Some of the Best Ways to Protect Plant-Related Inventions

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The increasing economic importance of plant-related innovations has spawned a myriad of mechanisms for protecting them. Each of these mechanisms carries its own costs and benefits, and each has had a tremendous impact on the applied agricultural and agricultural biotechnology industries. As a result, businesses and entrepreneurs in the agricultural arts are now enabled to license internally developed plant-related inventions, but they are also at risk for infringing plant-related inventions owned by others.

Utility patents offer the most expansive protection for plant-related inventions. However, utility patents can be expensive to obtain and maintain because of the requirements that must be met in order to achieve this type of protection.

The use of other forms of protection does not preempt the granting of utility patents, *Ex parte Hibbard*, 227 U.S.P.Q. 443,444 (Bd. Pat. App. & Int. 1985). Utility patents remain available as long as that which is being claimed was “man made” and otherwise meets the normal criteria for patentability. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10,206 U.S.P.Q. 193,197 (1980) (subject matter for patent protection can extend to anything under the sun that is made by man).

Patentable subject matter therefore extends to proteins, genes, gene fragments, DNA, RNA, microorganisms, and transformed cells derived from plants, as well as plants, plant parts (buds, pollen, fruit, flowers), plant cultivars, hybrids, plant-based chemicals, and the processes used in manufacture of the foregoing. 35 U.S.C. § 101. Accordingly, patents have been issued for plant inbreds, hybrids, plant parts, biotechnology methods and genes, and
a multitude of other plant innovations.

Utility patent protection can be secured for plants reproduced either sexually (by seeds; see *Pioneer Hi-Bred Int'l v. J.E.M. AG Supply Inc.*, No.,C-984016-DEO, (N.D. Iowa Aug. 19,1998)) or asexually (reproduced by means other than seeds, such as by rooting of cuttings, budding grafting, or in-arching; see M.P.E.P. § 1601), subject to the usual patentability requirements.

The standards accorded the chemical arts are applied during patenting of plant-related inventions. Thus, a claimed plant, seed or plant part must be novel and unobvious, and the description must comply with the requirements of 35 U.S.C. § 112.

Novelty is generally found as long as the plant innovation is not in the public domain. For example, a cotton cultivar has been found to be anticipated by a group of prior-art references that described commercially available cotton seeds. The finding was reached on the basis that a skilled artisan could employ methods known in the art, such as conventional techniques to plant and nurture seeds to maturity, to reach the claimed invention. *Ex parte Thompson*, 24 U.S.P.Q.2d 1618,1620 (Bd. Pat. App. & Int. 1992).

To be patentable, plant innovation must be not only novel, but also unobvious. For example, patent claims directed to genetically stable, true-breeding sunflower lines, plants and seeds that produce oil with enhanced oleic acid content have been deemed unobvious over prior-art references, which did not suggest that sunflower Lines with high oleic content could be made true-breeding. *In re Sigco Research*, 48 F.3d 1238, 36 U.S. P.Q.2d 1380, 1382 (Fed. Cir. 1995). Patentability may similarly be established by showing that the plant has improved properties that are unexpected. *Ex parte C*, 26 U.S.P.Q.2d 1492,1497 (Bd. Pat. App. & Int. 1993).

A patent application directed to a-related invention must also satisfy the requirements of 35 U.S.C. § 112. Thus, the specification must describe specific characteristics of the plant for which protection is sought (e.g., flower color, plant type, maturity group, pathogen resistance), and must also describe the best mode of carrying out the invention. *Ex parte C*, 26 U.S.P.Q.2d at 1497.

A plant breeder may meet this requirement by depositing seeds, plant tissue cell Lines or cell lines in a recognized public depository, such as the International Depository Authorities established under the Budapest Treaty. *Id.* at 1496. Deposit of the material in a public depository also satisfies the best-mode requirement. *Id.* In the case of a hybrid breeding line, both parent lines must be deposited in the public depository.
However, a deposit is not required where the cell lines, seed or breeding lines are known and readily available to the public. M.P.E.P. § 2404.01. Deposit is likewise not necessary if the plant material can be made or isolated without undue experimentation. M.P.E.P § 2404.02.

If the material is deposited, the specification must contain sufficient description of the deposited material. 37 C.F.R. 1.809(d)(3).

A utility plant patent application filed prior to June 8, 1995, has a term of 17 Years from its issue date. An application filed after June 8, 1995, has a term of 20 years measured from the filing date of the U.S. application.

As in other technologies, multiple aspects of a plant-related invention may be claimed. For example, an application for a corn variety developed by traditional breeding methods should have claims directed to the inbred parent line, plants and pollen produced by the parent, seeds of the parent, phenotypic characteristics of the parent, methods of producing a corn plant using the parent, and plants and seeds regenerated from tissue culture of the parent. Patent applications for genetically engineered plants should have claims directed to the transgenic plant, seeds of the transgenic plant, and the cloned genes and expression vectors, as well as methods of producing transgenic plants.

Any plant protected by a utility patent will be infringed if it is reproduced either sexually or asexually. Thus, a purchaser of a patented seed line may grow and sell the plant for consumption, but he or she cannot multiply or manufacture the seed line. Likewise, reproduction of a protected gene or expression vector without authorization and/or a license is an act of infringement.

A patentee should therefore be prepared to present isozyme, reverse-phase high-performance liquid chromatography or other data that would substantiate genetic relatedness, or show equivalence between the protected and accused plants or plant parts. Hilton Davis Chem. Co. v. Warner Jenkins Co. Inc., 520 U.S. 17, 41 U.S.P.Q.2d 1865 (1997).

**Plant Patent Act**

Plants have been allowed to receive protection under utility patents for only the past 12 years. Prior to that, asexually reproduced plants could receive protection only under the Plant Patent Act (PPA).

The PPA provides that plant patents may be granted for any asexually reproducible new variety of plant (including cultivated sports, mutants, hybrids and newly found seedlings) other than tuber-propagated plants and plants found in an uncultivated state. 35 U.S.C. §§ 161-164. Moreover, the PPA offers less protection than available under utility patents.
The PPA is used where protection for an asexually reproduced plant having a particular identifying phenotypic characteristic is sought, particularly if this characteristic can be easily identified by a color drawing or photograph. The advantage of PPA filings is that they are usually cheaper and easier to obtain than utility patents. However, the PPA is being used less frequently now than in the past because of the narrow scope of protection it affords.

Filing for a plant patent under the PPA is slightly different from filing for a utility patent. To obtain a plant patent, it is not necessary to put any material in a recognized public depository. Moreover, the oath or declaration accompanying the application must contain a statement by the applicant that he or she has asexually reproduced the plant in question.

The drawings filed in order to get a plant patent "should be artistically and competently executed" or, optionally, be in the form of photographs. If color is a distinguishing characteristic, then the drawings or photographs must be in color. (By contrast, no drawings need be filed to obtain a utility patent, although some other type of distinguishing data may be required.)

Other distinctions exist with regard to the enablement and description requirements of 35 U.S.C. § 112. It is important to note that a plant patent is not invalid for failure to comply with the sufficiency requirements of 35 U.S.C. § 112 if the description is as complete as is reasonably possible. Thus, the portions of the specification that describe the plant and the characteristics that distinguish it from known varieties and its antecedents, and that point out where and how the plant has been asexually reproduced, need only contain as full and complete a disclosure as possible.

If a newly found plant is being claimed, the specification must state the location where the plant was found and describe the character of the area.

Only a single claim is permitted, which must be directed "to the new and distinct variety of the specified plant as described and illustrated," and optionally, any principal distinguishing characteristics of the plant. The application must also include a proposed plant variety name. M.P.E.P. § 1612.

One of the most notable distinctions between the PPA and the utility patent scheme is the requirement of distinctness. Under the PPA, at least one single significant distinguishing characteristic must exist in order to establish the existence of a distinct variety. This "statutory distinctness" requirement is tantamount to the statutory novelty requirement for utility patents. Yoder Bros. Inc. v. California-Florida Plant Corp., 537 F.2d 1347, 1378 (5th Cir. 1976), cert. Denied, 429 U.S. 1094 (1977).

The term of the plant patent is the same as a utility patent. A plant patent, however, only excludes others from
"asexually reproducing the plant or selling or using the plant so reproduced." 35 U.S.C. § 163. In view of this requirement, there has been considerable debate over the years concerning what exactly constitutes infringement of plant patents. Id. at 1382-83.

Recently, the U.S. Court of Appeals for the Federal Circuit narrowed the scope of protection under the PPA, finding that infringement occurred only when a plant has been asexually reproduced from the actual plant protected by the plant patent. Zio Nursery Inc. v. Dania Greenhouse F3d 1560,1564-68,36 U.S.RQ.2d 1673,1676-80 (Fed. Cir. 1995), cert. Denied, 518 U.S. 1018 (1996).

Protection is thus limited to plants that are both descendants and genetic equals of the original plant; and a patentee seeking an infringement finding will be required to establish genetic identity. By way of contrast, an independently created plant having the same characteristics as that which was patented does not infringe a plant patent.

A third party may thus use a breeding line or variety protected under the PPA in a commercial breeding program without authorization and/or license from the patentee. This limit on the protection for plant patents has strongly affected the commercial plant breeding industry. A party may use a breeding line or variety protected under the PPA in a commercial breeding program without authorization and/or license by the patentee.

Part Two

The increasing economic importance of plant-related innovations has spawned myriad mechanisms for protecting them. Part I of this article discussed utility patents and plant patents. Part II of this paper examines plant variety protection and trade secret protection.

The Plant Variety Protection Act (PVPA), 7 U.S.C. §§ 2321-2582, was enacted in 1970 to supplement the patent protection accorded novel varieties of asexually reproduced plants under the Plant Patent Act (discussed last month). A certificate of protection, issued under the PVPA, provides the equivalent of patent protection to sexually reproduced plants, including first-generation hybrids and tuber-propagated plants which cannot be protected under the Plant Patent Act. Unlike utility and plant patents that are administered by the U.S. Patent and Trademark Office, the PVPA is administered by the Department of Agriculture.

Extensive amendments to the PVPA were enacted during 1994, which became effective April 4, 1995. Varieties protected under the 1970 act, and all applications submitted prior to the effective date of the amended act, are subject to the 1970 act. Applications filed after the effective date are governed by the 1994 amendments.
Pursuant to the 1994 amendments, sexually reproduced plant varieties, other than fungi or bacteria, may be protected as long as the variety is characterized by the presence of four separate requirements: The variety must be new, distinct, uniform and stable.

- Newness may be established with a showing that the variety has not been sold or otherwise disposed of in the United States for more than one year, or outside the United States for more than four years (six years in the case of trees and vines), prior to filing the request for protection. Acts of sale or disposal are those carried out by, or with the consent of, the breeder or a successor in interest for the purpose of exploitation. Therefore, the sale of hybrid seed or cut flowers emanating from a protected variety may defeat the newness requirement.
- A distinct variety must be clearly distinguishable from any other variety that is publicly known or that is a matter of common knowledge at the time the application is filed.
- Uniformity can be established by a showing that any variations that do occur between plants are describable, predictable and commercially acceptable.
- A variety is considered stable if, when reproduced, the variety remains unchanged with respect to its distinctive characteristics, with a reasonable degree of reliability.” 7 U.S.C. § 2402.

Applications for PVPA protection must describe the foregoing requirements, contain a statement regarding the basis for the claim that the variety is novel, and further contain a description of the genealogy and breeding procedure used to produce the variety. 7 U.S.C. § 2422.

For a seed-propagated variety, at least 2,500 seeds of “the viable basic seed to reproduce the variety” should be submitted with the application. In the case of a first-generation hybrid, seeds of the parent must also be deposited. Applications involving tuber-propagated varieties require verification that a viable cell culture will be deposited in a public depository. 37 C.F.R. 97.6.

Under the amended act, PVPA protection runs for a period of 20 years from the issue date of a PVPA certificate. Trees and vines, however, are subject to a 25-year term of protection. 7 U.S.C. § 2483.

Rights accorded a PVPA certificate holder vary slightly, depending upon the filing date of the PVPA application. Under the 1970 act, the certificate holder may control:

- Sale, offers for sale, and any other transfer of title or possession; import to or export from the United States;
- Sexual multiplication as a step in marketing (for growing purposes);
- Use in producing (as distinguished from developing) a hybrid or different variety, of seeds, transplants and plants of the novel variety.

These rights are limited by a fairly broad farmers' rights provision. That is to say, farmers whose primary occupation is growing crops for sale for other than reproductive purposes are permitted by this provision to save seed
produced from novel varieties and to use it for replanting or sale not only as a commodity to the ultimate end user - such as sale of grain for making bread - but also for reproductive purposes to other growers. 7 U.S.C. §2543. This farmers' rights provision is limited to the reproduction for sale of that quantity of seed sufficient to replant a farmer's own land. Asgrow v. Winterboer, 513 U.S. 179,190, 33 U.S.P.Q.2d 1430,1435-36 (1995).

The 1994 amendments limit farmers' rights to saving seeds for replanting on their own land, and to selling the seed for other than reproductive purposes. Thus, the holder of a certificate governed by the 1994 amendments has the right to control dealings in tubers, tissue-culture plantlets, first-generation hybrids and harvested plant parts.

The 1994 amendments also broaden the definition of infringement to provide that a certificate may be infringed if a "variety" is "essentially derived' from a protected variety.

Therefore, a plant breeder may use a protected variety in a commercial breeding program without having to obtain authorization and/or license to do so, but if progeny plants "essentially derived" from the protected variety are to be commercially exploited, a license must be obtained. The unauthorized asexual reproduction of a protected variety also constitutes an infringing act, with a limited exception for plants reproduced in order to obtain a patent under the Plant Patent Act.

**Trade Secret Protection**

Plant-related innovations may also be protectible as trade secrets. Trade secrets can provide protection for particular technologies that will never be disclosed or, alternatively, can provide interim protection before a patent application is filed. The particularities of this protection mechanism vary according to state law.

A trade secret may include any information or process relating to plants (including germplasm) that the owner took reasonable care to keep confidential and that gives the owner a competitive advantage. For example, certain plant varieties were found to be deserving of trade secret protection, as a seed corn producer took sufficient precaution to maintain the genetic makeup of the corn hybrid secret. Pioneer Hi-Bred Int'l v. Holden Found. Seeds, 31 U.S.P.Q-2d 1386,1393-94 (8th Cir. 1994)

In many instances, the use of confidentiality agreements to limit the disclosure of plant-related innovations will demonstrate sufficient care was taken to keep information confidential Mycogen Plant Science Inc. v. Monsanto Co., 164 F.R.D. 623, 626 (E.D. Pa. 1996).

**Opportunity and Danger**

There are many mechanisms for protecting plant-related inventions, including utility patents, plant patents, plant variety protection and trade secret protection. Indeed, as noted in Ex parte Hibbard, 227 U.S.P.Q. 443 (Bd. of Pat.
App. & Int. 1985), plant-related inventions may be the subject of multiple forms of protection.

Each protection mechanism carries its own costs and benefits. While utility patents offer the broadest scope of protection, they are expensive to obtain and maintain. The scope of plant patent protection has been narrowed to permit unauthorized use by a commercial breeder of a protected variety.

A PVPA certificate expands somewhat the protection accorded plant related inventions, since authorization is required for exploitation of a variety "essentially derived" from a protected variety. State trade secret law may provide an additional avenue for relief.

In each instance, the type of protection sought must be evaluated in light of the particular needs of the entity seeking protection.

The good news, overall, is that agricultural institutions can now exploit plant-related intellectual property rights through licensing, leveraging strategic alliances, and other financially rewarding means. The bad news is that these exploitation options have increased the necessity for agricultural entities to develop and maintain a heightened awareness of third party propriety plant rights throughout the research, development and commercialization phases of their business activities.

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**Practice:**

Intellectual Property