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INTELLECTUAL PROPERTY RIGHTS FOR BIOTECHNOLOGY

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INTRODUCTION

Intellectual property can be protected through the use of federal statutes or through the use of state statutes or common law. Two types of statutorily authorized intellectual property protection are currently available for protecting biotechnology. As discussed in detail below, these are by patent (either a utility patent or a plant patent) and by plant variety protection certificate. General patent statutes covering the full range of human inventive art have been in effect in the United States since 1790. Only recently have plants and animals *per se* been deemed to be patentable subject matter under the general patent statutes (hereafter "utility patent(s)"; 35 U.S.C. § 101 *et seq.*). Utility patents were first allowed for plants and plant varieties following the decisions of *Diamond, Commr. Patents v. Chakrabarty*, 447 U.S. 303 (1980); *Ex parte Hibberd*, 227 U.S.P.Q. 443 (BPAI 1985); and *Ex parte Allen*, 2 U.S.P.Q. 2d 1425 (BPAI 1987). Plant patents directed to asexually reproduced plants were first authorized by the 1930 Plant Patent Act (PPA; 35 U.S.C. § 161 *et seq.*). The 1970 Plant Variety Protection Act (PVPA; 7 U.S.C. § 2401 *et seq.*) was enacted to provide patent-like protection to sexually reproduced plant varieties. Two types of protection are available under state statutes or common law principles, namely trade secrets and contracts. Each of these alternatives is governed by state law; consequently, the specifics of each may vary somewhat from state to state. An additional alternative is the tort law of conversion. The present discussion will be limited to patent, plant variety and trade secret protection.[1]

PATENTS

Depending on the subject matter of the invention, two types of patents are available for the protection of plant biotechnology. The present discussion will be directed primarily to utility

patents. However, since a special statute (the PPA) was enacted to provide protection to asexually reproduced plants, a brief discussion of plant patents will also be presented.

Plant Patents

Applicability and Scope of Protection

A plant patent provides for the protection of "any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in the uncultivated state" to "whoever invents or discovers and asexually reproduces [the plant]." 35 U.S.C. § 161. Although plants found in an uncultivated state are not subject to protection by a plant patent, a plant seedling in a cultivated state which is discovered and asexually reproduced is protectable. A plant in an "uncultivated state" refers to a wild variety, a plant existing in nature, one for which protection is not available to the discoverer of the plant under the PPA. A plant seedling, or a plant in a cultivated state, however, has arisen by the action of the plant grower, and its protection is thus available under the PPA. Sexually reproduced plants cannot be protected by the PPA. Asexual reproduction was viewed by Congress as the only method to insure the production of an identical plant. Protection under the PPA is directed to only a single variety (e.g., the rose "Peace") and not to a group of varieties having a common trait (e.g., a rose having white flowers). PPA protection grants the patent owner the right to exclude others from asexually reproducing the plant or selling or using a plant so reproduced. 35 U.S.C. § 163. A major disadvantage in plant patent protection is that such protection does not extend to plant parts, flowers, fruit, cuttings and the like which may be the commercial embodiment of the variety but which would not be capable of asexually reproducing the plant.

For a variety to be patentable under the PPA, the plant must be new, distinct, nonobvious and asexually reproduced. In order to be new (35 U.S.C. § 102), the variety must not have existed before, e.g., it must not have been (a) known before the date of the invention (discovery) or more than one year before the filing date of the application, or (b) in public use or sold or offered for sale more than one year before the application date. To be distinctive, the plant variety "must have characteristics clearly distinguishable from those of existing varieties." In addition to these requirements, the new variety must also be adequately and completely described in the specification. The description for a plant patent can be less than that required for a utility patent, as long as it is "as complete as reasonably possible." 35 U.S.C. § 162. It is unlikely that the description would be so complete as to enable a skilled artisan to make (i.e., reproduce) the new variety without the benefit of the patented variety. For this reason, asexual reproduction was made a requirement of the right to a plant patent. Likewise, the purpose of the description was

to enable identification of the new variety for the purposes of determining infringement. A deposit is not required under the PPA.

Infringement

The mere existence of a plant variety which had been asexually reproduced is not sufficient to prohibit patentability of the variety if (a) the distinctive characteristics of the variety and its value were not appreciated by anyone prior to discovery by the inventor or (b) no one had known of the existence of the variety.[2] This finding was followed in Yoder Brothers, Inc. v. California-Florida Plant Corp. et al.,[3], in which the court said, "the whole key to the 'invention' of a new plant is the discovery of new traits plus the foresight and appreciation to take the step of asexual reproduction." The court in Yoder Brothers also determined that the requirement of distinctness for plants essentially replaced the utility patent requirements of utility and nonobviousness. The court concluded that (a) asexually reproducing a patented plant, (b) selling a plant so reproduced, or (c) using a plant so reproduced each constituted infringement under the PPA.

In determining infringement, a court will consider the characteristics of the alleged infringing variety against the description in the plant patent. If there is no match, infringement will not be found. For example, in Kim Brothers v. Hagler,[4] the court concluded that the size and color of the allegedly infringing nectarines were not the same as the size and color of the patented nectarines described and shown in the plant patent. In addition, a court requires a showing of an asexual reproduction of the patented plant, i.e., a physical appropriation from one of the patented plants. When asexual reproduction has been established, a finding of infringement will result. See Armstrong Nurseries Inc. v. Smith et al.[5]

Utility Patents

Applicability and Scope of Protection

Utility patents provide protection to "any new and useful manufacture, or composition of matter or any new and useful improvement thereof" (35 U.S.C. § 101) which, in accordance with the Chakrabarty, Hibberd and Allen cases, includes chemicals (e.g., herbicides, insecticides and fertilizers), proteins, genes, DNA, RNA, vectors, microorganisms, plants, plant varieties, plant parts (e.g., seeds, pollen, fruit and flowers), hybrids, animals, animal parts and processes of producing any of these items. A utility patent grants the patent owner the right to exclude others from making, using or selling the patented invention for a period of 17 years. No protection is available before the patent issues, and the extent of protection is determined by the patent's claims - not by the abstract or the specification.

In order to be patentable, an invention must be new, useful and nonobvious. In order to be new (35 U.S.C. § 102), the

invention must not have existed before, e.g., it must not have been (a) known before the date of the invention (discovery) or more than one year before the filing date of the application, or (b) in public use or sold or offered for sale more than one year before the application date. One argument that is often made against novelty of biological materials is that the material is a product of nature. The claims of an invention cannot be directed to the material as it exists in nature, but must distinguish the natural product in some manner. Thus, we see claims directed to a protein having a certain level of purity or no glycosylation or directed to a gene as a cDNA sequence.

Although the United States grants a one year grace period from the date of public disclosure (i.e., a publication, use or sale made in the absence of a duty of confidentiality) before the application must be filed, most countries do not have such a grace period. As such, any public disclosure which is enabling (teaches or suggests to a skilled artisan how to make and use the invention) and which is made before an application is filed will result in the loss of foreign rights. A public disclosure may include a publication, a published abstract, a poster, a product brochure, or even a seminar or a Ph.D. defense where non-university employees are present. Thus, it is imperative that all proposed publications be reviewed for patentable subject matter.

In order to be nonobvious, an invention must not be an obvious variation to a skilled artisan from the prior art (patents and other references). 35 U.S.C. § 103. The issue of nonobviousness for utility patents has been addressed in great detail for most types of inventions with the exceptions of plants and animals. However, it is likely that the criteria of distinctness for plant patents and PVP certificates would also be used to determine obviousness for a plant (or animal) utility patent.

An additional requirement for obtaining a utility patent is that the invention must be described in such a manner so to enable a skilled artisan to make and use that invention. 35 U.S.C. § 112. In certain instances, such as for plants, varieties or hybrids, this requirement probably cannot be met by a simple description. In those instances, the claimed invention, or an essential material for making the claimed invention, must be available to the public after a patent issues. This public availability may be accomplished either by a deposit in a public depository of the biological material which then will be available to the public after the patent issues or by commercial sale of the material. In addition, the specification must also set forth the best mode for carrying out the invention. The best mode is the one contemplated by the inventor at the time the application is filed.

As previously mentioned, a patent grants its owner the exclusive right to make, use or sell the patented article or process. The unauthorized making, using or selling of an invention

is termed infringement. The patent owner's right extends only to the claimed subject matter, which may include a whole plant, a part of a plant, or any of the subject matter outlined above. A patent application is maintained in secrecy by the Patent and Trademark Office, and is not public until it issues. The term of a patent is 17 years from the issue date, during which protection is available, as long as the patent is maintained in force. 35 U.S.C. § 154.

From this brief discussion, it is evident that a key part of the patent is its claims. It is important that claims be carefully drafted to be sure that they cover the actual invention as well as the commercial embodiment. It is the claims which define the scope of the protection available to the patent holder. Many examples can be found in which the claims of a patent did not adequately cover the commercial embodiment of the invention, and competitors were able to easily move into that product's market. For example, to obtain the full value of a plant or animal variety utility patent, it is helpful to have claims directed to either a characteristic or a select group of characteristics rather than directed simply to a phenotype. Where the underlying genetics have not been precisely characterized, it is also helpful to describe the characteristic as a genetic factor.[6] Providing that the specification teaches how to obtain and transfer the genetic factor to other varieties, the factor should be patentable without a detailed description of its genetic basis.

The experimental use exception is the sole restriction on the exclusive right granted by a patent. This exception is not found in the patent statutes but has been created by the courts. The extent of the exception is currently under debate within the legal profession. However, it is clear that the exception will be applicable in those instances of "pure" research often conducted in an academic setting. The exception may not be applicable, however, if the research is conducted with a commercial intent. Such an interpretation is based on dicta of recent cases.

A patent provides the patent holder with the right only to exclude <u>others</u> from practicing the claimed invention -- not with the right to do so. The ability to practice the invention may be restricted by an earlier, dominating patent or by statutes or regulations. Such statutes and regulations relating to new drugs, for example, restrict the ability of the patent holder to market a patented drug before the necessary regulatory approvals have been granted.

Infringement

Infringement of a patent is the unauthorized making, using or selling of the claimed invention during the life of the patent. There are three types of infringement recognized in the United States -- direct, induced and contributory infringement. In order to have either induced or contributory infringement, there must

first be direct infringement. Direct infringement is determined by comparing the accused product or method with the claims of the patent. Literal infringement occurs if the claims literally describe the accused product or method. If literal infringement does not exist, the accused product or method is then analyzed for infringement under the doctrine of equivalents. The doctrine of equivalents is an equitable solution to the problem which arises when an activity or product embodies trivial differences from a claimed invention. This doctrine provides for findings of infringement where an accused product or process performs substantially the same function in substantially the same way to obtain the same result as a patented invention.

An induced infringement is found in instances in which a party has aided and abetted another to infringe a patent. The inducer must have been an active participant in the line of conduct of the guilty actual infringer. That is, the inducer knowingly (i.e., purposefully or intentionally) must have taken active or affirmative steps with the knowledge that infringement is likely.

A contributory infringement is found in instances where a party has knowledge that the materials produced are especially made for infringement of the patent. A contributory infringer must also know that the materials are not staple articles of commerce and do not possess a substantial non-infringing use.

In many infringement actions, it is necessary to construe the claims in order to determine their proper scope. Several factors are involved in the construction of patent claims, including the prosecution history, the specification, the claims and expert testimony. Words which are defined in the specification must be given the same meaning when used in the claims. Specific limitations of dependent claims not present in broader independent claims cannot be read into those claims. Prosecution history can be used as an estoppel to prevent the patent owner from expanding the scope of the claims to include what was specifically given up during prosecution. Under the right circumstances, the estoppel can be applied to both claim amendments and arguments in efforts to obtain the patent.

PLANT VARIETY PROTECTION CERTIFICATES

Applicability and Scope of Protection

A plant variety protection (PVP) certificate provides for the protection of "any novel variety of sexually reproduced plant (other than fungi, bacteria or first generation hybrids)." 7 U.S.C. § 2402. Asexually reproduced plants and hybrids cannot be protected by the PVPA. The protection extends only to a single variety and not to a group of varieties having a common trait. An equivalent type of protection for animal varieties does not exist.

In order to be protectable under the PVPA, a variety must be new, uniform, distinctive and stable. 7 U.S.C. § 2401-2. In order to be new, the variety must not have been a public variety or available in this country or adequately described by a publication before the date of determination or more than one year before the filing date. This requirement is quite similar to the novelty requirement for patents.

To qualify as uniform, any variations in the variety must be predictable and describable. In order to be distinctive, the variety must differ from all other varieties by one or more characteristics. These characteristics need not be agronomically important characteristics. The definition of distinctness currently used by the PVP Office is one of the major weaknesses of PVP protection. A variety is stable if it remains unchanged when sexually reproduced.

PVPA protection grants the certificate owner the right to exclude others from selling, offering for sale, delivering, importing, exporting or sexually multiplying the variety, producing a hybrid from the variety, using its seed or progeny to propagate the variety and dispensing the variety without notice. 7 U.S.C. § 2541. The Secretary of Agriculture can require the certificate owner to grant licenses to third parties (compulsory licenses) if it is deemed to be in the public interest. 7 U.S.C. § 2404.

This grant, however, does include two important exemptions. The first exemption is a research exemption which provides others with the right to use the protected variety to develop new varieties. 7 U.S.C. § 2544. (As previously mentioned, there is currently a debate as to whether such an exception is available for patents.) The second exemption is a farmer's exemption. 7 U.S.C. § 2543. The farmer's exemption is a second major weakness of PVP protection. According to this exemption, it is not an infringement for a person whose primary farming occupation is the growing of crops for sale for other than reproductive purposes to save seed and use that seed either in the production of a crop on his farm or for sale to a person whose primary farming occupation is the same as his own.

Plant variety protection is granted for a period of 18 years from the issue date of the certificate, and is also available for the time between distribution of the variety with a proper notice and the issue date of the certificate. 7 U.S.C. § 2541. The application for a PVP certificate is maintained in confidence although the variety name, applicant, and filing date are published.

Infringement

The infringement issues which have been addressed by courts to date concern the farmer's exemption. In all of these cases, a farmer's exemption has been found to apply by the courts --

consequently, no infringement has been found. In Delta and Pine Land Co. v. Peoples Gin Co.,[7] the only reported case concerning infringement under the PVPA, the court concluded that the farmer's exemption did not apply to either a non-profit agricultural cooperative which arranged sales of a protected variety or to a company which dispensed the protected variety without giving notice that the variety was protected. The court believed that the intervention of a third party acting as a broker or sales agent would frustrate the basic purpose of the PVPA because the third party was larger in size than a single farmer and would be more aggressive in marketing the protected varieties. After concluding that the farmer's exemption did not apply, the court concluded that there was infringement because (1) the variety had been (a) sold, delivered, etc. (7 U.S.C. § 2541(1)) and (b) dispensed without notice of its protected status (7 U.S.C. § 2541(6)) and (2) these actions were instigated or actively induced (7 U.S.C. § 2541(8)).

In Asgrow Seed Co. v. Kunkle Seed Co., Inc. et al,[8] the district court refused to grant a preliminary injunction to halt the sale of seed of a protected variety of soybeans on the basis of the farmer's exemption, since less than half of the total volume of seed produced by the defendant was sold for reproductive purposes. The plaintiff alleged that the defendant's primary occupation was to sell seed, as evidenced by its (a) sale of some 1.42 million pounds of the specific protected seed (not including additional public varieties which were sold), (b) increase of acreage needed to grow such seed, and (c) intent to sell as much seed as possible, even though less than half of the farm income came from the sale of the specific protected seed.

TRADE SECRETS

Definition

To protect proprietary information, a company must possess a trade secret in order to avail itself of trade secret law. But what is a trade secret? Although there is no single definition, there are two widely accepted ones. The first is set forth in Section 757, Comment b, of the Restatement of Torts (1939) (hereinafter referred to as the Restatement). Comment b states, in part, that a trade secret

> ... may consist of any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

This definition prevails in the majority of state jurisdictions and has been adopted by the United States Supreme Court. A second definition is set forth in the Uniform Trade Secret Act. Since this latter definition is quite similar to the Restatement's, it will not be discussed here. According to the Restatement definition, in order to qualify as a trade secret, information must (a) be used in one's business, (b) provide a competitive advantage, and (c) be secret.

Subject Matter

It is clear in the above definitions that, unlike patents and plant variety protection certificates, there is no specific subject matter criteria for a trade secret. Almost any information can be a trade secret as long as the requisites of secrecy, competitive advantage and use (Restatement) are met. When the requisite criteria have been met, the following types of information have been found to be trade secrets:

> ... ingredients in foods, drugs and cosmetics; chemical compositions; computer programs and data bases; manufacturing, technological and scientific processes; geological and geophysical maps; flow-charts and blueprints; product specifications; customer lists; employee, training or other company manuals; and virtually any body of information.

Recently, a U.S. district court in Iowa held that a genetic message of an inbred corn line can be proper subject matter for a trade secret.[9]

Use and Competitive Advantage

In establishing the existence of a trade secret, the requirements of use and competitive advantage are minimal, while secrecy is by far the most important. Use and competitive advantage are often deemed to exist merely by virtue of a company's taking steps to meet the secrecy requirement. In fact, it may be more appropriate to consider use and competitive advantage merely as criteria rather than actual requirements, since very little case law has been devoted to a discussion of them. In essence, these criteria require that the designated information (such as plant germplasm) be believed reasonably to provide the trade secret owner with some non-speculative value and benefit in order to qualify as a trade secret.

Secrecy

While meeting use and competitive advantage requirements is arbitrary at best, the secrecy requirement must be met without exception. In general, if subject matter is not actually secret, it will not be protectable as a trade secret. Comment b, Section 757 of the Restatement sets forth the most frequently cited standard for secrecy, and states in part that:

> The subject matter of a trade secret must be secret. Matters of public knowledge or of general knowledge in an industry cannot be appropriated by one as his secret. Matters which are completely disclosed by the goods which one markets cannot be his secret. ... Nevertheless, a substantial element of secrecy must exist so that, except by the use of improper means, there would be difficulty in acquiring the information.

A trade secret has only to be maintained in relative secrecy. The secrecy does not have to be absolute, i.e., known only to its owner. The secrecy must be considered to be reasonable, and in essence to be such that the trade secret is confided only in those who need to know in order to commercially exploit it. It may be necessary to disclose a trade secret to employees, contractors, suppliers, co-venturers and the like, in order to commercially utilize the trade secret. However, any disclosure should be confidential, or made under conditions which imply confidentiality. Generally, the standards of secrecy can be examined by analyzing two fundamental elements: (a) the general knowledge or availability of the information, and (b) the presence of affirmative steps to protect the information.

A first fundamental element of secrecy is that the information should not be generally known or available. If the subject matter of the trade secret has been voluntarily disclosed by the owner, or is public knowledge or general knowledge in the trade or business, it can no longer be protected as a trade secret. In essence, then, it is likely that secrecy does not exist for any information which has been published or distributed in any way, such as that contained in a book, magazine, trade journal, advertising brochure or catalog, or in a patent or any other public format. Similarly, if the product itself discloses the trade secret, the product must remain confidential. It is this requirement, in fact, which may foster ineffectual protection of many types of plant biotechnology by trade secret. Public information, however, may be protected as a trade secret if the value or utility of the information is not obvious or is not otherwise known to competitors. The information may be independently developed by several companies and still be considered a trade secret for each of them.

A second fundamental element of secrecy is that the trade secret owner must take adequate affirmative steps to protect the trade secret information. In general, a company must take greater care to protect its trade secret than it would take to protect other aspects of its business. If a company believes that such a trade secret exists, then active steps must be taken to maintain its secrecy and confidentiality. If such steps are not taken, trade secret protection will be lost. The degree of secrecy does not have to be absolute, but it must be reasonable. An excellent

guide in determining such protective steps is the standard practice in each industry.

Several steps which should be taken by a company in the protection of proprietary information include the following: (1) establish a written trade secret policy; (2) inform employees of trade secrets and remind them of their obligations of confidentiality; (3) restrict access (by physical separation, if possible) to trade secrets; (4) institute physical security measures (including storing trade secret documents in locked, limited-access files); (5) protect trade secret documents by labeling them clearly with proprietary notices; (6) maintain computer secrecy; (7) restrict company tours; (8) screen speeches and publications for unnecessary disclosure of trade secrets, and (8) inform others of the confidentiality of any disclosed trade secrets.

Misappropriation

Trade secret law provides the trade secret owner with the right to prevent the unauthorized use and disclosure of a trade secret by other parties. Section 757(a) of the Restatement states that disclosure or use of a trade secret constitutes misappropriation if (a) the trade secret was discovered by improper means; (b) the disclosure or use of the trade secret breaches a duty of confidence to the party from whom the secret was obtained; (c) the party was on notice that the secret was acquired by improper means or through breach of duty to another; or (d) the party was on notice that the trade secret was mistakenly disclosed.

"Improper means" includes theft, bribery, misrepresentation, breach of duty (or inducement to breach) to maintain secrecy, trespass or espionage. An otherwise lawful means which evidences an intent to appropriate a trade secret without permission or independent invention or discovery may also be considered to be improper. A confidential relationship can be established by contract, such as a nondisclosure agreement or a post-employment restrictive covenant, or by an implied contract/special relationship which establishes that the disclosure was made in confidence and was not to be disclosed or used. A party can be put on notice that the information is a trade secret, and that the disclosure was the result of a breach of confidence by (1) actual notice (i.e., the party is expressly informed by the trade secret owner), or (2) constructive notice (i.e., the facts and circumstances are such that the party should have known the information was a trade secret and was obtained through a breach of confidence). In the absence of actual or constructive notice, a party is not liable to the trade secret owner. However, the party may be liable to the trade secret owner after receipt of such notice, unless the party has materially changed positions and paid value for the secret in good faith before receiving notice. The burden of proving misappropriation rests with the trade secret owner. If this burden is initially met, then the onus is shifted

to the alleged misappropriator to prove that the trade secret was obtained by legal means.

Although trade secret law protects an owner from the misappropriation of its trade secret, it does not protect against the discovery of the trade secret by proper means. Proper means of discovering a trade secret include independent discovery, accidental or actual disclosure, and reverse engineering. If a product discloses the trade secret, or the trade secret can be determined from an analysis of the product, then the marketing of the product will result in a loss of trade secret protection. Examples of actual disclosure include the sale of plant varieties, vectors, genes or machines. A possible example of an accidental disclosure may be a disclosure of the inbreds from a sale of hybrid seed. Trade secrets can also be lost by disclosure in patents, published patent applications or other published materials, including advertisements or product brochures. With trade secrets which may need to be disclosed to governmental agencies, it is critical to indicate their confidentiality in order to avoid an accidental disclosure of the trade secret as a result of Freedom of Information Act requests. If the trade secret can be readily obtained from public documents, trade secret law may not provide protection (depending on the jurisdiction in which the misappropriation occurred) against a party who misappropriates it.

ISSUES

A discussion of intellectual property rights for biotechnology would not be complete without a brief examination of some of the issues which are often considered in the field, especially concerning the protection of plants and animals. One issue relates to the ability to protect a particular plant or animal variety. In PVP and patents, the issue revolves, respectively, around minimum distance and obviousness. Under the PVPA there is a basic lack of a distinctiveness criteria, such that minor changes in any trait are usually sufficient for a breeder to receive a PVP certificate. There is activity currently to attempt to adopt a minimum distance standard which would avoid this problem. The Patent Office has recently adopted an overly stringent standard of obviousness for new varieties. In order to overcome the Patent Office's position, it will be necessary to present evidence as to the amount of effort involved in the development of a new variety.

A related issue in patents concerns the scope of the claims of patents to a novel variety. Will the claims be limited to the patented variety itself, such that slight changes in the variety will result in the new variety falling outside the scope of the claims, or will the claims be given a somewhat broader scope to encompass such varieties?

A major issue at the present time is the farmer's exemption under the PVPA and the proposed farmer's exemption for transgenic animals under the patent statutes. The farmer's exemption under the PVPA has been subject to much abuse and effectively allows large-scale farmer-dealers to sell substantial quantities of seed of the protected varieties. There is currently considerable discussion to amend the PVPA by removing the farmer's exemption. In view of the abuse seen under the PVPA and the absence of any rational argument or need for a farmer's exemption for patented transgenic animals, it appears unadvisable at the present time to adopt such an exemption in the patent system.

Another issue which is often raised is the research exemption in the PVPA and the experimental use exception to patent infringement. The research exemption allows the use of a protected variety for developing new varieties, i. e., the use of the variety in a breeding program. However, in the case of hybrid crops, this provision is abused since the parent materials protected are not available for use in a breeding program. The experimental use exception allows for the use of a patented invention for experimental purposes. There is some debate as to the extent of this exception. The prevailing views are (a) that the invention should be available for research so that improvements can be made and (b) that research can only be conducted if there is no commercial intent. This issue will likely be resolved by further litigation.

Effects on the exchange of germplasm have often been raised as an issue under PVPA or patent statutes. Germplasm exchange is an issue in the United States and in the international arena as well. It was initially believed that the PVPA would negatively impact upon germplasm exchange, although such an impact has not occurred. Similarly, it has been argued that patents will adversely effect germplasm exchange. The effects of patents on germplasm exchange cannot be determined at this early date. However, it is likely that they will not have an adverse effect on the exchange of germplasm, although the manner by which germplasm is exchanged may see some changes.

An additional issue in the international arena is the type of protection available for agricultural biotechnology. For example, breeder's rights (plant variety protection) may be the exclusive form of protection for plant varieties in several countries. In other countries it may not be possible to obtain any protection for plant or animal varieties. However, it may be possible to obtain patent protection for a generic plant or animal. For example, it is possible to obtain a patent in Europe for generic plants such as those resistant to a specific herbicide. Although Europe has granted patents for generic plants, it has yet to grant a patent for a generic animal, such as the recently publicized Harvard mouse, for example.

The final international issue relates to the competitiveness of United States industry. This issue arises in the context of the Omnibus Trade Bill and the current General Agreement on Tariffs and Trade (GATT) negotiations. Essentially the United States is attempting to convince other countries to recognize intellectual property rights and to give them meaningful protection as a means to maintain the competitiveness of United States' industry in the world economic environment.

CONCLUSION

Several types of protection for intellectual property in biotechnology are available. The applicability and usefulness of any particular type, however, will depend on the type of technology that is to be protected. In many instances, utility patents provide the best protection for intellectual property. In those instances where it is difficult to ascertain the property from the product, such as with a novel method for producing a product, then protection by a trade secret may be as valuable as a utility patent. Trade secrets are not useful if the property is disclosed by the product or is to be published. Trade secrets would be more useful in the context of a sale with a restrictive use provision if such provisions were found to be valid and enforceable (thus enlarging trade secret protection). In any event, trade secret law does not prohibit independent discovery or reverse engineering.

Although there are presently a number of alternatives for the protection of biotechnology, there are many questions and issues concerning the validity, enforceability and viability of several of these alternatives. These questions will undoubtedly be answered through litigation, and at that time more definitive conclusions can be made as to applicability of these alternatives in the protection of plant biotechnology.

1. For further details on this subject see Proceedings of the Midwest Plant Biotechnology Consortium Symposium, Oct. 4-5, 1989 (in press); ASA Special Publication No. 52, Intellectual Property Rights Associated with Plants (1989); and U.S. Congress, Office of Technology Assessment, New Developments in Biotechnology: Patenting Life - Special Report, OTA-BA 370 (1989).

2. Nicholson v. Bailey, 182 F.Supp. 509 (S.D. Fla., Orlando Div. 1960).

3. 537 F.2d. 1347, 1377-80 (5th Cir. 1976).

4. 276 F.2d. 259 (9th Cir. 1960). See also Pan-American Plant Co. v. Matsui, 433 F.Supp. 693 (N.D. Cal. 1977) (disease resistant plant marked with a patent number and not original plant not entitled to protection since disease resistance not set forth in the patent description).

5. 170 F.Supp. 519 (E.D. Tex. 1958). Infringement resulted from the asexual reproduction and sale of the asexually reproduced plants. Induced and contributory infringement were also found in this case.

6. Claim 20 of U.S. Patent 4,513,532: A genetic factor derived from corn, which genetic factor is capable of conferring an extra leaf phenotype which is capable of transmission to progeny substantially as a single dominant gene.

7. 694 F.2d. 1012 (5th Cir. 1983).

8. A preliminary injunction was denied by the district court (W.D. La. 1987), which was affirmed by the Federal Circuit.

9. Pioneer Hi-Bred International, Inc. v. Holden's Foundation Seeds, Inc., ____ F.Supp. ____ (S.D. Ia. 1987), slip opinion dated October 30, 1987.