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# ภาคผนวก

# APPENDIX I

## TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE[1, 2]

## (BUDAPEST TREATY)

Done at Budapest on April 28, 1977

### TABLE OF CONTENTS[3]



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[1]Official English title.

Source : International Bureau of WIPO.

Note : This Treaty was signed on April 28, 1977. at Budapest, by the following States: Bulgaria, Denmark, Finland, France, Germany (Federal Republic of), Hungary, Italy, Netherlands, Norway, Spain, Switzerland, United Kingdom, United States of America; it remained open for signature at Budapest until December 31, 1977.

[2]Reprinted from the text published by the World Intellectual Property Organization (WIPO) in Donald S. Chisum, Patents : A Treatise on the Law of Patentability, Validity and Infringement (New York: Matthew Bender, 1986) Vol. 6, Appendix 22.

[3]This Table of Contents is added for the convenience of the reader.

PATENTS

## INTRODUCTORY PROVISIONS

### Article 1

### Establishment of a Union

The States party to this Treaty (hereinafter called "the Contracting States") constitute a Union for the international recognition of the deposit of microorganisms for the purposes of patent procedure.

### Article 2

### Definitions

For the purposes of this Treaty and the Regulations:

(i) references to a "patent" shall be construed as references to patents for inventions, inventors' certificates, utility certificates, utility models, patents or certificates of addition, inventors' certificates of addition, and utility certificates of addition;

(ii) "deposit of a microorganism" means, according to the context in which these words appear, the following acts effected in accordance with this Treaty and the Regulations; the transmittal of

a microorganism to an international depositary authority, which receives and accepts it, or the storage of such a microorganism by the international depositary authority, or both the said transmittal and the said storage;

(iii) "patent procedure" means any administrative or judicial procedure relating to a patent application or a patent;

(iv) "publication for the purposes of patent procedure" means the official publication, or the official laying open for public inspection, of a patent application or a patent;

(v) "intergovernmental industrial property organization" means an organization that has filed a declaration under Article 9(1);

(vi) "industrial property office" means an authority of a Contracting State or an intergovernmental industrial property organization competent for the grant of patents;

(vii) "depositary institution" means an institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof;

(viii) "international depositary authorty" means a depositary institution which has acquired the status of international depositary authority as provided in Article 7 ;

(ix) "depositor" means the natural person or legal entity transmitting a microorganism to an international depositary authorty, which receives and accepts it, and any successor in title of the said natural person or legal entity;

(x) "Union" means the Union referred to in Article 1;

(xi) "Assembly" means the Assembly referred to in Article 10;

(xii) "Organization" means the World Intellectual Property Organization;

(xiii) "International Bureau" means the International Bureau of the Organization and, as long as it subsists, the United International Bureaux for the Protection of Intellectual Property (BIRPI);

(xiv) "Director General" means the Director General of the Organization;

(xv) "Regulations" means the Regulations referred to in Article 12.

## PATENTS

## CHAPTER I

## SUBSTANTIVE PROVISIONS

### Article 3

### Recognition and Effect of the Deposit of Microorganisms

(1) (a) Contracting States which allow or require the deposit of microorganisms for the purposes of patent procedure shall recognize, for such purposes, the deposit of a microorganism with any international depositary authority. Such recognition shall include the recognition of the fact and date of the deposit as indicated by the international depositary authority as well as the recognition of the fact that what is furnished as a sample is a sample of the deposited microorganism.

(b) Any contracting State may require a copy of the receipt of the deposit referred to in subparagraph (a), issued by the international depositary authority.

(2) As far as matters regulated in this Treaty and the Regulations are concerned, no Contracting State may require compliance with requirements different from or additional to those which are provided in this Treaty and the Regulations.

# APPENDIX II

## CONVENTION ON THE GRANT OF EUROPEAN PATENTS[1]

## (EUROPEAN PATENT CONVENTION)

Munich, 5 October 1973

[The Convention has been ratified by the United Kingdom]

### PREAMBLE

The Contracting States,

Desiring to strengthen co-operation between the States of Europe in respect of the protection of inventions,

Desiring that such protection may be obtained in those States by a single procedure for the grant of patents, and by the establishment of certain standard rules governing patents so granted,

Desiring, for this purpose, to conclude a Convention which establishes a European Patent Organisation and which constitutes a special agreement within the meaning of Article 19 of the Convention

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[1]จาก Encyclopedia of United Kingdom and European Patent Law, edited by T.A. Blanco White, Julian Jeffs, Robin Jacob and W.R. Cornish (London: Sweet & Maxwell/ Edinburg: W. Green & Son, 1977) p. 4007 et seq.

for the Protection of Industrial Property, signed in Paris on 20 March 1883 and last revised on 14 July 1967, and a regional patent treaty within the meaning on Article 45, paragraph I, of the Patent Co-operation Treaty of 19 June 1970.[2]

Have agreed on the following provisions:

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[2]GENERAL NOTE

This Convention, completed at Munich on October 5, 1973, and signed by 10 states in accordance with EPC Art. 165, was by July 7, 1977, ratificed by sufficient states (West Germany, U.K., Netherlands, Switzerland, France and Luxembourg ; Belgium has ratified since) for the Convention to enter into force three months later (see EPC Art. 169). For the Place of the European granting system in the patent law of the U.K. see PA77 (General Note).

European Patent Office: it is expected that the Office (hereafter "EPO"), which came into existence on November 2, 1977. will start to receive applications from June 1, 1978, subject to the arrangements for progressive expansion (EPC Art. 162).

Implementing Regulations, Protocols: these form integral parts of the Convention, but in case of conflict the Convention prevails: EPC Art. 164. Guidelines for Examination in the EPO have been made publicly available (in draft form : first complete edition, edition, March 1977, General Secretariat of the Council of the European Communities).

# PART I. GENERAL AND INSTITUTIONAL PROVISIONS

## Article 53

## Exceptions to patentability

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the explotation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

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

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[a]GENERAL NOTE

Conforms to SG 63 Art. 2. For comparable provisions, see PA77, s. 1 (3) and (as regards para. (b)) PCTr 39.1 (ii), 67.1 (ii).

" 'ordre public' or morality" : see PIP Arts. 4.4, 6.5 B (3) ; EPO Guidelines C IV 3.1-3. For the EPO's power to omit statements and other matter contrary to "ordre public" or morality, see EPCr 34 (1)(a), 34(2).

Plant varieties, essentially biological processes for the production of plants : see EPC Art. 57, 167 (2) (b); EPO Guidelines C IV 3.4-5. The Paris Convention for the Protection of New Varieties

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(ต่อ) Footnote 3

of Plants (1961, in force August 10, 1968) has been ratified by Denmark, France, West Germany, Netherlands, Sweden and U.K., all of which have opted (as the Convention allows) for a special scheme of protection, rather than extension of their patent system. For the U.K., see the Plant Varieties and Seeds Act 1964.

"animal varieties," "essentially biological processes for the production of animals": see EPC Arts. 57, 167 (2) (b); EPO Guidelines C IV 3.4.

# APPENDIX III

## INTERNATIONAL CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, 1883[1]

## (PARIS CONVENTION)

Prior to 1883, the rights of a foreigner to protection in the field of industrial property were dependent mainly on reciprocity between the laws of his own country and those of the country in which he desired to obtain protection. This was generally not a satisfactory position because of the many fundamental differences between the laws of different countries. A Union between various countries was therefore created to provide, as far as possible, for more uniform protection. The basis of this Union has always been that a national of, or a person who has established himself in, any country of the Union, receives the same protection in all other countries of the Union where he may apply for protection as is granted to the nationals of those countries.

The main instrument of the Union is the International Convention for the Protection of Industrial Property. It is concerned with patents, utility models, industrial designs or models, trade marks, trade names and indications of source or appellations of origin and the repression of unfair competition.

The International Convention was signed in Paris in 1883, and has since been revised at Brussels in 1900, Washington in 1911, The Hague in 1925, London in 1934, Lisbon in 1958 and Stockholm in 1967.

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[1]จาก J.W. Baxter, World Patent Law and Practice (New York: Matthew Bender, 1981) vol. 2, pp. 132.3-132.5.

The founder members of the Convention were:

| | | |
|---|---|---|
| Belgium | Netherlands | Tunisia |
| Brazil | Portugal | United Kingdom |
| France | Spain | |
| Italy | Switzerland | |

There are now more than 88 members of the Convention, as set out in the tables below. The situation of Viet-Nam in respect of the Union is under examination.

Probably the most important feature of the Convention is that contained in Article 4 whereby a person who had duly filed a patent application in a member country is given a right of priority of 12 months for filing corresponding applications in other convention countries. Consequently, a subequent application filed in one of those countries before expiry of the 12 month period cannot be invalidated by any act whatever accomplished in the interval, nor can such acts give rise to rights of third parties or any rights of personal possession.

International Convention - List of Member Countries

1. Hague Text 1925

Brazil

Dominican Republic

[6]Nauru

2. London Text 1934

Canada
Curacao
Iceland
Indonesia
Lebanon
New Zealand
San Marino
Sri Lanka
Syria
Turkey

3. Lisbon Text 1958

Argentina
Bahamas
Cyprus
Haiti
Iran
Malta
Nigeria
Philippines
Tanzania (except Zanzibar)
Trinidad/Tobago
Zambia

4. Stockholm Text 1967

Algeria
[3]Argentina
Australia
[4]Territory of Norfolk Island
Austria
[3]Bahamas
Belgium
Benin
[2,7]Brazil
Bulgaria
Burundi
Cameroon
[3]Canada
Central African Republic
Chad
Congo
[7]Cuba
[7]Czeehoslovakia
Denmark and Faroe Island
Egypt
Finland

France (including
Departments of Guadeloupe,
Guyane, Martinique and
Reunion and all Overseas
Territories)
Gabon
German Democratic Republic
Germany Federal Republic
Ghana
Greece
Holy See
[7]Hungary
[3]Indonesia
Iraq
Ireland
Israel
Italy
Ivory Coast
Japan
Jordan
Kenya
Korea; Democratic People's
Republic
Korea, Republic of
[7]Libyan Arab Jamahiriya
Liechtenstein
Morocco
Netherlands
Netherlands Antilles
Niger
Norway
[3]Phillippines
[7]Poland
Portugal with Azores and
Madeira
[7]Romania
Senegal
[7]South Africa
Spain
Sri Lanka
Surinam
Sweden
Switzerland
Togo
[7]Tunisia
[3]Turkey
Uganda
U.K. and Hogn Kong
U.S.A.

Territories of Puerto Rico,
Virgin Islands, Eastern

Luxembourg

Madagasear

Malawi

[3]Malta

Mauritania

Mauritius

Mexico

Monaco

Samoa and Guam

[7]U.S.S.R.

Upper Volta

Uruguay

[5]Viet-Nam

Yugoslavia

Zaire

[3]Zambia

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[2]Articles 1-12 only.

[3]Articles 13-30 only.

[4]London Text

[5]The situation of Viet-Nam in respect of the Paris Union in under examination

[6]The application of the Hague Text to Nauru is not entirely clear.

[7]Not bound by paragraph 1 of Article 28.

TEXT International Convention for the Protection of Industrial Property (Paris Convention) of March 20, 1883, as revised:-[a]

Official English Text

Article 1

[Establishment of the Union; Scope of Industrial Property]

Articles have been give titles to facilitate their identification. There are no titles in the signed (French) text.

(1) The countries to which this Convention applies constitute a Union for the protection of industrial property.

(2) The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.

(3) Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.

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[a]Reprinted from the text published by the World Intellectual Property Organization (WIPO) in Donald S. Chisum, Patents : A Treatise on the Law of Patentability, Validity and Infringement (New York: Matthew Bender, 1986) Vol. 5, Appendix 3.

(4) Patents shall include the various kinds of industrial patents recognized by the laws of the conmtries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc.

Article 2

[National Treatment for Nationals of Countries of the Union]

(1) Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention. Consequently, they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights, provided that the conditions and formalities imposed upon nationals are complied with.

(2) However, no requirement as to domicile or establishment in the country where protection is claimed may be imposed upon nationals of countries of the Union for the enjoyment of any industrial property rights.

(3) The provisions of the laws of each of the countries of the Union relating to judicial and administrative procedure and to jurisdiction, and to the designation of an address for service or the appointment of an agent, which may be required by the laws on industrial property are expressly reserved.

## Article 3

[Same Treatment for Certain Categories of Persons as for Nationals of Countries of the Union]

Nationals of countries outside the Union who are domiciled or who have real and effective industrial or commercial establishments in the territory of one of the countries of the Union shall be treated in the same manner as nationals of the countries of the Union.

# APPENDIX IV

## INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, 1961/1972 & 1978[1]

("Paris Act," 1961 & "Additional Act," 1972 and "Geneva Act", 1978)

Following a conference held in May 1957, a Committee comprising representatives of Germany (Federal Republic), Austria, Belgium, France, Spain, Italy, Netherlands and Sweden, with observers from Denmark, Norway, the United Kingdom and Switzerland, met during the period 1958-60 and drafted this new International Convention.

Originally it was hoped to retain the new instrument within the framework of the Union of Paris, or at least to ensure coordination between the new Convention and the International Convention, because the aim was to harmonize the new system with that already afforded to a limited extent by the International Convention. In the result, the majority of the Committee considered it necessary to draft an independent Convention.

A final conference was held at the end of 1961 with delegates from Germany (Federal Republic) Austria, Belgium, Denmark, Spain, Finland, France, Italy, Netherlands, the United Kingdom, Sweden and Switzerland and representatives from various organisations.

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[1]J.W. Baxter, World Patent Law and Practice (New York: Matthew Bender, 1981) Vol. 2, pp. 165-167.3.

## 1978 Convention

Experience over the years since the 1961 Convention came into force revealed that some States which were interested in acceding to UPOV, were having difficulty in conforming to some of the principles of the Convention because of the nature and provisions of their own existing laws which were not susceptible to fundamental revision. It was therefore decided by UPOV that the accession of such States to the Union could be simplified by a more flexible interpretation of the Convention and by revision of its provisions should this be necessary. Also in the light of experience, it was thought desirable to modernize the operation of the Union and to improve the wording of the Convention.

To these ends, and following detailed preparatory work, a Diplomatic Conference was held from October 9 to 23, 1978, attended by representatives of all the States members of UPOV. Representatives of other States, members of the United Nations or any other specialized agency of the United Nations system were invited to the Conference and 27 States were represented. Also invited as observers were representatives from nine international governmental and non-governmental organizations

On October 23, 1978, the Conference adopted a revised text of the International Convention for the Protection of New Varieties of Plants which was signed immediately after its adoption by all the member States of UPOV (except Sweden whose signing was delayed until December 6, 1978) and by the United States of America. The Conference also adopted two Recommendations.

Any state may express its consent to be bound by the Geneva Act by the deposit of:

a) its instrument of ratification, acceptance or approval if it has signed the Aet; or

b) its instrument of accession if it has not signed the Act.

The Act is open for signature by any member State of the Union and by any other State which was represented in the Diplomatic Conference adopting the Act. It will remain open for signature until October 31, 1979.

The Act will enter into force one month after:

a) the number of instruments of ratification, acceptance, approval or accession deposited is not less than five; and

b) at least three of the said instruments are instruments deposited by States parties to the Convention of 1961.

Once the Geneva Act enters into force no State may accede to the Convention of 1961 as amended by the Additional Act of 1972.

The following is a summary of the main substantive provisions, in which the new Convention is referred to as "the Geneva Act" and the original version as "the Paris Act."

1. In Article 1(1) "breeder" is defined as being the breeder of the new plant variety, or his successor in title, thus obviating references to the successor in title in the remainder of the text.

2. Article 2(1) providing that the right of the breeder may be recognized by the grant either of a special title of protection or of a patent and that both forms of protection may not coexist for one and the same botanical genus or species, has not been changed, but a derogation from it is found in Article 37(2). This derogation provides that any State which has introduced protection in the above-mentioned forms for one and the same genus or species prior to October 31, 1979, may retain that system of protection subject to notification of the fact.

3. The Paris Act, Article 2(2) gives certain indications as to the meaning of the "variety" concept. For sound reasons it was found desirable to remove the provision.

4. There has been inserted in Article 2 a new provision specifying that each State of the Union may apply the Convention to part of a genus or species according to the manner of reproduction or multiplication or the ultimate use of the varieties, and allowing the exclusion of certain types of varieties from protection, e.g., hybrid varieties.

5. Article 3 includes the provision on reciprocity, formerly in Article 4(4) of the Paris Act but simplified.

6. The Annex to the Paris Act, containing a list of species, has been removed, but there has been retained the principle of a progressive minimum application resulting in freedom of choice of categories of plants for protection and in an increase of the categories from thirteen to twenty-four.

7. The conditions required to be met by a variety, for the breeder to enjoy protection are set out in Article 6(1).

8. The conditions required for protection are set out in Article 6(1)(b). Innovations are the introduction of the possibility of giving breeders a period of one year for acts of marketing in the State of application and the extension from four to six years of the period during which the variety may have been the subject of marketing abroad, in the case of vines and trees.

Facts not prejudicing the grant of the title of protection include a principle to a specific case, namely trials of the variety, as well as the general principle that the fact that the variety is common knowleldge does not prejudice protection except where it results from the offering for sale or marketing of the variety.

9. Article 35 of the Paris Act allowed a State to limit the novelty requirement with regard to varieties of recent creation existing at the date of entry into force of the Convention in respect of that State. This provision now appears in Article 18 of the Geneva Act but it extends the possibility to varieties of a species existing at the date on which the Convention is applied, whether before or after its entry into force, for the first time to that species.

10. Article 8 has been simplified and is subject to the derogation in Article 37(2) which now permits a State which has provided for the protection of varieties in the form of patents and special titles of protection prior to October 31, 1979, to the exclusion of any other State to apply the patentability criteria, and the term of protection, of its patent legislation to such varieties as are protected according to that legislation.

11. Under Article 12(3) the breeder is allowed a period of four years after expiration of the priority period in which to furnish additional documents and materials to the State in which he has filed an application for protection with a claim to priority. Also it is now provided that that State may demand the documents and materials within an adequate period if the application whose priority is claimed is rejected or withdrawn, thus enabling the State to ensure that priority has not been wrongly claimed.

Examples of specific legislation in this field are:

| | |
|---|---|
| Argentina | Law on Seeds and Phytogenetic Creations, 1973 |
| Belgium | Law on the Protection of New Plant Varieties, of May 20, 1975 |
| Czechoslovakia | Law relating to Seeds, 1964. |
| Denmark | Plant Variety Breeders' (Protection of Rights) Law, 1962, and amending law of 1968. |
| France | Law on the Protection of New Plant Varieties, 1970 |
| Germany, F.R. | Law relating to Seeds, 1953; Law on the Protection of Plant Varieties, 1968, and Amending Law of 1974 |
| Italy | Decree No. 974 for the Protection of New Plant Varieties, of August 12, 1975 |
| Netherlands | Seeds and Planting Materials Act, 1966 |
| New Zealand | The Plant Varieties Act, 1973 |

| | |
|---|---|
| South Africa | Plant Breeders' Rights Act No. 15 of 1976 |
| Spain | Law on the Protection of Plant Varieties, No. 12 of 1975 |
| Sweden | Plant Breeder' Protection Act, 1971 |
| Switzerland | Law concerning the Protection of New Plant Varieties, of March 20, 1975 (in force June 1, 1977) |
| United Kingdom | Plant Varieties and Seeds Act, 1964 |
| United States | Plant Variety Protection Act, 1970 |

# APPENDIX V

## MANUAL OF PATENT EXAMINING PROCEDURE,

## Chapter 2100 "Patentability"[1]



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[1]Donald S. Chisum, Patents : A Treatise on the Law of Patentability, Validity and Infringement (New York: Matthew Bender, 1986) Vol. 6, Appendix 24.

## 2105. PATENTABLE SUBJECT MATTER-MICROORGANISMS [R-3]

The decision of the Supreme Court in Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980) held that microorganisms produced by genetic engineering are not excluded from patent protection by 35 U.S.C. 101. It is clear from the Supreme Court decision and opinion that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. The test set down by the Court for patentable subject matter in this area is whether the living matter is the result of human intervention.

In view of this decision the Office is issuing these guidelines as to how 35 U.S.C. 101 will be interpreted.

The Supreme Court made the following points in the Chakrabarty opinion:

1. "Guided by these cannons of construction, this Court has read the term 'manufacture' in § 101 in accordance with its dictionary definition to mean 'the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery.'"

2. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."

3. "The Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.' V Writings of Thomas Jefferson, at 75-76. See Graham v. John Deere Co., 383 U.S. 1, 7-10 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified Congress replaced the word 'art' with 'process,' but otherwise left Jefferson's language intact. The committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.' S. Rep. No. 1979, 82d Cong. 2d Sess., 5(1952)."

4. "This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable."

5. "Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity."

6. "His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter - a product of human ingenuity 'having a distinctive name, character [and] use.'"

7. "Congress thus recognized that the relevlant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's microorganism is the result of human ingenuity and research."

8. After reference to Funk Seed & Kalo Co., 333 U.S. 127 (1948), "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under & 101."

A review of the Court statements above as well as the whole Chakrabarty opinion reveals:

(1) That the court did not limit its decision to genetically engineered living organisms,

(2) The Court enunciated a very broad interpretation of "manufacture" and "composition of matter" in Section 101 (Note esp. quotes 1, 2, and 3 above),

(3) The Court set forth several tests for weighing whether patentable subject matter under Section 101 is present stating (in quote 7 above) that:

"The relevant distinction was not between living and inanimate things but between products of nature, whether living or not, and human-made inventions."

The tests set forth by the court are (note especially the underlined protions):

"The laws of nature, physical phenomena and abstract ideas" are not patentable subject matter

"A nonnaturally occurring manufacture or composition of matter - a product of human ingenuity - having a distinctive name, character, [and] use." is patentable subject matter

"A new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celevrated $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of... nature, free to all men and reserved exclusively to none.'"

"However, the production of articles for use from raw materials prepared by giving to these materials <u>new forms, qualities, properties or combinations whether by hand, labor or machinery</u> (emphasis added) is a manufacture under Section 101."

In analyzing the history of the Plant Patent Act of 1930, the Court stated: "In enacting the Plant Patent Act, Congress addressed both of these concerns [the belief that plants, even those

artificially bred, were products of nature for purposes of the patent law ... were thought not amendable to the written description]. It explained at length its belief that the work of the plant breeder 'in aid of nature' was patentable invention. S. Rep. No. 315, 71st Cong. 2d Sess. 6-8 (1930); H.R. Rep. No. 1129. 71st Cong. 2d Sess. 7-9 (1930)."

The PTO will decide the question as to patentable subject matter under 35 U.S.C. 101 on a case-by-case basis following the tests set forth in Chakrabarty, e.g., that "a nonnaturally occurring manufacture or composition of matter" is patentable, etc. It is inappropriate to try to attempt to set forth here in advance the exact parameters to be followed.

The standard of patentability has not and will not be lowered. The requirements of 35 U.S.C. 102 and 103 still apply. The tests outlined above simply mean that a rational basis will be present for any § 101 determination. In addition, the requirements of 35 U.S.C. 112 must also be met. In this regard, see § 608.01 (p).

# APPENDIX VI

## PATENT COOPERATION TREATY, 1970[1]

The Treaty was adopted on June 19, 1970, by the Washington Diplomatic Conference attended by delegations from 78 States and representatives of 22 international organizations, and has been signed by the following 35 States:

| | | |
|---|---|---|
| Algeria | Holy See | Norway |
| Argentina | Hungary | Philippines |
| Austria | Iran | Roumania |
| Belgium | Ireland | Senegal |
| Brazil | Israel | Sweden |
| Canada | Italy | Switzerland |
| Denmark | Ivory Coast | Syria |
| Egypt | Japan | Togo |
| Finland | Luxembourg | United Kingkom |
| France | Madagascar | United States of America |
| Germany (Federal Republic) | Monaco | U.S.S.R. |
| | Netherlands | Yugoslavia |

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[1] J.W. Baxter, World Patent Law and Practice (New York: Matthew Bender, 1981) Vol. 2, pp. 167.3-167.6.

Australia, Austria, Brazil, Cameroon, Central African Empire, Chad, Congo, Denmark, Finland, France, Gabon, Germany (F.R.), Hong Kong, Hungary, Japan, Korea, Democratic People's Republic of, Liechtenstein, Luxembourg, Madagasear, Malawi, Monaco, the Netherlands Norway, Romania, Senegal, Sweden, Switzerland, Togo, U.K., U.S.A. and U.S.S.R. have ratified the Treaty.

The States party to the Treaty constitute a Union, known as the International Patent Cooperation Union, for cooperation in the filing, searching, and examination, of applications for the protection of inventions, and for rendering special technical services.

The Treaty provides for entry into force three months after eight States have ratified it, provided that each of at least four of those States is a major nation with regard to patent activity (defined by the number of applications filed in the State and by nationals of the State in other countries). These requirements have been met and the Treaty entered into force on January 24, 1978.

The date from which international applications under the PCT could be filed was June 1, 1978.

As set out in the preamble to the Treaty its aims are to contribute to the progress of science and technology, to perfect the legal protection of inventions, to simplify and render more economical the obtaining of protection for inventions where protection is sought in several countries, to facilitate and accelerate access by the public to the technical information contained in documents describing new inventions, and to foster and accelerate the economic development of developing countries through the adoption

of measures designed to increase the efficiency of their legal systems instituted for the protection of inventions

At the present time protection of an invention in several countries necessitates the filing of individual national applications in the languages of each country, usually in different form and with a different approach as to the description of the invention and claims in each.

Chapter I of the Treaty will partially replace this system by a procedure based on the filing of a single "international" patent application filed in one country which is to have the same effect as if it had been filed in all the countries designated by the applicant. The formalities of the international application are regulated in detail. An international patent application may be filed at a national Office, of a State which has ratified or acceded to the Treaty, or at the European Patent Office, or at the International Bureau of WIPO, if necessary claiming priority under the Paris Convention in a similar way to a national application now; it will be checked for form and sent to an International Searching Authority which will establish a search report indicating the relevant prior art. The International Searching Authorities are the U.S. Patent and Trademark Office, the U.S.S.R. State Committee, the Swedish Patent Office, the European Patent Office in Munich and the Japanese Patent Office. The Austrian Patent Office is an International Searching Authority for developing countries. After an applicant has had the opportunity to amend his claims, the international application and search report will be published by WIPO 18

months after its priority date if the applicant has not requested earlier publication. Up to 20 months after the priority date, the applicant will then send copies of the application and translations as required to the national Office of each country in which he wishes to proceed, and pay the national fees. The national processing of his applications will then start and each application will proceed as a national one.

Under the optional Chapter II, an applicant may seek an international preliminary examination and report on whther the invention appears to be new, non-obvious and industrially applicable. The report of the International Preliminary Examining Authority performing this examination will be sent to the countries where the applicant wishes to use it. In such countries examination and processing of the application will only start at the end of the 25th month after the priority date and the national fees and translation will become due only at that time. The International Preliminary Examining Authorities are the United Kingdom Patent Office, the U.S.S.R. State Committee, the Swedish Patent Office and, from June 1, 1979 and then only for certain technical fields, the European Patent Office in Munich. The Japanese Patent Office also is an International Preliminary Examining Authority and the Austrian Patent Office now is an International Preliminary Examining Authority limited, however, to developing countries.

Denmark, France, Liechtenstein, Lusxembourg, Norway, Switzerland and the United States are not bound by the provision of Chapter II.

The principal benefits of the system are that an applicant will be able to file one application in one language in his own country obtaining at the same time the effect of a national application in all other designated countries. He will also be able to postpone his decision on whether to proceed in the designated countries and incur the costs of translation and legal and official fees until he has seen the search report, and if he makes use of Chapter II need not pay official fees or file translations until he has seen the preliminary examination report. On the basis of the search examination reports the national Offices will have their work greatly facilitated and in countries which at present do not examine patent applications but merely register them the value of these registrations will be clearer in view of the corresponding report issued with them.

The Regulations establish uniform requirements for sufficient, clear and complete description of an invention to enable an appropriately skilled person to carry it out, and lay down that the patent claims define the matter for which protection is sought, and that they shall be clear and precise and fully supported by the description. There are detailed formal requirements for making an application, claiming priority, and the contents and from of the description, claims and an abstract. Criteria for unity of invention and allowable types of patent claims are also laid down. The language in which the international application will be published is to be English unless the original application was in French, German, Japanese or Russian when that language will be used.

Novelty will be tested in relation to prior art published anywhere in the world, and an invention will be considered to involve an inventive step if the invention is not obvious having regard to the prior art to a person skilled in the art. An invention will be considered industrially applicable if according to its nature it can be made or used (in the technological sense) in any kind of industry.

The possibility exists under the Treaty of obtaining regional patents, where provisions for such exist, utilising an international application, provided such patents are available to all persons entitled to file international applications. Member States of regional patent treaties may require applicants to seek regional rather than national patents. Thus, in France only European patents are available if the Patent Cooperation Treaty is used.

# APPENDIX VII

## UNITED STATES CONSTITUTION,

## Article 1, Section 8[1]

ART. 1, SEC. 8. The Congress shall have power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writhings and Discoveries.

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[1]จาก Donald s. Chisum, Patents : A Treatise on the Law of Patentability, Validity and Infringement (New York: Matthew Bender, 1986) Vol. 5., Appendix 1.

# APPENDIX VIII

## 35 UNITED STATES CODE, 'PATENTS'[1]

(Selected Sections)

Section 101. Inventions patentable

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Section 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than 1 year prior to the date of the application for patent in the United States, or

(c) he has abandoned the invention, or

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[1]จาก US. Congress, Office of Technology Assessment, New Developments in Biotechnology : Patenting Life (Special Report, OTA-BA-370) (Washington DC: US. Government Printing Office, April 1989) Appendix A.

(d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than 12 months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of their invention, but also the reasonable deligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Section 103. Conditions for patentability; nonobvious subject matter

A patent may not be obtained though the invention is not identically disclosed or described as set forth in Section 102 of this title, if the differences between the subject matter sought to

be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of Section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Section 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 the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form.

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a futher limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

A claim in multiple dependent form shall contain a reference, in the alternative only, to more than one claim previvusly set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered.

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Section 161. Patents for plants

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuberpropagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.

The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

Section 162. Description, claim

No plant patent shall be declared invalid for noncompliance with Section 112 of this title if the description is as complete as is reasonably possible.

The claim in the specification shall be in formal terms to the plant shown and described.

Section 163. Grant

In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced.

Section 164. Assistance of Department of Agriculture

The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Commissioner, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to fumish available information of the Department of Agriculture, (2) to conduct throught the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Commissioner officers and employees of the Department.

# APPENDIX IX

## WORLD INTELLECTUAL PROPERTY ORGANIZATION[1]

The Organization was instituted by a Convention signed at Stockholm on July 14, 1967 which came into force on April 26, 1970, and established a new international organization at the intergovernmental level. By a unanimous decision of the General Assembly of the United Nations on December 17, 1974, the Organization became a United Nations Specialized Agency on that date.

The new Organization (WIPO) is a continuation of the United International Bureaux for the Protection of Intellectual Property (BIRPI). WIPO will gradually be substituted for BIRPI until all the States at present members of BIRPI have become members of WIPO.

The objectives of the Organization are:

(i) to promote the protection of intellectual property throughout the world through co-operation among States;

(ii) to ensure co-operation in the administration of international conventions and agreements for the protection of industrial property (patents, trade marks, industrial designs, appelations of origin) and literary and artistic property (copyright).

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[1] จาก J.W. Baxter, World Patent Law and Practice (New York: Matthew Bender, 1981) Vol. 2, pp. 167.7-167.9.

Membership of the Organization is open to any State which is a member of the Paris Union, the Special unions and Agreements established in relation to that Union, the Berne Union, or any other international agreement designed to promote the protection of intellectual peoperty whose administration is assumed by the Organization. Membership is equally open to any State not a member of any of the Unions, provided that:

(i) it is a member of the United Nations, any of the Specialized Agencies brought into relationship with the United Nations, or the International Atomic Energy Agency, or is a party to the Statute of the International Court of Justice, or

(ii) it is invited by the General Assembly of the Organization to become a party to the Convention.

The following States are members of the Organization

| | | |
|---|---|---|
| Algeria | France | Liechtenstein |
| Argentina | Gabon | Luxembourg |
| Australia | Gambia | Malalwi |
| Austria | German Democratic | Malta |
| Bahamas | Republic | Mauritania |
| Barbados | Germany, Federal | Mauritius |
| Belgium | Republic | Mexico |
| Benin | Ghana | Monaco |
| Brazil | Greece | Mongolia |

Bulgaria
Burundi
Byelorussian S.S.R.
Cameroon
Canada
Central African Empire
Chad
Chile
China
Columbia
Congo
Cuba
Czechoslovakia
Denmark
Egypt
El Salvador
Fiji
Finland
Tunisia
Turkey
Ukrainian S.S.R.
U.S.S.R.
United Arab Emirates
Guinea
Holy See
Hungary
India
Indonesia
Iraq
Ireland
Israel
Italy
Ivory coast
Jamaica
Japan
Jordan
Kenya
Korea (Democratic People's Republic)
Korea, Republic of
Libyan Arab Jamahiriya
U.K.
U.S.A.
Upper Volta
Uruguay
Morocco
Netherlands
Niger
Norway
Pakistan
Peru
Philippines
Poland
Portugal
Qatar
Romania
Senegal
South Africa
Spain
Sri Lanka
Sudan
Surinam
Sweden
Switzerland
Togo
Viet-Nam
Yemen
Yugoslavia
Zaire
Zambia

# APPENDIX X

DEPOSIT OF BIOLOGICAL MATERIALS FOR PATENT PURPOSES;

NOTICE OF PROPOSED RULEMAKING

OCTOBER 6, 1988

Proposed Rules on Deposit

Department of Commerce

Patent and Trademark Office

37 CFR Part 1[1]

(a) Deposit of Biological Material

Section 1.200 Biological Material.

Section 1.201 Need to make a deposit.

Section 1.202 Acceptable depository.

Section 1.203 Time of making an original deposit.

Section 1.204 Replacement of deposit.

Section 1.205 Term of deposit.

Section 1.206 Viability of deposit.

Section 1.207 Furnishing of samples.

Section 1.208 Examination procedures.

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[1]จาก U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology : Patenting Life (Special Report, OTA-BA-370) (Washington D.C. : U.S. Government Printing Office, April 1989), Appendix C.

SECTION 1.200 : BIOLOGICAL MATERIAL.

For the purposes of these regulations pertaining to the deposit of biological material for patent purposes, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens, and seeds. Viruses, vectors, cell organelles, and other nonliving material existing in and reproducible from a living cell may be deposited by depost of the host cell capable of reproducing the nonliving material.

SECTION 1.201 : NEED TO MAKE A DEPOSIT.

(a) Where a claimed invention is, or relies on, a biological material which is not known and readily available to the public and which cannot be described in writing alone, the disclosure may include a deposit of a biological material deposited in a depository and under conditions complying with these regulations.

(b) Biological material need not be deposited if it is known and readily available to the public or can be made or isolated without undue experimentation from known and readily available material. Samples will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health, or similar reasons.

(c) The reference to a specific organism or other biological material in a specification disclosure does not create any presumption that the specific material is necessary to satisfy 35 U.S.C. 112 or that a deposit in accordance with these regulations is required.

SECTION 1.2Ø2 : ACCEPTABLE DEPOSITORY.

(a) A deposit shall be made in :

(1) Any International Depository Authority (IDA) as established under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, or

(2) any other depository recognized to be suitable by the Office. Suitability will be determined by the Commissioner on the basis of the administrative and technical conpetence, and agreement of the depository to comply with the terms and conditions applicable to deposits for patent purposes. The Commissioner may seek the advice of impartial consultants from the biotechnology industry or governmental agencies on the suitability of a depository. The depository must:

(i) Have a continuous existence;

(ii) Exist independent of the control of the depositor;

(iii) Possess the staff and facilities sufficient to examine the viability of a deposit and store the deposit in a manner which ensures that it is kept viable and uncontaminated;

(iv) Provide for sufficient safety measures to minimize the risk of losing biological material deposited with it;

(v) Be impartial and objective : and

(vi) Furnish samples of the deposited material in an expeditious and proper manner.

(b) if any depository under paragraph (a) of this section defaults or discontinues the performance of any of the tasks it should perform, the Office will recognize as a substitute in any pending application or patent a deposit, which must be viable if the biological material is of a kind capable of self-replication, made with an IDA or depository recognized to be suitable by the Office which is transferred to said depository from the defaulting depository in the manner required for replacing a deposit under Section 1.204.

(c) A depository seeking status under paragraph (a) (2) of this section must direct a communication to the Commissioner which shall:

(1) Indicate the name and address of the depository to which the communication relates;

(2) Contain detailed information as to the capacity of the depository to comply with the requirements of paragraph (b) of this section, including information on its legal status, scientific standing, staff and facilities;

(3) Indicate that the depository intends to be available, for the purposes of deposit, to any depositor under these same conditions;

(4) Where the depository intends to accept for deposit only certain kinds of biological material, specify such kinds;

(5) Indicate the amount of any fees that the depository will, upon acquiring the status of suitable depository under paragraph (a)(2) of this section, charge for storage, viability statements and furnishings of samples of the deposit.

(d) A depository having status under paragraph (a) of this section limited to certain kinds of biological material may extend such status to additional kinds of biological material by directing a communication to the Commissioner in accordance with paragraph (c) of this section. If a previous communication under paragraph (c) of this section is of record, items in common with the previous communication may be incorporated by reference.

(e) Once a depository is recognized to be suitable by the Commissioner or has defaulted or discontinued its performance under this section, notice thereof will be published in the Official Gazette of the Patent and Trademark Office.

SECTION 1.2Ø3 : TIME OF MAKING AN ORIGINAL DEPOSIT.

(a) An original deposit may be made at any time before filing an application for patent or, pursuant to a requirement that will be made by the examiner no later than the date the Notice of Allowance and Issue Fee Due is mailed, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant shall promptly submit a verified statement from 2 person in a position to corroborate the fact, and shall state, that the biological material

which is deposited is the same biological material described in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which case the statement need not be verified.

SECTION 1.204 : REPLACEMENT OF DEPOSIT.

(a) Where a depository possessing the original deposit cannot furnish samples of the deposit for any reason, the depository shall, promptly after having noted its inability to furnish samples, notify the depositor of such inabiligy, indicating the cause thereof. Subject to paragraphs (e), (f), and (g) of this section, the depositor shall be required to make a replacement deposit of the biological material which was originally deposited within three months of receiving notification that the depository cannot furnish samples. The period for satisfying this requirement is extendable upon petition, only for sufficient cause, and for a reasonable time specified. Any request for such extension must be filed on or before the day on which the action is due, but in no case will the mere filing of the request effect any extension. The replacement shall be made in any acceptable depository under Section 1.202 (a).

(b) An applicant or patent owner shall notify the Office in writing, in each application or patent affected, as soon as reasonably possible after a replacement deposit is made. This notification shall state the name and address of the depository, the accession number for the deposit, the date of making the deposit, the date of making the deposit, the results of a viability

test if applicable (as Provided for in Section 1.206), the reason for making the replacement deposit, and include a verified statement, except that if made by an attorney or agent registered to practice before the Office, the statement need not be verified. If the replacement deposit relates to a pending application, the statement shall be by a person in a position to corroborate the fact, and shall state, that the biological material which is deposited as a replacement is identical to that originally deposited. The notification shall be placed in the relevant application or patent file.

(c) A depositor's failure to replace a deposit within the time required by this section may cause the application or patent involved to be treated in any office proceeding as if no deposit were made.

(d) In the event a deposit is replaced, the Office will apply a rebuttable presumption of identity between the original and the replacement deposit is relied upon during any Office proceeding.

(e) Where an application is still pending, the time for making a replacement deposit shall be the same as the time for making an original deposit under Section 1.203(a). The applicant shall promptly notify the Office after receiving notice that the depository possessing the original deposit cannot furnish samples of the deposit for any reason. A Replacement deposit may be made during this time for any reason, including where the depository can furnish samples but the original deposit has become contaminated or has lost its capability to function as described in the specification.

(f) In no case is a replacement deposit of a biological material necessary where the biological material, in accordance with Section 1.201(b), need not be deposited.

(g) No replacement deposit of the biological material is necessary where a viable deposit is in the depository but the depository for national security, health or environmental safety reasons is unable to provide samples to requesters outside of the jurisdiction where the depository is located.

(h) A patentee may not replace a viable deposit where the depository can furnish samples. Nothing in these regulations is intended to prohibit a patentee from making an additional deposit of a biological material where an earlier deposit, otherwise viable, has become contaminated or has lost its capability to function as described in the specification.

SECTION 1.205 : TERM OF DEPOSIT.

A deposit shall be made for a term of at leat thirty (30) years after the date of a viable deposit and at least five (5) years after the most recent request for the furnishing of a sample of the deposited biological material was received by the depository. In any case sample must be stored under agreements that would make them available beyond the enforceable life of the patent for which the deposit was made.

SECTION 1.2Ø6 : VIABILITY OF DEPOSIT.

(a) A deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. No evidence is necessarily required regarding the ability of the deposited material to perform any function described in the patent application.

(b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:

(1) The name and address of the depository;

(2) The name and address of the depositor;

(3) The date of deposit;

(4) The identity of the deposit and the accession number given by the depository;

(5) The date of the viability test;

(6) The procedures used to obtain a sample if the test is not done by the depository; and

(7) A statement that the deposit is capable of reproduction.

(c) If a viability test indicates that the deposit is not viable upon receipt, or the examiner cannot, for scientific or other valid reasons, accept the statement of viability received

from the applicant, the examiner shall proceed as if no deposit has been made. The examiner will accept the conclusion set forth in a viability statement issued by a depository recognized under Section 1.202(a).

SECTION 1.207 : FURNISHING OF SAMPLES.

(a) The deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under Section 1.14 and 35 U.S.C. 122 and

(2) Subject to paragraphs (b) and (c) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depository may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

(1) Is in writing, signed and dated;

(2) Contains the name and address of the requesting party and the accession number of the deposit; and

(3) Is communicated in writing by the depository to the depositor along with a copy of the request, the date on which the sample was furnished, and the name and address of the party to whom the sample was furnished.

(c) the depositor may require that sample of a deposited biological material shall be furnished only if the requesting party has agreed in writing, not to make the deposited biological material or any biological material derived therefrom available during the term of the patent to any third party without the written permission of the depositor, and to assume the burden of proof concerning compliance with the agreement. With the exception of the Commissioner and an acceptable depository under Section 1.202 in which the requesting party has made a new deposit for patent purposes of the deposited biological material or any biological material derived therefrom, any person or entity other whan the requesting party and the depositor shall be deemed to be a third party under this paragraph. For the purposes of this paragraph, any biological material shall be deemed to be derived from the deposited bilogical material if it is replicated from, or would not have been produced but for access to, the deposited biological material, provided that the derived matter still exhibits the essential characteristics of the deposited biological material.

(d) Upon request, the Office will certify whether the deposit has been stated to have been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

(1) The name and address of the depository;

(2) The accession number given to the deposit;

(3) The patent number and issue date of the patent referring to the deposit; and

(4) The name and address of the requesting party.

SECTION 1.208 : EXAMINATION PROCEDURES.

(a) The examiner shall determine pursuant to Section 1.104 in each application if a deposit is needed, in case one has not been made, or if a deposit actually made is acceptable for patent purposes. A deposit accepted in any acceptable depository under Section 1.202(a) shall be accepted for patent purposes if made under conditions complying with Section 1.207(a) . If a deposit is required and has not been made or replaced in accordance with these regulations, the examiner shall in an Office action reject the affected claims in the application under the appropriate provision of 35 U.S.C. 112, explaining why a deposit actually made cannot be accepted.

(b) The applicant shall respond to a rejection under paragraph (a) of this section by:

(1) Making an acceptable original or replacement deposit or assuring the office in writing that an acceptable deposit will be made on or before the date of payment of the issue fee, or

(2) Establishing that the involved biological material is known and readily available to the public, or

(3) Arguing why a deposit is not required under the circumstances of the application considered. Other replies to the examiner's action shall be consider non-responsive. The rejection will be repeated until either paragraph (b)(1) or (b)(2) of this section is satisfied or the examiner is convinced that a deposit is not required.

(c) If an application is otherwise in condition for allowance except for the required deposit and the Office has received a written assurance that an acceptable deposit will be made on or before payment of the issue fee, the Office will mail to the applicant a Notice of Allowance and Issue Fee Due together with a requirement that the required deposit be made within three months. The period for satisfying this requirement is extendable under 37 CFR 1.136. Failure to make the required deposit in accordance with this requirement will result in abandonment of the application for failure to prosecute.

(d) For each deposit made pursuant to these regulations, the specification shall contain:

(1) Accession number for the deposit;

(2) Date of the deposit;

(3) Taxonomic description of the deposit; and

(4) Name and address of the depository.

# ประวัติผู้เขียน

นางสาวกัญญา หิรัณย์วัฒนพงศ์ เกิดวันที่ 13 สิงหาคม พ.ศ. 2507 จังหวัดกรุงเทพมหานคร สำเร็จการศึกษาได้รับปริญญานิติศาสตร์บัณฑิต คณะนิติศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย ปีการศึกษา 2528 เข้ารับการศึกษาหลักสูตรมหาบัณฑิต ในปีการศึกษา 2529 ภาควิชานิติศาสตร์ สาขากฎหมายระหว่างประเทศ จุฬาลงกรณ์มหาวิทยาลัย