Chapter 10

International Protection for Micro-Organisms, Plants and Animals

"The European Patent Office's view on the patenting of living material is based strictly on the provisions of the European Patent Convention, which do permit patenting of certain elements of life forms providing they are novel, inventive, and industrially applicable, In the field of' living matter, however, the patent system imposes two broad restrictions, namely the invention should not be contrary to 'ordre public and morality, and should not cover plant nor animal varieties per se. "

European Patent Office, Introduction to
"Patenting of Life Forms," a compilation of nine
published patent applications on animal life forms.

CONTENTS

Box

Tables

Chapter 10
International Protection for Micro-Organisms, Plants and Animals

INTRODUCTION

Intellectual property protection of micro-organisms, plants, animals, and biological processes is of increasing concern to the world community. The purpose of this chapter is to describe international agreements relevant to the protection of biological inventions and to summarize existing intellectual property protection in various nations. International patent practice raises a multitude of complex issues beyond the scope of this report. **Emphasis in this chapter is given to subject matter jurisdiction, in order to determine to what degree micro-organisms, plants, and animals are protectable.**

INTERNATIONAL AGREEMENTS RELEVANT TO BIOLOGICAL INVENTIONS

Formal patent statutes were first enacted by England (1623), the United States (1790), and France (1791). The development of the laws in these three nations influenced the subsequent development of patent protection in the remaining countries, most of which were enacted in the late 1800s (5). As international trade grew, the need for harmonized protection of intellectual property rights was realized.

Intellectual property protection is enhanced by several international agreements that provide comity in the area of patents, plant breeder's certificates, and deposit. This section examines five agreements that are relevant to biological inventions (table 1o-1).

Pan-s Union Convention

The Paris Union Convention is a universal treaty establishing certain basic rights for residents and nationals of its member countries to protect industrial property rights (patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source and unfair competition) under the laws of other member countries. The original Convention was signed in 1883 by 11 countries. Nine revision conferences have been held during the treaty's first century of existence;[1] as of 1988, more than 90 nations were members of the Paris Union (table 10-2). The Union is administered by the World Intellectual Property Organization (WIPO) which was created by a Convention signed in 1967. The Convention came into force in 1970, and WIPO became a United Nations (UN) specialized agency in 1974.

The Paris Union Convention addresses four broad categories:

- international public law regulating rights and obligations of the member states;
- provisions that require or permit member states to legislate within the field of industrial property;
- provisions relating to the substantive law regarding rights and obligations of private parties, but only to the extent of requiring domestic law to be applied to these parties; and
- provisions containing rules of substantive law regarding rights and obligations of private parties that govern various situations.

Article 1(4) of the Convention defines the term "patents" broadly as including **"the various kinds**

Table 10-1--International Agreements and Biotechnology Patents

Agreement Signatories	Entered into Force	Number of Signatories
Budapest Treaty	Aug. 19, 1980	22
Patent Cooperation Treaty . .	Jan. 24, 1978	40
European Patent Convention	Oct. 7, 1977	13
Union for the Protection of New Varieties of Plants . . .	Aug. 10, 1968	17
Paris Union Convention	July 7, 1884	97

SOURCE: Office of Technology Assessment, 1989.

[1]Rome in 1886, Madrid in 1890, Brussels in 1897 and 1900, Washington in]911, The Hague in 1925, London in 1934, Lisbon in 1958, and Stockholm in 1967.

of industrial patents recognized by the laws of the countries of the Union, such as patents of importation, patents of improvement, patents and certificates of addition, etc." Such broad language permits any of the forms of industrial patents granted under the laws of the member countries to be included.

National Treatment

The keystone of the Convention is the principle of national treatment, which provides, as regards the protection of industrial property, nationals of any country of the Union to enjoy in all other countries of the Union the advantages that their respective laws grant to their own nationals. The purpose is to eliminate discrimination under national law against foreigners, who in turn must observe the conditions and formalities imposed upon nationals. This basic right is designed to protect foreign applicants against discrimination by placing them on equal footing with national applicants.

Right of Priority

A practical and important right granted by the Convention is the right of priority, which enables any resident or national of a member country to first file a patent application in any member country and thereafter to file a patent application for the same invention in any of the other member countries within 12 months of the original filing, The effect is that the subsequently filed applications will enjoy the right of priority established by the first filing date. Once established, the right of priority provides a defense against any patent defeating acts that may have occurred during the priority period (i.e., between the first filing and subsequent filing).

The right of priority could be particularly significant for biotechnology inventions, since the 12-month priority period may be essential to comply with culture deposit requirements. In at least one instance, a German applicant was unable during the priority period to perfect a deposit of a tissue culture in the only European depository that was capable of accepting the deposit (7).

Working Requirements

The Convention does not place an obligation of working the invention. It only limits the extent national law may provide for not working the patented invention.

The Convention places several limitations on member countries regarding the domestic law that they can enact to obligate the working of a patented invention, particularly the remedies that may be employed. For example, forfeiture of a patent may not occur except where the granting of a compulsory

Table 10-2-Member Countries, Paris Union Convention

Algeria	Korea, Republic of
Argentina	Lebanon
Australia	Libya
Austria	Liechtenstein
Bahamas	Luxemborg
Barbados	Madagascar
Belgium	Malawi
Benin	Malta
Brazil	Mauritania
Bulgaria	Mauritius
Burkina Faso	Mexico
Burundi	Monaco
Cameroon	Mongolia
Canada	Morocco
Central African Republic	Netherlands
Chad	New Zealand
China	Niger
Congo	Nigeria
Cuba	Norway
Cyprus	Philippines
Czechoslovakia	Poland
Denmark	Portugal
Dominican Republic	Romania
Egypt	Rwanda
Finland	San Marino
France	Senegal
Gabon	South Africa
German Democratic Republic	Soviet Union
Germany, Federal Republic of	Spain
Ghana	Sri Lanka
Greece	Sudan
Guinea	Suriname
Guinea—Bissau	Sweden
Haiti	Switzerland
Holy See	Syria
Hungary	Togo
Iceland	Trinidad and Tobago
Indonesia	Tunisia
Iran	Turkey
Iraq	Uganda
Ireland	United Kingdom
Israel	United Republic of Tanzania
Italy	United States
Ivory coast	Uruguay
Japan	Viet Nam
Jordan	Yugoslavia
Kenya	Zaire
Korea, Democratic People's Republic of	Zambia
	Zimbabwe

SOURCE: Office of Technology Assessment, 1989.

license is not sufficient to prevent the abuses. Forfeiture, revocation, and compulsory licenses cannot occur until specific time periods have elapsed (e.g., a compulsory license may not be applied for before the expiration of 4 years from the filing of a patent application or 3 years from the granting of a patent, whichever occurs last).

For owners of biotechnology inventions, working requirements represent perhaps the most serious loss of effective patent protection in foreign countries. If, because of the obligation for a patentee to make freely available a sample of the deposited organism, it proves to be easier for competitors within such foreign countries to practice certain biological inventions without technological assistance from the patentee, there may be more of a temptation for the competition to seek a compulsory license or revocation or forfeiture of the patent **(29).**

Article 19 of the Paris Convention permits member nations to enter into separate agreements for the protection of industrial property, as long as those agreements do not contravene the provisions of the Convention. Under this provision several multinational agreements (e.g., European Patent Convention, Budapest Treaty) have been concluded.

Patent Cooperation Treaty

The Patent Cooperation Treaty (PCT) is a worldwide convention open to membership to any Paris Convention country. It entered into force in 1978 and as of 1988 applied to 40 countries (table 10-3). PCT is not a convention dealing with substantive requirements as each signatory determines patentability under its own domestic law. Instead, PCT relates to **procedural requirements to simplify the filing, searching, and publication of international patent applications. Multiple filings are eliminated, as are duplicate filing costs.**

These procedural steps are carried out in essentially two stages—the international stage and the national stage (35 U.S.C. 361-376). The international stage begins when an applicant files the international patent application with one of the receiving offices (generally the national patent office of the country in which the applicant is a resident or national). An international search is then conducted by an appropriate international searching authority (ISA). In the case of U.S.-initiated applications, ISA is the U.S. Patent and Trademark Office (PTO) or the European Patent Office (EPO). Following the international search, the application is sent to the international bureau—the WIPO in Geneva—which then publishes the application and provides copies to each of the designated offices in the countries where protection is sought. The applicant then provides to each designated office a translation (as necessary) and any required national fee to begin the national stage. The application is then subjected to national procedures in each of the designated countries.

Since PCT does not contain any definition of patentable subject matter, any invention that is patentable under the laws of the member countries may be made the subject of an international application under PCT. However, in view of the nonpatentability of certain inventions (such as plant and animal varieties) in several member countries, ISA is not required to provide an international search report if these inventions are the subject of international applications (36). Further, the PCT application does not contain any requirements regarding the deposit of micro-organisms or the description of the characteristics of a deposited micro-organism.

Table 10-3-Member Countries, Patent Cooperation **Treaty**

Australia	Korea, Republic of
Austria	Liechtenstein
Barbados	Luxembourg
Belgium	Madagascar
Benin	Malawi
Brazil	Mali
Bulgaria	Mauritania
Cameroon	Monoco
Central African Republic	Netherlands
Chad	Norway
Congo	Romania
Denmark	Senegal
Finland	Soviet Union
France	Sri Lanka
Gabon	Sudan
Germany	Sweden
Great Britain	Switzerland
Hungary	Togo
Italy	United States
Japan	
Korea, Democratic People's Republic of	

SOURCE: Office of Technology Assessment, 1989.

European Patent Convention

The existence of a patchwork of traditional national patent systems in the member states of the European Common Market was recognized as creating a potential conflict both with the need for free movement of goods and against anticompetitive acts. Therefore in October 1973, 14 European countries signed the Convention on the Grant of European Patents. To date, 13 countries are members of that Convention, which came into force in 1977 (table 10-4).

The European Patent Convention (EPC) is actually a system of law, common to all of the member countries, established for the granting of so-called European patents. Primarily, the Convention establishes a single supranational EPO with a uniform procedural system for the centralized filing, searching, examination, and opposition with respect to a single European patent application. If granted, a patent matures into a bundle of individual European patents, one for each of the countries designated by the applicant. This European granting system and the resulting European patents exist in parallel with the conventional national granting procedures and resulting national patents. The ultimate goal is for each of the member countries to adopt in its national law the same substantive and procedural law of patents set forth in EPC.

An additional goal is to reduce the cost of obtaining patent protection by avoiding duplicate filing, searching, and examination; by minimizing the number of translations that must be made; and by economizing on the use of professional time, both on the part of the applicant's domestic patent representatives and those located in countries where filing is anticipated (6).

Table 10-4--Member Countries, European Patent Convention

Austria	Liechtenstein
Belgium	Luxembourg
France	Netherlands
Germany, Federal Republic of	Spain
Great Britain	Sweden
Greece	Switzerland
Italy	

SOURCE: Office of Technology Assessment, 1989.

Budapest Treaty

United States applicants wishing to file patent applications involving micro-organism-related inventions face many practical problems resulting from:

- the lack of information about national law requirements governing micro-organism deposits,
- the lack of uniformity of such national requirements. and
- the fact that certain national laws require a deposit within that country-even in the case of applications claiming priority based upon a first-filed application in another country where a deposit has already been made.

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure is a vehicle for solving these problems. It entered into force in 1980 and it provides that member states recognize for their own patent procedures a deposit of a micro-organism strain made in another country. As of 1988, 22 countries were signatories to the Budapest Treaty (table 10-5).

The backbone of the Budapest Treaty is the provision for a series of International Depositary Authorities (IDAs). In order to qualify as an IDA, a depository institution must be located in the territory of a member country, and have assurances that the institution complies, and will continue to comply, with the requirements essential for it to permanently carry out its tasks under the treaty (10). As of December 1987, a total of 18 depository institutions had acquired IDA status; of these, 3 are located in the United States (see ch. 9).

Perhaps the most important aspect of the Budapest Treaty is the provision for recognition by all member nations of a deposit in a single IDA. This deposit may be made in any IDA. Once the deposit is made, two facts are recognized: the deposit was made on the indicated date, and any sample furnished by IDA is a sample of the micro-organism which was deposited on that date (9).

Many aspects regarding micro-organism deposits are left up to national law as many nations are not prepared to accept this degree of harmonization. The

Table 10-5-Member Countries, Budapest Treaty on the International Recognition of Micro-organisms for the Purposes of Patent Procedure

Australia	Korea, Republic of
Austria	Liechtenstein
Belgium	Netherlands
Bulgaria	Norway
Denmark	Philippines
Finland	Soviet Union
France	Spain
Germany, Federal Republic of	Sweden
Hungary	Switzerland
Italy	United Kingdom
Japan	United States

SOURCE: Office of Technology Assessment, 1989.

treaty contains specific requirements for IDAs. These include the acceptance of a deposit, the period of storage, the right to redeposit, viability testing, secrecy, the furnishing of samples, and import/export restrictions. These requirements are discussed in more detail in chapter 8.

International Union for the Protection of New Varieties of Plants

It became evident to many European countries during the 1950s that the rights of plant breeders were entirely overlooked in many countries. In fact, the patent laws of many foreign countries specifically excluded the patenting of any type of life form. An international conference was held in Paris in 1957 for the purpose of drafting a convention for protecting new plant varieties. The Convention was signed in 1961 and entered into force in 1968.

The International Union for the Protection of New Varieties of Plants (UPOV) was designed "to recognize and to ensure to the breeder of a new plant variety . . . the right to a special title of protection or of a patent. " The UPOV's goal was to provide a model for the adoption of breeders' rights statutes in individual countries. Countries which desired to provide breeders' rights could model their statutes after UPOV and could join the convention to enjoy the reciprocity between countries provided by the Convention.

The United States was not an original party to UPOV. Numerous conferences were held during the 1970s in an attempt to resolve substantive differences between UPOV and U.S. patent law. These efforts were culminated successfully in the revised Act of October 23, 1978, to which there are now 17 signatories (table 10-6). According to the revised text, both sexually reproduced and vegetatively propagated (i.e., asexually reproduced) plants cart be protected, as determined by the individual members. In order to obtain protection in each member country, it is necessary to file a separate application in each country. There is no central filing system and international protection is not available by filing in only one member country. A breeder who develops a new variety has an exclusive right to produce and sell that variety. In all member states, except the United States, new varieties are subject to official field trials to establish that the conditions for protection are satisfied (31).

The UPOV Convention requires that each protected variety have a specific, unique name for marketing purposes. The Convention provides that either plant variety protection or patent protection be available for a new variety. This provision was waived for countries, such as the United States, which had other forms of protection available before it acceded to the Convention.

The UPOV does have limitations. National laws of UPOV member nations may provide protection only for a limited number of plant genera or species. Protection offered by UPOV member states, therefore, differs considerably according to the lists of protected taxa (33). Hence, reciprocity between nations can be key to actual protection.

Table 10-6-Member Countries, Union for the Protection of New Varieties of Plants

Belgium	Netherlands
Denmark	New Zealand
Frame	South Africa
Germany, Federal Republic of	Spain
Hungary	Sweden
Ireland	Switzerland
Israel	United Kingdom
Italy	United States

ap

SOURCE: Office of Technology Assessment, 1989.

INTERNATIONAL PROTECTION FOR MICRO-ORGANISMS, PLANTS, AND ANIMALS

The issue of what constitutes patentable subject matter is of increasing concern, particularly as a result of developing law in the United States. This section reviews subject matter protection of living organisms in several nations.

European Patent Convention Countries

Patentable Subject Matter

Article 52(1) of EPC defines patentable subject matter as: inventions which are susceptible of industrial application, which are new, and which involve an inventive step. This definition is extraordinarily general and broad. Rather than providing a definitive, positive definition of patentable subject matter EPC instead takes the approach of narrowing this broad definition by explicitly specifying negative restrictions thereto.

Thus, under Article 52(2), the term "inventions" in the above definition is limited by excluding the following:

- discoveries, scientific theories, and mathematical methods-including naturally occurring products;
- aesthetic creations;
- schemes, rules, and methods for performing mental acts, playing games, or doing business;
- programs for computers; and
- presentations of information.

As a further restriction on the part of the definition stating '*inventions which are susceptible of industrial application," Article 52(4) further excludes "methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body." This provision does not apply, however, to products, and in particular to substances or compositions, for use in any of the excluded methods.

Article 53(b) stipulates that European patents will not issue for plant or animal varieties and essentially biological processes for the production of plants and animals (with the exception of microbiological processes or the products thereof). There are two reasons for this approach, which EPC member nations adopted in 1973. First, it was felt that granting patents in this area would create legal and administrative difficulties. Second, plant variety protection enacted in several European nations was seen as the only applicable system concerning that category of inventions (4).

The question of whether a process is "essentially biological" depends on the extent of technical human intervention in the process. If such intervention plays a significant part in determining or controlling the desired result, the process would not be excluded. According to EPC, essentially biological processes and specific plant varieties, regardless of whether they were produced by breeding or genetic engineering, are not patentable.

Although plant varieties are specifically excluded, there is no general exclusion for plants. According to the Technical Board of Appeal of EPO, EPC Article 53(b) prohibits only the patenting of plants which are in the genetically fixed form of a plant variety (i.e., a specific variety such as the rose "Peace" or the wheat cultivar "Chinese Spring"). Thus, EPO will grant utility patent (generic) protection to plants, for example, where a gene has been inserted into a plant (e.g., corn having gene X) but is not fixed in a single plant variety (e.g., corn inbred A having gene X). Similarly, a process for transforming a plant to insert a desired gene would be patentable because human intervention played a greater role in the final result than biological forces. This viewpoint has been adopted by the Swiss Patent Office as well as by EPO, which in early 1988 granted a patent on a technique for increasing the protein content of forage crops (such as alfalfa) and for plants produced with the aid of the technique. Arguably, this decision opens the door for plant and animal patenting in Europe (14,17,19).

Although plant and animal varieties and "essentially biological" processes are specifically excluded from patentable subject matter, EPC does not appear to, in principle, exclude entirely the patenting of

microbiological inventions in any of the following major classes:

- micro-organisms per se (including viruses, cell lines, etc.),
- processes for producing micro-organisms,
- processes using micro-organisms,
- products obtained from microbiological processes, and
- DNA/RNA molecule or subcellular units (e.g., plasmids).

Plant variety protection is limited in EPC countries. In most countries the only varieties that can be protected under breeders' rights statutes are those specifically set forth in varietal lists compiled by each individual country. Varietal lists are different from country to country, these lists, periodically updated, include sexually reproduced plants (e.g., corn, wheat, and sorghum), asexually reproduced plants (e.g., roses, peach trees, and lilies), and also trees and woody plants (e.g., poplar, firethorn, and elm). The varieties are protected for 15-30 years (generally 20-25 years) from the issue date of the certificate.

Heightened interest in the patenting of living matter led to a proposal by the Commission of the European Communities on the legal protection of biotechnological inventions (13) (box 10-A).

National Patent Laws of EPC Members

The national patent laws of EPC member nations generally complement convention provisions. Generally, micro-organisms are patentable, but animal and plant varieties are not (31). A sample of several member nations follows.

Belgium

Belgium's revised patent law, effective in 1986, conforms with the European Patent Convention in terms of patentable subject matter. Micro-organisms are patentable, while animals and plant species and their varieties are not patentable. Belgium is a member of UPOV.

Federal Republic of Germany

West Germany case law has recognized the patentability of micro-organisms for years. After deciding in 1969 that patents could be obtained for inventions in the field of biology (in this case, a method of breeding animals) (28), the German Federal Supreme Court specifically held, in 1975, that micro-organisms per se constituted patentable subject matter (3). West Germany permits patenting of plant varieties that are not the subject matter of the specific plant variety law.

France

French law corresponds to the EPC in most respects relevant to biotechnology (6). A plant variety law was passed in 1970 (Law 70-489), and France ratified the UPOV 1978 text in 1983. France, like West Germany, permits patenting of plant varieties that are not the subject matter of the specific plant variety law.

Switzerland

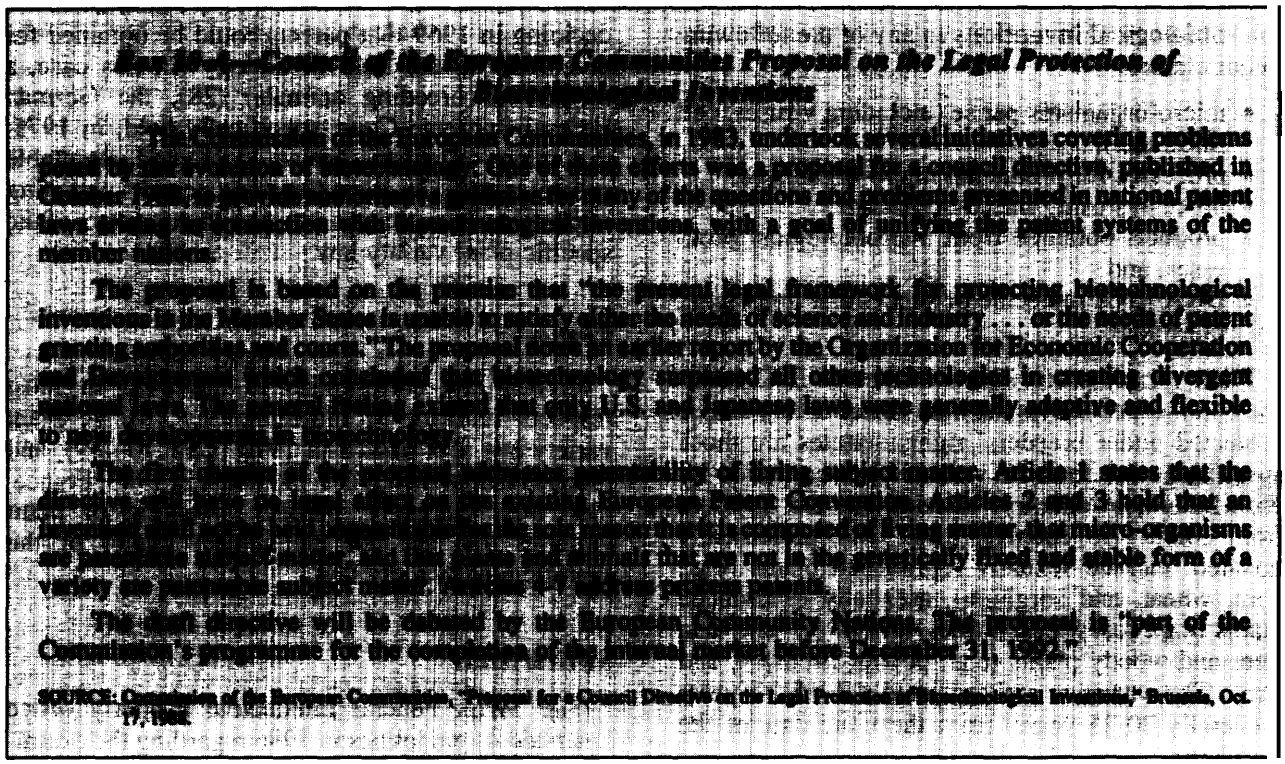
The Swiss Federal Intellectual Property office amended its guidelines in 1986 regarding the examination of patent applications in the field of biotechnology (14). The new guidelines held that:

> product claims [will be admitted] relating to whole plants or their propagating material (seeds, tubers, cuttings, etc) but in which no *variety is* specified, i.e., claims containing only characters that are valid for several varieties (for example a whole genus). In this context the variety notion must be interpreted as in the Plant Variety Protection Law . . . i.e., by reference to the criteria of homogeneity, stability, and distinctness from other plant varieties.

As regards "inventions relating to animals, the applicable criteria will be the same for plants" (34). One commentator has noted that in Switzerland, at least, if one introduces a foreign gene into an animal by microinjection, and claims the resulting genetically engineered animal without limitation to any particular variety (breed) of animal, the claim would be potentially patentable (14).

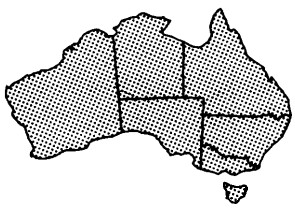
United Kingdom

The British patent act of 1977 adopted the EPC definition of patentable subject matter, and inventions concerning plants and animals are protectable only at the cellular level (e.g., a patent issued



claiming a cell culture system comprising cells derived from the baby golden hamster fibroblast cell line) (6).

Australia



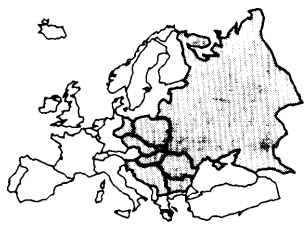
Australian law permits patents for "any manner of new manufacture," but it specifically excludes substances capable of being used as food or medicine consisting only of mixtures of known ingredients and the processes for producing them (2).

A 1976 case held that living things (specifically a new micro-organism) could be patented. The Australian Patent Office appears to hold a position similar to the U.S. PTO as regards patenting of living organisms:

> i.e., no distinction is to be made solely on the basis that a claimed product or process is, or uses, a living organism. Higher life forms will not be treated any differently than lower forms such as micro-organisms (1)

Australia, currently not a member of UPOV, offers a 20-year certificate for plant variety protection.

Eastern Europe



Eastern European nations generally grant, at the option of the applicant, either a patent or an inventor's certificate. For certain categories of subject matter, only an inventor's certificate can be obtained. An inventor's certificate is a form of recognition granted by socialist states to inventors. It does not grant to the inventor the exclusive right to use the invention or to preclude others from doing so but, rather, signifies that the invention is state property. Typically, the inventor is entitled to compensation by the state for it's use of the invention. Because

their economies are comprised mainly of state-controlled enterprises, no infringement occurs by state use of the invention.

Soviet Union

The Soviet Union grants patents and inventor's certificates for inventions covering "any new technical solution of a problem in any field of the national economy." New strains of micro-organisms are expressly recognized as inventions.

Although the USSR is not a member of UPOV, protection is available for new varieties and hybrids of agricultural crops and other cultivated plants through an inventor's certificate. Likewise, an inventor's certificate can be issued for new breeds of farm animals and poultry, new breeds of fur-bearing animals, and new species of mulberry silkworms.

Bulgaria

According to the U.S. PTO, Bulgaria provides **patent protection for** animals (35).

Czechoslovakia

In Czechoslovakia, inventions relating to medicaments, substances obtained through chemical processes, foodstuffs, and micro-organisms used in industrial manufacturing are protectable only by inventors' certificates (16).

German Democratic Republic

East Germany's 1984 patent law, which allows patents for "technical solutions that are characterized by novelty, industrial applicability, and technological progress," specifically includes microbiological processes as patentable subject matter. Specifically excluded, however, are solutions for the diagnosis, prevention, and treatment of human diseases, plant varieties and animal breeds, and strains of micro-organisms (6).

Hungary

Hungary's patent act has, since 1970, permitted patents for new plant varieties and animal breeds, as well as processes for obtaining them. The Patent Act, last revised in 1983, permits patents for plant varieties and animal breeds "if they are distinguishable, novel, homogeneous, stable, and have been given a variety denomination apt for registration" (18). Processes involving the use and preparation of micro-organisms are patentable, although products of these inventions are not patentable. As a result, the situation in Hungary is generally the reverse of that in most other countries (6).

Poland

Under Polish Law, neither patents nor inventor's certificates are granted for new plant varieties and animal breeds or for processes for curing disease. Patents may not be obtained for foodstuffs, pharmaceutical products, or products obtained by chemical processes-although processes for producing the named products are patentable (27).

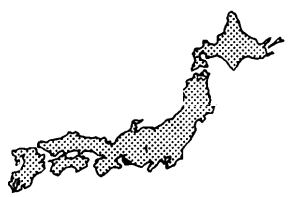
Romania

According to the U.S. PTO, Romania provides patent protection for animals (35).

Yugoslavia

Plant and animal varieties and essentially biological processes for the production of plants or animals are excluded from patent protection in Yugoslavia (4).

Japan



Japan's patent system is similar to U.S. law regarding biotechnological inventions (23). In Japan, a patentable invention utilizes a law of nature in the highly advanced creation-of technical ideas (21). The Japanese patent office currently precludes protection for inventions producing or utilizing recombinant DNA in higher animals, based on a statutory exclusion of inventions detrimental to public order, morality, or health (6).

Japan has been granting patent varieties for plants and processes of producing plants. Prior to 1970, an

invention relating to the production of plants (e.g., a method for cultivating mushrooms or a method for blooming irises) could be patented in Japan. Plants per se were not believed patentable because they were considered neither an invention nor reproducible. In 1970, the Japanese patent office set up anew examination standard and began granting patents on plants themselves, provided the plant was an artificially cultivated one and belonged to a group having characteristic features which would differentiate it from all other groups.

The Japanese patent office recently issued an internal notice announcing its intention to grant patents on nonhuman animals if they meet the requirements of the patent law. The office is expected to draft guidelines regarding the examination of such patents.

South America

Argentina

Argentina, although not a member of UPOV, has enacted plant variety protection. The 10-20 year right applies to the seeds, fruits, bulbs, tubers, buds, and graftings of the new variety. Patent protection does not extend to plant varieties.

Although patent protection extends to new industrial products, new means, and new applications of known means for obtaining an industrial result or product, pharmaceuticals are specifically excluded from patent protection. No policy has been established regarding the patentability of genetically engineered animals (6).

Brazil

Brazilian patent law contains an exclusion against protection for the discovery of varieties or species of micro-organisms. This exclusion has been cited as grounds for excluding biotechnology patents, despite the fact that 2,000 such applications have been filed (6). Pharmaceuticals and the processes for obtaining them are not patentable. Also, no plant variety or plant patent protection exists. Because of the growth of biotechnology in Brazil, the Patent Office has formed a committee to examine, with other governmental entities, potential solutions (30).

Chile

Chile is not a party to any patent-related bilateral treaty, and its trademark department has no policy or provisions regarding intellectual property protection for biotechnological products. The nation's law on seeds permits trademark protection on seed varieties, with a goal of protecting standards of purity and quality of seeds (25).

North America

Canada

The Canadian patent act, last amended in 1987, defines the term "invention" as being "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement" thereof (11). The act is essentially the same as U.S. law.

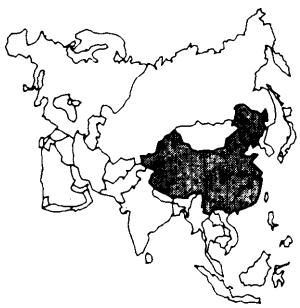
Patents are not granted for processes to medically treat humans and animals. Naturally occurring substances prepared or produced by microbiological processes and intended for use as food or medicine cannot be claimed per se but must be claimed in process-dependent form (12). As a result, product patents are more available now than prior to 1987 (8). In 1984, the Canadian patent office held that a mixture of fungi was patentable, since the claimed fungi met the test of being "sufficiently different from known species that it can be said that its creation involved the necessary element of inventive ingenuity" (20). The Patent Office, however, later rejected a claim for a variety of soybean obtained by crossbreeding (15). The rejection was upheld by the Federal Court of Appeals, which held that the claimed soybean did not come within the "common or ordinary meaning" of a manufacture or composition of matter (26). This

court decision is current] y on appeal to the Canadian Supreme Court.

Mexico

At present, biotechnology products and processes may not be patented in Mexico (32). This will change in 1997 as a result of recent legislative action permitting protection for a wide range of biotechnological processes (33).

People's Republic of China



The People's Republic of China adopted a new patent law effective in 1985, The law protects invention-creations, is to promote the development of science and technology for meeting the needs of socialist modernization, In Chinese law, "invention-creations" means inventions, utility models, and designs. **Inventions cover any new technical solution relating to a product, a process, or an improvement. A utility model** is any new technical solution relating to the shape, structure, or combination of a product that is fit for practical use. No patent rights can issue for any invention-creation that is contrary to the laws of the state or social morality or that is detrimental to public interest. Article 25 specifically precludes patent rights for scientific discoveries, rules and methods for mental activities, methods for the diagnosis or treatment of diseases, pharmaceutical products and substances obtained by a chemical process, and animal and plant varieties (24).

SUMMARY

A number of differences exist between nations regarding intellectual property protection for biotechnological inventions. Included in these differences is the issue of what constitutes patentable subject matter. Several international agreements are relevant to the worldwide protection of biological inventions. These agreements concern basic intellectual property rights and procedural mechanisms involved in international patent practice (e.g., filing and deposit). One agreement, the International Convention for the Protection of New Varieties of Plants, addresses plant breeders' rights to a special title of protection or a patent for this type of life form. No treaties or international agreements exist concerning animals as patentable subject matter.

Various analyses of the laws of other nations indicate that patent protection on animals is permissible or theoretically possible in a number of nations, Any projection of the number of nations permitting animal patents must be considered speculative in the absence of patent prosecution in this area. To date, only the United States has both announced a policy permitting patents on nonhuman animal life forms and issued a patent on an animal invented through biotechnological techniques.

CHAPTER 10 REFERENCES

1. Australian Off. J. Pat., 1980, page 1162.
2. Australian Patents Act, Sec. 155(1).
3. Baekerhefe (Baker's Yeast), 6 *IIC* 207 (1975).
4. Baeumer, L., "Protection of Inventions in the Field of Biotechnology," Symposium on the Protection of Biological Inventions, World Intellectual Property Organization and Cornell University, Ithaca, N. Y., June 1987.
5. Beier, F. K., Crespi, R. S., Straus, J., *Biotechnology and Patent Protection* (Paris: OECD, 1985).
6. Bent, S. A., Schwaab, R. L., Conlin, D. G., Jeffery, D. D., *Intellectual Property Rights in Biotechnology Worldwide (New* York, NY: Stockton Press, 1987).
7. Boeters, H. D., "Erfahrungen bei der Hinterlegung von Gewebekulturen," *Mitt,* 1982, p. 73.
8. Buchanan, J., Policy Analyst, Consumer and Corporate Affairs Canada, personal communication, Aug. 26, 1988.
9. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Art. 3(l)(a).
10. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Art. 6(1) and 6(2).
11. Canadian Patent Act, Revised Statutes of Canada, ch. P-4, Sec. 2 (1987).
12. Canadian Patent Act, Revised Statues of Canada, ch. P-4, Sec. 14(1) (1987).
13. Commission of the European Communities, "proposal for a Council Directive on the Legal Protection of Biotechnological Inventions," Brussels, Oct. 17, 1988.
14. Cooper, I., *Biotechnology and the Law, Sec. 6.05 (New* York, NY: Clark Boardman Co, Ltd., 1988).

15. Cooper, I., *Biotechnology and the Law, Sec. 10.08 (New* York, NY: Clark Boardman Co, Ltd., 1988).
16, Czechoslovakian Patent Law, Art. 28 (1972).
17. Dickson, D., "Europe Grants First Patent on Plants," *Science,* 240(4856):1 *142,* May 27, 1988.
18. Hungarian Patents Act II of 1%9, Sec. 67-71 (1983).
19, Ihnen, J. L., Attorney, Laramie & Robbins, Washington, DC, personal communication, August, 1988.
20. *In re Abitibi Co., 62* CPR 2d 81 (1982).
21. Japanese Patent Law, Sec. 1 (1978).
22. Law 70-489, Plant Variety Act of 1970.
23. Martin, C. C., "U.S. and Japan Join Effort to Support Protection of Intellectual Property," *Genetic Engineering News,* 8(5):12-13, May 1988.
24. Moga, T., "China's Patent Law Considered and Compared," University of Detroit Law Review, 64(3): 343-449, Spring 1987.
25. Obach, S., "Recent Development of Industrial Property Rights in Chile," California Western International Law Journal, 17:327-341, Summer 1987.
26. *Pioneer Hi-Bred, Ltd. v. Commissioner of Patents and Trademarks* ___:491 (Fed, Ct. App., Mar. 11, 1987).
27. Polish Law on Inventive Activity, Sec. 2, and 12 (1972).
28. Rote Taube (Red Dove), 1 *IIC* 136 (1970).
29. Schwaab, R. L., Jeffery, D. D., Conlin, D.G., U.S. *and Foreign Intellectual Property Law Relating to Biological Inventions,* contract submitted to the U.S. Congress, Office of Technology Assessment, Washington, D. C., 1984.
30. Siemsen, P.D. and Correa, J. A., "Recent Developments of Industrial Property Rights in Brazil," California Western International Law Journal, 17:320-326, Summer 1987.
31. Smolders, W., Patents and Trademarks Division, Sandoz, Basle, Switzerland, personal communication, Aug. 19, 1988.
32, Soni, M., "Recent Developments of Industrial Property Rights in Mexico," *California Western International Law Journal,* 17:342-348, Summer 1987.
33. Straus, J., Professor of Intellectual Property Law, Max Planck Institute, Munich, Federal Republic of Germany, personal communication, Aug. 29, 1988.
34. Swiss Patents, *Designs and Trademark Gazette,* Edition A, Mar. *27, 1986,* quoted in Cooper, I., *Biotechnology and the Law, Sec. 6.05 (New* York, NY: Clark Boardman Co, Ltd., 1988).
35. Van Horn, C., "Federal Regulation and Animal Patents," workshop held by the U.S. Congress, Office of Technology Assessment, Dec. 11, 1987.
36. Van Horn, C., Deputy Solicitor, U.S. Patent and Trademark Office, Washington, DC, personaI communication, Aug. 23, 1988.