Appendix G

Intellectual Property Law

Chapter 16: Intellectual Property Law discusses three areas of intellectual property law that are particularly relevant to the commercialization of biotechnology: patents, trade secrets, and plant breeders' rights. That chapter focuses initially on the United States and then discusses the laws of the other countries by comparing them to the U.S. laws. This appendix elaborates on the intellectual property laws of the five countries likely to be the major competitors of the United States in the commercialization of biotechnology-Japan, the Federal Republic of Germany, the United Kingdom, Switzerland, and France—and is the basis for the comparisons in chapter 16. The first section examines the laws of the four European countries, and the second section considers the intellectual property law of Japan.

Intellectual property laws of the Federal Republic of Germany, the United Kingdom, Switzerland, and France

The Federal Republic of Germany, the United Kingdom, Switzerland, and France, have created an intellectual property law similar to that of the United States, Important differences exist, however, especially on a country -by+ountry basis. Patent laws, laws of trade secrets, and plant breeders' rights in these countries are reviewed in the sections that follow.

PATENT LAW

Eleven European countries, including the Federal Republic of Germany, the United Kingdom, Switzerland, and France, have agreed to a treaty, the European Patent Convention (EPC), that creates a European patent system (8). These countries also have patent systems created by national laws.

European Patent Convention.—The EPC entered into force on october 7, 1977, and as of January 1, 1983, the treaty had been ratified by Belgium, the Federal Republic of Germany, France, the United Kingdom, Luxembourg, the Netherlands, Switzerland, Sweden, Italy, Austria, and Liechtenstein. The EPC establishes a legal system for granting European patents through a single supranational European Patent Office and a uniform procedural system with respect to patent applications, The single European patent application, if granted, becomes a bundle of individual European patents, one for each of the countries designated by the applicant.

The EPC system and the resulting patents exist in parallel with the patent systems of the member countries. The ultimate goal is for each of the member countries to adopt in its national law the same substantive law of patents set forth in the EPC; in the beginning, however, and perhaps always to a certain extent, differences in substantive law will exist between countries. Enforcement of European patents is handled by the same national authorities that are responsible for handling enforcement of national patents in the EPC member countries (EPC art. 64(3)).

Patentable Subject Matter. Under the EPC, patents can be granted for any invention susceptible of industrial application* that is new and involves an inventive step (EPC art. 52(l)). This broad definition is narrowed by specific exclusions. Discoveries, scientific theories, and naturally occurring products, for example, are not considered patentable inventions. Methods of treating humans or animals and related diagnostic methods are similarly excluded from patentability, although products so used are not. Finally, plant or animal varieties and essentially biological processes for the production of plants or animals are not patentable; however, their exclusion does not apply to microbiological processes or the products of such processes (EPC art, 53(a) and (b)). The question of whether a process is "essentially biological" depends on the extent to which there is technological intervention by humans in the process. Under the Guidelines for Examination of the European Patent Office, if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded **(G.E. pt.** C(IV)(3.4)).

Under EPC articles 52(1) and 53(b), as interpreted by the European Patent Office, microbiological inventions of the following kind would be patentable: 1) micro-organisms (including viruses and cell lines), 2) processes for making them, 3) processes using them, 4) products obtained from microbiological processes, and 5) DNA and RNA molecules or subcellular units (e.g., plasmids) (G.E. pt. C(IV)(3.5-3.6)). The European Patent Office also stated that the term "micro-organism" covers plasmids,

one major area that will require further clarification, however, is whether naturally occurring microorganisms, subcellular units, or DNA and RNA molecules are patentable. Under the EPC, there appears to be no absolute bar, it will simply be a question of

*l'he term industrial application includes agricultural applications (EPC art 57). This is actually the standard for utility under the EPC.

the degree to which such subject matter is naturally available and of the effort required to identify and/or isolate it (G.E. pt. C(IV)(2.1)).

Novelty. Under the EPC, an invention is new if it is not part of the state-of-the-art on the effective filing date of the patent application (EPC art. 54(l)). The EPC provides that the state~f-the-art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application (EPC art. 54(2)).* There are no restrictions as regards the geographical location where, or the language or manner in which, the relevant information is made available to the public.

This is known as an "absolute novelty standard" because certain public disclosures even by the inventor himself/herself before the filing can result in loss of patent rights. The absolute novelty standard is a major distinction of European patent law from that of the United States.

Standard ***of Invention.*** The EPC defines inventive step as follows (EPC art. 56):

> An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.

This definition parallels the definition of nonobvious - ness under section 103 of the U.S. patent law (35 U.S.C. 1o3), except that fI03 refers to a person of ***ordinary*** skill in the art and also to the differences between the invention and the prior art.

The European Patent Office's Guidelines for Examination indicate that the test of obviousness to be applied by the European patent examiners is consistent with the objective test under section 103 (G.E. pt. C(IV)(9.9)). In particular, the European Patent Office apparently will consider such factors as unexpected advantages, evidence of immediate commercial success, and evidence of long felt need (18,30).

Disclosure Requirements. The basic disclosure requirement under the EPC is as follows (EPC art. 83):

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

This enablement requirement has as its essential element the concept of the reproducibility or repeatability; i.e., the making of the invention must not be dependent on chance. For micro-organisms, enablement generally is satisfied by depositing a culture of the micro-organism in a depository to which the public has access and referencing the depository and file number in the patent application. However, a deposit **need not be made if the micro-organism is already** publicly available or can be described so as to be reproducible.

Deposit Requirements. If a deposit is required, it must be made with a recognized depository not later than the date the application is filed. The European Patent Office publishes a list of recognized depositories, and, since it adheres to the Budapest Treaty, the European Patent Office also recognizes deposits made pursuant to the treaty. Cultures must be maintained for at least 30 years.

Since all European patent applications are published approximately 18 months after their filing date (unless previously withdrawn) (EPC art. 93(l)), the deposited microorganism can become publicly available before the patent has been issued. The EPC sets up certain safeguards on access to prevent abuse. *

Claims. **Claims in an EPC application must define the subject matter for which protection is sought, be clear and concise, and be supported by the description** (EPC art. 84; G.E. A(III)(4)-(6)).

Enforcement. **Under** the EPC, European patents are granted for a term of 20 years. Enforcement is handled by the national courts of the EPC member countries. The question of infringement is considered under national law principles, but taking account of treaty requirements regarding claim interpretation. European patents may be revoked by a national court on certain specified grounds (EPC arts. 138(1) and 139(2)).

Patent Laws of the Federal Republic of Ge~ many, the United Kingdom, Switzerland, and France.—As described below, the patent laws in the Federal Republic of Germany, the United Kingdom, Switzerland, and France vary with respect to ***certain*** provisions regarding patentable subject matter, novelty, disclosure requirements, or enforcement.

Patentable Subject Matter. The provisions defining patentable subject matter in the patent law of the Federal Republic of Germany are virtually identical with the corresponding provisions of the EPC. Regarding biological inventions, the Federal Republic of Germany has been a pioneer in recognizing the patentability of microorganisms per se. After deciding in 1969 that patents could be obtained for inventions in the field of biology (22), the German Federal Supreme Court specifically held in 19i'.5 that micro-organisms per se constituted patentable subject matter (2). Therefore, in line with EPC law, the same categories of biologi-

"Implicit in the concept of the state-of-the-art **is the concept that the public** disclosure **must** beenabling

•The safeguards are **as follows" 1) the recipient** may **not pass the sample on to anyone** else **unless or until the application is abandoned or all European patents** haveexpired;**z) the recipient can** only **use the micro-organism for experimental purposes until** the **application is abandoned or a patent** issues;**3) the patentee ran elect to permit samples to be** given **only to certain neot** ral **experts** (EPC **Rule 28(3)-(4)).**

cal inventions are patentable in principle according to West German law. *

In its Patent Act of 1977, the United Kingdom adopted the EPC definition of patentable subject matter. The British Patent Office has taken the position that all of the five general categories of biological subject matter listed above are patentable (27).

Section 1a of the Swiss Patent Law corresponds to EPC Article 53(b), stating that "micro-biological methods and products obtained thereby shall be patentable." There is no specific provision in the law which states that '(discoveries" are not patentable subject matter, although prior case law recognizes such an exclusion (5).

Nevertheless, it appears that Swiss practice varies considerably from that under the EPC. According to the Swiss Patent Office, micro-organisms per se are not patentable, including human-made ones. The Patent Office has apparently not yet taken a position on the patentability of DNA and RNA molecules or subcellar units (7).

As to the remaining categories of subject matter involving microorganisms, the Swiss law provides for patent protection in the same manner as the EPC. Furthermore, since microbiological processes are explicitly patentable, some protection is obtainable for microorganisms per se under Swiss law, because section 8 of the Swiss Patent Act provides that the protection of a patent claiming a process shall extend also to the immediate products of the process.

The substantive law regarding patentable subject matter in France corresponds to the EPC, specifically in all respects which are relevant to microorganisms. However, article 7 of the French patent law (1978) excludes patents on plant varieties to the extent to which such varieties are protectable under French plant protection legislation.

Utility. All of the EPC countries have adopted the EPC requirement for utility-that the invention be useful in industry (including agriculture) (24). However, Swiss law restricts the concept of industrial use by excluding private use and use for research (15).

Novelty. The Federal Republic of Germany, United Kingdom, and France have adopted the EPC absolute novelty standard in their latest national patent laws (24). Switzerland also has adopted the absolute novelty standard with one technical exception relating to prior filed Swiss or EPC applications (Swiss Patent Law, art. 7a).

Disclosure and Deposit Requirements. The statutory provision of West German law governing disclosure requirements (West German patent law sec. 35(2), 1981) is identical to article 83 of the EPC, i.e., enablement of a person skilled in the art. However, there are certain differences in practice regarding biological inventions. By court decision, a new micro-organism cannot be patented unless the application discloses a *reproducible* method of producing it. Thus, a deposit without an enabling written description is inadequate to support a claim to the microorganism itself (3,26). This is in marked contrast to the law of the other countries. On the other hand, a deposit alone is sufficient to support a claim to a method of using a new micro-organism (32). A required deposit must be made no later than the filing date (or the priority date) (32). Although the applicant must furnish samples of the deposit to third parties after publication of the application, the applicant can require that the samples not be removed from the Federal Republic of Germany and not be passed on to others.

The British Patents Act, in section 14(3), has the same enablement standard as the EPC. In the case of an invention involving a microorganism, the application as filed must contain the relevant information on the characteristics of the micro-organisms, to the extent known to the applicant. The required deposit must be made no later than the filing date or the priority date (British Patent Office Rule 17(1) (1978)). Samples will be publicly available when the application is published 18 months after the priority date. Those who request samples must undertake not to pass them onto others and to use them only for experimentation until the patent is granted or the application is abandoned (British Patent Office Rule 17(2) (1978)).

The Swiss Patent Act, in section 50 (1978), contains the same enablement standard as the EPC. The Patent Ordinance, section 26(6) (1977), also requires that the description explain how the invention may be used industrially. In the case where the micro-organism is not publicly available or cannot be described in an enabling manner, a deposit in a recognized depository is required. The application must identify the depository, the deposit number, and the date of the deposit (Swiss Guidelines for Examination, Z-14.3 and 14.4, May 12, 1980). In the case of a microaganism that is available to the public, identification of a known source need not be disclosed in the application as originally filed. Such information (e.g., reference to a deposit that was publicly available on the application filing date) can be added to the application after the filing date (Swiss Guidelines for Examination, Z-13.2, May 12, 1980). Since Swiss applications are not published before the patent is granted, culture samples are not required to be furnished until the patent is granted. Then samples are released only to identified

* The German Federal Patent Court has also upheld a patent on a microorganism obtained as a pure culture from an unpurified, naturally occurring state through a selective culture process (16).

parties, who undertake not to pass them on (Swiss Patent Ordinance, sec. 27(6)).

The French patent law, in article 14bis (1978), sets forth the same standard of enablement as the EPC. Publicly available micro-oganisms need not be deposited. Required deposits must be made in a Government-authorized depository no later than the priority date. A regulation under the statute (Decree No. 79-822 on Sept. 19, 1979, amended by Decree No. 81-865 issued on Sept. 11, 1981) contains provisions regarding the content of a French patent application relating to a microorganism that are consistent with EPC Rule 28. Thus, the application must contain (French patent law, art. 10):

- the available information as to the characteristics of the micro-organism, and
- an identification of the depository and deposit number.

Access to the deposit, which is granted at the time of publication, can be limited to recognized experts until the patent is granted or the application is abandoned (French patent law, art. 31).

Claim Practice. Claims acceptable under EPC practice should be acceptable in the four countries. Switzerland, however, will not accept claims to a microorganism per se.

Enforcement. * Subject to specific requirements contained in the EPC regarding claim interpretation, European patents as well as national patents are interpreted and considered with respect to the questions of both infringement and validity in accordance with national law in the EPC member countries.

In the Federal Republic of Germany, an infringer is broadly defined as any person who makes use of a patented invention. Protection for a patented process extends to the product directly obtained by that process. Provisional rights for reasonable compensation are given for applications which have been published but not yet granted.

Infringement was defined for the first time in the new British law, and a separate Patent Court was established for the purpose of trying patent infringement cases. Infringement includes the acts of making, using, importing, disposing of, or offering to dispose of an infringing product. Similar provisions are provided with regard to a process and with regard to a product obtained by a patented process. Provisional rights are given for published applications, and full recovery for damages from the date of publication may be obtained after grant. The 1977 act also provides that the scope of the patent may extend beyond the literal meaning of the words of the claims.

Swiss law defines infringement to include any unlawful utilization of the patent invention, including imitation. patent protection for a process also extends to products which are directly made from the process. The patent rights begin at publication, but suit for damages may be initiated only after grant. Criminal sanctions may also be imposed as well as confiscation and destruction of the infringing goods.

Infringement in France is defined broadly to include the acts of manufacture, offer, commercial disposal, use, or import of the patented product. However, for actions other than manufacturing or importing, there is no liability unless the acts were committed with knowledge of infringement. Process patents extend coverage to products obtained directly by the process. provisional rights for published applications are limited to reasonable compensation. Suit maybe brought before grant but will probably be suspended until after grant.

In countries with national laws providing for provisional protection after preliminary publications—namely, the Federal Republic of Germany, the United Kingdom, and France—there should be no difference in treatment between published national applications and published European applications. In Britain and France, damages may be recovered for published national or European applications. Moreover, in France, damages are recoverable from the time of notification to the infringer of the patent application contents. Only reasonable compensation may be obtained in West Germany.

The EPC also provides for provisional protection after publication of a European patent application. Generally, the right is limited to recovery of damages after the patent issues.

In Switzerland, on the other hand, provisional protection is not provided. But, in ratifying the EPC, Switzerland has provided a provisional remedy for European patent applications.

Remedies for infringement include injunctions and monetary damages. In addition, as a general rule, the loser pays most or all of the costs of litigation of the winning party. Finally, in most cases, the infringing goods will be destroyed or handed over to the patentee.

Criminal sanctions exist in the national patent laws of the Federal Republic of Germany and Switzerland, but they are not of much practical importance.

LAW OF TRADE SECRETS

National laws that protect trade secrets, confidential information, and know-how (hereinafter sometimes referred to collectively as "proprietary information") are designed to prevent the misappropriation

* The discussion in this section is based substantially on ch. HI in Schwaab and Thurman (24).

of a competitor's technical and commercial information. These laws coexist with the patent laws of the various countries and are a necessary adjunct to those laws in order to provide basic protection in many areas where the patent laws do not reach.

There are no treaties, such as the EPC for patents, dealing with the international protection of proprietary information. Thus, when a question involving trade secrets comes before the European Court of Justice, it will be decided generally in accordance with the national laws of the member states, much like U.S. Federal Courts are governed by State law in trade secret cases.

Federal Republic of Germany.—The West German law dealing with trade secrets has at least two components, "industrial secrets" and "commercial secrets. " Although no distinction is made in enforcement of rights as to one type or the other, the fact that both are protected makes it clear that not only technical secrets are protected, but also secret commercial or business information,

With respect to the elements for establishing protectable industrial and commercial secrets, the German Supreme Court has stated on several occasions that such a secret maybe any fact that is: 1) connected with a business, 2) known only to a small number of persons, 3) for which its possessor has a justifiable interest in keeping secret, and 4) for which its possessor has manifested an express or recognizable intent to keep secret (33).

The West German law is more liberal than the U.S. law as to the degree of public knowledge required to destroy a trade secret. In the Federal Republic of Germany, if information is discernible only with a great deal of work and expense, it is still protectable as an industrial or commercial secret. Thus, for example, even the purchase of a machine does not destroy the secret nature of its contents if the purchaser must dismantle, tear apart, and put in substantial time and effort to uncover its secrets (33). Further, knowledge by a small group of persons, particularly if they are not competitors, will not destroy the secret nature of an industrial or commercial secret.

As in the United States and the United Kingdom, neither novelty nor technical advance need be established in order for information to be classified as an industrial or commercial secret in West Germany.

One element of a trade secret is whether the information gives its possessor an advantage in competition which would be lost if it were disclosed to competitors. But at least one commentator has suggested that the industrial or commercial secret need not be actually industrially or commercially utilized at the time of its loss (4). Thus, it would appear that research data that would or potentially could give the holder a competitive advantage would satisfy the requirements for an industrial secret.

Substantial civil and criminal liabilities for violation of trade secret rights are written in statutory law. The most pertinent provisions are in the German Unfair Competition Law of 1909 (UWG, Gesetzgegen den unlauteren Wettbewerb). An employee who wrongfully communicates an industrial or commercial secret may be imprisoned for up to 3 years and fined. If the employee uses the secret abroad, or knows it is to be used abroad, the prison sentence is increased to up to 5 years. Civil penalties and a civil right of action for damages or an injunction are also available (6,20,33).

United Kingdom.—The British courts, much like their American counterparts, have refrained in most instances from adopting a hard and fast definition of the term "trade secret. " One definition is as follows (31):

1. It consists of information;
2. The information must be secret either in an absolute or a relative sense;
3. The possessor must demonstrate that he has acted with an intention to treat the information as a secret;
4. The secret information must be capable of industrial or commercial application; and
5. The possessor must have an interest in the information worthy of legal protection, bearing in mind English principles of equity. This will generally be an economic interest.

The English (as well as the other Europeans) are rather parochial in their approach to the question of whether something is secret. They are concerned most with public knowledge in their own country. For example, knowledge by other people outside of the United Kingdom would not be as great a threat as knowledge of a few people inside of the United Kingdom (31).

One possible problem for biotechnology in Great Britain is the requirement that information must have some industrial or commercial use in order to qualify as a trade secret. Thus, research data or abstract ideas not capable of being used commercially in the near future may not be a trade secret (31). Such information may be protectable, however, as "confidential information" (23). While English legal scholars have debated the degree of secrecy necessary for information to be protected as confidential, it is clear that the degree necessary to protect such information pursuant to a confidentiality agreement is less than that required to establish a trade secret. The British "confidential information" approach might well be the way to avoid the problem raised by some U.S. cases which

have indicated that technical information will not be protected if it is not developed to the stage of practical application (9).

Enforcement of trade secret law in the United Kingdom is by way of civil actions for damages. Unlike other major industrialized countries, the United Kingdom has no specific statute making misappropriation of trade secrets a crime, and there has been no significant prosecution under more general theft or conspiracy statutes.

Switzerland.—Swiss law recognizes "industrial secrets" and "commercial secrets."* The elements of protectable industrial and commercial secrets are quite similar to those under West German law. Knowledge by a small number of people, or public availability, but only after substantial expense or effort, does not defeat the secrecy of the information (19,20). There must be an intention to maintain the secrecy of the information and an intent in maintaining its secret for the purpose of enhancing economic or competitive position (19). One additional element to the Swiss law, however, is that the secret must have a relationship to a particular business enterprise. Secrets held by professors, scientists, factory workers, and others not engaged in business do not qualify as industrial and commercial secrets, unless, of course, they own or participate in a business and the secret is possessed by the enterprise rather than themselves as individuals (19).

Switzerland's Unfair Competition Law of 1943 specifically prohibits the misappropriation of industrial or commercial secrets, and contains sections establishing both civil and criminal liability. One who is injured by an act of unfair competition may obtain injunctive relief and damages (19).

Switzerland has a wide variety of criminal statutes prohibiting misappropriation of industrial and commercial secrets and various other types of industrial espionage. The Unfair Competition law provides that those guilty of the same acts of unfair competition discussed above shall be punished by a fine or imprisonment, on complaint of the aggrieved party (19).

Thus, Switzerland has a formidable array of civil and criminal liabilities to discourage industrial espionage and misappropriation of propriety information.

France.—French law, like West German law, rather than following the single concept of "trade secret" found in the U.S. and English law, segregates the secrets into "manufacturing secrets" (secret de fabrique) and '(commercial secrets" (secret de commerce) (10). A commercial secret is treated by the commentators similarly to a manufacturing secret, although there is no direct reference to commercial secret in the French Code (10), For information to be a manufacturing secret, it must be: 1) relatively secret, 2) of industrial application, 3) of commercial or market value, 4) a secret of the factory; and 5) the misappropriator must know it is a secret (10).

The difficulty for researchers is the requirement of industrial application. The majority view seems to be that to be a manufacturing secret, the secret information must either be suitable for immediate industrial application or have already been used industrially. For example, a process not yet applied industrially, but used only in research and experimentation cannot be a manufacturing secret. Mere unapplied, theoretical ideas of a technical or scientific nature do not qualify (10).

Misappropriation of manufacturing secrets by an employee is a criminal violation under article 418 of the French Penal Code, if the employee has the requisite criminal intent for doing the act for his or her own benefit (10). Disclosure to aliens or non-French residents is punishable by significantly higher fines and much longer prison terms.

PLANT BREEDERS' RIGHTS

The important provisions of the plant breeders' rights laws of the Federal Republic of Germany, the United Kingdom, Switzerland, and France are as follows.

Federal Republic of Germany.—Article 2(3) of the Federal Republic of Germany's Law on the Protection of Plant Varieties (text of May 20, 1968) covers both sexually and asexually reproduced varieties. The variety must be new, sufficiently homogeneous, and stable. Novelty exists when the variety is clearly distinguishable by at least one important morphological or physiological characteristic from any other variety, the existence of which is a matter of common knowledge at the time for which protection is applied. Common knowledge is defined in terms of absolute novelty in Germany, with commercialization of the variety in Germany prior to filing the application constituting a statutory bar (art. 2(3)). *Homogeneous* means plants of the variety must be identical in all their essential characteristics (art. 5). Stability is demonstrated when plants of the variety retain their essential characteristics true to the definition of the

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• 'I'he Swiss Supreme Court has defined "industrial secret" as (BGE 64 II 66) (19):

> All facts related to a manufacturing process or method and neither in the public domain nor generally available, in the secrecy of which the holder has a justified interest and which he actually wishes to be maintained secret, can be the subject matter of an industrial secret.

and "commercial secret" as (BGE74IV 103) (19):

> The term "commercial trade secret" encompasses basically all facts of economic life in the maintenance of secrecy of which an interest worthy of protection exists,

variety after each successive reproduction or reproductive cycle (art. 6).

Article 36 provides that as a part of the examination procedure, the variety must be grown, either by the Federal Office of Plant Varieties or a delegated outside service. The holder of the protection right also is required to submit to the Federal Office of Plant Varieties, upon request, material for establishing the continued existence of that variety. If the holder is unable to do so, the protection right ceases (arts, 16 and 20).

The duration of protection or grant is for 20 years, except for certain varieties for which it is 25 years (art. 18). The law provides for criminal penalties comprising fine or imprisonment of a term of up to 1 year (arts. 48 and 49). The holder of the protection right may claim remuneration from any person who has propagated material without authorization in the interval between the publication of the application and the grant of title of protection (art. 47(4)).

United Kingdom.-The Plant Varieties and Seed Act of 1964 covering United Kingdom is the basis for adherence to the UPOV 1961 Convention, with ratification being effective September 17, 1965. * The act covers both sexually and asexually reproduced plant materials.

The new variety must be distinct, uniform, and stable. To meet the first requirement, it must be clearly distinguishable by one or more important morphological, physiological, or other characteristics from any other variety whose existence is a matter of common knowledge at the time of the application (pt. II, 1(1)). The variety must be sufficiently uniform or homogeneous (pt. II(4)). The variety must be stable in its essential characteristics—i .e., it must remain true to its description after repeated reproduction or propagation (pt. II(5)).

There is an absolute novelty requirement, that is, the variety may not have been offered for sale or sold in the United Kingdom prior to the filing of the application. Where such sales or offers for sales are made outside the United Kingdom, a grace period of 4 years is provided prior to the filing of the application (pt. 11, (2)(1) and (2)).

The scope of protection afforded by the rights include the exclusive right to produce or propagate the variety for the purpose of selling the variety or parts or products of the variety (pt. II, 3(1) and (2)). The term of protection ranges from 15 to 25 years, depending on the type of plant.

A growing trial is required during the examination period, thus requiring the submission of plant material. Further, every holder of plant breeders' rights must ensure that, throughout the period for which the rights are exercisable, he or she is in a position to provide reproductive material that is capable of producing the variety, and the holder must provide such information and facilities as the plant variety rights office may request for the purpose of fulfilling the maintenance requirements. If plant material cannot be so provided, the protection rights shall be terminated (pt. I(6)).

The law provides for a Plant Variety Rights Tribunal having jurisdiction over cases brought under the act, with the tribunal being authorized to sit in any designated place in Great Britain to hear any proceedings,

Switzerland.—Switzerland ratified the 1978 UPOV Text on June 17, 1981, Under Swiss law, sexually and asexually reproduced varieties are covered. Protected varieties must be novel, stable, and sufficiently homogeneous. The variety is considered novel unless, at the time the application is filed, the variety has already been offered for sale or marketed in Switzerland or for more than 4 years outside of Switzerland. A "variety" refers to any cultivar, clone, line, stock, or hybrid and is considered new if it is clearly distinguished by one or more important features from any other variety whose existence is generally known at the time the application is filed.

Variety protection precludes another, without the consent of the holder, from producing propagation material of the protected variety with a view to marketing it, offering it for sale, or selling it in the course of business. Propagation material includes seeds, fruits, or vegetative material. Protection is for a term of 20 years following issue, but it can be extended in certain cases.

The applicant is required to deposit propagation material for purposes of conducting examination for verifying the stated characteristics of the plant. The title of protection can be annulled when the title holder cannot supply a propagation material capable of producing the new variety with its morphological and physiological characteristics as defined when the right was granted.

Action for variety infringement is brought in the canton of the defendant's place of residence in Switzerland. Intentional infringement can be punished by imprisonment for up to 1 year or by a fine.

France.—Although France was an early ratifier of the 1961 UPOV Convention Text, and a signatory to the 1978 Text, it has not yet ratified the latter. France continues to operate under the Law on the Protection of New Plant Varieties, Law No. 70-489 of June 11, 1970,

Both sexually and asexually produced plant materials of all species are covered, including bacteria, although

*For further information about UPOV, see *Chapter 16: Intellectual Property Law.*

the schemes are limited to specified varieties. For a variety to be "new, " it must be distinct from similar known varieties, by reason of one characteristic that is important, specific, and subject to little fluctuation, or more than one characteristic where the combination thereof is such as to give it the quality of a new plant variety (ch. I, sec. 1). Further, the variety must not have been exploited in France, or appear in specified publications, before the filing of the application in France; if so, a valid certificate cannot be issued. The variety must be homogeneous in all of its characteristics, and must remain stable—i.e., it must remain identical with its original definition at the end of each propagating cycle (ch. 1, sec. 1). An application for each new variety fulfilling the above requirements must be given a denomination and a sample to be left in a collection (ch, II, sec. 2).

The plant variety certificate confers on the certificate owner the exclusive right to produce, import into France, sell, or offer for sale all or part of the plant (ch. II, sec. 3). The certificate is valid for 20 years from the date of issue, although this period shall be extended to 25 years if the constitution of the elements for production of the species requires a considerable time.

The breeder must at all times keep a vegetative collection of the plant variety (ch. 1, sec. 9). If the owner is unable to furnish the administration at any time with the elements of reproduction or vegetative propagation so that the specified characteristics of the variety can be ascertained, the rights of the owner will be forfeited (ch. IV, sec. 22).

Chapter IV, section 23 relates to infringement, which is broadly defined. It provides that any violation of the rights of the owner of a new plant variety certificate shall constitute an infringement for which the offender shall be liable.

Intellectual property law of Japan

Having discussed the patent law, trade secret law, and plant breeders' rights in the European competitor countries, we turn now to Japan.

PATENT LAW

Patentable Subject Matter.–The Japanese Patent Act contains the following broad definition of patentable subject matter (art. 29(1), 1976):

> Any person who has made an invention which can be utilized in industry may obtain a patent . . . .

Until 1979, the Japanese Patent Office took the position that micro~rganisms were unpatentable because they are not industrially applicable. After reversing that position, the Japanese Patent Office issued a set of Working Standards for micro-oganism inventions in November 1979, and in August of 1980, it issued a Classification of Inventions Relating to Genetic Engineering (14). * According to these guidelines, recombination of the genes of higher animals is not permitted, so that inventions in that area are thought to not be patentable (14).

In the intervening years, the greatest obstacle to securing patent protection for microbiological inventions in Japan was the rDNA research safety guidelines published by the Science and Technology Council and the Ministry of Education. These guidelines originally permitted only E. coli bacteria to be genetically modified. In January 1980, yeast strains were also included. Since then, other microorganisms have been included. * * Any rDNA inventions that were not directed to subject matter approved by the safety guidelines were considered to fall into the category of inventions "likely to injure the public health" and thus were precluded from patenting under article 32(2) of the patent law (13).

Subject to the above considerations, therefore, the following five basic categories of biotechnological inventions appear to be patentable: 1) micro-oganisms, 2) processes for producing micro-organisms, 3) processes using micro-organisms, 4) products obtained from microbiological processes, and, 5) DNA and RNA molecules or subcellular units.

Novelty.—Under article 29 of the Japanese Patent Act (1978), an invention is novel if it is not worked or publicly known in Japan, or it is not described in a publication anywhere prior to the application filing date (or priority date). A 6-month grace period is provided in article 30 (1978) for: 1) experimentation, publication, and papers presented before scientific organizations by the applicant, 2) unauthorized disclosure by a third party, and 3) displays at authorized exhibits.

Utility.—The standard of utility is one of industrial applicability, similar to the EPC. Processes in the field of medicine, diagnosis, therapy, and pharmacology in which the human body is an indispensable element are excluded from patentability by the Japanese Manual for Examination and by court decision, as not being usable in industry (11).

Standard of Invention. -Under article 29(2) of the Japanese Patent Act, a claimed invention is not patentable, even if novel, if it '(could easily have been made, at the filing of the application, by a person with ordinary skill in the art to which the invention pertains," This standard is similar to the concept of obviousness under U.S. law, except that U.S. law focuses

*The guidelines also mention vectors, DNA molecules, and enzymes.
* "See *Chapter 15: Health, Safety, and Environmental Regulation* for details.

on the difference between the claimed invention and the prior art.

Disclosure Requirements. -Disclosure requirements for inventions under article 37 of the Japanese Patent Act (1976) require that an application be accompanied by a specification setting forth a detailed explanation of the invention including the purpose, construction, and effect of the invention to the extent that any person having an ordinary knowledge in the technical field to which the invention belongs may easily make it. This is basically an enablement standard.

Deposit Requirements.—A micro-organism must be deposited except in the case where:

- it cannot be preserved in a depository for technical reasons or cannot be controlled under safe conditions; or
- it is readily available to those skilled in the art (e.g., a commercially available microorganism or one constituting a stock culture listed in a catalog published by a reliable depository) (35).

The situation is unclear in the case of micro~rganisms for which an enabling disclosure is presented in the patent application (35).

Japan is bound by the Budapest Treaty, and therefore, it must accept deposits made thereunder, without requiring deposit in Japan. For those deposits not made under the Budapest Treaty, the minimum required maintenance period for the culture deposit is the lifetime of the Japanese patent (28).

Generally, no sample of a deposited culture will be furnished to third parties (without consent of the depositor) until the patent application is accepted and published for opposition. After publication, access is granted on the condition that the party will not furnish the sample to others (28).

Claims Practice. -There are no formal limitations on the basic type, style, or category of claims (1).

Enforcement.—Infringement is defined in article 101 and 3(2) of the Japanese Patent Act (1978) to include the acts of making, using, selling, and importing the patented article and/or patented process, including importing an article produced by a patented process. There is a presumption that a claimed process for producing a *novel* product has been used to produce the product whenever found in Japan (art. 104, 1978).

It is the predominant view that claims in a Japanese patent define the outer boundary of the invention and that only in rare instances is it possible to establish infringement for anything outside of the literal language of the claims, i.e., there is no traditional doctrine of equivalents (29).

Article 65(3) of the Japanese Patent Act provides that after the first publication of a Japanese application, the applicant has a right to reasonable compensation. After acceptance and grant, the patentee has the right to injunctive relief as well as monetary damages and, in theory, criminal sanctions (29).

LAW OF TRADE SECRETS

There are no specific statutes assigning liability for misappropriation of trade secrets;* thus, one must rely on general principles of Japanese civil law (see 17). That is, an injured party may sue under general tort law principles. * * Employees, however, are viewed as having an implied contractual obligation not to misappropriate or improperly disclose trade secrets of their employer.

The Japanese Penal Code does not contain a provision specifically punishing misappropriation of trade secrets, manufacturing secrets, or commercial secrets. Criminal liability can only attach through the general sections of the penal code dealing with larceny, embezzlement, receiving stolen property, fraud, etc. Misappropriation of trade secrets has been successfully criminally prosecuted under such general statutes in Japan (see 12).

Trade secret protection in Japan for any type of technology is seen as very unsatisfactory. Liability for misappropriation has been the exception rather than the rule. In fact, one commentator has described Japan as the world's leading country for industrial espionage (34).

PLANT BREEDERS' RIGHTS

A Seed and Seedling Law in Japan, enacted July 10, 1978, conforms to the provisions of the UPOV Treaty, which Japan has signed (21). The details of the Japanese legislation are similar in essential respects to the EPC countries discussed previously.

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"While the term "trade secret" is sometimes used in Japanese law, one is more likely to find the terms "industrial secret" and "commercial secret" utilized, in a manner similar to that of German law (34).

•● The general tort principle is set out in art, 709 of the Japanese Civil Code as follows: "A person who, willfully or negligently, has injured the right of another is bound to compensate him for the damage which has arisen therefrom,"

••● Note: R.P.C. = Reports of Patent, Design, and Trade Mark Cases (Great Britain).

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