

Protecting Intellectual Property in Plants and Seeds

Editor's note: This is the final part of a six-part series on patent law.



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Modern biotechnology makes possible the selective transfer of genetic material between organisms, and has allowed for the development of seeds and plants that tolerate herbicides, resist pests, have improved nutritional profiles, grow in adverse conditions, and have better handling and processing characteristics (1, 2). The research and development behind such products can be costly. Presently, such products, and the innovations underlying them, can be protected by utility patents, plant patents, certification under the Plant Variety Protection Act, and trade secrets. This column introduces these forms of protection and their historical context.

Historical Review

The Seed Industry

In the 1800s, the federal government collected seeds from around the world to distribute to U.S. farmers (3, 4, 5). This government program brought new germplasm into the U.S. gene pool (6). The program ended in 1924 and at that point the U.S. government was distributing millions of packets of seeds annually (3, 4, 5). The elimination of the government program gave the emerging seed industry an incentive to invest in research and development. The elimination of the government seed program also coincided with a rediscovery of Gregor Mendel's groundbreaking pea-

breeding experiments of the mid-1860s, accelerating progress in plant and seed science. Consequently, there was an increased need to protect the "fruits" of such research and development. Unfortunately, the courts had not yet recognized utility patents as a viable means of protecting seeds.

The Nursery Industry

In this same time frame, the nursery industry successfully commercialized asexually reproduced plants. Asexual reproduction (e.g., grafting, budding, rooting) allowed for mass production of genetically identical plants, which was important for plants such as fruit trees and ornamentals. Unfortunately, once a company introduced a new plant variety into the market, a competitor nursery could buy the plant and start to mass produce it, taking profits from those who discovered or bred the new variety (5). This, combined with the fact that the courts did not think utility patents could protect

living organisms, such as plants, created a need for a new type of intellectual property protection.

The Plant Patent Act of 1930

Eventually, the nursery and seed industries fought for and obtained statutory provisions to protect their intellectual property, separate from the existing but unused utility patent provisions. First, Congress enacted the Plant Patent Act (PPA) in 1930. The PPA protected the invention or discovery of, and the asexual reproduction of, distinct and new varieties of plants, including ornamentals, fruit trees, and berry plants. In 1952, the provisions of the PPA were incorporated into the patent statute as 35 U.S.C. Sections 161–164 (3).

The Plant Variety Protection Act of 1970

In 1970, Congress enacted the Plant Variety Protection Act (PVPA). Unlike the asexually produced plants described above covered by the PPA, the PVPA protects such agriculturally important crops as cereal grains, grasses, and vegetables that are grown from seed (i.e., via sexual reproduction). The PVPA is a certification program run by the Plant Variety Protection Office (PVPO) of the USDA. The PVPO issues Certificates of Protection for new varieties of plants that are seed reproduced (or tuber propagated), upon examination to determine that a plant is a new, distinct variety, and genetically uniform and stable (7). The remedies for infringement include damages and injunctions (8). Thus, PVPA certification helps protect innovators who have invested large amounts of time and money into developing seed technologies and innovations in sexually reproduced plants.

The U.S. Supreme Court

Finally, in 1980, the U.S. Supreme Court began to clarify and expand the coverage of utility patents to include plants. In a seminal decision, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Supreme Court addressed the patentability of a genetically-modified bacterium capable of breaking down crude oil. The patent examiner had allowed claims to a method of producing the bacterium and to an inoculum containing the bacterium. However, the examiner denied the claims to the bacterium itself, in part because micro-organisms are "products of nature," and living things were not deemed patentable under U.S. patent law, which identifies patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter." The Supreme Court ruled that the bacterium was a "manufacture" or "composition of matter," and was therefore patentable subject matter (9).

In 2001, in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 534 U.S. 124 (2001), the Supreme Court re-emphasized what it had said in *Chakrabarty*, that the utility patent statute is "forward-looking" and that "Congress employed broad general language in drafting § 101 precisely because [new types of] inventions are often unforeseeable" (3). As such, the Supreme Court found that utility pat-

ents could be issued for plants, such as the new varieties of hybrid and inbred corn involved in the case.

These Supreme Court cases make it clear that utility patents are available for innovations in plants and seeds, provided the statutory requirements of patentability are met (i.e., utility, novelty, nonobviousness, definiteness, written description, enablement, and best mode (35 U.S.C. Sections 101, 102, 103, 112)).

Comparison of IP Protection for Plants

The PPA, PVPA, and utility patents are three potential means of protecting intellectual property relating to plants. Trade secret protection may also be available. These protections are compared and contrasted below.

PPA Plant Patents

Plant patents cover only asexually reproduced plants (e.g., grafting, budding, rooting) excluding tuber-propagated plants or plants found in an uncultivated state. Plant patents have only one claim written in a formal format, directed to the plant itself, and a less stringent written description requirement than utility patents. Commercially important plants eligible for plant patent protection include ornamentals, fruit trees, berry plants, and other plants typically associated with the nursery industry. Plant patent requirements are recited in 35 U.S.C. Sections 161 and 162. "Distinctness" is the primary hurdle to patentability (8). Additional information on plant patents is available at the USPTO website and in treatises (8, 10).

PVPA Certification

PVPA certification is overseen by the PVPO of the USDA. Certification protects innovation in sexually reproduced plants. Sexually reproduced plants were omitted from the PPA because when the PPA was enacted new varieties could not be reproduced true to type (3, 8). By 1970, the state of the technology had changed and the need to protect innovation in sexually reproduced plants was recognized (8). A PVPA certificate has no claims, and is directed to a single plant variety (8). Obtaining a PVPA certification entails filling out a form, paying the appropriate fee, and providing information such as breeding history, a statement of distinctness, and an objective description of the variety. PVPA applications are examined for distinctness, uniformity, and stability to assess whether a plant meets the statutory "novel variety" standard (8). Presently, the certification process costs about \$5,000, which includes costs for filing and examining the application, as well as certificate issuance fees. More information is available at the PVPO/USDA website (7).

Utility Patents

Utility patents are available for innovations in all technical areas, including plants and seeds, provided all patentability requirements are satisfied. Because utility patents can contain more than one claim and the claims can be directed to more than the plant itself, utility patent protection can protect a plant or seed more broadly than a plant patent or a PVPA certification. For example, U.S. 7,420,104, entitled "Soybean Cultivar S06-CL821457," contains 13 claims directed to, among other things: (a) a soybean seed; (b) a plant or parts thereof; (c) pollen of the soybean plant; (d) a tissue culture of regenerable cells; (e) a soybean plant regenerated from the tissue culture; and (f) a method for producing a soybean seed.

Trade Secret

Trade secret protection is available for information that provides some commercial advantage, as long as the information is kept secret. Secrecy is often hard to maintain with regard to plants and seeds because once distributed, the public and competitors can attempt to reverse engineer the trade secret. Trade secret protection may be more practical, with less secrecy issues, for innovations in parental lines for breeding programs, or other seeds, which are never themselves sold, and therefore difficult to reverse engineer. However, if a trade secret

IP Protection for Plants

- Innovations in plant and seed technologies may be protected by utility patent, plant patent, PVPA certification, and trade secret.
- Utility patents are available for plants that reproduce sexually and asexually, and are not confined to the plant itself.
- Plant patents protect asexually reproduced plants.
- PVPA certification is a program run by the USDA for sexually reproduced plants.

is kept secret and misappropriation can be proven, trade secret protection can be effective, although enforcement can be expensive. For example, the owner of a trade secret in the genetic make-up of certain seed corn recovered \$46 million in damages for trade secret misappropriation by a competitor upon proving that: the genetic make-up/messages had been kept secret; the competitor possessed the protected genetic messages; and the competitor obtained the protected genetic messages by improper means. The trial, which was followed by an appeal, lasted 37 days, involved over 1,100 exhibits, and resulted in over 9,000 pages of transcript (11).

As the above comparisons show, utility patents provide the greatest range of protection to innovations across the plant and seed world. However, utility patents are usually harder to obtain than plant patents or PVPA certifications.

Continuing Exploration of Patents and Patent Law

This article series provided an introduction to patent law for scientists, engineers, and other food industry professionals. Readers interested in continuing to learn about patents can explore the USPTO website (12). One can also search for and read patents in an area of interest. For example, searching the USPTO database for patents with "corn" in the title retrieves over 1,300 patents dating back to 1976. Included are patents on plants, seeds, methods of breeding, devices, and other technologies.

For more information regarding a particular patent, one can review its prosecution history. For recently issued patents, this information is posted on the USPTO website in the "Patent Application Information Retrieval" (PAIR) section under an electronic tab entitled: "image file wrapper" (13). Additional information available at the USPTO website includes: the assignment/ownership history of a patent; the status of maintenance fee payments; information regarding whether a patent term extension was requested or is pending; and information regarding whether an issued patent is in reexamination or reissue proceedings.

One can also learn more about patents by reading patent decisions. For example, the *JEM* case described above discusses utility patents, plant patents, and PVPA certification. A copy of the *JEM* decision is available at the Cornell University Law School Supreme Court collection website (14). Other decisions, such as decisions of the Federal Circuit (the appellate court for patent disputes) are available on the Federal Circuit website (15) where new decisions are posted daily.

References

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