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WIPO

WIPO/GRTKF/IC/2/15
ORIGINAL: English
DATE: December 13, 2001

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Second Session
Geneva, December 10 to 14, 2001

PATENTS USING BIOLOGICAL SOURCES MATERIAL (I) AND MENTION OF THE COUNTRY OF ORIGIN IN PATENTS USING BIOLOGICAL SOURCE MATERIAL (II)

Document submitted by the Delegation of Spain

1. On December 12, 2001, the Delegation of Spain submitted to the second session of the Intergovernmental Committee, for distribution, the document UNEP/CBD/COP/4/INF.30, "Patents using biological sources material (I) and mention of the Country of Origin in Patents using Biological Source Material (II)" which formed part of the documentation distributed at the IV COP of the CBD (Bratislava, May, 1998).

2. This document is reproduced in the Annex.

[Annex follows]

I

PATENTS USING BIOLOGICAL SOURCE MATERIAL

I

PATENTS USING BIOLOGICAL SOURCE MATERIAL

At the First Meeting of SBSTTA (Subsidiary Body on Scientific, Technical and Technological Advice), held in Paris during the first week of September, on the item "Ways and means to promote and facilitate access to and transfer and development of technologies as envisaged in Articles 16 and 18 of the Convention on Biological Diversity", one of the most discussed topic was the access to and transfer of technologies protected by patents, and more specifically by patent applications using biological source materials.

The SBSTTA's deliberations finally concluded on the utility of including, in patent applications using biological materials, information relating to country/countries of origin and common public knowledge of the use of those materials.

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Of all the patents using biological source material, such as plants, fungi, animals, microorganisms, firstly we are going to focus on patent applications related to plant extracts which are the most numerous within this sector.

As a general rule, when the plant(s) is (are) well known and widespread, such as rosemary, sage, oat, lemon, etc. the place of origin is not specified in the patent application.

On the other hand, when the object of the patent application is a "rare" or "exotic" plant extract, the applicant provides information relating to the country/countries of origin in the description and the traditional use(s) of the plant(s) as far as it is known to him.

We can verify this with the following examples:

* **US 3773931** (A. GROEBEL)
This american patent refers to an active susbstance which has hypotensive properties; this substance is isolated from a plant which grows in Madagascar.

> The present invention relates to a pharmacologically effective substance isolated from *Cabucala madagascariensis*, and to physiologically tolerable salts of said substance.
> *Cabucala madagascariensis* is a shrub belonging to the Apocynacea family which is found in the dry regions of the western coast of Madagascar (cf. M. Pichon, "Notulae Systematicae," XIII (1948), pp. 202–203).

*** WO 93/20832** (SMITHKLINE BEECHAM FARMACEUTICI S.P.A.)
The geographical distribution and the known therapeutical use of this palm are mentioned on the very first page of this PCT application.

WO 93/20832 PCT/EP93/00851

- 1 -

RECTAL PHARMACEUTICAL COMPOSITIONS FOR THE TREATMENT OF PROSTATIC HYPERTROPHY

The present invention relates to rectal pharmaceutical compositions for the treatment of prostatic hypertrophy. Particularly, the invention relates to rectal pharmaceutical compositions containing as the active ingredient **Serenoa repens** extract.

Serenoa repens, which is also known as **Sabal serrulatum**, is a small palm growing in United States, North Africa and Spain, the lipid-sterol extract of which, obtained according to FR-2480754 or EP-68055 patents, has been used for a long time for the treatment of benign prostatic hypertrophy (prostatic adenoma), prostatitis or other prostatic disorders. The therapeutic scheme used up to now envisages the oral administration of 300 - 1000 mg of extract daily. Therapy must generally be continued for at least two months before an improvement in symptomatology can be attained, and sometimes treatment has to be extended even for 3-4 or more months, in order to obtain a complete remission.

Now it has been found that **Serenoa repens** lipid-sterol extracts, administered by the rectal route in form of suitable pharmaceutical compositions, gives beneficial results in patients suffering from prostatic hypertrophy, prostatitis or related pathologies, in surprisingly shorter times compared with the conventional oral therapy.

*** EP 0323666** (THE PROCTER & GAMBLE COMPANY)
This European application mentions the different gum content of psyllium according to the origin of this species (*Plantago* genus). The psyllium gum can be used for reducing blood cholesterol levels.

DETAILED DESCRIPTION OF THE INVENTION

The psyllium gum used in the practice of this invention comes from psyllium seed, from plants of the Plantago genus. Various species such as Plantago lanceolate, P. rugelii, and P.major, are known. Commercial psyllium includes the French (black; Plantago indica), Spanish (P. psyllium) and Indian (blond; P. ovata). The gum content of the psyllium varies: French psyllium, 11.8%; Indian psyllium, 30.9%; and German psyllium, 11.5%. Indian (blond) psyllium is preferred for use herein.

*** EP 0513671** (INDENA S.p.A.)

This European application refers to the plant *Commiphora mukul;* the Indian and Pakistan districts where it comes from, as well as its use in Indian popular medicine for the treatment of obesity and some arthritic forms, are stated on the first page of the description.

EP 0 513 671 A1

The present invention relates to new therapeutical applications of extracts, fractions and single active ingredients prepared from Commiphora mukul; the invention further relates to processes for the preparation of the total steroidal fraction which is present in the exudate of the above plant. The Commiphora mukul - (Hook, ex Stocks) Engl. (syn. Balsamodendron mukul Hook) is a small tree of the Burseraceae family, endemic in the Indian peninsula, growing spontaneously in the dry and semidry Rajasthan, Gujarat and Madhya Pradesh districts in India, and in Beluchistan district in Pakistan. If the trunk is etched, the plant emits a yellowish gummy exudate, which coagulates rapidly in the form of stalactites having balsamic smell. In the ancient Sanskrit, this gum resin is called guggulu and is a product which is still used in Indian popular medicine for the treatment of obesity and some arthritic forms. Recently, a lipophilic extract has been prepared from this resin, said extract containing many classes of compounds, among which lignans, terpenes and some keto-steroids, named Guggulsterones. Hypolipidemic and platelet aggregation inhibiting activities are described for said lipophilic extract, which is normally obtained by simple resin extraction with ethyl acetate, or for Guggulsterone-Z and Guggulsterone-E, whose components in the extract are normally titrated.

*** US 5204101** (STUBBLEFIELD et al.)

Patent referring to a composition for the treatment of AIDS made up of two known plants and one known fruit. No mention is made of the place of origin, but both the common and the scientific names are cited..

5,204,101

1

METHOD AND COMPOSITION FOR TREATING ACQUIRED IMMUNODEFICIENCY SYNDROME

BACKGROUND OF THE INVENTION

The present invention relates to a plant derived pharmaceutical composition that has anti-viral HIV activity. The human immunodeficiency virus (HIV) is the causative agent associated with acquired immune deficiency syndrome (AIDS). AIDS and a less malignant form of the lethal disease AIDS Related Complex (ARC), and other related maladies respond to treatment with the composition of this invention.

AIDS was originally defined by the Centers for Disease Control as a disease at least moderately predictive of a defect in a cell mediated immunity, occurring in a person with no known cause for diminished resistance to the disease. It is now known that the syndrome AIDS is simply the end-stage manifestation of a prolonged, chronic erosion of the immune system caused by HIV. The syndrome defined term AIDS may be an outdated term. Perhaps the term "late stage HIV infection" may be a better term since it emphasizes the concept that HIV causes a spectrum of diseases.

HIV infection is a disease of the immune system just as hepatitis B is a disease of the liver, and influenza virus is a disease of the lung. Acute infection with HIV is usually asymptomatic but around the time of seroconversion one fourth of patients may experience transient low grade fever, malaise and other non-specific constitutional symptoms sometimes accompanied by a diffuse erythematous macropapular rash. The patient remains asymptomatic throughout most of the clinical course of

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logical improvement in the patient, i.e., restoring to the host their immune system.

DETAILED DESCRIPTION OF THE INVENTION

It has been discovered that if an HIV infected patient with AIDS is administered a compound mixture of constituents found in two naturally occurring plants, i.e., *Rumex acetosella* and *Phytolacca americana* and a naturally occurring fruit, i.e. *Citrus limonia* a substantial improvement in the condition of the patient.

The three plants are identified as:

COMMON NAME: Sheep Sorrel
FAMILY: Polygonaceae (Buckwheat)
GENUS: Rumex
SPECIES: *acetosella*

COMMON NAME: Pokeweed or pokeberry
FAMILY: Phytolaccaccea
GENUS: Phytolacca
SPECIES: *americana*

COMMON NAME: Lemon
GENUS: Citrus
FAMILY; Rutaceae
SPECIES; *limonia*

The chemical constituents of the plants are well known and are discussed in detail in several publications. Typical of the publications relating to *Phytolacca americana* are:

Constituents of Phytolacca Species. II. Comparative Examination

* **WO91/19507** (CEDARS-SINAI MEDICAL CENTER)
On the other hand, in this PCT application, which claims a composition with anti-HIV (Human Immunodeficiency Virus) activity, the applicant provides information about the place of origin.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61K 35/78 — A1

(11) International Publication Number: **WO 91/19507**

(43) International Publication Date: 26 December 1991 (26.12.91)

(21) International Application Number: PCT/US91/04126

(22) International Filing Date: 11 June 1991 (11.06.91)

(30) Priority data:
540,158 — 19 June 1990 (19.06.90) — US
712,062 — 7 June 1991 (07.06.91) — US

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(81) Designated States: AT (European patent), AU, BE (European patent), BF (OAPI patent), BJ (OAPI patent), CA, CF (OAPI patent), CG (OAPI patent), CH (European patent), CI (OAPI patent), CM (OAPI patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GA (OAPI patent), GB (European patent), GN (OAPI patent), GR (European patent), IT (European patent), JP, LU (European patent), ML (OAPI patent), MR (OAPI patent), NL (European patent), SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent).

Published
With international search report.
With amended claims and statement.

(54) Title: CHINESE HERBAL EXTRACTS IN THE TREATMENT OF HIV RELATED DISEASE

(57) Abstract

The invention features herbal extracts from ten (10) Chinese Herbal Medicines demonstrating significant *in vitro* and *ex vivo* anti-HIV activity and their use for the diagnosis and treatment of HIV and HIV-related disease.

Page 3 contains a disclosure of the number of herbal extracts examined and the number of them selected for their anti-HIV properties.

III. Disclosure of the Invention

A total of fifty-six (56) herbal extracts, some of which are known to have anti-infective properties and to be non-toxic in clinical use in China, were screened for their anti-HIV activity using in vitro techniques. Of these fifty-six (56) herbal extracts, ten (10) were shown to have potent anti-HIV activity in in vitro experiments, and two (2) of these ten (10) also exhibited anti-HIV activity in ex vivo experiments.

Claim 51 of this patent application seeks protection for the Chinese Herbal extracts to be used for this treatment.

WO 91/19507 PCT/US91/04126

51. In the assay method of claim 49, said extract being selected from the group of herbs of Coptis chineusis, Ligusticum wallichii, Illicium lanceolatum, Isatis tinctoria, Salvia miltiorrhiza, Erycibe obtusifolia, Acanthopanax graciliatylus, Bostaurus domesticus, Inula helenium, Lonicera japonica, Polygonum bistorta and Scutellaria baicaleusis.

Page 5 of the application contains TABLE I which shows the geographical distribution of this group of herbs in China.

TABLE I

SAMPLE	NAME OF HERB	CLASSIFICATION	MAJOR LOCATION
#1	Coptis chineusis Franch	Ranunculaceae	Western, Southern and Central China
#8	Ligusticum wallichii Franch and	Umbelliferae	Northern and Southwestern China; Most areas of China
	Salvia miltiorrhiza Bunge	Labiatae	
#21	Illicium lanceolatum A.C. Smith or Illicium henryi Diels	Illiciaceae	Eastern and Southern China
#30	Isatis tinctoria L. or Isatis indigotica Fort.,	Cruciferae	Central China
	Lonicera japonica Thunb and	Caprifoliaceae	Most areas of China
	Polygonum bistorta L.	Polygonaceae	Northern, Eastern and Southwestern China
#32	Salvia miltiorrhiza Bunge	Labiatae	Most areas of China
#35	Erycibe obtusifolia Benth	Convolvulaceae	Southern China, Taiwan, Japan, Indonesia and Northern Australia
#39	Acanthopanax graciliatylus W.W. Smith	Araliaceae	Central and Southwestern China, Philippines
#41	Bostaurus domesticus Gmel. and	Bovine choleic	Most areas of China
	Scutellaria baicaleusis Georgi	Labiatae	Northern, Western and Central China, S. Africa
#44	Salvia miltiorrhiza Bunge and	Labiatae	Most areas of China
	Inula helenium L.	Compositae	Northern, Northeastern and Northwestern China
#49	Lonicera japonica Thunb and	Caprifoliaceae	Most areas of China
	Scutellaria baicaleusis Georgi	Labiatae	Northern, Western and Central China, S. Africa

* A compound comprising more than one (1) herb.

If we examine patent applications using other biological materials, such as algae, animals, fungi or microorganisms, we can also find references to the place of origin.

*** US 4162309** (CALVIN et al.)

In this american patent the invention relates to water soluble extracts of certain red algae found in different areas of the Pacific coastal waters.

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WATER SOLUBLE EXTRACTS OF CERTAIN MARINE RED ALGAE AND PROCESSES FOR USE THEREOF

BACKGROUND OF THE INVENTION

The present invention relates to water soluble extracts of certain red algae, and more particularly to the water soluble extract of the alga *Neodilsea americana* and related species of algae, and to the processes for producing an aqueous extract from the algae, as well as processes for administering the water soluble extract for the treatment of certain viral infections attributable to herpes simplex virus, type 1 and type 2 and herpes zoster.

It has been suggested that certain marine red algae found off the California coast have some inhibiting activity on the replication of types 1 and 2 herpes simplex virus (hereinafter referred to as the herpes virus). See, for example, the articles by Ehresmann, D. W., et al., "Inhibition of Herpesvirus Replication by Marine Algae Extracts," *Antimicrobial Agents and Chemotherapy*, Vol. 6, No. 1, October, 1974, pp. 524 and 525, and "Antiviral Substances from California Marine Algae," *J. Phycol.*, Vol. 13, pp. 37–40, 1977.

DETAILED DESCRIPTION OF THE INVENTION

It has been found that a water soluble extract from the marine red alga *Neodilsea americana* Abbott is extremely effective to inhibit the replication of the herpes virus, as well as for almost immediately relieving pain caused by herpetic infections. *Neodilsea americana* has been identified in the reproductive stage in accordance with the description of Abbott. *Neodilsea americana* is indigenous to the Oregon, Washington, British Columbia, Canada, and Alaska Pacific coastal waters. In the nonreproductive stage, the alga *Neodilsea integra* is similar in appearance to *Neodilsea americana* and it is believed that in efficacy of treatment of herpes virus *N. integra* is virtually identical to and indistinguishable from *N. americana*. A water soluble extract from either of the aforementioned two red marine algae or mixtures thereof is effective to inhibit replication of the herpes virus and relieve the pain caused by herpetic infection.

*** US 3743722** (C. NOLAN)

This american patent refers to the venom of two pit vipers which is useful as an anti-coagulant. The global geographical distribution of these two species is mentioned.

DETAILED DESCRIPTION OF THE INVENTION

For some years, it has been known that the venom of certain pit vipers, e.g., *Agkistrodon rhodostoms*, contains a component which is useful as an anti-coagulant. More recently, it was discovered that this component actually is a coagulant for blood. In its action, the thrombin-like material to which this invention is directed forms non-crosslinked fibrin polymer which is removed readily by the body's reticulo-endothelial and/or its fibrinolytic system thus lowering or depleting the fibrinogen of the blood. It therefore produces an anti-coagulant effect.

The pit vipers which are known to include a thrombin-like active component that is useful as a defibrinolating agent include a number of species of the Agkistrodon and Bothrops genera of the Crotalidae family. These species are found in different parts of the world, predominantly in Southeast Asia (*Agkistrodon rhodostoma*) and South America (*Bothrops atrox*).

The term "native" used in describing the venom in the present description is meant to define the venom which has not been previously treated by other chromatographic or chemical procedures.

* **WO 91/09607** (R.-J. XIU)
This PCT application describes the different uses of a fungus which is well known in China.

A STIMULATOR OF VASCULAR ENDOTHELIAL CELLS AND USE THEREOF

The present invention relates to agents containing extracts of a fungus, Tremella Fuciformis, Berk (TFB), which is a non-toxical, nutritional remedy, which agents have a potential stimulating effect on the DNA synthesis of vascular endothelial cells.

Tremella Fuciformis, Berk (TFB) belongs to the class Hymenomycetes, in the division Eumycota (Ainsworth & Bisby's Dictionary of the Fungi, 1971).

Prior art

TFB has a high reputation of being a high standard, nutritional remedy in the long history of China. Thus, in ancient medicinal literature TFB has been ascribed curative properties, such as: Promoting saliva secretion, moistening lungs and stopping dry cough, decreasing itching in the throat, inhibiting cough with blood, relieving stomach pain, stopping constipation and blood in the stool, recovering tired muscles, supporting good spirit and memory, keeping skin young and hair shine etc.

During the last 15-20 years scientific studies of TFB have been carried out in China and Japan. Thus, In Journal of Medicine and Material Medica, 1978, p. 21-25, San Ming Research Station, treatment of chronic bronchitis and chronic pulmonary disease is described.

Liu zhi-bin et al reported that, oral or subcutaneus injection of TFB to mice raised the macrophage and enhanced the phagocytic function (Procoding of Beijing Medical University, 14(1); 14-15, 1982).

*** EP 0255256** (SMITHKLINE BECKMAN CORPORATION)
This European application describes a new microorganism; the applicant mentions the place where it was isolated on the second page of the description

DETAILED DESCRIPTION OF THE INVENTION

The Microorganism

The new antibiotic AAJ-271 is a complex of glycopeptides produced by the fermentation of a new microorganism Actinomadura parvosata Shearer sp. nov. (SK&F AAJ-271). The above microorganism was isolated from a soil sample collected from along the side of a body of fresh water near Myittanyunt, Burma. Actinomadura parvosata Shearer sp. nov. (SK&F AAJ-271) has been deposited in the Budapest Treaty Deposits, American Type Culture Collection, Rockville, Maryland, as the type culture under the accession number ATCC 53463.

In view of these examples [1], one can conclude that it is customary for the applicant to provide information of the country/countries of origin of the biological source materials and their traditional uses in his patent application.

Asha SUKHWANI
Spanish Patent & Trademark Office
Madrid (Spain).

[1] Examples taken from the book "Patentes Naturistas", published by the Spanish Patent & Trademark Office.

II

MENTION OF THE COUNTRY OF ORIGIN IN PATENTS USING BIOLOGICAL SOURCE MATERIAL

II

MENTION OF THE COUNTRY OF ORIGIN IN PATENTS USING BIOLOGICAL SOURCE MATERIAL

Legal aspects

Applicants for patent using biological source material are not obliged to mention the country (countries) of origin of the same by specificacions of the the national Patent Laws. However, this information is imperative in order to comply with the more general articles dealing with any type of patent applications, be it the invention related to a machine, an electronic device, the composition of a lubricant, the manufacturing procedure of a pharmaceutical product, etc.

European Patent Convention (EPC)

These articles, in the case of the EPC, are mainly Art. 83 and Rule 27.1(b)

> ***Article 83***
>
> Disclosure of the invention
>
> The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

Rule 27.1 of the **Implementing Regulations** to the EPC refers to the contents of the description, and in paragraph **b** reads as follows: ".... the description shall indicate the background art which, as far as known to the applicant, ..."

Rule 27

Content of the description

(1)* The description shall:

(a) specify the technical field to which the invention relates;

(b) indicate the background art which, as far as known to the applicant, can be regarded as useful for understanding the invention, for drawing up the European search report and for the examination, and, preferably, cite the documents reflecting such art;

(c) disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state any advantageous effects of the invention with reference to the background art;

The applicants of patents using biological source material, when dealing with "exotic" or "rare" material, which is therefore not easily accessible, are aware that for their applications to comply with such requirements they must mention the country of origin of the material. Failure to do so would make it difficult for the person skilled in the art to carry out the invention. There are thousands of different species, and with new ones being discovered everyday, it becomes impossible for the person skilled in the art to know the country (countries) where to find the raw material to carry out the invention in the case of "exotic" or "rare" species.

Moreover, in order to comply with the requirement of indicating the background art which, as far as known to the applicant, he usually mentions the traditional uses of such a material, which are, almost always, common public knowledge in the country where the species is found.

Patent Cooperation Treaty (PCT)

In the case of the **Patent Cooperation Treaty**, Article 5 is equivalent to Article 83 of the EPC, while Rule 5 1.a (ii) of the Regulations under the PCT is comparable to Rule 27.1(b) of the EPC.

Article 5
The Description

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

Rule 5
The Description

5.1 *Manner of the Description*

(a) The description shall first state the title of the invention as appearing in the request and shall:

(i) specify the technical field to which the invention relates;

(ii) indicate the background art which, as far as known to the applicant, can be regarded as useful for the understanding, searching and examination of the invention, and, preferably, cite the documents reflecting such art;

(iii) disclose the invention, as claimed, in such terms that the technical problem (even if not expressly stated as such) and its solution can be understood, and state the advantageous effects, if any, of the invention with reference to the background art;

(iv) briefly describe the figures in the drawings, if any;

(v) set forth at least the best mode contemplated by the applicant for carrying out the invention claimed; this shall be done in terms of examples, where appropriate, and with reference to the drawings, if any; where the national law of the designated State does not require the description of the best mode but is satisfied with the description of any mode (whether it is the best contemplated or not), failure to describe the best mode contemplated shall have no effect in that State;

(vi) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used; the term "industry" is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.

(b) The manner and order specified in paragraph (a) shall be followed except when, because of the nature of the invention, a different manner or a different order would result in a better understanding and a more economic presentation.

(c) Subject to the provisions of paragraph (b), each of the parts referred to in paragraph (a) shall preferably be preceded by an appropriate heading as suggested in the Administrative Instructions.

In many cases, the national Patent Laws in different countries follow the contents of these Articles. To take a few examples:

*** Spain**

The Art. 25 of the **Patent Law 11/1986**, dated 20 March, is equivalent to Article 83 of the EPC.

> **25.**- 1. The invention shall be described in the patent application in a sufficiently clear and comprehensive manner to enable a person skilled in the art to carry it out.

The Art. 5.2c) of the corresponding **Implementing Regulations** requires the state of the art known by the applicant to be cited.

> 2. En la misma se indicarán los siguientes datos:
>
> a) El título de la invención tal y como fué redactado en la instancia.
>
> b) La indicación del sector de la técnica al que se refiera la invención.
>
> c) La indicación del estado de la técnica anterior a la fecha de prioridad, conocido por el solicitante y que pueda ser útil para la comprensión de la invención y para la elaboración del informe sobre el estado de la técnica, citando, en la medida de lo posible, los documentos que sirvan para reflejar el estado de la técnica anterior.
>
> d) Una explicación de la invención, tal y como es caracterizada en las reinvindicaciones que permita la comprensión del problema técnico planteado, así como la solución al mismo, indicándose, en su caso, las ventajas de la invención en relación con el estado de la técnica anterior.
>
> e) Una breve descripción del contenido de los dibujos, si los hubiera.
>
> f) Una exposición detallada de, al menos, un modo de realización de la invención, que podrá ilustrarse con ejemplos y referencias, en su caso, a los dibujos, si los hubiera.
>
> g) La indicación de la manera en que la invención es susceptible de aplicación industrial, a no ser que ello resulte de una manera evidente de la descripción o de la naturaleza de la invención.

*** France**

Part II of the Intellectual Property Code contains the legislation which refers to the Protection of Inventions, whose Article L.612-5 is comparable to Article. 83 of the EPC.

> **L. 612-5.** The patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
>
> If an invention concerns the use of a microorganism which is not available to the public, the description shall only be regarded as disclosing the invention in an adequate manner if a culture of the microorganism has been deposited with an authorized body. The conditions governing public access to such culture shall be laid down by regulation.

Art. 9 of the Decree on the Implementation of such a legislation refers to the state of the prior art.

> **9.** The description shall comprise:
>
> *(a)* the title of the invention as appearing in the request for the grant of the patent;
>
> *(b)* an indication of the field of technology to which the invention relates;
>
> *(c)* an account of the state of the art known to the applicant that might be considered useful for the comprehension of the invention and for the drawing up of the search report; the documents serving to reflect the state of the art shall as far as possible be cited;

*** Belgium**

Article 17.-1 of the Patent Law (1984) is equivalent to Art. 83 of the EPC, and Article 9.-1(3) of the Royal Decree on Applications for Patents refers to the state of the prior art.

*** Germany**

In the German Democratic Republic, the Patent Law (1983) in Article 16.-(1) requires that "the invention must be described in such a manner that its use by other competent persons is possible".

Chapter 4

Grant, Correction and Invalidation of Patents

Application for Invention

16.—(1) The application for the grant of a patent shall be filed in writing with the Patent Office. The invention must be described therein in such a manner that its use by other competent persons is possible. The details for filing a patent application shall be provided for in a regulation issued by the President of the Patent Office.

*** United States of America**

Title 35 of the United States Code deals with Patents. The specification required for a patent application is given in Chapter 11, section 112.

112. Specification

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth

US

*** Canada**

The Patent Act of 1985 (amended in 1987) refers in its Article 34(1)(a) and (b) to the correct and complete manner in which an invention shall be set forth.

> **34.**–(1) An applicant shall in the specification of his invention
>
> *(a)* correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> *(b)* set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most closely connected, to make, construct, compound or use it;

*** Australia**

In the Patent Act of 1990 (amended in 1991), the Article 40.(2)(a) refers to the specifications that an application must comply with in order to be complete.

> *Division 2–Specifications*
>
> (Specifications)
>
> **40.**–(1) A provisional specification must describe the invention.
>
> (2) A complete specification must:
>
> (a) describe the invention fully, including the best method known to the applicant of performing the invention; and
>
> (b) where it relates to an application for a standard patent–end with a claim or claims defining the invention; and
>
> (c) where it relates to an application for a petty patent–end with a single claim, or a single independent claim and not more than two dependent claims, defining the invention.
>
> (3) The claim or claims must be clear and succinct and fairly based on the matter described in the specification.
>
> (4) The claim or claims must relate to one invention only.

*** China**

In the Patent Law of 1984 (amended in 1992), Article 26 describes the manner in which the invention shall be set forth.

> The description shall set forth the invention or utility model in a manner sufficiently clear and complete so as to enable a person skilled in the relevant field of technology to carry it out; where necessary, drawings are required. The abstract shall state briefly the main technical points of the invention or utility model.
>
> The claims shall be supported by the description and shall state the extent of the patent protection asked for.

In the Implementing Regulations of this Law, Chapter II, Article 18(3) refers to the state of the prior art.

> **18.** Except where the nature of the invention or utility model calls for a different type and order of presentation, the description of an application for a patent for invention or utility model shall, in the following order:
>
> (1) state the title of the invention or utility model as appearing in the request;
>
> (2) specify the technical field to which the invention or utility model relates;
>
> (3) indicate the prior art which, as far as known to the applicant can be regarded as useful for the understanding, searching and examination of the invention or utility model, and cite the documents reflecting such art;
>
> (4) specify the task which the invention or utility model is designed to fulfil;
>
> (5) disclose the invention or utility model in a manner sufficiently clear and complete so as to enable a person having ordinary skill in the art to carry it out;
>
> (6) state the merits or effective results of the invention or utility model as compared with the prior art;

[End of Annex and of document]