Chapter 16

Intellectual Property Law

Contents

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Introduction

Biotechnology will give rise to a vast array of new inventions. The inventions may be placed into two general categories: products and processes. Products will include organisms, such as genetically modified micro-organisms, cell lines, hybridomas, plants, and possibly even animals. Products also include parts of organisms and related material such as high expression plasmids, viral vectors, synthetic genes, probes, and restriction enzymes. Finally, there will be products of organisms, such as drugs, chemicals, biologics, and monoclinal antibodies (MAbs). Processes will include various ways to make new organisms or parts thereof or to use an organism to make some product such as insulin. Other examples of processes include various bioprocessing techniques, regeneration of plant tissue culture, breeding techniques, and methods of treating the human body. In addition, research and development (R&D) will give rise to new knowledge, which will be of value to whoever possesses it.

The ability to secure a property interest in an invention and to protect related know-how generally is perceived as providing an extremely important incentive for a private company to spend time and money to carry out research, development, and scale-up for the commercialization of new processes and products. Without the ability to prevent other companies from taking the results of this effort, many new and risky projects that could lead to important new products would not be undertaken. Empirically proving this notion, however, is difficult (47). It is beyond the scope of this chapter to delve into the debates among experts on that problem. This chapter will assume—as our society does—that the ability to secure property interests in or otherwise protect technological processes, products, and know-how will encourage development of technology. Therefore, one factor to evaluate in assessing U.S. competitiveness in biotechnology is how well the law of intellectual property of the United States and the five other major competitor countries—Japan, the Federal Republic of Germany, the United Kingdom, France, and Switzerland-allows inventors, private companies, and others to protect the results of their efforts.

The three categories of intellectual law most relevant to biotechnology are those dealing with trade secrets, patents, and plant breeders' rights. These are the focus of this chapter. * Copyright may also be relevant, because it protects the tangible expression of information, and a gene may be viewed as the tangible expression of information (36). Because this idea has not been widely accepted, and several commentators have criticized its usefulness (16)40)52)) here it will not be discussed any further.

The categories of intellectual property law work together as a system. If one has disadvantages, a company can look to another. To the extent that a country has available many alternative ways for companies to protect biotechnological inventions, it is more likely to be competitive in biotechnology.

This chapter compares and contrasts the law relating to the protection of biotechnological inventions and related know-how in the United States, the United Kingdom, the Federal Republic of Germany, Switzerland, France, and Japan. The chapter begins by examining U.S. law in order to provide a basis for comparisons, raise the relevant issues, and explain some basic legal concepts.

● Two other areas of law are also relevant to biotechnology but will not be considered in this chapter: personal property law and contract law. Traditional personal property law will apply to cell lines and many other biological inventions because they are physical objects—just like cars and jewelry. Contracts create legally enforceable rights and duties between the contracting parties. Thus, biotechnological inventions can be protected by contract, and in view of some of the uncertainties in the intellectual property law regarding biotechnology, contracts can be important to biotechnology companies in many instances. These topics will not be considered further in this chapter, because OTA was unable to obtain information on how they would apply to biotechnology in other countries. Some commentators have addressed their applicability to biotechnology in the United States (10,40,42).

Foreign intellectual property laws are considered after the discussion of the U.S. law and also in appendix G. The strengths and weaknesses of the laws of the six countries are then analyzed by considering three basic questions: 1) what interests will the law protect; 2) how well will they be protected; and 3) what questions are unanswered? Policy options for Congress addressing the issue of how to improve U.S. competitiveness in biotechnology by strengthening U.S. intellectual property law are identified and discussed at the end of the chapter.

Intellectual property law of the United States

As noted above, three categories of intellectual property law are particularly relevant to biotechnology: trade secrets, patents, and plant breeders' rights,

Law of trade secrets

An inventor is regarded in the United States as having a natural right to keep an invention secret. This right is recognized by the law of trade secrecy. A trade secret is generally viewed as "any formula, pattern, device, or compilation of information which is used in one's business, and which gives him (sic) an opportunity to obtain an advantage over competitors who do not knew or use it" (l). * Examples of trade secrets in biotechnology are a method for genetically manipulating an organism, a method for selecting among the organisms for those particular characteristics, and the organism itself.

The holder of a trade secret in the United States can enforce his or her interests in State courts by securing either an injunction or monetary damages against a person who takes or otherwise acquires the secret through improper means, or even against a person who acquired it through mistaken disclosure by the owner.** Criminal penalties may also be available in egregious cases in the majority of States. The underlying policy is that a person should not benefit by unfairly using another's efforts.

In the United States, virtually any biological invention, including cells and their components, or related information would be protectable by the law of trade secrets. *

It should be noted, however, there are some limitations on its scope. One important limitation arises from the fact that a trade secret must be continuously used in a business. This requirement raises questions about the results of basic research. Generally, the courts have held that if information is merely a preliminary idea, it does not qualify as a trade secret (41,51). Some degree of commercial value must be established if the information is to be considered a trade secret. A few States have taken a more expanded view of the concept of trade secret and protect information that also has only potential economic value. In those States—Arkansas, Idaho, Kansas, Minnesota, and Washington—the results of basic research clearly would be protected.

Another possible limitation on the scope of the law of trade secrets arises from the fact that the holder of a trade secret must know the information and attempt to keep it secret from others. In the well-known case involving disputed ownership of an interferon-producing cell line, ***Hoffmann-La Roche, hc. v. Go/de (28).*** Genentech (U. S.) and Hoffmann-La Roche (Switzerland) apparently argued that the University of California had no trade secret interest in the cell line because the university did not know about its ability to produce interferon (10).

The advantages of a trade secret to its holder are several. First, there is no time limit on trade

"In recognizing the existence of a trade secret, the courts do not use a hard and fast definition, but look at numerous factors, such as the extent to which the information is known outside of the business, the effort involved in developing and guarding the information, and the difficulty with which the information could be properly acquired by others (see ***34).***

** ● The cases also recognize secret information that does not qualify as a trade secret, but a person acquiring or using that information is liable only if he does so by "improper means" (l).

*Misappropriation of an organism or other tangible biological material constitutes misappropriation of the information it contains (see 53).

secret protection. It should be noted, however, that in a fast moving area like biotechnology, the "useful life" of a trade secret may actually be quite short. Second, a trade secret does not have to be a patentable invention. Third, maintenance and enforcement are generally less expensive for trade secret rights than for patents. Fourth, competitors are not apprised of the information, in contrast to the situation with patents (see below). Fifth, trade secret protection is valuable for certain inventions that would be hard to police if patented. For example, if a product is capable of being made by many different processes, keeping secret a new process for making the product might be preferable to patenting it. Sixth, if there is doubt as to the patentability of an invention, trade secrecy is a viable alternative. Finally, certain organisms and parts thereof, such as high-expression plasmids, may be better off held as trade secrets, since they could not be reverse engineered from the products that they produce, but, if patented, would be placed in the public domain.

Disadvantages of relying on trade secrecy include the following. First, the protection exists only as long as secrecy exists. The holder of a trade secret has no rights against someone who independently discovers and uses the trade secret and has no rights against someone who may have innocently learned the secret from someone who originally obtained it improperly. Second, reverse engineering (the examination of a product by experts to discover how it was made) is a legitimate way to discover a trade secret. The structure of a gene, for example, may be determined by reverse engineering a polypeptide that is on the market. Because of the complexity of biological processes and organisms, however, most of these will not be capable of being discovered by reverse engineering of their products. Third, trade secrecy is, by definition, incompatible with the desire of most scientists to publish the results of their research. If a company wishes to attract and retain good scientists, it may not be able to rely on trade secrecy to protect their work. Fourth, there is always the chance that a trade secret will be independently discovered by another, who then obtains a patent on it. The patent holder may then prevent the holder of the trade secret from using it. Finally, the acquisition of a trade secret by a competitor through misappropriation or breach of a confidential agreement may be difficult to prevent, discover, or prove. Microorganisms are especially easy to steal, once one gains access to them, because of their small size and self-replicating nature. Further, the thief would not even have to understand exactly the valuable information contained in the micro-organisms; he *or* she has acquired the factory (i.e., the microorganism) and the ability to grow it in any amount desired.

Patent law

U.S. patent law, Title 35 of the United States Code, is designed to encourage invention by granting inventors a limited property right in their inventions. A U.S. patent gives the inventor the right to exclude all others from making, using, or selling the invention within the United States without the inventor's consent for 17 years. In return, the inventor must make full public disclosure of the invention.

The policy behind U.S. patent law is twofold. First, by rewarding successful efforts, a patent provides inventors and their backers with an incentive to risk time and money in R&D. Second, and more importantly, the patent system encourages public disclosure of technical information, which may otherwise have remained secret, so that others are able to use it. The inducement in both cases is the potential for economic gain through exploitation of the patent right.

To qualify for patent protection in the United States, an invention must meet the following requirements:

- it must be capable of being classified as a process, machine, manufacture, or composition of matter;*
- it must be new, useful, and not obvious; and
- it must be disclosed to the public in sufficient detail to enable a person skilled in the same or the most closely related area of technology to construct and operate it.

*These categories are set out in § 101 of Title 35 of the United States Code (35 U.S.C. §101). Sec. 101 is the basic section under which most inventions are patented. Patents under 35 U.S.C. §101 are often called utility patents.

Plants that reproduce asexually may also be patented under slightly different criteria.

The criteria for obtaining and enforcing patents on biotechnological inventions are quite similar in the six countries being examined in this report. The following eight subsections discuss the criteria of patentable subject matter, novelty, utility, nonobviousness, disclosure requirements, deposit requirements, claims, and enforcement in the United States in order to provide a basis for a comparative analysis of how each country's patent law will affect its competitiveness in biotechnology.

PATENTABLE SUBJECT MATTER

The categories of patentable subject matter under 35 U.S.C. $101—process, machine, manufacture, or composition of matter—are quite broad but they are not unlimited. The courts have held scientific principles, mathematical formulas, and products of nature to be unpatentable on the grounds that they are only discoveries of preexisting things—not the result of the inventive, creative action of human beings, which is what the patent laws are designed to encourage.

One of the major patent law questions arising with respect to biotechnology is whether living organisms are patentable subject matter. The U.S. Supreme Court addressed this question in 1980 in the landmark case ***Diamond v. Chakrabarty (21).*** In a five to four decision, the Court held that the inventor of a new micro-organism, whose invention otherwise met the legal requirements for obtaining a patent, could not be denied a patent solely because the invention was alive. The Court ruled that Congress had not intended to distinguish between unpatentable and patentable subject matter on the basis of living v. nonliving, but on the basis of "products of nature, whether or living or not, and human-made inventions" (22).

The U.S. Supreme Court stated that its decision in the ***Chakrabarty*** case was limited to a human-made micro-organism, leaving unresolved questions of whether eukaryotic cells or other higher organisms would be patentable subject matter. In theory, however, the ***Chakrabarty*** decision stands for the proposition that any organism is potentially patentable, because the crucial test used by the Court was whether or not the organism is human-made. As a result, eukaryotic cells, cell lines, tissue culture, and even plants are generally viewed as being patentable under 35 U.S.C. $101. The harder question is whether the U.S. Patent and Trademark Office or the courts would permit patents on higher organisms such as animals. *

There is no question, however, that virtually any other biotechnological invention would be patentable subject matter, providing that it meets the other requirements. Such inventions would include processes using micro0organisms, recombinant DNA (rDNA) molecules, subcellular units such as plasmids, methods for making these inventions, and biotechnological methods for treating human or animal disease (29). * *

NOVELTY

The statutory requirement of novelty signifies that an invention must differ from the "prior art," which is publicly known technology. Novelty is not considered to exist, for example, if: 1) the applicant for a patent is not the inventor; 2) the invention was previously known or used publicly by others in the United States; or 3) the invention was previously described in a U.S. or foreign publication or patent (35 U.S.C. f102). The inability to meet novelty requirement is another reason why products of nature are unpatentable.

Two questions are particularly relevant to biotechnology. First, how can naturally occurring substances, such as genes, plasmids, and even organisms, be patentable? Second, what actions on the part of an inventor, such as discussing the invention with colleagues or publishing a paper about the results of research, can place the invention in a public domain, thus barring patentability because the invention will not be novel?

● **The U.S. Patent and Trademark Office has stated** that it will determine questions as to patentable subject matter on a case-by-case basis following the test **set forth in** *Chakrabarty* (49).

* ● A U.S. Patent and Trademark Office official estimated that there are currently 500 genetic manipulation related patent applications pending, that the office is receiving applications at the rate of 200 per year, and that the rate is increasing (46). **These applications are classified in Class *435,*** Subclass 172 in the U.S. Patent Classification System (46). This classification is ***not*** coextensive with OTA'S definition of biotechnology.

As to the first question, the crucial element of patentability for most biological inventions in the United States, as shown in the ***Chakrabarty*** case, will be the fact that the substance was in some way changed from the naturally occurring substance by human intervention. For example, although genes and regulatory sequences may be obtained from natural sources, it is the removal of the DNA sequences from their natural habitat and their joining to other DNA sequences that provides the human-made requirement of the ***Chakrabmty*** case. Thus, it is not the sequence that is new, but the environment, such as the host or flanking DNA regions (44). *

As to the second question, it should be noted that U.S. law, in contrast to the laws of most foreign countries, provides a l-year grace period between the date of any publication by the inventor relating to the invention and the filing of a patent application, This grace period in the United States is generally viewed as favorable to the rapid dissemination of new scientific knowledge, because knowledge pertaining to an invention can be published without the inventor's foregoing the opportunity to file for a patent. Most countries other than the United States require the patent application **to have** been filed before the invention is disclosed, for example, in **a** scientific paper. This requirement is known as "absolute novelty" and will be discussed in greater detail in the section comparing and contrasting U.S. and foreign law. * *

UTILITY

The utility standard in the United States is generally not a difficult standard for an invention **to meet to** qualify for a U.S. patent. There is one potential problem, however, with regard **to** biological inventions. Since the courts have held that an invention must show some practical or commercial utility (12,32,33), certain results of research that may be very important for research purposes (e.g., **a new** DNA probe or even certain organisms) may not meet the utility standard. This problem can generally be avoided by describing some practical **use** of the invention in the patent application, even if that use will not be the one that is of ultimate commercial value to the company.

NONOBVIOUSNESS

The nonobviousness standard that inventions must meet to qualify for a U.S. patent pertains to the degree of difference between the invention and the "prior art ." An invention that would have been obvious **at the** time it was made to a person with ordinary skill in the relevant field of technology is not patentable (35 U.S.C. ~103). The U.S. patent **law** requirements for nonobviousness and novelty together represent a policy that a patent should not take from the public something that it already enjoys or potentially enjoys as an obvious extension of current knowledge.

Given the fact **that** many of the basic techniques in biotechnology are well known and straightforward to competent scientists, how can the various inventions meet the nonobviousness standard? The answer is that biotechnology is still in many respects a very inexact science. Many of the various manipulations of genetic material, for example, will give unexpected results. Difficulty in the isolation or preparation of materials and the unexpected or superior nature of results are some of the criteria that would be used to show nonobviousness.

It is interesting **to note that some scientists view** hybridoma technology **as** more straightforward than rDNA technology. If this is true, patents may be more difficult **to** obtain for hybridoma technology than for rDNA inventions, necessitating a greater reliance on trade secrets. However, there are still many problems associated with human-human hybridomas, so broad patents may be able **to** be secured for inventions in that area. (See Box D.–patents on ***Hybridoma Inventions*** for further information on patenting hybridoma technology.)

The nonobviousness requirement may present another problem for biotechnology. The rapid

● In a **companion case to** *Chakrabarty*, a lower **court, the Court of Customs and Patent Appeals (now the Court of Appeals** for the Federal Circuit), held that a purified culture of naturally occurring bacteria was patentable subject matter (3). For procedural reasons, the Supreme Court did not rule on this issue.

• *Japan provides for a limited 6-month grace period for: 1) experimentation, publication, and papers presented before scientific organizations by the applicant; z) unauthorized disclosure by third parties; and 3) displays at authorized exhibits. Otherwise, it is considered an absolute novelty country.

Box D.—Patents on Hybridoma Inventions*

Many scientists and others unfamiliar with the patent law have questioned how a technology invented by Kohler and Milstein in the mid-1970's and well known to practitioners in the field could give rise to patentable inventions. It is important to remember, however, that hybridoma technology has many technical problems associated with it—anyone who solves any one or more of those problems will likely be able to obtain a patent on that improvement in the state of the art. The following improvements, for example, would be potentially patentable (17):

- new myeloma cell lines that offer improvements over existing myeloma cell lines,
- new culture media that offer improved growth,
- new methods of fusion that offer significant improvement over those currently employed,
- new and improved selection procedures,
- new hybridomas that are more stable and consistent in the production of MAbs,
- new MAbs that react to antigens different from those that prior patented MAbs react to, or
- new methods of using MAbs whether for diagnostic kits, cell sorting, tissue typing, purification, or other uses.

There may be some problems with respect to patenting hybridoma technology. One relates to the perception that the U.S. Patent and Trademark Office is allowing fairly narrow claims with respect to hybridoma technology, particularly with regard to MAbs themselves. If this turns out to be true, it may be easy to "invent around" the patented invention. Furthermore, because hybridoma cell lines are often unstable and may change over time, there may be a problem with regard to enablement. However, this problem may be solved by freezing the cell line so that it is available to the public when desired yet not continuously replicating and possibly changing.

*See Chapter 3: The Technologies for a discussion of hybridoma/MAb technology.

development and complexity of the field will make it difficult to determine as of a given point in time what is ordinary skill or what is obvious.

DISCLOSURE REQUIREMENTS

The requirement for adequate public disclosure of an invention is designed to ensure that the public receives the full benefit of the new knowledge in return for the granting a limited monopoly to the patent holder, Thus, a U.S. patent, which is a public document, must contain a sufficiently detailed description of the invention to enable others in that field of technology to build and use the invention without "undue experimentation. " This is known as the enablement requirement. The patent also must disclose the best mode known to the inventor for carrying out the invention at the time the patent application is filed.

In the case of biological inventions, satisfying the enablement requirement is a major hurdle. Because of their complex and unknown nature, many biological inventions, especially organisms, cannot be sufficiently described in writing to allow their predictable reproducibility on the basis of that description alone. Even with fairly precise techniques such as rDNA, random events provide uncertainty as to predicting the exact nature of the final product. There is always the possibility during the manipulation of DNA fragments, plasmids, and transformed organisms that random changes have occurred, The final product may in fact be quite different from the description provided by the experimenter, even though the experimentation process itself may have been accurately described.

This problem has been dealt with for patent applications on new micro-organisms or processes involving them by permitting the microorganisms to be placed in culture depositories, where they are available to the public (31). The depository and the culture catalog number are then referenced in the patent application, and if the patent issues, the public gains access to the culture. * There is some debate over whether such things as plasmids must be deposited, because there is some question as to the reproducibility of the plas - mids on the basis of a written description alone.**

● The case law has left open the possibility of satisfying enablement in ways other than through a deposit (25,31).

* ● One of the questions raised by the patent examiner in the pending Cohen-Boyer patent application on the products of rDNA technique, e.g., plasmids, was whether the application disclosed a reproducible way to make a certain plasmid (5).

In an-y event, the enablement requirement will be one major hurdle to the patentability of higher organisms because of the logistical problems associated with depositing those organisms.

DEPOSIT REQUIREMENTS

Deposit requirements in the United States have developed by court decision and administrative action. The practice of the U.S. Patent and Trademark office has been to require a deposit to be made at a recognized depository no later than the patent application filing date **(50).** The office further requires that deposits be maintained for the life of the patent (50).

Along with the other five countries being considered in this report, the United States is party to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (14), which attempts to harmonize the deposit requirements of the signatory countries. Under the treaty, the signatory states recognize in their own patent procedures a micro-organism deposit made in another country if the deposit is made in a depository meeting the requirements of the treaty. * Thus, if the patent applicant is filing applications in several countries, only one deposit need be made. Deposits made under the treaty must be maintained for at least 30 years.

A potential problem that arises with respect to deposits should be noted. Although any valid patent must describe an invention with sufficient specificity so as to enable a person of ordinary skill in that technology to make the invention, there is a significant difference between describing an invention and actually turning it over to the other person. The know-how that is associated with the actual making and subsequent perfection of an invention clearly provides the inventor with an advantage over a competitor who must construct the invention from the description in the patent. Yet in the case of a micro-organism, the invention must actually be turned over to any competitor who desires it. In essence, therefore, the holder of a patent on a micro-organism that produces a commercially useful polypeptide such as insulin must turn his or her "factory" (i.e., the micro-organism) over to competitors. Given the current state of the technology, this situation is probably unavoidable. Possibly, however, consideration could be given to allowing various restrictions to be placed on access to the deposits.

*The American Type Culture Collection in Rockville, Md., and USDA's Northern Regional Research Laboratory in Peoria, Ill., together with five foreign institutions, currently meet the requirements (45).

CLAIMS

Claims are the precise language that define the boundaries of an invention protected by a patent. U.S. law permits a series of claims, ranging from broad to narrow, to be made with respect to an invention, so that if one or more of the claims are subsequently held invalid (e.g., for covering some of the prior art or being indefinite), the inventor may still be able to rely on a narrower invention. of course, all of the claims could be held invalid.

The scope of permitted claims will be important for biotechnology. The scope is initially determined by what the U.S. Patent and Trademark Office will accept. In any new technology, the initial inventions tend to be broad and pioneering, so broad claims are usually permitted. As time passes, however, prior art develops and new extensions of the art become more obvious. Then, the claims permitted by the Patent and Trademark Office will be narrower. The Cohen-Boyer patent on the basic rDNA technique (U.S. Patent 4,237,224) is an excellent example of a broad, pioneering invention, although some commentators have questioned its validity (7). In the case of hybridomas and MAbs, however, there is some indication that the Patent and Trademark Office is being fairly conservative from the start. The data supporting this perception are largely anecdotal, because there have been few patents issued on hybridoma technology. If the claims being allowed are more narrow, however, the value of patents on this technology would be lessened.

A recent decision by the U.S. Patent and Trademark Office, Ex ***parte Jackson (24),*** has important implications for the scope of permitted claims on micro-organisms, cell lines, and processes for producing or using them (6). The case involved the isolation and purification of three strains of bacteria that made a new antibiotic. All three strains had been deposited and referenced in the patent application. Although the Board of Appeals

of the U.S. Patent and Trademark Office upheld a claim to producing the antibiotic by using a micro-organism selected from the deposited strains (or mutants thereof), it rejected a claim to producing the antibiotic by using any micro-organism of the same species on the grounds that the claim was not enabling. Thus, the scope of the patent on the applicant process for producing the antibiotic will be limited, and others may be able to legally practice the invention by using other strains. This case, if broadly applied, may have a significant adverse impact on the incentive to patent many kinds of biotechnological inventions, because inventors may see the scope of patent protection as being too narrow.

Subsequent to patenting, the scope of the claims will be determined by Federal courts ruling in patent infringement suits. If the patent is upheld, the court has some discretion on how broadly to interpret the written claims. It will tend to interpret the scope more broadly for fundamental inventions. Sometimes the scope of the literal wording of the claims can be extended, if the infringing invention does substantially the same thing, by substantially the same means, and in substantially the same way, as does the patented invention, yet the literal wording of the claims in the patent for the invention does not cover the infringing invention (26). In such cases, the courts will interpret the claim as covering the infringing invention. This is known in patent law as the "doctrine of equivalents."

The fact that the claims define a new invention does not mean that the new invention does not infringe on a previously patented invention. For example, consider the Cohen-Boyer patent on the fundamental rDNA technique. Its existence will not prevent new applications of the rDNA technique from being patented (providing they also meet the other requirements of the patent law); however, the new inventions may infringe the Cohen-Boyer patent. Thus, for a holder of the new patent to make use of that invention, he or she may have to pay royalties to the owners of the Cohen-Boyer patent.

ENFORCEMENT

Patent infringement in the United States is defined as the unauthorized making, using, or selling of any patented invention within the United States (35 U.S.C, \271(a)). No liability for infringement exists prior to the date the patent is issued.

With respect to enforcing a patent, certain problems arise. One problem, generally not a problem for products but potentially a very serious problem for processes, is knowing whether or not an infringer is using the patent. If an unpatented product can be made by many different processes, the owner of a patent on one of those processes may have no way of knowing whether a product made by a competitor has been made by a different process or by the patent owner's process. This is a special problem for any process involving a micro-organism or cell line. To get a patent on such a process, a deposit must be made, making the microorganism or cell line available to anybody who desires to use it. For this reason, processes using such organisms are likely to be held as trade secrets unless the process is truly a major advance.

Another problem with respect to enforcing process patents granted in the United States is the fact that the patented process may be used in other countries to make the same product, which can then be imported into the United States and compete with the product made by the owner of the U.S. process patent. Although many countries would define this action as infringement of that process patent, the United States does not. A remedy for the owner of the process patent is available through an action before the U.S. International Trade Commission. If the owner of the patent can prove that the foreign activity infringes the US. process patent and that importation of the product would injure an efficiently conducted U.S. industry (or prevent its establishment), the product can be excluded from the United States (19 U.S.C. \1337, \1337(a)). This remedy has been criticized as leaving much to be desired (39). However, one commentator has pointed out many substantial advantages of go-

ing this route as compared to an action in Federal district court (13). The requirement for proving injury to an industry is not as problematical as it might seem because the International Trade Commission has held that the domestic industry may consist of only one company, the U.S. patent owner (13). Thus, the issues of whether biotechnology is an industry or whether one imported product could injure that whole "industry" would not be relevant. In fact, an International Trade Commission action is one way the owners of the Cohen-Boyer patent might enforce it against foreign users of the rDNA process.

Another problem area relevant to biological inventions has been the general attitude of the courts in the United States toward patents. Despite a statutory presumption of validity, about one-half of all litigated patents are held invalid by the courts (48). There has been a certain judicial hostility toward patents because they are "monopolies," even though permitted by the U.S. Constitution and Title 35 of the U.S. Code (29). Certain language in U.S. Supreme Court decisions, for example, refers to such "monopolies" and states that patents must be construed very narrowly and must not be upheld on "mere gadgets" (27). In the 15 years before *Chakrabarty*, the Supreme Court had not ruled in favor of a single patent applicant or patentee (29).

On the other hand, this judicial hostility appears to be changing. In some recent U.S. Supreme Court decisions, including the ***Chakrabarty*** case, the Court has upheld the patents and has used broad language to do so (20,23).

PATENT V. TRADE SECRET PROTECTION •

Patents and trade secrets are alternative and not necessarily mutually exclusive ways to protect biotechnological inventions. Companies are likely to choose between them on a case-by-case basis. In choosing, they would evaluate the following factors:

- whether there is any significant doubt that the invention can meet the legal requirements for patenting,
- whether there is the likelihood of others discovering the invention independently or through reverse engineering,
- what the invention's projected commercial life is and how readily others could improve on it if it were disclosed in a patent,
- how easily the patent could be "policed)"
- whether it is a pioneer invention,
- the cost of the related R&D and regulatory approvals,
- whether there are any plans for scientific publication, and
- what the costs of patenting are versus reliance on trade secrecy.

The first factor speaks for itself. The next two factors require difficult decisions to be made on the basis of the characteristics of the invention and the competitive environment. If research to develop a particular product is widespread and intense (as is the case with interferon), the risk of a competitor developing the invention independently provides a significant incentive for patenting. On the other hand, reverse engineering by competitors is virtually impossible for most products of micro-organisms because of the variability and biochemical complexity of microbiological processes.

The fourth factor, how easily the patent could be policed, is especially relevant for processes. Greater protection may lie in keeping a process secret, even if the microbe and the process could be patented. This is especially true for a process that is only a minor improvement in the state of the art or that produces an unpatentable product already made by many competitors. The commercial life of the process might be limited if it were patented, beause infringement would be difficult to detect and not worth the time and money to prosecute. Reliance on trade secrecy might then extend its commercial life.

Most companies would patent truly pioneer inventions, which often provide the opportunity for developing large markets. Moreover, patents of this sort tend to have long commercial lives, since it is difficult to circumvent a pioneer invention and since any improvements are still subject to the pioneer patent. Furthermore, infringement is easy to detect because of the invention's trailblazing nature. This would be true for processes also.

'This section draws on the analogous section in OTA's report *Impact of Applied Genetics: Micro-Organisms, **Plants, and Animals*** (47).

High costs for research, development, and regulatory approval of products is a factor in favor of patenting because a company will want to protect its investment. The research-oriented pharmaceutical companies have traditionally relied on patents for this reason.

The last two factors involve considerations secondary to a product and its market. obviously, any publication of the experiments leading to an invention forecloses the option of trade secrecy. Also, a company must evaluate the options of protection via either patenting or trade secrecy in terms of their respective cost effectiveness.

Plant breeders' rights statutes

Ownership rights in new varieties of plants are specifically granted by two Federal statutes: 1) the Plant Patent Act of 1930 (35 U.S.C. ~~161-164) and 2) the Plant Variety Protection Act (PVPA) of 1970 (7 U.S.C. \2321 et seq.).

The Plant Patent Act, which covers new and distinct asexually reproduced varieties other than tuber-propagated plants or those found in nature, confers the right on the patent holder to exclude others from asexually reproducing the plant or from using or selling any plants so reproduced, for a period of 17 years. Because of the impossibility of describing plants with the same degree of specificity as machines and the inability to recreate a new plant solely from a written description, this law also liberalized the enablement requirement; the description need be only as complete as "reasonably possible."

PVPA provides for patent-like protection to new, distinct, uniform, and stable varieties of plants that are reproduced sexually, excluding fungi, bacteria, and first-generation hybrids. The breeder may exclude others from selling, offering for sale, reproducing (sexually or asexually), importing, or exporting the protected variety. In addition, others cannot use it to produce a hybrid or a different variety for sale. However, saving seed for crop production and for the use and reproduction of protected varieties for research is expressly permitted. The period of exclusion is 18 years for woody plants and 17 years for other varieties.

These acts are basically consistent with an international treaty designed to provide consistency in the international protection of plant breeders' rights—the International Union for the Protection of New Varieties and Plants—known as UPOV. * UPOV has been signed by 16 countries, including all those discussed in this chapter, but not all of those countries have yet conformed their laws to it.

Until the ***Chakrabarty*** decision, the Plant Patent Act and PVPA were generally viewed as the sole source of plant breeders' rights in the United States. The ***Chakrabarty*** decision raises the possibility of protecting plants under 35 U.S.C. 101, because the essential point of the decision is that a human-made organism is a "manufacture" or "composition of matter" as those terms are used in 101. Further, there is no indication in the decision that the Plant Patent Act and PVPA preempt protection for plants.

There would be certain advantages and disadvantages of securing protection of sexually and asexually reproduced plant varieties through 101. One advantage is that more than one claim could be presented, as opposed to the single claim permitted under the Rules of Practice relating to plant patent applications (37 C.F.R. $1.164) This would allow parts of the plant to be covered as well as the whole plant. Further, a patent grant under 35 U.S,C. 101 for a new variety would provide more comprehensive protection against infringement in certain situations.

The disadvantages of proceeding under 35 U.S.C. ~101 are that other currently irrelevant sections of the patent law would come into play. For example, the Plant Patent Act (35 U.S.C. $162) significantly modifies the disclosure requirements of 35 U.S.C. $112, simply requiring that the description be as complete as reasonably possible. This would at least theoretically no longer be true. However, the use of depositories for plant material, as required for micro-oganisms, could satisfy the enablement requirement. A further potential factor is the applicability of the nonobviousness

*"The Plant Patent Act conforms, but PVPA does not. Since the United States is a party to UPOV, some changes in PVPA may be necessary. At this time, however, it is hoped that conformity can be achieved through administrative practices (45).

requirement of 35 U.S.C. $103. This test is inherently difficult for plant material.

On balance, the ***Chakrabarty*** decision is likely to provide yet another protection option which can, in certain circumstances, be very useful. For example, tuber-propagated plants such as potatoes, which are not patentable under the Plant Patent Act, would appear to be patentable under 35 U.S.C. '$101.

Comparison of U.S. and foreign intellectual property law

Much of the analysis in this section is based on the more detailed description of intellectual property law of the Federal Republic of Germany, the United Kingdom, France, Switzerland, and **.Japan** found in ***Appendix' G: Intellectual Property Law.***

Patent law

The Federal Republic of Germany, the United Kingdom, France, and Switzerland, along with seven other Western European countries, are signatories to a treaty that creates a European patent system. That treaty, known as the European Patent Convention (EPC), went into force on October 7, 1977. 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, become 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. Enforcement, however, is handled by the individual 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. The following discussion compares the patent law of the EPC countries and Japan with that of the United States.

PATENTABLE SUBJECT MATTER

One of the most difficult problems facing the owners of biological inventions is the inability of the law to respond rapidly enough to keep pace with the development of the technology. This is especially a problem in the case of the law's definition of patentable subject matter. Questions about what constitutes patentable subject matter create a significant degree of uncertainty for owners of inventions.

One of the basic decisions to be made by owners of inventions is whether to maintain their inventions as trade secrets or to attempt to protect them by patents. An intelligent decision is nearly impossible when one does not even know which basic subject matter is patentable under the laws of particular countries. In the United States, the trade secret route can still be selected in the event that no patent protection is ultimately secured. In most foreign countries, including the United Kingdom, France, the Federal Republic of Germany, and Japan, however, pending applications are published before it is known whether patenting will be possible, thereby providing complete and enabling disclosure to the public, including samples of any deposited micromganisms necessary to carry out the invention. Such publication usually occurs 18 months after the application is filed. This situation effectively precludes reliance on trade secrecy once a patent application is filed. As a result, there exists in many foreign countries today considerable disincentive to seek patent protection for certain types of biological inventions, particularly those involving basic genetic procedures and the resulting products. However, with respect to the five

● **A proposed European Community Patent** Convention **would take the** EPC **one step further** by providing **for a** single **patent** covering **the entire European** Economic **Community,**

foreign countries under study here, much of the uncertainty surrounding subject matter patentability of biotechnological inventions has been resolved.

This uncertainty in many foreign countries may indirectly discourage U.S inventors from filing for patent protection in the United States, since there is no way available at present to confine within the United States the culture deposit samples which must be made available once a U.S. patent issues. While enabling disclosure theoretically is communicated upon issuance of a U.S. patent to all countries, regardless of whether corresponding protection is available or is actually sought in those countries, it is only in connection with many biological inventions that an applicant is required to provide also the physical means to carry out the invention, i.e., a self-replicating organism, which in many instances is a "factory" capable of carrying out the invention.

One important aspect of this problem of uncertainty in the definition of patentable subject matter is the uncertainty of classification of certain types of biological inventions. It is not clear in the case of certain lower organisms, for example, whether they are to be classified as plants, animals, or something else (e.g., protista) (see, e.g., 15,19). ***Fortunately,*** in the United States, it seems to be a matter of choosing between multiple options for protecting such subject matter by either utility patents or plant patents, but in most other countries, plants and animals are explicitly excluded from patentability. Thus, a definition may be determinative of patentability.

As a result of the 1980 U.S. Supreme Court's decision in the ***Diamond v. Chakrabarty*** case, the U.S. definition of patentable subject matter is very broad. It is broader than that under the EPC or any of the national laws of the five other countries being examined in this assessment. In contrast to the United States, the EPC, which has a very liberal definition of patentable subject matter, excludes methods for treatment of the human or animal body by surgery or therapy and diagnostic methods. Also, the EPC excludes plant and animal varieties and biological methods for producing them, which are apparently not excluded by ***Chakrabarty.*** In all other respects pertaining to biological inventions, the United States and EPC appear to permit patenting of the same general classes of subject matter. France, Switzerland, the United Kingdom, and the Federal Republic of Germany follow the EPC, except Switzerland does not allow patents on micro-organism themselves.

Japan's definition of patentable subject matter is essentially coextensive with the definition of the EPC, excluding processes in the fields of medicine, diagnosis, therapy, and pharmacology in which the human body is an indispensible element. However, certain microbiological inventions could be excluded from patentability in Japan if they are "likely to injure the public health." The situation with respect to plants and animals in Japan is unclear.

NOVELTY

U.S. law requires the patent application to be filed by the inventor. If two different applicants happen to have the same invention, the patent will issue to the one who invented it first. Hence, the U.S. system is called a "first-to-invent" system. The laws of the other five countries, in contrast to U.S. law, permit someone other than the inventor (e.g., the employer) to file the patent application. If there are two applications for the same invention, the patent will issue to the applicant who filed first. These countries thus have what is called a "first-to-file" system. The combination in the United States of a first-to-invent system with the provision of a l-year grace period between the date of any publication relating to an invention and the filing of a patent application makes the U.S. system fundamentally different from nearly all foreign systems, which are generally first-to-file systems are characterized by absolute novelty (i.e., allow no grace periods).

This difference manifests itself in connection with prior disclosures by the applicant. Under US, law, the general rule is that a disclosure of an applicant's own invention cannot be used to prevent the applicant from obtaining a patent, unless the disclosure satisfies the requirements of one of the statutory bars under 35 U.S.C. $102 (18). For example, consider the following types of possible disclosure by an inventor of his or her own work:

1. Communicating with colleagues by telephone, letter or in person;

a. under expressed confidentiality;
b. with no indication as to confidentiality; or
c. under expressed nonconfidentiality.

2. Delivering a paper at a conference or seminar, orally only.
3. Delivering a paper at a conference or seminar, both orally and with a disseminated written text.
4. Submitting a paper for publication.
5. Submitting an abstract prior to a conference to the conference promoting organization.

Under U.S. law, items 1, 2, 4, and 5 would not bar patentability. * Item 3 will become a statutory bar 1 year after the paper is disseminated in some tangible form, assuming the disclosure was enabling.

Under the laws of the four Western European countries, items 2 and 3 would prevent the granting of a patent if they occurred before the earliest effective filing date (e.g., before a U.S. applicant filed a patent application in the United States which will later serve as a basis for claiming the right of priority in corresponding foreign applications). * * Items 4 and 5 would normally not bar a patent, assuming that the paper and/or abstract were not disseminated to members of the public, (e.g., conference attendees) prior to the actual date the patent application was filed. This is based on the implied confidentiality under which submissions of this type are usually handled by publishers. Similarly, the concept of expressed or implied confidentiality prevents items l(a) and l(b) from constituting prior art under German law concepts, which commentators believe will apply to the EPC and other European countries (11). It appears that even item I(c), in and of itself, does not necessarily constitute prior art under German principles, inasmuch as such a nonconfidential disclosure must be available to an ***unlimited*** number of persons (43). If the disclosure were limited to the colleagues contacted and not otherwise made freely available, it would not defeat novelty of a subsequently filed application. It is too early to tell how EPC law will develop on this issue. The same can be said for the United Kingdom, where introduction of the EPC novelty standards represents a significant change from prior law and practice.

The Japanese law provides a limited 6-month grace period for publications and papers presented before scientific organizations. Thus, items 1, 4, and 5 would not bar patentability, and items 2 and 3 would bar patentability after 6 months.

It must be noted that the above discussion regarding bars to patents because of lack of novelty is predicated on the assumption that the disclosure is enabling. If the disclosure is ***not*** enabling, even a published paper about the invention would not bar patentability.

Because of the different approaches with respect to novelty, the US. patent law provides a competitive advantage in that scientific informa - tion can be quickly disseminated in the United States without forgoing patent rights, if the application for a patent is filed within a year. This advantage is qualified by the fact that the inventor who also wishes to file abroad cannot publicly disclose the invention until the priority application is filed. The case of the Cohen-Boyer patent on the rDNA technique is a well-known example of a case in which the inventors were able to obtain a U.S. patent, even though they had published papers about the techniques, but were unable to file for foreign patents because of the absolute novelty requirement in other countries. The probable result will be a substantial loss of income from foreign royalties.

UTILITY

The U.S. patent law's requirement for practical utility differs slightly from the requirement of European and Japanese law for industrial applicability. The U.S. utility doctrine has been criticized by the American patent bar, but has not proved to be a major obstacle for industry (45). It has undoubtedly disadvantaged some researchers and simultaneously deprived the public of

● **If a paper** or **proceedings of conference were published, however, then the inventor would be barred if he or she filed a patent application more than 1 year after the date** the **proceedings or paper were published.** Also **if** the **invention were sufficiently disseminated so that it was deemed to be "in public use, " then the int'enter would** be **barred by sec.** 102(b) **from patenting** it **after** the **expiration of the** 1 **-year grace period.**

•* Under **the** Paris Union **Convention, to which a]] six competitor countries subscribe, applications filed in any country within** 12 **months** of **the first filing in a member** country have, **as their** *effective* filing **date, the filing date of the first application.** This **is** known **as** the "right **of** priority."

prompt disclosure of research on, for instance, new pharmacological compounds and processes that do not yet have an established utility (45). In some cases, effort has undoubtedly been wasted in establishing trivial or unimportant yet "practical" utilities for such inventions in order to satisfy the U.S. Supreme Court's definition (45). This problem will affect researchers in biotechnology to some extent, particularly those working with pharmaceuticals.

On the other hand, the foreign systems present a different problem of "utility. " They exclude method inventions in the field of therapeutic or diagnostic treatment, at least those involving treatment of humans, as not being part of "industry. " Thus, certain types of biological inventions (e.g., monoclinal antibody diagnostic assays) will not be patentable in EPC member countries or possibly in Japan, although patent protection can be obtained for them in the United States. This is, in most cases, not a serious obstacle, since patent protection is not precluded for the materials that are used in the excluded methods or the products of those methods.

DISCLOSURE REQUIREMENTS

U.S. disclosure requirements are stricter than those of the EPC and Japan. The U.S. law requires (35 U.S.C. 112):

- a written description of the invention,
- enablement both with respect to "how to make" the invention and also with respect to "how to use" the invention, and
- a disclosure of the best mode known to the inventor for carrying out the invention as of the time of filing.

As to the basic enablement standard, however, U.S. law does not differ substantially from the foreign laws. Under the U.S. law, the test of enablement is whether the invention can be carried out by a person of ordinary skill in the art without "undue experimentation" (30). This is another way of stating the requirement for "reproducibility" which is fundamental to European law.

As previously mentioned, compliance with the enablement requirement creates serious difficulties for many biological inventions, because such intentions may have been produced by random mutation and selection or another procedure that cannot be repeated with the certainty of obtaining the same results. The solution that has been adopted essentially worldwide is to permit a deposit of the appropriate biological material in a depository, from which samples will be made available to the public.

The Federal Republic of Germany's requirement for reproducibility raises additional obstacles to patenting a micro-organism itself. It requires that a patent application describe a repeatable procedure for reproducing with certainty the deposited organism apart from the deposit itself (i.e., "from scratch" so to speak) before a patent can be granted on the organism per se. This is not required if one claims only a method of using such a deposited organism. Thus, this requirement, in effect, could preclude patents on many micro-organisms.

Neither the EPC countries nor Japan specify a best mode requirement in their respective laws. In the United States, the best mode requirement arguably requires the best producing micro-organism strain to be deposited, but this issue is not resolved.

The written description of the invention requirement under U.S. law is not articulated as such in foreign laws, but a requirement similar in principle is applied in some situations under the laws of most countries.

DEPOSIT REQUIREMENTS

At present, uncertainty regarding the deposit requirements exists in many countries. The circumstances under which a deposit is necessary are not clearly spelled out. Moreover, before receiving a substantive examination on this question in the EPC, for example, the patent applicant must take action that has the effect of making the deposit, and also access thereto upon publication of the application, irreversible. In the United States, the same basic uncertainty exists, but the applicant need not make a commitment until after substantive examination is completed. *

*As a practical matter, however, if patent protection is sought in other countries, this irreversible effect will have taken place already, prior to conclusion of the examination in the United States because of the 18-month publication practice in other countries.

The United States does not have any explicit deposit requirements in the patent statute or rules thereunder. For deposits necessary in order to comply with the enablement requirement, however, certain requirements for the deposit have been developed by aciministrative action (SO) and court decisions.

As far as timing and location of deposit, the U.S. practice is basically consistent with the practice most countries, i.e., the deposit is to be made no later than the patent application filing date and at a recognized depository (so). The United States does not have a specific list of recognized depositories and therefore maintains more flexibility than the EPC and certain national offices that do have such lists. Of course, the United States also recognizes deposits meeting the requirements of the Budapest Treaty.

The U.S. Patent and Trademark office has required only that deposited cultures be maintained for the life of the U.S. patent (although any deposit made under the Budapest Treaty must be maintained for a minimum of 30 years). The EPC and many European countries have opted to apply the longer period of the Budapest Treaty to any deposit made in accordance with national law. This will require additional costs for the applicants in those countries.

Samples of deposited micro-oganisms become available to the public under U.S. practice at the time the patent issues, after which time no restrictions on access are permitted. The situation in the United States is quite different than that in the EPC countries and Japan. In the EPC countries (except for Switzerland) and Japan, patent applications are published approximately 18 months after the effective filing date. Such publication, which also makes the deposit publicly available, may place foreign applicants at a disadvantage.

On the other hand, under many foreign systems, including the EPC, the patentee is entitled to maintain certain limited restrictions on those receiving samples of the deposited culture throughout the life of the patent. The restrictions also apply to cultures derived from the original one (EPC Rule 28(6)). The Federal Republic of Germany also allows territorial restrictions to be placed on deposited micro-organisms.

potential problems exist in the present deposit system as a result of import/export restrictions imposed by countries. In one case, a German applicant was unable to perfect a deposit in a US. depository (one of two in the world which accepted his type of cell line) within the 12-month priority period because of health-oriented import restrictions imposed by the United States (9). It is also possible that a patentee could lose his or her rights entirely in a given country if that country imposed restrictions on the import of samples of a culture in a foreign depository that is otherwise recognized by its patent office. The same result could occur if the country in which the depository is located refuses to permit export of samples of the deposited culture. In the latter instance, however, the Budapest Treaty permits a second deposit to be made in another depository without loss of deposit date.

CLAIM PRACTICE

Claim practice in the United States is extremely liberal and is regulated primarily by the requirement for definiteness contained in the second paragraph of 35 U.S.C. $112. This fact, together with the fact that patentable subject matter in the United States is generally less restricted than in most other countries, results in an very broad freedom for an applicant to claim his or her invention in a U.S. patent application.

There is a dearth of experience with claims directed to the relatively new inventions of biotechnology, and the EPC itself is too new for any significant precedent. Existing precedent primarily involves processes for the use of micro-oganisms.

Under U.S. practice, biological inventions can be claimed in many different ways. In addition to process claims directed to methods of genetic manipulation, the products thereof can be claimed with regard to their structure, or if their structure is not known, with regard to their chemical and/or physical characteristics or in terms of the process steps for preparing them. Despite this flexibility, however, the previously discussed ***Jackson*** case (24) indicates that the U.S. Patent and Trademark Office may impose significant limitations on the breadth of claims.

Some of the patent offices in foreign countries have taken positions similar to that taken in the ***Jackson*** case. Switzerland and Japan have refused to grant claims that are broader than the specific microorganisms disclosed in the application and deposited (Swiss Patent Ordinance, Section 15.15.3, May 12, 1980; Japanese Examination Guidelines).

There is little reported precedent regarding judicial interpretation of claims pertaining to biological inventions in infringement cases. Nevertheless, one can extrapolate from general principles of claim interpretation in the various foreign patent systems. The law in most countries provides for application of the doctrine of equivalents in some form, although in some countries, including Japan, the scope of equivalents is apparently very limited. As a general rule, it can be said that the scope of equivalents must be determined on a case-by-case basis, depending on factors such as the degree of unpredictability of the technology (i.e., equivalents must be obvious to persons of ordinary skill) and the degree of advance which the claimed invention exhibits over the "prior art ." The more unpredictable the subject matter, the smaller the scope of equivalents, whereas the more pioneering the invention, the broader the scope of equivalents. Biological inventions typically involve highly unpredictable phenomena; thus, claims are likely to be narrowly interpreted.

Even if it is assumed that a reasonable degree of equivalents will be given for biological inventions, the next problem is to determine what constitutes an equivalent. No precedent is available, and, of course, the determination will be made on a case-by-case basis. It would seem that good arguments can be made to the effect that closely related strains of the same species can be looked on as equivalents, that different species normally would not constitute equivalents, and that mutants of the basic strain would, in most instances, be expected to have equivalent properties to the basic strain (see 8).

ENFORCEMENT

The United States, the four European countries, and Japan define patent infringement in similar ways. The major difference is that, unlike the other countries, the United States does not grant extraterritorial effect to process patents by defining as infringement the importation of a product made by the patented process without the authorization of the patent owner.

The United States grants the basic remedies of injunction and monetary damages for infringement (35 U.S.C. $283, $284), as well as reasonable attorneys' fees to the prevailing party in exceptional cases (35 U.S.C. $285). The foreign countries provide for similar remedies. There are no criminal penalties provided under the U.S. patent statute, contrary to many foreign patent laws.

Enforcement of patents claiming biological inventions involves unique problems. The first is simply identification of infringing activity. Many of the products will be unpatentable for lack of novelty and will be manufactured in small quantities. Thus, it will be difficult to determine if a competing product infringes one's patented process. In addition, strains of micro-organisms can be altered through mutation and other modification techniques to produce different organisms that possess the same basic characteristics of the protected organism.

It may prove to be an essential, or at least important, element of the case for the patentee to establish that the alleged infringer actually derived his or her organism from a sample obtained directly or indirectly from the culture deposit of the patentee's organism. Without adequate controls on the access to samples of deposited strains, proof of this fact will be extremely difficult.

Proving the identity and equivalence of the patented microorganism with an allegedly infringing microorganism can also present difficult problems for the present state of this technology. The technology is still sufficiently undeveloped that much room exists for honest differences of opinion among experts. Most questions of infringement will probably turn out to be a battle between the respective parties' expert witnesses, until more objective criteria are established.

Trade secret law

Of the countries considered in this assessment, the Federal Republic of Germany seems to have

the strongest statutory system for the protection of proprietary information, and its courts are most consistent in enforcement of those statutes. Switzerland's system, which closely resembles West Germany's, has also been very effective in protecting such information. However, Swiss law does not recognize as trade secrets the secrets held by professors, scientists, and others not engaged in a business (45). This could affect the exploitation of commercial rights by educational institutions in Switzerland.

The United States and the United Kingdom appear to be slightly less effective than the countries just mentioned in protecting proprietary information. The British courts emphasize the '(confidential" over the "secret" aspects of such information. Breaches of confidence are therefore not tolerated, regardless of whether the particular information misappropriated fits within a preestablished "trade secret" category. The U.S. courts often overlook the breach of obligation aspect of misappropriation and concentrate on determining whether or not the information qualifies as a '(trade secret. " As a result, misappropriators of confidential information are sometimes held not liable in the United States, whereas they would be held liable for the same activity in the United Kingdom (45). Nevertheless, U.S. courts have shown much greater flexibility than their British counterparts in fashioning remedies that prevent the use of misappropriated information. Furthermore, U.S. law provides for criminal penalties in addition to the usual civil remedies provided for under U.K. law. Finally, the sheer mass of successful trade secret cases, including favorable rulings from the U.S. Supreme Court in the ***Kewanee*** case (38) and in ***Aronson v.*** **Quick point (4),** indicates that the United States is probably more effective than the United Kingdom in safeguarding such information (45).

France does not have as strong a system for protection of proprietary information as the United Kingdom or the United States. French courts have been rather restrictive in defining the types of information that may receive protection and more protective of the employee who leaves with the employer's confidential information than the courts in other industrialized countries (45).

The protection of proprietary information in Japan has been improving over the last two decades, but still is not on a level with the protection in the United States or the major European countries. As Japan continues its development from a technology-importing country to a technology-generating country, further progress in this area may be expected (45).

Plant breeders' rights

CHOICE OF TYPE OF PROTECTION

A breeder of asexually reproduced varieties of plants in the United States will normally proceed under the Plant Patent Act, However, 35 U.S.C. $101 may provide a viable option. Although additional disclosure requirements for asexually reproduced plant material will be required (e.g., the deposit of plant material in a satisfactory depository), this is not an onerous burden. Moreover, with the depository, there is the additional advantage that the patented plant material will be available during the life of the patent for comparison purposes with any alleged infringing varieties. The public would also be able to practice the invention when the patent expired.

For sexually reproduced plant varieties, the principal advantages of proceeding under 35 U.S.C. $101, as opposed to PVPA, are the substantially reduced costs of filing a patent application (as opposed to an application under PVPA)* and the possible increased protection afforded by the patent as opposed to the protection certificate issued pursuant to PVPA. Moreover, whereas numerous judicial decisions have been rendered under the patent statutes, judicial interpretation of PVPA is relatively limited.

In the United Kingdom, the Federal Republic of Germany, Switzerland, France, and Japan, a single statute covers both sexually and asexually reproduced plant varieties. As previously noted, protection is in the form of protection certificates rather than patents. Therefore, there is no choice of the type of protection obtained in these countries.

"The cost of filing an application under PVPA is $1,000, as compared with the cost of filing a utility patent application ($150 for small entities and $300 for others).

LIMITATION ON PROTECTABLE VARIETIES

In the United States, only tuber-propagated plants or plants found in an uncultivated state are excluded from protection under the U.S. Plant Patent Act. As a practical matter, this exclusion affects only the Irish potato and the Jerusalem artichoke. All other plant varieties that can be propagated true to type through asexual reproduction can be protected. Similarly, under PVPA, only first-generation hybrids are excluded, and all other varieties otherwise meeting the act requirements can be protected.

In most countries other than the United States, by contrast, the number of specific genera or species that can be protected is restricted. The 1978 UPOV Text requires only a very limited number of designated genera or species for a country to comply with the provisions of the text. Thus, the protection provided in the European countries and Japan is relatively limited when compared with the all-encompassing protection provided by the U.S. Plant Patent A& 'and PVPA'.

EFFECT ON COMPETITIVENESS

With respect to plant breeders' rights, U.S. law provides a competitive advantage over the other countries. The scope of protection is much broader in terms of the tvpes of varieties than can he protected, and U.S. law provides the additional option of using 101 of the patent law (35 U.S.C. $ 101).

Evaluation of effectiveness of intellectual property law to promote the development of biotechnology

United States

U.S. patent law embodies a number of pro-innovation features: a "first-to-invent" system coupled with a l-year grace period; secrecy of the invention subject matter until grant of the patent; and, as a result of the latter, no requirement for owners of biological inventions to grant access to deposited cultures until after protective rights have been established. These features provide incentive for owners of biological inventions to utilize the patent system, thereby making their inventions known to the public to aid further developrnent. They also provide a sufficient period of time for the patentee to develop a leading position in the technology before being forced to hand over his or her enabling disclosure (including means for immediately practicing the invention, in the case of culture deposit samples) to competitors, both domestic and foreign. The "first-to-file" systems in the other competitor countries do not provide these advantages to applicants.

Another strength of the U.S. system is the choice of protection routes it now offers to inventors. Developers of new varieties of plants can now choose between the special plant pro ection provisions of the law and the possibility of ob - taining a utility patent.

The 1980 ***Chakrabarty*** decision has far g reater significance than merely holding that living organisms constitute patentable subject matter under U.S. law. It, together with other recent cases, represents the first truly positive pronouncement in many decades from the U.S. Supreme Court regarding the role and value of the patent system in promoting and maintaining technological competitiveness of U.S. industry (37,45).* This should have an effect on the way in which the lower courts will treat patents in the future. In addition, creation of the new Court of Appeals for the Federal Circuit should provide uniformity and consistency at the appellate level, as well as a body of law that is well informed and respected by those whom the patent laws serve. The important role of trade secret protection has been reaffirmed by the Supreme Court in its 1974

*Justice Jackson was prompted to state in his dissenting opinion in *Jungerson v Ostby & Barton Co.* (35) that: "The only patent that is valid is one which this Court has not been able to get its hands 01]. "

Kewanee decision (38). Finally, the United States has responded to the needs of plant breeders of asexually reproduced varieties by adhering to UPOV, and conformity between UPOV and the Plant Variety Protection Act of 1970 involves only a matter of the time to necessary reconcile minor language differences. With these positive developments, the intellectual property law of the United States may be viewed as entering a period of unprecedented strength and vitality (45). It should play an important, positive role in the development of biotechnology in the United States and thereby aid the international competitiveness of U.S. companies.

There are also several weaknesses in the U.S. system. One is that the patentee is not permitted to maintain sufficient control over samples of deposited cultures. A second is that the U.S. system provides less protection for process inventions than foreign systems, because the U.S. system allows competitors to practice a patented process invention outside the United States (e.g., in a jurisdiction where patent protection may not be available) and import the product into the United States, thereby lowering the value of the U.S. process patent. This may prove to be particularly relevant to the field of biological process inventions, especially those inventions in connection with which the patentee is obliged to provide to competitors with a culture sample. The U.S. process patent holder has a remedy in the form of a proceeding before the U.S. International Trade Commission, but its usefulness has been questioned.

Foreign countries

It would appear that the United Kingdom, the Federal Republic of Germany, Switzerland, France, and Japan have provided adequate incentives under their intellectual property laws for development of biotechnology. All provide reasonably broad definitions of patentable subject matter, and most protect plant varieties, even though these are generally excluded from patent protection. Animal husbandry does not enjoy such widespread possibilities for protection. Trade secrets are adequately protected.

Some disadvantages or disincentives for the development of biotechnology can be seen in the rigid manner in which many of these countries approach the subjects of disclosure requirements, reproducibility, and culture deposits. In Switzerland and, to a large extent in the Federal Republic of Germany, micro-organisms per se are not protectable. This may not be a serious problem, at least not at this stage of the technology, in view of the other ways in which an invention can be claimed (e.g., as a process using the micro-organism). The practice in Europe and Japan of requiring access to deposited cultures upon the publication of unexamined applications can be viewed as a disincentive, and it may foster a greater reliance on trade secret protection. This could restrict the flow of information and thereby retard the development of the technology.

Findings

Although there is a large degree of uncertainty in most countries over what kinds of biotechnological inventions can be patented, much of this uncertainty has been resolved in the United States, the United Kingdom, the Federal Republic of Germany, Switzerland, France, and Japan. Of the six countries, the United States has the broadest interpretation of patentable subject matter for biotechnology. The EPC has adopted a broad interpretation of patentable subject matter in the field of microbiology, even though plant and animal varieties are excluded from patentability. This broad interpretation will make it possible to patent under the EPC most of the technology dealing with the techniques of genetic manipulation. The EPC has affected or will ultimately affect the law of the Federal Republic of Germany, the United Kingdom, France, and Switzerland. Switzerland now diverges from EPC practice, however, by not permitting micro-

organisms per se to be patented. A major departure from U.S. law under the EPC and in Japan is the exclusion from patentability of therapeutic and diagnostic methods.

Japan appears to be moving in the direction of providing significant patent protection for biotechnology products and processes. One possible obstacle, however, is that Japan has strict health and safety guidelines regarding genetic research, which may bar patenting of genetically manipulated organisms viewed as hazardous,

The concept of utility in the patent laws of most foreign countries is based on industrial (including agriculture) applicability, which differs in interpretation from the utility standard in the United States. In countries with the former concept, including the five foreign countries discussed in this chapter, even products and processes of scientific research satisfy the utility requirement, as long as the basic endeavor falls into the broad category of industry; however, therapeutic and diagnostic methods do not. In the United States, certain chemical products and processes of research interest only are considered not to satisfy the utility requirement. The fact that utility under U.S. law includes utility in the therapeutic and diagnostic fields, however, helps U.S. competitiveness in biotechnology.

The four European countries studied here have an absolute novelty standard, with no grace period for either oral or written disclosures of an invention by the inventor before the date he or she files an initial patent application covering the invention. The United States has a l-year grace period, and Japan has a limited 6-month grace period for presenting scientific papers before filing a patent application. In all of the countries, the novelty defeating disclosure must be enabling. Thus, the notion that ***any*** disclosure before filing a patent application will bar patentability is incorrect.

Most countries have a disclosure standard for inventions based on the concept of enablement. This standard typically includes an aspect of reproducibility, i.e., an invention must be repeatable with a fair degree of certainty and the results must not be merely randomly achievable. Particular problems in satisfying the disclosure standard have been encountered up until now in connection with many biological inventions. This situation has led to the practice of requiring a culture deposit of new micro-organisms used to carry out an invention or forming the subject matter of the invention. The Federal Republic of Germany has refused to grant patent protection on micro-oganisms themselves in those cases where disclosure of a reproducible method for producing the micro-organism cannot be given apart from a culture of the micro-organism itself.

In those countries that publish unexamined patent applications (all but the United States and Switzerland of the six competitor countries), a serious problem for owners of biological inventions is the fact that deposited cultures can become publicly available before any patent rights are granted. Although the access to deposited cultures usually is granted with some safeguards in the form of assurances given by the recipient, these safeguards often do not adequately protect the valid interests of the technology owner (e.g., they usually are not geographically limited or do not restrict the activities of the recipient to only experimental use). In fact, it may be desirable to have some restrictions on access even after the patent grant, in view of the fact that the patentee must furnish a “working model” of the invention, which patentees in other fields are not required to do.

Because of the nature of biotechnology, special problems are faced by patentees in the enforcement of their rights. Apart from the general problems of policing for infringement, the possibilities for disguising the use of a biological invention by genetic manipulation will present difficult questions of law and fact. The law and practice of claim interpretation in this field are in their infancy. In the present state of the technology, it is likely that patent-granting authorities generally will limit claims to the specific organisms or parts thereof disclosed in patent applications.

All of the countries studied provide some element of legal protection for trade secrets. Most aspects of biotechnology lend themselves to protection via the trade secret route, and owners of such technology may rely on trade secrets when patent rights are uncertain or when they judge

trade secrecy to be more advantageous in a particular case.

With the major international and national efforts regarding plant variety protection, culminating in the 1978 UPOV treaty, there is a trend toward providing such protection without requiring satisfaction of any enablement standard. The nature of the protection for plant varieties is different from traditional patent protection in that it protects basically against derivation and copying.

The U.S. intellectual property law system appears to offer the best protection for biotechnology of any system in the world. In general, it appears that the United States offers protection for broadest scope of biological subject matter, especially because of the 1980 ruling by the U.S. Supreme Court in the ***Diamond v. Chakrabarty*** case ***(21)*** that the inventor of a microorganism could not be denied a patent solely because the invention was alive. The United States also offers some of the best procedural safeguards for inventors, including the l-year grace period and no publication of the patent application before patent grant. In addition, the United States offers a choice of protection to plant breeders. Finally, the trade secrecy protection "offered in the United States is as good as that offered in most countries, with the exception of the Federal Republic of Germany and Switzerland.

Issue and options

ISSUE: How could Congress improve U.S. competitiveness in biotechnology by strengthening U.S. intellectual property law?

Option 1: Pass a statute specifically covering living organisms and related biological inventions,

The advent of the new biotechnology has raised questions in the United States regarding what inventions will be patentable, under what conditions, and what the scope of protection will be. Although the ***Diamond v. Chakrabarty*** case in 1980 answered in the affirmative the basic question of whether Iiving organisms would be patentable, other questions remain.

A statute specifically covering living organisms and related materials could help resolve this uncertainty. Greater certainty would allow companies to plan their R&D and marketing strategies better and in some cases would lower the financial risks involved. The result should be increased innovation. The alternative is to rely on case-by-case developments in the U.S. Patent and Trademark Office and the courts. Patent litigation is extremely expensive and may be unaffordable for small, new biotechnologgy firms.

Another argument in favor of a special statute is that it could help patentees to secure better ownership rights in biological inventions. The existing U.S. patent law was developed primarily for inanimate objects and processes. Living organisms are fundamentally different. Unlike a machine, a living organism reproduces itself and occasionally mutates during its lifetime. Furthermore, a living organism is extraordinarily more complex than any machine. Although the inventor of the most complex machine knows all of its parts and understands completely how it functions, no one knows all of the components of the simplest micro-organism or understands completely how it functions. Finally, many biochemical pathways in an organism are not unique to that organism; because there are many different ways to produce a product, a patent on one of the ways may provide only limited protection. In the case of biological inventions, therefore, there may be problems in meeting the enablement and written description requirements, in securing an adequate scope of protection for inventions, and in policing for infringement.

The complexity of living inventions will make it difficult to fully describe them, Although depositing a microorganism in a culture collection may circumvent these difficulties with regard to enablement, it may be of little help in establishing novelty and the bounds of patent protection. Mi -

crobial taxonomy is an imprecise art. Micro-organisms have different characteristics in different environments, and taxonomists often disagree on their classification and description. Thus, it may be impossible to distinguish sufficiently a micro-organism for patent law purposes from similar ones created by other inventors or from ones existing in nature.

The fact that organisms reproduce may require a change in the definition of infringement. The law currently defines infringement as the unauthorized making, using, or selling of the patented invention. If someone took a patented organism from a public depository, reproduced it, and gave it away to many users, would this be infringement? One could argue that the person did not "make" the invention.

The fact that organisms mutate may cause problems with respect to the scope of the claims and infringement, For example, if a patented organism subsequently mutated, it might no longer be within the scope of the claims. Also, if the deposited organism is the standard against which infringement is measured, a patent holder may have difficulty enforcing the patent if the organism mutated after it had been deposited. On the other hand, culture deposits generally are preserved by freezing, so mutations may not be much of a problem.

Finally, there is the problem of adequately protecting a product that can be made many different ways, only some of which may be known at the time the patent application is filed. For example, because of the degeneracy of the genetic code, a particular protein can be made by various base sequences. Claiming a particular sequence will provide insufficient protection, and claiming the protein will not help if the protein is not novel. Claiming the novel organism is one solution, but others can easily construct different organisms to produce the same product.

These problems have been addressed in PVPA (and to a lesser extent in the Plant Patent Act), which could be used as a model. For a plant variety to be protected under PVPA, for example, it must be distinct, uniform, and stable. The definitions of these terms embody the concept that it is necessary only to know the important characteristics of a new plant variety in order to distinguish it from others and that only these characteristics need to be stable through succeeding generations. In addition, PVPA defines infringement to include unauthorized reproduction. If this approach were taken, the plant acts could be subsumed in the new statute.

There are several arguments against this option. First, any new technology raises questions about the scope and nature of patent protection, and many of these will only be able to be resolved on a case-by-case basis rather than by statute. Second, most patent attorneys argue that the patent laws are flexible enough to accommodate any new technology, including biotechnology. Third, despite the possible limitations in applying the patent law to living organisms, utility patents actually may provide the patentee with the greatest degree of protection when compared to the protection provided by a statute like PVPA. One of the principal reasons is that a multiplicity of claims is permitted for utility patents, which could cover components of organisms, whereas just the plant itself (and its seeds) is covered by a plant variety protection certificate. Fourth, many experts would argue that since the ***Chakrabarty*** case resolved the fundamental issue—the patentability of living organisms—there is no need to undertake the major effort needed to pass legislation to solve more minor problems. In addition, since there is some degree of public sentiment against patenting living organisms, the fundamental issue also would be raised again. Finally, a new statute would create its own new issues and questions of interpretation.

Option 2: Allow patentees to place restrictions on micro-organism cultures supplied to third parties.

U.S. patent law requires complete and enabling disclosure of an invention in order to place it in the public domain. In the case of patented micro-organisms, the patentee is in effect required to turn over more than his or her invention—the micro-organism is virtually a complete "factory" ready to begin production. For this reason, inventors may be more inclined to rely on trade secrets than on patents, and the public will not gain the benefits of the new knowledge

embodied in their inventions. This problem is even greater for process patents involving micro-organisms, which are difficult to police. Reasonable restrictions on micro-organism cultures supplied to third parties, designed not to prevent public access to the culture deposits but to prevent patent infringement, would be consistent with the aims of the U.S. patent system. For example, restrictions might be placed on how the organism is used and subsequent transfers of the organism. The other countries surveyed, particularly the Federal Republic of Germany permit certain restrictions on culture deposits.

A drawback to the option might be that the restrictions could hinder the dissemination of information, one of the fundamental goals of the patent law. However, those who support such restrictions argue that they can be devised so as not to hinder the dissemination of information yet prevent infringement, another important goal of the law.

Option 3: Amend section 271 of Title 35 of the United States Code to define as infringement the importation of a product made outside the United States by a process patented in the United States without the authorization of the patent owner.

The four Western European countries and Japan grant extraterritorial effect to their process patents in the way that is envisioned by this option. Although U.S. law provides a different remedy to the situation—an action for unfair competition before the International Trade Commission—many attorneys believe this remedy leaves much to be desired. This option would strengthen the patent system by providing an additional way for patentees to protect their rights. Although the effect of this option would not be limited to biotechnology, it would be important to this technology because of the ease with which micro-organisms used in patented processes can be acquired and used by overseas competitors. Many companies using biotechnology and their patent attorneys see this option as a potentially important part of their program to protect the results of their R&D efforts.

A bill to implement this option (H.R. 3577) was introduced on July 14, 1983.

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*Notes: C.C.P.A. = Court of Customs and Patent Appeals.
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