Bio Patent

Japan Patent Office

Asia-Pacific Industrial Property Center, JIII

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BIOTECHNOLOGICAL PATENT

1. INTRODUCTION

Biotechnology a new technology expected to develop extensively and rapidly in the coming 21st century. It is said that the promise offered by biotechnology is so great that the present "information age" may even be supplanted by the "biotechnology age" of the next generation.

The application of biotechnology extends over many industries, including the chemical, pharmaceutical, and food industries as well as those relating to agriculture, forestry, fishery, electronics and mechanics, to name just a few. It may also be applied to industry in connection with the utilization of natural resources and energy, cleaning up toxic waste and spills, medical treatment, and legal and medical informatics. Certainly, the importance of biotechnology for the welfare of humankind will only expand over the 21st century.

Concurrent with the continuing development of the so-called new biotechnologies represented by, in particular, genetic engineering, a broad number of new issues are being raised with regard to patent protection of biotechnological inventions or products, thus inviting controversial arguments here in Japan and overseas. Under these circumstances, cross-border patent infringement suits are being filed with greater frequency than ever before.

The following pages explore characteristic features of the patent protection system for biotechnological inventions or products and include discussions on issues pertaining to obtaining rights on the fruits of biotechnology; and on relevant international treaties.

With respect to protecting biotechnological inventions or products, it should be mentioned that a protection system based on the UPOV Convention rather than on a regular patent system is alternatively possible for new plant varieties. However, since protection under the UPOV convention for new plant varieties is similar to industrial property protection afforded by the patent system, problems involved with protecting new plant varieties will be discussed in view of both protection systems.

2. BIOTECHNOLOGICAL INVENTIONS AND PROTECTED INVENTIONS

The term "biotechnology" is defined broadly so that it includes not only old biotechnology such as traditional methods of manufacturing fermented products, including alcoholic beverages, soy sauce, cheese, and so forth, and traditional methods of breeding plants and animals, such as through selection or crossbreeding, but also new biotechnology as represented by genetic engineering.

Inventions or products hailing from old and the new biotechnologies can be generally classified into the following four categories. It is imperative that all of the below items be adequately protected under a patent or other intellectual property system in order that the development of biotechnology and biotechnological industries be encouraged.

i. Living organisms: Animals, plants or microorganisms.

ii. Constituent elements of living organisms: Cell, DNA gene, etc.

iii. Non-living matters obtained through the utilization of living organisms: Fermented products, recombinant proteins, monoclonal antibodies, etc.

iv. Methods of utilizing living organisms: Fermentation method, breeding method of animals and plants, method of transformation, method of cleaning the environment by making use of microorganisms, etc.

One of the most important issues in protecting biotechnological inventions or products is related to the protection of plants, animals and such, which has been historically under the regulation of each country. Another is related to a general problem of protecting inventions relating to genes, recombinant proteins, antibody medicine, stem cells and such. Therefore, in the following description, these two problems will be mainly discussed, while touching on other problems related to the protection of biotechnological inventions.

3. PROTECTION OF LIVING ORGANISMS

The history of obtaining rights to man-made living organisms goes back to the rediscovery of Mendel's genetic law in 1900. Namely, the breeding technology used for plants was revolutionized owing to this rediscovery of genetic law, thereby giving rise to the process of scientific breeding. As a result, a large number of excellent new plant varieties began to be produced through breeding by governmental and private institutions as well as by individuals. Accordingly, protection of living organisms began with the protection of new plant varieties as described below.

In Europe, as early as 1904, a demand that plant products be protected was voiced by a fruit cultivating institution in France and in the same year, a commendation system for superior plants was initiated by the British Royal Horticultural Association in the United Kingdom. In the 1930's and through the 1940's, regular patents to new plant varieties were granted in Germany, France, Italy and Belgium. Also, starting in the 1900's in the United States of America, increasing demand by breeders, horticulturists, and scholars for the protection of new plant varieties culminated in the amendment of Patent Law in 1930 to introduce special regulation of the plant patent system. This made patenting new varieties of asexually produced plants possible. Since then, there have been diverging histories regarding protection of plants in Europe, the USA, and Japan, and the features of these differing protections offered by the individual countries will be explained below. Meanwhile, as it has become possible to apply new biotechnology, as represented in particular by genetic engineering, to the breeding of plants, the grant of patents not only to new plant varieties but to all aspects of plants has now become a real issue of controversy in the USA, Europe and Japan.

On the other hand, protection given to inventions of animals is quite new as compared with that of plant patents. In fact, only a few cases of protection of new animal varieties were ever known until recently. These refer to a small number of patents granted to new animal varieties through a special provision in Romanian Patent Law enacted in 1986 and a new provision regarding the invention of new animal varieties introduced into the Patent Law in Hungary around 1986. Protection for inventions of animals not limited to new animal varieties was available in Japan, Australia, New Zealand and others countries only after 1988, the year in which a patent to an animal was first granted in the USA.

Patents directed to microorganisms were granted in the United Kingdom from around 1960. However, most advanced countries did not grant patents directed to microorganisms until after 1980, the year in which the US Supreme Court granted a patent for a microorganism.

Since the history of and the existing protection system for living organisms are different with each country, contrasting histories and systems will be explained below with respect to practices in Europe, the USA, and Japan.

3-1. The protection of living organisms in Europe

3-1-1. The protection of plants in Europe and the UPOV Convention

(1) The protection of new plant varieties in Europe and the UPOV Convention

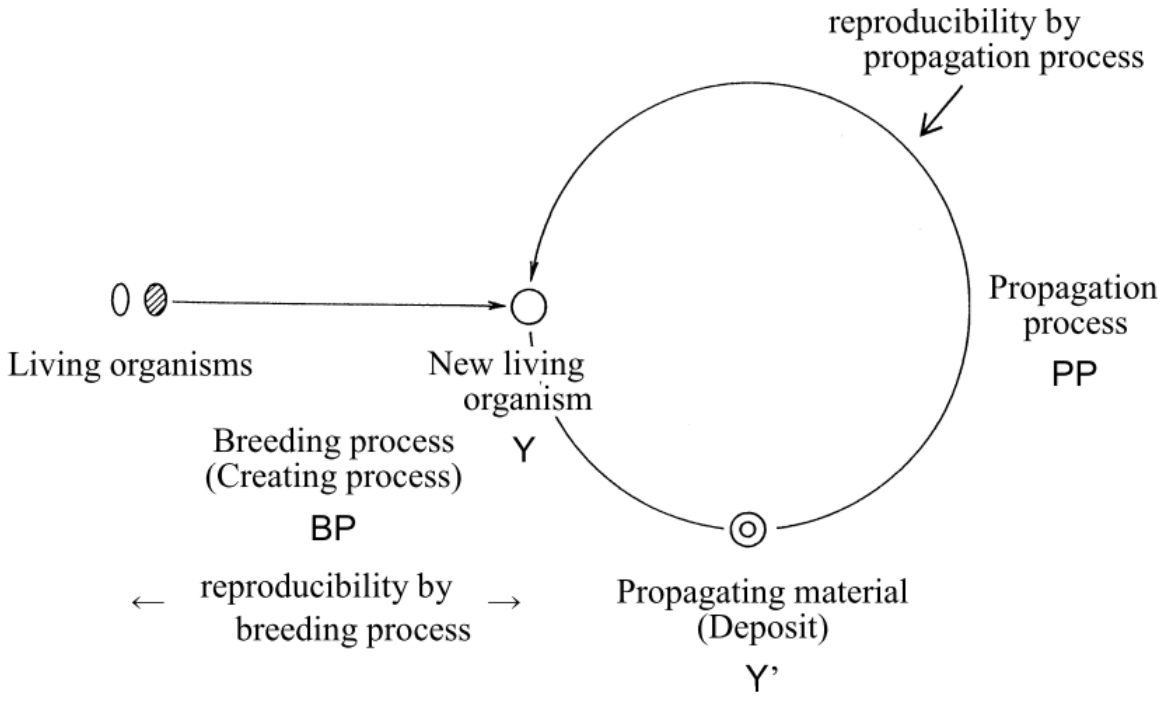
i. The trend during a period beginning in the 1930's up to the signing of the UPOV Convention in 1961:

Although countries including Germany, France, Italy and Belgium began to grant patents for new plant varieties through regular Patent Law in the 1930's and 40's, as mentioned above, this attempt ultimately failed.

Reasons for the failure were thought to be that it was very difficult to demonstrate the same degree of technical reproducibility as that for other kinds of industrial inventions relating to machinery, chemistry and electricity and, at the same time, it was difficult to clarify the object and effective scope of the claim. Another main reason for the failure was thought to be that the pervading influential opinion of the time, at least into the 1970's among scholars in Europe and, in particular, Germany, that the reproducibility requirement of a biological invention could not be met simply by the reproducibility of the biological invention's propagation process unless the reproducibility of the biological invention's breeding process was demonstrated (hereinafter referred to as the doctrine of "reproducibility by breeding process") (see Fig. 1). Another opinion, voiced by a German scholar and others, stated that although reproducibility by processes generating non-living matters, which corresponds to reproducibility by breeding process for living organisms,

may be mandatory in the case of non-living matters if they are to be admitted as inventions of technical and industrial utility, the same requirements should not be imposed on biological inventions. That is, a patent should be granted to biological inventions as long as the reproducibility of the biological invention's propagation process was demonstrated (hereinafter referred to as the doctrine of "reproducibility by propagation process").

Fig.1 Reproducibility by breeding process and Reproducibility by propagating process



One of the decisions explicitly supporting the doctrine of reproducibility by breeding process can be found in the decision of the "Red Rose" Case handed down by a Swiss Confederation law court in 1953.

This judgment denied the patentability of a claim directed to a novel red rose bred through polyphyletic mating by declaring that if the breeding process of the red rose were to be reproduced, at least 269 million variant plant groupings would be required, and this would effectively render reproducibility by breeding process infeasible, and consequently, the claimed invention could not be admitted as being technically and industrially useful. This judgment further stated that since the invention in question was found in the breeding process of a plant, the invention was not patentable even if it were possible to reproduce the novel red rose by its propagation process.

On the other hand, a fruitless campaign was waged at the beginning of 1930 by AIPPI (International Association for the Protection of the Industrial Property) and another at the end of 1940 by ASSINSEL (The International Association of Plant Breeders for the Protection of Plant Varieties), demanding international protection of breeding rights within the framework of the Paris Convention for the protection of industrial property. Under the circumstances, ASSINSEL changed its policy, thus approaching the French government in 1956 to hold an international conference for the study of the protection of breeder's rights. As a result, an international conference for the protection of inventions in fruits or new plants was held in Paris in 1957, giving birth to the UPOV Convention in 1961 apart from the Paris Convention for industrial property rights.

ii. The process after the signing of the UPOV Convention in 1961:

ii-1. The enforcement of the UPOV Convention in 1968

The UPOV Convention signed in 1961 and enforced in 1968 was limited to member nations, mainly to EC countries, thus making it appear to be a local treaty.

ii-2. The signing of the European Patent Convention in 1973 and its enforcement in 1978

Article 53(b) of the European Patent Convention (hereinafter referred to as EPC) signed in 1973 stipulates that "plant or animal varieties or essentially biological processes for the production of plants or animals" are not patentable. This Article reflected the fact that some of the main countries of the EC, which are member nations of the UPOV Convention, had already stipulated a special law for the protection of new plant varieties in compliance with the provisions of the UPOV Convention.

ii-3. The revision of the UPOV Convention in 1978

In order to encourage the participation of nations other than the European countries, a revision of the UPOV Convention was effected in 1978. As a result, Israel, the USA, Japan, Australia, and Eastern European countries, to name a few, subsequently adapted the UPOV Convention, thus substantially reinforcing the UPOV Convention so that it literally stand as an international treaty (see Table 1). Every member country, excluding some exceptional cases, has already enacted the so-called plant variety protection law independently from Patent Law to protect new plant varieties. Accordingly, at least as far as systems for protecting new plant varieties created through traditional breeding methods were concerned, the system under the UPOV Convention became a standard not only in Europe but also for the entire world.

Next, a summary of this revised UPOV Convention of 1978 will be discussed while touching on the major differences between protections according to the revised UPOV Convention and protection under regular Patent Law.

Table 1

MEMBERS OF THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

International Convention for the Protection of New Varieties of Plants*
UPOV Convention (1961), as revised at Geneva (1972, 1978 and 1991)

Status on October 22, 2009

State/Organization	Date on which State/Organization became member of UPOV	Number of contribution units	Latest Act[1] of the Convention to which State/Organization is party and date on which State/Organization became party to that Act	
Albania	October 15, 2005	0.2	1991 Act	October 15, 2005
Argentina	December 25, 1994	0.5	1978 Act	December 25, 1994
Australia	March 1, 1989	1.0	1991 Act	January 20, 2000
Austria	July 14, 1994	0.75	1991 Act	July 1, 2004
Azerbaijan	December 9, 2004	0.2	1991 Act	December 9, 2004
Belarus	January 5, 2003	0.2	1991 Act	January 5, 2003
Belgium[2]	December 5, 1976	1.5	1961/1972 Act	December 5, 1976
Bolivia (Plurinational State of)	May 21, 1999	0.2	1978 Act	May 21, 1999
Brazil	May 23, 1999	0.25	1978 Act	May 23, 1999
Bulgaria	April 24, 1998	0.2	1991 Act	April 24, 1998
Canada	March 4, 1991	1.0	1978 Act	March 4, 1991
Chile	January 5, 1996	0.2	1978 Act	January 5, 1996
China	April 23, 1999	0.5	1978 Act[3]	April 23, 1999
Colombia	September 13, 1996	0.2	1978 Act	September 13, 1996
Costa Rica	January 12, 2009	0.2	1991 Act	January 12, 2009
Croatia	September 1, 2001	0.2	1991 Act	September 1, 2001
Czech Republic	January 1, 1993	0.5	1991 Act	November 24, 2002
Denmark[4]	October 6, 1968	1.5	1991 Act	April 24, 1998
Dominican Republic	June 16, 2007	0.2	1991 Act	June 16, 2007
Ecuador	August 8, 1997	0.2	1978 Act	August 8, 1997
Estonia	September 24, 2000	0.2	1991 Act	September 24, 2000
European Community	July 29, 2005	5.0	1991 Act	July 29, 2005
Finland	April 16, 1993	1.0	1991 Act	July 20, 2001
France[5]	October 3, 1971	5.0	1978 Act	March 17, 1983
Georgia	November 29, 2008	0.2	1991 Act	November 29, 2008
Germany	August 10, 1968	5.0	1991 Act	July 25, 1998
Hungary	April 16, 1983	0.5	1991 Act	January 1, 2003
Iceland	May 3, 2006	0.2	1991 Act	May 3, 2006
Ireland	November 8, 1981	1.0	1978 Act	November 8, 1981
Israel	December 12, 1979	0.5	1991 Act	April 24, 1998
Italy	July 1, 1977	2.0	1978 Act	May 28, 1986
Japan	September 3, 1982	5.0	1991 Act	December 24, 1998
Jordan	October 24, 2004	0.2	1991 Act	October 24, 2004
Kenya	May 13, 1999	0.2	1978 Act	May 13, 1999
Kyrgyzstan	June 26, 2000	0.2	1991 Act	June 26, 2000
Latvia	August 30, 2002	0.2	1991 Act	August 30, 2002
Lithuania	December 10, 2003	0.2	1991 Act	December 10, 2003
Mexico	August 9, 1997	0.75	1978 Act	August 9, 1997
Morocco	October 8, 2006	0.2	1991 Act	October 8, 2006
Netherlands	August 10, 1968	3.0	1991 Act[6]	April 24, 1998
New Zealand	November 8, 1981	1.0	1978 Act	November 8, 1981
Nicaragua	September 6, 2001	0.2	1978 Act	September 6, 2001
Norway	September 13, 1993	1.0	1978 Act	September 13, 1993
Oman	November 22, 2009	1.0	1991 Act	November 22, 2009
Panama	May 23, 1999	0.2	1978 Act	May 23, 1999
Paraguay	February 8, 1997	0.2	1978 Act	February 8, 1997
Poland	November 11, 1989	0.5	1991 Act	August 15, 2003
Portugal	October 14, 1995	0.2	1978 Act	October 14, 1995
Republic of Korea	January 7, 2002	0.75	1991 Act	January 7, 2002
Republic of Moldova	October 28, 1998	0.2	1991 Act	October 28, 1998
Romania	March 16, 2001	0.2	1991 Act	March 16, 2001
Russian Federation	April 24, 1998	0.5	1991 Act	April 24, 1998
Singapore	July 30, 2004	0.2	1991 Act	July 30, 2004

MEMBERS OF THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS

International Convention for the Protection of New Varieties of Plants*

UPOV Convention (1961), as revised at Geneva (1972, 1978 and 1991)

(continued)

State/Organization	Date on which State/Organization became member of UPOV	Number of contribution units	Latest Act[1] of the Convention to which State/Organization is party and date on which State/Organization became party to that Act	
Slovakia	January 1, 1993	0.5	1991 Act	June 12, 2009
Slovenia	July 29, 1999	0.2	1991 Act	July 29, 1999
South Africa	November 6, 1977	1.0	1978 Act	November 8, 1981
Spain	May 18, 1980	2.0	1991 Act	July 18, 2007
Sweden	December 17, 1971	1.5	1991 Act	April 24, 1998
Switzerland	July 10, 1977	1.5	1991 Act	September 1, 2008
Trinidad and Tobago	January 30, 1998	0.2	1978 Act	January 30, 1998
Tunisia	August 31, 2003	0.2	1991 Act	August 31, 2003
Turkey	November 18, 2007	0.5	1991 Act	November 18, 2007
Ukraine	November 3, 1995	0.2	1991Act	January 19, 2007
United Kingdom	August 10, 1968	2.0	1991 Act	January 3, 1999
United States of America	November 8, 1981	5.0	1991 Act[7]	February 22, 1999
Uruguay	November 13, 1994	0.2	1978 Act	November 13, 1994
Uzbekistan	November 14, 2004	0.2	1991 Act	November 14, 2004
Viet Nam	December 24, 2006	0.2	1991 Act	December 24, 2006

(Total: 68)

* The International Union for the Protection of New Varieties of Plants (UPOV), established by the International Convention for the Protection of New Varieties of Plants, is an independent intergovernmental organization having legal personality. Pursuant to an agreement concluded between the World Intellectual Property Organization (WIPO) and UPOV, the Director General of WIPO is the Secretary-General of UPOV and WIPO provides administrative services to UPOV.

[1] "1961/1972 Act" means the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as amended by the Additional Act of November 10, 1972; "1978 Act" means the Act of October 23, 1978, of the Convention; "1991 Act" means the Act of March 19, 1991, of the Convention.

[2] With a notification under Article 34(2) of the 1978 Act.

[3] With a declaration that the 1978 Act is not applicable to the Hong Kong Special Administrative Region.

[4] With a declaration that the Convention of 1961, the Additional Act of 1972, the 1978 Act and the 1991 Act are not applicable to Greenland and the Faroe Islands.

[5] With a declaration that the 1978 Act applies to the territory of the French Republic, including the Overseas Departments and Territories.

[6] Ratification for the Kingdom in Europe.

[7] With a reservation pursuant to Article 35(2) of the 1991 Act.

* * *

◆ SUMMARY OF THE REVISED UPOV CONVENTION OF 1978

(a) Object

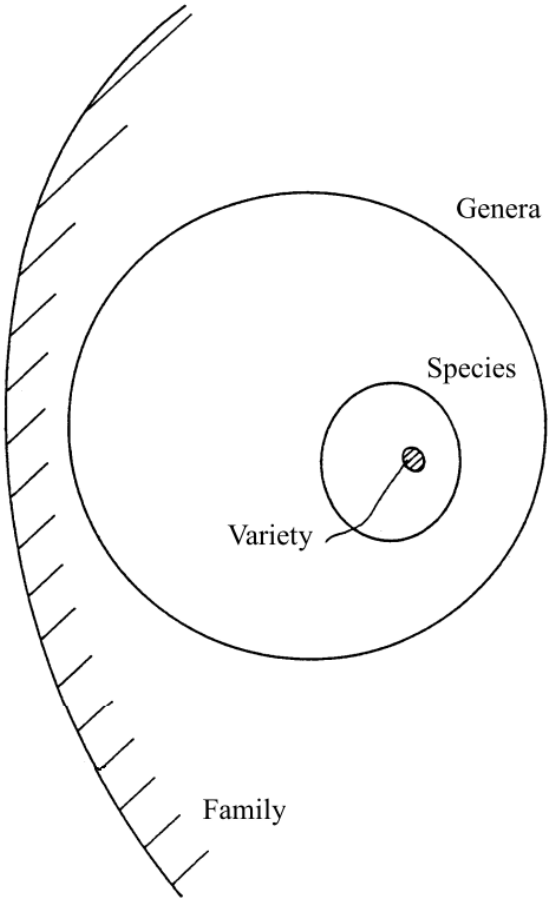
The object of this treaty is to protect the rights of breeders according to the provisions of this treaty.

(b) Protected Subjects

(b)-1. Protected under this Convention are new plant varieties

Although, the revised UPOV Convention of 1978 contains no definition of the term, "variety," it may be deemed to be the same as variety defined in the revised UPOV Convention of 1991; i.e. variety is a plant grouping within the lowest known botanical taxonomic classification identified by a genetic type or other characteristics having, for instance, distinction and stability. Since the lowest known botanical taxonomic classification is species, taxonomic positioning of varieties can be illustrated as shown in Fig. 2.

Fig.2 Taxonomic positioning of varieties



Therefore, an invention claiming a general plant such as a dicotyledon having a particular gene introduced therein and exhibiting a particular characteristic cannot be protected by the UPOV Convention.

Under the UPOV Convention, it does not matter whether the variation leading to the production of new varieties occurred by artificial or natural means. Further, since the object of protection under Patent Law is confined to an invention, when a new variety is derived from a spontaneous mutation such as a bud mutation or is bred through a selection process from local varieties, such a variety constitutes merely a discovery and the discovered subject matter cannot be protected under Patent Law. Under the UPOV Convention, however, such a variety can indeed be protected.

(b)-2. Botanical Genera and Species which Must or May be Protected

It is stipulated that member countries will protect as many botanical genera and species as possible. The minimum number of botanical genera and species that must be protected within a predetermined time limit is also stipulated.

(c) Forms of Protection

New plant varieties can be protected by either a special law or a Patent Law. However, the same botanical genus or species can be protected by only one of these laws under what is called prohibition of double protection, para. 2(1), exceptional regulation para. 37.

Incidentally, some member countries such as Italy and Hungary fulfill the protection of breeder's rights as stipulated in the UPOV Convention by introducing special regulations, which are identical to the provision of the UPOV Convention, into existing Patent Law. Therefore, a patent directed to a new plant variety under the UPOV Convention is quite different in relation to its protected subject and its manner of protection under a plant patent based on regular Patent Law.

(d) The Content of Rights

(d)-1. Basic Rights

① Exclusive rights to sell seeds and seedlings and to produce these for sale.

The breeder's rights extend only to production and sales activities of breeders, so that breeders' rights cannot encompass the production and sales activities of farmers.

② With respect to ornamental plants, an exceptional regulation for extending the breeder's rights beyond those given in paragraph ① above.

③ The breeder's rights cannot encompass the use of registered new varieties if the new varieties are employed as a raw material for breeding other kinds of varieties. However, the breeder's rights may be exercised if the registered new varieties are

repeatedly employed for the purpose of commercially producing other kinds of plants (F1 variety).

(d)-2. Supplemental Rights

Rights other than the aforementioned basic rights (for example, the right encompassing products such as cut flowers sold to consumers) may be given to the breeder.

(e) Requirements for protection

① Distinctness

The new variety should be distinct by one or more important characteristics from the known varieties at the time of the application thereof.

② Not offered for sale before the application. The new variety must not have been offered for sale by the breeder's consent before the application thereof in a country where the application was filed.

This requirement corresponds to the novelty requirement in Patent Law. However, according to Patent Law, the novelty of invention is forfeited where the invention has been described in a publication, worked in public, or known to the public. Whereas, unlike regular Patent Law, the registerability of a new variety cannot be forfeited by these facts according to the protection system of new varieties under the UPOV Convention.

③ Uniformity

It is required that the new variety be sufficiently uniform in characteristics.

④ Stability

It is required that the characteristics of the new variety remain unchanged even after a repeated propagation thereof.

(f) Examination system: In principle, an actual examination (including a cultivation test and site investigation to be performed by the Examination Department) is required.

(g) Period of protection: 15 years or more (18 years or more in the case of trees, etc.).

(h) Nullity and Forfeiture

Nullity: The right shall be declared null when it is found that the new variety fails to meet the requirements of protection at the time the right was granted.

Forfeiture: When the seeds or seedlings are not submitted to the authorities concerned after the registration thereof, the registration of the new variety shall become forfeited.

This provision of forfeiture is a unique regulation not found in regular Patent Law.

(i) The provisions of national treatment and the right of priority

The provisions of national treatment and priority, which are similar to those in the Paris Convention for the Protection of Industrial Property, are stipulated in the UPOV Convention.

ii-4. The signing of the revised UPOV Convention of 1991 and the enforcement thereof in 1998

In order to stay in line with the latest developments in biotechnology in the field of plants, a revised UPOV Convention notably strengthening breeders' rights was signed in 1991 and enforced in 1998.

◆ MAIN REVISED POINTS OF THE UPOV CONVENTION OF 1991

(a) Augmentation of the Scope of Protection of Botanical Genera and Species by the Treaty

According to the UPOV Convention of 1978, it was stipulated that member countries protect as many botanical genera and species as possible (a minimum number of botanical genera and species for protection was specified). However, the revised UPOV Convention of 1991 stipulates that all botanical genera and species be protected.

(b) Deletion of the Article Prohibiting Double Protection

In the revised Convention, the article prohibiting double protection of new varieties under the UPOV Convention of 1978 was deleted, and the system for protecting new varieties was entrusted to each member country.

(c) The expansion of breeders' rights

According to the UPOV Convention of 1978, it was stipulated that breeders' rights be limited to selling seeds and seedlings, and producing seeds and seedlings for the purpose of selling the same. However, the revised UPOV Convention of 1991 stipulates in principle that the breeder's rights encompass the propagation, selling, exporting, importing and stocking of seedlings.

The revised UPOV Convention of 1991 also stipulates that if it was impossible for the breeder to exercise rights over the seeds and seedlings, the breeder may then exercise rights to the harvested material as well, and that if it was impossible for the breeder to exercise rights over the harvested material, the breeder may then exercise rights to the product made directly from the harvested material (this provision is entrusted to each country).

(d) The introduction of provisional protection

It was optional for each member country under to the UPOV Convention of 1978 to adopt provisional protection for protecting breeders over the course of the period from the filing of an application for breeder's rights and the granting of those rights. According to the revised UPOV Convention of 1991 however, every member country is required to adopt this provisional protection.

(e) The Introduction of the Dependent Relationship

The provisions of the dependent relationship stipulate that the breeder's rights based on the registered varieties encompass varieties that are essentially derived from the protected varieties (or the varieties with only their characteristics slightly modified from the registered varieties).

(f) The Introduction of the Optional Exception to Restrict Breeder's Rights in order to Permit Farmers to Use the Protected Variety for Propagating Purposes

Within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, each member country may restrict the breeder's rights on any variety in order to permit farmers to use the product of the harvest obtained by planting the protected variety on their own lands for propagating purposes thereon.

ii-5. The Establishment of the Regulation of Plant Variety Rights in the European Community in 1995

Based on the UPOV Convention, the regulation of plant variety rights in the European Community was enacted in 1995. Breeder's rights under this regulation are enforceable over the entire region of the European Community.

(2) Patent Claiming a General Plant in Europe

i. The background of a trial decision permitting patentability of a general plant by the EPO:

As mentioned above, there is now a system of protecting new plant varieties under the UPOV Convention, and, in addition, the breeder's rights have been enlarged and strengthened by the revised UPOV Convention of 1991 in conformity with the advancement of new biotechnology such as genetic engineering. However, since the subjects under protection by the UPOV Convention are confined to plant varieties, inventions directed to non-variety plants that do not meet the requirements of variety as defined under the UPOV Convention as well as inventions directed to plants in general such as an insect-resistant plant or a herbicide-resistant plant, which can be created by means of genetic engineering, that apparently fall outside the definition of variety cannot be effectively protected.

Following are points based on legal, technical and economic backgrounds that lead to the possibility of patenting general plants.

(a) Recognition of the Doctrine of Reproducibility by Propagation Process in the EPO

As described hereinafter at Paragraph 3-1-3, (2) and (3), with respect to the reproducibility of microorganisms, it is now possible in Europe to show reproducibility by propagation process by depositing the microorganisms. Accordingly, it is now possible to employ mutatis mutandis the above-mentioned practice to show reproducibility by propagation process of a plant by depositing seeds or seedlings or transformed cells of the plant.

(b) The Characteristics of a Plant Produced by New Biotechnology such as Genetic Engineering

Plants bred by traditional breeding methods such as artificial mating often cannot fulfill the disclosure requirements including the showing of reproducibility thereof or the patentability requirements such as inventive step. In contrast, plants produced by genetic engineering can readily meet these requirements.

(c) The Necessity of Recovering Enormous Investment Costs for the Production of Plants by New Biotechnology such as Genetic Engineering

The production of plants by using new biotechnology such as genetic engineering involves enormous investment costs for the study and development thereof; and if only a narrow scope of right restricted to an individual variety is granted, it would not be possible to fully recover the investment costs.

In view of this, a trial decision to admit the patentability of a general plant as explained below was made by the EPO in spite of the provisions of EPC Article 53(b) that denies patentability of plant varieties. Furthermore, an instruction in a form of a directive was delivered by the EU to admit the patentability of the aforementioned general plants.

ii. A trial decision permitting the patentability of non-variety plants in the EPC:

A plant patent first admitted under the European Patent Convention was a trial decision on a propagating material/CIBA-GEIGY case, which was decided by the Technical Board of Appeals of the EPO in 1983.

This case is related to claims directed to propagating materials and seedlings treated with a chemical agent. The Examiner rejected these claims as claiming plant varieties that are excluded from patentable matters in Article 53(b) of the Patent Law. However, the Technical Board of Appeals of the EPO admitted these claims by declaring that new plant varieties excluded from patentable subject matters stipulated in Article 53(b) of the Patent Law are only those new plant varieties meeting the requirements of distinctness, uniformity and stability as defined under the UPOV Convention of 1961, and that Article 53(b) should not be construed to exclude a cultivated plant that has been chemically treated. In spite of the existence of Article 53(b), this trial decision thereafter was frequently cited as strong grounds for supporting the patentability of a general plant created, for instance, by a genetic engineering method, and hence, not limited to a plant variety.

Further, the Technical Board of Appeals of the EPO admitted, in the hybrid plant/LUBRIZOL case, the patentability thereof by saying that if the plant in question fails to meet any of the requirements of a plant variety such as stability, the plant may be patentable, and that even if the invention is related to a breeding method using classic mating, the

invention may still be patentable provided that the invention is characterized by a technical feature not found in nature, such as a combination of special artificial processes to realize a high yield, since such a method is not an essential biological process.

iii. A trial decision permitting patentability of general animals in the EPC (which leads to the admission of patentability of general plants):

An animal patent (oncomouse patent) was first admitted under the European Patent Convention in 1992.

The circumstances resulting in the allowance of an animal patent are as follows. Namely, according to the opinion of the Examining Divisions of the EPO, Article 53(b) of the EPC was understood as denying not only the patentability of animal varieties but also the patentability of animals in general, and hence, the claims directed to a non-human mammal having an oncogene and exhibiting high carcinogenecity were deemed as being unpatentable under this Article 53(b). As a result, the patent application including these claims was finally rejected by the Examining Divisions of the EPO. In contrast, , according to the opinion of the Technical Board of Appeals of the EPO, the Article 53(b) of the EPC was understood as denying only the patentability of animal varieties, and hence, the final rejection made by the Examining Divisions of the EPO was revoked by the Technical Board of Appeals. This case was remanded to the Examining Divisions of the EPO. Upon reexamination, the Examining Divisions of the EPO allowed these claims, stating that the non-human mammal claimed in these claims belong to a taxonomic classification higher than species, so that the non-human mammal claimed would not fall within the definition of animal variety (belonging to a subclass of species) and hence, these claims do not fall within the definition of unpatentable subject matters stipulated in Article 53(b).

This reasoning adopted by the EPO that the non-human mammal belong to a taxonomic classification higher than species, so that the non-human mammal would not fall within the definition of animal variety (belonging to a subclass of species), and hence the non-human mammal does not fall within the definition of unpatentable matters stipulated in Article 53(b) is apparently applicable to patentability of any general plants that belong to a taxonomic classification higher than species.

In conformity with the above trial decision, the Examining Divisions of the EPO had started to grant patents to general plants of a plant classification higher than plant variety (for example, species and genus) such as transgenic plants transformed with foreign genes.

Further, in accordance with the above trial decision, the German Patent Office had started to grant patents on several cases directed to hybrid plants produced by means of cell fusion and transgenic plants and such.

The PGS trial decision (T356/93) handed down by the Technical Board of Appeals of the EPO on February 1995 caused paralysis on the above situation.

iv. Patentability of General Plants after the EU Directive on Biotechnology Adopted on July 6, 1998 and enforced on July 30, 1998:

The EU Directive on legal protection of biotechnological inventions (hereinafter, referred to as "EU Bio-Directive"), which has been a point of controversy for a long time, was finally adopted by the European Parliament on July 6, 1998 and enforced on July 30, 1998. Every member country of the EU is requested to implement suitable amendments to its domestic patent laws to exercise the contents of the EU Bio-Directive within 2 years from the date of enforcement (i.e. by July 30, 2000).

The following regulation is prescribed in the EU Bio-Directive with respect to the patentability of plants and animals.

[Article 4]

1. The following shall not be patentable:

(a) plant and animal varieties;

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

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

General plants characterized by a specific gene as in the cases of the PGS trial decision fall within the patentable plant stipulated in the EU-Directive. Since every member state of the EU is requested to make the necessary amendments to their domestic Patent Laws to implement the EU Bio-Directive within 2 years as mentioned above, it is expected that the general plants would be recognized as being patentable according to the domestic law of each EU member country.

(Note) The Netherlands along with France and Italy have lodged a suit with the European Court of Justice for the invalidation of the EU Bio-Directive. The ECJ decided to dismiss the suit in October 2001.

v. Revision of EPC implementing regulations and Decision of Enlarged Board of Appeals:

EPC implementing regulation was revised in June 1999 so as to conform Article 23c(b) with Article 4(2) of the EU Bio-Directive. This revision has been in force since September 16, 1999.

In December 1999, the Enlarged Board of Appeals made a decision on the referred Novartis case (G1/98) making it clear that "A claim wherein plant varieties are not individually claimed is not excluded from patentability under Article 53(b), even though it may embrace plant varieties."

In response to the situation brought about by the above, the EPO has resumed examination on applications claiming plants in generic terms and granted patents.

vi. Essentially Biological Process

Questions regarding essentially biological process are pending before Enlarged Board of Appeals, that have been referred from two appealed cases. These questions relate to (1) whether a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants is regarded as essentially biological process only if these steps reflect and correspond to phenomena which could occur in nature without human intervention, (2) whether a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants could be treated as not being essentially biological process merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature, and (3) what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection from non-excluded ones?

T0083/05 relates to "Method for selective increase of the anticarcinogenic glucosinolates in Brassica species", and T1242/06 relates to "Method for breeding tomatoes having reduced water content and product of the method". Both cases are appealed against decisions by Opposition Divisions.

3-1-2. The Protection of Animals in Europe

(1) The Circumstances Prior to the Grant of the First Animal Patent by the EPO in 1992:

The grant of a patent to an animal was not considered a realistic issue in Europe as well as in the USA before the new biotechnology such as genetic engineering was found applicable to reproducing animals.

This may be attributed to the fact that animal varieties created by old biotechnology, i.e. traditional breeding methods such as artificial crossing, have been considered much more inherently and technically unsuitable than plant varieties as a subject for protection via a patent (see Note); and that animal breeders were not so inclined in their campaign to seek protection on animal varieties than plant breeders.

(Note) While most of cultivated plants are either self-fertilizing plants or asexually reproduced plants, and therefore, have a higher possibility of meeting the three conditions of variety, i.e. distinctness, uniformity and stability, which are important conditions for the protection of variety as an intellectual property, animals are reproduced by cross-fertilization so that the animals have a relatively lower possibility of meeting the three conditions of variety.

In respect to the above we have the following case. The Supreme Court of the Federal Republic of Germany held a judgment in the Red Dove case in 1969 that even if an invention is related to a living thing, it can become the subject of a patent. However, patentability of the invention was denied by the Supreme Court declaring that the method of breeding doves having red feathers lacked reproducibility (breeding process or creating process) which begins with a variety of the doves and ends with the desired red doves after going through the process of mating and selection. At the time, since most of the breeding methods of plants or animal varieties by old biotechnology such as mating actually lacked reproducibility by breeding process as indicated by the above judgment, the decision made in the red dove was actually equivalent to denying patentability of animals even though the Supreme Court indicated that inventions related to living organisms including animals are theoretically patentable.

It was reported long ago that protection of animals was being discussed as a study theme with respect to the UPOV Convention. However, to date, no information has come forth from this activity.

As an exceptional case, Rumania and Hungary have a system for protecting animal varieties in the same manner as protecting plant varieties, where the system is stipulated as a special regulation in their patent laws.

Thus, there are some examples of patents in Rumania directed to animal varieties bred by old biotechnology.

However, once it became actually possible to reproduce animals by means of new biotechnology such as genetic engineering, these genetically engineered animals became possible subjects for patent protection. Moreover, there was a rapidly increasing awareness for a need to protect transgenic animals and the like for use in experiments, which have been created by new biotechnology.

In this background, a patent to an animal was first granted in the USA in 1988, which had a great impact on the entire world. Subsequently, there have been reported several examples of patents to an animals in Japan, South Africa, New Zealand, and Australia. In Europe also, a patent to animal was first admitted by the EPO in 1992 as explained below.

(2) The Circumstances after the Grant of the First Patent to an Animal by the EPO in 1992:

i. The Grant of the First Animal Patent by the EPO in 1992 (European Patent No. 169 672):

The circumstances resulting in the allowance of an animal patent by the EPO are as follows. According to the opinion of the Examining Divisions of the EPO, Article 53(b) of the EPC was understood as denying not only patentability of animal varieties but also patentability of animals in general, and hence, the claims directed to a non-human

mammal having an oncogene and exhibiting high carcinogenicity were deemed to be unpatentable under Article 53(b). As a result, the patent application was finally rejected by the Examining Divisions of the EPO. As for the problem of public order and good moral prescribed in Article 53(a), the Examining Divisions abstained from making a judgment on this problem by saying that the Patent Law was not appropriate in handling this problem.

Then the Technical Board of Appeals of the EPO remanded this case to the Examining Divisions of the EPO for the following reasons.

(a) The determination as to whether the regulation of Article 53(a) becomes an obstacle or not to the patentability of the outstanding invention should be made by mainly taking into consideration the balance between the benefit of the invention to man and the suffering of the animals as well as the risk to the environment. The Examining Divisions should also issue a judgment on this point.

(b) Since the subjects whose patentability are excluded by Article 53(b) of the EPC are limited only to animal varieties, the rejection of the present invention by the Examining Divisions on the basis of reasoning that Article 53(b) of the EPC excludes patentability of animals is legally inappropriate. Thus, the Examining Divisions should issue a judgment as to whether or not the animal claimed falls within the definition of animal varieties.

The Examining Divisions issued their judgment as described below on the above two points ordered by the Technical Board of Appeals to reexamine and delivered a decision of allowance on the present invention.

(a) With respect to the problem of Article 53(a) of the EPC, this case involves three different interests, i.e. "(1) the benefit to man since it is effective in treating dangerous sickness spread over a wide region; (2) the benefit of protecting the environment from uncontrolled dispersion of undesirable genes; and (3) the avoidance of cruel acts on the animal", and a balance of these interests should be taken into consideration. In view of this balance, the present invention is not considered to violate the morality or the public order.

(b) The non-human mammal claimed in this invention belong to a taxonomic classification higher than species, while the animal varieties are a subclass of species, so that the non-human mammal claimed would not fall within the definition of animal varieties whose patentability is excluded by Article 53(b) of the EPC.

A number of oppositions have been filed against this European Patent No. 169 672 on the grounds that this patent was allowed in violation of public order and morality

and others. It took years for the opposition division to decide the case. The opposition division ruled to maintain the oncomouse patent with amendment to limit mammal to transgenic rodent in 2001.

ii. Patentability of animals under the EU directive and revised EPC regulations

As mentioned above, it is stipulated in Article 4(2) of the EU Bio-Directive, which came into effect on July 30, 1998, as well as in the Rule 23c(b) of the revised EPC regulations which came into force on 16 September 1999, in either case, that a generic animal not limited to a variety is patentable.

In Europe, at the EPO, as well as in member states of the EPO and the EU, from now on, a generic animal may be patented as long as other patentability requirements are met.

3-1-3. The protection of microorganisms in Europe

As already mentioned above, patents directed to microorganisms have been granted in the United Kingdom since 1960. However, most of the other advanced countries did not grant patents to microorganisms until after 1980, the year the US Supreme Court granted a patent to a microorganism.

However, in Europe, before patents to microorganisms were granted, there were a series of important steps as described below in overcoming an unavoidable barrier to patentability--a shift in the practice based on the doctrine of reproducibility by breeding process to the doctrine of reproducibility by propagation process.

(1) The Judgment of the Supreme Court of the Federal Republic of Germany based on the Doctrine of Reproducibility by Breeding Process:

In 1975, the Supreme Court of the Federal Republic of Germany delivered a judgment in the Baker's Yeast case that, while referring to the above Red Dove case, the microbiological method and the products thereof should not be excluded from patentability for the sole reason that the microorganism is a living organism, thus recognizing the patentability of microorganisms. However, this judgment indicated further that in order to render the present microorganism patentable, not only evidence for propagation from the culture but also for reproducibility in the process of producing the present microorganism from a starting microorganism must be furnished (reproducibility by breeding process or creating process). As a result, the patentability of this case was ultimately denied by the Supreme Court as failing to meet the above conditions.

Although it was first made clear by this judgment that microorganisms are patentable subject matter, in those days it was almost impossible to substantiate reproducibility by breeding process or creating process demanded by this judgment via ordinary breeding

means, such as screening for natural mutations to produce a new kind of microorganism.

Therefore, in reality a path to obtaining a patent to a microorganism remained long and difficult so long as the "doctrine of reproducibility by breeding process" of the Baker's Yeast case constituted the test for judging patentability of microorganism.

In the judgment of the Supreme Court of the Federal Republic of Germany in 1978 on the *Lactobacillus bavarivus* case, this doctrine of reproducibility by breeding process was followed. However, as far as the new microorganism *Lactobacillus bavarivus* of this case was concerned, it was possible to demonstrate the reproducibility of the screening process for the microorganism from the pickle of cabbage, i.e. the creating/growing process of the microorganism (in response to the demand made by the Supreme Court, the reproducibility was demonstrated by repeatedly screening the microorganism from the pickle of cabbage). As a result, a patent to this microorganism was granted. This was a rare case in which the reproducibility of creating/growing process was demonstrated.

(2) The "Doctrine of Reproducibility by Propagation Process" by the EPO with regard to an invention of microorganism:

As already mentioned above, with regard to reproducibility, a prerequisite for obtaining a patent to an invention of living material, there was another opinion by a German scholar and others advocating a different doctrine from the above. They opined that a patent should be granted to an invention of a living organism if the reproducibility of the propagation process of the living organism is demonstrated, which is the doctrine of reproducibility by propagation process.

In relative to the interpretation and practice of Articles 52, 53 and 83 of the European Patent Convention that came into force in 1977, there is prescribed in the Guidelines for Examination in the EPO that the reproducibility of an invention directed to amicroorganism can be fully met by depositing the microorganism having a propagating ability (see Note 1). This prescription in the Guidelines for the Examination apparently corresponds with the latter doctrine of reproducibility by propagation process.

(Note 1) The Guidelines for Examination in the EPO C-IV, 3.6 (1983 Edition) prescribes as follows:

> "In the case of microbiological processes, particular regard should be had to the requirement of repeatability referred to in II, 4.11 As for microorganisms deposited under the terms of Rule 28, repeatability is assured by the possibility of taking samples (Rule 28, paragraph 3), and there is thus no need to indicate another process for the production of the micro-organism."

(3) The judgment of the Supreme Court of the Federal Republic of Germany based on the Doctrine of Reproducibility by Propagation Process:

In 1987, the Supreme Court of the Federal Republic of Germany delivered a new judgment on the Tullwatvirus case to harmonize it with the aforementioned practice of the EPO, the judgment being quite the opposite to the conventional judgment after the Red Dove case. An epoch making judgment was delivered in which the patentability of a novel microorganism was admitted based on the propagation ability of the deposited sample.

◆ The content of judgment: for obtaining patent protection on a novel microorganism, the novel microorganism having a propagation ability can be deposited and made public in lieu of showing reproducibility of the crating process of the microorganism.

This judgment in the Tullwatvirus case is now considered a clear departure from the conventional doctrine of reproducibility by breeding process, which has been an obstacle for a long time for each European country in granting a patent to a living organism. As a matter of fact, microorganisms are now patented without any problem so long as they satisfy the rest of the patentability requirements in accordance with the domestic law of each European country.

3-2 The protection of living organisms in the USA

3-2-1. The protection of plants in the USA

In the USA, in contrast to Europe, no arguments were initially raised as to whether or not reproducibility by breeding process should be a prerequisite for granting patents to biological inventions. Thus, the only problem discussed in conferences with respect to protection of plant varieties under the patent system was whether or not the plant varieties sought for protection were capable of reproducing themselves without causing a change in their characteristics, i.e. whether or not the plant varieties were capable of reproducing via the propagating processes. At the time of establishing the plant patent, it was generally thought that while asexually reproduced plants had reproducibility by propagating process, sexually reproduced plants propagated through seeds did not have reproducibility by propagating process. Accordingly, in the Plant Patent Law established in 1930, plants to be protected by this Plant Patent Law were limited to those reproduced asexually.

However, having been stimulated by the signing of the UPOV Convention in 1961, demands increased for protecting sexually reproduced plants in the same manner as that of asexually reproduced plants, and at the same time, a sufficient degree of reproducibility or stability of sexually reproduced plants were already recognized for the purposes of protection. Under these circumstances, the Plant Variety Protection Act covering protection of sexually

reproduced plants was established in 1970.

Thereafter, the USA became a member of the revised UPOV Convention of 1978 in 1981.

Further, in the "Diamond v. Chakrabarty" case, the Supreme Court delivered an epoch-making judgment in 1980, in which an invention to a microorganism was admitted by way of an ordinary patent (utility patent), thus opening a path for allowing patents to all kinds of living organisms.

Plants have been protected by utility patents since the trial decision of the Hibberd case in 1985. As for plant varieties bred by traditional breeding methods such as artificial crossing or selection, the Plant Patent Law and the Plant Variety Protection Act are generally used to protect them. As for general plants and plant varieties created by genetic engineering, the utility patent is generally used.

(1) The Patent on Asexually Reproduced Plant Varieties under the Plant Patent Law Established in 1930

The USA was the first in the world to start granting patents to asexually reproduced plant varieties by stipulating special regulations (so-called Plant Patent Law) in the Patent Law in 1930.

i. Summary of plant patents for the protection of plant varieties:

(a) Patentable matters: asexually reproduced plant varieties invented or discovered, including cultivated spores, mutants, hybrids and newly found seedlings other than tuber plants or plants found in an uncultivated state.

(b) Claims

Only a single claim directed to the entire plant body of the variety concerned can be allowed.

Furthermore, the scope of the plant patent right is determined not by the description set forth in the claim but by the detailed description of the plant variety in the specification.

(c) Requirements for Protection

According to the regulations of the plant patent, the same requirements as those of the utility patent are set forth therein. In actual examination, however, inventive step is generally disregarded, so that a plant variety can be patented as long as there are distinctness and novelty over other varieties.

(d) Disclosure of the Art

If the description of the specification is complete in a reasonable degree, then the description does not violate 35 USC Section 112 (Specification).

This regulation is intended to alleviate the enablement requirement (requiring that the specification should contain a description of claimed invention in such a manner as to enable a person skilled in the art to carry out the invention) (Note).

(Note) See 4-1. Technical disclosure of the invention in the specification.

(e) Deposit (see 5-1)

As described in item (d), since the enablement requirement is alleviated in the description of the specification of the plant patent, a deposit usually required for a patent application of an invention directed to a living material is not required.

(f) Right

An exclusive right for asexually reproducing plants belonging to a variety and selling and using the asexually reproduced plants

(g) Farmer's Privilege

Not prescribed.

(h) Period of right

20 years from the date of application.

ii. Examples of claim in the plant patent:

① Plant patent No. 6,314 (chrysanthemum plant, BRONZE CHARM 1988.9)

"A new and distinct chrysanthemum plant Bronze Charm as described and illustrated and particularly characterized … by the combination of flat capitulum form; decorative capitulum type; bronzing ray floret color; diameter across face of capitulum of up to 11 cm at maturity …"

② Plant patent No. 6,769 (dahlia plant, MARGARET 1989.5)

"A new and distinct cultivar of Dahlia plant named Margaret, as illustrated and described." (Note).

(Note) As mentioned in item (b), since the scope of the plant patent is determined not by the description set forth in the claim, the claim is often described in a very simple manner omitting most of the novel characteristics of the plant variety as indicated by the underlined part of the claim in sample ②.

(2) The protection under the Plant Variety Protection Act established in 1970

In 1970, the Plant Variety Protection Act was established thereby making it possible to protect sexually reproduced plants in a similar manner as the plant patent.

Further, the PVPA was revised in 1994 so as to be in alignment with the revised UPOV Convention of 1991.

i. Summary of protection of plant varieties under the PVPA:

(a) Protectable Subjects:

Sexually reproduced or tuber propagated plant variety other than fungi or bacteria.

(b) Claims

None.

(c) Requirements for protection

Three requirements (distinctness, uniformity and stability) (see 3-1-1. (1) ii-1 Summary of the Revised UPOV Convention 1978 (e) and novelty (not offered for sale or marketed).

(d) Disclosure of the art

Technical disclosures possible under supplementary tests required by the Patent Law are not required.

(Note) See 4-1. Technical disclosure of the invention in the specification.

(e) Deposit

Deposit as required by the Patent Law (deposit of a biological material with a recognized institution and furnishing of samples thereof to a third party, etc.) is not required.

(f) Right: An exclusive right with respect to selling, offering for sale, production, import and export of the registered variety and a variety essentially derived there from, and to the use thereof for the production of hybrids or other kinds of variety.

(g) Farmer's privilege: the restriction on the breeder's rights in order to permit farmers to save seeds of the registered variety for propagating purposes on their own holdings and such.

(h) Period of right: twenty years from the issue date, and 25 years in the cases of trees and grapes.

(3) The trend of patenting plants under the utility patent system in the USA:

The Board of Patent Appeals of the Patent and Trademark Office (PTO) has delivered a decision in 1985 with regard to the Hibberd case in which the final rejection made by the Examiner on the grounds that claims directed to a maize tissue culture capable of generating a plant capable of producing seeds having increased levels of free tryptophan as compared with the natural varieties within the purview of the plant Patent Law, whereas claims directed to said seeds and plants within the purview of the Plant Variety

Protection Act, was revoked by the Technical Board of Appeals, thus indicating the allowability of these claims. As a result of this decision, it has become clear that plants can be protected under the utility patent, and that the overlapping protection provided by the utility patent, the plant patent and the Plant Variety Protection Act would not be a problem. Subsequent to this decision, a large number of plants, in particular, transgenic plants were patented under the utility patent system. In December 2001, in a case involving validity of a patent on a plant per se, the Supreme court held that newly developed plant breeds fall within the terms of §101, and that neither the PPA nor the PVPA limits the scope of §101's coverage. It is now without doubt that a plant per se is patentable subject matter.

i. Summary of Protection of Plants by the Utility Patent:

(a) Patentable matters: Patentable invention or discovery as prescribed in Article 101 of the Patent Law.

(b) Claims: Plants, seeds, parts of plant (flower, fruit, pollen, etc.), plant cells, tissue cultures, genes, vectors, etc., the manufacturing method thereof, the method of use, etc. Namely, various aspects of inventions to plants can be claimed.

(c) Requirements for protection: utility, novelty and inventive step.

(d) Disclosure of the art: Complete disclosures of the techniques so as to meet the requirements regarding enablement and description as prescribed in the law.

(e) Deposit: If the disclosure of the techniques are deemed to be insufficient without the deposit thereof, the deposit thereof must be made.

(f) Rights: an exclusive right with respect to the production, use and selling of the patented plants or parts of the plant.

(g) Farmer's Privilege: None.

(h) Period of rights: twenty years from the date of application.

ii. Examples of claim of the utility patent with respect to plants, etc.:

(1) A main claim of Patent No. 5,491,080

"1. A method of producing a plant a plant having resistance against RNA viruses, comprising integrating a DNA sequence which encodes a protein having an enzyme activity that specifically cleaves a double-stranded RNA, into a chromosome of a plant and making the DNA sequence express in the plant cells..

3. A plant having resistance to RNA viruses, in which a heterologous DNA sequence, which encodes a protein having an enzyme activity that specifically cleaves a double-strand RNA, is integrated into its chromosome and expressed therein.."

(2) Claims of Patent No. 4,812,599

"1. An inbred corn line designated PHV78.

2. A plant or plants of the inbred corn line designated PHV78 of claim 1.

3. Pollen of the plant of claim 2.

4. Seed of seeds of the inbred corn line designated PHV78 of claim 1.

5. An inbred corn plant with the phenotypic, physiological and morphologic characteristics of inbred corn line designated PHV78."

(4) Comparison Among the Protection Systems of Plants in the USA.-

i. Superiority of each protection system:

In view of the versatility of protection and the wide scope of the claim offered by the utility patents (i.e., a large scope of protection of plants including genes, cells, plant parts, method, plants in general, plant varieties and the none-existence of provisions corresponding to the farmer's privilege existing in the PVPA), applicants seeking protection of plants in the USA generally prefer to file utility patent applications first as long as plants to be protected meet the requirements of protection for the utility patent.

However, since each protection system may overlap the other, an applicant sometimes files, though the actual number of the case is very small, an application to the PVPA or a plant patent application concurrent with a utility patent application. In this case, although a claim directed to the same subject matter (variety) cannot be redundantly patented by both the utility patent and plant patent system, if the same subject matter claimed in one of the patent system is deemed obvious from the subject matter claimed in the other patent system, the applicant may file a terminal disclaimer in order to obtain allowance on both of these claims.

ii. Selection of a system based on breeding techniques:

For plants bred by a traditional breeding method, i.e. by old biotechnology, the PVPA or the plant patent are used for most of them. For transgenic plants produced by genetic engineering, i.e. by new biotechnology, the utility patent is the preferred means of protection.

3-2-2. The Protection of Animals in the USA

With respect to the Year-Round Oyster case, although the Examiner's rejection was supported by the Board of Appeals of the PTO in view of lack of inventive step, the Examiner's rejection of the invention on the grounds that the polyploid oyster manufactured artificially is a living thing was revoked by the Board of Appeals of the PTO, indicating that an animal, which is non-naturally manufactured or composition matter, can

be a subject of a utility patent.

Immediately after this trail decision, the PTO issued a statement clarifying that non-naturally occurring non-human living multi-cellular organisms including animals can be a patentable subject matter.

Consequently, the first animal patent was granted on April, 1988. The main claim thereof is as follows:

"A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or ancestor of said mammal, at embryonic stage."

Thereafter, a large number of animal patents have been admitted.

Furthermore, the news of this groundbreaking first animal patent was spread throughout the world. Thereafter, some of the countries including Japan, Australia, New Zealand started to grant patents on animals under the regular Patent Law equivalent to the Utility Patent Law of the US.

3-2-3. The Protection of Microorganisms in the USA

The Supreme Court delivered an epoch-making judgment in 1980 in the "Diamond v. Chakrabarty" case in which an invention of a microorganism was admitted by way of a regular patent (utility patent). This patented claim directed to a microorganism is as follows:

"A bacterium from the genus Pseudomonas containing therein at least two stable energy-generating plasmids, each of said plasmids having a separate hydrocarbon degrative pathway."

This judgment made by the Supreme Court contained a precedent-setting statement, which was frequently cited in subsequent cases. It was said in the judgment that a patentable subject matter includes "anything under the sun that is made by man," thus opening the door for patenting all kinds of living organisms.

After this judgment, the PTO started to grant patents on various kinds of microorganisms including bacteria, yeasts, and cell-lines.

3-3. The protection of Living Organisms in Japan

The protection of plant varieties in Japan started in 1978 in conformity with the regulations of the UPOV Convention. As for patenting of plants, however, Japanese patent practice regarding reproducibility of invention was based on the doctrine of reproducibility by breeding process, i.e. the same severe attitude as found in Europe. As it were, there was much difficulty in satisfying the disclosure requirements and the patentability requirements

stipulated in the law in order to show enablement of plants bred by means of old biotechnology such as mating and selection. Hence, to date, only two cases directed to plants bred by interspecific hybridization have been patented (patented in 1985). In contrast, with respect to plants created by new biotechnology, cases directed to general plants (transgenic plants) transformed through genetic manipulation have been patented since 1997. It is expected that plants of this kind would continue to be patented as long as the invention meets the regular patentability requirements.

Patenting of animals started in Japan one year after 1988 when the first animal patent was granted in the USA. Consequently, a lot of case cases directed to animals bred by means of old or new biotechnology have been patented as of November, 1998.

Further, patenting of microorganisms has started in Japan the year after a patent to a microorganism was granted in the USA by the US Supreme Court decision of the "Diamond v. Chakrabarty" case in 1980. As a result, a large number of patents have been granted to microorganisms since then.

3-3-1. The Protection of Plants in Japan

(1) The protection of plant varieties in Japan:

The Seedling Law was established in 1978 in conformity with the UPOV Convention of 1978, thereby making it possible to smoothly carry out the protection of plant varieties. Thereafter, the Seedling Law was revised in 1998 in conformity with the revised UPOV Convention of 1991, which came into force on December 24, 1998.

According to this revised Seedling Law of 1998, the breeder's rights were enlarged and strengthened in conformity with the mandatory clauses of the revised UPOV Convention of 1991 (see 3-1-1. (1)ii-4. MAIN POINTS REVISED IN THE UPOV CONVENTION OF 1991).

(2) The Patenting of Plants in Japan:

i. The Examination Standard for a Patent for a Plant and the Manual of Examination

The following Examination Standards were successively published with respect to patents for plants, and at present, the examination of patent applications directed to plants is carried out according to the manual of 1977.

① "Examination standard for the "plant varieties" in 1975;

② "Examination standard," Chapter 2. Biological Inventions 2. Plant

③ "Implementing Guidelines for Inventions in Specific Fields," Chapter 2 Biological Inventions (hereinafter referred to as "Bio-Guidelines"), 1. Genetic Engineering, 3. Plants in 1997.

④ Examination Guideline, "Part VII Inventions in Specific Fields", Chapter 2. Biological Inventions 1. Genetic Engineering, 3. Plants in 2001.

ii. The regulations of the Examination Guidelines related to plants:

(a) The guidelines of the Examination Guidelines related to the inventive step of inventions of plants:

The inventive step of inventions of plants is stipulated in the Examination Guidelines as follows:

"An invention of a plant per se does not have an inventive step, where characteristics of the plant created can be easily predicted from the characteristics of publicly known plants within the species to which the plant belongs and where the invention does not have advantageous effects that a person skilled in the art cannot foresee."

Example 1: A plant whose shape or color is similar to that of publicly known plants within the species to which the plant belongs.

Example 2: Mere combination of the characteristics of publicly known plants within the species to which the plant belongs."

The above examination guidelines is considered to reflect conventional practice with regard to the inventive step of inventions of plants. It would be quite clear that if examination is carried out according to the aforementioned Examination guidelines, it would be very difficult to obtain a patent for a plant variety bred by old biotechnology because such inventions fall under the following situations.

① Most of the plant varieties are created generally through crossing within the same species, and hence, the resultant plants exhibit very little difference in characteristics.

② The aforementioned crossing within the same species is relatively easy from a technical viewpoint, and hence, obtaining a combination of desirable characteristics among various kinds of varieties within the same species is also relatively easy from a technical viewpoint.

As a matter of fact, there have been several patent applications to plant varieties bred by means of old biotechnology. However, none of them has been patented to date. As for examples of patents to plants bred by means of old biotechnology, there are only two cases, both related to medicinal mugmort and patented in 1985. These patents are related to general plants not restricted to a single variety and bred by a special means of enabling a difficult crossing between species. The patented plants are specified by a crossing process, a certain range in the number of genome, and a small number of characteristics.

(b) The guidelines of the Examination Guidelines on transformed plants, and examples of patents:

In the paragraph "1. Genetic engineering; (4) Transformant" of the Examination Guidelines, there are described general guidelines and an example of a transformed plant as follows.

"The transformant may be described by specifying at least one of (1) host and (2) introduced gene (or recombinant vector).

Example 2: A plant inserted therein with toxigenic gene consisting of a base sequence ATGACT---, and at the same time, expressing said toxigenic gene."

Actually, cases of general plants (transgenic plants) transformed as in Example 2 meeting the guidelines have been already patented from 1997 to date. More patents of similar nature are expected in the future.

3-3-2. The Protection of Animals in Japan

As already mentioned above, patenting of animals has started in Japan the year after 1988 when the first patent to an animal was granted in the USA. As a result, significant number of applications directed to animals bred by means of old or new biotechnology have been since patented.

3-3-3. The Protection of Microorganisms in Japan

The Japan Patent Office published in 1979, the "Examination Standard for the Invention of Microorganisms", thus making it clear that microorganisms are patentable. Thus, patents to microorganisms began to be granted in Japan from 1981, i.e. a year after a patent to a microorganism was first granted in the USA by the decision of the US Supreme Court of the "Diamond v. Chakrabarty" case. Thereafter, a large number of patents have been granted to microorganisms.

Examination is now carried out according to the regulation of "1. Genetic engineering; 2. Microorganisms" of the Examination Guidelines.

3-4. The Protection of Living Organisms in Countries other than Japan, Europe, and the USA:

The most progressive protection system adopted in countries other than Japan, Europe and USA is the protection of plant varieties under the UPOV Convention.

On the other hand, plant and animal varieties are still stipulated as unpatentable matters in a fairly large number of countries, exceptions being Republic of Korea and Republic of the Philippines. They have a plant patent system directed to protecting varieties of asexual propagation plants, which is similar to that of the USA. Further, Australia and New Zealand now protect generic animals under their regular Patent Law. Most of the countries, however, are prepared to grant patents to microorganisms so long as they meet all of the patentability requirements.

4. PROTECTION OF INVENTION RELATED TO GENES

In contrast to the circumstances involved with the protection of living organisms, at least most of the progressive (with respect to patents) countries such as Japan, Europe and the USA are substantially in agreement with regard to the basic concept of protecting inventions of genes. Therefore, the general problems involved in protecting genetic inventions will be discussed hereinafter in reference to the actual situation in Japan.

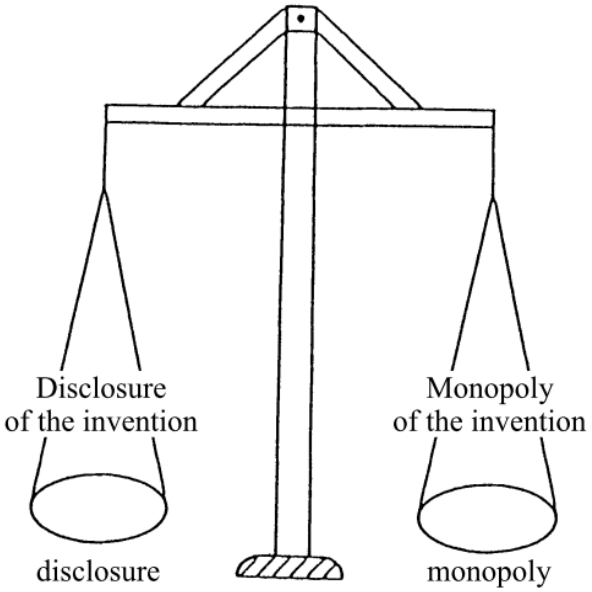
4-1. Disclosure of the Invention Related to Genes and the Claims

4-1-1. Disclosure of the Invention in the Patent Specification:

The Inventor(s) is/are entitled, as a compensation for the disclosure of his novel invention, to obtain a patent right which is commensurate in scope with the contents of the technique disclosed (see Fig. 3). This is one of the important basic principles supporting the patent system. Consequently, it becomes possible to promote the advancement of technique and to contribute to the development of industry, while, at the same time, securing harmony between the person(s) receiving the patent right and a third party restricted by the patent right.

This disclosure of the technique is made in the description thereof in the patent specification filed.

Fig.3 Exclusive right commensurate with the disclosure



Mr. Kazuhiko Takeda, Twelve Chapters for Easy Understanding of Patent (Tokkyoga wakaru jyu-ni sho, Daiamond Sha, 1996)

4-1-2. The Enablement Requirement in the Disclosure:

Since the purpose of disclosing an invented technique in a patent specification to be filed is to ensure the utility of the technique by a third party, the specification must be written in such a manner that a person of ordinary skill in the art to which the invention pertains (hereinafter referred to as an artisan) can exercise the invention. That is, the enablement requirement must be met. When the invention is related to a material such as a gene or recombinant protein, in conformity with the aforementioned enablement requirement, it is required that an artisan is enabled to make and use the material from the description of the specification.

Further, when the use of a biological material, such as DNA, a recombinant vector, or cells is essential for the practice of the invention related to genes, the deposit of this biological material is required, provided that the biological material concerned is unavailable and at the same time, the creation of the biological material concerned is impossible to practice in spite of the description in the specification. If the biological material is not deposited, the patent application would be rejected for being defective in not satisfying the enablement requirement.

4-1-3. Claims in Inventions Related to Genes:

(1) General problems involved in a claim to an invention related to genes:

Even if the invention is disclosed in the patent specification, the scope of the patent right cannot be determined from the patent specification.

Therefore, the applicant is requested to describe in claims the scope of the invention, which the applicant desires to obtain, selected from the inventions disclosed in the patent specification. The Examiner then examines the inventions claimed in the claims. After the granting of a patent, according to the present patent system the scope of the patent right is determined by the description of the claims.

Therefore, the applicant naturally would desire to obtain as broad a scope of claim as possible. In this instance, the problem particularly concerned with the invention related to genes is the scope of the claim permissible in view of the enablement requirement based on the description of the patent specification.

In the case of a conventional invention related to chemistry, it is rather rare that sufficiency of disclosure becomes a decisive issue in a law case. Thus, most issues concerning chemical inventions have been whether or not the inventions meet the novelty and inventive step requirements. However, in the case of biotechnological inventions, sufficiency of disclosure does become a decisive issue not only in the actual examination and trial examination in the Patent Office of each country but also in the law case. Accordingly, this problem has been frequently raised in international meetings convened to discuss patent matters. This has

become the main theme for the project titled "Comparative Study on Biotechnology Patent Practice" undertaken by Trilateral Patent Offices in Japan, Europe and the USA.

One of the reasons for this problem is that since the technique of this field is very complicated and developing very fast, and further, since the common technical means or available technical means that may form the basis for the enablement of the invention continues to develop day by day, it is very difficult to provide a suitably sufficient technical disclosure at the time of application and to anticipate the scope of the enablement based on the examples of the invention.

Another prominent reason may be attributed to the peculiarity of the invention related to genes, which differ from conventional inventions of chemical materials. Namely, the commercial value of genes generally depends on the usefulness of the protein coded by the gene. However, the genetic code of the protein includes a degenerate code, and hence, even if the bases of the sequence of the gene coding the protein are damaged more or less by substitution, insertion, or deletion and such, the essential functions of the protein are rarely altered unless the damaged portion is found at the main functional portion of the protein.

Further, the cloning of the gene of an unknown and useful protein frequently requires a lot of labor and creative power. However, once the information of this gene is disclosed, it is quite easy for a third party to create a mutant exhibiting a similar function.

Therefore, if the claim of the invention related to a gene or a protein corresponding to the gene is specified by a base sequence or by a coded amino acid sequence analogous to an invention of chemical substances specified in principle by their chemical structure in the claim, the granted patent right would inevitably be very narrow in comparison with a pioneer-like technical contribution by the inventor.

On the other hand, if a claim with a functional expression is permitted with respect to an invention related to a gene to avoid the aforementioned problem, there is a good possibility that the scope of the claim may be enlarged to an unreasonable extent, extending beyond the disclosure described in the specification. As a result, a difficult problem arises with respect to the relationship between a broad claim and the aforementioned enablement requirement.

(2) History on the Scope of Claim to an Invention Related to a Gene:

i. A claim to a gene or a recombinant protein specified in principle by the sequence thereof, and the associated problems.

In an early stage, the examination in Japan was carried out based on the principle that the claim of a gene or a recombinant protein should be specified by a base sequence or a coded amino acid sequence.

According to the "Tentative Manual for Examination of an Invention in the Field of

Genetic Engineering of Microorganisms" published in 1984 by the JPO, it is instructed that a claim to a foreign gene be described as follows.

DESCRIPTION OF CLAIM TO FOREIGN GENE

(1) Principle: Specify a base sequence in a similar manner as follows:

"A human interferon gene represented by a base sequence of TGTGAT…AAGGAA."

(2) Exception: If an amino acid sequence coded by a foreign gene is novel, the claim may be described by a base sequence expressing an amino acid sequence as follows:

"A human interferon gene coding an amino acid sequence represented by MetAsp…LysGlu"

This "Manual for Examination" related to a gene was also applied to the description of a claim directed to a recombinant protein, thus necessitating to specify a recombinant protein by an amino acid sequence in principle.

However, the claim of a gene or a recombinant protein specified in this manner by a single definite sequence is necessarily very narrow in scope. If the product of a third party can be distinguished from the claimed sequence by even one base or one amino acid, that product is deemed to literally fall outside of the scope of the claim. This rule regarding the description of a claim directed to a gene was maintained substantially in the Examination Standard regarding inventions related to living organisms, which was published in 1993.

ii. The t-PA case and the doctrine of equivalents:

The narrowness of a claim specified by a single definite sequence as mentioned above was revealed initially in the infringement case of the t-PA patent, which was appealed by "G" Co. of the USA against "S" Co. of Japan in 1989. This t-PA is a protein useful as a medicament for cardiac infarction. The claim of the t-PA patent of "G" Co. was as follows.

Claim of Patent No. 159908 (t-PA patent) of "G" Co.

(Priority date: April 7, 1983)

"An activator comprising a recombinant t-PA* produced from a host cell other than human cell, having the following characteristics: 1)---, 2)---, 3)---, 4)---, 5)---, and being free from other kinds of protein derived from human, said activator containing the following partial amino acid sequence: SER(No.69)ASP PHE---VAL(No.245)---MET ARG PRO (No.527)."

"S" Co.: "---- MET(No.245) ----."

(Note) * "t-PA" is an abbreviation of "a tissue plasminogen activator".

(No.--) was inserted by this writer.

According to this patented claim of "G" Co., the t-PA is specified by the characteristics of the recombinant t-PA set forth in the claim, and by an amino acid

sequence consisting of 459 amino acids starting from SER(No.69) and ending at PRO(No.527).

The t-PA embodied by "S" Co. is identical with the patented t-PA of "G" Co. except that VAL at the 245th amino acid of "G" Co. was replaced by MET.

Since the scope of the right of a patented invention is determined based on the description of the claim, only when the product being worked by a third party is literally included within the patented claim, the product is considered, in principle, to fall within the scope of the patent right. That is, whether or not a product falls within the scope of a claim is determined through a literal interpretation of the claim. Therefore, if the product is defective in any one aspect of the patented claim, the product is considered to fall outside the scope of the patent right in view of the literal interpretation of the claim.

In the case of the relationship between the t-PA of "G" Co. and the t-PA of "S" Co., since this single 245th amino acid is altered from VAL to MET, the t-PA of "S" Co. is defective in one aspect of the claim of the t-PA of "G" Co. Therefore, the t-PA of "S" Co. falls outside the scope of the claimed t-PA of "G" Co.

Fig.4 Scope of right

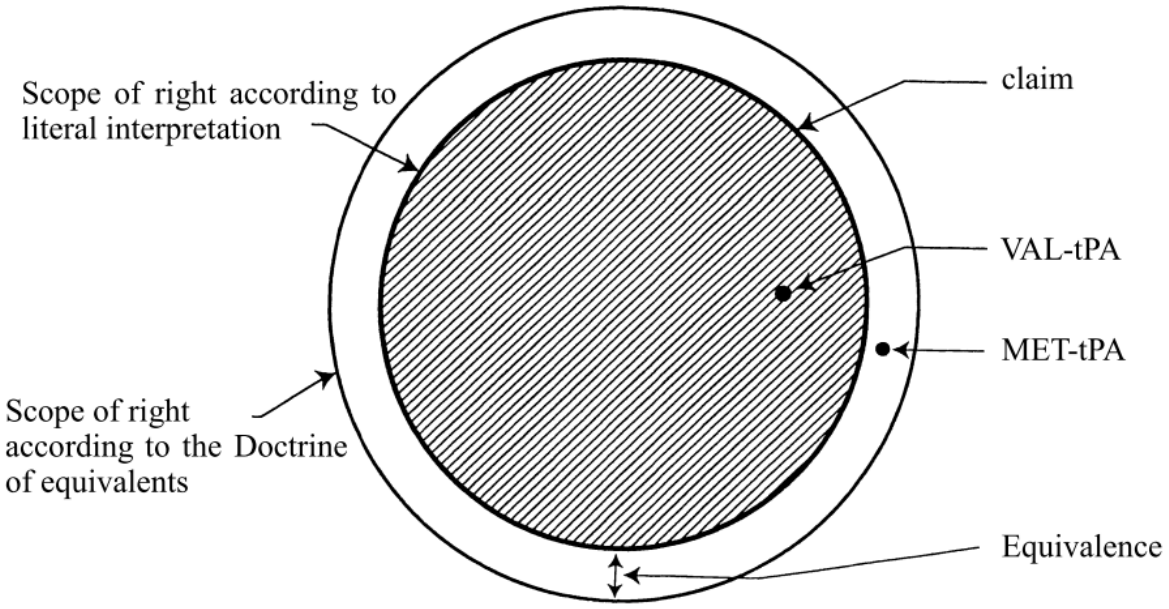


Fig. 4 illustrates the relationship of the right between the patented t-PA **of "G" Co. and the t-PA of "S" Co. The shaded portion indicates the scope** of the right meeting all of the claimed requirements as they are literally interpreted. As shown in this Fig., because for the single reason that only one amino acid is different from each other, i.e. t-PA (MET-tPA) of "S" Co. vs. t-PA (VAL-tPA) of "G" Co., it becomes possible for the product of "S" Co. to fall outside the scope of the claimed t-PA of "G" Co. Therefore, the infringement of "S" Co. was not recognized in the decision of the Osaka District Court.

It can be seen from the above explanation that the scope of the claim specified by a single definite sequence can be very narrow.

However, even if the product being worked by a third party is deemed to fall outside the claimed scope as the claim is literally interpreted as shown in Fig. 4, the product may be considered to be equivalent to the patented invention, provided that when the product employed is substituted with the patented invention, the same object and the same effects as those of the patented invention can be obtained. Namely, as shown by the white circle in Fig. 4, the product may be included within the scope of the right under the doctrine of equivalents, thus constituting an infringement.

Indeed, against the judgment of the Osaka District Court, "G" Co. appealed to the Osaka High Court during which intensive efforts were made by "G" Co., submitting a large number of written expert opinions and providing expert testimonies. Consequently, "G" Co. succeeded in obtaining a decision that the MET-tPA of "S" Co. was equivalent to the VAL-tPA of "G" Co., thus "S" Co. was found to infringe the patent right of "G" Co. This judgment since became binding as the appeal of "S" Co. to the Supreme Court was withdrawn.

iii. Typical forms of a generic claim now admitted in Japan:

From the mid 1990's, patents to generic claims not limited by a single sequence and hence broader in scope have begun to be admitted on some applications for biological inventions filed in the early or mid 1980's.

Further, with respect to the transformed living organisms, patents to broad claims or a more generally form of claims not limited to classification of living organisms such as species or genus, which have been required by the old Examination Standard, have begun to be admitted on patent applications of transformed living organisms.

According to the "Bio-Guidelines" published in 1997, the following typical forms with regard to a generic claim directed to an invention related to a gene are presented. These expression forms are also included in the Examination Guidelines..

① A Generic Claim to a Gene

According to the Examination Bio-Guidelines, a broad claim to a gene as exemplified by following Examples 1 and 2 is permitted, provided that the clarity requirement and the enablement requirement are met

Example 1: A gene encoding a protein (a) or (b) as follows:

(a) A protein whose amino acid sequence is represented by Met-Tyr ---- Cys-Leu;

(b) A protein derived from the protein of (a) by substitution, deletion, or addition of one or several amino acids in the amino acid sequence in (a) and having the activity of enzyme A.

(Note) The protein of (a) has the activity of enzyme A. The gene encoding the protein of (b) is described in the Detailed Description of the Invention in such a manner that a person skilled in the art can make the said gene without requiring undue experiment.

Example 2: A gene selected from the group consisting of:

(a) A DNA whose nucleotide sequence is represented by ATGTATCGG ---- TGCCTG;

(b) A DNA which hybridizes under stringent conditions to the DNA defined in (a) and encodes the human protein having the activity of enzyme B.

(Note) The protein encoded by the DNA (a) has the activity of enzyme B.

(Note) "Stringent conditions" are described in the Detailed Description of the Invention.

Actually, claims for a gene, described in a comprehensive manner as exemplified in the aforementioned Examples (1) and (2) are now allowed in large number.

② Generic Claims to Transformant:

According to this Examination Bio-Guidelines, a broad claim to transformant, in particular for the host, as exemplified by the following Examples 1 to 3 is permitted, provided that the clarity requirement and enablement requirement are met.

Example 1: "A transformant comprising a recombinant vector containing a gene encoding a protein whose amino acid sequence is represented by Met-Asp-…Lys-Glu."

Example 2: "A plant wherein a toxic gene having a base sequence of ATGACT… is inserted and the said gene is expressed."

Example 3: "A transgenic non-human mammal, having a recombinant DNA obtained by linking a structural gene encoding any protein to the regulatory region of a gene involved in the production of milk protein, and secreting the said protein into milk."

Actually, claims for transformants which are described in a form as exemplified in the aforementioned Example (1) are now patented in large number. Further, as already mentioned above, there have been several cases of claims to plants and animals granted with the forms as exemplified in the above Examples (2) and (3).

③ A Generic Claim for a Recombinant Protein:

According to this Examination Bio-Guidelines, a broad claim for a recombinant protein as exemplified by the following Example (b) is permitted, provided that the clarity requirement and the enablement requirement are met.

Example: A recombinant protein of (a) or (b) as follows:

(a) A protein whose amino acid sequence is represented by Met-Tyr ---- Cys-Leu;

(b) A protein derived from the protein of (a) by substitution, deletion, or addition of one or several amino acids in the amino acid sequence in (a) and having the activity of enzyme A.

(Note) The protein of (a) has the activity of enzyme A. The protein (b) is described in the detailed description of the invention in such a manner that a person skilled in the art can make the said protein without undue experimentation.

Actually, claims exemplified in the aforementioned Example (b) have now been patented in several cases.

Since the aforementioned Example (b) adopts the expression of: "a protein derived from the protein of (a) by substitution, deletion, or addition of one or several amino acids in the amino acid sequence in (a)," even if the sequence related to a protein of a third party differs from the aforementioned amino acid sequence (a) at several points, it is possible, so long as the patent is valid and the expected function is the same, to insist that the aforementioned protein of the third party falls literally within the scope of the patented claim of a protein without arguing for the doctrine of equivalents as was done in the above patent infringement case of "G" Co.

Therefore, since it has become possible to obtain a patent for a claim of this kind, it is apparent that the right of a patentee has been extremely enlarged.

After the publication of the Bio-Guidelines, the "G" Co. filed a divisional application to the t-PA patent of the above patent infringement case, thereby obtaining a patent on a claim containing the expression, "deletion, substitution or addition."

Namely, Claim 1 of patent No. 2,564,444 of the "G" Co., which is related to a t-PA-expressing vector (the third priority date: April 7, 1983) reads as follows:

"A recombinant expressing vector which is capable of expressing a DNA for coding a human t-PA* having the following amino acid sequence consisting of 1 to 527, or for

coding a human t-PA* derivative exhibiting characteristics of t-PA and which has an amino acid sequence derived from the following amino acid sequence, wherein amino acid residues are deleted, substituted, or added."

(Note) * "t-PA" is an abbreviation of "a tissue plasminogen activator."

Since this claim contains the expression, "amino acid residues are deleted, substituted, or added" even if VAL of the 245th amino acid is substituted by MET, interpreting the claim literally would still include the resultant vector within the scope of the claim.

4-2. Written Description Requirement, and Utility (Industrial Applicability) Special problems with regard to the patentability of the invention related to a gene

4-2-1. Usefulness or industrial utility of the invention related to a gene:

Since the aim of the patent law is to develop industries, only inventions that are useful or having industrial applicability are patentable.

Although it is very rare for an ordinary industrial invention to face problems concerning usefulness or industrial utility, biotechnological inventions encounter this sort of problem quite frequently. The reason for this can be attributed to the fact that it is quite often difficult to know or to clarify the useful function of a DNA fragment or peptide derived from nature.

A typical example of this type of problem is the invention of ESTs as explained below.

4-2-2 Patentability of ESTs:

The "Human Genome Project," which is aimed at sequencing all of the human genome having about 3 billion DNA bases, actually started on a full scale basis in the 1990's. Consequently, a large quantity of ESTs (expressed sequence tag: a cDNA sequence having a length of about 150bp to 500bp obtained through sequencing a human cDNA clone; typically, its specific function is unknown except that it can be employed as a probe) are being produced, thus invoking the issue of patentability of such cDNA fragments in Japan, Europe and the USA.

(1) Trilateral comparative study on patentability of DNA fragments

In November 1998, in response to such circumstances, trilateral patent offices of Japan, U.S., and Europe agreed to conduct a comparative study on the patentability of DNA fragments. This comparative study involved nine questions, on which each Office answers by reporting on examination practice in respect of industrial applicability (utility), enablement requirements, novelty, inventive step, unity of invention, and a comparative analysis of the answers were made. In June 1999, a report entitled "Trilateral Comparative

Study on Patentability of DNA Fragments" was published.

Furthermore, the Trilateral Offices conducted a further comparative study on patentability of nucleic acid molecule-related inventions, whose functions are inferred based on their similarities to known DNA sequences obtained by conventional computer search (homology search). In November 2000, a report on the study was published.

In case of high homology, the EPO and the JPO share the same view that the claimed invention does not have inventive step. On the other hand, the USPTO indicates that the claimed invention has non-obviousness.

4-2-3. Review of description requirements, and utility requirements

In 2003 Examination Guideline was revised to provide a guideline in examination of a patent application relating to gene fragment of which function had not been elucidated. It made clear that enablement requirements of a "product" mean not only requirements to describe how to make but also requirements to describe how to use the product in the specification.

In the US it was confirmed that written description requirement exists separately from enablement requirements. In the assessment whether a specification meets written description requirements, it is important to determine whether the inventor was in possession of the invention as a whole, as of filing, more specifically, determine based on actual reduction into practice, drawings and chemical formula, sufficient relevant characteristics (complete structure, partial structure, physical and /or chemical properties, and functional characteristics coupled with a known or disclosed correlation between function and structure), method of making the invention, level of skill and knowledge in the art, and predictability in the art.

Furthermore, utility guideline has updated. In this guideline, it is checked whether the invention has a well-established utility that is specific, substantial and credible. If not, it is checked whether utility asserted by applicant is specific and substantial. If so, the it is checked whether the asserted utility is credible. By adopting written description guideline and revised utility guideline, it is possible to curb the tendency to seek for a patent protection without disclosing useful invention though it is the very object of patent system to disclose useful invention.

4-2-4 Reach-through Claims (claims to future inventions based on currently disclosed inventions).

So called reach-through claims include claims directed to candidate compounds that might be identified by using basic screening methods and to downstream uses of such candidate compounds.

The Trilateral Patent Office conducted a comparative study on the examination practices on reach-through claims. A report on the study was published in November 2001 and revealed that:

(1) In cases where the specific function (e.g., the relationship to a specific disease) of areceptor protein is disclosed, and specific agonists (activating compounds) are identified (found) by screening methods using said receptor, the claims for methods, uses, or medicaments utilizing the specific agonists (activating compounds) meet all the requirements of patentability as long as there is adequate guidance with respect to how such uses would be put into effect, but

(2) the claims for agonists (activating compounds) in general identified by said screening methods and methods, uses, or medicaments utilizing said agonists (activating compounds) in general do not meet enablement and/or support requirements, considering the general scope of the claims.

In Ariad v Eli Lilly, inventors claimed a method comprising reducing NF-κB activity, as the inventors found that activation of NF-κB relates to symptoms of diseases and considered that reduction of a NF-κB activity would ameliorate the symptomer of the disease. Regarding what compounds reduces activity of NF-κB, the specification discloses as an example only l-κX which is bound to NF-κB in nature, but was not described in the priority document. The specification also includes description of dominantly interfering molecules or decoys as prophetic examples, but it was concluded that the description of dominantly interfering molecule represent a plan for future research and description of decoys is mere mention of desired outcome. The CAFC decided that the claimed inventions do not meet written description requirements. Afterwards, request for rehearing en banc was granted (2009 Nov.).

4-2-5. The Novelty and Inventive Step of Biological Inventions:

The aim of patent law is to protect and encourage inventions and thereby spurring industries to be born or existing industries to develop further. However, if an exclusive right is granted to an invention lacking novelty and inventive step, the development of industries may be obstructed. Therefore, novelty and inventive step are fundamental requisite for patenting an invention.

These requirements of novelty and inventive step are of course required in biological inventions such as those related to genes. The basic concepts of novelty and inventive step are almost the same in every country, and the examination of inventions related to genes is carried out in each country on the basis of the basic concepts. With regard to practice of determining inventive step (or unobviousness), a distinct difference may had be seen in Japan, Europe and the USA, but the difference in practice seems narrowing in recent years..

(1) The guideline in the Examination Guidelines of Japan for determining novelty and inventive step :

Following handlings are set forth in the Examination Guidelines with respect to novelty and inventive step of biological inventions.

i. Novelty

Recombinant proteins

Where a protein X as an isolated and purified single substance is publicly known, a claimed invention concerning a recombinant protein X specified by a process of production, the said recombinant protein being identical as a chemical substance with the publicly known protein X, is not novel.

ii. Inventive Step

(a) Where protein A is publicly known but its amino acid sequence is not publicly known, an invention of a gene encoding Protein A does not have an inventive step, provided that a person skilled in the art could determine they amino acid sequence easily at the time of filing. However, when it is considered that the gene is specified by a specific base sequence and has advantageous effects that person skilled in the art cannot foresee in comparison with other genes having a different base sequence encoding the Protein A, the invention of the said gene has an inventive step.

(b) When an amino acid sequence of Protein A is publicly known, an invention of a gene encoding the Protein A does not have an inventive step. However, when it is considered that the gene is specified by a specific base sequence and has advantageous effects that a person skilled in the art cannot foresee in comparison with other genes having a different base sequence encoding the Protein A, the invention of the said gene has an inventive step.

(c) When a structural gene is publicly known, an invention related to a structural gene of naturally obtainable mutant (allelic mutant, etc.) of the said publicly known structural gene and which is derived from the same species as the said structural gene and has the same properties and functions as the said structural gene does not have an inventive step. However, if the claimed structural gene has advantageous

effects that a person skilled in the art cannot foresee in comparison with the said publicly known structural gene, the claimed invention of the structural gene has an inventive step.

The denial of inventive step under the aforementioned guidelines i and ii is based on the concept that if the amino acid sequence of protein A is known, it would be easy to try to isolate and sequence of a specific gene coding protein A by means of known and customary cloning procedures on the basis of the known amino acid sequence. Namely, these guidelines are intended to make clear that in the absence of any hindrance of providing the gene and unless there is any remarkable effect in the resultant gene, inventive step would be denied on the ground of "obvious-to-try." The guideline of iii is the same as the guidelines of i and ii in that the denial of inventive step is based on the ground of "obvious-to-try."

The main reason for adopting the aforementioned standard in the Bio-Guidelines with respect to inventive step may be ascribed to the fact that under the present technical standard, once the amino acid sequence of protein A is known, it would reasonably be expected (i.e. there is a reasonable expectation of success), based on this information, to find out the target gene of a specific sequence coding protein A.

Even though the Examination Guidelines sets up above mentioned judgment standards, it is necessary to take into consideration specific facts relating to the claimed invention. For, example, in a case (H9 Gyoke 302) where a hormone was isolated and known, but the hormone isolated by conventional method was not free form a trace amount of other contaminating hormones, and influence by other contamination hormones was significant on the hormone, the hormone produced by recombinant gene method was found to be novel as the recombinant gene method enables to produce the hormone free from other hormones.

(2) The practice in the EPO with respect to the evaluation of inventive step of a gene :

In Europe, so-called "could-would test" is relied on for the evaluation of inventive step. For the negation of inventive step, it is not sufficient to rationalize that a person in the art could do is, but it is required to show that a person in the art would do it. Furthermore, even if it is obvious to try a project, without a reasonable expectation of a success, inventive step may not be denied. A reasonable expectation of success is different from a hope for success. Along with progress and establishment of gene technology, in more cases, it was found that there was a reasonable expectation of success, thus, evaluation of inventive step of a gene is practiced in similarity with practice by the Examination Guidelines of Japan.

(3) A judgment in the USA where the determination of unobviousness of a gene on the basis of "obvious-to-try" was determined to be inappropriate:

The CAFC of the USA delivered the following judgment in the Deuel case in 1995, wherein the determination of inventive step of a gene on the basis of availability of a method of making the gene" in the case where the amino acid sequence of protein corresponding to the invented gene was known, was determined to be inappropriate. The precedent is summarized as follows:

"A prior art method of gene cloning and a patent application disclosing a partial amino acid sequence of a protein do not render the DNA and cDNA molecules encoding the protein prima facie obvious, the US Court of Appeals for the Federal Circuit held March 28. Reversing a rejection by the Board of Patent Appeals and Interferences, the court observed that knowledge of a protein does not give one a conception of a particular DNA that encodes it, and that the existence of a general method of isolating cDNA or DNA molecules is irrelevant to whether the specific molecules themselves would have been obvious."

The examination practice followed the above court decision, but various criticisms are set off against such examination practices. Furthermore, too rigidly application of so called TSM test (Teaching, Suggestion, Motivation) to find unobviousness was considered in KSR. vs. Teleflex case (Supreme Court , 2007). In that decision, the US Supreme Court clarified that there is a certain case where obviousness may be proved by showing "obvious-to-try. Examination guideline published after the decision indicates, as a rational for finding unobviousness, "obvious-to-try" by choosing from a finite number of identified, predictable solutions, with reasonable expectation of success. In regards to Kubin, CAFC considered, in view of the Supreme Court decision, whether it is obvious to isolate a human gene encoding a domain of a protein. CAFC held that the claimed inventions by Kubin were obvious to a person in the art because prior art publications described that the protein was isolated, monoclonal antibody against the protein was prepared, and method for isolating its DNA using the monoclonal antibody.

5. Other problems

5-1. The Deposit System of Biological Material:

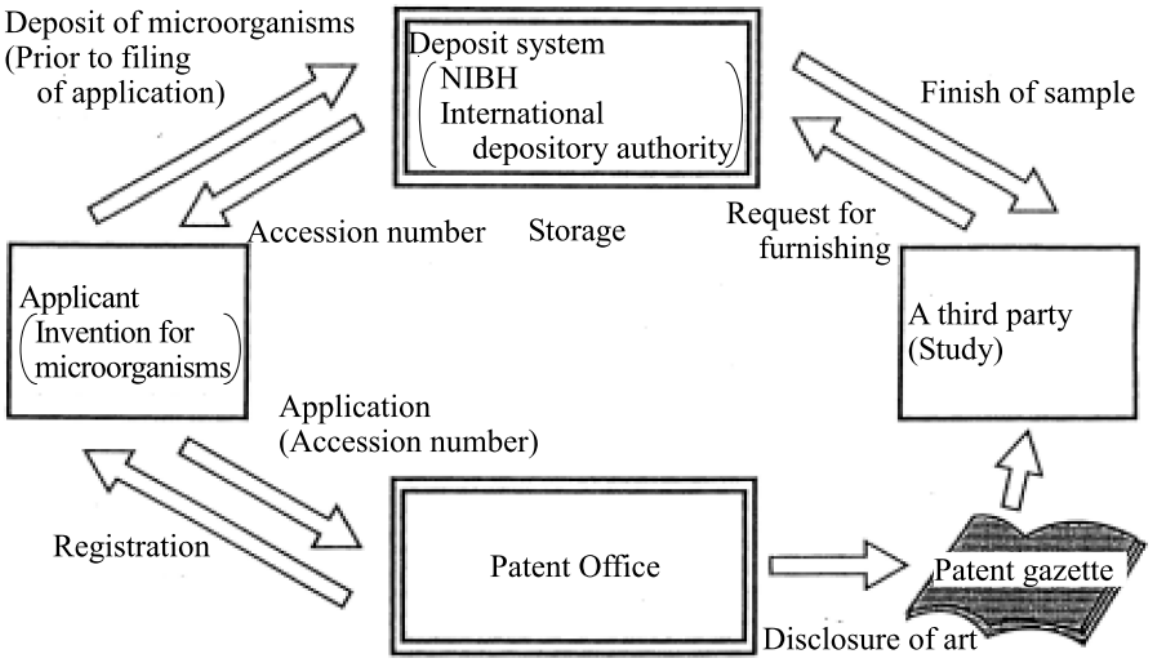
As mentioned in paragraph 4-1, the specification must be written in such a manner as to enable an artisan to exercise the invention (enablement requirement).

However, in situations where the employment of a specific microorganism is essential to practice the invention, where the microorganism is not available, and where it is impossible to

create the microorganism from the description of the specification, it is impossible for an artisan to carry out the invention only from the description of the specification (lack of enablement requirement). To fulfill the enablement requirement of the description of the specification and to enable an artisan to carry out the invention in the aforementioned situations, the deposit system of microorganism was established.

Namely, in most countries, the deposit of microorganism before the patent application (in most cases) is required, and there is an obligation to furnish the samples of the microorganism to the third party desiring to obtain the microorganism for a predetermined time, except for those microorganisms that are available in the market, such as bread yeast, or those that can be created by an artisan on the basis of the description of the specification. According to the Bio-Guidelines, it is required in the aforementioned cases to attach a certificate of deposit issued by the National Institute of Bioscience and Human-Technology (NIBH), a depository institution designated by the Commissioner of the JPO, or provide a copy of a receipt issued by the international depository authority under the Budapest Treaty, and to describe an accession number in the specification. If the applicant fails to meet these requirements, the specification will be deemed to be defective for lacking enablement, resulting in the rejection of the application (see Fig. 5).

Fig.5 Deposit System

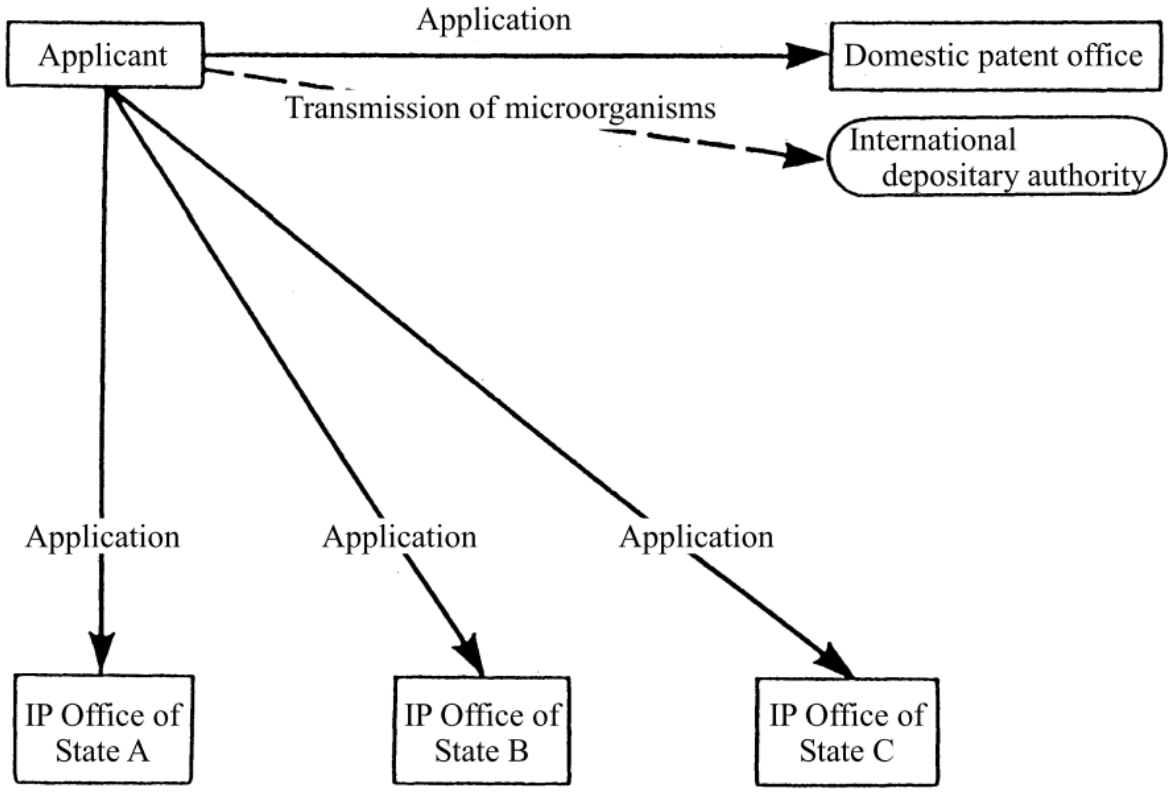


From Report of the Intellectual Policy Committee of Industrial Structured Council

If an applicant is required to make the deposit of a microorganism to each country separately, the procedure would become very complicated and at the same time, the cost would become prohibitively large. In order to alleviate this situation, the Budapest Treaty was established. According to this treaty, when an applicant deposits a microorganism to a single international depository authority, the effect of the deposit comes into force in every member of the Budapest Treaty (Fig. 6).

Presently, deposits are no longer limited to microorganisms and are being made on animal/plant cells, seeds, and animal embryos, among other things.

Fig.6 Application system by Budapest Treaty



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5-2. Convention on Biological Diversity

With the enforcement of the Convention on Biological Diversity, it is now required to proceed the study and development of biotechnology as well as the acquisition of intellectual property rights by taking into consideration the relationship between biotechnological inventions and the Convention on Biological Diversity.

(1) Background of the Establishment of the Convention on Biological Diversity

The preservation of diversity of living organisms is a very important worldwide problem. It is a reality that immoderate developments around the world are now threatening this diversity. With the development of biotechnology, the utilization of genetic resources is being greatly expanded. However, the utilization of genetic resources should proceed while giving careful consideration to the preservation of bio-diversity.

Generally, genetic resources are unevenly distributed and concentrated in developing countries, and the advanced countries are now continuing the study and development of biotechnology by making use of the genetic resources found in the developing countries. Therefore, it would be very important to impartially distribute profits derived from the development of biotechnology to all of the countries involved.

With this view, a study by the United Nations Environmental Programme (UNEP) was initiated. As a result, this "Convention on Biological Diversity" was agreed upon in the treaty negotiating meeting of May 1992, and put into force in December, 1993.

A total of 193 countries (as of December, 2009) including Japan have participated in this treaty. However, the USA has not ratified this treaty as of this writing.

(2) Summary of the Convention

i. Object of the Convention

To preserve bio-diversity on the Earth in every aspect--ecosystem, seed, gene, etc.-- and to utilize bio-diversity for generating profits continuously and impartially.

ii. Main Regulations of the Convention

① The Preservation of Bio-Diversity:

To prepare a national strategy and a comprehensive project with regard to preservation and utilization of bio-diversity, and to specify the constituent elements of bio-diversity deemed to be important in view of preservation and utilization. To practice and promote preservation of intra and extra-habitats through the designation of protected areas.

② The access to genetic resources and benefit sharing :

Under the recognition of the sovereignty of the genetic resource retaining countries, for access to genetic resources it requires a recognition from the genetic resource-retaining country under agreed conditions between countries. In research of genetic resources, efforts should be made to enable the genetic resource-rich country to participate in the research. The fruits obtained from the study and development as well as profits derived from the genetic resources should be fairly distributed under the conditions agreed upon between the side utilizing the genetic resources and the side offering the genetic resources.

③ The promotion and cooperation of technological transfer:

Technological transfer related to the preservation and utilization of biodiversity to developing countries should be promoted, and at the same time, international technical and scientific cooperation should be promoted.

④ Financial support:

Advanced countries should offer new and additional capital for the purpose of exercising this treaty, and at the same time, a system for providing capital to advanced countries should be established.

iii. Relationship with Patent

There has been a discussion that disclosure of a genetic resources in patent application are necessary for the smooth practice of the access and benefit sharing mentioned above ii(2).

Countries like China, India, and European countries start to set up such regulations. However, some countries stipulate that absence of such disclosure in the patent application does not affect patent examination or validity of patent.

5-3. Issues relating to Regenerative Medicine, and Stem Cells

5-3-1. Patent protection of stem cell, ethical and public aspect

(1) It have been expected that stem cells would be applied to regenerative medicine or cell therapy because stem cells have differentiating ability. A lot of research has been done on various stem cells such as hemopoietic stem cells. Among stem cells, embryonic stem cell attracted particularly expectation for application to regenerative medicine as the ES cell has pluriopotent differentiating ability.

(2) However, necessity of fertilized embryo for the preparation of ES cell raises ethical questions. In a case relating to an application filed by Wisconsin University (WARF) directed to ES cell, enlarged board of appeal at the EPO decided that ES cells at the filing date that could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived are not allowable in view of EPC rule 28(C), even though the method is not part of the claims. Furthermore, the Enlarged Board of Appeal mentioned it is not of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos.

(3) In the US, concern was expressed that patents held by WARF hinders the progress of medical technology using human ES cells, and the Public Patent Foundation and others filed requests for reexamination of the patents. According to the Public Patent Foundation, it is said that WARF has relaxed licensing conditions with non-profit organization in view of the above

actions. The examiner decided the amended claims were allowable, but the Public Patent Foundation appealed against such decision. (2009 Nov.)

5-3-2. Preparation of cell for cell therapy and industrial applicability in JAPAN

In Japan, it was handled that method for surgery, treatment or diagnosis includes an invention treating a product collected from a person with the intension of returning the treated product to the same person. However, along the progress of regenerative medicine, there are cases that personnel other than doctors treat a product collected from a person with the intension of returning the treated product to the same person, in such case as preparation of artificial skin sheet. In 2003 it was made clear in the revised Examination Guideline that method for preparing a gene preparation or artificial skin sheet with the intension of returning it to the same person still involves industrial applicability. Furthermore, the newly revised Examination Guideline of 2009 indicates that the method for differentiating a cell does not fall within a method for surgery, treatment or diagnosis of a human being.