Invited commentary

Intellectual property protection for plant research in the USA: a cornucopia of opportunity

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Introduction

Over the past decade, beginning with the 1985 case in re Hibberd (227 USPQ 443 [PTO BPAI 1985]), intellectual property protection for plants has undergone some remarkable changes in the United States. In the early 1980s, it was uncertain whether traditional systems for protecting intellectual property could be applied to the emerging field of biotechnology. In general, however, the patent system and related forms of protection have provided the incentives for investment in the high-cost, high-risk research required to bring about new innovations in plant biotechnology. Today, this technology offers superior food and fiber products, increased agricultural efficiencies, decreased use of chemical pesticides and the use of plants to make products never before produced by agricultural means.

In the United States, three federal statutes provide systems for protecting intellectual property relating to plants (a fourth form of intellectual property protection arises from the state laws of trade secrets and unfair competition). These statutes are the Plant Patent Act (35 USC, §161 et seq.), the Plant Variety Protection Act (PVPA) (7 USC, §2401 et seq.), and the general utility patent statute (35 USC, §100 et seq.). As a result of these diverse statutory schemes, both traditional plant breeders and plant molecular biologists have available an unusual selection of forms of protection for their inventions and discoveries. A brief overview of each of the statutory systems is provided below.

Plant patents

The Plant Patent Act, enacted in 1930, is the oldest form of protection for plants in the United States. This Act was established to recognize the contributions of notable plant breeders, such as Luther Burbank. Special legislation was thought to be necessary, because of the perceived impossibility of providing and enabling written description of a plant, as required for patent applications for other types of invention.

A plant patent is granted to one who "invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state..." (35 USC, §161). At the time of enactment of the Plant Patent Act, tuber propagated plants, such as potatoes, were excluded from protection because of a concern that tubers are propagated by the same part of the plant that is sold as food.

In addition to the requirements for distinctness and asexual reproduction, the statute imposes the same standards of novelty and 'non-obviousness' that are required for other types of invention. 'Distinctness' has been defined by one court as having characteristics clearly distinguishable from those of existing plant varieties, whether such characteristics are inferior or superior to the existing varieties (Yoder Brothers Inc versus California–Florida Plant Corporation, 537 F2d 1347, 1378 [5th Cir. 1976]).

There is very little judicial guidance for the application of the non-obviousness requirement with respect to plants. In the Yoder Brothers case, the Court held that "[i]n the case of plants, to develop or discover a new variety that retains the desirable qualities of the parent stock and adds significant improvements, and to preserve the new specimen by asexually reproducing it constitutes no small feat." The United States Court of Appeals for the Federal Circuit, which is the court that hears all appeals of patent cases, has not yet had an opportunity to apply the non-obviousness standard in the plant patent context.

The term of a plant patent currently is 17 years. However, this will soon be changed to 20 years from the date of application as a result of the recent Uruguay Round Agreements Act.

The description requirements for a plant patent application are much less onerous than those for a conventional

Abbreviation
PVPA—Plant Variety Protection Act.

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utility patent application. The application need only include a description that is "as complete as reasonably possible" (35 USC §162). In general, the description includes a photograph or drawing along with a discussion of important distinguishing morphological and agronomic characteristics.

Although the Plant Patent Act has been in existence for more than 60 years, uncertainty still exists concerning the scope of protection afforded by a plant patent. In the Yoder Brothers case, the court held that proof of infringement of a plant patent requires proof that the infringer asexually reproduced the plant claimed in the patent. Under this ruling, a showing of independent creation of the plant would be a defense against a charge of patent infringement. In a recent decision in the case of Imazio Nursery Inc versus Dania Greenhouse (29 USPQ 2d 1217, 1219 [ND California, 1992]), independent creation was held not to be a defense to a charge of patent infringement. The court held that the Plant Patent Act "bars the asexual reproduction and sale of any plant which is the same variety (i.e. has the same essential characteristics) as the patented plant, whether or not the infringing plant was originally cloned from the patented plant." An appeal of the Imazio Nursery case is presently pending before the Court of Appeals for the Federal Circuit. This decision will be of obvious importance to those who rely upon plant patents to protect their research activities.

There has been considerable interest in extending the protection of plant patents to include plant parts. Such a change would allow a patentee to exclude others from importing and selling the fruit, flowers or other parts of a plant grown outside of the United States. Those who depend upon plant patents to protect their plant breeding programs have long advocated amendment of the statute to close what they see as an obvious loophole.

Utility patents

Until 1985, it was the position of the United States Patent and Trademark Office that plants, seeds and plant tissue cultures did not constitute patentable subject matter. It was the Patent Office's position that, since protection was available under the PVPA and the Plant Patent Act, protection under the utility statute was not available.

In 1985, this position was reversed with the decision of the Patent and Trademark Office Board of Appeals and Interferences in the Hibberd case. Relying on the landmark Supreme Court decision of Diamond versus Chakrabarty (447 US, 303 [1980]), which stated that a genetically engineered microorganism constituted patentable subject matter, the Board in the Hibberd case held that claims to a maize plant (and to seeds and tissue cultures of such plants) were patentable under the general utility patent statute. Since the Hibberd decision, the Patent Office has recognized the patentability of novel and unobvious plants, whether created through traditional plant breeding procedures or through genetic engineering.

The utility patent statute provides much greater flexibility in protecting inventions of new plants and related subject matter than is available under the Plant Patent Act or the PVPA. This greater flexibility does, however, have a price, which is the substantially more detailed disclosure that is required. Through a utility patent, an inventor can claim the novel plant, seeds and other propagating material, and even fruit and flowers. For transgenic plants, claims to DNA molecules, vectors, transformed plant cells, intact plants, seeds and processes for making and using such materials are typically included in a utility plant application.

The disclosure of a utility patent application must contain a written description of the invention as claimed, a description of how to make and use the claimed invention (i.e. an enabling disclosure) and the best mode contemplated by the applicant for carrying out the invention at the time of filing. Frequently, compliance with the disclosure requirement necessitates the deposit of seeds, propagating material, or other biological specimens with a public depository. The specification must conclude with one or more claims distinctly stating and specifically pointing out what the applicant regards as the invention.

Because of the disclosure requirements, utility patent applications are much more complicated and lengthy (and accordingly, more expensive) than applications for plant patents or plant variety protection certificates. This additional complexity and expense is usually justified by the scope of protection that is provided.

The prosecution of utility patent applications in the biotechnology field can be quite complicated. The most difficult issues usually relate to the claim scope, the sufficiency of the disclosure and obviousness.

The above issues have been highlighted in the ongoing debate concerning US patent 5,159,135, which was issued to Agracetus, a subsidiary of WR Grace and Company. This patent broadly claims transgenic cotton plants in which at least some of the cells of the plant contain a heterologous gene that is expressed to produce a foreign protein or a negative strand of RNA. The Agracetus patent has received a great deal of attention, because its claims are so broad as to encompass essentially any transgenic cotton plant. Yet, the disclosure is limited to a single transformation procedure. Last year, the Patent Office agreed to re-examine the Agracetus patent and, at the end of the year, issued an initial action rejecting the claims as obvious over several published scientific articles.

The public criticism of the Agracetus patent and its subsequent re-examination illustrate how difficult it can be to resolve tissues of obviousness and claim scope in this field. The proceedings involving this patent are not final and may continue for some time.

Despite their problems, utility patents provide an invaluable form of protection for novel varieties of plants. The ability to obtain multiple claims to different aspects of the invention usually justifies the time and expense associated with such patents.

The Plant Variety Protection Act

By 1970, it became apparent to Congress that true-to-type reproduction was possible for sexually reproduced plants. The result was the enactment of the PVPA. This Act was intended to complement the Plant Patent Act and provide patent-like protection for plants reproduced from seed. The PVPA is administered by the United States Department of Agriculture.

The Plant Variety Protection Act was amended substantially last year. The purpose of these amendments was to conform the Act to recent changes to the UPOV Convention and to strengthen this form of protection.

PVPA protection is available for sexually reproduced or tuber propagated plant varieties (other than fungi or bacteria), provided that the variety is new, distinct, uniform and stable (7 USC §2402 [a]). Applications are filed with the Secretary of Agriculture and must contain a description of the variety setting forth its distinctiveness, uniformity, and stability, as well as description of the genealogy and breeding procedures used for producing the variety. Applications for Plant Variety Protection Certificates are relatively straightforward and inexpensive.

Among the rights conferred are those to exclude others from selling, marketing, offering for sale, importing, exporting, or using the protected variety in producing (as distinguished from developing) a hybrid or different variety. An important change introduced with last year's amendments to the PVPA extend the protection to "essentially derived" varieties, that is, a variety which was derived from, and retains, expression of the essential characteristics of the protected variety.

Another important change resulting from last year's amendments was the substantial narrowing of the so-called 'farmer's saved seed exemption'. Before the amendments, the PVPA contained a provision that allowed farmers to sell, for reproductive purposes, some of the seed of a protected variety planted on their farms. The language of this provision was quite vague and resulted in farmers selling large volumes of seed for planting purposes, a practice known as 'brown bagging'. This provision was the subject of litigation that was appealed all the way to the Supreme Court (Asgrow Seed Company versus Winterboer, 115 S. Ct. 788 [1995]). The Supreme Court ruled that the saved seed provision only allowed a farmer to sell the amount of seed that had been saved for replanting on that farmer's farm.

The recent amendments to the PVPA changed the saved seed provision to allow farmers to save seed only for replanting on their own farms. Under the new act, any sale of a protected seed for reproductive purposes requires the permission of the certificate holder. The recent changes to the PVPA significantly enhance the value of this form of protection.

Conclusions

Those involved in plant breeding and plant molecular biology in the United States have an unusually wide spectrum of intellectual property protection schemes available to protect their inventions and discoveries. These various forms of intellectual property protection provide the incentives necessary to encourage investment in plant breeding and plant molecular biology.

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