in a manner which is acceptable and which is in compliance with the terms of the licence.
A compulsory licence shall not prevent the patent holder from exploiting the invention himself or from granting licences.

A compulsory licence shall only be assignable in conjunction with the enterprise where it is exploited or in which the exploitation was intended. Furthermore, a compulsory licence obtained according to the first paragraph of section 46 may only be assigned in conjunction with the dependent patent.

In the case of semi-conductor technology, compulsory licences shall only be granted for public non-commercial use or to remedy practice determined after judicial or administrative process to be anti-competitive or based on section 47 nr.2.

A compulsory licence shall mainly be given with the aim of supplying the domestic market. The King may, by regulation, determine provisions which depart from this.

Section 50. The court shall grant a compulsory licence in accordance with this section, and the Norwegian Competition Authority in accordance with section 50 a.

In a decision considering a compulsory licence, the court shall also determine to what extent the invention may be exploited and stipulate the compensation and the other terms of the licence. The compensation shall be appropriate, taking into account the circumstances in each case. The value of the licence shall be taken in consideration when assessing the compensation.

If circumstances should change considerably, the court may, at the request of either party, cancel the licence or stipulate new terms.

In a decision granting or extending a compulsory licence, the court may find that the owner of the compulsory licence shall have the right to exploit the invention in accordance with the decision during the period prior to the decision becoming legally binding. Motion for preliminary enforcement has to be put forward prior to the judge's final deliberations on the merits of the case. If the compulsory licence is cancelled because the decision is opposed before becoming legally binding, the owner of the compulsory licence shall be obliged to pay compensation for the loss caused by the exploitation, to an extent considered reasonable. The third sentence shall apply correspondingly if restrictions are imposed on the compulsory licence. In a decision under the first sentence, the court may instruct the licensee to furnish security for liability under the third and fourth sentences. If a decision granting or extending a compulsory licence is opposed before becoming legally binding, the court to which the decision is brought, may make or reverse a decision under the first and fourth sentences. The decision is made by a ruling or by the final decision in the matter, cf. the second sentence. A ruling under the sixth sentence may only be opposed in connection with an appeal of the final decision in the matter.

Section 50 a. A request for a compulsory licence made to the Norwegian Competition Authority, shall state the grounds for the request and provide details of the circumstances referred to in section 49 first paragraph. The claim shall set out the scope of the licence and compensation and any further conditions the party considers reasonable. A prescribed fee shall be paid. If the application does not fulfil these requirements, The Norwegian Competition Authority shall grant a reasonable period of time for rectification. The demand shall be rejected if the deficiency in the request is not rectified within the time limit, unless the Norwegian Competition Authority finds reasons to grant a new period of time for rectification.

The Norwegian Industrial Property Office, Board of Plant Varieties, or any other public agency shall, upon request from the Norwegian Competition Authority or the Board of Appeals, provide an opinion on the case within 6 weeks from the date of the request.

Anyone can provide the Norwegian Competition Authority or the Board of Appeals with the information these authorities require in connection with cases concerning compulsory licences. The Norwegian Competition Authority may summon the parties to an oral hearing if necessary. The King may, by regulation, determine specific rules for the procedures.

The regulation in section 50 third paragraph apply correspondingly for cases under this section, nevertheless the Norwegian Competition Authority or the Board of Appeals do not have the authority to cancel or amend a licence which has been granted or tried by a court of law.

For implementation of an administrative decision, the Public Administration Act section 42 applies. If the compulsory licence is cancelled or limited following a challenge or a lawsuit filed within two months of the Norwegian Competition Authority's or the Board of Appeals' decision, the licensee is obliged to pay reasonable compensation for the economic loss the exploitation has caused. The Norwegian Competition Authority or the Board of Appeals may in the decision concerning the compulsory licence require as a condition that the licence holder provide security for the liability, in accordance with this paragraph's second sentence.

In a lawsuit the court has full judicial power to review all aspects of the Norwegian Competition Authority's or the Board of Appeals' decision in accordance with this paragraph. A lawsuit may not be filed on the grounds that the decision on a compulsory licence has been dismissed summarily or rejected. A lawsuit, filed by the patent holder in accordance with this paragraph, must be brought against the holder of the compulsory licence.

Regulations

Section 107. When the requirements set out in section 108 have been complied with, a producer of pharmaceutical products in Norway shall be granted on application a compulsory licence pursuant to section 47 of the Patents Act to manufacture pharmaceutical products for export to an eligible importing State that has requested the producer to supply the products. For the purpose of these regulations, an eligible importing State is a State or a customs territory that:

1. at the time in question has been designated by the UN as a least developed country or customs territory, or that has insufficient manufacturing capacity in accordance with the Annex to the decision of the WTO General Council of 30 August 2003 (the General Council Decision), and

2. has made a notification to the Council for TRIPS in accordance with the General Council Decision, paragraphs 1(b) and 2(a).

States that are not party to the WTO Agreement shall make the notification referred to in the first paragraph (2) above to the Norwegian Ministry of Foreign Affairs.

Section 108. A compulsory licence may only be granted pursuant to section 107 if

1. the producer has tried to obtain a licence by agreement in Norway insofar as this is required pursuant to section 49, first paragraph, of the Patents Act,

2. the product is covered by paragraph 1(a) of the General Council Decision,

3. the product is only to be produced for export to the eligible importing State in order to cover the said State's current need for the product for health purposes, as described in the notification mentioned in section 107, and

4. the invention is not protected by a patent in the eligible importing State, or the eligible importing State has granted a compulsory licence or legal proceedings to obtain such a licence

have been initiated pursuant to Article 31 of the Agreement of 15 April 1994 on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) and the General Council Decision.

When assessing what are reasonable commercial terms and conditions pursuant to section 49, first paragraph, of the Patents Act, and when determining the remuneration pursuant to section 50, second paragraph, of the Patents Act, account shall be taken of the economic value to the importing State of the use of the invention.

More detailed requirements for granting a compulsory licence may be imposed in the decision to grant such a licence, cf. section 50, first paragraph, of the Patents Act. These shall include the following requirements

1. the packaging and container shall be distinct from those of products being offered for sale in Norway or in another state by the patent-holder himself or with his consent,
2. the products shall be labelled so as to clearly indicate that the pharmaceutical product has been manufactured under compulsory licence in Norway for export to a specified importing state in accordance with the General Council Decision, and
3. the manufacture and export shall cease if the licence-holder learns the products are being used to an appreciable degree for purposes that are not in accordance with the conditions for granting the licence, cf. first paragraph (3).

OMAN : *Sections 1 and 15-16 of the Royal Decree Promulgating the Patent Law No. 82 of 21/05/2000*

1. In implementing the provisions of this law, the following words and expressions shall have the meaning specified for it, unless otherwise specified.

The Minister: The Minister of Commerce and Industry

The Ministry: The Ministry of Commerce and Industry

The Department: The Department of Agencies and Intellectual Property (Patent Office).

Patent: The document awarded by the Department to the patent owner in order of invention, to enjoy the legal protection in accordance with this law and its bylaws.

Contractual License: The license issued on the basis of the patent owner's approval for others to use the patent.

Compulsory License: The license issued by a decision from the Minister without the patent holder's approval, for the cases specified in this law.

15. Three years after awarding the patent, whomever is concerned, may request a compulsory license to utilize the invention for any of the following reasons:

(a) Not utilizing the patent actively and seriously within three years from being awarded.

(b) Suspension of the utilization of the invention protected by the patent, by the patent utilizer, for two consecutive years.

(c) The patent holder's refusal to grant license contract to utilize it, which may impact the establishment, or development, of industrial or commercial activities within the Sultanate of Oman.

In all cases, compulsory license may not be issued if patent holder justified the position. Import of the produce is not considered a justified reason. The Minister issues compulsory license and the patent holder may complain against this decision before the committee, as stipulated in Article 7, in accordance with the conditions and regulation stipulated in the bylaws.

16. Compulsory license grants the licensee the right to initiate some, or all, the activities entrusted to the patent holder, in accordance with the license conditions, with the exception of the right to import the produce. License holder may use the civil and penal rights associated with the patent holder, to protect and utilize the invention, in the event of failure despite of being notified.

PAKISTAN : *Sections 58 and 59 of the Patents Ordinance No. LXI of 02/12/2000 (as amended by the Patents Amendment Ordinance of 2002)*

58. Exploitation by a Government agency or third person.-

(1) Subject to sub-section (2), where -

- (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or
- (ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices; or
- (iii) the patent holder refuses to grant a license to a third party on reasonable commercial terms and conditions; or
- (iv) where patent has not been exploited in a manner which contributes to the promotion of technological innovation and to the transfer and dissemination of technology, the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated by the Federal Government may exploit a patented invention.

(2) The Federal Government shall, before taking any decision under sub-section (2), give the owner of the patent and any interested person an opportunity of being heard if he wishes to be heard.

(3) The exploitation of the patented invention shall be limited to the purpose for which it was authorized and shall be subject to the payment to the said owner of an adequate remuneration therefor, taking into account the economic value of the Federal Government authorization, as determined in the said decision, and where a decision has been taken under sub-section (1), the need to correct anti-competitive practices.

(4) A request for the Federal Government authorization shall be accompanied by evidence that the owner of the patent has received, from the person seeking the authorization, a request for a contractual license, but that person has been unable to obtain such a license on reasonable commercial terms and conditions and within a reasonable time:

Provided that this sub-section shall not apply in cases of –

- (i) national emergency or other circumstantial urgency provided that in such cases the owner of the patent shall be informed of the decision of the Federal Government as soon as reasonably practicable;
- (ii) public non-commercial use; and
- (iii) anti-competitive practices determined as such by a judicial or administrative body in accordance with clause (ii) of sub-section (1).

(5) The exploitation of a patented invention in the field of semi-conductor technology shall only be authorized either for public non-commercial use or where a judicial or administrative body has determined that the manner of exploitation of the patented invention, by the owner of the patent or his licensee, is anti-competitive and if the Federal Government is satisfied that the issuance of the non-voluntary license would remedy such practices.

(6) The authorization shall be considered on its individual merits and shall not prohibit-

- (i) the conclusion of license contracts by the owner of the patent;
- (ii) the continued exercise, by the owner of the patent, of his rights under section 30; or
- (iii) the issuance of a non-voluntary license under section 59.

(7) Where a third person has been designated by the Federal Government, the authorization may only be transferred with the enterprise or business of the person or with the part of the enterprise or business within which the patented invention is being exploited.

(8) Where the exploitation of the invention by the Government agency or third person designated by the Federal Government is authorized under clause (i) of sub-section (1), it shall be predominantly for the supply of the market in Pakistan.

(9) Upon request of the owner of the patent, or of the Government agency or of the third person authorized to exploit the patented invention, the Federal Government may, after hearing the parties, if either or both wish to be heard, vary the terms of the decision authorizing the exploitation of the patented invention to the extent that changed circumstances justify such variation.

(10) Upon the request of the owner of the patent, the Federal Government shall, subject to adequate protection of the legitimate interest of the persons so authorized, terminate an authorization if it is satisfied, after hearing the parties, if either or both wish to be heard, that the circumstances which led to the decision have ceased to exist and are unlikely to recur or that the Government agency or third person designated by it has failed to comply with the terms of the decision.

(11) Notwithstanding the provisions of sub-section (10), the Federal Government shall not terminate an authorization if it is satisfied that the need for adequate protection of the legitimate interests of the Government agency or third person designated by it justified the maintenance of the decision.

(12) An appeal shall lie to the High Court against the decisions of the Federal Government under sub-sections (1) to (9).

59. Powers of Controller in granting compulsory licenses.-

(1) On request, made in the prescribed manner to the Controller after the expiration of a period of four years from the date of filing of the patent application or three years from the

date of the grant of the patent, whichever period expires last, the Controller may issue a non-voluntary license to prevent the abuses which might result from the exercise of the rights conferred by the patent, for example, failure to work.

(2) Notwithstanding the provisions of sub-section (1), a non-voluntary license shall not be issued if the owner of the patent satisfies the Controller that circumstances exist which justify the non exploitation or insufficient exploitation of the patented invention in Pakistan.

(3) The decision issuing the non-voluntary license shall fix-

- (i) the scope and function of the license;
- (ii) the time limit within which the licensee must begin to exploit the patented invention; and
- (iii) the amount of the adequate remuneration to be paid to the owner of the patent and the conditions of payment.

(4) The beneficiary of the non-voluntary license shall have the right to exploit the patented invention in Pakistan according to the terms set out in the decision issuing the license, shall commence the exploitation of the patented invention within the time limit fixed in the said decision and, thereafter, shall exploit the patented invention sufficiently.

(5) If the invention claimed in a patent, hereinafter referred to as “later patent”, cannot be exploited in Pakistan without infringing a patent granted on the basis of an application benefiting from an earlier filing or, where appropriate, priority date, hereinafter referred to as “earlier patent”, and provided that the invention claimed in the later patent involves an important technical advance of considerable economic importance in relation to the invention claimed in the earlier patent, the Controller, upon the request of the owner of the later patent, may issue a non-voluntary license to the extent necessary to avoid infringement of the earlier patent.

(6) Where a non-voluntary license is issued under sub-section (5), the Controller upon the request of the owner of the earlier patent shall issue a non-voluntary license in respect of the later patent.

(7) In the case of a request for the issuance of a non-voluntary license under sub-sections (5) and (6), sub-section (3) shall apply mutatis mutandis with the provision that no time limit needs to be fixed.

(8) In the case of a non-voluntary license issued under sub-section (5), the transfer may be made only with the later patent, or, in the case of a non-voluntary license issued under sub-section (6), only with the earlier patent.

(9) The request for the issuance of a non-voluntary license shall be subject to payment of the prescribed fee.

(10) The provisions of sub-sections (2) to (10) of section 58 shall apply mutatis mutandis for issuance of an non-voluntary license under this section.

PAPUA NEW GUINEA : *Section 32 of the Industrial Property Act No. 30 of 19/07/2000*

32. Exploitation by Government or person authorized by Government

(1) Where -

(a) the public interest, in particular, national security, nutrition, health or the development of other sectors of the national economy so requires; or

(b) the Minister has determined that the manner of exploitation of a patented invention by the owner or his licensee is anti-competitive, and he is satisfied that the exploitation of a patented invention in accordance with this Division would remedy such practice, the Minister may at the request of a Government agency or other person authorise, by notice in the National Gazette, the exploitation of the patented invention by the requesting agency or person predominantly for the supply of the market in Papua New Guinea, even without the agreement of the owner of the patent.

(2) The Minister may impose such terms and conditions on an authorisation under section* (1) as he thinks fit.

(3) Subject to Subsection (5), prior to granting an authorisation under Subsection (1), the Minister must be satisfied that the owner of the patent has received from the Government agency or person requesting the authorisation, a request for a contractual licence, but that that Government agency or person has been unable to obtain such a licence on reasonable commercial terms and conditions and within a reasonable time.

(4) Subject to Subsection (5), the Minister shall not authorise the exploitation of the patented invention under Subsection (1) until he has given the owner of the patent and any other person known to the Minister to be an interested person, an opportunity to be heard, and where they wish to be heard, has heard them.

(5) Subsections (3) and (4) do not apply in cases of national emergency under Part X of the Constitution or in other circumstances of extreme emergency, but in such cases the owner of the patent shall be notified of the decision of the Minister as soon as is reasonably practicable.

(6) The exploitation of a patented invention which is authorised by the Minister under Subsection (1) shall -

(a) be limited to the purpose for which the Minister authorised its use; and

(b) be subject to payment to the owner of the patent of adequate remuneration as determined by the Minister; and

(c) shall not exclude -

(i) the conclusion of licensing contracts by the owner of the patent; and

(ii) the continued exercise, by the owner of the patent, of his rights under Section 29 (1).

(7) In determining the amount of compensation referred to in Subsection (6) (b), the Minister shall take into account -

(a) the economic value of his decision under Subsection (1); and

(b) where the decision has been taken under Subsection (1) (b), the need to remedy the anti-competitive practices.

PARAGUAY : *Articles 42- 46 of the Patents Law No. 1630 of 29/11/2000*

Article 42. Other uses without authorization of the holder. In the event that a potential user shall have attempted to obtain the concession of a license from the holder of a patent under reasonable terms and commercial conditions and such attempts shall not have produced results, the Industrial Property Department, after a term of ninety days from the date of application for the relevant license, may permit other uses of the said patent without authorization of the holder, pursuant to the provisions of the present law.

When the application refers to technology sectors that do not enjoy protection in the country on the effective date of the present law and the patent applied for comprises the raw material from which the end product is to be developed, the licensee shall be obliged to purchase the said raw material, molecule or principle, from the holder of the patent or from whoever he shall indicate. The price to be paid shall be the price that at which the same are offered in the international market. In the event that a preferential price exists in favor of the holder's affiliates, the said holder shall offer that price to the licensee. The holder shall sell the same to the licensee promptly and in due course.

In the event that another supplier offers the relevant raw material to the licensee at a price 15% (fifteen percent) lower than that offered by the license holder, the licensee may purchase the same duly justifying that the purchased raw material has been legally placed in the national or international market by the patent holder, by a third party with consent thereof, or is legally permitted.

Article 43. Compulsory licenses or other uses due to lack of exploitation. Any interested party may apply to the Industrial Property Department for a compulsory license after three years from the concession of the patent or four years after presentation of the application, the later of which shall be applicable if the invention has not been exploited, or effective and serious preparations to do so have not been made or when exploitation thereof has been suspended for a period of more than one year, whenever the situation is not attributable to circumstances of force majeure.

The objective difficulties or of a legal technical character that are beyond the will of the holder of the patent, and which prevent the exploitation of the invention shall be considered causes of force majeure, besides those so recognized by the law.

The lack of technical or economic resources, or the economic unfeasibility of the exploitation shall be beyond the will of the patent holder, shall also be recognized as justification.

Article 44. Compulsory licenses or other uses without authorization of the patent holder for public interest reasons. The Executive Branch may grant compulsory licenses or other uses not authorized by the patent holder for reasons of sanitary emergency, national defense or security, socio-economic and technological development of certain strategic sectors, as well as when exceptional situations may affect the national interest, scope and duration of which shall be defined in the relevant decree.

Article 45. Compulsory licenses due to anticompetitive practices. By express resolution, the Industrial Property Department may grant compulsory licenses of an invention patent when the competent authority, through a procedure that grants rights of defense and other guarantees to the holder, shall determine that the latter has incurred in anticompetitive

practices, abuse of rights conferred by the patent or abuse of a dominant position in the market.

To the effects of the present law, anticompetitive practices shall be deemed to be, among others, the following:

- a) price fixing of the patented product at comparatively excessive levels in comparison with the average international prices;
- b) the existence of offers to supply the market at prices significantly lower than those offered by the patent holder;
- c) the refusal to supply the local market adequately and regularly with the raw materials or patented product under commercially reasonable conditions;
- d) when the efficient exploitation in the country of the patented invention contributing to technological development is prevented or impeded by the patent holder; and,
- e) the sundry other cases considered in special laws.

Article 46. Licenses for dependent patents. A compulsory license shall be granted to allow exploitation of a new patent –second patent- when the same cannot be exploited without infringing another patent –first patent- in the event that the following conditions are fulfilled:

- a) that the invention claimed in the second patent shall contemplate an important technical advance in regard to the invention claimed in the first patent;
- b) that the holder of the first patent shall have the right to obtain a crossed license under reasonable conditions to exploit the invention claimed in the second patent; and,
- c) that the use authorized under the first patent cannot be assigned without assignment of the second patent;

PHILIPPINES : *Sections 74, 93-97 and 100 of the Intellectual Property Code, Act No. 8293 of 06/06/1997(as last amended by Act No. 9502 of 2008)*

Use of Invention by overnment.-

74.1 A Government Agency of third person authorized by the Government may exploit the invention even without the agreement of the patetn owner where:

- (a) The public interest, in particular national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or
- (b) A judicial or administative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive; or
- (c) In the case of drugs and medicines, there is a national emergency or other circumstance of extrem urgency requiring the use of the invention; or
- (d) In the case of drugs and medicines, there is non-commercial use of the patent by the patentee, without satisfactory reason; or
- (e) In the case of drugs and medicines, the demand for the patented article in the Philippines is not being met to an adequate extent and on reasonable tems, as determined by the Secretary of the Department of Health.

(...)

Grounds for Compulsory Licensing

93. The Director General of the Intellectual property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person

who has shown his capability to exploit the invention, under any of the following circumstances:

1. National emergency or other circumstances of extreme urgency;
2. Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government, so requires; or
3. Where a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or his licensee is anti-competitive; or
4. In case of public non-commercial use of the patent by the patentee, without satisfactory reason;
5. If the patented invention is not being worked in the Philippines on a commercial scale, although capable of being worked, without satisfactory reason: Provided, That the importation of the patented article shall constitute working or using the patent; (Secs. 34, 34-A, 34-B, R.A. No. 165a) and
6. Where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms, as determined by the secretary of the Department of Health.

Procedures on Issuance of a Special Compulsory License under the TRIPS Agreement.

93 A.1 The Director General of the Intellectual property Office, upon the written recommendation of the Secretary of the Department of Health, shall, upon filing of a petition, grant a special compulsory license for the importation of patented drugs and medicines. The special compulsory license for the importation contemplated under this provision shall be an additional special alternative procedure to ensure access to quality affordable medicines and shall be primarily for domestic consumption: Provided, that adequate remuneration shall be paid to the patent owner either by the exporting or importing country. The compulsory license shall also contain a provision directing the grantee the license to exercise reasonable measures to prevent the re-exportation of the product imported under this provision.

The grant of a special compulsory license under this provision shall be an exception to Section 100.4 and 100.6 of Republic Act No. 8293 and shall be immediately executory.

No court, except the Supreme Court of the Philippines, shall issue any temporary restraining order or preliminary injunction or such other provisional remedies that will prevent the grant of the special compulsory license.

93 A.2. A compulsory license shall also be available for the manufacture and export of drugs and medicines to any country having insufficient or no manufacturing capacity in the pharmaceutical sector to address public health problems: Provided, that, a compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation into its jurisdiction of the patented drugs and medicines from the Philippines in compliance with the TRIPS Agreement.

93 A. 3 The right to grant a special compulsory license under this section shall not limit or prejudice the rights, obligations and flexibilities provided under the TRIPS Agreement and under Philippines laws, particularly Section 72.1 and section 74 of the Intellectual property Code, as amended under this Act. It is also without prejudice to the extent to which drugs and medicines produced under a compulsory license can be exported as allowed in the TRIPS Agreement and applicable laws.

Period for Filing a Petition for a Compulsory License

94.—1. A compulsory license may not be applied for on the grounds stated in Subsection 93.5 before the expiration of a period of four (4) years from the date of filing of the application or three (3) years from the date of the patent whichever period expires last.

2. A compulsory license which is applied for on any of the grounds stated in Subsections 93.2, 93.3, 93.4 and 93.6 and Section 97 may be applied for at any time after the grant of the patent. (Sec. 34(1), R.A. No. 165)

Requirement to Obtain a License on Reasonable Commercial Terms

95.—1. The license will only be granted after the petitioner has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.

2. The requirement under Subsection 95.1 shall not apply in the following cases:
(a) Where the petition for compulsory license seeks to remedy a practice determined after judicial or administrative process to be anti-competitive;
(b) In situations of national emergency or other circumstances of extreme urgency;
(c) In cases of public non commercial use.
(d) In cases where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the Secretary of the department of Health

3. In situations of national emergency or other circumstances of extreme urgency, the right holder shall be notified as soon as reasonably practicable.

4. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. (n)

5. Where the demand for the patented drugs and medicines in the Philippines is not being met to an adequate extent and on reasonable terms, as determined by the secretary of the department of Health, the right holder shall be informed promptly.

Compulsory Licensing of Patents Involving Semi-Conductor Technology

96. In the case of compulsory licensing of patents involving semi-conductor technology, the license may only be granted in case of public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive. (n)

Compulsory License Based on Interdependence of Patents

97. If the invention protected by a patent, hereafter referred to as the “second patent,” within the country cannot be worked without infringing another patent, hereafter referred to as the “first patent,” granted on a prior application or benefiting from an earlier priority, a compulsory license may be granted to the owner of the second patent to the extent necessary for the working of his invention, subject to the following conditions:

1. The invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the first patent;

2. The owner of the first patent shall be entitled to a cross-license on reasonable terms to use the invention claimed in the second patent;
3. The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent; and
4. The terms and conditions of Sections 95, 96, and 98 to 100 of this Act. (Sec. 34-C, R.A. No. 165a)

Terms and Conditions of Compulsory License

100. The basic terms and conditions including the rate of royalties of a compulsory license shall be fixed by the Director of Legal Affairs subject to the following conditions:

1. The scope and duration of such license shall be limited to the purpose for which it was authorized;
2. The license shall be non-exclusive;
3. The license shall be non-assignable, except with that part of the enterprise or business with which the invention is being exploited;
4. Use of the subject matter of the license shall be devoted predominantly for the supply of the Philippine market: Provided, That this limitation shall not apply where the grant of the license is based on the ground that the patentee's manner of exploiting the patent is determined by judicial or administrative process, to be anti-competitive;
5. The license may be terminated upon proper showing that circumstances which led to its grant have ceased to exist and are unlikely to recur: Provided, That adequate protection shall be afforded to the legitimate interest of the licensee; and
6. The patentee shall be paid adequate remuneration taking into account the economic value of the grant or authorization, except that in cases where the license was granted to remedy a practice which was determined after judicial or administrative process, to be anti-competitive, the need to correct the anti-competitive practice may be taken into account in fixing the amount of remuneration. (Sec. 35-B, R.A. No. 165a)

POLAND (EU) : *Articles 82-83 and 88 of the Industrial Property Law of 30/06/2000, as amended by Act of 23/01/2004 and Act of 29/06/2007*

Article 82

1. The Patent Office may grant authorisation to exploit a patented invention of another person (a compulsory license), where:
 - (i) it is necessary to prevent or eliminate a state of national emergency, in particular in the field of defence, public order, the protection of human life and health, as well as the protection of natural environment, or
 - (ii) it has been established that the patent has been abused within the meaning of Article 68, or

(iii) it has been established that the patent holder enjoying the right of priority of an earlier application (the earlier patent) prevents, by refusing to conclude a license contract, the meeting of home market demands through the exploitation of the patented invention (the dependent patent), whose exploitation would encroach upon the earlier patent; in such case, the holder of the earlier patent may demand that an authorisation be given to him for the exploitation of the invention that is the subject matter of the dependent patent (cross-license).

2. The grant of a compulsory license for the exploitation of an invention in the case referred to in paragraph (1)(iii) shall be conditional upon ascertainment that the exploitation of the invention that is the subject matter of the dependent patent, where the both inventions concern the same subject matter, involves an important technical advance of considerable economic significance. In case of an invention concerning semi-conductor technology, a compulsory license may only be granted to counteract unreasonable anti-competitive practices.

3. Where the Patent Office finds that the patent is abused within the meaning of Article 68, it may decide that a compulsory license may be applied for and shall announce this in “*Wiadomości Urzędu Patentowego*”.

4. A compulsory license may be granted, if the applying party is able to prove that it has earlier made, in good faith, efforts to obtain a license. This requirement may be waived in the case of a compulsory license to be granted for the purpose of preventing or eliminating a state of national emergency or where it is announced that a compulsory license may be applied for.

5. Where it is announced that a compulsory license may be applied for, waiver of the requirement referred to in paragraph (4) shall not be applicable in respect of applications for the grant of a license submitted after the expiration of a period of one year counted from the date of that announcement.

6. The provision of paragraph (1)(iii) shall apply accordingly, where a plant breeder is not able to exercise his right to the protected plant variety or demands a cross-license to be granted to him by the patent holder.

Article 83

The compulsory license shall be non-exclusive.

Article 88

The provisions on the grant of a compulsory license in the case referred to in Article 82(1)(iii) shall apply accordingly to a utility model, whose exploitation would encroach upon the earlier patent.

PORTUGAL (EU) : *Articles 106-110 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 106

Obligation to exploit

- 1) The patentee is obliged to exploit a patented invention directly or through a person authorised by him and to market the results obtained in order to fulfil the needs of the national market.
- 2) Exploitation shall begin within four years of the date of the patent application or three years of the grant date, whichever is greater.
- 3) It is possible to enjoy patent rights with no discrimination as to place of invention, the technological field or the fact that the products are imported from any country belonging to the European Union or WTO or produced locally.

Article 107

Compulsory licences

- 1) Compulsory licences may be granted for a certain patent, in any of the following cases:
 - a) Lack or insufficient exploitation of a patented invention;
 - b) Dependency between patents;
 - c) Reasons of public interest.
- 2) Compulsory licences shall be non-exclusive and may only be transferred with the part of the company or establishment that exploits them.
- 3) Compulsory licences may only be granted if the potential licensee has made efforts to obtain a contractual licence from the patentee on acceptable commercial conditions and said efforts have not been successful within a reasonable period of time.
- 4) A compulsory licence may be revoked without prejudice to the appropriate protection of the licensees' legitimate interests if and when the circumstances that gave rise to it cease to exist or are not likely to occur again. The competent authority may re-examine the continuation of said circumstances on duly justified request.
- 5) If a patent concerns semiconductor technology, compulsory licences may only be granted for a noncommercial, public purpose.
- 6) The patentee shall receive appropriate payment in each concrete case on the basis of the economic value of the licence.
- 7) A decision granting or denying payment is subject to judicial or arbitral appeal under Articles 48 to 50.

Article 108

Licence due to failure to exploit invention

1 – After the time limits referred to in Article 106(2) have expired, a patentee who, without a good reason or legal basis, does not exploit an invention, directly or under licence, or does not

do so in such a way as to meet national needs, may be obliged to grant a licence for its exploitation.

2 – A patentee may also be obliged to grant an exploitation licence for an invention if he ceases to exploit it for three consecutive years without a good reason or legal basis.

3 – Objective technical or legal reasons beyond the patentee's control and irrespective of his situation making the exploitation of the invention impossible or insufficient are considered good reason, but not economic or financial difficulties.

4 – For as long as a compulsory licence remains in force, the patentee may not be obliged to grant another before the previous one is cancelled.

5 – A compulsory licence may be cancelled if the licensee does not exploit the invention in such a way as to meet national needs.

Article 109

Dependent licences

1) If it is not possible to exploit a patented invention, without prejudice to the rights conferred by a previous patent, and the two inventions are used for different industrial purposes, a licence may only be granted if the first invention is essential to the exploitation of the second, and only in the part necessary for said exploitation, and the holder of the first patent is entitled to fair compensation.

2) If inventions protected by dependent patents serve the same industrial purpose and a compulsory licence is to be granted, the previous patentee may also demand a compulsory licence for the previous patent.

3) If an invention concerns a process for preparing a chemical, pharmaceutical or food product protected by a current patent, and whenever this process patent represents notable technical progress in relation to the previous patent, both the holder of the process patent and the holder of the product patent are entitled to demand a compulsory licence for the other holder's patent.

4) If the obtainer of a plant variety cannot obtain or exploit a plant securing right without infringing a prior patent, he may request a compulsory licence for nonexclusive exploitation of the invention protected by the patent, provided that this licence is necessary for the exploitation of the same plant variety, on payment of appropriate remuneration.

5) Whenever a licence of the type provided for in the previous paragraph is granted, the patentee is entitled to a reciprocal licence on reasonable terms to use the protected variety.

6) If the holder of a patent for a biotechnological invention is unable to exploit it without infringing a previous plant variety securing right, he may request a compulsory licence for non-exclusive exploitation of the variety protected by the securing right on payment of an appropriate sum.

7) Whenever a licence of the type provided for in the previous paragraph is granted, the holder of the securing right is entitled to a reciprocal licence on reasonable terms to use the protected invention.

8) Applicants for the licences referred to in paragraphs 4 and 6 must prove that:

a) They approached the patentee or plant securing right holder in vain to obtain a contractual licence;

b) The plant variety or invention represents important technical progress of considerable economic interest in relation to the invention claimed in the patent or to the plant variety being protected.

9 – This article also applies whenever one of the inventions is protected by a patent and the other by a utility model.

Article 110

Public Interest

- 1) A patentee may, in the public interest, be obliged to grant a licence for the exploitation of his invention.
- 2) There are considered to be reasons of public interest if the start, increase or generalisation of the exploitation of the invention, or an improvement in the conditions of its exploitation, is of vital importance to public health or national defence.
- 3) There are also considered to be reasons of public interest if failure to exploit or insufficient quality or quantity of exploitation is highly detrimental to the country's economic or technological development.
- 4) The government shall be responsible for granting a licence in the public interest.

REPUBLIC OF KOREA : *Article 107 of the Patent Act promulgated on 28/11/1949 by Military Act No. 950, as last amended by Act No. 9381 of 30/01/2009*

Article 107 - Adjudication for the Grant of a Nonexclusive License

- (1) Where a patented invention falls under any of the following subparagraphs, a person who intends to work the patented invention may request the Commissioner of the Korean Intellectual Property Office to make an adjudication (referred to as “an adjudication”) for the establishment of a nonexclusive license, provided no agreement is reached despite having a consultation (referred to as “a consultation” in this Article) under reasonable conditions with the patentee or exclusive licensee on the grant of a nonexclusive license for the patented invention or a consultation is impossible to arrange; however, the person may request an adjudication even in the absence of a consultation if the patented invention is to be worked non commercially for the public interest or in any case that falls under subparagraph (iv):
 - (i) where the patented invention has not been worked for more than three consecutive years in the Republic of Korea, except for natural disasters, unavoidable circumstances or other justifiable reasons prescribed by Presidential Decree;
 - (ii) where the patented invention has not continuously been worked commercially or industrially in the Republic of Korea on a substantial scale during a period of three years or more without justification, or where the domestic demand for the patented invention has not been satisfied to an appropriate extent and under reasonable conditions;
 - (iii) where working the patented invention noncommercially is necessary for the interests of the public; or
 - (iv) where working the patented invention is necessary to remedy a practice determined to be unfair after the judicial or administrative process;

- (v) where working the patented invention is necessary for the export of medicine to a country (referred to as “an importing country”) that intends to import the medicine (including effective ingredients that are necessary for the production of the medicine and diagnostic kits necessary for the use of the medicine) in order to treat diseases that threaten the health of the majority of its citizens.
- (2) Paragraph (1)(i) and (ii) of this Article shall not apply unless a period of four years has elapsed after the filing date of the application for the patented invention.
- (3) In adjudicating the authorization of a nonexclusive license, the Commissioner of the Korean Intellectual Property Office shall consider the necessity of each request.
- (4) When the Commissioner of the Korean Intellectual Property Office makes an adjudication under subparagraphs (i) to (iii) or (v) of paragraph (1), the following conditions apply to the person for whom the adjudication was made:
- (i) where the adjudication is made under subparagraphs (i) to (iii) of paragraph (1), the nonexclusive license must be implemented for the primary purpose of meeting domestic demand; and
 - (ii) where the adjudication is made under subparagraph (v) of paragraph (1), all the medicine produced under the terms of the adjudication must be exported to importing countries.
- (5) The Commissioner of the Korean Intellectual Property Office shall ensure that reasonable consideration is given to every adjudication. When making an adjudication under subparagraph (iv) or (v) of paragraph (1), the Commissioner of the Korean Intellectual Property Office may consider the factors in each of the following subparagraphs:
- (i) where an adjudication is made under subparagraph (iv) of paragraph (1), the need to rectify unfair transactions; and
 - (ii) where an adjudication is made under subparagraph (v) of paragraph (1), the economic value generated in importing countries by the working of the patented invention.
- (6) For semiconductor technology, a request for adjudication may be made only in the cases set forth in subparagraph (1)(iii) (where the noncommercial working of the patented invention is permitted in a limited way for the interests of the public) and (1)(iv).
- (7) An importing country is limited to a country which is either a World Trade Organization (WTO) member country that has notified the WTO of the following particulars or a non-WTO member country listed in a Presidential decree, and which has notified the Republic of Korea of the following particulars:
- (i) the name of the medicine and the quantity required by an importing country;
 - (ii) where the importing country is not one of the least developed countries listed in a resolution of the General Assembly of the United Nations, confirmation by the importing country that it has insufficient or no manufacturing capability to produce the medicine concerned; and
 - (iii) where the medicine concerned is patented in the importing country, confirmation by the importing country that it has granted or intends to grant a compulsory license.

- (8) The term medicine in paragraph (1)(v) of this Article refers to any of the definitions in the following subparagraphs:
- (i) patented medicine;
 - (ii) medicine manufactured by means of a patented process;
 - (iii) patented effective ingredients necessary for the production of the medicine; or
 - (iv) patented diagnostic kits necessary for the production of the medicine.
- (9) The documents for submission and other necessary matters concerning a request for adjudication are prescribed by Presidential Decree.

REPUBLIC OF MOLDOVA : *Articles 28-29 of the Law on the protection of Inventions No. 50-XVI of 07/03/2008*

Article 28 - Compulsory License

- (1) If after the expiration of a period of 4 years from the day of filing of the patent application or 3 years from the grant of the patent, whichever is later, the patent owner has not exploited the patent in the territory of the Republic of Moldova or if he has not undertaken serious and effective preparations for such purpose, the courts may grant a compulsory license, on request, to any interested person, unless the patent owner justifies the lack or insufficiency of exploitation. No distinction shall be made between the domestic products or imported products for the purposes of establishing the fact of the lack of exploitation or insufficient exploitation of the patent.
- (2) A compulsory license shall be granted solely where the proposed user has made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived in the cases referred to in paragraph (3) below. In such cases, the patent owner shall be notified as soon as reasonable practicable.
- (3) A compulsory license may be granted in the case of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.
- (4) In the case of semiconductor technology, a compulsory license may only be granted for public non-commercial use or to remedy a practice, determined after judicial or administrative process to be anti-competitive.
- (5) A compulsory license may be granted to a patent owner or an owner of a plant variety patent who cannot exploit his invention or protected plant variety (the second patent) without infringing another patent (the first patent), provided the invention or plant variety claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. The court shall have the authority to review the existence of these circumstances. In the case of a compulsory license in respect of a patent for an invention or a patent for a plant variety, the owner of the first patent shall be entitled to a cross-license on reasonable terms to use the patented invention or the protected plant variety.
- (6) The respective methods and procedures for the implementation of principles contained in this article are laid down in the Regulations.

Article 29 - Conditions Applicable to Compulsory Licenses

(1) At the time of grant of a compulsory license to exploit the patent under Article 28 above, the court shall specify the types of use covered by such license and the terms and conditions to be observed. The following conditions shall apply:

- a) the scope and duration of such use shall be limited to the purpose for which it was authorized;
- b) such use shall be non-exclusive;
- c) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- d) any such use shall be authorized predominantly for the supply of the domestic market, except where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive;
- e) a court may authorize, upon motivated request, that authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The judicial authority shall have the authority to refuse termination of authorization if and where the circumstances which led to such authorization are likely to recur;
- f) the license holder shall pay the patent owner an adequate remuneration, taking into account the economic value of the authorization and, eventually, the need to remedy an anti-competitive practice;
- g) in case of a compulsory license for a dependent patent or a plant variety patent, the use authorized in respect of the first patent shall be non-assignable, except with the assignment of the second patent.

(2) The legal validity of any decision relating to the authorization of use referred to in paragraph (1) and any other decision relating to the remuneration provided for in respect of such use shall be subject to judicial review or other independent review by a higher authority.

(3) The holder of the license shall notify the AGEPI the decision of the judicial authority to grant or, where appropriate, to terminate a compulsory license. The Agency shall enter the court decision in the National Register of Patents and publish it in BOPI.

(4) If the holder of a compulsory license has not undertaken any effective and serious preparation for exploiting the invention within one year following grant of the license, the compulsory license may be cancelled by the decision of the court. In any event, a compulsory license shall terminate if its holder has not begun exploitation of the invention within 2 years following the date on which the license was granted to him.

ROMANIA (EU) : *Articles 46-47 of the Patent Law no. 64 of 1991 as republished in the Official Gazette of Romania, Part I, No. 456/18.VI.2008*

Art. 46 - Upon request by any interested person, the Court of Bucharest may grant a compulsory license after 4 years have elapsed from the patent application filing date or after 3 years have elapsed from the grant of the patent, whichever period expires later. The provisions of paragraph 1 shall only apply where the invention has not been exploited or has been insufficiently exploited on the territory of Romania, and the patent owner cannot justify his inaction and where no agreement has been reached with him regarding the conditions and commercial methods for applying the invention.

The Court of Bucharest shall authorize the compulsory license, provided that it considers, based on given circumstances, that, in spite of all efforts made by the interested person, no agreement could be reached within a reasonable time period.

Besides the cases referred to in paragraph 2, a compulsory license may be authorized by the Court of Bucharest:

- a) in national emergency cases;
- b) in other cases of extreme emergency;
- c) in cases of public use for non-commercial purposes.

The grant of the compulsory license, for one of the reasons provided under paragraph 4, shall not require the fulfillment of the conditions mentioned under paragraph 2. Nevertheless, the licensee shall inform the applicant or patent owner about the authorization given by the Court, within the shortest delay.

In cases of public use for non-commercial purposes, the Government or third parties authorized by the Government, if they know or have demonstrable reasons to know that a valid patent is or will be used by the Government or the third parties, shall inform the patent owner accordingly, within a reasonable time.

In cases where a patent cannot be exploited without infringing the rights conferred by other patent granted for an application having a prior regular national filing date, a compulsory license for exploiting the second patent may only be authorized if the following additional conditions are cumulatively fulfilled:

- a) the invention claimed in the second patent involves an important technical advance of considerable economic significance as compared with the invention in the first patent;
- b) the owner of the first patent is entitled to a cross-license on reasonable terms for using the invention claimed in the second patent;
- c) the use authorized in respect of the first patent shall be non-transferable, except for the transfer of the second patent.

Art. 47 - Compulsory licenses shall be non-exclusive and shall be granted by the Court of Bucharest, under specific conditions regarding their extent and duration, as well as the amount of royalties to which the right holder is entitled, established in accordance to the commercial value of the granted licenses.

Beneficiaries of the compulsory license can also be the Government or third parties authorized by the Government.

Compulsory licenses shall be authorized mainly for supplying the market.

The extent and duration of compulsory licenses shall be limited to the purposes for which they have been authorized. In case of the inventions in the semiconductor technology field, the license shall be granted only for public non-commercial purposes or to remedy a practice declared as anti-competitive, as a result of a judiciary or administrative procedure.

When the owner of a plant variety patent cannot exploit the patent without infringing a prior patent, he may request a compulsory license for the invention protected by said patent.

When the owner of a patent relating to a biotechnological invention cannot exploit the patent without infringing a prior plant variety patent, he may request a compulsory license for the exploitation of the plant variety protected by said patent.

Where a compulsory license is authorized for remedying an anti-competitive practice, the provisions of Art. 46, paragraphs 3 and 4 and Art. 47, paragraph 3 shall not be applicable.

RUSSIAN FEDERATION : *Articles 1360 and 1362 of the Patent Act (Chapter 72)*

Article 1360. Use of an Invention, Utility Model, or Industrial Design in the Interests of National Security

In the interests of national security the Government of the Russian Federation shall have the right to permit the use of an invention, utility model, or industrial design without the consent of the patent holder provided that he is notified as soon as possible and payment to him a reasonable remuneration.

Article 1362. Compulsory License to an Invention, Utility Model, or Industrial Design

1. If an invention or industrial design fails to be used or is insufficiently used by the patent holder during the four years from date of the issuance of a patent, or a utility model – during three years from the date of granting the patent, which leads to insufficient offer of respective goods, works or services on the market, any person willing and ready to use such invention, utility model, or industrial design, given the refusal of the patent holder to conclude with such a person a license contract on terms corresponding to common practice shall have the right to initiate a legal action against the patent holder for the granting of a compulsory simple (non-exclusive) license for the use within the territory of the Russian Federation of an invention, utility model, or industrial design. In the writ, this person shall indicate the proposed terms of the granting to him of such a license, including the scope of use of the invention, utility model, or industrial design, the amount, procedure, and terms of payments.

If the patent holder does not prove that nonuse or insufficient use by him of the invention, utility model, or industrial design is based on valid excuses, the court shall rule the granting of the license indicated in the first subparagraph of the present Paragraph and the terms of its granting. A total amount of payments for such a license shall be determined in the decision of the court on the level not lower than the cost of a license determined in similar cases.

The effect of a compulsory simple (nonexclusive) license may be terminated by judicial procedure on a suit initiated by the patent holder if the circumstances that resulted in granting of such a license cease to exist and their reappearance is unlikely. In such a case the court shall fix the time and procedure for termination of the compulsory simple (nonexclusive) license and of the rights that arose under this license.

2. If the patent holder cannot use the invention to which he has the exclusive right without infringing thereby the rights of the holder of another patent (the first patent) to an invention or utility model who has refused to conclude a license contract on terms corresponding to common practice, the patent holder shall have the right to initiate court action against the holder of the patent (the second patent) for the granting of a compulsory simple (nonexclusive) license for the use within the territory of the Russian Federation of the invention or utility model of the holder of the first patent. The terms of granting such a license proposed by the holder of the second patent, including the scope of use of the invention or utility model, the amount, procedure, and schedule of payments shall be indicated in the lawsuit. If this patent holder having the exclusive right to such a dependent invention proves that it is an important technical achievement and has a significant economic advantage over the invention or utility model of the holder of the first patent, the court shall rule the granting compulsory simple (nonexclusive) license. A right obtained under this license to use the

invention protected by the first patent may not be transferred to other persons except in case of alienation of the second patent.

A total amount of payments for such a compulsory simple (nonexclusive) license shall must be determined in the decision court on the level not lower than the cost of a license determined in similar cases.

In the case of granting under the present Paragraph of a compulsory simple (nonexclusive) license, the holder of the patent for the invention or utility model, the right to use of which is granted on the basis of the aforesaid license shall also have the right to obtain a simple (nonexclusive) license for use of the dependent invention in connection with which the compulsory simple (nonexclusive) license was granted on terms corresponding to the common practice.

3. On the basis of the court ruling provided for by Paragraphs 1 and 2 of the present Article, the federal executive authority for intellectual property shall effect official registration of the compulsory simple (nonexclusive) license.

SAINT LUCIA : *Sections 51-52, 57-59 and 61 of the Patents Act No. 16 of 27/08/2001*

Compulsory licences

51.— (1) At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the Registrar —

- (a) for a licence under the patent;
 - (b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
 - (c) where the applicant is a Government department, for the grant to any person specified in the application of a licence under the patent;
- if it appears at the time such application is filed, one or more of the grounds specified in subsection (2) are met.

(2) The grounds referred to in subsection (1) are —

(a) that there is no production of the patented product or application of the patented process in Saint Lucia without any legitimate reason;

(b) that there is no product produced in Saint Lucia under the patent for sale in Saint Lucia or there are some but they are sold at unreasonably high prices or do not meet the public demand without any legitimate reason;

(c) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms —

(i) a market for the export of any patented product made in Saint Lucia is not being supplied;

(ii) the working or efficient working in Saint Lucia of any other patented invention which makes a substantial contribution to the art is prevented or hindered; or

(iii) the establishment or development of commercial or industrial activities in Saint Lucia is unfairly prejudiced; and

(d) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the

patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in Saint Lucia, is unfairly prejudiced.

(3) Subject to subsections (4) to (6), if the Registrar is satisfied that any of those grounds under subsection (2) are established, the Registrar may —
(a) where the application is made pursuant to subsection (1) (a), order the grant of a licence to the applicant on such terms, including the transfer of know-how associated with the patented invention, as the Registrar thinks fit;

(4) Where —
(a) an application is made on the ground that there is no production of the patented product or application of the patented process in Saint Lucia; or
(b) there is insufficient or no product produced under the patent for sale in Saint Lucia; and it appears to the Registrar that the time which has elapsed since the publication in the Gazette of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, the Registrar may by order adjourn the application for such period as will in the Registrar's opinion give sufficient time for the invention to be so worked.

(5) No entry shall be made in the register under this section on the ground mentioned in subsection (2) (c) (i), and any licence granted under this section on that ground shall contain such provisions as appear to the Registrar to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(6) No order or entry shall be made under this section in respect of a patent on the ground mentioned in subsection (2) (c) (ii) unless the Registrar is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent and his or her licensees a licence under the patent for the other invention on reasonable terms.

(7) An application may be made under this section in respect of a patent notwithstanding that the applicant is already the holder of a licence under the patent, and no person shall be stopped or barred from alleging any of the matters specified in subsection (2) by reason of any admission made by him or her, whether in such a licence or otherwise, or by reason of his or her having accepted such a licence.

Inventions relating to food or medicine or surgical or curative device

52.— (1) At any time after the date of the grant of a patent in respect of —

(a) a substance capable of being used as food or medicine or in the production of food or medicine;

(b) a process for producing any substance mentioned in paragraph (a); or

(c) any invention capable of being used as or as part of a surgical or curative device;

the Registrar may, on application made to him or her by any person, order the grant to the applicant of a licence under the patent on such terms as the Registrar thinks fit, unless it appears to the Registrar that there are good reasons for refusing the application.

(2) A licence granted under this section shall entitle the licensee to make, use or dispose of the invention as a food or medicine, or for the purpose of the production of food or medicine or as part of a surgical or curative device.

(3) An application under this section may be made notwithstanding that the applicant is already the holder of a licence under the patent.

(4) A licence granted under this section and section 51 may permit the licensee to import the patented product.

Use of patented inventions for services of Government

57. — (1) Notwithstanding anything in this Act, any Government department and any person authorised in writing by a Government department may, for the services of the Government and in accordance with this section, do any of the following acts in Saint Lucia in relation to a patented invention without the consent of the proprietor of the patent —

(a) where the invention is a product, may —

(i) make, use, import, obtain or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing, obtaining or keeping it; or

(ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of any drug and medicine, or dispose or offer to dispose of it for any purpose whatever;

(b) where the invention is a process, may use it or, in relation to any product obtained directly by means of the process, do anything mentioned in paragraph (a);

(c) without prejudice to paragraphs (a) and (b), where the invention or any product obtained directly by means of the invention is a drug or medicine, may sell or offer to sell the drug or medicine;

(d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;

(e) may dispose or offer to dispose of anything which was made, used, imported, obtained or kept in the exercise of the powers conferred by this section and which is no longer required for the purpose for which it was made, used, imported, obtained or kept, as the case may be;

and anything done by virtue of this subsection shall not amount to an infringement of the patent.

(2) Any act done in relation to an invention by virtue of this section is in this section referred to as use of the invention; and “use”, in relation to an invention, in sections 58 to 60 shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a Government department otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either —

(a) after the publication of the application for the patent for the invention; or

(b) without prejudice to paragraph (a), in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence; shall be made on such terms as may be agreed either before or after the use by the Government department and the proprietor of the patent or as may in default of agreement be referred to an arbitrator agreed on by the parties or, in default of agreement, appointed by the Registrar.

- (5) The arbitrator to whom any reference is made under subsection (4) shall report his or her findings to the Registrar.
- (6) The expenses of and incidental to an arbitrator under subsection (4) shall, in default of agreement between the parties, be borne equally by the parties to the reference.
- (7) Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) include terms as to payment for the use, then, notwithstanding anything in those terms, any such payment shall be recoverable only —
- (a) after such a patent is granted; and
 - (b) if, apart from this section, the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims, as interpreted by the description or claims, in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Registry.
- (8) The authority of a Government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he or she is authorised, directly or indirectly, by the proprietor of the patent to do anything in relation to the invention.
- (9) Where any use of an invention is made by or with the authority of a Government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him or her with such information as to the extent of the use as he or she may from time to time require.
- (10) A person acquiring anything disposed of in the exercise of the powers conferred by this section, and any person claiming through him or her, may deal with it in the same manner as if the patent were held on behalf of the Government.
- (11) In determining under this section any dispute between a Government department and any person as to the terms for the use of an invention for the services of the Government, the arbitrator shall have regard —
- (a) to any benefit or compensation which that person or any person from whom he or she derives title may have received or may be entitled to receive, directly or indirectly, from any Government department in respect of the invention; and
 - (b) to whether that person or any person from whom he or she derives title has in the arbitrator's opinion without reasonable cause failed to comply with a request of the department to use the invention for the services of the Government on reasonable terms.
- (12) On a reference under this section, the arbitrator may refuse to grant relief by way of compensation in respect of the use of an invention for the services of the Government during any further period specified under section 32(3), but before the payment of the renewal fee and any additional fee prescribed for the purposes of that section.

(13) Where an amendment of the specification of a patent has been allowed under any of the provisions of this Act, the arbitrator shall not grant relief by way of compensation under this section in respect of any such use before the decision to allow the amendment unless the Registrar is satisfied that the specification of the patent as published was framed in good faith and with reasonable skill and knowledge.

(14) In considering the amount of any compensation for the use of an invention for the services of the Government after publication of an application for a patent for the invention and before such a patent is granted, the arbitrator shall consider whether or not it would have been reasonable to expect, from a consideration of the application as published under section 23, that a patent would be granted conferring on the proprietor of the patent protection for an act of the same description as that found to constitute that use, and if the arbitrator finds that it would not have been reasonable, he or she shall reduce the compensation to such amount as he or she thinks just.

(15) Where, by virtue of a transaction, instrument or event to which section 39 applies, a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent, the new proprietor or licensee, and a Government department or a person authorised by a Government department subsequently makes use of the patented invention under this section, the new proprietor or licensee shall not be entitled to any compensation under subsection (4), as it stands or as modified by section 59 (3), in respect of a subsequent use of the invention before the transaction, instrument or event is registered unless —

(a) the transaction, instrument or event is registered within the period of six months beginning with its date; or

(b) the Registrar is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it was registered as soon as practicable thereafter.

(16) In this section, “relevant communication”, in relation to an invention, means a communication of the invention, directly or indirectly, by the proprietor of the patent or any person from whom he or she derives title.

(17) Subsection (4) is without prejudice to any rule of law relating to the confidentiality of information.

Interpretation, etc., of provisions about Government use

58.— (1) Any reference in section 57 to a patented invention, in relation to any time, is a reference to an invention for which a patent has before that time been, or is subsequently, granted.

(2) In this Part, unless the context otherwise requires, “the services of the Government” includes —

(a) the supply of anything for foreign defence purposes;

(b) the production or supply of drugs and medicines required for the provision of pharmaceutical, medical or dental services in any prescribed dispensary, hospital or other medical institution maintained by or on behalf of the Government and in any dispensary, hospital or medical institution which the Minister may specify by notification in the Gazette; and

(c) such purposes relating to the production or use of atomic energy or research into matters connected therewith as the Minister thinks necessary or expedient;

and “use for the services of the Government” shall be construed accordingly.

(3) In subsection (2) (a) and section 57 (1) (a), references to a sale or supply of anything for foreign defence purposes are references to a sale or supply of the thing —

(a) to the government of any country outside Saint Lucia pursuant to an agreement or arrangement between the Government and the government of that country, where the thing is required for the defence of that country, where the thing is required for the defence of that country or of any other country whose government is party to any agreement or arrangement with the Government in respect of defence matters; or

(b) to the United Nations, or to the government of any country belonging to that organisation, pursuant to an agreement or arrangement between the Government and that organisation or government of the country belonging to that organisation, where the thing is required for any armed forces operating pursuant to a resolution of that organisation or any organ of that organisation.

Rights of third parties in respect of Government use

59.— (1) In relation to —

(a) any use made for the services of the Government of an invention by a Government department, or a person authorised by a Government department, by virtue of section 57; or

(c) anything done for the services of the Government to the order of a Government department by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending; the provisions of any licence, assignment or agreement to which this subsection applies shall be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use, and the reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(2) Subsection (1) shall apply to any licence, assignment or agreement which is made, whether before or after the commencement date, between, on the one hand, any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and, on the other hand, any person other than a Government department.

(3) Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application, then —

(a) in relation to anything done in respect of the invention which, but for this section and section 57, would constitute an infringement of the rights of the licensee, section 57 (4) shall have effect as if for the reference to the proprietor of the patent there were substituted a reference to the licensee; and

(b) in relation to anything done in respect of the invention by the licensee by virtue of an authority given under section 57, that section shall have effect as if section 57(4) were omitted.

(4) Subject to subsection (3), where a patent, or the right to the grant of a patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then —

(a) in relation to any use of the invention by virtue of section 57, subsection (4) of that section shall have effect as if the reference to the proprietor of the patent included a reference to the assignor, and any sum payable by virtue of that subsection shall be divided between the proprietor of the patent or application and the assignor in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 57; and

(b) in relation to any act done in respect of the invention for the services of the Government by the proprietor of the patent or application to the order of a Government department, section 57 (4) shall have effect as if the act was use made by virtue of an authority given under that section.

(5) Where section 57 (4) applies to any use of an invention and a person holds an exclusive licence under the patent or application, other than such a licence as is mentioned in subsection (3) authorising him or her to work the invention, then subsections (7) and (8) shall apply.

(6) In subsections (7) and (8), “the section 57 (4) payment” means such payment, if any, as the proprietor of the patent or application and the Government department agree under section 57, or the arbitrator determines under that section, should be made by the department to the proprietor in respect of the use of the invention.

(7) The licensee shall be entitled to recover from the proprietor of the patent or application such part, if any, of the section 57 (4) payment as may be agreed on by them or as may, in default of agreement, be determined by the court under section 57 to be just having regard to any expenditure incurred by the licensee —

(a) in developing the invention; or

(b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

(8) Any agreement by the proprietor of the patent or application and the Government department under section 57 (4) as to the amount of the section 57 (4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the arbitrator under section 57 (4) as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the arbitrator and is given an opportunity to be heard.

(9) Where any model, document or information relating to an invention is used in connection with —

(a) any use of the invention which falls within subsection (1) (a); or

(b) with anything done in respect of the invention which falls within subsection (1) (b); section 57 (4) shall, whether or not it applies to any such use of the invention, apply to the use of the model, document or information as if for the reference in it to the proprietor of the a patent there was substituted a reference to the person entitled to the benefit of any provision of an agreement which is rendered in operative by this section in relation to that use, and in section 57 the references to terms for the use of an invention shall be construed accordingly.

(10) Nothing in this section shall be construed as authorising the disclosure to a Government department or any other person of any model, document or information to the use of which this section applies in contravention of any such licence, assignment or agreement as is mentioned in this section.

Special provisions as to Government use during emergency

61.— (1) During any period of emergency within the meaning of this section, the powers exercisable in relation to an invention by a Government department or a person authorised by a Government department under section 57 shall include power to use the invention for any purpose which appears to the department necessary or expedient —

- (a) for the efficient prosecution of any war in which Saint Lucia may be engaged;
- (b) for the maintenance of supplies and services essential to the life of the community;
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community;
- (d) for promoting the productivity of industry, commerce and agriculture;
- (e) for fostering and directing exports and reducing imports, or imports of any class, from all or any countries and for redressing the balance of trade;
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or
- (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside Saint Lucia which is in grave distress as a result of a war;

and any reference in this Act to the services of the Government shall, in respect of any period of emergency, include a reference to those purposes.

(2) In this section, “the use of an invention” includes, in addition to any act constituting such use by virtue of section 57, any act which would, apart from that section and this section, amount to an infringement of the patent or, as the case may be, give rise to a right under section 72 to bring proceedings in respect of the application, and any reference in this Act to “use for the services of the Government” shall, as respects any period of emergency, be construed accordingly.

(3) In this section, “period of emergency” means any period beginning with such date as may be declared by the Minister by order published in the Gazette to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

SAUDI ARABIA : *Articles 24- 26 of the Law of Patents, Layout-Designs of Integrated Circuits, Plant Varieties, and Industrial Designs of 2004*

Article Twenty Four:

(a) The City may grant a compulsory license to a third party to exploit an invention covered by the patent or a layout design of an integrated circuit covered by a certificate of design upon an application submitted to it, according to the following:

(1) The application shall be submitted after the elapse of four years from the date of filing the patent application or three years from the date of granting the patent, whichever expires later, without the owner of the protection document exploiting his invention or having exploited it in an inadequate fashion, unless he justifies that with a legitimate excuse.

(2) The applicant for the compulsory license must prove that he has exerted -over a reasonable period of time- efforts in order to obtain a contractual license on the basis of reasonable commercial conditions, and for a reasonable financial compensation. However, this provision and the provision of the preceding paragraph do not apply where the applicant

is a government body or a person authorized by it, and the aim was to meet public interest - especially security, health, nutrition or the development other vital sectors of the national economy- or to meet a state of emergency or other very compelling circumstances, or where the aim thereof was public non-commercial purposes. In the latter case, and upon knowledge of the existence of a patent or a certificate of design, their holder shall be promptly informed.

(3) The compulsory license is basically granted to make the invention or design available in the local markets. But this provision does not apply where the aim of the license is to prevent or restrict practices against which a decision or judgment is issued declaring them to be acts of unlawful competition.

(4) The decision granting the license shall specify the scope and term of the license, according to the purpose for which it was granted. The license shall be subject to termination if the conditions for which it was granted cease to exist and their recurrence is not likely, with due regards to the lawful interests of the licensee.

(5) The license shall not be exclusive.

(6) Each application shall be independently decided.

(7) The owner of the protection document or the holder of a certificate of a design shall be awarded a fair compensation. The Committee shall determine the amount of the compensation, and the licensee undertakes to pay it.

(b) If the compulsory license is related to a patent of semiconductor technology, the purpose of the license shall be for public non-commercial purposes only or to control acts concerning which a decision or judgment is issued declaring them to be acts of unlawful competition.

(c) If the patent involves a significant technological advance with a considerable economic value, which requires the exploitation of another patent, the City may grant that owner of the protection document a compulsory license to exploit the other patent. In such a case the compulsory license shall not be assigned unless the other patent is assigned. The owner of the other patent shall be entitled to a counter license from the compulsory licensee, in accordance with reasonable conditions.

Article Twenty Five:

(a) The City may grant a compulsory license to a third party to exploit a plant variety patented by a plant patent, upon an application submitted to it in accordance with the following:

(1) The compulsory license is necessary to protect public interest.

(2) The applicant for the compulsory license being able financially and technically.

(3) Failure of the applicant to obtain a license from the owner of the plant patent at reasonable terms.

(4) The elapse of three years between the date of granting the plant patent and the date of applying for the compulsory license.

(5) The compulsory license shall not be restricted to performing all or some of the acts referred to in Article 56 of this Law to meet the needs of the local market.

(6) The owner of the patent shall be awarded a fair compensation. The Committee shall determine the amount of compensation, and the licensee shall undertake to pay it.

(b) The City may instruct the owner of the plant patent to provide the holder of a compulsory license with the required quantity of propagation material for the use of the compulsory license in a reasonable fashion.

(c) In other than exceptional circumstances, the compulsory license shall not be granted for a period less than two years or more than four years. The City may extend the term for additional periods, upon verifying that the grounds for granting the compulsory license still exist.

Article Twenty Six:

If a compulsory license is granted for a patented subject matter the beneficiary of the compulsory license may not assign it to others, unless the assignment includes all or part of the firm benefiting from the license or its goodwill. The City's approval of the assignment is required; otherwise, it shall be null and void. If the City approves such assignment, the assignee becomes liable for the obligations assumed by the first beneficiary prior to the approval of the assignment.

SERBIA : *Articles 63, 65, 66 and 68 of the Patents Law No. 15 of 02/07/2004*

Compulsory Licences

Article 63

If an owner of a patent refuses to license the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the authority competent in the field in which the invention shall be employed may, after considering the merits of each individual case, grant a compulsory licence upon application of the interested person:

- 1) if the patent owner himself or a person authorised by him does not use the protected invention or uses it insufficiently in Serbia and Montenegro;
- 2) if the commercial use of an invention that has been subsequently protected in the name of another person is not possible, without the use of the protected invention in whole or in part.

The interested person shall be required to prove that he has made efforts, before filing the application referred to in paragraph 1 of this Article, to obtain authorisation from the right holder to use the protected invention on reasonable commercial terms and conditions and that he has not received such authorization within a reasonable period of time.

The interested person, referred to in paragraph 1, item (1) of this Article, may only be a person who proves that he has the appropriate technological capacity and production facilities for the commercial use of the protected invention.

The interested person referred to in paragraph 1, item (2) of this Article may only be the owner of the second invention, provided that:

- 1) the second invention involves a technical advancement of special economic significance in relation to the invention protected by the first patent; and that
- 2) the owner of the first patent is entitled, on reasonable terms, to a cross-licence to use the second invention.

Authorisation for the use of the invention protected by first patent shall be non-transferable except with the assignment of the second patent.

Article 65

The scope and duration of a compulsory licence shall be limited to the purpose for which it has been granted.

A compulsory licence shall not be exclusive.

A compulsory licence may be assigned only with the enterprise or part of the enterprise in which it is used.

A compulsory licence shall predominantly be granted for the supply of the domestic market.

A compulsory licence may be terminated if and when circumstances that have led to its grant cease to exist and are unlikely to recur. On reasoned request, the competent authority shall re-examine the further existence of such circumstances.

An application for the grant of a compulsory licence cannot be filed before the expiry of a period of four years from the filing date of the patent application or three years from the date of the grant of a patent, whichever of the two time limits expires later.

A compulsory licence shall not be granted if the patent owner provides valid reasons for non-use or for insufficient use of a protected invention.

Compulsory Licence in the Public Interest

Article 66

The compulsory licence under Article 63 of this Law may also be granted prior to the expiry of the time limit specified in Article 65, paragraph 6, if the exploitation of the protected invention is necessary for the fulfilment of national or other exceptional needs (the protection of public health and nutrition, and the protection of public interests in fields of vital significance for socio economic and technological development) or if the protected invention is used in a manner considered by the competent authority to be contrary to the principles of free competition.

In the event of national or any other exceptional need, the provisions of Article 63, paragraph 2 shall not apply. Nevertheless, the right holder shall be notified of the compulsory licence grant proceedings as soon as possible. In the event of public noncommercial exploitation of a protected invention, the provisions of Article 63, paragraph 2 shall not apply. However, where the Council of Ministers or the person contracted for such exploitation knows or has grounds to know, without conducting a patent search, that the a valid patent or petty patent shall be exploited or that there is intent for it to be exploited by the government or by any other entity acting on its behalf, the right holder shall be informed of the compulsory licence grant proceedings promptly.

The decision on the application of an interested person for the grant of a compulsory licence in the public interest shall be taken by the Council of Ministers, after it reviews the merits of each individual case.

A compulsory licence may be terminated if and when circumstances that have led to its grant cease to exist and are unlikely to recur. Upon reasoned request, the competent authority shall re-examine the further existence of such circumstances.

In order to rectify an anti-competitive practice, the competent authority may refuse the termination of a compulsory licence in the public interest, if and when circumstances which have led to its grant are likely to recur.

Compulsory Licence Granted to Plant Breeders

Article 68

Where a plant breeder cannot obtain or exploit a plant variety right without infringing a prior patent concerning a biotechnological invention, he may file an application with the competent authority for a non-exclusive compulsory licence for the use of the invention protected by the patent inasmuch as the licence is necessary for the exploitation of the protected plant variety, subject to payment of an appropriate royalty. If such a licence is granted, the owner of the patent shall be entitled to a compulsory cross-licence to use the protected plant variety on reasonable terms.

Where the owner of a patent concerning a biotechnological invention cannot exploit it without infringing a prior plant variety right, he may file an application with the competent authority for a non-exclusive compulsory licence for the use of the plant variety protected by that right, subject to payment of an appropriate royalty. If such a licence is granted, the holder of the variety right will be entitled to a compulsory cross-licence to use the protected biotechnological invention on reasonable terms.

The compulsory licence referred to in paragraphs 1 and 2 of this Article can not be exclusive. An applicant for the compulsory licence referred to in paragraphs 1 and 2 of this Article must prove that:

- 1) he has unsuccessfully made efforts to obtain a contractual licence;
- 2) the plant variety or the biotechnological invention constitutes significant technical advance of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.

The compulsory licence referred to in paragraphs 1 and 2 of this Article may only be assigned with the enterprise or part of the enterprise in which it is used.

SINGAPORE : *Sections 55-57 and 60 of the Patents Act No. 21 of 25/11/1994 as of 01/12/2008*

Compulsory licences

55.—(1) Any interested person may apply to the court for the grant of a licence under a patent on the ground that the grant of the licence is necessary to remedy an anti-competitive practice.

(2) Without prejudice to the generality of subsection (1), the court may determine that the grant of a licence is necessary to remedy an anti-competitive practice if —

(a) there is a market for the patented invention in Singapore;

(b) that market —

(i) is not being supplied; or

(ii) is not being supplied on reasonable terms; and

(c) the court is of the view that the proprietor of the patent has no valid reason for failing to supply that market with the patented invention, whether directly or through a licensee, on reasonable terms.

(3) Subject to this section, if the court is satisfied that the ground referred to in subsection (1) is established, the court may make an order for the grant of a licence in accordance with the application upon such terms as the court thinks fit.

(4) A licence granted under this section —

(a) is not exclusive; and

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used.

(5) Any licence granted under this section may, on the application of any interested party, be terminated by the court where the court is satisfied that the ground upon which the licence was granted has ceased to exist and is unlikely to recur.

(6) Where a licence is granted under this section to any person, the person shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed between the person and the patentee or, in default of agreement, as is determined by the court on the application of the person or the patentee.

(7) The powers of the court on an application under this section shall be exercised with a view to securing that the inventor or other person beneficially entitled to a patent shall receive reasonable remuneration having regard to the economic value of the licence.

(8) No order shall be made in pursuance of any application under this section which would be at variance with any treaty or international convention relating to patents to which Singapore is a party.

Use of patented inventions by Government and authorised parties

56.—(1) Subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may do anything in relation to a patented invention —

- (a) for a public non-commercial purpose; or
- (b) for or during a national emergency or other circumstances of extreme urgency, and anything done by virtue of this section shall not amount to an infringement of the patent.

(1A) Without prejudice to the generality of subsection (1), subject to sections 60, 61 and 62, but notwithstanding any other section of this Act, the Government and any party authorised in writing by the Government may import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances of extreme urgency, if the Government has given the Council for TRIPS a relevant notification in relation to the relevant health product.

(2) For the purposes of this section and section 57 —

(a) any use of an invention for the supply to the government of any country outside Singapore, in pursuance of any agreement or arrangement between the Government of Singapore and the government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention for a public non-commercial purpose; and

(b) the power of the Government or any party authorised by the Government to do anything in accordance with this section shall not, in the case of a patent relating to an integrated circuit, extend to sale of the invention to the public.

(3) The purchaser of any article sold in the exercise of the powers conferred by this section, and any person claiming through the purchaser, shall have power to deal with it in the same manner as if the patent were held on behalf of the Government.

(4) In this section —

“integrated circuit” means a product, in its final or an intermediate form, in which the elements, at least one of which is an active element, and some or all of the interconnections are integrally formed in and on, or in or on, a piece of material and which is intended to perform an electronic function;

“relevant notification” means a notification that satisfies the requirements of —

- (a) paragraph 2(a) of the Doha Declaration Implementation Decision; or
- (b) paragraph 2(a) of the Annex to the TRIPS Agreement.

Rights of third parties in respect of Government use

57.—(1) In relation to —

(a) anything done in accordance with section 56 by the Government or any party authorised in writing by the Government; or

(b) anything done to the order of the Government —

(i) for a public non-commercial purpose; or

(ii) for or during a national emergency or other circumstances of extreme urgency, by the proprietor of a patent in respect of the patented invention or by the proprietor of an application for a patent in respect of the invention for which the application has been filed and is still pending, the provisions of any licence, assignment or agreement to which this subsection applies shall, subject to sections 60, 61 and 62, be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use.

(2) The reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(3) Subsection (1) shall apply to any licence, assignment or agreement which is made, whether before or after 23rd February 1995, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person other than the Government.

Nature and scope of rights under section 56

60.—(1) The right to use a patented invention under section 56 —

(a) is not exclusive;

(b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and

(c) is, notwithstanding subsection (2) (a) of section 56, limited to the supply of the patented invention predominantly in Singapore by the Government or a party authorised by the Government under that section.

(1A) The right under section 56 to use a relevant health product which is imported under section 56(1A) does not include a right to export the relevant health product.

(2) The right to use a patented invention under section 56 may, on the application of any interested party, be terminated by the court, where the court is satisfied that the circumstances

that gave rise to the right to use the patented invention have ceased to exist and are unlikely to recur.

(3) Where the court has terminated the right under section 56 to use a patented invention, the court may make such consequential orders as it thinks necessary.

SLOVAKIA (EU) : *Article 27 of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended by Act No. 402/2002 Coll., Act No. 84/2007 Coll. and Act No. 517/2007 Coll.*

*Compulsory licence
Article 27*

(1) On request the court shall be entitled to grant a compulsory licence to any person who can prove the capability to exploit an invention, which is a subject-matter of a granted patent, within the territory of the Slovak Republic, provided that

a) 4 years have expired since filing of an application or 3 years have expired from granting a patent, where the time limit, which expires later, shall apply,

b) person requesting granting of a compulsory licence has offered before filing a request to a patent owner a proper conclusion of a licence agreement, whilst this offer was not accepted by a patent owner within three months from its filing, and

c) invention has not been exploited within the territory of the Slovak Republic without an appropriate reason by a patent owner, or it has been exploited insufficiently, while a subject-matter of a patented invention as a product has not been supplied to the market of the Slovak Republic in a sufficient quantity. Non-existence of an appropriate reason shall be presupposed, unless proved otherwise.

(2) Compulsory licence may be granted only as a non-exclusive licence, whilst its duration and scope shall be limited to purpose for which it has been granted provided that domestic market needs shall be satisfied preferentially.

(3) If a subject-matter of a patent is a technology of semiconductor products, compulsory licence may be granted only for public non-commercial exploitation or to prevent a patent owner from further action, which pursuant to a decision of a competent body can be considered as an action abusing or restricting economic competition, or in case of serious public interest menace.

(4) Notwithstanding paragraph 1(a) and (b) compulsory licence may be granted in case of serious public interest menace.

(5) Notwithstanding presuppositions pursuant to paragraph 1 and conditions pursuant to paragraph 2, a court shall be entitled to grant a compulsory non-exclusive licence for utilisation of a biotechnological invention on request, if a cultivator shall not be able to exploit or acquire right to a plant variety without infringing earlier right to a patent, if the plaintiff proves that

a) before filing a request he has offered to a patent owner a proper conclusion of a licence agreement, whilst this offer was not been accepted by a patent owner within three months from its filing , and

b) plant variety represents an important technical progress of a considerable economic importance comparable with an invention which is a subject-matter of a request for granting a compulsory licence.

(6) In case of granting a compulsory licence pursuant to paragraph 5, a patent owner shall have right for granting a cross compulsory licence for utilisation of a plant variety pursuant to a special regulation.

(7) If a patent owner has granted a compulsory licence for utilisation of a plant variety pursuant to a special regulation, 13b) an owner of a cultivator certificate shall have right for granting a cross compulsory licence for utilisation of a biotechnological invention.

(8) Assignment or transfer of right of a compulsory licence holder shall be possible exclusively as a part of an assignment or transfer of a company or of its part, within which an invention is being used on a basis of a compulsory licence.

(9) A holder of a compulsory licence shall be entitled to waive rights from a compulsory licence by a written notice delivered to the Office. Waiver of right shall come into effect from the day of delivery of a notice to the Office or on a later day which is stated in a notice as a day from which a compulsory licence rights holder waives his rights.

SLOVENIA (EU) : *Articles 125-126 of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

Article 125

Compulsory licences

(1) The court may decide that a third party or the Government of the Republic of Slovenia exploit the invention without the authorisation of the owner of the patent:

(a) where the public interest concerning, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, or

(b) where the court has determined that the owner of the patent or his licensee abuses the patent rights, in particular where the manner of exploitation, contrary to the adopted regulations, restrains competition.

(2) The court shall grant compulsory licences under paragraph (1) with regard to given circumstances and after hearing the owner of the patent.

(3) Compulsory licences under paragraph (1) shall be granted provided that the person filing the request proves that he has made efforts to conclude a licence contract with the owner of the patent on reasonable commercial terms and that such efforts failed to succeed within a reasonable period of time.

(4) Paragraph (3) shall not apply if a state of war or similar state of emergency has been declared. Nevertheless, the owner of the patent shall be notified of the decision of the court as soon as reasonably practicable.

Article 126

Conditions for granting compulsory licences

(1) Compulsory licences under Article 125 shall be granted under the following conditions:

- (a) scope and duration shall be limited with regard to their purpose;
- (b) they shall be non-exclusive;
- (c) they shall be non-transferable, with the exception of the part of the enterprise or business of the licence owner to which the licence refers;
- (d) they shall be granted primarily for the supply of the market of the Republic of Slovenia.

(2) Where a patent, hereinafter referred to as “the second patent”, cannot be exploited without infringing another patent, hereinafter referred to as “the first patent”, the following conditions, in addition to those of Article 125 and paragraph (1) above, for the grant of compulsory licence in respect of the first patent shall be met:

- (a) the invention claimed in the second patent shall involve a technical advance of considerable economic significance compared to the invention claimed in the first patent;
- (b) the owner of the first patent shall under reasonable conditions be entitled to a crosslicence to use the invention claimed in the second patent;
- (c) the use authorised in respect of the first patent shall not be transferable except with the simultaneous transfer of the second patent.

(3) The court shall decide that a compulsory licence expire if the circumstances which led to it being granted have ceased to exist and are unlikely to recur.

SOUTH AFRICA : *Sections 55-56 of the Patents Act No. 57 of 1978 as last amended by Act, No. 58 of 2002*

55. Compulsory licences in respect of dependent patents.

Where the working of a patent (hereinafter referred to as a dependent patent) without infringement of a prior patent is dependent upon the obtaining of a licence under that prior patent, the proprietor of the dependent patent may, if agreement cannot be reached as to such licence with the proprietor of the prior patent, apply to the commissioner for a licence under the prior patent, and the commissioner may grant such a licence on such conditions as he may impose, but including a condition that such licence shall be used only for the purpose of permitting the dependent patent to be worked and for no other purpose: Provided that the commissioner shall not grant such a licence unless—

- (a) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;
- (b) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-licence to use the invention claimed in the dependent patent; and
- (c) the use authorised in respect of the prior patent is not assignable except with the assignment of the dependent patent.

[S. 55 amended by s. 44 of Act No. 38 of 1997.]

56. Compulsory licence in case of abuse of patent rights.

(1) Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.

(2) The rights in a patent shall be deemed to be abused if—

- (a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the

application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;

(b) [Para. (b) deleted by s. 45 (b) of Act No. 38 of 1997.]

(c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;

(d) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, is being prejudiced, and it is in the public interest that a licence or licences should be granted; or

(e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

(3) The patentee or any other person appearing from the register to be interested in the patent may in the prescribed manner oppose the application.

(4) (a) The commissioner shall consider the application on its merits and may order the grant to the applicant of a licence on such conditions as he or she may deem fit, including a condition precluding the licensee from importing into the Republic any patented articles.

[Para. (a) substituted by s. 45 (c) of Act No. 38 of 1997.]

(b) If the commissioner is of the opinion that an order directing the grant of a licence is not justified, he may refuse the application.

(c) A licence granted under this section shall include a provision that, subject to adequate protection of the legitimate interests of the licensee, the licence shall, on application by the patentee, be terminated if the circumstances which led to its grant cease to exist and, in the opinion of the commissioner, are unlikely to recur.

[Para. (c) added by s. 45 (d) of Act No. 38 of 1997.]

(5) Any licence granted under this section shall be non-exclusive and shall not be transferable except to a person to whom the business or part of the business in connection with which the rights under the licence were exercised has been transferred.

[Sub-s. (5) substituted by s. 45 (e) of Act No. 38 of 1997.]

(6) [Sub-s. (6) deleted by s. 45 (f) of Act No. 38 of 1997.]

(7) In determining the conditions on which any licence is granted the commissioner shall have regard to any relevant facts, including the risks to be undertaken by the licensee, the research and development undertaken by the patentee and the terms and conditions usually stipulated in licence agreements in respect of the subject-matter of the invention, between persons who voluntarily enter into such agreements.

(7A) The commissioner may order that a licence granted in terms of this section shall be deemed to have been granted on the date on which the application has been received by the registrar.

[Sub-s. (7A) inserted by s. 2 (b) of Act No. 76 of 1988.]

(8) Any order of the commissioner under this section shall be made with a view to avoiding the abuse found by the commissioner to have been established.

- (9) The commissioner may amend or revoke any licence granted under this section.
- (10) Subject to the conditions that may be attached to the licence, a licensee under this section shall have the same rights and obligations as any other licensee under a patent. [Sub-s. (10) substituted by s. 45 (g) of Act No. 38 of 1997.]
- (11) [Sub-s. (11) deleted by s. 45 (h) of Act No. 38 of 1997.]
- (12) [Sub-s. (12) deleted by s. 45 (h) of Act No. 38 of 1997.]
- (13) (a) The commissioner may, when ordering the grant of a licence under subsection (4) (a), award costs against the applicant or patentee concerned or any person opposing the relevant application.
- (b) In so awarding costs, the commissioner shall inter alia have regard to—
- (i) the nature and extent of the abuse found by him to have been established; and
 - (ii) whether the application for a licence under this section might have been avoided by the grant, by the patentee concerned to the applicant, of a voluntary licence on reasonable terms.
- (14) For the purposes of this section the expression “patented article” includes any composition of matter or any product of a patented process or method or any product produced by a patented machine.

SPAIN (EU) : *Articles 83-86, 88-90 and 101-104 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 83. El titular de la patente está obligado a explotar la invención patentada, bien por sí o por persona autorizada por él, mediante su ejecución en España o en el territorio de un miembro de la Organización Mundial del Comercio de forma que dicha explotación resulte suficiente para satisfacer la demanda del mercado nacional. La explotación deberá realizarse dentro del plazo de cuatro años desde la fecha de presentación de la solicitud de patente, o de tres años desde la fecha en que se publique la concesión de ésta en el “Boletín Oficial de la Propiedad Industrial”, con aplicación automática del plazo que expire más tarde.

Artículo 84. 1. El titular de la patente podrá justificar la explotación de la misma ante el Registro de la Propiedad Industrial[1] por medio de un certificado oficial, que se expedirá por el organismo que en cada caso corresponda y deberá ajustarse a los criterios y normas generales que se establezcan reglamentariamente.

2. El certificado de explotación deberá basarse en la inspección del proceso de fabricación en las instalaciones industriales donde la invención esté siendo explotada y en la comprobación de que el objeto de la invención patentada está siendo efectivamente comercializado.

3. Dicho certificado deberá ser expedido dentro de los tres meses siguientes a la fecha en que se hubiere solicitado y habrá de declarar expresamente que la invención patentada está siendo explotada, reseñando los datos que justifiquen esa declaración.

4. El certificado de explotación deberá ser inscrito en el Registro de la Propiedad Industrial[1]

Artículo 85. Justificada la explotación ante el Registro de la Propiedad Industrial[1] mediante el correspondiente certificado, se presume que, salvo prueba en contrario, la invención patentada está siendo explotada en la forma exigida por el artículo 84 de la presente Ley.

Artículo 86. Procederá la concesión de licencias obligatorias sobre una determinada patente, cuando, no estando sujeta al ofrecimiento de licencias de pleno derecho, concorra alguno de los supuestos siguientes:

- a) Falta o insuficiencia de explotación de la invención patentada.
- b) Necesidad de la exportación.
- c) Dependencia entre las patentes, o entre patentes y derechos de obtención vegetal.
- d) Existencia de motivos de interés público para la concesión.

Artículo 88. Cuando un mercado de exportación no pueda ser adecuadamente abastecido por la insuficiencia de la producción del objeto de una patente, originando con ello un grave perjuicio para el desarrollo económico o tecnológico del país, el Gobierno, mediante Real Decreto, podrá someter dicha patente al régimen de licencias obligatorias, cuya finalidad será exclusivamente atender a las necesidades no cubiertas de la exportación.

Artículo 89. 1. Cuando no sea posible la explotación del invento protegido por una patente sin menoscabo de los derechos conferidos por una patente o por un derecho de obtención vegetal anterior, el titular de la patente posterior podrá solicitar una licencia obligatoria, que será no exclusiva, para la explotación del objeto de la patente o de la variedad objeto del derecho de obtención vegetal anterior, mediante el pago de un canon adecuado.

2. Cuando no sea posible obtener o explotar un derecho de obtención vegetal sin menoscabo de los derechos conferidos por una patente anterior, el obtentor podrá solicitar una licencia obligatoria, que será no exclusiva, para la explotación del invento protegido por la patente, mediante el pago de un canon adecuado.

3. Si una patente tuviera por objeto un procedimiento para la obtención de una sustancia química o farmacéutica protegida por una patente en vigor, tanto el titular de la patente de procedimiento como el de la patente de producto, tendrán derecho a la obtención de una licencia obligatoria no exclusiva sobre la patente del otro titular.

4. Los solicitantes de las licencias a que se refieren los apartados anteriores deberán demostrar:

a) Que la invención o la variedad representa un progreso técnico significativo de considerable importancia económica con relación a la invención reivindicada en la patente anterior o a la variedad protegida por el derecho de obtención vegetal anterior.

b) Que han intentado, sin conseguirlo en un plazo prudencial, obtener del titular de la patente o del derecho de obtención vegetal anterior una licencia contractual en términos y condiciones razonables.

5. Cuando según lo previsto en el presente artículo proceda la concesión de una licencia obligatoria por dependencia, también el titular de la patente o del derecho de obtención vegetal anterior podrá solicitar el otorgamiento, en condiciones razonables, de una licencia por dependencia para utilizar la invención o la variedad protegida por la patente o por el derecho de obtención vegetal posterior.

6. La licencia obligatoria por dependencia se otorgará solamente con el contenido necesario para permitir la explotación de la invención protegida por la patente, o de la variedad protegida por el derecho de obtención vegetal de que se trate, y quedará sin efecto al declararse la nulidad o la caducidad de alguno de los títulos entre los cuales se dé la dependencia.

7. La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso no exclusivo de una invención patentada, se regirán por lo dispuesto en la presente Ley.

La tramitación y la resolución de las solicitudes de licencias obligatorias por dependencia para el uso no exclusivo de la variedad protegida por un derecho de obtentor se regirán por su legislación específica.

Artículo 90. 1. Por motivo de interés público, el gobierno podrá someter en cualquier momento una solicitud de patente o una patente ya otorgada a la concesión de licencias obligatorias, disponiéndolo así por Real Decreto.

2. Se considerará que existen motivos de interés público cuando la iniciación, el incremento o la generalización de la explotación del invento, o la mejora de las condiciones en que tal explotación se realiza, sean de primordial importancia para la salud pública o para la defensa nacional.

Se considerará, asimismo, que existen motivos de interés público cuando la falta de explotación o la insuficiencia en calidad o en cantidad de la explotación realizada implique grave perjuicio para el desarrollo económico o tecnológico del país.

3. El Real Decreto que disponga la concesión de licencias obligatorias deberá ser acordado a propuesta del Ministerio de Industria y Energía. En los casos en que la importancia de la explotación del invento se relacione con la salud pública o con la defensa nacional, la propuesta deberá formularse conjuntamente con el Ministro competente en materia de sanidad o de defensa, respectivamente.

4. El Real Decreto que someta una patente a la concesión de licencias obligatorias por su importancia para la defensa nacional podrá reservar la posibilidad de solicitar tales licencias a una o varias empresas determinadas.

5. Cuando el interés público puede satisfacerse sin necesidad de generalizar la explotación del invento, ni de encomendar esa explotación a una persona distinta del titular de la patente, el Real Decreto podrá disponer el sometimiento condicional de la patente a la concesión de licencias obligatorias, autorizando al Ministro de Industria y Energía para que otorgue al titular un plazo no superior a un año para iniciar, aumentar o mejorar la explotación del invento en la medida necesaria para satisfacer el interés público. En tal caso, el Ministro de Industria y Energía, una vez oído al titular de la patente, podrá concederle el plazo que estime oportuno o someter la patente de forma inmediata a la concesión de las licencias. Una vez transcurrido el plazo que, en su caso, hubiere sido fijado, el Ministro de Industria y Energía determinará si ha quedado satisfecho el interés público, y, si no fuera así, someterá la patente a la concesión de licencias obligatorias.

Artículo 101. 1. Las licencias obligatorias no serán exclusivas.

2. La licencia llevará aparejada una remuneración adecuada según las circunstancias propias de cada caso, habida cuenta de la importancia económica del invento.

Artículo 102. 1. Las relaciones que mantengan el titular de la patente y el licenciataria, con motivo de la concesión de una licencia obligatoria, deberán ser presididas por el principio de buena fe.

2. En caso de violación de este principio, declarada por sentencia judicial, por parte del titular de la patente, el licenciataria podrá pedir al Registro que reduzca la regalía fijada para la licencia, en proporción a la importancia que tenga para la explotación del invento la obligación incumplida.

Artículo 103. 1. La licencia obligatoria comprenderá las adiciones que tuviera la patente objeto de la misma en el momento de otorgarse la licencia.

2. Cuando, después del otorgamiento de la licencia obligatoria, se concedan nuevas adiciones para la patente, que tengan por objeto la misma aplicación industrial del invento patentado a que se refiere la licencia, el licenciataria podrá pedir al Registro que incluya en la licencia las nuevas adiciones. En el caso de que los interesados no lleguen a un acuerdo con la mediación previa del Registro, será éste quien fije la regalía y demás condiciones con arreglo a las cuales haya de tener lugar la ampliación de la licencia.

Artículo 104. 1. Para que la cesión de una licencia obligatoria sea válida, será preciso que la licencia se transmita junto con la empresa o parte de la empresa que la explote y que la cesión sea expresamente anotada por el Registro de la Propiedad Industrial[1] Tratándose de licencias por dependencia de patentes será preciso, además, que la licencia se transmita junto con la patente dependiente.

2. Será nula, en todo caso, la concesión de sublicencias por parte del titular de una licencia obligatoria.

SRI LANKA : *Section 86 of the Intellectual property Act No. 36 of 2003*

86. (1) The provisions of section 84 shall—

- (i) extend only to acts done for industrial or commercial purposes and in particular shall not extend to acts done only for the purpose of scientific research ;
- (ii) not preclude a person having the rights referred to in section 87 or a licensee, from exploiting the patented invention ;
- (iii) not extend to the presence or use of products on foreign vessels, aircraft, spacecraft, or land vehicles which temporarily or accidentally enter the waters, airspace or territory of Sri Lanka ;
- (iv) not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under licence.

(2) (a) Any person, body of persons, a government department or a statutory body may make an application to the Director General for the purpose of obtaining a licence to exploit a patent in the manner hereafter provided.

(b) Upon the receipt of such application, the Director General may issue a license for exploitation if he is satisfied that the applicant has made efforts to obtain approval from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

(c) Director-General may waive the requirements set out in paragraph (b) where he has satisfied himself of the existence of a national emergency or any other circumstances of extreme urgency or in case of public non-commercial use for the purposes such as national security, nutrition, health or for the development of others vital section of the national economy.

(d) The exploitation of the patent shall be limited in scope and duration to the purpose as is specified in the licence. Such exploitation shall be predominantly for the purpose of supply to the domestic market.

(e) The Director-General shall consider each application on its individual merits before granting a licence to exploit a patent.

(f) The issuance of a licence shall be non-exclusive and subject to the payment of adequate remuneration to the owner of the patent taking into consideration the economic value as determined by the Director-General, and where applicable, the need to correct anti competitive practices.

(g) Where such application is for the exploitation of the patent (the second patent) which cannot be exploited without infringing another patent (the first patent), the following conditions shall apply :

(i) the invention claimed in the second patent shall involve and important technical advance of considerable economic significance in relation to the invention claimed in the first patent ;

(ii) the owner of the first patent shall be entitled to a cross licence on reasonable terms to exploit the invention claimed in the second patent ; and

(iii) the exploitation authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

(h) The decision of the Director-General, shall be notified in writing to the owner of the patent as soon as practicable.

(i) The Director-General, shall upon, the request of the owner or of the beneficiary of the licence, after hearing the parties, vary his decision by amending the terms subject to which licence for the exploitation of the patent is issued to the extent only that the changed circumstances justify such variation.

(j) The Director-General shall upon the request of the owner, terminate the non-voluntary license if he is satisfied that the circumstances which led to his decision have ceased to exist and are unlikely to recur or that the license has failed to comply with terms of such licence.

(k) Notwithstanding anything contained in paragraph, (j) the Director-General shall not terminate a licence, if he is satisfied that adequate protection of the legitimate interest of the beneficiary of the licence justifies the continuity of such licence.

(l) The licence to exploit a patent may be transferred only with the enterprise or the business of the licensee of such patent or with the part of such enterprise or business, in relation to which the licence to exploit has been granted.

(m) Where a judicial or administrative body has determined that the manner of exploitation of a patent by its owner or its licensee is anti-competitive, and the Director-General is satisfied that the exploitation of a patent in accordance with this section would remedy such practice, the Director-General may authorize any person, body of persons, government departments or statutory body to exploit the patent without a licence of the owner of the patent. The provisions of the above paragraphs except those of paragraphs (b), (c) and (g) shall be applicable to such licence.

(3) Any person aggrieved by any decision of the Director-General under subsection (2), may tender an appeal therefrom. The provisions of section 173 shall, mutatis mutandis, apply in respect of such appeal.

SWAZILAND : *Section 12 paragraph 6 of the Patents, Utility Models and Industrial Designs Act No. 6 of 1997*

Rights conferred by patent, ARIPO Protocol patents, exploitation by Government or person thereby authorised.

12. (1) The exploitation of the patented invention in Swaziland by persons other than the owner of the patent shall require the latter's agreement.

(2) For the purposes of this Act, "exploitation" of a patented invention means any of the following acts -

- (a) when the patent has been granted in respect of a product -
 - (i) making, importing, offering for sale, selling and using the product;
 - (ii) stocking such products for the purposes of offering for sale, selling or using;
- (b) when the patent has been granted in respect of a process -
 - (i) using the process;
 - (ii) doing any of the acts referred to in paragraph (a) in respect of a product obtained directly by means of the process.

(3) The owner of the patent shall, in addition to any other rights, remedies or actions available to him, have the right, subject to subsection (4) and (6) and section 14 to institute court-proceedings against any person who infringes the patent by performing, without his agreement, any of the acts referred to in subsection (2) or who performs acts which make it likely that infringement will occur.

(4) The rights under the patent shall not extend to:

- (a) acts in respect of articles which have been put on the market in Swaziland by the owner of the patent or with his consent;
- (b) the use of articles on aircraft, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Swaziland; or
- (c) acts done for experimental purposes relating to a patented invention;
- (d) acts performed by any person who in good faith, before the filing of, where priority is claimed, the priority date of application on which the patent is granted and In Swaziland, was using the invention or making effective and serious preparations for such use. to the extent such acts do not differ in nature or purpose from the: actual or envisaged prior use and provided that the right of prior user referred to 'herein may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business in which the use or preparations for use or have been made.

(5) A patent in respect of which Swaziland is a designated State, granted by ARIPO by virtue of the ARIPO Protocol, shall have the same effect in Swaziland as a patent under this Act unless the Registrar of Patents has communicated to ARIPO. in respect of the application therefor:

a decision in accordance with the provisions of the Protocol, that if a patent is granted by ARIPO that patent shall have no effect in Swaziland.

(6) (a) Where the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires, the Minister may decide that even without the agreement of the owner of the patent, a government agency or a third person designated by the Minister may exploit the invention, subject to the payment of an equitable remuneration to the said owner therefor.

(b) The decision of the Minister may be appealable before the court within three (3) months from the date it was made.

SWEDEN (EU) : *Sections 44-49 of the Patents Act No. 837 of 01/12/1967 as last amended by Law No. 159 of 01/04/2004*

44. If a patent has been transferred to another party or a license has been granted, this shall, upon request, be recorded in the Register of Patents.

If it is proved that a license recorded in the Register has ceased to be valid, the records of the license shall be cancelled from the Register.

The provisions of the first and second paragraphs shall apply correspondingly to compulsory licenses and rights referred to in Section 53, second paragraph.

In lawsuits or other legal cases concerning a patent, that party shall be regarded as the proprietor of the patent who was last entered in the Register of Patents in such capacity.

45. A compulsory license for the use of an invention in Sweden may be granted if

1. three years have expired from the granting of the patent and four years from the filing of the patent application,
2. the invention is not used to a reasonable extent in Sweden, and
3. there is no acceptable reason for the non-use of the invention.

For the purposes of the application of the first Paragraph, item 2, use of an invention equals importation of the invention to Sweden from a State within the European Economic Area or a State which is party to, or a territory which is member of, the World Trade Organization (WTO).

46. A holder of a patent for an invention of which the exploitation is depending on a patent which belongs to someone else may be granted a compulsory license to exploit the invention protected by the other patent. Such a license may be granted only if the applicant proves that the first-mentioned invention constitutes a significant technical progress of considerable economic interest compared with the other invention.

If a compulsory license is issued in accordance with the first Paragraph, the holder of the patent for which a compulsory license has been granted is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the other invention.

46a. A plant breeder who can not obtain or exploit a plant breeders' right without infringing a prior patent, may obtain a compulsory license to exploit the invention which is protected by the patent, inasmuch as such a license is necessary for the plant variety to be exploited. Such a license may be granted only if the applicant proves that the plant variety constitutes a significant technical progress of considerable economic interest compared with the invention. If a holder of a patent obtains a compulsory license in a plant breeders' right, the holder of the plant breeders' right is entitled to obtain, on reasonable conditions, a compulsory license (cross-license) to exploit the invention of the holder of the patent.

Provisions on the possibility for the holder of a patent on a biotechnical invention to obtain, under certain conditions, a compulsory license to exploit a protected plant variety are contained in Chapter 7, Article 3a, of the Act on the Protection of Plant Breeders' Rights (1997:306).

47. When required by public interests of extreme importance, anyone who desires to make commercial use of an invention for which another party holds a patent may obtain a compulsory license to that effect.

48. Any person who in this country was commercially exploiting an invention which is the subject of a patent application, when the application documents were made available in accordance with Section 22, shall be entitled, if the application matures into a patent, to obtain a compulsory license for the said use if very special reasons speak in its favor and if he had no knowledge of the application and had not reasonably been able to obtain such knowledge. Under corresponding conditions such right shall also be granted to anyone who has made substantial preparations for commercial exploitation of the invention in this country. Such compulsory license may also apply in respect of a period of time before the patent was granted.

49. A compulsory license may be granted only to a person who can be assumed to exploit the invention in an acceptable manner and in accordance with the license. The applicant must also prove that he or she has unsuccessfully turned to the patent holder to obtain a contractual license on reasonable conditions.

A compulsory license does not prevent the patent holder from exploiting himself or herself the invention or to grant licenses. A compulsory license may be assigned to someone else only together with a business where it is exploited or intended to be exploited. In respect of such compulsory licenses as mentioned in Article 46, first Paragraph, and Article 46a, first Paragraph, also applies that the license may be assigned only together with the patent or the plant breeders' right to which the license applies.

SWITZERLAND : *Articles 36-40e of the Federal Patents Law of 25/06/1954 as on 01/07/2009*

Art. 36

(1) Si l'invention faisant l'objet d'un brevet ne peut être utilisée sans violer un brevet antérieur, le titulaire du brevet plus récent a droit à l'octroi d'une licence non exclusive dans la mesure nécessaire à l'exploitation de son invention, lorsque cette invention, par rapport à celle qui fait l'objet du premier brevet, présente un progrès technique important d'un intérêt économique considérable.

(2) La licence pour l'utilisation de l'invention faisant l'objet du premier brevet ne peut être cédée que conjointement avec le second brevet.

(3) Le titulaire du premier brevet peut lier l'octroi de la licence à la condition que le titulaire du second brevet lui accorde à son tour une licence pour l'utilisation de son invention.

Art. 36a

(1) Lorsqu'un titre de protection d'une variété végétale ne peut être obtenu ni exploité sans porter atteinte à un brevet antérieur, l'obteneur ou le détenteur du titre de protection a droit à une licence non exclusive, dans la mesure nécessaire à l'obtention et à l'exercice de son droit,

pour autant que la variété végétale représente un progrès considérable et économiquement important par rapport à l'invention protégée par un brevet. Les critères de l'ordonnance du 7 décembre 1998 sur les semences⁷⁸ doivent être pris en considération lorsqu'il s'agit de variétés destinées à une utilisation agricole ou alimentaire.

(2) Le titulaire du brevet peut lier l'octroi de la licence à la condition que le détenteur du titre de protection lui accorde à son tour une licence pour l'utilisation de son droit.

Art. 37

(1) Après un délai de trois ans à compter de la délivrance du brevet, mais au plus tôt quatre ans après le dépôt, toute personne qui justifie d'un intérêt peut demander au juge l'octroi d'une licence non exclusive pour utiliser l'invention si, jusqu'à l'introduction de l'action, le titulaire du brevet n'a pas exploité l'invention dans une mesure suffisante en Suisse et pour autant qu'il ne puisse justifier son inaction.

L'importation est considérée comme exploitation du brevet en Suisse.

(2) ... (abrogé)

(3) Sur requête du demandeur, le juge peut lui accorder une licence sitôt l'action introduite, sous réserve du jugement au fond, lorsque, outre les conditions énoncées à l'al. 1, le demandeur rend vraisemblable qu'il a un intérêt à utiliser immédiatement l'invention et qu'il fournit au défendeur des sûretés suffisantes; le défendeur doit être entendu préalablement.

Art. 39

Le Conseil fédéral peut déclarer les art. 37 et 38 inapplicables à l'égard des ressortissants des pays qui accordent la réciprocité.

Art. 40

(1) Lorsque l'intérêt public l'exige, celui auquel le titulaire du brevet a refusé, sans raisons suffisantes, d'accorder la licence requise peut demander au juge l'octroi d'une licence pour utiliser l'invention.

(2) ... (abrogé)

Art. 40a

Dans le cas d'une invention dans le domaine de la technologie des semi-conducteurs, une licence non exclusive ne peut être accordée que pour remédier à une pratique déclarée anticoncurrentielle à l'issue d'une procédure judiciaire ou administrative.

Art. 40b

Quiconque entend utiliser une invention biotechnologique brevetée comme instrument ou comme accessoire de recherche a droit à une licence non exclusive.

Art. 40c

Dans le cas d'une invention portant sur un produit ou un procédé de diagnostic dans le domaine humain, une licence non exclusive est octroyée pour remédier à une pratique déclarée anticoncurrentielle à l'issue d'une procédure judiciaire ou administrative.

Art. 40d

(1) Toute personne peut demander au juge l'octroi d'une licence non exclusive pour la fabrication de produits pharmaceutiques brevetés et leur exportation vers un pays n'ayant aucune capacité de fabrication ou ayant une capacité insuffisante dans le secteur pharmaceutique mais auquel ces produits sont nécessaires pour lutter contre des problèmes de

santé publique, en particulier ceux résultant du VIH/sida, de la tuberculose, du paludisme et d'autres épidémies (pays bénéficiaire).

(2) Les pays ayant déclaré à l'Organisation mondiale du commerce (OMC) qu'ils renoncent partiellement ou totalement à bénéficier d'une licence visée à l'al. 1 ne seront pas considérés comme pays bénéficiaires dans la mesure de leurs déclarations. Les autres pays qui remplissent les conditions de l'al. 1 peuvent être des pays bénéficiaires.

(3) Seule la quantité de produits pharmaceutiques nécessaire pour répondre aux besoins du pays bénéficiaire peut être produite sous la licence prévue à l'al. 1; la totalité de cette production doit y être exportée.

(4) Le titulaire de la licence prévue à l'al. 1 et tout producteur qui fabrique les produits sous licence doivent garantir que leurs produits seront clairement identifiés comme ayant été produits sous une licence visée à l'al. 1 et qu'ils se distingueront des produits brevetés par leur emballage spécial, ou leur coloration ou leur mise en forme, à condition que ces distinctions n'aient pas une incidence importante sur le prix des produits dans le pays bénéficiaire.

(5) Le Conseil fédéral règle les conditions d'octroi de la licence prévue à l'al. 1. Il détermine en particulier les informations ou les notifications dont le juge compétent doit disposer pour décider de cet octroi et des mesures visées à l'al. 4.

Art. 40e

(1) Les licences prévues aux art. 36 à 40d ne sont octroyées que lorsque les efforts entrepris par le requérant afin d'obtenir une licence contractuelle à des conditions commerciales raisonnables n'ont pas abouti dans un délai raisonnable; dans le cas d'une licence prévue à l'art. 40d, un délai de 30 jours ouvrables est réputé comme raisonnable.

De tels efforts ne sont pas nécessaires dans des situations d'urgence nationale, dans d'autres circonstances d'extrême urgence, ou en cas d'utilisation publique à des fins non commerciales.

(2) L'étendue et la durée de la licence sont limitées aux fins auxquelles elle a été octroyée.

(3) La licence ne peut être cédée qu'avec la partie de l'entreprise qui l'exploite. Il en va de même des sous-licences.

(4) La licence est octroyée principalement pour l'approvisionnement du marché intérieur. L'art. 40d est réservé.

(5) Le titulaire du brevet a droit à une rémunération adéquate. Celle-ci est déterminée compte tenu du cas d'espèce et de la valeur économique de la licence. Dans le cas d'une licence prévue à l'art. 40d, la rémunération est déterminée en tenant compte de la valeur économique de la licence dans le pays d'importation, du niveau de développement et de l'urgence sanitaire et humanitaire. Le Conseil fédéral précise le mode de calcul.

(6) Le juge décide de l'octroi et du retrait de la licence, de son étendue et de sa durée, et de la rémunération à verser. En particulier, il retire la licence à l'ayant droit si les circonstances qui ont justifié son octroi cessent d'exister et qu'il est vraisemblable qu'elles ne se reproduiront pas. La protection adéquate des intérêts légitimes de l'ayant droit est réservée. Dans le cas de l'octroi d'une licence prévue à l'art. 40d les recours n'ont pas d'effet suspensif.

THAILAND : *Sections 45-47 bis and 50-52 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 45 - Any patentee may, in accordance with the rules and procedures as prescribed in the Ministerial Regulations, apply to the Director-General for an entry to be made in the register to the effect that any other person may obtain a license.

At any time after an entry has been made, the Director-General shall grant a license under the patent to any person who applies for such a license on such conditions, restrictions and royalty terms as agreed upon by the patentee and the applicant. If the patentee and the applicant cannot agree within the period as prescribed by the Director-General, the Director-General shall grant a license on such conditions, restrictions and royalty terms as he deems appropriate.

Any of the parties may appeal the decision of the Director-General made under the preceding paragraph to the Board within thirty days from the receipt of the decision.

The decision of the Board shall be final.

The application for and grant of a license under the second paragraph shall comply with the rules and procedures as described by the Ministerial Regulations.

Where an entry is made pursuant to the first paragraph, the annual fees in respect of the patent after the date of the entry shall be reduced as prescribed by a Ministerial Regulations, by at least one half of the annual fees which would be payable if the entry had not been made.

Section 46 - At any time after the expiration of three years from the grant of a patent or four years from the date of application, whichever is later, any person may apply to the Director-General for a license if it appears, at the time when such application is filed, that the patentee unjustifiably fails to exercise his legitimate rights as follows:

- (1) that the patented product has not been produced or the patented process has not been applied in the country, without any legitimate reason; or
- (2) that no product produced under the patent is sold in any domestic market, or that such a product is sold but at unreasonably high prices or does not meet the public demand, without any legitimate reason.

Whether it is an application under (1) or (2), the applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed in the Ministerial Regulations.

Section 47 - If the working of any claim in a patent is likely to constitute an infringement of a claim in a patent of any other person, the patentee, desiring to exploit his own patent, may apply to the Director-General for a license under the patent of the other person under the following criteria:

- (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;
- (2) the patentee shall be entitled to a cross-license on reasonable terms;
- (3) the applicant shall not assign his right in the license to other persons except with the assignment of his patent.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having proposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedures prescribed by the Ministerial Regulations.

Section 47 bis - If the working of any claim in the patent having obtained a license under Section 46 is likely to constitute an infringement of a claim in a patent of any other person, the applicant for a license under Section 46 may apply to the Director-General for a license under the patent of the other person under the following criteria:

- (1) the invention of the applicant involves an important technical advance of considerable economic significance in relation to the invention for which the license is applied;
- (2) the applicant shall not assign his right in the license to other persons.

The applicant for a license must show that he has made an effort to obtain a license from the patentee having purposed conditions and remuneration reasonably sufficient under the circumstances but unable to reach an agreement within a reasonable period.

The application for a license shall comply with the rules and procedure prescribed by the Ministerial Regulations.

Section 50 - Where it is decided by the Director-General that a license shall be granted to the applicant under Section 46, 46 bis or 47, the Director-General shall set forth the royalty and the conditions for the exploitation of the patent and the restrictions on the rights of the patentee and the exclusive licensee under Section 48 paragraph 2 as agreed upon by the patentee and the applicant. If no agreement has been reached by the parties within the period prescribed by the Director-General, the Director-General shall fix the royalty and prescribed the conditions and restriction as he deems appropriate subject to the following requirements:

- (1) the scope and duration of the license shall not be more than necessary under the circumstances;
- (2) the patentee shall be entitled to further license others;
- (3) the license shall not be entitled to assign the license to others, except with that part of the enterprise or goodwill particularly of the part under the license;
- (4) the licensing shall be aimed predominantly for the supply of the domestic market;
- (5) the remuneration fixed shall be adequate for the circumstances of the case.

The decision of the Director-General made under the first paragraph of the Section is appealable to the Board within sixty days from the date on which such decision is received. The issuance of a licensing certificate shall comply with the form, rules and procedures prescribed in the Ministerial Regulations.

Section 50 bis - A license issued under Section 46 may be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur provided that the termination does not affect the rights or interests of the licensee under the license.

The application for termination of a license under the first paragraph shall be in accordance with the forms, rules and procedures prescribed in the Ministerial Regulations, the provisions of Section 49 paragraphs two and three and Section 50 applying *mutatis mutandis*.

Section 51 - In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 46 bis and 47.

In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply *mutatis mutandis*.

Section 52 - During a state of war or emergency, the Prime Minister, with the approval of the Cabinet, shall have the power to issue an order to exercise any right under any patent necessary for the defense and security of the country by paying a fair remuneration to the patentee and shall notify the patentee in writing without delay.

The patentee may appeal the order or the amount of remuneration to the court within sixty days from the receipt of the order.

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA : *Articles 97-98, 100, 102, 104, 107-108 of the Law on Industrial Property No. 07-1006/1 of 12/02/2009*

Compulsory license

Article 97

(1) If the patent holder does not use the invention protected by a patent or uses it in a scope which is insufficient to the needs of the national market, and rejects to enter into a license agreement or sets unmarketable conditions for entering into that contract, the right to use the invention, by a compulsory license, may be assigned to another person, with the obligation to pay the fee to the patent holder.

(2) Compulsory license may also be issued if the utilisation of the invention protected by a patent is necessary due to emergency situations in the country, protection of public interest in the area of health, food, protection and promotion of the environment or if it is of particular interest to a certain industrial field or if it is necessary for implementing the judicial and administrative procedure related to protection of competition.

(3) The exemptions in granting compulsory license as referred to in paragraph (1) of this Article shall be possible in the situations referred to in paragraph (2) of this Article, for which the patent holder shall be notified as soon as possible.

(4) Request for a compulsory licence referred to in paragraph (1) of this Article may not be submitted prior to the expiry of a period of four years from the date of filing the patent application i.e. prior to the expiry of a period of three years from the date of the patent granting, in case this period expires later.

(5) A compulsory licence shall not be issued if the patent holder proves that there are legal constraints which justify the fact that invention protected by a patent has not been used or has been insufficiently used.

(6) In the cases referred to in paragraph (2) of this Article, the compulsory license may be issued even prior to the expiry of the period laid down in paragraph (4) of this Article.

Particularities of the compulsory license

Article 98

(1) A compulsory license may not be exclusive.

(2) The compulsory licence shall be valid as long as there is reason for which it has been issued.

(3) On the elaborated request of the interested person, the compulsory license shall be cancelled if there are no longer the reasons for which the license has been issued, and there is no possibility for those reasons to occur again, provided that the legitimate rights to the assignee of the compulsory licence are protected.

(4) The compulsory license may not be transferred, unless the transfer is done together with the production capacity i.e. with part of it that uses the invention for which the license has been issued.

(5) Compulsory license shall be issued for the needs of the national market, unless it is proved in the legal proceedings that this is contrary to the protection of competition on the market.

Compulsory licence for dependent patent

Article 100

(1) A compulsory licence may also be issued if the invention protected by a patent cannot be used as a whole or partially without using another invention protected by a former patent, whereby the later invention, representing a more significant technical improvement, is of particular importance to the economy or to fulfilling the general needs.

(2) If a compulsory license is issued in accordance with paragraph (1) of this Article, the holder of the previous patent may request a compulsory license to use the invention of the latter patent for a relevant fee.

Compulsory license for the needs of public health

Article 102

(1) Any person that has filed an application in compliance with the provisions of this Law may be issued, by the court, a compulsory patent license i.e. a supplementary protection certificate for the needs of production and sale of pharmaceutical products, where such a product is intended to be exported in the importing countries with problems in public health.

(2) When deciding upon issuing compulsory license, the court shall take into consideration the WTO General Council Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health of 14 November 2001, (hereinafter referred to as: "Decision").

(3) The pharmaceutical product referred to in paragraph (1) of this Article shall be any product in the pharmaceutical industry, including the medications for human use, which include any substance or mixture of substances designed for treatment or prevention of human diseases including any substance or mixture of substances which may be applied to people in terms of renewal, improvement, or adjustment to their physiological functions by causing pharmaceutical, immunological, or metabolic effects or by giving the medical diagnosis, including active components and accessories to diagnose outside the alive human body.

Lawsuit to issue compulsory license for the needs of public health

Article 104

(1) The lawsuit that includes an application for issuing a compulsory license for the needs of the public health shall be submitted to the court in compliance with Article 101 of this Law if there is a patent or a supplementary protection certificate in the territory of the Republic of Macedonia that covers the works for production and sale for the purpose of exporting.

(2) The one submitting the lawsuit for compulsory license shall be bound to attach the following to the lawsuit:

- 1) applications for compulsory licenses in other countries for the same product, with data on the quantities and the importing countries;
- 2) the applicant for compulsory license, and in case there is an agent, data about the agent;
- 3) name of the pharmaceutical product i.e. not subject to protection, which the applicant plans to produce on the basis of compulsory license;
- 4) quantity of the pharmaceutical product that the applicant plans to produce on the basis of compulsory license;
- 5) data on the importing country;
- 6) evidence about the previous negotiations with the right holder in compliance with paragraph (5) of this Article; and

7) evidence about the application of the authorised agent of the importing country or the non-governmental organisation which operates with an authorisation from one or more importing countries or UN bodies or another international health organisation, which operates with an authorisation of one or more importing countries indicating the quantity of the required product.

Properties of the issuing compulsory license for the needs of public health
Article 107

- (1) The compulsory license may not be exclusive.
- (2) The duration and the scope of the compulsory license stated in the court decision regarding the license shall depend only from the duration of the reason due to which it had been issued.
- (3) The quantity of products that may be produced on the basis of the compulsory license must not exceed the quantity which is necessary to respond to the needs of the importing countries i.e. the importing countries stated in the lawsuit, taking into consideration the quantity of products produced in other countries on the basis of the compulsory license.
- (4) The compulsory license may be transferred only together with the production capacity i.e. with the part of it, in which the invention for which the compulsory license has been issued is used.

Requirements for issuing compulsory license for the needs of public health
Article 108

- (1) The product which is produced or imported on the basis of a compulsory licence may not be offered for sale or placed on the market of a country i.e. not indicated in the application, except when the importing country, in compliance with item 6, subitem (i) of the Decision, imports in a country that has also signed the regional trade agreement and has the same problem in the field of health.
- (2) The packing or any relevant text must contain a clear indication that the product is a subject to a compulsory license, the name of the court granting the license and the number of the subject, a clear indication that the product is intended exclusively for export and distribution in the importing country or the importing countries and detailed data regarding the product provided for customs authorities in the Republic of Macedonia.
- (3) Compulsory license shall be issued for the needs of the local market, unless proved in the judicial procedure of issuing that this is contrary to the protection of competition on the market.
- (4) If the product for which in the Republic of Macedonia a compulsory license has been issued, is patent granted in the import country indicated in the application, the product may be exported only if that country has issued a compulsory license for export, sale, and/or distribution of that product.
- (5) The conditions under which the license is issued shall not affect the method of distribution in the importing country.

TONGA : Sections 13 and 15 of the Industrial Property Act No. 19 of 09/11/1994

13 - Rights conferred by patent; exploitation by Government or person thereby authorized

- (1) Exploitation in respect of a patented invention means any of the following acts —
 - (a) when the patent has been granted in respect of a product, the making, importing, exporting, offering for sale, setting and using the products or stocking such products for the purposes of offering for sale;

(b) when the patent has been granted in respect of a process, using the process or doing any of the acts referred to in sub-paragraph (a) in respect of a product obtained directly by means of the process.

(2) Subject to subsections (4) and (5) and section 15, the exploitation of the patented invention in Tonga by persons other than the owner of the patent shall require the patentee's permission.

(3) The patentee shall, in addition to any other rights, remedies or actions available to him, have the right, subject to subsections (4) and (5) and section 15, to institute court proceedings against any person who exploits the patent without his permission, or who performs acts which may likely infringe the patented invention.

(4) The rights under the patent shall not extend,

(a) to acts in respect of articles which have been put on the market in Tonga by the patentee or with his consent;

(b) to the use of articles on aircraft, land vehicles, or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Tonga;

(c) to acts done only for experimental purposes relating to a patented invention;

(d) to acts performed by any person who in good faith, before the filing or, where priority is claimed, the priority date of the application on which the patent is granted, was using the invention in Tonga or was making effective and serious preparations in Tonga for such use, to the extent that such acts do not differ in nature or purpose from the actual or envisaged prior use; this right may be transferred or devolve only together with the enterprise or business, or with that part of the enterprise or business, in which the use or preparations for use have been made.

(5) (a) Where the public interest, in particular, national security, nutrition, health or the development of other vital sector of the national economy so require, the Minister may decide that, even without the permission of the patentee, a government agency or a third person designated by the Minister may exploit the invention, subject to the payment of an equitable remuneration to the patentee.

(b) The decision of the Minister with regard to remuneration may be the subject of an appeal before the Court.

15 - Non-voluntary licences

(1) On the request of any person who proves his ability to work a patented invention in Tonga made to the Registrar after the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last, the Registrar may grant a non-voluntary licence if the patented invention is not worked or is insufficiently worked in Tonga.

(2) Notwithstanding subsection (1), a non-voluntary licence shall not be granted if the patentee satisfies the Registrar that circumstances exist which justify the non-working or insufficient working of the patented invention in Tonga. Importation shall not constitute such a circumstance.

(3) The beneficiary of the non-voluntary licence shall have the right to exploit, other than to import, the patented invention in Tonga according to the terms set down in the decision granting the licence and, shall commence the working of the patented invention in Tonga

within the time limit fixed in the said decision and, thereafter, shall work the patented invention sufficiently in Tonga, subject to the payment of an equitable remuneration therefor as determined in the said decision.

- (4) The grant of the non-voluntary licence shall not exclude, —
- (a) the conclusion of a licence contract by the patentee or the grant of other non-voluntary licences; or
 - (b) the exploitation of the patented invention under section 13(5).

TRINIDAD AND TOBAGO : *Sections 46-48 of the Patents Act No. 21 of 1996 as last amended by the Act No. 18 of 2000*

Non-voluntary licences

46.-(1) At any time after the expiration of three years from the date of grant of a patent under this Act or four years from the date of the filing, whichever is later, any person interested may apply to the Court for the grant of a licence under the patent on any of the following grounds, namely that a market for the patented invention is not being supplied, or is not being supplied on reasonable terms in Trinidad and Tobago.

(2) Subject to subsections (4), (5), (6) and (7), if the Court is satisfied that either of the grounds referred to in subsection (1) is established, the Court may make an order for the grant of the licence in accordance with the application on such terms as the Court thinks fit.

(3) A licence granted under this section:

- (a) is not exclusive;
- (b) shall not be assigned otherwise than in connection with the goodwill of the business in which the patented invention is used; and
- (c) is limited to the supply of the patented invention predominantly in Trinidad and Tobago.

(4) Where the Court is satisfied that the grounds on which any licence granted under this section have ceased to exist, it may, on the application of any interested party, terminate such licence.

(5) Any person to whom a licence is granted under this section shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed upon between that person and the patentee, or in default of agreement, as the Court may, taking into account the economic value of the licence, determine on the application of either party.

(6) Before a licence is granted under subsection (1), the Court must be satisfied that the person applying for the licence has made efforts to obtain a licence from the patentee on reasonable commercial terms and conditions within a reasonable time, but has failed to do so.

(7) A licence shall not be granted under this section in respect of a patent relating to semiconductor technology except for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive.

Use of patented invention for services of the State

48.-(1) Where the public interest so requires, or where the Minister decides that the manner of exploitation by the owner of a patent or his licensee is anti-competitive, then subject to subsection (2) the Minister may authorize a State agency or any person in writing, to make use, exercise or vend the patented invention for the services of the State subject to the payment of adequate compensation to the owner thereof, taking into account the economic value of the exploitation, and anything done by virtue of this subsection shall not amount to an infringement of the patent.

(2) Before issuing his authorization under subsection (1), the Minister shall hear the owner of the patent and any other interested party who may wish to be heard.

(3) Subsection (2) does not apply in the case of a national emergency.

(4) The Minister may upon the request of any of the parties, vary the terms of the authorization.

(5) (a) Upon the request of the owner of the patent, the Minister shall terminate the authorization if he is satisfied that the circumstances which led to his decision have ceased to exist and are unlikely to recur, or that the State agency or person authorized by him has failed to comply with the terms of the authorization;

(b) Notwithstanding paragraph (a), the Minister shall not terminate the authorization if he is satisfied that the need for adequate protection of the legitimate interests of the State agency or the person authorized by him justifies maintaining the decision.

(6) An authorization granted to a person other than a State agency shall be subject to the conditions prescribed by subsection (3) of section 46.

(7) (a) Before an authorization is granted under subsection (1), the Minister must be satisfied that the proposed user has made efforts to obtain a licence from the patentee on reasonable commercial terms and conditions within a reasonable time, but has failed to do so;

(b) Paragraph (a) shall not apply in cases of national emergency or other circumstances of extreme urgency, provided however, that in such cases the owner of the patent shall be notified of the Minister's decision as soon as is reasonably practicable.

(8) Any decision of the Minister under subsections (1), (4) or (5) may be subject to judicial review.

TUNISIA : Articles 69- 70, 78 and 80 of the Patents Law No. 2000-84 of 24/08/2000

69. Any interested party may, after the expiry of the period provided for in Article 51 of this Law, obtain a compulsory license at any time in any of the following cases:

— where the invention to which the patent relates has not started to be worked industrially in Tunisia, or where no real and effective preparations have been made for such working, within the period provided for in Article 51 of this Law;

— where the product which is the subject matter of the invention has not been marketed in sufficient quantities to meet the needs of the Tunisian market;

— where the industrial or commercial exploitation of the invention to which the patent relates has been abandoned for more than three years in Tunisia.

70. Any application for the grant of the compulsory license shall be filed with the competent court.

The applicant for a compulsory license shall provide proof that he has already sent the owner of the patent a registered letter with advice of receipt to request a contractual license, but has not been able to obtain such a license on reasonable terms and conditions or within a reasonable period. He shall also supply proof that he is capable of exploiting the invention effectively and conscientiously.

In no event shall a compulsory license for non-working or insufficient working be granted if the owner of the patent provides evidence of a legitimate excuse.

The compulsory license shall be non-exclusive. The rights deriving from the license may only be transferred together with the business, the company or the part of the company to which they are attached.

78. The minister responsible for industry may formally call upon the owners of patents to undertake the working thereof in such a way as to meet the needs of the national economy or the need to safeguard the environment.

Where the formal notice has not been acceded to within a period of one year, and where the non-working or the qualitative or quantitative inadequacy of the working undertaken seriously prejudices economic development and the public interest, the patents to which the notice relates may be made subject to the ex officio license regime by order of the minister responsible for industry.

The minister responsible for industry may extend the period provided for in the second paragraph of this Article where the owner of the patent provides proof of legitimate reasons attributable to the demands of the national economy.

Where public health interests dictate, patents granted for drugs, for the products necessary for the production of such drugs or for processes for the manufacture of such products may, where the drugs are made available to the public at levels of quality or quantity that are inadequate or at abnormally high prices, be made subject, at the request of the minister responsible for public health, to the ex officio license regime by order of the minister responsible for industry.

The State may at any time, for the purposes of national defense or national security, obtain an ex officio license for the exploitation of an invention covered by a patent application or patent, whether that exploitation is engaged in by itself or through a third party.

The ex officio license shall be granted at the request of the minister concerned by order of the minister responsible for industry.

80. The ex officio license shall be non-exclusive. The rights deriving from that license may only be transferred together with the business or the company or part of the company to which they are attached.

TURKEY : *Articles 79, 93, 96-99, 101-103, 114 and 116 of the Decree-Law on the Protection of Patent Rights No. 551 of 27/06/1995 and Sections 39, 40 and 43 of the Implementing Regulations under Decree-Law No. 551 pertaining to the Protection of Patent Rights, including Amended Regulation of 06/12/1998*

Dependency of subject matters of Patents

Article 79 :

The fact that a patented invention can not be worked without using an invention, protected under a prior patent shall not be an obstacle to its validity. In such cases, neither the right holder of the prior patent, nor the right holder of the latter patent may use, the patent of the other party, without his consent, during the term of validity of his patent. However, the right holder of the latter patent may use, also, the prior patent where he has been authorized by the right holder of the prior patent to use same or has been granted compulsory license to use said prior patent.

Abuse of Competition

Article 93 :

Where a patentee commits an act in violation of the general provisions on unfair competition while putting his patent (application) to use, the court may condemn the patentee to offer his patent for licensing.

Obligation to Work/Use

Article 96 :

The patentee or the person authorized by him is under obligation to put to use/work, the invention under patent protection. The obligation to put to use/work must be realized within three years as from the date of publication in the relevant bulletin of the announcement related to the issue of the patent.

Market conditions are (to be) taken into consideration when/for assessing use/working.

Evidence of Use

Article 97 :

The patentee or the person authorized by him shall prove his use of the invention by an official certificate to be filed before the Institute. The official certificate attesting the use of the patent shall be established according to the general criteria and rules foreseen in the Regulation by the authority designated therein.

The certificate (of use) is issued at the conclusion of the inspection of the production in the industrial premises where the invention is being put to use/worked. The certificate (of use) shall confirm the fact that the patented invention is being implemented or that the (goods) object of the invention is offered for sale.

The certificate (of use) must be prepared within three months as from the date of filing the relative application before the concerned authority. The certificate shall cover the data relative to the actual/effective use of the patented invention.

The certificate of use is entered in the Patent Register.

Acceptance of Use

Article 98 :

When working of the patented invention is attested (before the Turkish Patent Institute) by documentary evidence, the patented invention shall be deemed to have been put to use in compliance of Article 97, unless proof to the contrary is brought through court action.

Requirements for granting Compulsory Licensee

Article 99 :

Compulsory license is (to be) granted where no offer for licensing offer has been made and where any one of the following situations/conditions materializes:

1. Failure to put to use/work the patented invention in accordance with Article 96;
2. Dependency of subject matter of patents as mentioned in Article 79.
3. On grounds of public interest as mentioned in Article 103.

Compulsory license in case of dependency between Patents

Article 101 :

Where the patented invention can not be put to use without infringing the rights conferred by a prior patent, the latter patentee, by bringing evidence that his patent, with reference to the prior patent will serve a different industrial purpose or achieves significant technical improvement, may request the court to grant license for using the patent of prior date.

Where patented inventions, dependent in the sense of Article 79, serve the same industrial purpose and where a compulsory license has been granted in favour of one of the dependent patents, the patentee of the dependent patent upon which compulsory license is granted may request from the court that a compulsory license be granted in his favour on the other dependent patent.

Where the subject matter of a patent concerns a process aiming to obtain a patented chemical product or substance related to pharmacology, and where said process patent achieves a significant technical improvement, with respect to the patent of prior date both the patentee of the process patent and the patentee of the product patent may request from the court the grant of compulsory license for using the patented invention of the other party.

The scope of compulsory license granted for reasons of dependency between patents in the sense of Article 79, permits use of the concerned patented invention. In case when one of the dependent patents is invalidated or expires, the decision on compulsory license shall remain without effect.

Exportation as ground for Compulsory license

Article 102 :

The exportation (situation/possibility) of the patented invention shall not be accepted to constitute a ground for compulsory license.

Compulsory license on grounds of Public Interest

Article 103 :

The Council of Ministers may decide that the invention subject matter a patent or an application for patent be put to use on grounds of public interest by means of compulsory license where putting the invention to use, increasing its or, generally spreading, its usage or improving same for a useful end are of great importance for public health or national defense purposes, public interest shall be deemed to be involved.

Situations where the non use of the invention or its insufficient use in terms of quality and quantity, causes serious damage to the country's economic or technical development shall be deemed to also involve public interest.

The concerned Ministry proposes to the Council of Ministers to issue a decree pertaining to the grant of compulsory license. In case, where the use of the invention is important for national defense or public health, the proposal is prepared jointly by the concerned ministry, and the Ministry of National Defense or the Ministry of Health.

The decision to grant compulsory license, may, restrict the use of the invention to one or some enterprises on grounds of its importance for national defense.

In case when the patentee can realize to put the invention to use for public interest without having the need to generalize/spread the use thereof or to grant the use thereof to a person other than the patentee, the patented invention may be, conditionally, subjected to compulsory license. In such a situation, on the basis of the Decree of the Council of Ministers, the Court shall decide that the patentee shall put the invention to use for a period it will set, not longer than one year, in such a manner to sufficiently satisfy public interest, to develop/spread and enhance the actual use made of it.

The court shall decide on the period it will deem appropriate or subject the patented invention to compulsory license after taking into consideration the viewpoint of the patentee. The court shall decide, whether use has been made of, in the public interest, or not, after the expiry of the period prescribed. Where the court rules that use had not been made of in the public interest, it shall subject the patented invention to compulsory license.

Legal nature of compulsory licensing

Article 114 :

Compulsory license shall not be exclusive. Only, the compulsory license on grounds of public interest according to Article 103, may be granted as an exclusive license. However, exclusivity shall not be contradictory to the purpose of compulsory license and must be necessary for economically valourising the invention under patent protection.

In case a compulsory license is granted, the licensee has no right in principle to import the subject matter of the patent. However, the subject matter of the patent may be imported only when the compulsory license has been granted to the licensee on grounds of public interest and when the licensee has been specifically authorized to import. Such authorization to import shall be issued but on a temporary basis and shall be limited to meeting the demand.

In case of a compulsory license the patentee shall be paid an economically reasonable fee. The license fee shall be determined especially by taking into consideration the economic importance of the invention.

Scope of compulsory license for Patent-of-Addition

Article 116 :

Compulsory license covers the addition(s) to the existing patent, at the date of the acceptance/grant of the license. Where after grant of compulsory license patent(s)-of-addition to the patent have newly issued and where such patent(s)-of-addition serve the same industrial purpose as the patent, subject of the license, the licensee may request from the court that the patent(s)-of-addition be also included within the scope of the compulsory license.

Where despite the mediation of the Institute, the parties can not agree on the license fee and other terms/conditions of the license whose scope has been enlarged with the patent(s)-of-addition, these shall be determined by court.

TURKMENISTAN : *Article 38 of the Patent Act No. 867-XII of 01/10/1993*

Article 38. License

1. Any natural person or entity who wishes to use patented invention, industrial pattern or registered trade mark should have patent from the holder for invention or industrial pattern and the license from the holder of evidence for trade mark. License agreement is concluded for certain period, subject to registration in Turkmenpatent and comes into force from the date of its registration. Without registration the license agreement is considered invalid.
2. The holder of patent (temporary patent) for invention may ask Turkmenpatent to publish application on giving to any natural person or entity the right to use invention (open license). In this case duty for maintenance of patent (temporary patent) is decreased by 50% beginning from the year following the year of publication of such application.
Person who wishes to use indicated invention should conclude an agreement with patent holder on payments.
3. In the interests of defense of Turkmenistan and for maintenance of public order the Cabinet of Ministers of Turkmenistan has the right to permit to use the object of industrial property without agreement of patent holder with payment of money compensation, which are comparable with market price of the license.
4. When issuing the state order to the enterprise on manufacturing the products with using inventions the patent (temporary patent) on which belonging to other natural persons or entities in Turkmenistan and also to foreign citizens, the body issuing the state order provides the license acquisition.

UGANDA : *Sections 29 and 30 of the Patents Act of 15/10/1993*

29. Exploitation by the Government or persons authorised by the Government.

- (1) Where the Minister is of the opinion that it is in the vital public interest to do so, he or she, in consultation with the registrar, and without the authority of the owner of a patent, may direct that a patented invention be exploited by a Government agent or other person designated by the Minister, on the following conditions—
 - (a) that the owner of the patent and any licensee has been given an opportunity to be heard before the direction is made; and
 - (b) that the Government provides for the payment of adequate remuneration, as fixed by the registrar, to the owner of the patent for the use of his or her invention.
- (2) The owner of any patent affected by any direction of the Minister under this section may appeal to the High Court—
 - (a) against the direction of the Minister;
 - (b) against a decision of the registrar fixing the amount of remuneration under subsection (1), but an appeal shall not suspend the effect of the direction of the Minister under subsection (1).
- (3) For the purposes of this section, “vital public interest” includes matters of paramount importance pertaining to national security, public health, public order and morality and the national economy.
- (4) For the purposes of forming an opinion under subsection (1), the Minister may consult with such technical experts in the particular field of the patented invention as may be necessary.

30. Compulsory licences.

(1) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may, in proceedings instituted by him or her against the owner of the patent or in proceedings instituted against him or her by the owner request the court for the grant of a compulsory licence on any of the following grounds—

(a) that the patented invention, being capable of being worked in Uganda, has not been so worked;

(b) that the existing degree of working of the patented invention in Uganda does not meet on reasonable terms the demand for the patented product on the domestic market or for the purposes of exploitation;

(c) that the working of the patented invention in Uganda is being hindered or prevented by the importation of the patented product; and

(d) that, by reason of the refusal of the owner of the patent to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Uganda, or the possibilities of exportation from Uganda, are unfairly and substantially prejudiced.

(2) A compulsory licence under this section shall be on such terms as to payment of remuneration by the licensee to the owner of the patent and otherwise as the court may consider just.

(3) Where the patented invention is a process, “patented product” in subsection (1) means a product obtained directly by means of the process.

UKRAINE : *Article 30 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*

Article 30 - Expropriation of the Right to an Invention (Utility Model)

(1) If an invention (utility model), excluding a secret invention (utility model) is not used or is inadequately used in Ukraine within 3 years from the date of publishing the data on granting a patent or from the date when the use of an invention (utility model) has been terminated, any person who wishes and is ready to use an invention (utility model) may appeal to the court for granting the right to use an invention (utility model) provided that the owner of rights has rejected the conclusion of the license agreement.

If the patent owner does not prove that the fact of nonuse of an invention (utility model) is caused by important reasons, the court shall make a decision on granting the permission to an interested person to use an invention (utility model) and define the volume of its use, the term of the permission, the amount and procedure of remunerating the patent owner. In this case, the right of the patent owner to grant permissions to use an invention (utility model) shall not be restricted.

(2) The patent owner shall be obliged to grant the permission (license) to use an invention (utility model) to the owner of the patent that has been granted later provided that an invention (utility model) of the latter is intended for other purpose or has significant technical and economical advantages and may not be used without infringement of the rights of the owner the patent that has been granted earlier. The permission shall be granted in the volume that is necessary for the use of an invention (utility model) by the owner of the patent that has

been granted later. In this case, the owner of the patent that has been granted earlier shall have the right to obtain on acceptable conditions a license to use an invention (utility model) that is protected by the patent that has been granted later.

(3) With the purpose to protect the health of population, ecological safety and other public interests, the Cabinet of Ministers of Ukraine may permit the use of the patented invention (utility model) by a defined person without the consent of the patent (declarative patent) owner provided that this owner has groundlessly rejected granting a license for the use of an invention (utility model).

In this case:

1. the permission for such a use shall be granted with consideration of specific circumstances;
2. the volume and the duration of such a use shall be determined by purpose of the granted permission and, in the case of semiconductor technology this shall be purely noncommercial use by bodies of the state power or implementing an anticompetition practice by the decision of a relevant body of the state power;
3. the permission for such a use shall not deprive the patent owner of the right to grant permissions for the use of an invention (utility model);
4. the right to such a use shall not be transferred excluding the case when it is transferred together with the part of the enterprise or business practice in which this use is carried out;
5. the use shall be permitted mainly for providing the internal market needs;
6. the notification concerning the grant of the permission for the use of an invention (utility model) shall be sent to the patent owner at the first opportune moment;
7. the permission for the use shall be revoked in case of discontinuance of circumstances under which this permission has been granted;
8. an adequate compensation in accordance with an economic value of an invention (utility model) shall be paid to the patent owner.

The resolution of the Cabinet of Ministers of Ukraine concerning the grant of the permission for the use of an invention (utility model), the validity period and conditions of the grant, revocation of the permission for the use, amount and procedure of paying a remuneration to the patent owner may be appealed in court procedure.

(4) The owner of the patent (declarative patent) for a secret invention or a declarative patent for a secret utility model may grant a license for the use of his invention (utility model) only to a person that has a permission of the State Expert to access to this invention (utility model). If the said person cannot come to the agreement with the patent owner on the grant of the license, the Cabinet of Ministers of Ukraine shall have the right to permit the use of a secret invention (utility model) according to Paragraph 3 of this Article.

(5) The court shall resolve any disputes on the conditions of the grant of licenses, on the amounts and the procedure of obtaining money compensation.

UNITED ARAB EMIRATES : *Articles 24-25 and 30 of the Law No. 17 of 2002 pertaining to the Industrial Regulation and Protection of Patents, Industrial Drawings, and Designs*

Article – 24 : (1) If the owner of the letters patent or the holder of the utility certificate have not used or made use of the letters patent or the utility certificate, then any interested party

may according to article (30) of this law obtain a compulsory license under the following conditions:

- a- The period of at least 3 years since the issuance of the letters patent has passed.
- b- The proposed licensee should demonstrate the efforts made to obtain the license from the patentee for a reasonable price and under reasonable commercial conditions. The required procedures will be set in the implementing regulations in this regard.
- c- The license should not be issued in absolute terms. The license may include obligations and boundaries for both the licensor and the licensee.
- d- The license should be intended to satisfy the basic requirements of the local market. The proposed licensee must offer the necessary guarantees set in the implementing regulations of this law in order to sufficiently exploit the invention to remedy the deficiency or meet the needs that lead to requesting the compulsory license.
- e- The scope of the license should be in line with the objective for which it has been issued.
- f- The patentee should receive a fair compensation.
- g- The use of the patent should be restricted to the licensee. The license cannot be transferred to a third party except where the ownership of the establishment of the licensee or the part thereof utilizing the patent has been assigned. Such a transfer should be approved by the competent court and be bound to articles (28) and (32) of this law.
- h- In the case of semi-conductor technology, the license shall only be for public, non-commercial use, or to remedy a practice determined after judicial or administrative process to be anti-competitive.

(2) The compulsory license shall not be granted if the owner of the letters patent or utility certificate offers plausible justification. Importing the product is not considered as plausible justification.

Article – 25 :

(1) The compulsory license shall warrant the licensee the right to undertake some or all of the activities referred to in article (15) of this law under the licensing conditions, with the exception of the right of importing the product.

(2) The licensee shall be entitled to practice the civil and the penal rights against the owner of the letters patent or the holder of the utility certificate if they are unduly utilizing their invention or being aware of illegal practices related thereto.

Article – 30 :

(1) If it is impossible to use an invention protected by a patent or a utility certificate in the United Arab Emirates without violating rights derived from a patent or a utility certificate granted by virtue of a previous application, then it is permissible to grant the owner of the letters patent or the utility certificate a compulsory license according to the conditions set forth in article (24) of such law to the degree necessary to use his invention if such invention serves industrial purposes different from such purposes related to the invention of the former patent or utility certificate or represents a marked technical advance in relation thereto.

(2) If the two inventions serve the same industrial purpose, the compulsory license shall be granted to the subsequent patent or utility certificate while keeping the right for the owner of the former patent or utility certificate to obtain a license for the subsequent patent or utility certificate, if he applies for such.

(3) The two parties may also agree in writing between them and notify the Administration of their agreement to record it in the related register.

UNITED KINGDOM (EU) : *Sections 48-51, 55, 57 and 59 of the Patents Act of 1977(unofficial consolidation of 01/01/2010)*

Compulsory licences: general

48.-(1) At any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the comptroller on one or more of the relevant grounds –

- a) for a licence under the patent;
- (b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or
- (c) where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent.

(2) Subject to sections 48A and 48B below, if he is satisfied that any of the relevant grounds are established, the comptroller may -

- (a) where the application is under subsection (1)(a) above, order the grant of a licence to the applicant on such terms as the comptroller thinks fit;
- (b) where the application is under subsection (1)(b) above, make such an entry as is there mentioned;
- (c) where the application is under subsection (1)(c) above, order the grant of a licence to the person specified in the application on such terms as the comptroller thinks fit.

(3) An application may be made under this section in respect of a patent even though the applicant is already the holder of a licence under the patent; and no person shall be estopped or barred from alleging any of the matters specified in the relevant grounds by reason of any admission made by him, whether in such a licence or otherwise, or by reason of his having accepted a licence.

(4) In this section “the relevant grounds” means -

- (a) in the case of an application made in respect of a patent whose proprietor is a WTO proprietor, the grounds set out in section 48A(1) below;
- (b) in any other case, the grounds set out in section 48B(1) below.

(5) A proprietor is a WTO proprietor for the purposes of this section and sections 48A, 48B, 50 and 52 below if -

- (a) he is a national of, or is domiciled in, a country which is a member of the World Trade Organisation; or
- (b) he has a real and effective industrial or commercial establishment in such a country.

(6) A rule prescribing any such other period under subsection (1) above shall not be made unless a draft of the rule has been laid before, and approved by resolution of, each House of Parliament.

Compulsory licences: WTO proprietors

48A.-(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is a WTO proprietor, the relevant grounds are -

- (a) where the patented invention is a product, that a demand in the United Kingdom for that product is not being met on reasonable terms;
- (b) that by reason of the refusal of the proprietor of the patent concerned to grant a licence or licences on reasonable terms -
- (i) the exploitation in the United Kingdom of any other patented invention which involves an important technical advance of considerable economic significance in relation to the invention for which the patent concerned was granted is prevented or hindered, or
 - (ii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;
- (c) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.
- (2) No order or entry shall be made under section 48 above in respect of a patent whose proprietor is a WTO proprietor unless -
- (a) the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions; and
 - (b) his efforts have not been successful within a reasonable period.
- (3) No order or entry shall be so made if the patented invention is in the field of semiconductor technology.
- (4) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(b)(i) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.
- (5) A licence granted in pursuance of an order or entry so made shall not be assigned except to a person to whom the patent for the other invention is also assigned.
- (6) A licence granted in pursuance of an order or entry made under section 48 above in respect of a patent whose proprietor is a WTO proprietor -
- (a) shall not be exclusive;
 - (b) shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part;
 - (c) shall be predominantly for the supply of the market in the United Kingdom;
 - (d) shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence; and
 - (e) shall be limited in scope and in duration to the purpose for which the licence was granted.

Compulsory licences: other cases

48B.-(1) In the case of an application made under section 48 above in respect of a patent whose proprietor is not a WTO proprietor, the relevant grounds are -

(a) where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked or is not being so worked to the fullest extent that is reasonably practicable;

(b) where the patented invention is a product, that a demand for the product in the United Kingdom -

(i) is not being met on reasonable terms, or

(ii) is being met to a substantial extent by importation from a country which is not a member State;

(c) where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked -

(i) where the invention is a product, by the importation of the product from a country which is not a member State,

(ii) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;

(d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms -

(i) a market for the export of any patented product made in the United Kingdom is not being supplied, or

(ii) the working or efficient working in the United Kingdom of any other patented invention which makes a substantial contribution to the art is prevented or hindered, or

(iii) the establishment or development of commercial or industrial activities in the United Kingdom is unfairly prejudiced;

(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the United Kingdom, is unfairly prejudiced.

(2) Where -

(a) an application is made on the ground that the patented invention is not being commercially worked in the United Kingdom or is not being so worked to the fullest extent that is reasonably practicable; and

(b) it appears to the comptroller that the time which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, he may by order adjourn the application for such period as will in his opinion give sufficient time for the invention to be so worked.

(3) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(a) above if -

(a) the patented invention is being commercially worked in a country which is a member State; and

(b) demand in the United Kingdom is being met by importation from that country.

(4) No entry shall be made in the register under section 48 above on the ground mentioned in subsection (1)(d)(i) above, and any licence granted under section 48 above on that ground shall contain such provisions as appear to the comptroller to be expedient for restricting the countries in which any product concerned may be disposed of or used by the licensee.

(5) No order or entry shall be made under section 48 above in respect of a patent on the ground mentioned in subsection (1)(d)(ii) above unless the comptroller is satisfied that the proprietor of the patent for the other invention is able and willing to grant to the proprietor of the patent concerned and his licensees a licence under the patent for the other invention on reasonable terms.

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.

Powers exercisable in consequence of report of Competition Commission

51.-(1) Where a report of the Competition Commission has been laid before Parliament containing conclusions to the effect -

- (a) [repealed]
- (b) [repealed]
- (c) on a competition reference, that a person was engaged in an anti-competitive practice which operated or may be expected to operate against the public interest, or
- (d) on a reference under section 11 of the Competition Act 1980 (reference of public bodies and certain other persons), that a person is pursuing a course of conduct which operates against the public interest, the appropriate Minister or Ministers may apply to the comptroller to take action under this section.

(2) Before making an application the appropriate Minister or Ministers shall publish, in such manner as he or they think 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 him or them to be affected.

(3) If on an application under this section it appears to the comptroller that the matters specified in the Commission's report as being those which in the Commission's opinion operate, or operated or may be expected to operate, against the public interest include -

- (a) 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
- (b) a refusal by the proprietor of a patent to grant licences on reasonable terms he may by order cancel or modify any such condition 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.

(4) In this section "the appropriate Minister or Ministers" means the Minister or Ministers to whom the report of the Commission was made.

Use of patented inventions for services of the Crown

55.-(1) Notwithstanding anything in this Act, any government department and any person authorised in writing by a government department may, for the services of the Crown and in accordance with this section, do any of the following acts in the United Kingdom in relation to a patented invention without the consent of the proprietor of the patent, that is to say -

- (a) where the invention is a product, may -
 - (i) make, use, import or keep the product, or sell or offer to sell it where to do so would be incidental or ancillary to making, using, importing or keeping it; or
 - (ii) in any event, sell or offer to sell it for foreign defence purposes or for the production or supply of specified drugs and medicines, or dispose or offer to dispose of it (otherwise than by selling it) for any purpose whatever;
- (b) where the invention is a process, may use it or do in relation to any product obtained directly by means of the process anything mentioned in paragraph (a) above;
- (c) without prejudice to the foregoing, where the invention or any product obtained directly by means of the invention is a specified drug or medicine, may sell or offer to sell the drug or medicine;
- (d) may supply or offer to supply to any person any of the means, relating to an essential element of the invention, for putting the invention into effect;
- (e) may dispose or offer to dispose of anything which was made, used, imported or kept in the exercise of the powers conferred by this section and which is no longer required for the

purpose for which it was made, used, imported or kept (as the case may be), and anything done by virtue of this subsection shall not amount to an infringement of the patent concerned.

(2) Any act done in relation to an invention by virtue of this section is in the following provisions of this section referred to as use of the invention; and “use”, in relation to an invention, in sections 56 to 58 below shall be construed accordingly.

(3) So far as the invention has before its priority date been duly recorded by or tried by or on behalf of a government department or the United Kingdom Atomic Energy Authority otherwise than in consequence of a relevant communication made in confidence, any use of the invention by virtue of this section may be made free of any royalty or other payment to the proprietor.

(4) So far as the invention has not been so recorded or tried, any use of it made by virtue of this section at any time either –

(a) after the publication of the application for the patent for the invention; or
(b) without prejudice to paragraph (a) above, in consequence of a relevant communication made after the priority date of the invention otherwise than in confidence; shall be made on such terms as may be agreed either before or after the use by the government department and the proprietor of the patent with the approval of the Treasury or as may in default of agreement be determined by the court on a reference under section 58 below.

(5) Where an invention is used by virtue of this section at any time after publication of an application for a patent for the invention but before such a patent is granted, and the terms for its use agreed or determined as mentioned in subsection (4) above include terms as to payment for the use, then (notwithstanding anything in those terms) any such payment shall be recoverable only -

(a) after such a patent is granted; and
(b) if (apart from this section) the use would, if the patent had been granted on the date of the publication of the application, have infringed not only the patent but also the claims (as interpreted by the description and any drawings referred to in the description or claims) in the form in which they were contained in the application immediately before the preparations for its publication were completed by the Patent Office.

(6) The authority of a government department in respect of an invention may be given under this section either before or after the patent is granted and either before or after the use in respect of which the authority is given is made, and may be given to any person whether or not he is authorised directly or indirectly by the proprietor of the patent to do anything in relation to the invention.

(7) Where any use of an invention is made by or with the authority of a government department under this section, then, unless it appears to the department that it would be contrary to the public interest to do so, the department shall notify the proprietor of the patent as soon as practicable after the second of the following events, that is to say, the use is begun and the patent is granted, and furnish him with such information as to the extent of the use as he may from time to time require.

(8) A person acquiring anything disposed of in the exercise of powers conferred by this section, and any person claiming through him, may deal with it in the same manner as if the patent were held on behalf of the Crown.

(9) In this section “relevant communication”, in relation to an invention, means a communication of the invention directly or indirectly by the proprietor of the patent or any person from whom he derives title.

(10) Subsection (4) above is without prejudice to any rule of law relating to the confidentiality of information.

(11) In the application of this section to Northern Ireland, the reference in subsection (4) above to the Treasury shall, where the government department referred to in that subsection is a department of the Government of Northern Ireland, be construed as a reference to the Department of Finance for Northern Ireland.

Rights of third parties in respect of Crown use

57.-(1) In relation to -

(a) any use made for the services of the Crown of an invention by a government department, or a person authorised by a government department, by virtue of section 55 above, or

(b) anything done for the services of the Crown to the order of a government department by the proprietor of a patent in respect of a patented invention or by the proprietor of an application in respect of an invention for which an application for a patent has been filed and is still pending, the provisions of any licence, assignment, assignation or agreement to which this subsection applies shall be of no effect so far as those provisions restrict or regulate the working of the invention, or the use of any model, document or information relating to it, or provide for the making of payments in respect of, or calculated by reference to, such working or use; and the reproduction or publication of any model or document in connection with the said working or use shall not be deemed to be an infringement of any copyright or design right subsisting in the model or document.

(2) Subsection (1) above applies to a licence, assignment, assignation or agreement which is made, whether before or after the appointed day, between (on the one hand) any person who is a proprietor of or an applicant for the patent, or anyone who derives title from any such person or from whom such person derives title, and (on the other hand) any person whatever other than a government department.

(3) Where an exclusive licence granted otherwise than for royalties or other benefits determined by reference to the working of the invention is in force under the patent or application concerned, then -

(a) in relation to anything done in respect of the invention which, but for the provisions of this section and section 55 above, would constitute an infringement of the rights of the licensee, subsection (4) of that section shall have effect as if for the reference to the proprietor of the patent there were substituted a reference to the licensee; and

(b) in relation to anything done in respect of the invention by virtue of an authority given under that section, that section shall have effect as if the said subsection (4) were omitted.

(4) Subject to the provisions of subsection (3) above, where the patent, or the right to the grant of the patent, has been assigned to the proprietor of the patent or application in consideration of royalties or other benefits determined by reference to the working of the invention, then -

(a) in relation to any use of the invention by virtue of section 55 above, subsection (4) of that section shall have effect as if the reference to the proprietor of the patent included a reference to the assignor, and any sum payable by virtue of that subsection shall be divided between the proprietor of the patent or application and the assignor in such proportion as may be agreed on by them or as may in default of agreement be determined by the court on a reference under section 58 below; and

(b) in relation to any act done in respect of the invention for the services of the Crown by the proprietor of the patent or application to the order of a government department, section 55(4) above shall have effect as if that act were use made by virtue of an authority given under that section.

(5) Where section 55(4) above applies to any use of an invention and a person holds an exclusive licence under the patent or application concerned (other than such a licence as is mentioned in subsection (3) above) authorising him to work the invention, then subsections (7) and (8) below shall apply.

(6) In those subsections "the section 55(4)" payment means such payment (if any) as the proprietor of the patent or application and the department agree under section 55 above, or the court determines under section 58 below, should be made by the department to the proprietor in respect of the use of the invention.

(7) The licensee shall be entitled to recover from the proprietor of the patent or application such part (if any) of the section 55(4) payment as may be agreed on by them or as may in default of agreement be determined by the court under section 58 below to be just having regard to any expenditure incurred by the licensee -

(a) in developing the invention, or

(b) in making payments to the proprietor in consideration of the licence, other than royalties or other payments determined by reference to the use of the invention.

(8) Any agreement by the proprietor of the patent or application and the department under section 55(4) above as to the amount of the section 55(4) payment shall be of no effect unless the licensee consents to the agreement; and any determination by the court under section 55(4) above as to the amount of that payment shall be of no effect unless the licensee has been informed of the reference to the court and is given an opportunity to be heard.

(9) Where any models, documents or information relating to an invention are used in connection with any use of the invention which falls within subsection (1)(a) above, or with anything done in respect of the invention which falls within subsection (1)(b) above, subsection (4) of section 55 above shall (whether or not it applies to any such use of the invention) apply to the use of the models, documents or information as if for the reference in it to the proprietor of the patent there were substituted a reference to the person entitled to the benefit of any provision of an agreement which is rendered inoperative by this section in relation to that use; and in section 58 below the references to terms for the use of an invention shall be construed accordingly.

(10) Nothing in this section shall be construed as authorising the disclosure to a government department or any other person of any model, document or information to the use of which this section applies in contravention of any such licence, assignment, assignation or agreement as is mentioned in this section.

Special provisions as to Crown use during emergency

59.-(1) During any period of emergency within the meaning of this section the powers exercisable in relation to an invention by a government department or a person authorised by a government department under section 55 above shall include power to use the invention for any purpose which appears to the department necessary or expedient -

- (a) for the efficient prosecution of any war in which Her Majesty may be engaged;
- (b) for the maintenance of supplies and services essential to the life of the community;
- (c) for securing a sufficiency of supplies and services essential to the well-being of the community;
- (d) for promoting the productivity of industry, commerce and agriculture;
- (e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade;
- (f) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or
- (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the United Kingdom which is in grave distress as the result of war; and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes.

(2) In this section the use of an invention includes, in addition to any act constituting such use by virtue of section 55 above, any act which would, apart from that section and this section, amount to an infringement of the patent concerned or, as the case may be, give rise to a right under section 69 below to bring proceedings in respect of the application concerned, and any reference in this Act to “use for the services of the Crown” shall, as respects any period of emergency, be construed accordingly.

(3) In this section “period of emergency” means any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section.

(4) A draft of an Order under this section shall not be submitted to Her Majesty unless it has been laid before, and approved by resolution of, each House of Parliament.

UNITED REPUBLIC OF TANZANIA : *Sections 52-59 and 61 of the Patents Act No. 1 of 1987*

52. (1) (a) At any time after four years from the filing date of an application or three years from the grant of a patent, whichever period last expires, any person may, in proceedings instituted by him against the owner of the patent or ill proceedings instituted against him by the said owner, request the court for the grant of a compulsory licence on any of the following grounds that is to say-

- (i) that the patented invention, being capable of being worked in the United Republic, has not been so worked,

- (ii) that the existing degree of working of the patented invention in the United Republic does not meet in reasonable terms the demand for the patented product on the domestic market or for the purposes of exportation;
- (iii) that the working of the patented invention in the United Republic is being hindered or prevented by the importation of the patented product, and
- (iv) that, by reason of the refusal of the owner of the patent to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in the United Republic, or the possibilities of exportation from the United Republic, are unfairly and substantially prejudiced.

(b) “Where the patented invention is a process, the phrase “patented product” in paragraph (a) means a product obtained directly by means of the process.

(2) A compulsory licence shall not be granted in respect of a patent if the owner of the patent satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances.

53.-(1) Where the patented invention cannot be worked without infringing rights derived from an earlier patent the owner of the later patent may, in proceedings instituted by him against the owner of the earlier patent or in proceedings instituted against him by the latter owner, request the court at any time for the grant of a compulsory licence with respect to the earlier patent to the extent necessary for the working of his invention if the invention-

- (i) serves industrial purposes different from those served by the invention which is the subject of the earlier patent; or
- (ii) constitutes substantial technical progress in relation to that last mentioned invention;

(2) If the two inventions mentioned in subsection (1) serve the same industrial purposes, a compulsory licence may be granted under that subsection only on condition that a compulsory licence shall also be granted in respect of the later patent to the owner of the earlier patent if he so requests.

(3) In this section, “earlier patent” means a patent granted on an earlier application or benefiting from an earlier validly claimed priority date, and “later patent” shall be construed accordingly.

54.-(1) The Minister may by order published in the *Gazette* direct that, for patented inventions concerning certain kinds of products, or processes for the manufacture of such products, declared in the order to be of vital importance for the defence or the economy of the or for public health, compulsory licences may be granted.

(2) Compulsory licences with respect to any products or processes specified in the order referred to in subsection (1) may be requested at any time after the grant of the relevant patent, in court proceedings instituted against or by the owner of the said patent.

55. A compulsory licence shall not be granted unless the person-requesting such licence-

(a) satisfies the court that he has asked the owner of the patent for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time, and

(b) offers guarantees satisfactory to the court to work the relevant invention sufficiently to remedy the deficiencies or to satisfy the requirements, which gave rise to his request.

56.-(1).In considering a request for a compulsory licence, the court shall first decide whether a compulsory licence may be granted and shall then, if it decides in favour of the grant and taking into account any terms agreed by the parties, proceed to fix the terms, which shall be deemed to constitute a valid contract, -between the parties and shall be governed by the provisions of Part X.

(2) Infixing the terms under subsection (1), the court shall ensure that the compulsory licence-

(a) entitles the licensee to do any act which is mentioned in section 35, except that this shall not apply to importation unless the application was made under section 54;

(b) does not entitle the licensee to grant further licences, without the consent of the owner of the patent;

(c) is non-exclusive, and

(d) provides for the payment to the owner of the patent of remuneration which is equitable with due regard to all the circumstances of the case.

(3) A representative of the Registrar shall have the right to appear and be heard at the hearing of an application for a compulsory licence,

61.-(1) Where a vital public interest and in particular, national security, health or the development of vital sectors of the public economy-requires that one or more acts referred to in section 35 be performed respect to a patented invention, the Minister ma, patented invention shall, even in the absence of the owner of the patent, be exploited by a government person designated by the Minister subject to ther tion to the owner of the patent.

(2) The Minister shall take his decision in accordance with,

(1) after consultation with the Registrar and after hearing , the patent owner and any licensee shall be invited.

(3) Once the decision of the Minister has been taken, the Registrar shall fix the amount of the remuneration to be paid to the owner of the patent, such remuneration being equitable with due regard to all the circumstances of the case.

(4) The owner of the patent may appeal to the court against the decision of the Registrar fixing the amount of remuneration referred to in subsection (3) but such appeal shall not suspend the effects of the decision referred to in subsection (1),

UNITED STATES OF AMERICA : *Title 28, part IV, Chapter 91, paragraph 1498 letter a) of the USC*

a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. Reasonable and entire compensation shall include the owner's reasonable costs, including reasonable fees for expert witnesses and attorneys, in pursuing the action if the owner is an independent inventor, a nonprofit organization, or an entity that had no more than 500 employees at any time during the 5-year

period preceding the use or manufacture of the patented invention by or for the United States. Notwithstanding [1] the preceding sentences, unless the action has been pending for more than 10 years from the time of filing to the time that the owner applies for such costs and fees, reasonable and entire compensation shall not include such costs and fees if the court finds that the position of the United States was substantially justified or that special circumstances make an award unjust.

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The court shall not award compensation under this section if the claim is based on the use or manufacture by or for the United States of any article owned, leased, used by, or in the possession of the United States prior to July 1, 1918.

A Government employee shall have the right to bring suit against the Government under this section except where he was in a position to order, influence, or induce use of the invention by the Government. This section shall not confer a right of action on any patentee or any assignee of such patentee with respect to any invention discovered or invented by a person while in the employment or service of the United States, where the invention was related to the official functions of the employee, in cases in which such functions included research and development, or in the making of which Government time, materials or facilities were used.

(b) Hereafter, whenever the copyright in any work protected under the copyright laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government and with the authorization or consent of the Government, the exclusive action which may be brought for such infringement shall be an action by the copyright owner against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation as damages for such infringement, including the minimum statutory damages as set forth in section 504 (c) of title 17, United States Code: Provided, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the copyrighted work by the Government: Provided, however, That this subsection shall not confer a right of action on any copyright owner or any assignee of such owner with respect to any copyrighted work prepared by a person while in the employment or service of the United States, where the copyrighted work was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: And provided further, That before such action against the United States has been instituted the appropriate corporation owned or controlled by the United States or the head of the appropriate department or agency of the Government, as the case may be, is authorized to enter into an agreement with the copyright owner in full settlement and compromise for the damages accruing to him by reason of such infringement and to settle the claim administratively out of available appropriations.

Except as otherwise provided by law, no recovery shall be had for any infringement of a copyright covered by this subsection committed more than three years prior to the filing of the complaint or counterclaim for infringement in the action, except that the period between the date of receipt of a written claim for compensation by the Department or agency of the Government or corporation owned or controlled by the United States, as the case may be, having authority to settle such claim and the date of mailing by the Government of a notice to the claimant that his claim has been denied shall not be counted as a part of the three years, unless suit is brought before the last-mentioned date.

(c) The provisions of this section shall not apply to any claim arising in a foreign country.

(d) Hereafter, whenever a plant variety protected by a certificate of plant variety protection under the laws of the United States shall be infringed by the United States, by a corporation owned or controlled by the United States, or by a contractor, subcontractor, or any person, firm, or corporation acting for the Government, and with the authorization and consent of the Government, the exclusive remedy of the owner of such certificate shall be by action against the United States in the Court of Federal Claims for the recovery of his reasonable and entire compensation as damages for such infringement: Provided, That a Government employee shall have a right of action against the Government under this subsection except where he was in a position to order, influence, or induce use of the protected plant variety by the Government: Provided, however, That this subsection shall not confer a right of action on any certificate owner or any assignee of such owner with respect to any protected plant variety made by a person while in the employment or service of the United States, where such variety was prepared as a part of the official functions of the employee, or in the preparation of which Government time, material, or facilities were used: And provided further, That before such action against the United States has been instituted, the appropriate corporation owned or controlled by the United States or the head of the appropriate agency of the Government, as the case may be, is authorized to enter into an agreement with the certificate owner in full settlement and compromise, for the damages accrued to him by reason of such infringement and to settle the claim administratively out of available appropriations.

(e) Subsections (b) and (c) of this section apply to exclusive rights in mask works under chapter 9 of title 17, and to exclusive rights in designs under chapter 13 of title 17, to the same extent as such subsections apply to copyrights.

URUGUAY :*Articles 54-55, 60-61, 69-70 and 73 of the Law No. 17.164 of 13/01/2000
Regulating Rights and Obligations Relating to Patents, Utility Models and
Industrial Designs*

54. Any interested party may request a compulsory license after three years have elapsed since the grant of the patent or four years since the date of application, whichever expires last, if the invention has not been exploited or if serious and effective preparations have not been made for its exploitation or if exploitation has been suspended for more than one year, provided that there are no reasons of force majeure.

In addition to the reasons recognized in the legislation, insurmountable objective problems of a technical or legal nature such as delays in the granting of authorizations by government bodies, independent of the will of the owner of the patent, which make working the patent impossible, shall be considered reasons of force majeure.

The exploitation of a patent shall include its production, use, import or any other commercial activity undertaken and related to its subject matter.

In this respect, the working of the patent by a representative or licensee shall be considered carried out by the owner of the patent.

55. In special situations that might affect the general interest, defense or national security, the economic, social and technological development of certain sectors strategic for Uruguay, as well as for urgent health reasons or other like reasons of public interest, the Executive may, by means of a special resolution, grant compulsory licenses or other uses without the patent

owner's consent and their scope and term shall be adapted to the purpose for which they were granted.

60. By means of a special decision, the National Industrial Property Directorate may grant compulsory licenses for a patent if the competent authority, following administrative or judicial proceedings which give the owner the right of defense and other guarantees, has determined that the owner has been involved in anti-competitive practices, or has abused the rights conferred by the patent or a dominant market position.

61. The circumstances cited in the preceding Article shall include the following:

- (a) the fixing of prices that are excessive in comparison with the average international market price for the patented product;
- (b) offers to supply the market at prices significantly lower than those proposed by the owner of the patent;
- (c) refusal to furnish the local market with adequate and regular supplies of the raw materials or the product patented, on fair commercial terms;
- (d) obstructing or causing prejudice to commercial or production activities in Uruguay;
- (e) any acts which restrict trade to an unjustified degree or are detrimental to the transfer of technology.

69. If a patented invention or utility model cannot be exploited in Uruguay without infringing an earlier patent, the owner or a licensee under any title of one of the patents may request the grant of a compulsory license covering the other dependent patent if it is needed to work the patent and avoid infringement.

Where the subject matter of one patent is a product and the subject matter of the other a process, it shall be considered that they are dependent patents for the purposes of their working.

70. Licenses or uses without the owner's consent for the purpose of working a dependent patent shall be granted subject to the following conditions:

- (a) the invention claimed in the second patent must represent a significant technical step of considerable economic importance in comparison with the invention claimed in the first patent;
- (b) the owner of the first patent shall have the right to obtain a cross license on fair terms in order to work the invention claimed in the second patent;
- (c) assignment of the authorized use of the first patent shall include use of the second patent.

73. A compulsory license or other uses without the owner's consent may not:

- (a) be exclusive;
- (b) be the subject of a sublicense;
- (c) be granted to a defrauder;
- (d) be transferred without the firm or enterprise or the part thereof which exploits the subject matter of the license.

UZBEKISTAN : *Article 32 of the Law on Inventions, Utility Models and Industrial Designs of 29/08/2002*

Article 32. Provision of the right to use industrial property subject matter

Any person who is not a patent owner shall be entitled to use industrial property subject matter protected by a patent only with the consent of the patent owner on the basis of a licensing agreement.

A patent owner may submit to the Patent Office a request to grant any person the right to use industrial property subject matter (open license). In this case, the patent fee for maintaining the patent in force shall be reduced by 50 per cent from the year following that of publication of information concerning such a request by the Patent Office.

A person who has expressed a desire to acquire an open license shall conclude with a patent owner an agreement to grant a non-exclusive license. Disputes relating to the conditions of an agreement shall be examined by the courts. A request by a patent owner for the grant of the right to an open license shall not be withdrawn.

In the cases provided for by legislation, the Cabinet of Ministers of the Republic of Uzbekistan may permit the use of industrial property subject matter without the consent of the patent owner but with the payment of appropriate compensation thereto.

If a patent owner is unable to use industrial property subject matter in connection with the fact that other protected subject matter, belonging to another natural or legal person, is used therein, he shall be entitled to demand from that person the grant of a license for the use of this subject matter on the conditions provided for by agreement.

VIET NAM : *Articles 132, 133, 136, 137 and 145-146 of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005*

Article 132.- Elements limiting industrial property rights

Under this Law, industrial property rights may be limited by the following elements:

1. Right of prior users to inventions or industrial designs;
2. Obligations of owners, including:
 - a/ To pay remunerations to the authors of inventions, industrial designs or layout-designs;
 - b/ To use inventions or marks.
3. Licensing of inventions under decisions of state competent agencies.

Article 133.- Rights to use inventions on behalf of the State

1. Ministries and ministerial-level agencies shall have the right to, on behalf of the State, use or permit other organizations or individuals to use inventions in domains under their respective management for public and non-commercial purposes, national defense, security, disease prevention and treatment and nutrition for the people, and to meet other urgent social needs without having to obtain permission of invention owners or their licensees under exclusive contracts (hereinafter referred to as holders of exclusive right to use inventions) according to Articles 145 and 146 of this Law.

2. The use of inventions mentioned in Clause 1 of this Article shall be limited within the scope of and under the conditions for licensing provided for in Clause 1, Article 146 of this Law, except where such inventions are created by using material-technical facilities and funds from the state budget.

Article 136.- Obligation to use inventions and marks

1. Owners of inventions are obliged to manufacture protected products or apply protected processes to satisfy the requirements of national defense, security, disease prevention and treatment and nutrition for the people or to meet other social urgent needs. When there arise the needs mentioned in this Clause but invention owners fail to perform such obligation, the competent state agency may license such inventions to others without permission of invention owners according to the provisions of Articles 145 and 146 of this Law.
2. Owners of marks are obliged to use such marks continuously. Where a mark has not been used for 5 consecutive years or more, the ownership right to such mark shall be invalidated according to the provisions of Article 95 of this Law.

Article 137.- Obligations to authorize the use of principal inventions for the purpose of using dependent inventions

1. A dependent invention means an invention created based on another invention (hereinafter referred to as principal invention) and may only be used on the condition that the principal invention is also used.
2. Where the owner of a dependent invention can prove that his/her invention makes an important technical advance as compared with the principal invention and has a great economic significance, he/she may request the owner of the principal invention to license such principal invention with reasonably commercial price and conditions.
Where the owner of a principal invention fails to satisfy the request of the owner of a dependent invention without justifiable reasons, the concerned competent state agency may license such invention to the owner of the dependent invention without permission of the owner of the principal invention according to the provisions of Articles 145 and 146 of this Law.

Article 145.- Bases for compulsory licensing of inventions

1. In the following cases, the right to use an invention may be licensed to another organization or individual under a decision of the competent state agency defined in Clause 1, Article 147 of this Law without permission from the holder of exclusive right to use such invention:
 - a/ Where the use of such invention is for public and non-commercial purposes or in service of national defense, security, disease prevention and treatment and nutrition for people or other urgent needs of the society.
 - b/ Where the holder of exclusive right to use such invention fails to fulfill the obligations to use such invention provided for in Clause 1, Article 136 and Clause 5, Article 142 of this Law upon the expiration of a 4-year duration as from the date of filing the invention registration application and the expiration of a 3-year duration as from the date of granting the invention patent;
 - c/ Where a person who wishes to use the invention fails to reach an agreement with the holder of exclusive right to use such invention on the entry of an invention license contract in spite of his/her efforts made within a reasonable time for negotiation on satisfactory commercial price and conditions;
 - d/ Where the holder of exclusive right to use such invention is considered having performed anticompetition practices banned by competition law.
2. The holder of exclusive right to use an invention may request the termination of the use right when the bases for licensing provided for in Clause 1 of this Article no longer exist and are unlikely to recur, provided that such termination shall not be prejudicial to the invention licensee;

Article 146.- Conditions of limitation on the right to use inventions licensed under compulsory decisions

1. The right to use an invention licensed under a decision of a competent state agency must be compliant with the following conditions:

- a/ Such licensed use right is non-exclusive;
- b/ Such licensed use right is only limited to a scope and duration sufficient to achieve the licensing objectives, and largely for the domestic market, except for the cases specified at Point d, Clause 1, Article 145 of this Law. For an invention in semi-conductor technology, the licensing thereof shall be only for public and non-commercial purposes or for handling anti-competition practices according to the provisions of the competition law;
- c/ The licensee must neither assign nor sub-license such right to others, except where the assignment is effected together with the transfer of his/her business establishment;
- d/ The licensee shall have to pay the holder of exclusive right to use the invention a satisfactory compensation depending on the economic value of such use right in each specific case, and compliant with the compensation bracket set by the Government.

2. Apart from the conditions specified in Clause 1 of this Article, the right to use an invention licensed in any of the cases specified in Clause 2, Article 137 of this Law must also satisfy the following conditions:

- a/ The holder of exclusive right to use the principal invention shall also be licensed to use the dependent invention on reasonable terms;
- b/ The licensee of the right to use the principal invention must not assign such right, except where the assignment is effected together with all rights to the dependent invention.

ZAMBIA : Sections 37-38 and 40-41 of the Patent Act of 1958 (Chapter 400) as last amended by Act No. 26 of 28/12/1987

Compulsory licence in case of abuse or insufficient use of patent rights

37. (1) Subject to the provisions of subsection (14), any person interested who can show that he has been unable to obtain a licence under a patent on reasonable terms may, after the expiration of a period of three years subsequent to the date on which that patent was sealed or four years subsequent to the date on which the application in respect thereof was lodged, whichever period last expires, apply to the Registrar in the prescribed manner for a compulsory licence on the ground that the reasonable requirements of the public with respect to the invention in question have not been or will not be satisfied.

(2) Every application under this section shall set out fully the nature of the applicant's interest, the facts on which he bases his case and the relief he seeks, and shall be accompanied by an affidavit verifying the facts set out in such application.

(3) If, after consideration of any such application, the Registrar is satisfied that the applicant has a bona fide interest, and that a prima facie case for relief has been made out, he shall direct the applicant to serve copies of the application and of the relevant affidavit upon the patentee and upon any other person appearing from the register to be interested in the patent, and to advertise the application in the prescribed manner.

(4) If the patentee or any other person wishes to oppose the grant of a licence under this section, he may, within the prescribed period or within such further period as the Registrar may on application allow, deliver to the Registrar a counter-statement, verified by affidavit.

setting out fully the grounds on which the application is opposed, and shall at the same time serve upon the applicant copies of the counter-statement.

(5) When, in relation to an application or an opposition thereto, the foregoing provisions of this section have been complied with to the extent therein required, the Registrar shall send all relevant papers to the High Court and that court shall arrange for the matter to be heard in the manner prescribed and, subject to the provisions of this section, the High Court may make such order therein as it deems just.

(6) The reasonable requirements of the public referred to in subsection (1) shall be deemed not to have been satisfied in any of the following circumstances, namely:

(a) if the patented invention, being an invention capable of being worked in Zambia, is not being worked therein on a commercial scale and there is no satisfactory reason for such non-working:

Provided that, if an application for a compulsory licence is made on this ground and the High Court is of the opinion that the time which has elapsed since the sealing of the patent has by reason of the nature of the invention or for any other reason been insufficient to enable the invention to be worked within Zambia on a commercial scale, the High Court may make an order adjourning the hearing of the application for such period as will in its opinion be sufficient for that purpose;

(b) if the working of the invention within Zambia on a commercial scale is being prevented or hindered by the importation of the patented article by the patentee or persons claiming under him, or by persons directly or indirectly purchasing from him or by persons against whom the patentee is not taking or has not taken proceedings for infringement;

(c) if the demand for the patented article in Zambia is not being met to an adequate extent and on reasonable terms;

(d) if by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry of Zambia or the trade of any person or class of persons trading in Zambia, or the establishment of any new trade or industry in Zambia, is being prejudiced, and it is in the public interest that a licence or licences should be granted;

(e) if any trade or industry in Zambia, or any person or class of persons engaged therein, is being prejudiced by unfair conditions attached by the patentee, whether before or after the commencement of this Act, to the purchase, hire, licence or use of the patented article, or the using or working of the patented process;

(f) if any condition which under the provisions of section forty-nine is null and void as being in restraint of trade and contrary to public policy, has been inserted in any contract made in relation to the sale or lease of or any licence to use or work any article or process protected by the patent:

Provided that, for the purpose of determining whether there has been any abuse of the monopoly rights under a patent, due regard shall be had to the fact that patents are granted not only to encourage invention but also to secure that inventions shall so far as possible be worked on a commercial scale in Zambia without undue delay.

Inventions relating to food and certain other commodities

38. (1) Subject to the provisions of subsection (14) of section thirty-seven and without prejudice to the other foregoing provisions of this Act, where a patent is in force in respect of-

(a) a substance capable of being used as food or medicine, or in the production of food or medicine;

(b) a process for producing such a substance as aforesaid; or

(c) any invention capable of being used as or as part of a surgical or curative device;

the High Court shall, on application made to it by any person interested, order the grant to the applicant of a licence under the patent on such terms as it thinks fit unless it appears to the Court that there are good reasons for refusing the application.

(2) In setting the terms of licences under this section, the High Court shall endeavour to secure that food, medicines, and surgical and curative devices shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

(3) A licence granted under this section shall entitle the licensee to make, use, exercise and vend the invention as a food or medicine, or for the purposes of the production of food or medicine or as part of a surgical or curative device, but for no other purposes.

(As amended by Act No. 18 of 1980)

Use of patented inventions for the services of the State

40. (1) Notwithstanding anything in this Act, any Government department or any person authorised in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with the provisions of this section.

(2) If and so far as the invention has, before the effective date of the relevant claim of the completed specification, been duly recorded by or tried by or on behalf of a Government department or a person authorised in terms of subsection (1), otherwise than in consequence of the communication thereof directly or indirectly by the patentee or any person from whom he derives title, any use of the invention by virtue of this section may be made by such Government department or person free of any royalty or other payment to the patentee.

(3) If and so far as the invention has not been so recorded or tried as aforesaid, any use of the invention made by virtue of this section at any time after the acceptance of the complete specification in respect of the patent, or in consequence of any such communication as aforesaid, shall be made upon such terms as may be agreed upon, either before or after the use, between the Minister and the patentee with the approval of the Minister responsible for finance, or as may in default of agreement be determined by the High Court on a reference under subsection (1) of section forty-two.

(4) The authority of the Minister in respect of an invention may be given under this section either before or after the patent is granted and either before or after the acts in respect of which the authority is given are done, and may be given to any person, whether or not he is authorised directly or indirectly by the patentee to make, use, exercise or vend the invention.

(5) Where any use of an invention is made by or with the authority of the Minister under this section, then, unless it appears to him that it would be contrary to the public interest so to do, the Minister shall notify the patentee as soon as practicable after the use is begun, and furnish him with such information as to the extent of the use as he may from time to time require.

(6) For the purposes of this section, section forty-one and section forty-two, any use of an invention for the supply to the government of any country outside Zambia, in pursuance of any agreement or arrangement between the Government and the government of that country, of articles required for the defence of that country shall be deemed to be a use of the invention

for the services of the State, and the power of a Government department or a person authorised by the Minister under this section to make, use and exercise an invention shall include power-

(a) to sell such articles to the government of any country in pursuance of any such agreement or arrangement as aforesaid; and

(b) to sell to any person any articles made in the exercise of the powers conferred by this section which are no longer required for the purpose for which they were made.

(7) The purchaser of any articles sold in the exercise of powers conferred by this section, and any person claiming through him, shall have power to deal with them in the same manner as if the patent were held on behalf of the President.

(8) The Minister may, by statutory instrument, make regulations governing the rights of third parties in relation to any use of a patented invention, or an invention in respect of which an application for a patent is pending, made for the services of the State in terms of this section or section forty-one.

Special provisions as to State use during emergency

41. (1) For the purposes of this section, the expression "period of emergency" means any period beginning on such date as may be declared by the Minister by statutory notice to be the commencement, and ending on such date as may be so declared to be the termination, of a period of emergency.

(2) During any period of emergency the powers exercisable in relation to an invention by a Government department or a person authorised by the Minister under section forty, shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient-

(a) for the efficient prosecution of any war in which the Republic may be engaged;

(b) for the maintenance of supplies and services essential to the life of the community;

(c) for securing a sufficiency of supplies and services essential to the well-being of the community;

(d) for promoting the productivity of industry, commerce and agriculture;

(e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade;

(j) generally for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or

(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Her Britannic Majesty's dominions or any foreign countries that are in grave distress as the result of war;

and any reference in that section or in section forty-two to the services of the State shall be construed as including a reference to the purposes aforesaid.

(As amended by C.N. No. 185 of 1964 and S.I. No. 175 of 1965)

ANDEAN COMMUNITY (BOLIVIA, COLOMBIA, ECUADOR, PERU, VENEZUELA) :
*Articles 61 and 65-68 of the Decision No. 486 of 14/09/ 2000 of the Commission of the
Andean Community - Common Industrial Property Regime (Cartagena Agreement)*

*Chapter VII
Compulsory License Regime*

61. On the expiry of a period of three years following the grant of the patent, or four years following the application for the patent, whichever is the longer, the competent national office may grant a compulsory license for the industrial manufacture of the product to which the patent relates, or for the full use of the patented process, at the request of any interested party, but only where, at the time of the request, the patent has not been worked as provided in Articles 59 and 60 in the member country in which the license is applied for, or where the working of the invention has been suspended for more than a year.

The compulsory license shall not be granted if the owner of the patent provides legitimate reasons for his failure to act, which may be reasons of force majeure, in accordance with the domestic provisions of each member country.

A compulsory license shall only be granted where the person who requests it has previously attempted to obtain a contractual license from the owner of the patent on reasonable commercial terms and conditions, and where that attempt has not had any effect within a reasonable time.

65. On a declaration by a member country of the existence of public interest, emergency or national security considerations, and only for as long as those considerations obtain, the patent may be made subject to compulsory licensing. In that case the competent national office shall grant such licenses as may be applied for. The owner of the patent so licensed shall be notified where reasonably possible.

The competent national office shall specify the scope or extent of the compulsory license, and in particular the term for which it is granted, its subject matter and the amount of royalties and the conditions for the payment thereof.

The grant of a compulsory license for reasons of public interest shall not diminish the right of the owner of the patent to continue to work the said patent.

66. The competent national office shall, either ex officio or at the request of a party, and after having obtained the consent of the national authority on free competition, grant compulsory licenses where practices are noted that adversely affect free competition, especially an abuse by the owner of the patent of his dominant position on the market.

In such cases, when the amount of royalties is determined, due regard shall be given to the need to correct anti-competitive practices.

The competent national office shall refuse to revoke the compulsory license where it is probable that the circumstances that gave rise to it could recur.

67. The competent national office shall grant a license at any time where it is applied for by the owner of a patent the working of which requires the use of another, and where the said owner has been unable to secure a contractual license on reasonable terms. Such a license shall, without prejudice to the provisions of Article 68, be subject to the following:

(a) the invention claimed in the second patent must embody substantial technological progress in relation to that claimed in the first;

(b) the owner of the first patent shall have the right to a cross-license on reasonable terms for exploitation of the invention claimed in the patent; and

(c) the license under the first patent may not be assigned without assignment also of the second.

68. Compulsory licenses shall be subject to the following in addition to the foregoing provisions:

- (a) they shall not be exclusive, and no sublicense may be granted;
- (b) they may only be transferred with the part of the enterprise or its intangible assets that enable them to be worked; the transfer shall be evidenced in writing and registered with the competent national office. Failing this they shall be devoid of legal effect;
- (c) they may be revoked, subject to the adequate protection of the legitimate interests of persons who have been authorized under them, where the circumstances that gave rise to them no longer obtain and are unlikely to recur;
- (d) their scope and duration shall be limited according to the purposes for which they have been granted;
- (e) in the case of patents for invention that protect semiconductor technology, the compulsory license shall be granted only for public, non-commercial use or to remedy or rectify a practice declared contrary to free competition by the competent national authority under Articles 65 and 66;
- (f) they shall provide for adequate remuneration according to the circumstances of each case, due regard being had to their economic value, without prejudice to the provisions of Article 66; and
- (g) their use shall be mainly to supply the domestic market.

EUROPEAN UNION : *Article 1 of the Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.*

Article 1

Scope

This Regulation establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems.

Member States shall grant a compulsory licence to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10.

GCC : *Section 19 of the Patent Regulation of the Cooperation Council for the Arab States of the Gulf (as at 23704/2002)*

Article 19

19/1 where the owner has never exploited the patented invention, or has insufficiently exploited it according to Article (13), the Board of Directors may grant a compulsory license, with observation of the following:

19/1/1 At least three years have elapsed after the grant of the patent.

19/1/2 the applicant proves that he exerted, over a reasonable period of time, efforts to obtain license from the patent owner for an adequate compensation, under fair terms.

19/1/3 that the license is not exclusive.

19/1/4 that the license is essentially granted to meet the demands of the local market.

19/1/5 that the license decision defines the scope and terms of the license, according to the purposes for which it was granted.

19/1/6 that the patent owner shall be paid an adequate compensation.

19/1/7 that the exploitation of the patent shall be limited to the licensee.

The license shall not be transferable to others except in case of change of ownership of the licensee's establishment, or the section, which exploits the patent, provided the Board of Directors, approves such transfer.

19/2 should the invention relate to "semi - Conductors" technologies, licensing shall only be permitted for public, general, and none commercial purposes, or to rectify practices that proved none competitive by judiciary or administrative decisions.

OAPI (Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, Côte d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Togo): *Articles 46-57 of the Agreement Revising the Bangui Agreement of 02/03/1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic), 24/02/ 1999)*

Article 46

Non-Voluntary License for Non-Working

(1) At the request of any person made after the expiry of a period of four years from the filing date of the patent application or three years from the date of grant of the patent, whichever period expires last, a non-voluntary license may be granted where one or more of the following conditions are fulfilled:

(a) the patented invention is not being worked on the territory of a member State at the time the request is made;

(b) the working of the patented invention on such territory does not meet the demand for the protected product on reasonable terms;

(c) on account of the refusal of the owner of the patent to grant licenses on reasonable commercial terms and procedures, the establishment or development of industrial or commercial activities on such territory is unfairly and substantially prejudiced.

(2) Notwithstanding the provisions of paragraph (1) above, a non-voluntary license may not be granted if the owner of the patent provides legitimate reasons for the non-working of the invention.

Article 47

Non-Voluntary License for a Dependent Patent

Where a patented invention cannot be worked without infringing the rights under an earlier patent whose owner refuses to authorize its use on reasonable commercial terms and procedures, the owner of the later patent may obtain a non-voluntary license for such use from the court on the same terms as those that apply to the non-voluntary licenses granted under Article 46 and on the following additional conditions:

(a) the invention claimed in the later patent must represent substantial technical progress, of considerable economic interest, in relation to the invention claimed in the earlier patent;

(b) the owner of the earlier patent has the right to a reciprocal license on reasonable terms for the use of the invention claimed in the later patent;

(c) the use authorized in relation to the earlier patent shall be intransferable except where the later patent is also transferred.

Article 50

Rights and Obligations of the Holder of a Non-Voluntary License

(1) After the expiry of the time limit for appeal specified in Article 52 of this Annex, or once an appeal decision has been handed down that wholly or partly upholds the decision by which the civil court granted the non-voluntary license, the grant of the latter shall authorize the licensee to exploit the patented invention according to the terms laid down in the decision of the civil court or in the appeal decision, and shall require him to pay the remuneration specified in the said decisions.

(2) The grant of a non-voluntary license shall not affect either license contracts in force or non-voluntary licenses in force and shall not preclude the conclusion of other license contracts or the grant of other non-voluntary licenses. The patentee may not however grant to other licensees more favorable terms than those of the non-voluntary license.

Article 56

Ex-Officio Licenses

(1) Where certain patents are of vital interest to the economy of the country, public health or national defense, or where non-working or insufficient working of such patents seriously compromises the satisfaction of the country's needs, they may be made subject, by an administrative enactment of the competent Minister of the member State concerned, to the non-voluntary license regime. The said enactment shall specify the beneficiary administration or organization, the conditions, term and scope of the non-voluntary license and the amount of royalties payable.

(2) In the absence of amicable agreement between the owner of the patent and the administration concerned on the said conditions, they shall be set by the civil court.

(3) Ex-officio licenses shall be subject to the same conditions as the non-voluntary licenses granted under Article 46.

Article 57

Licenses of Right

(1) Any owner of a patent not precluded by the terms of any previously registered license from granting further licenses may apply to the Organization to have, in respect of his patent, the notice "licenses of right" entered in the Register. The notice shall be entered in the Register and published by the Organization as soon as possible.

(2) The entry of such a notice in the Register shall entitle any person to obtain a license to work the said patent on terms that shall, in the absence of agreement between the parties concerned, be fixed by the civil court. It shall also cause the annual fee to be reduced.

(3) The owner of the patent may at any time apply to the Organization for cancellation of the "licenses of right" entry. If no license is in force, or if all the licensees agree to cancellation, the Organization shall cancel the entry after payment of all the annual fees that would have been payable had the entry not been made in the Register.

- (4) The provisions of Article 26(1) of this Annex shall also apply to licenses of right.
- (5) The beneficiary of a license of right may neither assign it nor grant sublicenses under it.

(2) PROVISIONS OF LAW ON PATENT EXHAUSTION

ALBANIA : *Article 39 of the Patents Act of 07/07/2008*

Article 39

Exhaustion of rights

The rights conferred by a patent shall not extend to acts committed in the Republic of Albania with regard to a product protected by the patent after the said product has been put on the market in the Republic of Albania by the patent's owner or with his consent.

ALGERIA : *Article 12 no.2 of the Patent Ordinance No. 03-07 of 19/07/2003*

Article 12:

— Les droits découlant d'un brevet d'invention ne s'étendent qu'aux actes accomplis à des fins industrielles ou commerciales.

Ces droits ne s'étendent pas :

2°) aux actes concernant le produit couvert par ce brevet après que le produit ait été licitement mis dans le commerce;

ANDORRA : *Article 23 (4) a) of the Patent Act of 10/06/1999*

Article 23 - Rights conferred by a patent

(4) The rights conferred by a patent shall not extend to:

(a) acts concerning a product covered by the patent after that product has been put on the market by the proprietor of the patent, or with his express consent, in Andorra or in any other territory specified in the Implementing Regulations;

ANTIGUA AND BARBUDA : *Section 11 (4) a) of the Patent Act No. 23 of 2003*

Rights conferred 11.

(4) (1) The rights under the patent shall not extend:

(a) to acts in respect of articles which have been put on the market in any country by the owner of the patent or with his consent; or

ARGENTINA : *Article 36 c) of the Patents and Utility Models Law no. 24.481 of 1996*

Artículo 36 - El derecho que confiere una patente no producirá efecto alguno contra:

c) Cualquier persona que adquiriera, use, importe o de cualquier modo comercialice el producto patentado u obtenido por el proceso patentado, una vez que dicho producto hubiera sido puesto lícitamente en el comercio de cualquier país. Se entenderá que la puesta en el comercio es lícita cuando sea de conformidad con el Acuerdo de Derechos de Propiedad Intelectual vinculados con el comercio. Parte III Sección IV Acuerdo TRIP's-GATT.

ARMENIA : *Article 19 (1) and (2) of the Law on Inventions, Utility Models and Industrial Designs of 10/06/2008*

Article 19. Limitations of Rights Conferred by Patent

(1) The patent owner or the owner of exclusive license has no right to prevent to put into civil circulation in the Republic of Armenia a patented invention or utility model or product, developed by patented process, if this product or article has been legally put on the market in the Republic of Armenia by the patent owner or with his consent.

(2) Import of a patented product including an industrial property subject matter or developed by a patented process into the territory of the Republic of Armenia shall not be deemed as infringement of exclusive rights of the patent owner if it has been legally put on the market in a foreign country by the patent owner or with his consent.

BARBADOS : *Article 6 b) of the Patent Act No. 18 of 26/07/2001*
[Limitations of rights.]

6.-(1) The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to

(b) acts in relation to products that have been put on the market in Barbados by the owner of the product or with his consent;

BELARUS : *Article 10 of the Law No. 160-Z on Patents for Inventions, Utility Models and Industrial Designs of 16/12/ 2002*

Acts Not Constituting Infringement of the Exclusive Rights of Patent Owners

10. The following shall not be considered infringements of the exclusive right of the owner of the patent:

– the use, offering for sale, sale, importation or storage for those purposes of a product incorporating a patented invention, utility model or industrial design if that product has been lawfully put on the market in the Republic of Belarus.

BELIZE : *Article 33 (4) a) of the Patents Act, Chapter 253, of 21/06/2000,*

Rights conferred by a patent

(4) The rights under the patent shall not extend to:-

(a) acts in respect of articles which have been put on the market in Belize by the owner of the patent or with his consent;

BHUTAN : *Section 13 (4) (i) of the Industrial Property Act of the Kingdom of Bhutan, 2001*

(4) (a) The rights under the patent shall not extend :

(i) to acts in respect of articles which have been put on the market in Bhutan by the owner of the patent or with his consent;

BOTSWANA : *Section 24(3) a) (i) of the Industrial Property Act No. 14 of 1996*

- (3) (a) The rights under the patent shall not extend to -
(i) acts in respect of articles which have been put on the market in Botswana by the owner of the patent or with his consent,

BRAZIL : *Article 43 IV of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001*

Article 43 - The provisions of the previous article do not apply:

IV - to a product manufactured in accordance with a process or product patent that has been placed on the internal market directly by the patentee or with his consent;

BULGARIA (EU) : *Article 20a (1) of the Law on Patents and Utility Models Registration No. 27/2 of 1993 as last amended by Law no. 59/20 of July 2007*

Exhaustion of Rights

Art. 20a. (new, State Gazette No. 66/2004; amended, State Gazette No. 64/2006, in force as from 09.11.2006) (1) (in force as from the date of accession of the Republic of Bulgaria to the European Union) The exclusive patent right in an invention shall not extend to acts relating to the product enjoying patent protection, where that product has been put on the market in the territory of the European Economic Area by the patent owner or with his consent.

CHINA : *Article 69(1) of the Patent Law of 12/03/1984 as last amended on 27/12/2008*

Article 69. None of the following shall be deemed an infringement of the patent right:

(1) Where, after the sale of a patented product or products directly obtained by using the patented process, which was made by the patentee or an entity/individual authorized by the patentee, any other person uses, offers to sell, sells or imports that product;

COSTA RICA : *Article 16 (2) d) of the Patents Law No. 6867 of 25/04/1983, as last amended by Law No. 8039 of 12/10/2000*

16. -

2. Siempre que las siguientes excepciones no atenten de manera injustificable contra la explotación normal de la patente, ni causen un perjuicio injustificado a los legítimos intereses de su titular o su licenciataria, los derechos conferidos por la patente no se extienden a:

d) Los actos de venta, oferta para la venta, uso, usufructo, importación o cualquier modo de comercialización de un producto protegido por la patente u obtenido por procedimiento patentado, una vez que ha sido puesto en el comercio de cualquier país, con el consentimiento del titular o un licenciataria.

(Así reformado por el artículo 2.d) de la Ley 7979 del 6 de enero del 2000)

DENMARK (EU) : *Section 3 (3) (ii) of the Consolidate Patent Act No. 91 of 28/01/2009*

3 (3) The exclusive right shall not extend to
(ii) acts concerning products put on the market in this country or in another country within the European economic Area (EEA) by the proprietor of the patent or with his consent ,

DOMINICA : *Article 33 (4) (a) of the Patent Act No. 8 of 07/10/1999*

Article 33 (4) the right under the patent shall not extend to:
(a) acts in respect of articles which have been put on the market in Dominica by the owner of the patent or with his consent ;

DOMINICAN REPUBLIC : *Article 30 d) of the Law on Industrial Property No. 20-00 of 18/04/2000*

Artículo 30.- Limitación y agotamiento de los derechos de la patente.

La patente no da el derecho de impedir:

d) La venta, locación, uso, usufructo, la importación o cualquier modo de comercialización de un producto protegido por la patente u obtenido por el procedimiento patentado, una vez que dicho producto ha sido puesto en el comercio de cualquier país, con el consentimiento del titular o de un licenciatario o de cualquier otra forma lícita. No se consideran puestos lícitamente los productos o los procedimientos en infracción de derecho de propiedad industrial;

EGYPT : *Article 10 (1) of the Law on the Protection of Intellectual Property Rights No. 82 of 2002*

Article 10

A patent shall confer on its owner the right to prevent a third party from exploiting the invention by any means.

The right of a patent owner to prevent a third party from importing, using, selling or distributing a product shall lapse when he commercializes the product in any country or authorizes a third party to do so.

EL SALVADOR : *Article 116 d) of the Legislative Decree No. 604 of 15/07/1993 on the Promotion and Protection of Intellectual Property Rights as last amended by Legislative Decree No. 912 of 14/12/2005*

Art. 116. The effects of the patent shall not extend:

(d) to the marketing or use of a product after it has been legally placed on the market for the first time on the national territory.

ESTONIA: *Section 17 of the Patent Act of 16/03/1994, as last amended by the Act of 10/03/2004*

§ 17. Exhaustion of rights

The proprietor of a patent has no right to prohibit acquisition (including import), use, distribution, sale or offer for sale of a product containing the patented invention when the product has been put on the market in the territory of the Republic of Estonia or a State party to the Agreement on the European Economic Area by the proprietor of the patent or with the proprietor's consent.

FINLAND (EU) : *Section 3 (2) no.2 of the Patents Act No. 550 of 15/12/1967 as last amended on 21/07/2006*

Section 3 (6.6.1980/407)

The exclusive right shall not apply to:

(2) use of a patented product that has been put on the market within the European Economic Area by the proprietor of the patent or with his consent; (18.12.1992/1409)

FRANCE (EU) : *Articles L613-2-4 and L613-6 of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 as last amended by Law No. 2007-1544*

Article L613-2-4

Créé par Loi n°2004-1338 du 8 décembre 2004 - art. 5 JORF 9 décembre 2004

La protection visée aux articles L. 613-2-2 et L. 613-2-3 ne s'étend pas à la matière biologique obtenue par reproduction ou multiplication d'une matière biologique mise sur le marché sur le territoire d'un Etat membre de la Communauté européenne ou d'un Etat partie à l'accord sur l'Espace économique européen par le titulaire du brevet ou avec son consentement, lorsque la reproduction ou la multiplication résulte nécessairement de l'utilisation pour laquelle la matière biologique a été mise sur le marché, dès lors que la matière obtenue n'est pas utilisée ensuite pour d'autres reproductions ou multiplications.

Article L613-6

Modifié par Loi n°93-1420 du 31 décembre 1993 - art. 5 JORF 1er janvier 1994

Les droits conférés par le brevet ne s'étendent pas aux actes concernant le produit couvert par ce brevet, accomplis sur le territoire français, après que ce produit a été mis dans le commerce en France ou sur le territoire d'un Etat partie à l'accord sur l' Espace économique européen par le propriétaire du brevet ou avec son consentement exprès.

GEORGIA : *Article 52 a) of the Patent Law of 05/02/1999*

Article 52

Proceeding from the patent, under the infringement of the exclusive right shall not be considered:

a) putting of the product in the civil circulation by the patent owner or with his consent;

GHANA : *Section 30 b) of the Patent Law No. 305A of 30/12/1992*

Limitation of rights

30. The rights under the patent shall—

(b) not extend to acts in respect of articles which have been put on the market in Ghana by the owner of the patent or with his express consent;

GRENADA : *Section 12(4) (a) (i) of the Industrial Property Act of 2002*

(4) (a) The rights under the patent do not extend -

(i) to acts in respect of articles which have been put on the market in Grenada by the owner of the patent or with the owner's consent;

GUATEMALA : *Article 131 of the Industrial Property Law, Decree No. 57 of 18/09/2000*

Artículo 131. Agotamiento del derecho. La patente no dará el derecho de impedir a un tercero realizar negocios mercantiles respecto de un producto protegido por la patente u obtenido por un procedimiento patentado, después de que ese producto se hubiese introducido en el comercio en cualquier país por el titular de la patente o por otra persona con consentimiento del titular o económicamente vinculada a él.

Para los efectos del párrafo anterior, se entenderá que dos personas están económicamente vinculadas cuando una pueda ejercer directa o indirectamente sobre la otra una influencia decisiva con respecto a la explotación de la patente, o cuando un tercero pueda ejercer tal influencia sobre ambas personas.

Cuando la patente proteja material biológico capaz de reproducirse, la patente no se extenderá al material obtenido por multiplicación o propagación del material introducido en el comercio conforme al primer párrafo, siempre que la multiplicación o propagación sea consecuencia necesaria de la utilización del material conforme a los fines para los cuales se introdujo en el comercio, y que el material derivado de tal uso no se emplee para fines de multiplicación o propagación.

HONDURAS : *Article 18 of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

Artículo 18.- (2) Los derechos conferidos por la patente no podrán hacerse valer contra cualquier persona que comercialice, adquiera o use el producto patentado u obtenido por el procesó patentado, luego de que dicho producto hubiera sido introducido lícitamente en el comercio nacional o internacional por el titular de la patente o por sus licenciarios. La patente no confiere el derecho de impedir los actos referidos en el Artículo 50 del Convenio de París para la Protección de la Propiedad Industrial.

HUNGARY (EU) : *Article 20 of the Law on the Protection of Inventions by Patents No. XXXIII of 1995 (Consolidated text of 01.10.2009)*

Exhaustion of the exclusive right of exploitation conferred by patent protection
Article 20

The exclusive right of exploitation conferred by patent protection shall not extend to acts concerning a product put on the market in the territory of the European Economic Area by the patentee or with his express consent, except where the patentee has legitimate interests in opposing the further marketing of the product.

ICELAND (EUROPEAN ECONOMIC AREA) : *Article 3 (2) no.2 of the Patents Act No. 17 of 1991 as last amended according to Act No. 167/2007*

Article 3(2)The following are excepted from the exclusive right:

2. use of the product protected by the patent which is put on the market within the European Economic Area, within a member state of the incorporation of the European Free Trade Association or in the Faroe Islands by the proprietor of the patent or with his consent;

INDIA : *Section 107A of the Patent Act No. 39 of 1970 as last amended in 2005*

107A. For the purposes of this Act,-

- (a) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;
- (b) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights.

IRELAND (EU) : *Sections 41 and 43 of the Patents Act No. 1 of 27/02/1992, as last amended by Law No. 31 of 2006*

Prevention of indirect use of invention. 41.—(1) A patent while it is in force shall also confer on its proprietor the right to prevent all third parties not having his consent from supplying or offering to supply in the State a person, other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention, for putting it into effect therein, when the third party knows, or it is obvious in the circumstances to a reasonable person, that the said means are suitable and intended for putting that invention into effect.

(2) Subsection (1) shall not apply when the means referred to therein are staple commercial products, except when the third party induces the person supplied to commit acts which the proprietor of a patent is enabled to prevent by virtue of section 40.

(3) Persons performing acts referred to in paragraph (a), (b), or (c) of section 42 shall not be considered to be parties entitled to exploit an invention pursuant to subsection (1).

Limitation of rights. 43.—The rights conferred by a patent shall not extend to any act which, pursuant to any obligations imposed by the law of the Treaties establishing the European Communities, cannot be prevented by the proprietor of the patent.

ITALY (EU) : *Article 5 of the Industrial Property Code, Legislative Decree No.30 of 10/02/2005*

Art. 5. Esaurimento

1. Le facoltà esclusive attribuite dal presente codice al titolare di un diritto di proprietà industriale si esauriscono una volta che i prodotti protetti da un diritto di proprietà industriale siano stati messi in commercio dal titolare o con il suo consenso nel territorio dello Stato o nel territorio di uno Stato membro della Comunità europea o dello Spazio economico europeo.

2. Questa limitazione dei poteri del titolare tuttavia non si applica, con riferimento al marchio, quando sussistano motivi legittimi perche' il titolare stesso si opponga all'ulteriore commercializzazione dei prodotti, in particolare quando lo stato di questi e' modificato o alterato dopo la loro immissione in commercio.

3. Le facoltà esclusive attribuite al costitutore di una varietà protetta e delle varietà essenzialmente derivate dalla varietà protetta quando questa non sia, a sua volta, una varietà essenzialmente derivata, al costitutore delle varietà che non si distinguono nettamente dalla varietà protetta e al costitutore delle varietà la cui produzione necessita del ripetuto impiego della varietà protetta, non si estendono:

- a) al materiale di riproduzione o di moltiplicazione vegetativa, quale che ne sia la forma;
- b) al prodotto della raccolta, comprese piante intere e parti di esse;
- c) a qualsiasi prodotto fabbricato direttamente a partire dal prodotto della raccolta e,
- d) ad ogni altro materiale derivato da quelli indicati che siano stati venduti o commercializzati dallo stesso costitutore o con il suo consenso nel territorio dello Stato o di uno Stato membro della Comunità europea o dello Spazio economico europeo, a meno che si tratti di atti che implicano una nuova riproduzione o moltiplicazione della varietà protetta oppure un'esportazione del materiale della varietà stessa che consenta di riprodurla in uno Stato che non protegge la varietà del genere o della specie vegetale a cui appartiene, salvo che il materiale esportato sia destinato al consumo.

JORDAN : *Article 37 of the Law on Patents No. 32 of 1999, as last amended by Law No. 71 of 2001*

Article 37

A. The provisions of this law shall not prevent any person from importing any materials or goods from a third party if that party enjoys the legal protection of the same patent protected in the Kingdom and if that importation is lawful, complies with the principles of commercial competition and fairly takes into account the economic value of the protected patent.

B. In spite of the inclusions of paragraph (A) of this article and without prejudice to the provisions of the related International conventions, goods covered by patent of invention may not be imported by any Licensee, if the Licensing contract prohibit him from importation to the kingdom, provided that the patent owner notify in writing the Customs Administration and the Registrar in this respect. The Registrar shall, at the expense of the patent owner, publish this notification in at least one of Local daily gazettes; and the applicable legislations shall apply to this case.

KAZAKHSTAN : *Article 12 of the Patent Act No. 427 of 16/07/1999*

Article 12. Acts Not Infringing the Exclusive Right of the Patent Owner

The following shall not constitute acts infringing the exclusive right of the patent owner:

◦ the use of the subject matter incorporating the protected industrial property subject matter for the marketing purposes in the territory of the Republic of Kazakhstan where the act is done in a legal way.

KENYA: *Section 58 (2) of the Industrial Property Act No. 3 of 27/07/2001*

Limitation of Rights

58 (2) The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya.

KYRGYZSTAN: *Article 13 no.4 of the Patent Law of 14/01/1998, as lat amended on 27/02/2003*

Article 13. Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner

The following is not recognized as an infringement of the exclusive right of the patent owner:

4) application of means containing objects of industrial property protected by patents if these means are introduced into an economic turnover in a legal way in compliance with the rights granted by a patent owner. In this case the person who under the permission of the patent owner acquires a mean containing patented object of an industrial property or manufactured with the use of the patented method, shall have the right to use or dispose this mean without additional permission, unless otherwise is provided by the agreement.

LATVIA (EU) : *Section 21 of the Patent Law of 15/02/2007*

Section 21. Exhaustion of Rights

(1) The rights resulting from the patent shall not extend to the activities which have been carried out with the patented product in the European Economic Area, after this product has been put on the market in the European Economic Area by the proprietor of the patent himself or herself or another person with his or her consent, unless the proprietor of the patent has a legal basis to object against the further commercialisation of the product.

(2) The protection referred to in Section 19, Paragraphs one, two and three of this Law shall not extend to the biological material, which has been obtained by multiplying such biological material, which has been put on market in the European Economic Area by the proprietor of the patent himself or herself or by another person with his or her consent, if multiplication arises directly from the use thereof, for the purposes of which the biological material was sold with a condition that the obtained material shall not be used afterwards for another multiplication.

LIBERIA : *Section 17 (4) (a) (i) of the Industrial Property Act of 20/03/2003*

(-1)(a) The rights under the patent shall not extend

- (i) to acts in respect of articles which have been put on the market in Liberia by the owner of the patent or with his consent,

LUXEMBOURG (EU) : *Article 48 of the Patents Law of 20/07/1992*

Exhaustion of Rights Conferred by the Patent

Art. 48.-1. The rights afforded by a patent shall not extend to acts concerning a product covered by that patent which are done on Luxembourg territory after such product has been put on the market in one of the States of the European Economic Community by the owner of the patent or with his express consent unless there exist reasons in accordance with the rules of Community law for the rights conferred by the patent to extend to such acts.

2. Paragraph 1 shall also apply with respect to a product put on the market by the owner of the national patent, granted in another Community State for the same invention, who is economically linked to the owner of the patent referred to in paragraph 1. For the purposes of this paragraph, two persons shall be deemed economically linked where one of them may exercise on the other, directly or indirectly, with regard to the working of the patent, a decisive influence or where a third person may exercise such influence on one of such persons.

3. Paragraphs 1 and 2 shall not apply where the product has been put on the market under a compulsory or ex officio license.

MADAGASCAR: *Section 30 (2) of the Industrial Property Law, Ordinance No. 89—019 of 31/07/1989*

30.—(2) The rights deriving from a patent or an inventor's certificate shall not extend to acts carried out with respect to the product covered by the patent or inventor's certificate once the product has been lawfully sold within the country.

MALAYSIA : *Section 37 (2) of the Patents Act No. 291 of 1983 as last amended on 2006*

Section 37. Limitation of rights.

(2) Without prejudice to section 58A, the rights under the patent shall not extend to acts in respect of products which have been put on the market –

[Am. Act A1088: s.6]

(i) by the owner of the patent; (ii) by a person having the right referred to in section 38; (iii) by a person having the right referred to in section 43; (iv) by the beneficiary of a compulsory licence within the meaning of section 48.

MALTA (EU) : *Article 27 (9) of the Patents and Designs Act, Chapter 417, of 01/06/2002, as amended by Acts IX of 2003 and XVIII of 2005*

27.(9) (a) The propagation of a patent shall have no right to prevent third parties from performing acts referred to in subarticles (1)(b) and (2)(b) where the act concerns a product which has been put on the market by the proprietor of the patent, or with his express consent, insofar as such an act is performed after that product has been so put on the market.

(b) The protection referred to in subarticles (3), (4) and (5) shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the holder of a patent or with his consent where the multiplication or propagation necessarily results from the application for which the biological material was marketed:

Provided that the material obtained is not subsequently used for the propagation or multiplication.

(c) For the purposes of this subarticle “market” means the market in Malta and from 1st May, 2004, the European Union.

(10) The Minister may make regulations giving effect to any international agreement or obligation entered into by Malta with regard to matters covered by this article and may by such regulations regulate the above rights and limitations to reflect the provisions of any such agreement or obligation.

MEXICO : *Article 22 II of the Industrial Property Law of 25/06/1991, last amended version of 06/12/2005*

Article 22. The right conferred by a patent shall not have any effect against: II. any person who markets, acquires or uses the patented product or the product obtained by means of the patented process, after said product has been lawfully placed on the market;

MONGOLIA : *Article 18 (2) no.1 of the Patents Act of 25/06/1993, as last amended in 1997*

Article 18. Exploitation of patented inventions and industrial designs

2. The performance of the following acts of using patented inventions or industrial designs shall not constitute an infringement of the exclusive rights of patent owners:

1) the use of articles which have been put on the market in this country by a patent owner or by another person with the patent owner’s consent;

MOROCCO : *Article 55 d) of the Law No. 17-97 of 15/02/2000 concerning Protection of Industrial Property as implemented by the Decree No. 2-00-368 of 07/06/2004*

Article 55

Les droits conférés par le brevet ne s’étendent pas:

d) aux actes concernant le produit couvert par ce brevet, accomplis sur le territoire marocain, après que ce produit ait été mis dans le commerce au Maroc par le propriétaire du brevet ou avec son consentement exprès;

MOZAMBIQUE : *Article 68 b) of the Industrial Property Code, Decree No. 4 of 12/04/2006*

Article 68 Limits of rights conferred by the patent

The following shall not be within the scope of the patent:

b) Acts related to products placed on the market in Mozambique by the proprietor of the patent or so placed with the proprietor's consent;

NAMIBIA : *Section 17 (3) a) of the Industrial Property Bill of 1999*

Rights conferred by patent, ARIPO Protocol Patents, exploitation by Government or person thereby authorized

17.(3) The rights under the patent shall not extend -

(a) to acts in respect of articles which have been put on the market in Namibia by the owner of the patent or with his or her consent;

NETHERLANDS (EU) : *Article 53 (5) of the Patent Act of 15/12/1994, (Text as it applies on 03/06/2009)*

Article 53

5. If a product as referred to in paragraph (1)(a) or (b) has been put on the market lawfully in the Netherlands or the Netherlands Antilles or in one of the Member States of the European Union or in another State that is party to the Agreement concerning the European Economic Area by the patent holder or with his consent, the person who obtains or later holds the product shall not be deemed to have contravened the patent by using, selling, hiring out or delivering that product or by otherwise dealing in it in or for his business, or by offering, importing, or stocking the product for any of those purposes.

NICARAGUA : *Article 47 of the Industrial Property Law No. 354 of 19/09/2000*

Exhaustion of Patent Rights

47. The patent does not confer the right to prohibit a third party from engaging in commercial acts in relation to a product protected by the patent after that product has been brought on to the market in any country by the owner of the patent or by another person who has the owner's consent or is economically connected with him.

For the purposes of the foregoing paragraph, two persons shall be considered economically connected where one of them can exert a direct and decisive influence on the other with respect to the working of the patent, or where a third party can exert such influence on both persons.

Where the patent protects biological material capable of reproduction, the patent shall not extend to material obtained by multiplication or propagation of the material that is brought on to the market as provided in the first paragraph of this Article insofar as the multiplication or propagation is the necessary consequence of the use of the material for the purposes for which

it was brought on to the market, and the material resulting from that use is not used for multiplication or propagation purposes.

NORWAY (EUROPEAN ECONOMIC AREA) : *Section 3 (2) of the Patent Act No. 9 of 15/12/1967 (as last amended by Act No.80 of 29/06/2007)*

Section 3.

The exclusive right shall not include:

Exploitation of products protected by the patent which have been put on the market in the European Economic Area by the patent holder or with his consent, if this is not determined differently by regulation laid down by the King.

PAKISTAN : *Section 30 (5) a) of the Patents Ordinance No. LXI of 02/12/2000 (as amended by the Patents Amendment Ordinance of 2002)*

- (5) The rights under the patent shall not extend to-
- (a) acts in respect of articles which have been put on the market anywhere in the world by the owner of the patent or with his consent or by an authorized person or in any other legitimate manner such as compulsory licenses;

PANAMA : *Article 19 No. 3 of the Industrial Property Law No. 35 of 10/05/1996*

19. The right conferred by a patent shall have no effect whatever against:

- 3. any person who markets, acquires or used the patented product or the product obtained using the patented process after the said product has been lawfully placed on the market;

PAPUA NEW GUINEA : *Section 29 (4) a) of the Industrial Property Act No. 30 of 19/07/2000*

29. Rights conferred by a patent.

- (4) The rights of an owner of a patent shall not extend to -
- (a) acts in respect of articles which have been put on the market in Papua New Guinea by the owner of the patent or with his consent; or

PARAGUAY : *Article 34 c) of the Patents Law No. 1630 of 29/11/2000*

Artículo 34.- De las limitaciones al derecho de patente y agotamiento del derecho.

La patente no dará el derecho de impedir:

- c) actos de comercio realizados por un tercero respecto de un producto protegido por la patente después de que se hubiese introducido lícitamente en el comercio en cualquier país por el titular de la patente o por otra persona con consentimiento del titular o habilitada legalmente;

PHILIPPINES : *Section 72 no.1 of the Intellectual Property Code, Act No. 8293 of 06/06/1997a last amended by Act No. 9502 of 2008*

Limitations of Patent Rights

72. The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been so put on the said market; provided that, with regard to drugs and medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced in the Philippines or anywhere else in the world by the patent owner, or by any party authorized to use the invention: provided, further, that the right to import the drugs and medicines contemplated in this section shall be available to any government agency or any private third party;

POLAND (EU) : *Article 70 of the Industrial Property Law of 30/06/2000, as amended by Act of 23/01/2004 and Act of 29/06/2007*

Article 70

1. The rights conferred by a patent shall not extend to acts concerning a product embodying the invention or manufactured by means of the invention, consisting in particular of its offering for sale or further putting on the market, if that product has been put on the market on the territory of the Republic of Poland by the patent holder or with his consent.

2. A patent shall neither be considered infringed by an act of importation into the territory of the Republic of Poland or other acts referred to in paragraph (1) in respect of a product that has earlier been put on the market on the territory of the European Economic Area by the patent holder or with his consent.

PORTUGAL (EU) : *Article 103 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 103

Exhaustion of the rights

1 – The rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it after its sale by the patentee or with his consent, in the European economic area.

2 – The protection referred to in Article 97(3) to 97(5) does not cover biological material obtained by propagation or multiplication of a biological material sold by the patentee or with his consent, in the European economic area, if the propagation or multiplication is the necessary result of the use for which the biological material was placed on the market, provided that the material obtained is not then used for further propagation or multiplication.

ROMANIA (EU) : *Article 34 d) of the Patent Law no. 64 of 1991 as republished in the Official Gazette of Romania, Part I, No. 456/18.VI.2008*

Art. 34 - The following acts shall not constitute infringements of the rights provided in Art. 32 and Art. 33:

(d) marketing or offering for sale within the territory of the European Union of specimens of the product constituting the subject-matter of the invention that have been previously sold by the patent owner or with his express consent;

RUSSIAN FEDERATION : *Article 1359 no.6 of the Patent Law (Chapter 72)*

Article 1359. Acts which Shall Not an Infringement of the Exclusive Right to an Invention, Utility Model, or Industrial Design

The performance of the following acts shall not constitute an infringement of the exclusive right to an invention, utility model, or industrial design:

(6) import into the territory of the Russian Federation, utilization, offer for sale, selling, other introduction into civil circulation or storage for these purposes of a product, incorporating the invention or utility model or of a device, incorporating the industrial design if such product or device had been early introduced into civil circulation within the territory of the Russian Federation by the patent holder or by another person with the consent of the patent holder.

SERBIA : *Article 60 of the Patents Law No. 15 of 02/07/2004*

Exhaustion of Patent Owner Rights

Article 60

If a protected product is placed on the market in the territory of Serbia and Montenegro by the patent owner or with his consent, the person coming into possession of such product may use and dispose of it freely.

SINGAPORE : *Section 66 (2) g), (3), (4), (5), (5A) and (6) of the Patents Act No. 21 of 25/11/1994 as of 01/12/2008*

Meaning of infringement

66.—

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —

(g) subject to subsections (3) and (5A), it consists of the import, use or disposal of, or the offer to dispose of, any patented product or any product obtained by means of a patented process or to which a patented process has been applied, which is produced by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by him, and for this purpose “patent” includes a patent granted in any country outside Singapore in respect of the same or substantially the same invention as that for which a patent is granted under this Act and “patented product”, “patented process” and “licensed” shall be construed accordingly;

(3) Subsection (2) (g) shall not apply to the import of any patented pharmaceutical product by any person (referred to in this subsection and subsection (4) as the importer) if —

(a) the product has not previously been sold or distributed in Singapore by or with the consent (conditional or otherwise) of the proprietor of the patent or any person licensed by the proprietor of the patent to sell or distribute the product in Singapore;

(b) the import of the product by the importer would result in the product being distributed in breach of a contract between —

(i) the proprietor of the patent; and

(ii) any person licensed by the proprietor of the patent to distribute the product outside Singapore; and

(c) the importer has actual or constructive knowledge of the matters referred to in paragraph (b).

(4) For the purposes of subsection (3), where the importer has received a written notice containing the prescribed particulars, he shall be deemed to have constructive knowledge of the matters referred to in subsection (3) (b).

(5) For the avoidance of doubt, in subsection (3), “patent” does not include a patent granted in any country outside Singapore in respect of the same or substantially the same product and “licensed” shall be construed accordingly.

(5A) Subsection (2)(g) and (i) shall not apply to the import or sale of, or the offer to sell, any relevant health product produced for export to any country, other than Singapore, which is an eligible importing member of the World Trade Organisation

(6) In this section —

“eligible importing member”, in relation to the World Trade Organisation, means a member of the World Trade Organisation which —

(a) is a least-developed country; or

(b) has given the Council for TRIPS the notification referred to in —

(i) paragraph 1(b) of the Doha Declaration Implementation Decision; or

(ii) paragraph 1(b) of the Annex to the TRIPS Agreement;

“exempted aircraft” means an aircraft to which section 5 of the Air Navigation Act (Cap. 6) applies;

“relevant ship” and “relevant aircraft, hovercraft or vehicle” mean, respectively, a ship and an aircraft, a hovercraft or a vehicle registered in, or belonging to, any country, other than Singapore, which is —

(a) a party to the Paris Convention; or

(b) a member of the World Trade Organisation.

SLOVAKIA (EU) : *Article 16 of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended by Act No. 402/2002 Coll., Act No. 84/2007 Coll. and Act No. 517/2007 Coll.*

Article 16

Exhaustion of rights

(1) A patent owner shall not be entitled to prohibit third parties to dispose of a product which is a subject-matter of a patent protection after this product has been placed on the market in the member state of the European Union or in the state which is a contracting party

to the Agreement on the European Economic Area by a patent owner or with his explicit consent. This shall not apply if there are reasons for extension of rights to a patent for such treatment.

(2) Paragraph 1 shall also apply to a biological material obtained by reproduction of a protected biological material provided that such reproduction necessarily results from using for which the biological material has been placed on the market, if biological material obtained in this way is not subsequently utilised for its further reproduction.

(3) Acquisition of protected plant reproduction material by a farmer within the scope of a commercial relation with a patent owner or with his consent implies right of a farmer to utilise a product of his work for reproduction of this product in his farm. Provisions of a special regulation shall apply *mutatis mutandis* for determination of a scope of right of a farmer pursuant to sentence one and condition of claiming such right.

(4) Acquisition of protected animal reproduction material by a farmer within the scope of a commercial relation with a patent owner or with his consent implies for right of a farmer to use a protected livestock for agricultural purposes including using of an animal reproductive material for his agricultural activity with exception of sale of animal reproduction material form performing agricultural activities of a farmer with exception of a sale of an animal reproduction material in relation with business or for the purpose of business in the form of a subsequent reproduction activity.

SPAIN (EU) : *Article 52 (2) of the Law about Patents of Invention and Utility Models No.11/1986 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

Artículo 52.

2. Los derechos conferidos por la patente no se extienden a los actos relativos a un producto protegido por ella después de que ese producto haya sido puesto en el comercio en el territorio de un Estado miembro de la Comunidad Europea por el titular de la patente o con su consentimiento.

(Afectado por Ley 10/2002, de 29 de Abril, por la que se modifica la Ley 11/1986, de 20 de Marzo, de Patentes, para la incorporación al derecho español de la directiva 98/44/CE, del Parlamento Europeo y del Consejo, de 6 de Julio, relativa a la protección jurídica de las invenciones biotecnológicas).

SRI LANKA : *Section 86 (1) (iv) of the Intellectual Property Act No. 36 of 2003*

86. (1) The provisions of section 84 shall—

(iv) not extend to acts in respect of articles which have been put in the market by the owner of the patent or by a manufacturer under licence.

SWAZILAND : *Section 12 (4) a) of the Patents, Utility Models and Industrial Designs Act No. 6 of 04/09/1997*

Rights conferred by patent, ARIPO Protocol patents, exploitation by Government or person thereby authorised.

12. (4) The rights under the patent shall not extend to:

(a) acts in respect of articles which have been put on the market in Swaziland by the owner of the patent or with his consent;

SWEDEN (EU) : *Section 3 (2) no.2 of the Patent Act No. 837 of 01/12/1967 as last amended by Law No. 159 of 01/04/2004*

3. (2) From the exclusive right are exempted

2. acts of exploitation of a product protected by a patent which has been put on the market within the European Economic Area by the holder of the patent or with his or her consent; as regards biological material this applies also to acts of exploitation in the form of propagation or multiplication when the propagation or multiplication is a necessary step in the use for which the biological material has been put on the market, on condition that the product obtained is not subsequently used for further propagation or multiplication.

SWITZERLAND : *Article 9a of the Patent Law of 25 June 1954 (as on 01/07/ 2009)*

Art. 9a

(1) Lorsqu'une marchandise brevetée est mise en circulation en Suisse ou dans l'Espace économique européen par le titulaire du brevet ou avec son accord, elle peut être importée et utilisée ou revendue en Suisse à titre professionnel.

(2) Lorsqu'un dispositif permettant l'utilisation d'un procédé breveté est mis en circulation en Suisse ou dans l'Espace économique européen par le titulaire du brevet ou avec son accord, le premier acquéreur ou tout acquéreur ultérieur de ce dispositif est autorisé à utiliser ce procédé.

(3) Lorsque de la matière biologique brevetée est mise en circulation en Suisse ou dans l'Espace économique européen par le titulaire du brevet ou avec son accord, elle peut être importée et multipliée en Suisse pour autant que cela soit nécessaire à l'utilisation prévue. La matière ainsi obtenue ne doit pas être utilisée pour une multiplication ultérieure. L'art. 35a est réservé.

(4) Lorsqu'une marchandise brevetée est mise en circulation hors de l'Espace économique européen par le titulaire du brevet ou avec son accord et que par rapport aux caractéristiques fonctionnelles de cette marchandise la protection découlant du brevet revêt une importance moindre, la marchandise peut être importée à titre professionnel. La protection découlant du brevet est supposée d'importance moindre si le titulaire du brevet ne rend pas vraisemblable le contraire.

(5) Nonobstant les al. 1 à 4, une marchandise brevetée ne peut être mise en circulation en Suisse qu'avec l'accord du titulaire du brevet lorsque, en Suisse ou dans le pays de mise en circulation, le prix de cette marchandise est imposé par l'Etat.

THAILAND : *Section 36 (2) no. 7 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 36 (2) The preceding paragraph shall not apply to:

(7) the use, sale, having in possession for sale, offering for sale or importation of a patented product when it has been produced or sold with the authorization or consent of the patentee.

TONGA : *Section 13 (4) a) of the Industrial Property Act No. 19 of 09/11/1994*

(4) The rights under the patent shall not extend,

(a) to acts in respect of articles which have been put on the market in Tonga by the patentee or with his consent;

TRINIDAD AND TOBAGO : *Section 43 of the Patents Act No. 21 of 1996 as last amended by the Act No. 18 of 2000*

(Exhaustion of rights)

43. The rights conferred by a patent shall not extend to acts in respect of articles which have been put on the market in Trinidad and Tobago by the owner of the patent or with his consent.

TUNISIA : *Article 47 d) of the Patents Law No. 2000-84 of 24/08/2000*

47. The rights conferred by the patent shall not extend to the following:

(d) the advertising, import, stocking or use of the patented product or the product obtained using a patented process, done on Tunisian territory after the product has been lawfully brought on to the market in any country by the owner of the patent or with his express consent;

TURKEY : *Section 76 of the Decree-Law on the Protection of Patent Rights No. 551 of 27/06/1995*

Exhaustion of Rights Conferred by a Patent

Article 76 :

Rights conferred by a patent shall not extend to acts committed with regard to a product under patent protection after said product has been put to sale in Turkey by the right holder of the patent or with his consent.

UGANDA : *Section 28 b) of the Patents Act (Chapter 216) of 15/10/1993*

28. Limitation.

The rights of an owner of a patent shall extend only to the use of the patented invention for industrial or commercial purposes, but those rights shall not be deemed to be infringed by the following—

(b) acts in respect of articles which have been put on the market in Uganda by the owner of the patent or with his or her express consent;

UKRAINE : *Article 31 (3) 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*

Article 31. Actions that are not Considered to be the Infringement of Rights

3. The introduction of a product that has been manufactured with the use of the patented invention (utility model) into the commercial circuit by any person, which has obtained a product without violation of the patent owner rights, shall not be considered to be the infringement of rights deriving from a patent.

The product manufactured with the use of the patented invention (utility model) shall be considered to be obtained without the violation of the patent owner rights provided that this product has been manufactured by the patent owner and (or) after manufacturing has been introduced into the commercial circuit by the patent owner or other person according to the special permission (license) of the patent owner.

UNITED ARAB EMIRATES : *Section 17 of the Patent Law No. 44 of 12/10/1992 – 1413*

17. The rights conferred by a patent or utility certificate shall cover only acts performed for industrial or commercial purposes. They shall not extend to acts in relation to the protected product once it has been sold in the United Arab Emirates. However, if the patent or utility certificate relates also to a specific use of the product, the owner shall have the right to reserve that use for himself.

UNITED REPUBLIC OF TANZANIA : *Section 37 (2) of the Patents Act No. 1 of 20/01/1987*

37- (2) Tire rights under the patent shall not extend to acts in respect of articles which have been put on the market in the United Republic by the owner of the patent or with his express consent.

URUGUAY : *Article 40 of the Industrial Property Law No. 17.164 of 02/09/1999*

Artículo 40.- El titular de la patente no podrá impedir que cualquier persona use, importe o comercialice de cualquier modo un producto patentado, después que el mismo ha sido puesto lícitamente en el comercio dentro del país o en el exterior por dicho titular o bien por un tercero con su consentimiento o legítimamente habilitado. No se considerarán puestos lícitamente en el mercado los productos o los procedimientos en infracción de derechos de propiedad intelectual (Parte III, Sección 4, del Acuerdo ADPIC de la Organización Mundial de Comercio).

UZBEKISTAN : *Article 12 of the Law on Inventions, Utility Models and Industrial Designs No. 1068-XII of 29/08/2002*

Article 12. Acts not recognized as an infringement of a patent owner's exclusive right

The following shall not be recognized as an infringement of a patent owner's exclusive right:

- the use of means containing industrial property subject matter protected by patents, where these means have been lawfully introduced into civilian circulation;

VIET NAM : *Section 125 (2) (b) of the Intellectual Property Law No. 50/2005/QH11 of 29/11/2005*

Article 125.- Right to prevent others from using industrial property objects (...)

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

b/ Circulating, importing, exploiting utilities of products having been lawfully put on the market, including overseas markets, except for products put on the overseas markets not by the mark owners or their licensees;

ANDEAN COMMUNITY : *Article 54 of the Cartagena Agreement, Decision No. 486 of 14/09/2000 of the Commission of the Andean Community*

54. The patent shall not give the right to prohibit a third party from engaging in commercial acts in relation to a product protected by the patent after that product has been brought on to the market in any country by the owner of the patent, or by another person who has obtained his consent or is economically associated with him.

For the purposes of the foregoing paragraph, two persons shall be considered economically associated where one can directly or indirectly exercise a decisive influence on the other concerning the working of the patent, or where a third party can exercise such an influence on both.

Where the patent protects biological material, that can be reproduced, the patent shall not extend to the biological material obtained by reproduction, multiplication or propagation of the material that has been brought on to the market in accordance with the first paragraph above, provided that the reproduction, multiplication or propagation was necessary so that the material might be used to achieve the purposes for which it was brought on to the market, and provided that the material derived from such use is not used for multiplication or propagation purposes.

EUROPEAN UNION : *Articles 28 and 30 of the Treaty of Rome and Article 28 of the Convention for the European Patent*

Treaty of Rome

Article 28

Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States.

Article 29

Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States.

Article 30

The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Article 28 of the Convention for the European Patent

The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territories of the Contracting States after that product has been put on the market in one of these States by the proprietor of the patent or with his express consent, unless there are grounds which, under Community law, would justify the extension to such acts of the rights conferred by the patent

OAPI : *Article 8 (1) a) of annex I patents, title I of the revised Bangui Agreement of 02/03/1977 (as on 24/02/1999)*

Article 8 - Limitation of the Rights Conferred by the Patent

- (1) The rights deriving from the patent shall not extend
 - (a) to acts in relation to subject matter brought on to the market on the territory of a member State by the owner of the patent or with his consent;

(3) PROVISIONS OF LAW ON RESEARCH EXEMPTION

ALBANIA : *Article 38 (1) b) of the Patent Law No. 9977 of 07/07/2008*

Article 38

Limitation of the Effects of the Patent

The rights conferred by the patent shall not extend to:

b) acts performed merely for experimental purposes relating to the subject matter of the invention;

ALGERIA : *Article 12 (1) n. 1 of the Ordinance on Patents No. 03-07 of 19/07/2003*

Article 12:

— Les droits découlant d'un brevet d'invention ne s'étendent qu'aux actes accomplis à des fins industrielles ou commerciales.

Ces droits ne s'étendent pas :

1°) aux actes accomplis aux seules fins de la recherche scientifique ;

ANDORRA : *Article 23 (4) of the Patent Act of 10/06/1999*

(4) The rights conferred by a patent shall not extend to:

(c) acts done for experimental purposes relating to the subject-matter of the patented invention;

ANTIGUA AND BARBUDA : *Section 11 (4) c) of the Patent Bill No. 23 of 2003*

(4) (1) The rights under the patent shall not extend:

(c) to acts done only for experimental purposes relating to a patented invention;

ARGENTINA : *Article 36 a) of the Law on Patents and Utility Models No. 24.481 of 1996*

Article 36(a): a third party who privately or in an academic environment and without gainful intent, conducts scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or applies a process identical to the one patented;

ARMENIA : *Article 13 of the Law on Patents of 26/10/1999*

Article 13: The use of industrial property subject matter protected by a patent shall not be considered to infringe a patent owner's exclusive right:

(1) as the subject of a scientific experiment or scientific research.

BARBADOS : *Article 6 (1) of the Patents Act, 2001-18*

Article 6(1): The rights vested in the owner of a patent by section 5 in respect of any invention do not apply to:

- (a) the use of the invention for scientific research only;

BELARUS : *Article 10 of the Law of the Republic of Belarus on “patents for inventions, utility models and industrial designs” of 16/12/2002, No. 160-Z*

Article 10: The following is not recognized as violations of the exclusive right of the patent-holder:

conducting the scientific research or experiment on the method in which the invention, industrial model or industrial design protected by the patent are used; (not an official translation)

BELGIUM (EU) : *Article 28 (1) b) of the Patent Law of 28/03/1984 (as of 01/01/2010)*

§ 1er. Les droits conférés par le brevet ne s'étendent pas :

- b) aux actes accomplis à des fins scientifiques sur et/ou avec l'objet de l'invention brevetée ; (as modified by Law of 28 April 2005)

BELIZE : *Article 33 (4) c) of the Patents Act (Ch. 253) of 2000*

Article 33(4): The rights under the patent shall not extend to:

- (c) acts done only for experimental purposes relating to a patented invention;

BHUTAN : *Section 13 (4) a) of the Industrial Property Act of 2001*

Section 13(4)(a): The rights under the patent shall not extend:

- (3) to acts done only for experimental purposes relating to a patented invention;

BOTSWANA : *Section 24(3)(a) (iii) of the Industrial Property Act No. 14 of 1996*

Section 24(3)(a) The rights under the patent shall not extend to:

- iii) acts done only for experimental purposes relating to a patented invention

BRAZIL : *Article 43 II of the Patent Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001*

Article 43: The provisions of the previous Article do not apply:

(II) to acts carried out by unauthorized third parties for experimental purposes, in connection with scientific or technological studies or researches;

BULGARIA (EU) : *Article 20 (1) no. 2 of the Law on Patents and Utility Models Registration No. 27/2 of 1993 as last amended by Law No. 59/20 of July 2007*

Art. 20. The effect of a patent shall not extend to:

2. use of the invention for experimental or research and development purposes relating to the subject matter of the patented invention;

CHINA: *Article 69 (4) of the Patent Law of 12/03/1984 as last amended on 27/12/2008*

Article 69. None of the following shall be deemed an infringement of the patent right:

(4) Where any person uses the patent concerned solely for the purposes of scientific research and experimentation.

COSTA RICA : *Article 16 (2) b) and c) of the Law on Patents, Industrial Designs and Utility Models No. 6867 of 25/04/1983, as amended by Law No. 7979 of 10/12/2000*

Article 16(2) Siempre que las siguientes excepciones no atenten de manera injustificable contra la explotación normal de la patente, ni causen un perjuicio injustificado a los legítimos intereses de su titular o su licenciataria, los derechos conferidos por la patente no se extienden a:

b) Los actos realizados con fines experimentales que se refieran al objeto de la invención patentada.

c) Los actos realizados exclusivamente con fines de enseñanza o de investigación científica o académica respecto del objeto de la invención patentada.

CROATIA : *Article 63 no. 2 of the Patent Act No. 173 of 2003, as amended by Acts No. 87/2005 and No. 76/2007*

The patent owner's exclusive right of exploitation of the invention shall not apply to:

2. acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for obtaining registration or authorization for putting on the market a product comprising a medicine intended for people or animals, or a medicinal product,

CUBA : *Article 54 no. 3 of the Decree Law No. 68 of 14/05/1983*

Article 54: No se reconocen como violaciones del derecho exclusivo de una invención protegida:

3) La utilización de la misma con fines de investigación científica.

CYPRUS (EU) : *Article 27 (3) (ii) and (iii) of the Patent Act of 1998 (amended in 2000, 2002 and 2006 but English version not available.)*

Art. 27.-(3) Notwithstanding paragraphs (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:

- (ii) where the act is done privately and on a non-commercial scale, provided that it does not significantly prejudice the economic interests of the proprietor of the patent;
- (iii) where the act consists of making or using for purely experimental purposes or for scientific research;

CZECH REPUBLIC (EU) : *Section 18 e) of the Patents Act No. 527 of 1990 as last amended by Act No. 378/2007*

Section 18

The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

e) in acts relating to the subject-matter of the invention done for experimental purposes including experiments and tests necessary, pursuant to the special legal regulation, before placing a medicine on the market

DENMARK (EU) : *Section 3 (3) (iii) of the Patent Act no. 91 of 28/01/2009*

3.3 the exclusive right shall not extend to:

- (iii) acts done for experimental purposes relating to the subject matter of the patented invention.

DOMINICA : *Article 33 (4) c) of the Patents Act No. 8 of 07/10/1999*

Article 33(4) The rights under the patent shall not extend to:

- c) acts done only for experimental purposes relating to the patented invention.

DOMINICAN REPUBLIC : *Article 30 b) and c) of the Law on Industrial Property No. 20-00 of 18/04/2000*

Article 30: La patente no da el derecho de impedir:

- b) Actos realizados exclusivamente con fines de experimentación con respecto a la invención patentada;
- c) Actos realizados exclusivamente con fines de enseñanza o de investigación científica o académica;

EGYPT : *Article 10 no. 1 of the Intellectual Property Law 82 of 2002*

Article 10: the Following shall not be considered as infringements of that right when carried out by third parties

- 1) Activities carried out for scientific research purposes.

EL SALVADOR : *Article 116 b) and c) of the Legislative Decree No. 604 of 15/07/1993 on the Promotion and Protection of Intellectual Property Rights as last amended by Legislative Decree No. 912 of 14/12/2005*

Article 116: The effects of the patent shall not extend:

- b) to a third party who, privately and on a noncommercial scale, or for non-profit making purposes, performs acts in relation to the patented invention
- c) to a third party who, without gainful intent, engages in the manufacture or use of the subject matter of the patented invention either for experimental purposes or for the purpose of scientific, academic or educational research;

ESTONIA (EU) : *Section 16 no.3 of the Patent Act of 16/03/1994, as last amended by the Act of 10/03/2004*

Proceedings non-infringing exclusive right of patentee

16.- The following proceedings shall not be considered as infringement of the exclusive right of a patentee:

3. the use of a patented invention in experiments concerning the invention itself;

ETHIOPIA : *Section 25 (1) b of the Industrial Property Law (Proclamation) No. 123 of 10/05/1995*

1. The rights of the patentee shall not extend to:

- b) the use of the patented invention solely for the purposes of scientific research & experimentation;

FINLAND (EU) : *Section 3 (2) no. 3 of the Patent Act No. 550 of 15/12/1967, as last amended by Act 684/2006 of 21/07/2006*

The exclusive right shall not apply to:

- (3) use in experiments relating to the invention as such;

FRANCE (EU) : *Article L613-5 b) of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 as last amended by Law No. 2007-1544*

Article L613-5 En savoir plus sur cet article...

Modifié par LOI n°2008-518 du 3 juin 2008 - art. 22

Les droits conférés par le brevet ne s'étendent pas :

- b) Aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée ;

GERMANY (EU): *Section 11 no. 2 of the Patent Act as last amended by the Act on Improvement of Enforcement of Intellectual Property Rights of 31/07/2009*

The effects of a patent shall not extend to:

2. acts done for experimental purposes relating to the subject matter of the patented invention;

GHANA : *Section 30 a) of the Patent Law No. 305A of 30/12/1992*

30. The rights under the patent shall—

(a) extend only to acts done for industrial and commercial purposes and in particular not to acts done for scientific research;

GREECE (EU) : *Article 10 (2) a) of the Law 1733 of 1987 “Technology transfer, inventions and technological innovation”*

2. The owner of the patent may not forbid, in the meaning of the preceding paragraph, the following activities:

(a) The use of the invention for nonprofessional or research purposes;

GRENADA : *Section 12 (4) (a) of the Industrial Property Act of 2002*

Section 12(4)(a): The rights under the patent do not extend:

iii) to acts done only for experimental purposes relating to a patented invention;

GUATEMALA : *Article 130 b) and c) of the Industrial Property Law, Decree No. 57-2000 of 18/09/2000*

Article 130: La patente no dará el derecho a su titular de impedir:

b) Actos realizados exclusivamente con fines de experimentación respecto al objeto de la invención patentada;

c) Actos realizados exclusivamente con fines de enseñanza o investigación científica o académica, sin propósitos comerciales, respecto al objeto de la investigación patentada;

HONDURAS : *Article 18 of the Law on Industrial Property, Decree Law No. 12-99-E of 30/12/1999*

Article 18: Los Derechos conferidos por la patente solo podran hacerse valer contra actos realizados por terceros con fines industriales o comerciales.

En particular, tales derechos no podran hacerse valer contra actos realizados exclusivamente en el ambito privado y con fines no comerciales, o con fines de experimentacion, investigacion cientifica or ensenanza relativos al objeto de la invencion patentada

HUNGARY (EU) : *Article 19 (6) b) of the Law on the Protection of Inventions by Patents No. XXXIII of 1995 (Consolidated text of 01.10.2009)*

- (6) The exclusive right of exploitation shall not extend to:
- (b) acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorisation of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention;

ICELAND : *Article 3 (2) no.3 of the Patents Act No. 17 of 1991 as last amended by Act No. 167/2007*

Article 3

The following are excepted from the exclusive right:

- (3) use of the invention for experiments which relate to the invention itself, [i.a. studies and trials and other related procedures that are necessary to make possible an application for marketing authorization for e.g. a generic medicinal product and an improved pharmaceutical form;

INDIA : *Section 47 of the Patent Act No. 39 of 1970 (as last amended in 2005)*

Article 47: The grant of a patent under this Act shall be subject to the condition that:

- (3) any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils;

INDONESIA : *Article 16 (3) of the Patent Law No. 14 of 2001*

Article 16

- (3) Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said Patent is for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder.

IRELAND (EU) : *Section 42 b) of the Patents Act No. 1 of 27/02/1992 as last amended in 2006*

42.-

The rights conferred by a patent shall not extend to-

- (b) acts done for experimental purposes relating to the subject-matter of the relevant patented invention;

JAPAN : *Article 69 no. 1 of the Patent Act Act No. 121 of 1959 as last amended by Act No. 109 of 2006*

Article 69 (Limitations of patent right)

(1) A patent right shall not be effective against the working of the patented invention for experimental or research purposes.

JORDAN : *Article 21 C of the Patent Act 1999, No. 32 as last amended by Act No. 71/2001*

Article 21

C. Notwithstanding any conflicting provision in this law or any other law, all types of scientific research and development and filing applications for obtaining marketing permits carried out before the elapse of the patent protection period shall not be regarded as infringement neither civil nor criminal.

KAZAKHSTAN : *Article 12 of the Patent Act of 16/07/1999*

Article 12: The following shall not constitute acts infringing the exclusive right of the patent owner:

- the use of the subject matter incorporating the protected industrial property subject matter for scientific research and experimental purposes;

KENYA : *Section 58 (1) of the Industrial Property Act No. 3 of 27/07/2001*

Section 58(1): The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.

KYRGYZSTAN : *Article 13 no. 2 of the Patent Law of 14/01/1998 # 8 (as last amended in 2003)*

Article 13. Actions Not Considered as an Infringement of the Exclusive Right of the Patent Owner

The following is not recognized as an infringement of the exclusive right of the patent owner:

2) conducting scientific research or an experiment with an article containing an object of industrial property;

LATVIA (EU) : *Section 20 no.2 of the Patent Law adopted on 15/02/2007*

Section 20. Limitations of Exclusive Rights Resulting from the Patent

The exclusive rights resulting from the patent shall not extend to:

2) experimental or investigative activities;

LEBANON : *Article 42 of the Law No. 240 of 07/08/2000*

Article 42:

- A person infringing the rights of a basically published patent while being aware of such action, shall be penalized by a fine ranging from five to fifty million Lebanese Liras and imprisonment from three months up to three years or by either of the penalties hereinbefore mentioned.
- Exploiting the invention on non-commercial, nonindustrial personal aims or for scientific research reasons shall not be considered counterfeit according to the provisions of the Article herein.

LIBERIA : *Section 17 (4) a) (iii) of the Industrial Property Act of 20/03/2003*

- (4)(a) The rights under the patent shall not extend
(iii) to acts done only for experimental purposes relating to a patented invention

LITHUANIA (EU) : *Article 26 of the Patent Law No. I-372 of 18/01/1994(as last amended by Act – No. X-1119 of 10/05/2007)*

The owner of the patent shall have no right to prevent third parties from performing acts referred to in paragraphs 1 and 2, provided that:

- 2) the act is done for experimental purposes or for scientific research, and this does not conflict with a normal exploitation of the patent and does not unreasonably prejudice the legitimate interests of the patent owner;

LUXEMBOURG (EU) : *Article 47 b) of the Patent Law of 20/07/1992*

Art. 47. Limitation des effets du brevet

Les droits conférés par le brevet ne s'étendent pas :

- b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;

MALAYSIA : *Section 37 (1) of the Patents Act of 1983 as last amended in 2006*

Section 37. Limitation of rights. (1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.

MALTA (EU) : *Article 27 (6) lett. b) of the Patents and Designs Act, Chapter 417, of 01/06/2002, as amended by Acts IX of 2003 and XVIII of 2005*

(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:

- (b) where the act consists of making or using such product for purely experimental purposes or for scientific research

MAURITIUS : *Section 21(4)(d) of the Patents, Industrial Designs and Trademarks Act of 2002*

Section 21(4)(d): Any right under the patent shall not extend –

d) to acts done only for research and experimental purposes relating to a patented invention;

MEXICO : *Article 22 (1) of the Industrial Property Law of 25/06/1991, last amended version of 06/12/2005*

Article 22. The right conferred by a patent shall not have any effect against:

I. a third party who, in the private or academic sphere and for non-commercial purposes, engages in scientific or technological research activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or a process identical to the one patented.

MONGOLIA : *Article 18 (2) no. 2 of the Patents Act of 25/06/1993, as last amended in 1997*

Article 18. Exploitation of patented inventions and industrial designs.

2. The performance of the following acts of using patented inventions or industrial designs shall not constitute an infringement of the exclusive rights of patent owners:

2) use for scientific research or experimental purposes in Mongolia;

MOROCCO : *Article 55 b) of the Industrial Property Law No. 17-97, 1997 as implemented by the Decree No. 2-00-368 of 07/06/2004*

Article 55

b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;

MOZAMBIQUE : *Article 68 no. 1 of the Industrial Property Code, Decree No. 4 of 12/04/2006*

Article 68 Limits of rights conferred by the patent

The following shall not be within the scope of the patent:

a) Acts related to a patented invention for the purposes of scientific research;

NAMIBIA : *Section 17 (3) c) of the Unified Bill on Intellectual Property Rights 2000-2001*

Section 17(3) The rights under the patent shall not extend:

c) to acts done for scientific research

NETHERLANDS (EU) : *Section 53 (3) of the Kingdom Act of 15/12/1994, containing rules in respect of patents (Text as it applies on 03/06/2009)*

3. The exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process.

NICARAGUA : *Article 46 a) and b) of the Law on Patents, Utility Models and Industrial Design No. 354 of 19/09/2000*

Article 46: A patent shall not confer the right to prohibit the following acts:

a) those conducted in a private circle and for noncommercial purposes, and also those conducted solely for the purposes of experimentation in relation to the subject matter of the patented invention;

b) those performed exclusively for teaching or scientific or academic research purposes in relation to the subject matter of the patented invention, and those referred to in Article 5ter of the Paris Convention for the Protection of Industrial Property;

NORWAY : *Section 3 (3) no. 3 of the Act No. 9 of 15/12/1967 on patents (The Norwegian Patents Act) (as last amended by Act No. 80 of 29/06/2007)*

The exclusive right shall not include:

3) Exploitation by experiment relating to the subject matter of the invention

PAKISTAN : *Section 30 (5) of the Patents Ordinance of 2000 (as amended by Patents (Amendment) Ordinance, 2002)*

Section 30(5): The rights under the patent shall not extend to:

c) Acts done only for experimental purposes relating to a patented invention

f) Acts done for teaching purposes in educational or research institutions

PANAMA : *Article 19 no. 1 and 2 of the Law on Industrial Property No. 35 of 10/05/1996*

Article 19: The right conferred by a patent shall have no effect whatever against:

(1) a third party who, in the private sphere and on a non-commercial scale, or for a noncommercial purpose, engages in acts involving the patented invention;

(2) an industry or enterprise in the general sense, or an educational or scientific body, that engages in acts of manufacture or use of the invention for experimental purposes relating to the subject matter there or for the purposes of scientific or educational research;

PAPUA NEW GUINEA : *Section 29 (4) c) of the Patent and Industrial Act No. 30 of 19/07/2000*

Section 29(4) The rights of an owner of a patent shall not extend to:

c) acts done only for experimental purposes relating to a patented invention

PARAGUAY : *Article 34 a) and b) of the Law on Patents for Invention No.1630 of 29/11/2000*

Article 34: la patente no dara el derecho de impedir:

- a) los actos realizados exclusavimente con fines de expeimentacion y sin fines comerciales respecto al objeto de la invencion patentada
- b) los actos realizados exclusavimente con fines de ensenanza o de investigacion cientifica o academica

PHILIPPINES : *Section 72 no.3 of the Intellectual Property Rights Code, Act No. 8293 of 1997as last amended by Act no. 9502 of 2008*

Section 72: The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:

- (3) Where the act consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use;

POLAND (EU) : *Article 69 (1), (iii) of the Industrial Property Law of 30/06/2000 as last amended by Act of 29/06/2007*

Article 69

- (1) The following shall not be considered acts of infringement of a patent:
 - (iii) employing of an invention for search and experimental purposes, for the evaluation thereof, analysis or teaching;

PORTUGAL (EU) : *Article 102 c) of the Industrial Property Code (approved by Decree-Law 36/2003 of 5/03/2003 as last amended by Law No. 16 of 01/04/2008)*

Article 102

Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

- c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them.

REPUBLIC OF KOREA : *Article 96 (1) (i) of the Patent Act No. 950 of 1959 (as last amended on 30/01/2009 by Act No. 9381)*

Article 96 Limitations on a Patent Right

- (1) The effect of a patent right does not extend to any of the following subparagraphs:
 - (i) working a patented invention for research or experimental purposes;

REPUBLIC OF MOLDOVA: *Article 22 (1) b) of the Law on the protection of Inventions No. 50-XVI of 07/03/2008*

- (1) The rights conferred by a patent shall not extend to:
- b) acts done for experimental purposes relating to the subject-matter of the patented invention;

ROMANIA (EU) : *Article 80 (1) c) of the Patent Law No. 64/1991 as republished in the Official Gazette of Romania No. 456/18.VI.2008*

Article 80

Exceptions concerning the infringement of rights

- (1) In the application of Art. 34 paragraph (1) letter e) of the Law, the following shall not constitute an infringement of the rights provided for in Art. 32 and 33 of the Law:

- c) the acts concerning the research and development of information contained in the patent, on condition that they are destined exclusively to experiments or studies which intend to evaluate the technical data from the patents.

RUSSIAN FEDERATION : *Article 1359 no.2 of the Patent Law (Chapter 72)*

Article 1359. Acts which Shall Not an Infringement of the Exclusive Right to an Invention, Utility Model, or Industrial Design

The performance of the following acts shall not constitute an infringement of the exclusive right to an invention, utility model, or industrial design:

- 2) scientific research of a product or process incorporating an invention or utility model, or scientific research of a device incorporating an industrial design or the conduct of an experiment with such a product, process, or device;

SAINT LUCIA : *Section 62 (2) a) of the Patents Act No. 16 of 27/08/2001*

Section 62(2) An act, which apart from this subsection would constitute an infringement of a patent for an invention shall not do so if

- a) it is done for experimental purposes relating to the subject matter of the invention

SERBIA : *Article 59 no.2 of the Patent Law No. 15 of 02/07/2004*

Article 59

The exclusive rights of a patent owner referred to in Articles 52 and 53 of this Law shall not apply to:

- 2) research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorisation from the competent state authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product;

SINGAPORE : *Section 66 (2) b) of the Patent Act (Chapter 221) No. 21 of 25/11/1994 as of 01/12/2008*

- (2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —
(b) it is done for experimental purposes relating to the subject-matter of the invention;

SLOVAKIA (EU) : *Article 18 (1) f) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and on Amendment of Some Acts as Amended (The Patent Act)*

Article 18

- (1) Rights of a patent owner shall not be infringed if an invention is exploited:
(...) f) in activity conducted for experimental purposes which shall also be studies, exams necessary for registration proceedings pursuant to a special regulation.

SLOVENIA (EU) : *Article 19 b) of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

Article 19

Limitation of rights conferred by a patent

The rights conferred by a patent within the meaning of Article 18 shall not extend to:

- (b) acts done for research and experimental purposes of any kind relating to the subject matter of the patent irrespective of their final purpose;

SPAIN (EU) : *Article 52 (1) b) of the Law about Patents of Invention and Utility Models No.11/1986 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

Artículo 52. 1. Los derechos contenidos por la patente no se extienden:

- b) A los actos realizados con fines experimentales que se refieran al objeto de la invención patentada, en particular los estudios y ensayos realizados para la autorización de medicamentos genéricos, en España o fuera de España, y los consiguientes requisitos prácticos, incluidos la preparación, obtención y utilización del principio activo para estos fines. (Párrafo redactado conforme a la disposición final segunda Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios)

SRI LANKA : *Section 86 (1) (i) of the Intellectual Property Act, No. 36 of 2003*

86. (1) The provisions of section 84 shall—

- (i) extend only to acts done for industrial or commercial purposes and in particular shall not extend to acts done only for the purpose of scientific research ;

SWAZILAND : *Section 12 (4) c) of the Patents, Utility Models and Industrial Designs Act No. 6 of 1997*

Section 12(4): The rights under the patent shall not extend to:

- (c) acts done for experimental purposes related to a patented invention.

SWEDEN (EU) : *Section 3 (3) no. 3 of the Patents, Act No. 837 of 01/12/1967 as last amended by Law No. 159 of 01/04/2004*

The following are excepted from the exclusive right:

(3) use of the invention for experiments which relate to the invention itself;

SWITZERLAND : *Article 9 (1) b) of the Patent Law of 25/06/1954 (as on 01/07/2009)*

(1) Les effets du brevet ne s'étendent pas:

b. aux actes accomplis à des fins expérimentales et de recherche servant à obtenir des connaissances sur l'objet de l'invention, y compris sur ses utilisations possibles; est permise notamment toute recherche scientifique portant sur l'objet de l'invention;

THAILAND : *Section 36 (2) no.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 36 (2)*The preceding paragraph shall not apply to:

(1) any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA: *Section 91 no.2 of the Law on Industrial Property adopted on 12/02/2009*

Article 91

The right of the patent holder laid down in Article 89 of this Law regarding the exclusive utilisation of the invention shall not relate to:

2) undertaking activities for research and development of the subject of the protected invention, in particular: manufacture, use, offer for sale, export or import of the protected invention, including also activities for obtaining approval for placing medications for human and veterinary medicine and products for protection of plants on the market;

TONGA : *Section 13 (4) (4) of the Industrial Property Act No. 19 of 09/11/1994*

Section 13(4) (4) The rights under the patent shall not extend:

(c) to acts done only for experimental purposes relating to a patented invention;

TRINIDAD AND TOBAGO : *Section 42 b) of the Patent Act No. 21 of 1996 as last amended by the Act No. 18 of 2000*

Section 42: The rights conferred by a patent shall not extend to:

b) acts done for experimental purposes relating to the subject matter of the relevant patented invention;

TUNISIA : *Article 47 b) of the Patents Law No. 2000-84 of 24/08/2000*

Article 47 Les droits conférés par le brevet ne s'étendent pas:

b) aux actes accomplis à titre expérimental qui portent sur l'objet de l'invention brevetée;

TURKEY : *Article 75 b) of the Patent Act No.551 of 27/06/1995*

Limits of the Scope of Rights Conferred by a Patent

Article 75 :

The following acts shall remain outside the scope of rights conferred by a patent :

b/ Acts involving, for experimental purposes, the invention, subject matter of a patent;

UGANDA : *Section 28 a) of the Patent Act of 15/10/1993*

28. Limitation

The rights of an owner of a patent shall extend only to the use of the patented invention for industrial or commercial purposes, but those rights shall not be deemed to be infringed by the following—

(a) acts done in pursuance of scientific research;

UKRAINE : *Article 31 (2) of the Law on the Protection of Rights to Inventions and Utility Models (The translation is not official) No. 3687-XII of 15/12/1993 as last amended in 2003*

2. The use of the patented invention (utility model) shall not be considered to be the infringement of rights deriving from a patent provided that it is used:
for scientific or experimental purposes;

UNITED KINGDOM (EU) : *Section 60 (5) b) of the Patents Act of 1977(unofficial consolidation of 01/01/2010)*

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if -

(b) it is done for experimental purposes relating to the subject-matter of the invention;

UNITED REPUBLIC OF TANZANIA : *Section 37 (1) of the Patents Act No. 1 of 1987 as amended by Acts No.13 and 18 of 1991*

Tanzania: Article 37:

1) The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research.

URUGUAY : *Article 39 D) and E) of the Industrial Property Law No. 17.164 of 02/09/1999*
Sección III Excepciones, alcance y agotamiento del derecho

Artículo 39.- El derecho que confiere una patente no alcanzará a los siguientes actos:

D) Los realizados exclusivamente con fines de experimentación, incluso preparatorios de una futura explotación comercial, realizados dentro del año anterior al vencimiento de la patente.

E) Los realizados con fines de enseñanza o investigación científica o académica.

UZBEKISTAN : *Section 12 of the Law on Inventions, Utility Models and Industrial Designs*
No. 1068-XII of 29/08/2002

The following shall not be recognized as an infringement of a patent owner's exclusive right:
- the conduct of scientific research or an experiment on means containing industrial property subject matter protected by patents;

VIET NAM : *Article 125 (2) a) of the Intellectual Property Law No. 50/2005/QH11 of*
29/11/2005

Article 125.- Right to prevent others from using industrial property objects

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

a) Using inventions, industrial designs or layout-designs in service of their personal needs or for noncommercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products;

ANDEAN COMMUNITY: *Article 53 (b) of the decision no. 486 of 14/09/2000 of the*
Commission of the Andean Community

53. The owner of the patent may not exercise the right referred to in the foregoing Article in relation to the following acts:

(b) acts performed for exclusively experimental purposes on the subject matter of the patented invention;

GCC : *Section 14 (1) of the Patent Regulation of the GCC (approved by the Supreme Council*
of the Cooperation Council for the Arab States of the Gulf) of 1992 (as at 23/04/2002)

Article 14: The rights under the patent shall not extend to:

1) Acts done particularly for experimental purposes

OAPI : *Article 8 (1) c) of the Bangui Agreement of 02/03/1977 (Annex I), as last amended in*
February 1999

Article 8(1): The rights deriving from the patent shall not extend:

(c) to acts in relation to a patented invention that are carried out for experimental purposes in the course of scientific and technical research;

(4) PROVISIONS OF LAW ON REGULATORY REVIEW (BOLAR) EXCEPTION

AUSTRALIA : *Section 119 A of the Patent Act 1990 as last amended by Law No. 106 of 2006*

119A Infringement exemptions: acts for obtaining regulatory approval of pharmaceuticals

(1) The rights of a patentee of a pharmaceutical patent are not infringed by a person exploiting an invention claimed in the patent if the exploitation is solely for:

(a) purposes connected with obtaining the inclusion in the Australian Register of Therapeutic Goods of goods that:

(i) are intended for therapeutic use; and

(ii) are not medical devices, or therapeutic devices, as defined in the Therapeutic Goods Act 1989; or

(b) purposes connected with obtaining similar regulatory approval under a law of a foreign country or of a part of a foreign country.

(2) Subsection (1) does not apply to the export from Australia of goods for purposes described in paragraph (1)(b) unless the term of the patent has been extended under Part 3 of Chapter 6 and the goods consist of or contain:

(a) a pharmaceutical substance per se that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification; or

(b) a pharmaceutical substance when produced by a process that involves the use of recombinant DNA technology, that is in substance disclosed in the complete specification of the patent and in substance falls within the scope of the claim or claims of that specification. [Note: Part 3 of Chapter 6 provides for the extension of the term of standard patents claiming pharmaceutical substances.]

(3) In this section:

pharmaceutical patent means a patent claiming:

(a) a pharmaceutical substance; or

(b) a method, use or product relating to a pharmaceutical substance, including any of the following:

(i) a method for producing a raw material needed to produce the substance;

(ii) a product that is a raw material needed to produce the substance;

(iii) a product that is a pro-drug, metabolite or derivative of the substance.

BRAZIL : *Article 43 (VII) of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001*

43. The provisions of the previous Article do not apply:

VII- to acts performed by non-authorized third parties, regarding patented inventions, which aim exclusively the production of information, data and test results directed to procure commerce registration, in Brazil or any other country, to allow the exploitation and commercialisation of the patented product, after the termination of the terms provided in article 10.”

BULGARIA (EU) : *Article 20 (7) of the Law on Patents and Utility Models Registration No. 27/2 of 1993 as last amended by Law no. 59/20 of July 2007*

Art. 20. The effect of a patent shall not extend to:

7. (new, State Gazette No. 64/2006, in force as from 09.11.2006; deleted, State Gazette No.31/2007, in force as from 13 April 2007) conduction of necessary researches and tests for the purpose of filing a marketing authorization request for a generic medical product to be used in the human medicine or a generic medical product to be used in the veterinary medicine, as well as any other act related to subsequent practical requirements in connection with the filing of the request.

CANADA : *Section 55.2 (1), (5) and (6) of the Patent Act (R.S., 1985, c. P-4) (Act current to 21/01/ 2010) and Manufacturing and Storage of Patented Medicines Regulations Exception*

55.2 (1) It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

Inconsistency or conflict

CHINA : *Article 69 (5) of the Patent Act of 12/03/1984 as last amended on 27/12/2008*

Article 69: None of the following shall be deemed an infringement of the patent right:

(5) For the purpose of providing the information needed for the administrative approval, manufacture, use, import of a drug or a medical apparatus, and exclusively for such manufacture any import of a patented drug or a patented medical apparatus.

COSTA RICA : *Article 16 (2) e) of the Law on Patents, Industrial Designs and Utility Models No. 6867 of 25/04/1983, as amended by Law No. 7979 of 12/10/2000*

2. Siempre que las siguientes excepciones no atenten de manera injustificable contra la explotación normal de la patente, ni causen un perjuicio injustificado a los legítimos intereses de su titular o su licenciataria, los derechos conferidos por la patente no se extienden a:

e) Los usos necesarios para investigar, tramitar, procesar o cualesquiera otros requisitos para obtener la aprobación sanitaria con el fin de comercializar un producto después de expirar la patente que lo protege.

(Así reformado por el artículo 2.d) de la Ley 7979 del 6 de enero del 2000)

CROATIA : *Article 63 no.2 of the Patent Act No. 173 of 2003, as amended by Acts No. 87/2005 and No. 76/2007*

Article 63

The patent owner's exclusive right of exploitation of the invention shall not apply to:

2. acts done for the purposes of research and development and for experiments relating to the subject-matter of the protected invention, including where such acts are necessary for

obtaining registration or authorization for putting on the market a product comprising a medicine intended for people or animals, or a medicinal product.

CZECH REPUBLIC (EU) : *Section 18 e) of the Patents Act No. 527 of 1990 as last amended by Act No. 378/2007*

Section 18

The rights of the proprietor of the patent shall not be infringed by use of the protected invention:

e) in acts relating to the subject-matter of the invention done for experimental purposes including experiments and tests necessary, pursuant to the special legal regulation, before placing a medicine on the market

DENMARK (EU) : *Section 3 (3) (iv) of the Consolidate Patent Act No. 91 of 28/01/2009*

(iv) acts delimited to the subject-matter of the patented invention which are necessary for obtaining a marketing authorization for a medicinal products for humans or animals in the EU, in an EU member state or in other countries, or (...)

DOMINICAN REPUBLIC : *Article 30 g) of the Law on Industrial Property No. 20-00 of 18/04/2000*

Article 30.- limitation and Extent of the Rights of the Patent

The patent does not give the right to prevent:

g) Those uses necessary for obtaining health approval and for marketing a product after the expiration of the patent protecting it.

EGYPT : *Article 10 (5) of the Intellectual Property Law 82 of 2002*

(5) Where a third party proceeds, during the protection period of a product, with its manufacturing, assembly, use or sale, with a view to obtain a marketing license, provided that the marketing starts after the expiry of such a protection period.

FINLAND (EU) : *Section 3 (2) no. 4 of the Patent Act No. 550 of 15/12/1967, as last amended by Act 684/2006 of 21/07/2006.*

Section 3 (2)

The exclusive right shall not apply to:

(4) examinations or experiments or measures arising from practical demands which are needed for an application to obtain a marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product (21.4.2006/295); or

FRANCE (EU) : *Article L613-5 d) of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 as last amended by Law No. 2007-1540*

Article L613-5 En savoir plus sur cet article...
Modifié par LOI n°2008-518 du 3 juin 2008 - art. 22
Les droits conférés par le brevet ne s'étendent pas :

d) Aux études et essais requis en vue de l'obtention d'une autorisation de mise sur le marché pour un médicament, ainsi qu'aux actes nécessaires à leur réalisation et à l'obtention de l'autorisation ;

GERMANY (EU): *Section 11 no. 2 b of the Patent Act as last amended by the Act on Improvement of Enforcement of Intellectual Property Rights of 31/07/2009*

The effects of a patent shall not extend to:

2b. studies and trials and the resulting practical requirements necessary for obtaining a marketing authorization to place a medicinal product on the market in the European Union or a marketing approval for a medicinal product in the Member States of the European Union or in third countries;

HUNGARY (EU) : *Article 19 (6) b) of the Law on the Protection of Inventions by Patents No. XXXIII of 1995 (Consolidated text of 01.10.2009)*

(6) The exclusive right of exploitation shall not extend to:

(b) acts done for experimental purposes relating to the subject matter of the invention, including experiments and tests necessary for the marketing authorisation of the product constituting the subject matter of the invention or the product obtained through the process constituting the subject matter of the invention;

ICELAND : *Article 3 (2) no.3 of the Patents Act No. 17/1991 as last amended by Act No. 167/2007*

Article 3

The following are excepted from the exclusive right:

3. use of the invention for experiments which relate to the invention itself, [i.a. studies and trials and other related procedures that are necessary to make possible an application for marketing authorization for e.g. a generic medicinal product and an improved pharmaceutical form;

INDIA : *Section 107A of the Patent Act of 1970 as last amended in 2005*

107A. For the purposes of this Act,-

(c) any act of making, constructing, using or selling or importing a patented invention solely for uses reasonably relating to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use or sale of any product;

(d) importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product,

shall not be considered as an infringement of patent rights.

ISRAEL : *Section 54a of the Patents Law 5727-1967*

Experimental act in order to obtain license

54A. An experimental act, which is part of an effort to obtain a license to market the product after the patent has lapsed, does not constitute “exploitation of an invention”, if the following two conditions are met:

- (1) the effort to obtain a license is made in order to obtain a license in Israel or in a country, in which an experimental act on a patent protected invention for the purpose of obtaining a license is permitted before the patent lapses;
- (2) any product produced under the terms of this section is not used-both while the patent is in effect or thereafter-for any purpose other than obtaining a license as aforesaid; for purposes of this section, “license”-certification, permit or any other document required under Law in order to market the product.

ITALY (EU) : *Article 68 of the Industrial Property Code, Legislative Decree No. 30 of 10/02/2005*

Art. 68.

Limitazioni del diritto di brevetto

1. La facoltà esclusiva attribuita dal diritto di brevetto non si estende, quale che sia l'oggetto dell'invenzione:
 - a) agli atti compiuti in ambito privato ed a fini non commerciali, ovvero in via sperimentale ancorché diretti all'ottenimento, anche in paesi esteri, di un'autorizzazione all'immissione in commercio di un farmaco ed ai conseguenti adempimenti pratici ivi compresi la preparazione e l'utilizzazione delle materie prime farmacologicamente attive a ciò strettamente necessarie;

JORDAN : *Article 21 C of the Patent Act No. 32 of 1999, as last amended by Act No. 71/2001*

Article 21

C. Notwithstanding any conflicting provision in this law or any other law, all types of scientific research and development and filing applications for obtaining marketing permits carried out before the elapse of the patent protection period shall not be regarded as infringement neither civil nor criminal.

KENYA : *Section 54 (2) of the Industrial Property Act No. 3 of 27/07/2001*

Rights of Owner of Patent

54.—(2) The rights conferred on the owner of the patent under this section shall not apply to acts by third parties necessary to obtain approval or registration of a product from the Institute, for the purpose of commercialising the product after expiry of the patent.

LATVIA (UE) : *Section 20 no.3 of the Patent Law adopted on 15/02/2007*

Section 20. Limitations of Exclusive Rights Resulting from the Patent

The exclusive rights resulting from the patent shall not extend to:

3) examination of the subject-matter of a patent, as well as to the research of patented or protected with a supplementary protection certificate medicinal products or plant protection means, which is carried out in order to obtain a permission for the placing on the market thereof;

MALAYSIA : *Section 37 (1A) of the Patents Act of 1983 as last amended in 2006*

Section 37. Limitation of rights.

(1A) The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs.

MALTA (EU) : *Article 27 (6) lett. d of the Patents and Designs Act, Chapter 417, of 01/06/2002, as last amended by Acts IX of 2003 and XVIII of 2005*

(6) Notwithstanding subarticles (1) and (2), the proprietor of a patent shall have no right to prevent third parties from performing the acts referred to in subarticles (1) and (2)(b) in the following circumstances:

(d) when an act is done for purposes which can reasonably be related to the development and presentation of information required by the law of Malta or any other country that regulates the production, use or sale of medicinal or phytopharmaceutical products;

NETHERLANDS (EU) : *Section 53 (4) of the Kingdom Act of 15/12/1994, containing rules in respect of patents (the Dutch Patents Act) (Text as it applies on 03/06/2009)*

4. The performance of necessary studies, tests and experiments in connection with the application of Article 10(1) to (4) of Directive 2001/83/EC on the Community Code relating to medicinal products for human use (Official EC Journal L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community Code relating to veterinary medicinal products (Official EC Journal L 311) and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively.

NEW ZEALAND : *Section 68B of the Patent Act of 1953 as at 01/08/2008*

“68B Regulatory review exception

It is not an infringement of a patent for a person to make, use, exercise, or vend the invention concerned solely for uses reasonably related to the development and submission of

information required under New Zealand law or the law of any other country that regulates the manufacture, construction, use, or sale of any product.”

NORWAY : *Section 3 (3) no. 5 of the Act No. 9 of 15/12/1967 on patents (The Norwegian Patents Act) (as last amended by Act No.80 of 29/06/2007)*

The exclusive right shall not include:

5) Trials, experiments and similar of a patented medicine that are required to obtain a marketing authorisation for a medicine in a state that is a contracting party to the agreement of 15 April 1994 on the establishment of the World Trade Organization (The WTO Agreement).

POLAND (EU) : *Article 69 (1), (iv) and (5) of the Industrial Property Law of 30/06/2000 as amended by Act of 23/01/2004 and Act of 29/06/2007*

Article 69

1. The following shall not be considered acts of infringement of a patent:

(iv) the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products;

5. Grant of the registration or the authorisation referred to in paragraph (1)(iv) shall be without prejudice to civil liability for putting on the market of a product without the patent holder's consent, where such consent is required.

PHILIPPINES: *Section 72 no. 4 of the Intellectual Property Code, Act No. 8293 of 06/06/1997 as last amended by Act No. 9502 of 2008*

In the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product: provided that, in order to protect the data submitted by the original patent holder from unfair commercial use provided in article 39.3 of the Agreement on Trade-Related Aspects on intellectual property Rights (TRIPS Agreement), the Intellectual property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein not later than one hundred twenty (120) days after the enactment of this law;

PORTUGAL (EU) : *Article 102 c) of the Industrial Property Code (approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April)*

Article 102

Limitation of rights conferred by a patent

The rights conferred by a patent do not extend to:

c) Acts performed exclusively for trial or experimental purposes, including experiments for the preparation of the administrative processes required for the approval of products by the competent official bodies, though industrial or commercial exploitation of these products may not commence before expiry of the patent protecting them;

ROMANIA (EU) : *Article 80 (1) a) of the Patent Law No. 64 of 1991 as republished in the Official Gazette of Romania No. 456/18.VI.2008*

Article 80

Exceptions concerning the infringement of rights

(1) In the application of Art. 34 paragraph (1) letter e) of the Law, the following shall not constitute an infringement of the rights provided for in Art. 32 and 33 of the Law:

- a) the carrying out of the tests and studies necessary for obtaining the authorization for placing a medicament on the market, as well as the practical requirements resulting therefrom;
- b) use for education purposes of the information contained in the patent;
- c) the acts concerning the research and development of information contained in the patent, on condition that they are destined exclusively to experiments or studies which intend to evaluate the technical data from the patents.

SERBIA : *Article 59 no. 2 of the Patent Law No. 15 of 02/07/2004*

Article 59

The exclusive rights of a patent owner referred to in Articles 52 and 53 of this Law shall not apply to:

- 2) research and development activities relating to the subject matter of a protected invention, including activities that are necessary for obtaining an authorisation from the competent state authority for placing on the market a product which is a drug intended for use on humans or animals, or a medicinal product;

SINGAPORE : *Section 66 (2) h) of the Patent Act (Chapter 221) No. 21 of 25/11/1994 as of 01/12/2008*

(2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —

(h) it consists of the doing of any thing set out in subsection (1) in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that any thing produced to support the application is not —

- (i) made, used or sold in Singapore; or
- (ii) exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product;

SLOVAKIA (EU) : *Article 18 (2) f) of the Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates as last amended by Act No. 517/2007 Coll.*

Article 18

(2) Rights of a patent owner shall not be infringed if an invention is exploited:

f) in activity conducted for experimental purposes which shall also be studies, exams necessary for registration proceedings pursuant to a special regulation.

SLOVENIA (EU) : *Article 19 b) of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

Article 19

Limitation of rights conferred by a patent

The rights conferred by a patent within the meaning of Article 18 shall not extend to:

(b) acts done for research and experimental purposes of any kind relating to the subject matter of the patent irrespective of their final purpose;

SOUTH AFRICA : *Section 69A of the Patents Act No. 57 of 1978 (as last amended by Act No. 58 of 2002)*

69A. Acts of non-infringement.

(1) It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

(2) It shall not be permitted to possess the patented invention made, used, imported or acquired in terms of subsection (1) for any purpose other than for the obtaining, development or submission of information as contemplated in that subsection.

[S. 69A inserted by s. 16 of Act No. 58 of 2002.]

SPAIN (EU) : *Article 52 (1) b) of the Law about Patents of Invention and Utility Models No.11/1986 of 20/03/1986 as last amended by Law No. 10 of 29/04/2002*

Artículo 52. 1. Los derechos contenidos por la patente no se extienden:

b) A los actos realizados con fines experimentales que se refieran al objeto de la invención patentada, en particular los estudios y ensayos realizados para la autorización de medicamentos genéricos, en España o fuera de España, y los consiguientes requisitos prácticos, incluidos la preparación, obtención y utilización del principio activo para estos fines.

(Párrafo redactado conforme a la disposición final segunda Ley 29/2006, de 26 de julio, de garantías y uso racional de los medicamentos y productos sanitarios)

SWITZERLAND : *Article 9 (1) c) of the Patent Law of 25/06/1954 (as on 01/07/2009)*

1 Les effets du brevet ne s'étendent pas:

c. aux actes nécessaires à l'obtention d'une autorisation de mise sur le marché d'un médicament en Suisse ou dans un pays ayant institué un contrôle de médicament équivalent;

THAILAND : *Section 36 (2) no.4 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 36 (2)

The preceding paragraph shall not apply to:

(4) any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term;

THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA : *Article 91 no. 2 of the Law on Industrial Property adopted on 12/02/2009*

Article 91

The right of the patent holder laid down in Article 89 of this Law regarding the exclusive utilisation of the invention shall not relate to:

2) undertaking activities for research and development of the subject of the protected invention, in particular: manufacture, use, offer for sale, export or import of the protected invention, including also activities for obtaining approval for placing medications for human and veterinary medicine and products for protection of plants on the market; and

TUNISIA : *Article 47 (e) of the Patents Law No. 2000-84 of 24/08/2000*

47. The rights conferred by the patent shall not extend to the following:

(e) acts necessary for the manufacture of generic drugs, provided that the commercial exploitation of the product of those acts may not be engaged in until the term of patent protection has expired;

UNITED KINGDOM (EU) : *Section 60 (5) (i) of the Patents Act of 1977(unofficial consolidation of 01/01/2010)*

(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if – (...)

(i) it consists of –

(i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of article 10 of Directive 2001/83/EC, or

- (ii) any other act which is required for the purpose of the application of those paragraphs.

UNITED STATES OF AMERICA : 35 USC § 271(e)

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit —

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151 - 158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)—

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product, and

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug or veterinary biological product.

The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

URUGUAY : *Article 39 D) of the Industrial Property Law No. 17.164 of 02/09/1999*

Artículo 39.- El derecho que confiere una patente no alcanzará a los siguientes actos:

D) Los realizados exclusivamente con fines de experimentación, incluso preparatorios de una futura explotación comercial, realizados dentro del año anterior al vencimiento de la patente.

VIET NAM : *Article 125 (2) a) of the Intellectual Property Law No. 50/2005/QH11 of 29/11/2005*

Article 125.- Right to prevent others from using industrial property objects

2. Owners of industrial property objects as well as organizations and individuals granted the right to use or the right to manage geographical indications shall not have the right to prevent others from performing the following acts:

a) Using inventions, industrial designs or layout-designs in service of their personal needs or for noncommercial purposes, or for purpose of evaluation, analysis, research, teaching, testing, trial production or information collection for carrying out procedures of application for licenses for production, importation or circulation of products;

EUROPEAN UNION : *Directive 2001/82/EC (for veterinary medicinal products) and 2001/83/EC (medicinal products for human use) and the amending Directives 2004/27/EC and 2004/28/EC*

(5) PROVISIONS OF LAW ON UTILITY MODELS

ALBANIA : *Articles 88-89 and 92-93 of the Law on Industrial Property No. 9977 of 07/07/2008*

Article 88

Conditions for Protection

With the exception of processes, animal and plant varieties, the following inventions can be protected by a utility model:

- a) inventions which are patentable according to this Law;
- b) inventions which are new, susceptible of industrial application and are the result of a creative effort.

Article 89

Novelty and Applicability in Industry

Novelty and applicability in industry of utility models are defined in conformity with the provisions of articles 7 and 10 of this Law.

Article 92

Treatment

The treatment of utility models is the same as the treatment of patents according to this Law, unless otherwise provided in this chapter.

Article 93

Articles 52, 53, 54, 73 and 74 of this Law are valid for and shall be also applied to utility models.

ANTIGUA AND BARBUDA : *Sections 26- 27 of the Patents Act No. 23 of 2003*

26. (1) Subject to section 27, the provisions of this Applicability of Act shall apply, *mutatis mutandis*, to utility model certificates or applications therefor as the case may be.

(2) Where the right to a patent conflicts with the right to a utility model certificate in the case referred to in section 4(3), the said provision shall apply as if the word “patent” were replaced by the words “patent or utility model certificate.”

27. (1) An invention qualifies for a utility model certificate if it is new and is industrially applicable. relating to utility model certificates.

(2) Section 3 (1) and (5) shall not apply in the case of inventions for which utility model certificates are requested.

ARGENTINA : *articles 53, 55 and 58 of the Patents and Utility Models Law No. 24.481 of 1996*

Artículo 53 - Toda disposición o forma nueva obtenida o introducida en herramientas, instrumentos de trabajo, utensilios, dispositivos u objetos conocidos que se presten a un trabajo práctico, en cuanto importen una mejor utilización en la función a que estén

destinados, conferirán a su creador el derecho exclusivo de explotación, que se justificará por títulos denominados certificados de modelos de utilidad.

Este derecho se concederá solamente a la nueva forma o disposición tal como se la define, pero no podrá concederse un certificado de modelo de utilidad dentro del campo de protección de una patente de invención vigente.

Artículo 55 - Serán requisitos esenciales para que proceda la expedición de estos certificados que los inventos contemplados en este título sean nuevos y tengan carácter industrial; pero no constituirá impedimento el que carezca de actividad inventiva o sean conocidos o hayan sido divulgadas en el exterior.

Artículo 58 - Son aplicables al modelo de utilidad las disposiciones sobre patentes de invención que no le sean incompatibles.

ARMENIA : *Article 15 of the Law on Inventions, Utility Models and Industrial Designs of 10/06/2008*

Article 15. Conditions for patentability of Utility Model

- (1) Any new and industrially applicable solution that concerns a production (equipment, material) or a method (condition for patentability of utility model) shall be protected as a utility model in the order established by the Law.
- (2) A utility model shall be considered to be new if it does not form separate part of the state of the art.
- (3) The state of the art shall be defined to comprise any kind of information on technical solutions made available to the public anywhere in the world before the date of priority of the utility model concerned, as well as realization of these solutions in the Republic of Armenia. As well, the state of the art shall comprise the content of inventions and utility models by disclosed applications with earlier priority filed with the State Authorized Body, provided that the State Authorized Body subsequently publishes those applications or the patents granted on the basis thereof.
- (4) The utility models shall not be considered patentable if:
 - (a) it is a technical solution on biological substance;
 - (b) it is a technical solution on chemical or pharmaceutical substances or means, as well as methods of human and animal curing;
 - (c) the subject matters mentioned in Article 10 (2) of this Law.
- (5) The provisions of this Law on inventions, utility models shall be considered *mutatis mutandis*, unless otherwise provided by this Law.

AUSTRALIA : *Section 18 (1A) and (2) of the Patent Act No. 83 of 1990 as amended by Act No. 106 of 2006*

Patentable inventions for the purposes of an innovation patent

(1A) Subject to subsections (2) and (3), an invention is a patentable invention for the purposes of an innovation patent if the invention, so far as claimed in any claim:

- (a) is a manner of manufacture within the meaning of section 6 of the Statute of Monopolies; and
- (b) when compared with the prior art base as it existed before the priority date of that claim:

(i) is novel; and
(ii) involves an innovative step; and
(c) is useful; and
(d) was not secretly used in the patent area before the priority date of that claim by, or on behalf of, or with the authority of, the patentee or nominated person or the patentee's or nominated person's predecessor in title to the invention.

(2) Human beings, and the biological processes for their generation, are not patentable inventions.

Certain inventions not patentable inventions for the purposes of an innovation patent

(3) For the purposes of an innovation patent, plants and animals, and the biological processes for the generation of plants and animals, are not patentable inventions.

(4) Subsection (3) does not apply if the invention is a microbiological process or a product of such a process.

AUSTRIA (EU) : *Sections 1-3 of the Utility Model Act No. 211/1994 as amended by BGBl. No. 175 of 1998 and 143 of 2001*

Section 1 Subject Matter

(1) Upon application inventions which are new (Section 3), which are based on an inventive step and which are susceptible to industrial application shall be protected as utility models.

(2) The program logic on which programs for data processing systems are based shall also be regarded as an invention as defined by subsection (1).

(3) The following in particular shall not be regarded as inventions as defined by subsection (1):

1. discoveries, scientific theories, and mathematical methods;
2. aesthetic creations;
3. schemes, rules and methods for performing mental acts, for playing games or for doing business, and programs for data processing systems;
4. presentations of information.

(4) The provisions of subsection (3) shall exclude the protection as utility models of the subject matter or activities referred to in that subsection only to the extent to which protection is demanded for them as such.

Section 2 Exceptions

The following shall not be protected as utility models:

1. inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by regulations;
2. methods for treatment of humans by surgery or therapy and diagnostic methods practiced on humans; this shall not apply to products, in particular substances or compositions, for use in any of these methods;
3. plant or animal varieties (animal races) including microorganisms or essentially biological processes for the production of plants or animals.

Section 3 Novelty

(1) An invention shall be considered to be novel if it does not form part of the state of art. The state of art shall be held to comprise everything made available to the public by means of a

written or oral description, by use or in any other way, before the priority date of the application.

(2) As state of the art shall also be considered the contents of earlier priority date.

1. utility model applications on the basis of this Federal Law,
2. patent applications on the basis of the 1970 Patents Act, Federal Law Gazette no. 259,
3. international applications in the meaning of section 1, (6) of the Act Introducing Patent Treaties, Federal Law Gazette no. 52/1979, provided the conditions as set out in section 16, subsection 2 of the Act Introducing Patent Treaties are fulfilled, and
4. European patent applications in the meaning of section 1, (4) of the Act Introducing Patent Treaties, provided the conditions of article 79, subsection 2 of the European Patent Convention, Federal Law Gazette no. 350/1979, or, where the European patent application was filed on the basis of an international application, the conditions of article 158, subsection 2 of the European Patent Convention are fulfilled,

in the version as originally filed whose contents were not officially published before the priority date of the later applications or thereafter. When assessing the question whether the invention is not obvious to the person skilled in the art from the prior art, such applications of an earlier priority date are not taken into consideration.

(3) The protectability of substances or compositions that are comprised in the state of art shall not be excluded by subsection (1) if intended for use in a method referred to in Section 2(2) or in any such method for animals and unless their use in any of these methods is part of the state of art.

(4) For the application of subsection (1) a disclosure of the invention shall not be taken into consideration if it occurred not earlier than six months prior to the filing date of the application and if it was directly or indirectly due to:

1. the applicant or his legal predecessor, or
2. an evident abuse to the prejudice of the applicant or his legal predecessor.

BELARUS : Section 3 of the Law on Patents for Inventions, Utility Models and Industrial Designs No. 160-Z of 16/12/2002

Conditions of Patentability of Utility Models

3.—(1) A technical solution relating to a device shall constitute a utility model eligible for legal protection under this Law if it is novel and industrially applicable.

A utility model shall be considered novel if the sum of its essential features does not form part of the prior art.

The prior art shall consist of any kind of information which has been made available to the public anywhere in the world, before the priority date of the claimed utility model, concerning devices of similar function and their use in the Republic of Belarus. When determining the novelty of a utility model, the prior art shall likewise include all applications for the protection of inventions and utility models that have been filed in the Republic of Belarus, that enjoy earlier priority and that have not been withdrawn, and also inventions and utility models that have been patented in the Republic of Belarus.

A utility model shall be considered industrially applicable if it can be used in industry, agriculture, public health and other fields of activity.

Disclosure of information concerning the utility model shall not adversely affect its patentability where it has the effect of making information on the utility model generally accessible, where such disclosure is made by the applicant (or author) or by any other person who has obtained such information directly or indirectly from them and where such disclosure

occurred during the 12 months preceding the filing of the application with the Patent Office. The burden of proof of the foregoing shall be on the applicant.

- (2) Under paragraph (1) of this Law, no legal protection shall be granted for:
- solutions concerning solely the outward appearance of manufactured articles and intended to satisfy aesthetic requirements;
 - solutions contrary to public interest, humanitarian principles or morality.

BELIZE : Sections 49-50 of the Patents Act (Ch. 253) No. 14 of 21/06/2000

- 49.-(1) Except as otherwise provided under this Part, the provisions of this Act relating to patents and applications shall apply to utility model certificates and applications therefor.
(2) Sections 8, 10, 28 and 47(1) shall not apply to utility model certificates and to applications therefor.

Qualification of Invention for Utility Model Certificate

- 50.-(1) An invention shall qualify for a utility model certificate if it is new and industrially applicable.
(2) An invention for which a utility model certificate is applied for shall not be considered new if it differs from earlier inventions only in minor respects or in details which are immaterial to the function or application of the invention.

BOTSWANA : Sections 34-35 of the Industrial Property Act No. 14 of 21/08/1996

34. Save as provided under the provisions of this Part, the provisions of Part II shall apply, mutatis mutandis, to utility model certificates or applications therefor.
35. (1) An invention shall qualify for a utility model certificate if it is new and industrially applicable.
(2) Section 22 (2) shall not apply to any application for a utility model certificate.

BRAZIL : Articles 9-11 of the Industrial Property Law No. 9.279 of 14/05/1996 as last amended by Law No. 10.196 of 14/02/2001

9. An object of practical use, or part thereof, is patentable as utility model if it is susceptible of industrial application, has a new form or arrangement, and involves an inventive act, that results in functioning improvement in its use or manufacture.

10. The following are not considered to be inventions or utility models:

- I. discoveries, scientific theories, and mathematical methods;
- II. purely abstract conceptions;
- III. commercial, accounting, financial, educational, advertising, raffling, and inspection schemes, plans, principles or methods;
- IV. literary, architectural, artistic and scientific works, or any aesthetic creation;
- V. computer programs per se;
- VI. presentation of information;
- VII. rules of games;

VIII. surgical techniques and methods, as well as therapeutic or diagnostic methods, for application to human or animal body; and

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.

11. An invention and a utility model are considered to be new if they are not part of the state of the art.

(1) The state of the art consists of everything that became accessible to the public prior to the filing date of the patent application, by means of a written or oral description, by use or by any other means, in Brazil or abroad, except as provided in Articles 12, 16, and 17.

(2) For the purposes of determining novelty, the entire content of an application filed in Brazil, and not yet published, shall be considered to be state of the art from the date of filing or of claimed priority, provided that it comes to be published, even subsequently.

(3) The provisions of the preceding Paragraph shall apply to an international patent application filed according to a treaty or convention in force in Brazil, provided that there is national processing.

*BULGARIA (EU) : Articles 73-73d of the Law on Patents and Utility model Registration
(Title amended, State Gazette No. 64/2006; in force as from 09/11/2006)*

Patentable Utility Models

Art. 73. (amended, State Gazette No. 64/2006, in force as from 09.11.2006) (1) Legal protection for utility models shall be granted through registration with the Patent Office. The registration shall have effect with respect to third parties as of the date of publication in the Official Bulletin of the Patent Office.

(2) The right to a registration shall belong to the person who has the right to file an application under Article 13.

(3) Utility models shall be registered, which are new, involve an inventive step and are susceptible of industrial application.

(4) The objects referred to in Articles 6(2) and (4) shall not be regarded as utility models, in so far as legal protection is sought for them as such.

(5) No utility model registration shall be granted to biotechnological inventions within the meaning of Article 7a, methods, chemical compounds or the use thereof, and the objects referred to in Article 7.

Novelty

Art. 73a (new, State Gazette No. 64/2006, in force as from 09.11.2006)

(1) A utility model shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise:

1. everything made available to the public through use in the Republic of Bulgaria by means of a written or oral description or in any other way, anywhere in the world, before the filing date or the priority date, as appropriate, of the utility model application.

2. the contents of all national, European and international applications referred to in Article 8(3) and (4).

Disclosure Which is not Prejudicial to Novelty

Art. 73b (new, State Gazette No. 64/2006, in force as from 09.11.2006) (1) A disclosure of the utility model shall not be prejudicial to novelty if it was carried out within twelve months

preceding the filing date or the priority date, as appropriate, of the application for registration by:

1. the applicant or his grantor;
 2. a third party in an evident abuse with respect to the applicant or his grantor.
- (2) The privilege under paragraph (1) may be claimed at any time.

Inventive Step

Art. 73c (new, State Gazette No. 64/2006, in force as from 09.11.2006) A utility model shall be considered to involve an inventive step if a person possessing ordinary knowledge and skills in the art cannot easily realize it on the basis of the state of the art under Article 73a(2) item 1.

Industrial Applicability

Art. 73d (new, State Gazette No. 64/2006, in force as from 09.11.2006) The industrial applicability of utility models shall be determined in accordance with Article 10.

CHILE : *Articles 54-56 of the Industrial Property Law No. 19.039 of 24/01/1991, as last amended in 2005*

Artículo 54.- Se considerarán como modelos de utilidad los instrumentos, aparatos, herramientas, dispositivos y objetos o partes de los mismos, en los que la forma sea reivindicable, tanto en su aspecto externo como en su funcionamiento, y siempre que ésta produzca una utilidad, esto es, que aporte a la función a que son destinados un beneficio, ventaja o efecto técnico que antes no tenía.

Artículo 55.- Las disposiciones del título III, relativas a las patentes de invención, son aplicables, en cuanto corresponda, a las patentes de modelos de utilidad, sin perjuicio de las disposiciones especiales contenidas en el presente título.

Artículo 56.- Un modelo de utilidad será patentable cuando sea nuevo y susceptible de aplicación industrial.

No se concederá una patente cuando el modelo de utilidad solamente presente diferencias menores o secundarias que no aporten ninguna característica utilitaria discernible con respecto a invenciones o a modelos de utilidad anteriores.

La solicitud de patente de modelo de utilidad sólo podrá referirse a un objeto individual, sin perjuicio de que puedan reivindicarse varios elementos o aspectos de dicho objeto en la misma solicitud.

CHINA: *Article 2 of the Rules for the implementation of the Patent Law (Decree No. 306 of 15/06/2001) and Articles 22 and 25 of the Patent Law of 12/03/1984 as last amended on 27/12/2008*

Article 2. “Utility model” in the Patent Law means any new technical solution relating to the shape, the structure, or their combination, of a product, which is fit for practical use.

Article 22. Any invention or utility model for which patent right may be granted must possess novelty, inventiveness and usefulness.

“Novelty” means that the invention or utility model shall neither belong to the prior art, nor has any entity or individual previously filed before the date of filing with the patent

administrative department under the State Council an application on an identical invention or utility model which was recorded in patent application documents or other gazetted patent documents published after the said date of filing.

“Inventiveness” means that, compared with the prior art the invention has prominent and substantive distinguishing features and represents a marked improvement, or the utility model possesses substantive distinguishing features and represents an improvement.

“Usefulness” means that the invention or utility model can be made or used and can create positive results.

The “prior art” referred to in this Law refers to any technology known to the public before the filing date of the patent application in China or abroad.

Article 25 For any of the following, no patent right shall be granted:

- (1) scientific discoveries;
- (2) rules and methods for mental activities;
- (3) methods for the diagnosis or for the treatment of diseases;
- (4) animal and plant varieties;
- (5) substances obtained by means of nuclear transformation;
- (6) two dimensional designs of images, colours or combinations of the two mainly serve as indicators.

For processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of this Law.

COSTA RICA : Articles 25-26 and 31 of the Patent Law No.6867 of 25/04/1983, as last amended in 2000

25. - 1. Para los efectos de la presente ley, se considerará dibujo industrial toda reunión de líneas o de colores, modelo industrial toda forma plástica, asociada o no a líneas o colores, siempre que esa reunión o esa forma de una apariencia especial a un producto industrial o de artesanía y pueda servir de tipo para su fabricación. Se considerará modelo de utilidad toda nueva disposición o forma obtenida o introducida en herramientas, instrumentos de trabajo o utensilios conocidos, que permitan una mejor función o una función especial para su uso.

2. La protección concedida por la presente ley no comprende los elementos ni las características del dibujo o modelo industrial que sirvan únicamente para obtener un efecto técnico o funcional.

(Así reformado por el artículo 2.g) de la Ley 7979 del 6 de enero del 2000).

3. La protección concedida por la presente ley no excluye ni afecta los derechos derivados de otras disposiciones legales, en particular de las normas vigentes sobre derechos de autor.

4. El titular de un dibujo o modelo industrial protegido tendrá derecho a impedir que, sin su consentimiento, terceros fabriquen, vendan o importen artículos que ostenten o incorporen un dibujo o modelo que sea una copia o fundamentalmente una copia del dibujo o modelo protegido, cuando esos actos se realicen con fines comerciales.

(Así reformado por el artículo 2.g) de la Ley 7979 del 6 de enero del 2000).

Requisitos para la protección. Materia excluida

26. - 1. Los dibujos y modelos industriales nuevos y originales obtenidos independientemente, serán protegidos por esta ley.

2. No se registrarán los dibujos o modelos contrarios al orden público, la moral o las buenas costumbres, a condición de que estas excepciones no atenten, de manera injustificable, contra la explotación normal de los dibujos y modelos industriales protegidos, ni causen perjuicio injustificado a los intereses legítimos del titular del dibujo o modelo protegido; se tendrán en cuenta los intereses legítimos de terceros.

(Así reformado por el artículo 2.h) de la Ley 7979 del 6 de enero del 2000).

Normas supletorias

31. La parte primera de esta ley será aplicable, en lo conducente, a la protección de los dibujos y modelos Industriales y de los modelos de utilidad.

CROATIA : *Article 41 of the Patent Act No.173 of 2003, as amended by Acts no.87 of 2005 and no.76 of 2007*

Consensual patent

Article 41

A consensual patent shall be granted for an invention the subject-matter of which is patentable in compliance with Article 5 of this Act and is not excluded from patentability in compliance with Articles 6 and 7 of this Act, and which is industrially applicable in compliance with Article 11 of this Act.

CZECH REPUBLIC (EU) : *Sections 1-5 of the Utility Models Act No. 478 of 1992 as implemented by Act No. 116 of 2000 Coll.*

Section 1

Technical solutions which are new, exceed the framework of mere professional skill and are industrially applicable shall be protected as utility models.

Section 2

The following in particular shall not be deemed technical solutions:

- a) discoveries, scientific theories and mathematical methods;
- b) the mere appearance of products;
- c) schemes, rules and methods for performing mental acts;
- d) computer programs;
- e) the mere presentation of information.

Section 3

The following shall not be protected as utility models:

- a) technical solutions contrary to public interest, particularly the principles of humanity and public morality;
- b) plant or animal varieties and biological reproductive materials;
- c) production processes or work activities.

Section 4

(1) A technical solution shall be considered new if it does not form part of the state of the art.

(2) For the purposes of this Act, the state of the art shall be deemed to comprise everything made available to the public prior to the date from which the applicant claimed the right of priority (Section 9).

(3) The state of the art shall not be held to comprise any disclosure of the applicant's work or that of his predecessor in title, which took place within six months before the filing of the utility model application.

Section 5

A technical solution shall be considered susceptible of industrial application if it can be used repeatedly in economic activities.

DENMARK: Sections 1-4 of the Utility Model Act No. 130 of 26. February 1992, as amended by Act No. 972 of 17/12/1997

1.-(1) Any creation which is susceptible of industrial application or which provides a solution to a technical problem may on application, in accordance with this Act, be registered as a utility model.

(2) Any person who has created a utility model, or his successor in title, shall obtain an exclusive right to exploit the creation commercially upon registration.

2.-(1) Creations shall not be registered as utility models if relating to

(i) One of the items referred to in section 1, (2) to (4), in the Danish Patents Act,

(ii) plants or animals,

(iii) war materiel or

(iv) methods, cf. however section 47 of this Act.

(2) The Minister of Business and Industry shall lay down rules, after negotiation with the Minister of Defence and the Minister of Justice, concerning what is meant by war materiel for the purposes of this Act.

3.-(1) The creation shall be new in relation to the state of the art and shall differ distinctly therefrom.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, lectures, exhibition, offer for sale, use, reproduction or in any other way. Additionally, the contents of patent applications or utility model applications filed with effect for Denmark before the said date of filing shall be regarded as comprised in the state of the art, if such applications are made available to the public. However, the requirement in subsection 1 hereof that the creation shall differ distinctly from the state of art shall not apply in relation to the contents of such applications.

(3) The provisions in section 2 (5) of the Patents Act relating to exceptions from the requirement that creations shall be new shall apply mutatis mutandis.

4.-(1) Section 3 (1) to (3) of the Patens Act relating to the contents of the exclusive right, section 4 relating to a prior right of exploitation and section 5 relating to the right of exploitation shall apply mutatis mutandis.

(2) Article 76 in the Community Patent Convention shall apply to any acts concerning products put on the market in another State which has ratified or acceded to the Agreement relating to Community Patents.

DOMINICA : *Sections 49-50 of the Patents Act No. 8 of 07/10/1999*

49. (1) Except as otherwise provided under this Part, the provisions of this Act relating to patents and applications shall apply to utility model cetificates and applications therefore.

(2) sections 8, 10, 28 and 47 (1) shall not apply to utility model certificates and to applications therefore.

50. (1) an invention shall qualify for a utility model certificate if it is new and industrially applicable.

(2) an invention for which a utility certificate is applied for shall not be considered new if it differs from earlier inventions only in minor respects or in details which are immaterial to the function or application of the invention.

DOMINICAN REPUBLIC : *Articles 49-51 of the Industrial Property Law No. 20-00 of 08/05/2000*

Article 49.- Definition of a Utility Model

1) A utility model is considered to be any new form, configuration or arrangement of elements of any device, tool, instrument, mechanism or other object, or some part of the same, which permits better or different functioning, utilization or manufacture of the object incorporating it, or which gives it some utility, advantage or technical effect it did not have before.

2) Utility models are protected through the granting of patents.

Article 50.- Application of the Provisions Regarding Patents for Invention

The provisions of Chapter I relating to patents for invention are applicable, insofar as they are appropriate, to patents for utility model, except for the special provisions contained in this chapter. Article 28, numeral 1), is not applicable to patents for utility model.

Article 51.- Items Excluded from Protection as Utility Models

The following cannot be the object of a patent for utility model:

a) procedures.

b) chemical, metallurgical or any other kind of substances or compounds.

c) items excluded from protection by invention patent invention pursuant to this law.

EGYPT : *Article 29 of the Industrial Property Law No. 82 of 2002*

Article 29

A utility model patent shall be granted, under this Law for any new technical addition in the structure or composition of devices, tools, equipment or their components, or products, processes or means of manufacturing the above, and the like that is in current use.

The applicant may convert his application into a patent application, and the patent applicant may also convert his application to a utility model application.

In both cases the date of the original application shall prevail.

The Patent Office may, spontaneously, convert the application for a utility model to an application for a patent, when the relevant requirements are met.

EL SALVADOR : *Articles 120-122 of the Intellectual Property Law, legislative decree No. 604 of 15/07/1993 as last amended by Law No. No. 912 of 14/12/2005*

Art. 120. Utility model means any shape, configuration or arrangement of elements of any artefact, tool, instrument, mechanism or other object, or of any part thereof, that makes for the better or different operation, use or manufacture of the object incorporating it, or which lends it some usefulness, advantage or technical effect that it did not have previously.

Utility models that are new and susceptible of industrial application shall be registrable.

Art. 121. The Registry shall extend a utility model patent, which shall remain in force for a non-renewable period of 10 years, from the filing date of the application

Art. 122. Articles 108, 113, 115, 116, 117, 118 and 119 of this Law shall be applicable to utility models.

ESTONIA (EU) : *Sections 5-7 of the Utility Model Act of 16/03/1994 (consolidate version of 09/02/2000)*

§ 5.-(1) Utility models are inventions which are new, which involve an inventive step and which are susceptible of industrial application.

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

1. industrial designs;
2. layout-designs of integrated circuits;
3. discoveries, scientific theories and mathematical methods;
4. schemes, rules and methods for performing mental acts or doing business;
5. design documentation for and plans of constructions, buildings or areas;
6. symbols;
7. algorithms for computers and computer programs;
8. presentations of information;
9. human bodies or parts thereof;
10. plant or animal varieties.

(3) An invention is granted legal protection upon registration in the state register of utility models (hereinafter register).

(4) The scope of legal protection of a utility model is determined by the terms of the claims of the utility model.

- (5) Equipment, processes and materials can be protected as utility models.
(09.02.2000 entered into force 01.07.2000-RT I 2000, 19, 117)

Inventions not Protected as Utility Models

§ 6.-(1) The following shall not be protected as utility models:

1. inventions which are contrary to public order and morality;
2. methods of treatment and diagnostic methods practised on the human or animal body;
3. biotechnological inventions.

(2) For the purposes of this Act, “biotechnological inventions” specified in clause (1) 3) of this section mean:

1. inventions concerning biological materials or products which contain such materials;
2. inventions concerning the derivation or use of biological materials.

(3) For the purposes of this Act, “biological material” specified in subsection (2) of this section means any material, including micro-organisms, which contains genetic information and is capable of reproducing itself or being reproduced in a biological system.

(09.02.2000 entered into force 01.07.2000-RT I 2000, 19, 117)

Novelty, Inventive Step and Industrial Application

§ 7.-(1) An invention shall be considered to be new if it does not form part of the state of the art. The state of the art shall be held to comprise everything made available to the public by means of written or oral description, by use, or in any other way, before the filing date of the registration application of a utility model (hereinafter registration application) or before the date of priority if priority is claimed. In determining novelty, the content of registration applications published pursuant to § 33 of this Act and of patent applications published pursuant to § 24 of the Patents Act (RT I 1994, 25, 406; 1998, 74, 1227; 107, 1768; 1999, 84, 764) prior to the filing date of the registration application or the date of priority, if priority is claimed, shall also be taken into consideration if the filing dates or, if priority is claimed, the dates of priority of such applications are earlier.

(2) In determining the state of the art, no such information is taken into consideration which is disclosed within twelve months before the filing date of a registration application or, if priority is claimed, before the date of priority, by a person who is entitled to the registration of a utility model pursuant to § 11 of this Act, or by any other person who has received the information from such person against or according to the will of the person.

(3) For the purposes of this Act, an invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious.

(4) A utility model shall be considered as susceptible to industrial application if it can be manufactured or used in economy.

(09.02.2000 entered into force 01.07.2000-RT I 2000, 19, 117)

ETHIOPIA : *Sections 38-40 of the Law on Inventions, Minor Inventions and Industrial Designs No. 123 of 1995*

38. Protection IIf .Minor Inventions

1. A minor invention that possesses novelty and industrial applicability shall give rise to a right to protection in favour of the author there of 2. the right shall be evidenced by a utility model certificate issued by the Commission.

3. The grant of the certificate shall confer the exclusive right to exploit the minor invention and prevent third parties from exploiting the minor invention without the authorization of the holder of the certificate.

39. Non-existence of Novelty

1. A minor invention shall not be considered new if, at the time of filing the application, it has already been described in printed publications, made available to the public or has already been publicly used in Ethiopia.

2. Any description or use, within six months prior to the filing of the application, shall not destroy novelty if it is based on the work of the applicant.

40. Things not Protected by Utility Model Certificate

The following shall not be protected by utility model certificate:

1. Changes in the shape, proportions or material of a patented object or of one that is public property, except where such a change alters the qualities or functions of the object thereby producing an improvement in its use or the effects of its intended functions;

2. The mere replacement of elements in a known combination by other known elements having an equivalent function, which does not thereby produce an improvement in its use or the effect of its intended functions;

or

3. Minor inventions that are contrary to public order or morality.

FINLAND (EU) : *Sections 1-2 of the Utility Model Act No. 800 of 10/05/1991*

Section 1

Anyone who has made an invention, or his successor in title, shall be entitled, on application, to a utility model right to his invention, and thereby to the exclusive right to exploit the invention commercially, in accordance with the provisions of this Act.

For the purposes of this Act, "invention" shall mean a technical solution that is commercially exploitable.

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

(1) discoveries, scientific theories and mathematical methods;

(2) aesthetic creations;

(3) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and

(4) presentations of information.

Utility model rights shall not be granted for:

(1) inventions the exploitation of which would be contrary to morality or public policy;

(2) plant or animal varieties; or

(3) processes.

Section 2

An invention must be new in relation to what was known before the filing date of the utility model right application and must differ distinctly therefrom.

The prior art shall be held to comprise everything made available to the public by means of a written or oral description, by use or in any other way. Additionally, the content of utility model right, patent and design applications as filed in this country prior to the above-mentioned filing date shall be regarded as comprised in the prior art if such applications are made available to the public under Section 18 of this Act, Section 22 of the Patents Act or Section 19 of the Registered Designs Act. The requirement set out in the first paragraph, that the invention must differ distinctly from the prior art known before the filing date of the application for a utility model right, shall not apply, however, in such cases.

Applications referred to in Chapter 8 shall, for the purposes of the second paragraph, have the same legal effect as applications for utility model right filed in this country, pursuant to provisions laid down in Sections 45b and 45f.

A utility model may nevertheless be registered for inventions made available to the public within the six months preceding the filing date of the application if disclosure was the result of:

- 1) an evident abuse in relation to the applicant or his predecessor in title; or
- 2) the fact that the applicant or his predecessor in title had displayed the invention at an official or officially recognized international exhibition falling within the terms of the Convention on International Exhibitions (Finnish Treaty Series 36/37).

For the purposes of the second paragraph, publication according to Article 93 of the European Patent Convention (Finnish Treaty Series 8/96) shall be equated with the making available to the public of application documents according to Section 22 of the Patents Act. What is said above, also applies to publication according to Article 158(1) of the European Patent Convention where the European Patent Office equates such publication with publication according to Article 93.

FRANCE (EU) : *Article L611-2 of the Intellectual Property Code, Law No. 92-597 of 01/07/1992 as last amended by Law No. 2007-1544*

Les titres de propriété industrielle protégeant les inventions sont :

- 1) Les brevets d'invention, délivrés pour une durée de vingt ans à compter du jour du dépôt de la demande ;
- 2) Les certificats d'utilité, délivrés pour une durée de six ans à compter du jour du dépôt de la demande ;
- 3) Les certificats complémentaires de protection rattachés à un brevet dans les conditions prévues à l'article L. 611-3, prenant effet au terme légal du brevet auquel ils se rattachent pour une durée ne pouvant excéder sept ans à compter de ce terme et dix-sept ans à compter de la délivrance de l'autorisation de mise sur le marché mentionnée à ce même article.

Les dispositions du présent livre concernant les brevets sont applicables aux certificats d'utilité à l'exception de celles prévues aux articles L. 612-14, L. 612-15 et au premier alinéa de l'article L. 612-17. Elles le sont également aux certificats complémentaires de protection à l'exception de celles prévues aux articles L. 611-12, L. 612-1 à L. 612-10, L. 612-12 à L. 612-15, L. 612-17, L. 612-20, L. 613-1 et L. 613-25.

GERMANY: *Sections 1-3 of the Utility models Act of 28/08/1986 as last amended in 1994*
(*Consolidate version of 31/07/2009 not available in English*)

1.—(1) Utility model protection shall be afforded to inventions that are new, involve an inventive step and are susceptible of industrial application.

(2) The following, in particular, shall not be regarded as the subject matter of a utility model within the meaning of subsection (1):

1. discoveries, scientific theories and mathematical methods;
2. aesthetic creations;
3. schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
4. presentations of information.

(3) Subsection (2) shall oppose utility model protection only to the extent to which protection is sought for the above-mentioned subject matter or activities as such.

2. Utility model protection shall not be granted in respect of:

1. inventions the publication or exploitation of which would be contrary to public policy or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation. The first sentence above shall not exclude protection of an invention falling under Section 9;
2. plant or animal varieties;
3. processes.

3.—(1) The subject matter of a utility model shall be considered to be new if it does not form part of the state of the art. The state of the art comprises any knowledge made available to the public by means of a written description or by use within the territory to which this Law applies before the date relevant for the priority of the application. Description or use within the six months preceding the date relevant for the priority of the application shall not be taken into consideration if it is based on the conception of the applicant or his predecessor in title.

(2) The subject matter of a utility model shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

GEORGIA : *Articles 13 and 16 of the Patent Law of 05/02/1999*

Article 13

(1) By a patent shall be protected such a utility model, which relates to improved devices, substances, or methods and satisfies the criteria of novelty and industrial applicability.

(2) The utility model is regarded novel, if it is not known from the existing state of the art.

(3) The industrial applicability of the utility model implies the capability of its production, or making use of it in the sphere of industry, agriculture, public health, and other spheres of activity.

(4) The state of the art is defined by all those data that have become widely known by written, or verbal description, also by applying it in Georgia and which refer to devices,

substances, or methods having similar application before the filing date, or if the Convention priority is claimed before this priority date.

(5) At determination of novelty of the utility model in the state of the art shall be included apart from the other information sources all the applications for utility models filed earlier with Sakpatenti provided that they have earlier priority. The novelty is defined only on basis of considering one information source.

Article 16

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

- a) a discovery, scientific theory, or mathematical method;
- b) a result of artistic design;
- c) algorithms and programs for computers;
- d) education, teaching method and system, grammatical system of language, also methods for performing mental acts, rules for games or doing business.
- e) economical organization and managing method;
- f) plan and scheme of structures, buildings, territories;
- g) a presentation of the information;

If the objects mentioned in sub-paragraphs “a-g” of the Article are presented as such.

GHANA : *Sections 64-65 of the Patent Law No. 305A of 30/12/1992*

Application of provisions relating to patents to utility certificates

64.—(1) Subject to section 65 of this Law, the provisions of Parts I to XIII shall apply, with such modifications as may be necessary, to utility certificates or applications for such certificates as the case may be.

(2) Where—

(a) the right to a patent conflicts with the right to a utility certificate in the case referred to in section 8(3) of this Law; or

(b) a patent and a utility certificate are interdependent within the meaning of section 46 of this Law;

the said provisions shall apply as if the word “patent” wherever it occurs, was replaced by the words “patent or utility certificate”.

Special provisions relating to utility certificates

65.—(1) An invention is eligible for a utility certificate if it is new and industrially applicable.

(2) Sections 2 and 4 of this Law shall not apply in the case of inventions for which utility certificates are requested.

(3) Section 20 of this Law shall not apply in the case of applications for utility certificates.

(4) Utility certificates shall be registered in a separate part of the register.

(5) A utility certificate shall expire at the end of the seventh year after the date of the filing of the application and is not renewable.

(6) Subsections (1), (2), (3) and (5) of section 31 shall not apply in the case of utility certificates.

(7) In proceedings under section 56 of this Law, the court shall invalidate a utility certificate on any of the following grounds—

(a) that the claimed invention was not eligible for a utility certificate, having regard to subsection (1) of this section or to section 3 or sections 5 to 7;

(b) that the description or claims do not comply with the requirements prescribed by section 12(1)(a), (b) and (c) and the rules pertaining thereto;

(c) that any drawing which is necessary for the understanding of the invention has not been furnished;

(d) that the person to whom the utility certificate was granted had no right to the utility certificate, provided that the utility certificate has not been assigned to the person who has the right to the utility certificate.

(8) Section 56(2) shall not apply in the case of utility certificates.

(9) Utility certificate means a certificate granted in a case where the invention although new and useful would be considered obvious from the point of view of a person skilled in the art.

GREECE (EU) : Article 19 of the law no. 1733/1987 “technology transfer, inventions and technological innovation”

(1) The utility model certificate shall be granted for each novel and industrially applicable three-dimensional object with definite shape and form, such as a tool, an instrument, a device, an apparatus or even parts thereof, proposed as novel and industrially applicable and capable of giving a solution to a technical problem.

(2) Whoever files a patent application may request up to the date of grant of the patent the conversion of his patent application into application for a utility model certificate.

(3) The duration of validity of the utility model certificate is seven years from the day following the application for the grant of a utility model certificate or for the grant of a patent, in case of conversion in accordance with paragraph 2.

(4) The application for the grant of a utility model certificate shall be submitted to O.B.I. The requirements for filing the application, the relevant supporting documentation, and all other pertinent details are determined by decision of the Minister of Industry, Energy, and Technology.

(5) If the application for a utility model certificate complies with the requirements of paragraph 4, O.B.I. grants a utility model certificate without prior examination of the novelty and industrial applicability of the utility model at the responsibility of the applicant.

(6) As regards all other matters, the respective dispositions of the present law regarding patents shall apply.

GUATEMALA : Articles 142-144 of the Industrial Property Law, Decree No. 57 of 18/09/2000

Normas Aplicables

142. Las disposiciones relativas a las patentes de invención son, en lo conducente, aplicables a las patentes de modelo de utilidad, en tanto no contravengan las disposiciones especiales contenidas en este capítulo.

Materia Excluida de Protección

143. No podrán ser objeto de una patente de modelo de utilidad:

- a) Los procedimientos;
- b) Las sustancias o composiciones; y
- c) La materia excluida de patentabilidad de conformidad con esta ley.

Modelos de Utilidad Patentables

144. Un modelo de utilidad será patentable cuando sea susceptible de aplicación industrial y tenga novedad. No se considerará novedoso un modelo de utilidad cuando no aporte ninguna característica utilitaria discernible con respecto al estado de la técnica.

Entre otros, se considerarán modelos de utilidad los utensilios, objetos, aparatos, instrumentos, herramientas y dispositivos, así como las partes de los mismos, que como resultado de una modificación en su disposición, configuración, estructura o forma, presenten una función diferente respecto de las partes que lo integran o ventajas en cuanto a su utilidad.

HONDURAS : *Articles 23-26 of the Industrial Property Law, Decree Law No. 12-99-E of 30/12/1999*

Artículo 23.- Se considerará como modelo de utilidad cualquier forma, configuración o disposición de elementos de algún artefacto, herramienta, instrumento, mecanismo u otro objeto, o de alguna parte del mismo, que permita un mejor o diferente funcionamiento, utilización o fabricación del objeto que lo incorpora, o que le proporcione alguna utilidad, ventaja o efecto técnico que antes no tenía.

Los modelos de utilidad se protegerán mediante la concesión de patentes.

Artículo 24.- No podrá ser objeto de una patente de modelo de utilidad:

- 1) Los procedimientos;
- 2) Las sustancias o composiciones química, metalúrgicas o de cualquier otra índole; y,
- 3) La materia excluida de protección por patente de invención de conformidad con esta Ley.

Artículo 25.- Un modelo de utilidad será patentable cuando es novedoso y de susceptible aplicación industrial.

No se concederá una patente cuando el modelo de utilidad solamente presente diferencias menores o secundarias que no aportan ninguna característica utilitaria discernible con respecto al estado de la técnica.

Artículo 26.- La solicitud de patente de modelo de utilidad sólo podrá referirse a un objeto; sin perjuicio de que dicho objeto pueda comprender dos (2) o más partes que funcionan como un conjunto unitario, podrán reivindicarse varios elementos o aspectos de dicho objeto en la misma solicitud.

HUNGARY (EU) : *Articles 1-4 of the Act on the Protection of Utility models No. XXXVIII of 1991*

Article 1

(1) Utility model protection shall be granted to any solution relating to the configuration or construction of an article or to the arrangement of parts thereof (hereinafter referred to as “utility model”) which is new, involves inventive step and is susceptible of industrial application.

(2) Utility model protection, within the meaning of paragraph (1), shall not be granted in particular for

- (a) the aesthetic design of an article;
- (b) plant varieties.

Article 2

(1) A utility model shall be considered new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise everything made available to the public by means of a written description or by public use in the country before the date of priority.

(3) The content of any patent application or utility model application having an earlier date of priority shall also be considered as comprised in the state of the art, provided that it was published or announced in the course of the granting procedure at a date following the date of priority. The content of such a European patent application and international patent application shall only be considered as comprised in the state of the art on special conditions laid down in the Act on the protection of inventions by patents (hereinafter referred to as “the Patent Act”). For the purposes of these provisions, the abstract shall not be considered as comprised in the content of the application.

(4) For the application of paragraphs (1) and (2), a written description or public use during the six months preceding the date of priority of the application shall not be taken into consideration if it was made by or with the consent of the applicant or his predecessor in title, or if it was due to an abuse of the rights of the applicant or his predecessor in title.

Article 3

(1) The utility model shall be considered to involve an inventive step if it is not obvious to a skilled craftsman as compared with the state of the art.

(2) For the application of paragraph (1), the part of the state of the art referred to in Article 2(3) shall not be taken into consideration.

Article 4

The utility model shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

INDONESIA : *Articles 6 and 104 of the Patents Law No. 14 of 2001*

Article 6

Any Invention in the form of a product or device, which is novel and possesses practical use values because of its shape, configuration, construction, or component may be granted a legal protection in the form of a Simple Patent.

Article 104

Except for matters that are specifically regulated for Simple Patents, all other provisions regarding Patents as regulated in this Law shall apply mutatis mutandis to Simple Patents.

IRELAND (EU) : *Section 63 (1), (2), (3), (4) of the Patents Act No. 1 of 27/02/1992, as last amended by law No. 31 of 2006*

63.—(1) An application under this Part may be made for a patent the term of which shall be ten years in lieu of the term provided for by or under section 36 in respect of a patent granted under Part II.

(2) A patent granted on such an application is referred to in this Part as a short-term patent.

(3) Part II shall apply to a short-term patent and an application for a short-term patent as it applies to a patent and an application for a patent under that Part subject to the necessary modifications and to the provisions of this Part.

(4) An invention shall be patentable under this Part if it is new and susceptible of industrial application provided it is not clearly lacking an inventive step.

ITALY (EU) : *Articles 82 and 86 of the Industrial Property Code, Legislative Decree No. 30 of 10/02/2005*

Art. 82. Oggetto del brevetto

1. Possono costituire oggetto di brevetto per modello di utilità i nuovi modelli atti a conferire particolare efficacia o comodità di applicazione o di impiego a macchine, o parti di esse, strumenti, utensili od oggetti di uso in genere, quali i nuovi modelli consistenti in particolari conformazioni, disposizioni, configurazioni o combinazioni di parti.

2. Il brevetto per le macchine nel loro complesso non comprende la protezione delle singole parti.

3. Gli effetti del brevetto per modello di utilità si estendono ai modelli che conseguono pari utilità, purché utilizzino lo stesso concetto innovativo.

Art. 86. Rinvio

1. Le disposizioni della sezione IV, sulle invenzioni industriali, oltre che a tali invenzioni, spiegano effetto anche nella materia dei modelli di utilità, in quanto applicabili.

2. In particolare sono estese ai brevetti per modello di utilità le disposizioni in materia di invenzioni dei dipendenti e licenze obbligatorie.

JAPAN : *Articles 3-4 of the Utility Model Act No. 123 of 1959 as last amended by Act No. 55 of 2006*

Article 3 (Conditions for Utility Model Registration)

(1) A creator of a device that relates to the shape or structure of an article or combination of articles and is industrially applicable may be entitled to obtain a utility model registration for the said device, except when the following applies:

- (i) the device was publicly known in Japan or a foreign country, prior to the filing of the application for a utility model registration therefor;
- (ii) the device was publicly worked in Japan or a foreign country, prior to the filing of the application for a utility model registration therefor; or
- (iii) the device was described in a distributed publication, or a device that was made publicly available through an electric telecommunication line in Japan or a foreign country, prior to the filing of the application for a utility model registration therefor.

(2) Where, prior to the filing of the application for a utility model registration, a person ordinarily skilled in the art of the device would have been exceedingly easy to create the device based on a device prescribed in any of the items of the preceding paragraph, a utility model registration shall not be granted for such a device notwithstanding the preceding paragraph.

Article 3-2

Where a device claimed in an application for a utility model registration is identical with a device or invention (excluding a device created or an invention made by the creator of the device claimed in the said application for a utility model registration) disclosed in the description, scope of claims or drawings (in the case of the written application in foreign language under Article 36-2(2) of the Patent Act, the document in foreign language as provided in Article 36-2(1)) originally attached to the written application of another application for a utility model registration or for a patent which has been filed prior to the date of filing of the said application for a utility model registration and published after the filing of the said application for a utility model registration in the utility model bulletin under Article 14(3) (hereinafter the "Utility Model Bulletin") or in the patent bulletin under Article 66 (3) of the Patent Act describing matters provided for in each of the paragraphs of the respective Article or for which the publication of the patent application has been effected, a utility model registration shall not be granted for such a device notwithstanding paragraph (1) of the preceding Article; provided, however, that this shall not apply where, at the time of the filing of the said application for a utility model registration, the applicant of the said application and the applicant of the other application for a utility model registration or for a patent are the same person.

Article 4 (Unregistrable devices)

Notwithstanding Article 3(1), any device that is liable to injure public policy or public health shall not be granted a utility model registration.

KAZAKHSTAN : *Article 7 of the Patent Law No. 427 of 16/07/1999*

Article 7. Conditions of Patentability of Utility Models

1) Utility models shall be construed as inventions that impart a new construction to means of production and consumer articles or parts thereof.

A utility model shall be granted protection if it is new and industrially applicable.

A utility model shall be new if the sum of its essential features is not anticipated by prior art.

The state of the art shall consist of any kind of information published anywhere in the world and made available to the public, before the priority date of the claimed utility model, concerning devices of similar function and the use thereof in the Republic of

Kazakhstan. The state of the art shall likewise include applications for the protection of inventions and utility models that have been filed by other persons in the Republic of Kazakhstan, benefit from earlier priority and have not been withdrawn, and also inventions and utility models that have been patented in the Republic of Kazakhstan.

A utility model shall be industrially applicable if it can be used in economy.

2) Disclosure of information that otherwise would affect the patentability of the utility model claimed in the application shall not do so where the information has been disclosed, during the six months preceding the filing date of the application, including disclosure of the utility model incorporated in an exhibit displayed at an official or officially recognized international exhibition held in the territory of a State party to the Paris Convention, by the inventor or applicant or by any person having obtained the information directly or indirectly from them. The burden of proof of the foregoing shall be on the applicant.

3) The subject matter specified in Article 6(3) of this Law shall not be protected as utility models.

KENYA : Sections 2, 82 (1) and (2) of the Industrial Property Act No. 3 of 27/07/2001

Section 2 “utility model” means any form, configuration or disposition of element of some appliance, utensil, tool, electrical and electronic circuitry, instrument, handicraft mechanism or other object or any part of the same allowing a better or different functioning, use, or manufacture of the subject matter or that gives some utility, advantage, environmental benefit, saving or technical effect not available in Kenya before and includes micro-organisms or other self-replicable material, products of genetic resources, herbal as well as nutritional formulations which give new effects.

Section 82.—(1) An invention qualifies for a utility model certificate if it is new and industrially applicable.

(2) Section 22, 24, 43, 44 and 60 shall not apply in the case of applications for utility model certificates.

KYRGYZSTAN : Article 6 of the Patent Law of 14/01/1998 # 8, as lat amended on 27/02/2003

Article 6 - Conditions of Patentability of Utility Model

Devices shall be related to utility models.

The object claimed as a utility model shall be provided with legal protection if it is new and applicable in industry.

Utility model shall be considered new if the whole of its significant features is not known from the level of engineering.

The information on the level of engineering shall include data published on the means designed for the same purpose as the utility model claimed, which have become generally available before the date of priority of the application for utility model, the data on their use in the Kyrgyz Republic, not withdrawn applications for inventions and utility models submitted earlier by other persons as well as inventions and utility models patented in the Kyrgyz Republic.

No disclosure of information related to the utility model shall be recognized as affecting novelty of the utility model if made by the applicant or by any other persons who obtained from him the information directly or indirectly under which the information on the essence of the utility model became public, not earlier that six months before the date of submission of a application or the priority date if its sought. The burden of proof of that fact lies with the applicant.

A utility model is applicable in industry if it can be practically used.

Objects mentioned in paragraph 9, Article 5 of this Law are not protected as utility models.

LAO PEOPLE'S DEMOCRATIC REPUBLIC: *Sections 3 (no. 6 and 7), 14 and 21 of the Intellectual Property Law of 14/01/2008*

Section 3: Definition

The terminologies in this intellectual property laws shall mean as follows:

6. "Petty patent" is an official document from state organization issued to protect devices.

7. "Device" is newly invented work derived from the technical development using technology not high as invention.

Section 14: Conditions for obtaining petty patent

The inventions eligible for obtaining petty patent have similar conditions for obtaining patent. However, it has technical level lower than the inventions.

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.

MALAYSIA : *Sections 17 and 17A of the patent act of 1983 as last amended in 2006*

Section 17. Definition. For the purposes of this Part and any regulations made under this Act in relation to this Part, "utility innovation" means any innovation which creates a new product or process, or any new improvement of a known product or process, which is capable of industrial application, and includes an invention.

[Subs. Act A648: s.11; Subs. Act A863: s.7, Am. Act A1088: s.2]

Section 17A. Application. (1) Except as otherwise provided in this Part, the provisions of this Act, subject to the modifications in the Second Schedule, shall apply to utility innovations in the same manner as they apply to inventions. (2) Sections 11, 15, 26, Part X, and sections 89 and 90 shall not apply to utility innovations.

[Ins. Act A648: s.12, Am. Act A863: s.8, Am. Act A1088: s.3]

MEXICO : *Articles 27-28 and 30 of the Industrial Property Law of 25/06/1991 (Consolidation of 2005)*

Article 27 - Utility models that are new and industrially applicable shall be eligible for registration.

Article 28 - Objects, utensils, appliances or tools which, as a result of a modification in their arrangement, configuration, structure or form, offer a different function with respect to their component parts or advantages with respect to their usefulness shall be considered utility models.

Article 30. The rules contained in Chapter V of this Title, with the exception of Articles 45 and 52, shall apply as appropriate to the processing of a utility model registration.

Article amended August 2, 1994

MONGOLIA : *Article 3 no.3 and 5 and Article 4 of the Patent Law of 25/06/1993 as last amended in 1997*

Article 3. Definitions in this law

3. “utility model” means an industrial device, product, their basic part, and a new, industrially applicable solution

5. “a utility model certificate” means the document granted by the competent authorities after filing in the state record and recognizing the exclusive right of the author to own it for certain of time

Article 4. Objects of patent and patentability

1. A patent shall be granted to the author of an invention or to a natural person or legal entity to whom the author has assigned his or her right to a patent if that author has created a product or process which is absolutely new or involves an inventive step and the product or process is industrially applicable.

2. An invention shall be regarded as involving an inventive step if that step is not obvious to a person skilled in the relevant field. The existence of an inventive step shall be determined by an examiner appointed by the [Intellectual Property Office.

3. An invention shall be considered industrially applicable if it can be made or used in industry.

4. A product or process shall be considered new if it is not preceded by a product or process of the same design.

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

- 1) discoveries, scientific theories and mathematical methods;
- 2) computer program and algorithms;
- 3) schemes, rules or methods for doing business, performing mental acts or playing games;
- 4) solutions that are contrary to public health or environmental protection;
- 5) methods of treatment and diagnosis, or prophylaxis of human and animal diseases;
- 6) biological processes for the production of animals, or plants other than micro-organisms. This shall not include non-biological, and microbiological processes;

6. A patent shall be granted to an author of an industrial design or to natural person or legal entity to whom that author has assigned his or her right to a patent if that author has created a new and original solution relating to an industrially applicable article and that solution has not, prior to the filing date of that author’s application, has been disclosed anywhere in the world by publication in a tangible form or by publication in any manner in this country.

MOZAMBIQUE : *Articles 1 d), 89-91 of the Industrial Property Code, Decree No. 18/99 of 04/05/1999, as last amended by Law No. 04 of 12/04/2006*

Article 1 d)

d) Utility model: an invention that gives an object or part of an object a shape, structure, mechanism or layout which functionally increases its utility or improves the conditions of its manufacture;

Article 89 Requirements

Every new invention that involves a significant inventive activity and is capable of industrial application shall be eligible for protection as a utility model.

Article 90 Inventive activity

For the purposes of this chapter, an invention shall be considered to involve an inventive activity if it functionally increases the utility of an object or improves the conditions of its manufacture.

Article 91- Application of the provisions on patents

Except for the provisions of the preceding article, the provisions in respect of patents for inventions shall apply, with the necessary changes, to utility models and to applications in respect of utility models, provided that such provisions are not incompatible with the specific characteristics of utility models.

NAMIBIA : Sections 30-31 of the Industrial Property Bill of 1999

Applicability of provisions relating to patents

30. (1) Subject to section 31, the provisions of Part TI shall apply, subject to the necessary changes, to utility model certificates or applications therefor, as the case maybe.

(2) Where the right to a patent conflicts with the right to a utility model certificate in the case referred to in section 10(3), the said provision shall apply as if the word “patent” were replaced by the words “patent or utility model certificate”.

Special provisions relating to utility model certificates

31. (1) An invention qualifies for a utility model certificate if it is new and is industrially applicable.

(2) Section 9(1) shall not apply in the case of inventions for which utility model certificates are requested.

(3) Section 15(6) shall not apply in the case of applications for utility model certificates.

(4) A utility model certificate shall expire, without any possibility of renewal, at the end of the seventh year after the date of the filing of the application.

(5) With the exception of subsection (5) of section 15, section 15 shall not apply in the case of utility model certificates.

(6) In proceedings under section 20, the court shall invalidate the utility model certificates on the following grounds -

(a) that the claimed invention did not qualify for a utility model certificate, having regard to subsection(1) and to section 9(2), (3), (4) and (5);

(b) that the description and the claims do not apply with the requirements prescribed by section 11 (3) and (4) and the regulations relating thereto;

(c) that any drawing which is necessary for the understanding of the invention has not been furnished;

(d) that the owner of the utility model certificate is not the inventor or his or her successor in title.

(7) Section 20(2) shall not apply in the case of utility model certificates.

NICARAGUA : *Articles 3, 62-65 of the Law No. 354 on Patents, Utility Models and Industrial Designs of 19/09/2000*

3. “utility model” means an invention consisting of a shape, configuration or arrangement of the components of any object, or of a part thereof, that gives it a certain technical effect in its manufacture, operation or use;

62. The following may not be the subject matter of a utility model patent:

(a) processes;

(b) chemical, metallurgical or any other substances or compositions;

(c) subject matter excluded from invention patent protection under this Law.

Utility Model Patentability Requirements

63. A utility model shall be patentable when it is industrially applicable and novel. It shall not be considered novel where it does not add any discernible utilitarian characteristic to the state of the art.

Utility Model Unity Requirements

64. An application for a utility model patent may only relate to one object or to a set of two or more parts that constitute a functional unit. Two or more elements or aspects of that object or unit may be claimed in the same application.

Term of the Utility Model Patent

65. A utility model patent shall have a non-renewable term of 10 years, counted from the filing date of the application therefor.

Application of Provisions to Utility Models

66. The provisions relating to patents shall be applicable to utility models where appropriate

PANAMA : *Articles 24-28 of the Law No. 35 of 10/05/1996, Enacting Provisions on Industrial Property*

24. A utility model is any shape, configuration or arrangement of the components of any appliance, tool, instrument, mechanism or other object, or any part thereof, that makes for the better or different operation, use or manufacture of the object incorporating it, or lends it any usefulness, advantage or technical effect that it did not have previously.

25. Utility models that are new and susceptible of industrial application shall be registrable. A utility model shall not be registrable when it possesses only minor differences, those that lead to no discernible utilitarian characteristic as compared with previous inventions or utility models being considered such.

26. The registration of utility models shall have a non-renewable term of ten years, counted from the filing date of the application, and shall be subject to the payment of the fees laid down in the corresponding law.

27. The present provisions on patents shall be applicable as appropriate to utility models, without prejudice to the special provisions contained in this Law.

28. The rules contained in the following Chapter shall be applied as appropriate to the processing of a utility model registration.

PARAGUAY : Articles 50-53 of the Patents Law No. 1630 of 29/11/2000

Artículo 50.- De la definición de modelo de utilidad. Se entenderá por modelo de utilidad una invención constituida por una forma, configuración o disposición de elementos de un artefacto, herramienta, instrumento, mecanismo u otro objeto, o de alguna parte del mismo, que permita un mejor o diferente funcionamiento, utilización o fabricación del objeto que lo incorpora, o que le proporcione alguna utilidad o efecto técnico que antes no tenía. Los modelos de utilidad se protegerán mediante la concesión de patentes.

Artículo 51.- De la aplicación de disposiciones sobre patentes de invenciones. Las disposiciones del Capítulo I relativas a las patentes de invención son aplicables a las patentes de modelo de utilidad, bajo reserva de las disposiciones especiales contenidas en el presente Capítulo.

Artículo 52.- De los requisitos de patentabilidad. Un modelo de utilidad será protegido cuando sea susceptible de aplicación industrial y tenga novedad. El modelo de utilidad no se considerará novedoso cuando sólo presente diferencias menores o secundarias que no aporten ninguna característica utilitaria discernible a lo que se encuentra en el estado de la técnica.

Artículo 53.- De las materias excluidas de protección como modelo de utilidad.

No podrán ser objeto de una patente de modelo de utilidad:

- a) los procedimientos;
- b) las sustancias o composiciones químicas, metalúrgicas o de cualquier otra índole; y,
- c) la materia excluida de protección por patente de invención de conformidad con esta ley.

PHILIPPINES : Rules 200-201 of the Rules and Regulations on Utility Models and Industrial Designs (as amended by Order No. 61 series 2001 and Office Order No. 09 series of 2000)

Rule 200. Registrable Utility Models. — Any technical solution of a problem in any field of human activity which is new and industrially applicable shall be registrable. RULE 200. 1 Non-Registrable Utility Models. — The following shall be excluded from protection as utility models:

- (a) Discoveries, scientific theories and mathematical method;
- (b) Schemes, rules and methods of performing mental acts, playing games or doing business, and programs for computers;
- (c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. This provision shall not apply to products and compositions for use in any of these methods;

(d) Plant varieties or animal breeds or essentially biological process for the production of plants or animals. This provision shall not apply to microorganisms and non-biological and microbiological processes;

(e) Aesthetic creations; and

(f) Anything which is contrary to public order or morality.

Rule 200.2 Industrial Applicability. — A utility model which can be produced and used in any industry shall be industrially applicable.

Rule 201. Statutory Classes of Utility Models. — A utility model may be, or may relate to

(a) a useful machine;

(b) an implement or tool;

(c) a product or composition;

(d) a method or process; or

(e) an improvement of any of the foregoing.[As amended by Office Order No. 09 (2000)]

POLAND (EU) : *Articles 94 and 100 of the Industrial Property Law of 30 June 2000, as amended by Act of 23/01/2004 and Act of 29/06/2007*

Article 94

1) Any new and useful solution of a technical nature affecting shape, construction or durable assembly of an object shall constitute a utility model.

2) A utility model shall be considered a useful solution if by means of that solution a practical effect is attainable, expedient in the process of manufacturing or exploitation of the product.

Article 100

1) Subject to paragraph (2), the provisions of Articles: 25, 28, 29, 35-37, 39-52, 55-60, 62, 66-75, 76-90 and 92 shall apply accordingly to utility models and rights of protection for utility models.

PORTUGAL (EU) : *Sections 117-120 of the Industrial Property Code (approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April)*

Article 117

Object

1) New inventions involving an inventive step can be protected as utility models, if they have an industrial application.

2) The aim of utility models is to protect inventions by means of a simpler, speedier administrative procedure than that for patents.

3) An invention that abides by the conditions established in paragraph 1 can be protected by a utility model or patent, as the applicant chooses.

4) The same invention may be simultaneously or successively the subject of a patent and utility model application.

- 5) The successive submission of applications referred to in the previous paragraph may only be allowed within one year of the date of submission of the first application.
- 6) In the cases set forth in paragraph 4, a utility model shall expire after grant of a patent for the same invention.

Article 118

Limitations as to object

Article 52 is applicable to utility models.

Article 119

Limitation as to Utility Model

The following cannot be the object of a utility model:

- a) Inventions whose commercial exploitation is against the law or contrary to public policy, public health or morality and their exploitation may not be considered as such due to the simple fact that it is forbidden by law or regulations;
- b) Inventions involving biological material;
- c) Inventions involving chemical or pharmaceutical substances or processes.

Article 120

Grant requirements

- 1) An invention shall be considered new if it does not form part of the state of the art.
- 2) An invention shall be considered as involving an inventive step, if it meets one of the following requirements:
 - a) If it is not obvious to a person skilled in the art;
 - b) If it offers a practical or technical advantage for the manufacture or use of the product or process in question.
- 3) An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry or in agriculture.
- 4) The provisions of Articles 56 and 57 apply to utility models with the necessary adaptations.

REPUBLIC OF KOREA : *Articles 2-5 of the Utility Models Act Promulgated on 31/12/1961 by Act No. 952 (Last amended by Act No. 9371 of 30/01/2009)*

Article 2 Definitions

The definitions of terms used in this Act are as follows:

- (i) “device” means the creation of technical ideas using the rules of nature;
- (ii) “registered utility model” means a device for which a utility model has been granted; and
- (iii) “working” means acts of manufacturing, using, assigning, leasing, importing, or offering for assignment or lease (including displaying for assignment or lease) an article to which a device has been applied.

Article 3 Mutatis Mutandis Application of the Patent Act

Articles 3 to 7, 7bis, 8 to 26, 28, 28bis to 28quinquies of the Patent Act apply mutatis mutandis to utility models.

Article 4 Requirements for Utility Model Registration

(1) A utility model may be granted for devices that are industrially applicable and relate to the shape or structure of an article or a combination of articles, unless they fall under either of the following subparagraphs:

- (i) devices publicly known or worked in the Republic of Korea before the filing of the utility model application; or
- (ii) devices described in a publication distributed in the Republic of Korea or in a foreign country before the filing of the utility model application or made available to the public through electronic telecommunication lines under Presidential Decree.

(2) Notwithstanding paragraph(1), where a device could easily have been made before the filing of the utility model application by a person with ordinary skill in the art to which the device pertains, on the basis of a device referred to in either subparagraph of paragraph (1), a utility model registration may not be granted to that device.

(3) Notwithstanding paragraph (1), where a device for which a utility model application is filed is identical to a device or an invention described in the description or drawing(s) originally attached to another utility model application or a patent application, and where the other utility model application was filed before the utility model application and published after registration for public inspection after the filing date of the utility model application, or where a patent application was filed before the utility model application and laid open or published after grant for public inspection after the filing date of the utility model application, a utility model may not be granted for the device of the utility model application. This provision does not apply, however, where the inventor of the utility model application and the inventor of the other utility model or patent application are the same person or where the applicant of the utility model application and the applicant of the other utility model or patent application are the same person at the time of filing.

(4) In applying paragraph (3), where the other utility model or patent application falls under one of the following subparagraphs, “laid open” of paragraph 3 reads “laid open or was the subject of an international publication under Article 21 of the Patent Cooperation Treaty”, and “a device or invention described in the description or drawing(s) originally attached” reads, in case the application was filed in Korean, “a device or invention described in the description, claim(s) or drawing(s) of the international application as of the international filing date” and, in case the application was filed in a foreign language, “a device or an invention described in the description, claim(s) or drawing(s) described both in the international application as of the international filing date and its translated version”:

- (i) the other utility model application is an international application (including an international application that is deemed a utility model application according to Article 40(4)) that is deemed a utility model application according to Article 34(1); and
- (ii) the patent application is an international application that is deemed a patent application according to Article 199(1) of the Patent Act (including an International application that is deemed a patent application according to Article 214(4) of the Patent Act).

Article 5 Devices Deemed to be Not Known etc.

(1) Where a device that belongs to a person with the right to obtain a utility model registration falls under any of the following subparagraphs, the device is not considered to fall under either subparagraph of Article 4(1) where Article 4(1) or (2) applies if the utility model application is filed within six months of the applicable date:

- (i) where a person with the right to obtain a utility model registration causes the device to fall under either subparagraph of Article 4(1); however, this provision does not apply if an application is laid open or the registration is published in the Republic of Korea or in a foreign country in accordance with a treaty or applicable law.
- (ii) where the device falls under either subparagraph of Article 4(1) against the intention of the person with the right to obtain a utility model registration;

(2) A person seeking to take advantage of paragraph (1)(i) of this Article shall file an application for utility model registration, and, within thirty days of the filing date of the application, specify in the application the purport of the intention to take advantage of paragraph (1)(i) of this Article and submit documents proving the relevant facts to the Commissioner of the Korean Intellectual Property Office.

REPUBLIC OF MOLDOVA : *Article 4 of the Law on the Protection of Invention No. 50-XVI of 07/03/2008*

Article 4. Forms of Protection of Inventions

- (1) Inventions shall be protected by the titles of protection granted in accordance with this Law.
- (2) Inventions shall be protected by the following titles of protection:
 - a) patent for an invention;
 - b) short-term patent for an invention;
 - c) supplementary protection certificate.
- (3) The provisions of this Law shall apply equally to the patents for invention and the short-term patents for invention, except for the provisions of Chapter V Section 2 of this Law, which only apply to patents for invention.

Article 12. Subject-Matter Protected by a Short-Term Patent for Invention

- (1) A short-term patent for invention shall be granted for any invention which is new, involves an inventive step and is susceptible of industrial application.
- (2) An invention shall be considered as involving an inventive step within the meaning of paragraph (1) if it gives a technical or practical advantage.
- (3) Additionally to Article 7, short-term patents for invention shall not be granted in respect of inventions concerning:
 - a) biological material;
 - b) chemical or pharmaceutical substances and/or processes.

ROMANIA (EU) : *Articles 1, 3, 4 of the Law on Utility Models, Official Gazette of Romania, Part I, No.851/12 December 2007*

Art. 1 - (1) The utility model shall protect, under this law, any technical invention, provided that it is new, it exceeds the framework of mere professional skill and it is susceptible of industrial application.

(2) The following, in particular, shall not be deemed to be inventions under paragraph (1):

- a) discoveries, scientific theories and mathematical methods;
- b) aesthetic creations;
- c) schemes, rules and methods for performing mental activities, playing games or doing business, as well as computer programs;
- d) presentations of information.

(3) The provisions of paragraph (2) shall exclude the protection of the above mentioned activities or subject matters only to the extent to which the utility model application or utility model relates to such activities or subject-matters as such.

(4) The following shall not be protected as utility models:

- a) inventions the commercial exploitation of which would be contrary to public order or morality, including inventions harmful to the health or life of persons, animals or plants or which are likely to seriously harm the environment, provided that said exception shall not depend merely on the fact that exploitation thereof is prohibited by a legal provision;
- b) plant varieties and animal breeds;
- c) inventions having as a subject-matter biological material;
- d) inventions having as a subject-matter a product consisting of a chemical or pharmaceutical substance;
- e) inventions having as a subject-matter a process or a method.

Art. 3 - (1) An invention shall be considered to be new if it does not form part of the state of the art.

(2) The state of the art shall be held to comprise all knowledge that has been made available to the public by means of an oral or written description, by use or in any other way, prior to the date of filing of the utility model application.

(3) The state of the art shall be also held to comprise the content of the utility model and patent applications filed with the State Office for Inventions and Trademarks (hereinafter referred to as OSIM), as well as the content of the applications with effects in Romania, as filed, provided that they have the date of filing prior to the date referred to in paragraph (2) and they were duly published on or after that date.

(4) When applying the provisions of paragraphs (2) and (3), the disclosure of the invention shall not be taken into consideration if it occurred within the six months preceding the filing date of the utility model application and if it was made, directly or indirectly:

- a) by the applicant or his predecessor in title; or
- b) as a consequence of an obvious abuse in relation to the applicant or his predecessor in title.

Art. 4. - An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

RUSSIAN FEDERATION : *Article 1351 of the Patent Law (Chapter 72)*

Article 1351. Conditions of Patentability of a Utility Model

1. A technical solution relating to a device shall be protected as a utility model.
A utility model shall be granted legal protection if it is new and industrially applicable.
2. A utility model shall be new if the sum of its essential features is not anticipated by prior art.
The state of the art shall include any kind of information published anywhere in the world and made available to the public, before the priority date of the claimed utility model, concerning devices of similar function and the use thereof in the Russian Federation. The state of the art shall also include, on condition of their earlier priority, all applications filed in the Russian Federation by other applicants for inventions and utility models, to the documents of which any person is entitled to get access as per Paragraph 2 of Article 1385 or Paragraph 2 of Article 1394 of the present Code, and inventions and utility models that have been patented in the Russian Federation.
3. Disclosure of information relating to a utility model by the author of the utility model, applicant, or other person having received this information directly or indirectly from them, that made information on the essence of the utility model public shall not be a circumstances precluding the recognition of the patentability of the utility model if an application for the grant of a patent for the utility model has been filed with the federal executive authority for intellectual property within six months from the date of disclosure of the information. The burden of proof that the circumstances have taken place by virtue of which the disclosure of information does not prevent the recognition of the patentability of the utility model shall be on the applicant.
4. A utility model shall be deemed industrially applicable if it can be used in industry, agriculture, public health, other branches of the economy, or the social sphere.
5. Legal protection as utility models shall not be granted to:
 - 1) proposals concerning solely the outward appearance of manufactured articles and intended to satisfy aesthetic requirements;
 - 2) layout-designs (topographies) of integrated circuits.

SERBIA : *Articles 134-135 of the Patent Law No. 15 of 02/07/2004*

17. Petty patent

Article 134

A petty patent shall mean a right of protection for a new, industrially applicable invention that involves an inventive step.

In the event of protection by a petty patent, an invention shall involve an inventive step if it is the result of activities extending beyond the routine use of the state of the art by a skilled person, but lacks the inventive step required for a patent.

Only a solution relating to the configuration or structure of a product or the layout of its components may be the subject matter of an invention protected by a petty patent.

Article 135

Provisions of this Law shall duly apply to petty patents, unless expressly stipulated otherwise.

SLOVAKIA (EU) : *Articles 4-9 of the Act No. 517/2007 Coll. on Utility Models*

Article 4

Technical solution, which is new, is a result of an inventive activity, and is industrially applicable, shall be protected as a utility model.

Article 5

(1) According to this Act the following shall not be deemed to be a technical solution:

- a) discoveries, scientific theories and mathematical methods;
- b) aesthetic creations;
- c) plans, rules and methods for performing mental acts, playing games or trade activities;
- d) computer programmes;
- e) presentation of information.

(2) Subject-matters or activities stated in paragraph 1 shall be excluded from utility model protection only to extent to which an application of a utility model (hereinafter referred to as “application”) relates to these subject-matters or activities as such.

Article 6

Exceptions to protection

The following cannot be protected by utility model:

- a) technical solutions commercial exploitation of which would be in contradiction with public order or good manners; prohibition of a technical solution exploitation as such shall not be considered to be in contradiction with public order or good manners within the meaning of this provision;
- b) plant and animal varieties;
- c) essentially biological processes for production of plants or animals;
- d) methods of surgical or therapeutic treatment of human or animal body and diagnostic methods and methods of diseases prevention used on a human or animal body;
- e) technical solutions concerning products consisting of biological material or containing biological material or a process by means of which the biological material is produced, processed or used;
- f) methods for production of chemical substances;
- g) methods for production of pharmaceutical substances; and
- h) medical use of substances and compositions of substances.

Article 7

Novelty

(1) A technical solution shall be considered to be new if it does not form a part of state of the art in accordance with paragraphs 2 to 4.

(2) State of the art for purposes of this Act shall be everything made available to the public by any means of disclosure before the day from which an applicant for a utility model (hereinafter referred to as “applicant”) enjoys priority right pursuant to Article 34(1).

(3) The content of applications and patent applications filed in the Slovak Republic with an earlier priority right shall be also considered as state of the art, if they are published in the Official Journal of the Industrial Property Office of the Slovak Republic (hereinafter referred

to as “Journal”) on the day from which the applicant enjoys the priority right or after this day. This shall also apply to international applications with designation for the Slovak Republic; publication of an international application shall be the publication in the Journal, and for European patent applications with designation for the Slovak Republic (hereinafter referred to as “European patent application”); publication of a European patent application shall be the publication pursuant to Article 93 or Article 153 of the European Patent Convention. Confidential patent application shall be deemed to be published after the expiry of 18 months from the day of rise of priority right.

(4) Disclosure of results of an applicant’s work or his legal predecessor shall not be considered as state of the art provided that such disclosure occurred no earlier than six months preceding the filing the application.

Article 8

Inventive activity

(1) Technical solution shall be considered as a result of an inventive activity if it is not for a person skilled in the art obvious from state of the art.

(2) Contents of applications, patent applications, international applications and European patent applications which have not been published by the day from which an applicant enjoys the priority right shall not be taken into consideration in determination of an inventive activity.

Article 9

Industrial application

Technical solution shall be considered to be industrially applicable if its subjectmatter can be produced or used in any branch, particularly in any branch of industry and agriculture.

SLOVENIA (EU) : *Article 16 of the Industrial Property Act of 23/05/2001 as last amended on 06/02/2006*

Article 16

Subject-matter of short-term patent protection

(1) With the exception of processes, plant varieties and animal breeds, a short-term patent may be granted for inventions which are new, susceptible of industrial application and are the result of a creative effort.

(2) An invention shall be considered to be the result of a creative effort if it exhibits either particular effectiveness or a practical industrial advantage.

(3) The provisions of this Act relating to patents shall apply *mutatis mutandis* to shortterm patents, unless otherwise provided by this Act.

SPAIN (EU) : *Articles 143-146 of the Law on Patents and Utility Models No. 11/1986 of 20/03/ 1986 as last amended by Law No. 10 of 29/04/2002*

Artículo 143 - (1) Serán protegibles como modelos de utilidad, de acuerdo con lo dispuesto en el presente título, las invenciones que, siendo nuevas e implicando una actividad inventiva, consisten en dar a un objeto una configuración, estructura o constitución de la que resulte alguna ventaja prácticamente apreciable para su uso o fabricación.

(2) En particular, podrán protegerse como modelos de utilidad los utensilios, instrumentos, herramientas, aparatos, dispositivos o partes de los mismos, que reúnan los requisitos enunciados en el apartado anterior.

(3) No podrán ser protegidas como modelos de utilidad las invenciones de procedimiento y las variedades vegetales.

(Apartado 3, nueva redacción según la >disposición final primera de la Ley 3/2000 de Protección de las Obtenciones Vegetales)

Artículo 144 - (1) El derecho a la protección de modelos de utilidad pertenece al inventor o a su causahabiente y es transmisible por todos los medios que el derecho reconoce.

(2) Será de aplicación a la protección de modelo de utilidad lo dispuesto en los apartados 2 a 4 del artículo 10.

(3) No podrán ser protegidas como modelos de utilidad las invenciones de procedimiento y las variedades vegetales.

(Nueva redacción según la >disposición final de la Ley 3/2000 de Protección de las Obtenciones Vegetales.)

Artículo 145 - (1) El estado de la técnica con referencia al cual debe juzgarse la novedad y la actividad inventiva de las invenciones protegibles como modelos de utilidad, está constituido por todo aquello que antes de la fecha de presentación de la solicitud de protección como modelo ha sido divulgado en España, por una descripción escrita u oral, por una utilización o por cualquier otro medio.

(2) Se entiende igualmente comprendido en el estado de la técnica el contenido de las solicitudes españolas de patentes o de modelos de utilidad tal como hubieren sido originariamente presentadas, cuya fecha de presentación sea anterior a la fecha que se menciona en el apartado precedente y que hubieren sido publicadas en aquella fecha o en otra posterior.

Artículo 146. (1) Para su protección como modelo de utilidad, se considera que una invención implica una actividad inventiva si no resulta del estado de la técnica de una manera muy evidente para un experto en la materia.

(2) Si el estado de la técnica comprende documentos de los mencionados en el artículo 145, apartado 2, no serán tomados en consideración para decidir sobre la existencia de la actividad inventiva.

SWAZILAND : *Sections 15 and 16 (1) and (2) of the Patents, Utility Models and Industrial Designs Act No. 6 of 04/09/1997*

Applicability of provisions relating to patents.

15. (1) Subject to section 16, the provisions of Part I shall apply, mutatis mutandis, to utility model certificates or applications therefor.

(2) Where the right to a patent conflicts with the right to a utility model certificate in the case referred to in section 5 (3), that section shall apply as if the word “patent” were replaced by the word “patent or utility model certificate”.

Special provisions relating to utility model certificates.

16.- (1) (a) An invention qualifies for a utility model certificate if it is new and industrially applicable.

(b) Section 4 (1) and (3) shall not apply in the case of inventions for which utility model certificates are requested.

(2) Section 10 (4) shall not apply in the case of application for utility model certificates.

THAILAND : *Sections 65 bis and 65 decies 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 65 bis - A petty patent may be granted for an invention in respect of which the following conditions are satisfied:

- (1) the invention is new;
- (2) it is capable of industrial application.

Section 65 decies The provisions of Sections 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 19 bis, 20, 21, 22, 23, 25, 26, 27, 28, 35 bis, 36, 36 bis, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 47 bis, 48, 49, 50, 50 bis, 51, 52, 53, and 55 in Chapter II concerning patents for inventions shall apply, mutatis mutandis, to Chapter III bis concerning petty patents.

TONGA : *Sections 17 (1) and 18 (1) of the industrial Property Act No. 19 of 1994*

17 - Applicability of provisions pertaining to patents.

(1) Subject to section 18, the provisions of Part II shall apply, mutatis mutandis, to utility model certificates or applications therefor, as the case may be.

18 - Special provisions pertaining to utility model certificates.

(1) An invention qualifies for a utility model certificate if it is new and is industrially applicable.

(2) Sections 5(1) and 5(5) shall not apply in the case of inventions for which utility model certificates are requested.

TRINIDAD AND TOBAGO : *Sections 64 and 65 of the Patents Act No. 21 of 1996 as last amended by the Act No. 18 of 2000*

Provisions applicable to utility certificates

64.-(1) The provisions in this Act relating to patents or to patent applications shall, unless otherwise provided under this Part, be applicable to utility certificates or to utility certificate applications, as the case may be.

(2) Sections 8, 10, 24, 29, 30(1) and 60(a) shall not apply to utility certificates nor to utility certificate applications. (reference to inventive step, substantive examination, term of protection, annual fees).

Protection by utility certificate

65.-(1) A utility certificate may be granted only for an invention which is new and is capable of industrial application.

(2) An invention for which a utility certificate is requested shall not be considered new if it differs from earlier inventions only in minor respects or in details which are immaterial to the function or application of the invention.

TURKEY : *Articles 154-156 of the Patent Act No.551 of 27/06/1995*

Inventions Protected by Granting Utility Model Certificates

Article 154 :

Inventions which are novel according to Article 156 of this present Decree-Law and applicable in industry in the sense of Article 10 of this present Decree-Law shall be protected by grant of Utility Model Certificate.

Inventions and subject matter non-patentable by Grant of Utility Model Certificate

Article 155 :

No Utility Model Certificate shall be granted for subject matters mentioned in Article 6 of this present Decree-Law as well as for processes and products obtained by such processes and for chemical products.

Novelty

Article 156 :

The invention, subject matter of the application for utility model certificate, shall not be deemed to be novel when prior to the date of filing the application, it has been rendered accessible to the public, whether in Turkey or in the world, by disclosure in writing or in any other way or when it has been put to use within the country, whether regionally or nationwide.

Disclosure, whether by publication or in any other way or use, by the applicant for utility model certificate or his predecessors, twelve months prior to the date of filing of the application or to the date of priority, if any, shall not be deemed to be destructive of the novelty of the invention, subject matter of the application.

Applications filed in Turkey for patents or for utility model certificates prior to the date of filing the application for Utility Model Certificate shall be deemed to be destructive of the novelty of the application for Utility Model Certificate even when they are published subsequently to the date of filing of the application for Utility Model Certificate.

UGANDA : *Sections 41-42 of the Patent Act of 15/10/1993*

41. Utility certificate.

- (1) The registrar may grant a utility certificate in respect of an invention under this Part.
- (2) Except as otherwise expressly specified in this Act, Parts I to VII and Part IX of this Act shall apply with necessary modifications to utility certificates and applications for them.

42. Special provisions relating to utility certificates.

- (1) An invention is eligible for a utility certificate if it is new and is industrially applicable.

(2) It is immaterial that the invention does not involve an inventive step within the meaning of section 10.

(3) The provisions in respect of patents relating to examinations as to substance under section 20 shall not apply to applications for utility certificates.

UKRAINE : *Articles 1, 6 (1-4) and 7 (2-6 and 8) of the Law on the Protection of Rights to Inventions and Utility Models No. 7 of 1994*

Article 1. Notions

“Invention (utility model)” means a result of intellectual activity of a human being in any field of technology;

Article 6. Conditions of Granting the Legal Protection

1) The legal protection shall be granted to an invention (utility model) that does not contradict the public order, humanity and morality and complies with the requirements of patentability.

2) The object of an invention (utility model), to which the legal protection is granted under this Law, may be:

a product (device, substance, microorganism strain, plant or animal cells culture etc.);

a process (method) as well as the novel use of a known product or process.

3) According to this Law, the legal protection shall not extend to such technology objects:
plant varieties and animal breeds;
processes of the reproduction of plants and animals that are biological in its basis and do not belong to non-biological and microbiological processes;
topographies of integrated circuits;
results of art constructing.

4) The priority, authorship and property right to an invention are certified by a patent (declarative patent).

The priority, authorship and property right to a utility model are certified by a declarative patent.

The term of the patent for an invention shall be 20 years as from the date of filing of the application with the Office.

The term of the declarative patent for a utility model shall be 6 years as from the date of filing of the application with the Office.

The term of the patent for an invention, the object of which is a drug, means for the protection of animals, means for the protection of plants and for the use of which a permission of the relevant authorized body is required, may be extended at the request of the owner of this patent for a period that is equal to the period between the date of filing of the application and the date of the receipt of such a permission, but for no more than 5 years. The filing of a request is subject to the payment of the respective fee.

In this case the Office shall define the procedure for filing a request and extending the validity period of a patent.

The term of a declarative patent for a utility model shall be 10 years from the date of filing of the application with the Office.

The term of a patent (declarative patent) for a secret invention and of a declarative patent for a secret utility model is equal to the period of the classification of an invention (utility model), but may not be longer than the period for the protection of an invention (utility model) defined under this Law.

The validity of a patent shall be terminated before the appointed time under conditions prescribed in Article 32 of this Law.

Article 7. Patentability Requirements to an Invention, Utility Model

- 2) A utility model meets the patentability requirements provided that it is new and industrially applicable.
- 3) An invention (utility model) shall be considered to be new provided that it does not form part of the state of the art. Objects that are a part of the state of the art shall be considered only separately when determining the novelty of an invention.
- 4) The state of the art comprises everything made available to the public throughout the world before the date of filing of the application with the Office or, if the priority has been claimed, before the date of its priority.
- 5) The state of the art also includes a content of any application for granting a patent in Ukraine (including an international application, in which Ukraine is designated) in the wording, in which this application has been primarily filed, provided that the date of its filing (if the priority has been claimed, the date of the priority) is prior to the date referred to in Paragraph 4 of this Article, and that the application has been already published on or after this date.
- 6) The recognition of an invention (utility model) as a patentable one does not depend on the disclosure of information on the invention (utility model) by an inventor or by a person which has received such an information directly from an inventor or indirectly within 12 months before the date of filing of the application with the Office or, if the priority has been claimed, before the priority date. In this case, the person, who is interested in using this provision, is obliged to prove the circumstances of the disclosure of information.
- 8) An invention (utility model) shall be considered to be industrially applicable provided that it may be used in industry or other field of activity.

UNITED ARAB EMIRATES : *Articles 1, 4, 5 and 6 of the Patent Law No. 44 of 12/10/1992*
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Article (1)

Utility Certificate:-

A deed of protection being issued by the Administration of Industrial Property in the name of this state for an invention that does not result from intellectual effort sufficient for granting a letters patent.

Article (4)

A letters patent shall be awarded to any new invention resulting from an innovative idea or inventive step in all fields of technology, provided that such an idea or inventive step has a scientific basis and is capable of industrial application. The invention shall be deemed industrially applicable in its broadest term if used or utilized in such fields as agriculture, fisheries, handicrafts, and services.

The application must be restricted to one invention only or to a group of interrelated inventions yielding one general innovative concept. If it is evident after the issuance of the letters patent that the condition of interrelationship has not been met in accordance with the aforementioned statement, then such an evidence shall not negate the patent.

Article (5)

A utility certificate may be issued for new inventions capable of industrial application but having no innovative character warranting patentability.

Upon request of the inventor or his legal representative, the utility certificate shall also be issued for the invention satisfying the conditions provided for in article (4).

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.

b) Diagnostic methods, treatments, and surgical operations needed for humans and animals.

c) Scientific and Mathematical principles, discoveries and methods.

d) Guides, rules or methods followed to conduct business or perform mental activities or play games.

e) Invention that may lead to violation of the public order or morals.

2) If it is evident to the administration upon examination of the patent application that the scope of the invention relates to the national defense, then the procedures provided for in the implementing regulations of this law shall be undertaken thereon

UNITED REPUBLIC OF TANZANIA : *Section 72 (1) and 73 (1) a) and b) of the Patent Act No. 1 of 20/01/1987*

72,-(1) Subject to section 73, the provisions of Parts I to XV and XVII shall apply, mutatis mutandis, to utility certificate or applications as the case may be.

73.-(1)(a) An invention is eligible for a utility certificate if it is new and industrially applicable.

(b) section 8 and 10 shall not apply in the case of inventions for which utility certificates are requested.

(2) Section 27 shall not apply in the case of applications for utility certificates.

URUGUAY : *Articles 81, 82, 83 and 85 of the Law Regulating Rights and Obligations Relating to Patents, Utility Models and Industrial Designs no. 17.164 of 02/09/1999*

Artículo 81.- Considerase modelo de utilidad patentable a toda nueva disposición o conformación obtenida o introducida en herramientas, instrumentos de trabajo, utensilios, dispositivos, equipos u otros objetos conocidos, que importen una mejor utilización o un mejor resultado en la función a que están destinados, u otra ventaja para su uso o fabricación. Se entenderá que un modelo de utilidad es novedoso cuando no se encuentre en el estado de la

técnica. Un modelo de utilidad para ser patentable deberá implicar una mínima actividad inventiva.

Artículo 82.- La solicitud de modelo de utilidad sólo podrá referirse a un objeto, sin perjuicio de que pueda comprender dos o más partes que funcionen como un conjunto unitario. Podrán reivindicarse varios elementos o aspectos de dicho objeto en la misma solicitud.

Artículo 83.- No pueden ser objeto de protección mediante una solicitud de patente de modelo de utilidad:

- A) Los cambios de forma, dimensiones, proporciones o material de un objeto, a no ser que tales cambios modifiquen sus cualidades o funciones.
- B) La simple sustitución de elementos por otros ya conocidos como equivalentes.
- C) Los procedimientos.
- D) La materia excluida de protección por patente de invención de conformidad con la presente ley.

UZBEKISTAN : *Article 7 of the Law on Inventions, Utility models and Industrial Designs of 06/05/1994*

Article 7. Patentability requirements for a utility model

Subject matter claimed as a utility model shall be granted legal protection, provided that it is novel and industrially applicable.

A utility model shall be novel, if all its essential features are unknown from the prior art.

The prior art shall include all the information made generally accessible in the Republic of Uzbekistan concerning means for the same purpose as the claimed utility model and also information on their application.

A utility model shall be industrially applicable, provided that it can be used in practice.

The public disclosure of information relating to a utility model, by the inventor, applicant or any person who has received this information therefrom, either directly or indirectly, shall not be recognized as a circumstance influencing the novelty of the utility model, if the application for the grant of a patent for the utility model has been filed with the Patent Office not later than six months from the date of disclosure of the information. In that regard, the obligation to prove the fact in question shall lie with the inventor and the applicant.

The constructive design of devices shall relate to utility models.

The subject matter indicated in part nine of article six of this Law shall not be protected as utility models.

VIET NAM : *Articles 58 (2), 59 and 60 of the Law on Intellectual Property No. 50/2005/QH11 of 29/11/2005*

Article 58.- General conditions for inventions eligible for protection

1) An invention shall be protected by mode of grant of invention patent when it satisfies the following conditions:

- a/ Being novel;
- b/ Involving an inventive step;
- c/ Being susceptible of industrial application.

2) Unless it is a common knowledge, an invention shall be protected by mode of grant of utility solution patent when it satisfies the following conditions:

- a/ Being novel;
- b/ Being susceptible of industrial application.

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;
- 2) Schemes, plans, rules and methods for performing mental acts, training domestic animals, playing games, doing business; computer programs;
- 3) Presentations of information;
- 4) Solutions of aesthetical characteristics only;
- 5) Plant varieties, animal breeds;
- 6) Processes of plant or animal production which are principally of biological nature other than microbiological ones;
- 7) Human and animal disease prevention, diagnostic and treatment methods.

Article 60.- Novelty of inventions

- 1) An invention shall be considered novel if it has not yet been publicly disclosed through use or by means of a written description or any other form, inside or outside the country, before the filing date or the priority date, as applicable, of the invention registration application.
- 2) An invention shall be considered having not yet been publicly disclosed if it is known to only a limited number of persons who are obliged to keep it secret.
- 3) An invention shall not be considered having lost its novelty if it is published in the following cases, provided that the invention registration application is filed within 6 months from the date of publication:
 - a) It is published by another person without permission of the person having the right to register it defined in Article 86 of this Law;
 - b) It is published in the form of a scientific presentation by the person having the right to register it defined in Article 86 of this Law;
 - c) It is displayed at a national exhibition of Vietnam or at an official or officially recognized international exhibition by the person having the right to register it defined in Article 86 of this Law.

ANDEAN COMMUNITY : *Articles 81, 82 and 85 of the Cartagena Agreement, Decision No. 486 of 14/09/2000 of the Commission of the Andean Community*

81. Any new shape, configuration or arrangement of components of any device, tool, implement, mechanism or other object, or any part thereof, that makes for improved or different operation, use or manufacture of the object incorporating it, or which endows it with any usefulness, advantage or technical effect that it did not have previously, shall be considered a utility model.

Utility models shall be protected by means of patents.

82. Three-dimensional works, architectural works and objects that are of solely aesthetic character shall not be considered utility models.
Procedures and materials excluded from patent protection may not be the subject of utility model patents.

85. The provisions of this Decision on patents for invention shall be applicable to utility model patents where appropriate, with the exception of the provisions on processing times,

which shall be reduced by half. Without prejudice to the foregoing, the period laid down in Article 40 shall be reduced to 12 months.

ARIPO: Section 3 ter (1) and (2) of the Harare Protocol of 10/12/1982 as last amended on 26/11/1999

Section 3ter
Utility Models

(1) In this Section, “utility model” means any form, configuration or disposition of elements of some appliance, working tools and implements as articles of everyday use, electrical and electronic circuitry or other object or part thereof in so far as they are capable of contributing some benefit or new effect or saving in time, energy, or labour or improving the hygienic or sociophysiological working conditions by means of new configuration, arrangement or device or a combination thereof and are industrially applicable.

(2) A utility model shall be protected under the Protocol if it is new and industrially applicable.

OAPI : Articles 1-4 of Annex II Utility Models, Title I, of the revised Bangui Agreement of 02/03/1977 (as on 24/02/1999)

Article 1
Definition and Criteria

Within the meaning of this Annex, utility models protected by registration certificates granted by the Organization shall be implements of work or objects to be utilized or parts of such implements or objects in so far as they are useful for the work or employment for which they are intended on account of a new configuration, a new arrangement or a new component device, and are industrially applicable.

Article 2
Novelty

(1) The implement or object or the parts of the one or the other as specified in Article 1 above shall not be considered new if, on the date of the filing of the application for registration with the Organization, they have been described in publications or if they have been publicly used on the territory of a member State.

(2) The novelty referred to in paragraph (1) above shall not be denied if, during the twelve months preceding the date specified in paragraph (1) above, the implement or object or the parts of the one or the other have been the subject of a disclosure resulting from

(a) an obvious violation committed against the applicant or his predecessor in title; or

(b) the fact that the applicant or his predecessor in title has displayed them at an official or officially recognized international exhibition.

Article 3
Industrial Applicability

A utility model shall be considered industrially applicable if it can be made or used in any kind of industry. The term “industry” shall be understood in its broadest sense; in particular it shall cover handicraft, agriculture, fishery and services.

Article 4
Subject Matter Not Qualifying for Utility Model Protection

The following may not be registered as a utility model:

- (1) A utility model according to Article 1 of this Annex that is contrary to public policy or morality, public health, the national economy or national defense, provided that the exploitation of the said model shall not be considered contrary to public policy or morality merely because it is prohibited by law or regulation.
- (2) No utility model may be protected under this Annex if it has already been the subject of a patent or a utility model registration based on a prior application or an application validly claiming an earlier priority.

[Annex II follows]