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Intellectual Property Issues in Plant Breeding and Plant Biotechnology

MARK D. JANIS*

Introduction

Intellectual property protection has never been more important to the enterprise of plant breeding than it is today, for two principal reasons. First, commercial plant breeding is now largely carried on by private enterprise, or by private/public partnerships that rely heavily on private funding. Second, the required level of private investment may be substantial. Commercial plant breeding now requires significant capital investments in research and development (R&D), especially where the breeding entails use of biotechnology techniques. Intellectual property protection plays a key role. It may act as security for private R&D investments in plant innovation, insuring that investors will be able to exercise some amount of control over commercialization of the new plant-related technology that results from their investment in R&D.

Although strong intellectual property protection is vital to stimulating R&D investment in the plant breeding industry, intellectual property protection also comes at a price. Breeders who are developing proprietary crop lines may be unwilling to transfer seeds freely to other breeders to develop their own new varieties. Seed companies that own patents on genetically-modified (GM) seeds may impose license fees that are passed along to growers. The pool of publicly available germplasm may shrink, making it more costly (or perhaps economically unfeasible) for breeders to improve on existing varieties. And, the system may be costly for the government to administer, unless supported by user fees.

It has not been an easy task to adapt traditional intellectual property systems (like the nation's general patent system – the so-called “utility” patent system) to balance these competing needs in the plant breeding industry. Congress has experimented with a number of specialized intellectual property systems for plants that continue to exist alongside the general patent system, resulting in a confusing array of overlapping intellectual property regimes. This paper surveys existing forms of intellectual property protection available to plant breeders under U.S. law, offering a brief introduction to the area. It also discusses the use of technology agreements in connection with seed distribution to growers.

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Utility Patent Protection

Utility patent protection is an increasingly important form of intellectual property protection in the seed industry. The U.S. Patent and Trademark Office (PTO) has issued several thousand U.S. patents covering the products and methodologies of both conventional breeding programs and plant biotechnology research. The United States Supreme Court has recently confirmed that plants qualify as eligible subject matter for utility patent protection notwithstanding the existence of other forms of intellectual property protection for plants.¹ Plant breeders are likely to file more utility patent applications in the wake of this ruling.

What Rights Does a Patent Owner Have?

The utility patent scheme is the nation's general patent system, encompassing technologies that range from traditional mechanical inventions to exotic software and biotechnology inventions. A utility patent endures for twenty years from the application date, and confers on its owner the right to exclude others from making, using, selling, offering to sell, or importing the invention claimed in the patent, among various other rights.² One who carries out any of these acts without the patent owner's authorization may be liable for patent infringement, and may be made subject to a court order enjoining future infringing acts and a judgment of damages to compensate the patent owner for past infringing acts. The statute requires -- at a minimum -- that compensatory damages be computed on the basis of the "reasonable royalty" that the patent owner would have received had the infringer entered into a license agreement with the patent owner.

The patent statute confers powerful rights on patent owners. For example, the statute imposes liability for innocent as well as intentional acts of infringement. If seed company "A" patents a method for inserting transgenes in a corn plant, and seed company "B" later independently develops and begins to use the same method, "B"'s use is infringing even if "B" did not rely on the teachings of A's patent and was unaware of its existence.

In a widely publicized Canadian case, Monsanto sued a canola farmer in Saskatchewan, asserting that the farmer was growing a Monsanto genetically-modified canola variety without Monsanto's authorization. The farmer raised an "innocent" infringement defense, arguing that the presence of genetically-modified canola in his crop must have been due to pollen drift from neighboring fields or spillage from bypassing trucks.

Although the Canadian court recited the rule that "innocent" infringement could not be excused as a matter of Canadian patent law, the court plainly did not believe that Schmeiser was innocent. Instead, the court credited Monsanto's expert testimony that the proportion of genetically-modified canola in the farmer's crop was so high as to indicate that it had not resulted from adventitious drift. The farmer had argued that tests on at least one of his samples did not show a high proportion of genetically-modified content, but the court expressed skepticism about whether the sample was genuine.³ The farmer has appealed.

1. J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, Inc., 122 S.Ct. 1600 (2001).

2. 35 U.S.C. §271(a).

3. Monsanto Canada, Inc. v. Schmeiser, 12 C.P.R. (4th) 204 (2001).

Reportedly, Monsanto has filed a few similar cases in the United States, though none has yet resulted in a reported judicial opinion, and it is not yet clear whether the evidentiary record in any of these cases will persuasively demonstrate that the presence of proprietary plant material was solely the result of pollen drift. Thus, neither Canadian nor U.S. courts have yet been confronted squarely with the question of whether to depart from traditional patent infringement principles to accept a defense of innocent infringement based on adventitious pollen drift.

No doubt anticipating such suits, the North Dakota state legislature passed House Bill No. 1442 in the spring 2001.⁴ The bill specifies that before owners of patents on genetically-modified seed may enter onto a farmer's land to obtain crop samples to determine whether patent infringement has occurred, the patent owner must notify the state's agriculture commissioner and the farmer, and must obtain the farmer's written permission to enter. If the farmer withholds permission, the patent owner must petition the state district court for an entry order, though the bill identifies no standard that the court is to apply in determining whether to grant the petition. The bill also supplies certain guidelines for custody over the samples.

In addition, the bill purports to require the patent owner to designate an "independent laboratory" which "shall conduct all tests to determine whether patent infringement has occurred." This part of the bill is not likely to be held enforceable. A patent is a federally-created right enforceable in federal court. A state legislature lacks authority to limit a patent owner in the forms by which patent infringement may be proven, and certainly lacks authority to delegate the determination of patent infringement to an "independent laboratory."

The U.S. patent statute also imposes liability for all unauthorized "uses" even if those uses are not directly linked to any sales. Suppose that a university researcher uses a patented soybean variety, without a license from the patent owner, in a breeding program to develop a new variety. Although courts in a handful of cases have recognized a "non-commercial research" exemption from patent infringement, most research, even in a university setting, can be connected to commercial motivations, even if only indirectly. Accordingly, it would be unwise for plant breeders to assume that research activities can invariably be shielded from patent infringement liability. The law is unsettled on this point.

Finally, the statute imposes liability for unauthorized "making" even if the making results in no sale. Suppose that a farmer purchases a patented item from an authorized dealer -- say, a patented no-till drill from the patent owner's regional distributor. Absent an express agreement to the contrary, the patent law principle holds that the farmer has the authority to use and resell the drill without paying any patent-related fees to the patent owner. The farmer also would have authority to repair the drill; that is a customary and (perhaps unfortunately) expected aspect of "use." On the other hand, if the farmer rebuilt the entire

4. For a chronology of events leading to the bill's passage, *see* http://ranch.state.nd.us/L/R/01/bill_actions/BA1442.html.

drill, the farmer might be doing the functional equivalent of “making” a new drill without the patent owner’s authorization. Imagine, for example, that the farmer went into the business of buying discarded drills, refurbishing them, and reselling them in competition with the patent owner. The reconstruction of the drills might be deemed a new “making” triggering infringement liability.

These principles are not easily translated to the domain of seed patents. Suppose that a farmer purchases soybean seed from a seed company, plants the seed, harvests the soybeans, and saves back a small portion of the harvested crop for use in planting a new crop. When the patented seed grows and produces new seed, is the new seed a new “making” of the patented seed, like the wholesale reconstruction of the patented drill? Or is it simply an aspect of the original “using”?

It is not clear how patent law would draw the line here between permissible use and impermissible “reconstruction.” However, it is also not clear that courts will be called upon to answer this question. Seed companies do not currently make unrestricted sales of seed to customers. They impose numerous restrictions by way of “technology agreements,” ordinarily printed on the seed bag. Such agreements typically restrict the customer’s authority to reuse the seed. To the extent that these agreements are enforceable, they could override the patent law rules on repair and reconstruction. For a discussion of the enforceability of seed bag technology agreements see a later section in this paper on technology agreements.

How Are Patent Rights Acquired?

A would-be patent owner acquires utility patent rights by filing a patent application with the PTO. The PTO examines the application to determine whether it complies with various formal requirements, and whether the application claims subject matter that is patent-eligible, useful, adequately described, novel, and non-obvious.⁵ If the PTO concludes that the application satisfies these requirements, a patent is issued.

An issued patent is presumed to be valid. A patent challenger – typically a defendant in patent infringement litigation – bears the burden of establishing invalidity by clear and convincing evidence.

The PTO and the courts have had difficulty applying a number of the patentability requirements to plants. First, under a longstanding patent law maxim, “natural products” are not eligible for patent protection. It might seem that the “natural products” exception would preclude patent protection for biological subject matter, and, indeed, in the early twentieth century, that view of the law prevailed in some quarters, although no definitive line of cases had emerged. However, more recent patent jurisprudence has firmly established that living subject matter is patent eligible – avoiding the natural products exception – so long as there is evidence of that man exercised even modest control over its creation or purification.

5. These terms are terms of art in the Patent Statute. The relevant provisions are 35 U.S.C. §§101, 102, 103, and 112. The Patent Statute, PTO regulations, and other information about the U.S. patent system can be found at the PTO’s website, <<http://www.uspto.gov>>.

Breeding practices, for example, would qualify as sufficient human intervention.

Second, patentees must deliver a written description of the patented invention, rendered in sufficient detail to enable a person of ordinary skill in the relevant art area to make and use the patented invention. To satisfy these requirements, patentees in the plant area routinely deposit viable seed samples in a publicly-accessible seed depository. PTO regulations prescribe how and where deposits must be made, conditions for access, and other details.⁶

Third, an invention claimed in a U.S. patent must be “non-obvious” at the time the invention was made, taking into account what one of “ordinary skill in the art” would have known about developments in the field. Courts have had few opportunities to apply this requirement to plant-related inventions. So, for example, a number of patents include claims to the application of standard plant breeding techniques to the creation of a new plant variety. The obviousness requirement may prove to be pivotal in these cases.

More detailed analysis of these issues can be found in the references cited in the endnote.⁷

Plant Variety Protection

Plant breeders may also acquire intellectual property protection through another U.S. statutory regime, the Plant Variety Protection Act (PVPA).⁸ A PVP certificate protects a discrete plant “variety” – i.e., “a plant grouping within a single botanical taxon of the lowest known rank.” Any sexually reproduced variety that is “new,” “distinct,” “uniform,” and “stable,” qualifies for protection.⁹ F1 hybrids are now protectable under the PVPA, as a result of a 1994 statutory amendment. PVP applicants must file an application with the PVP Office (of the U.S.D.A.) that evidences compliance with these requirements, and must submit a seed deposit. A PVP certificate remains in force for either 20 or 25 years from the date of certificate issuance, depending on the variety.¹⁰

PVP certificates are sometimes described as “patent-like,” but plant variety protection in fact differs from patent protection in two fundamental ways. First, the PVP scheme imposes less rigorous requirements for protectability than does the patent scheme. For

6.37 C.F.R. §1.802-9.

7. For additional information on the topic of utility patent protection for plants, see Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEGAL STUDIES 91 (2001); Mark D. Janis & Jay P. Kesan, *Designing an Optimal Intellectual Property System for Plants: A Supreme Court Debate*, 19 NATURE/BIOTECHNOLOGY 981 (with Kesan) (October 2001); Jay P. Kesan, *The Relationship Between IP Protection and Biotechnology - A Multidisciplinary Perspective*, 44 AM BEHAV. SCI. 464 (2000).

8. For the statutory text, see 7 U.S.C. §§2321-2583.

9. Each of the quoted terms is a statutory term of art in the PVPA. See 7 U.S.C. §2402(a).

10. 7 U.S.C. §2483(b)(1).

example, it does not require that the variety for which protection is sought be “nonobvious” in view of existing varieties.

Second, the PVPA affords much narrower protection than does the utility patent grant. A PVP certificate protects only the discrete variety identified in the certificate and varieties that are “essentially derived” from the protected variety.¹¹ In addition, PVP rights are subject to numerous exceptions, allowing use of a protected variety for “noncommercial purposes,” for “bona fide research,” for “developing” a different variety, or as saved seed for reuse on the farm.¹² The Secretary of Agriculture may also force PVP certificate owners to license the use of a protected variety for a set royalty under specified circumstances.¹³

For further reading on the Plant Variety Protection Act, consult the references listed in the footnote.¹⁴

Other Forms of Protection

Two other forms of intellectual property protection for plant breeders deserve brief mention here: plant patents and trade secrets.

Plant Patents

A plant patent is a narrow and specialized form of protection that differs from utility patent protection. Plant patents came into existence in the United States in 1930, in response to lobbying from the nursery industry. Typical nursery stock (fruit trees, ornamentals, roses) is reproduced asexually, by grafting cuttings onto rootstock. It is not surprising, then, that the plant patent provisions protect only varieties obtained through asexual reproduction (and which meet several additional requirements, including novelty and nonobviousness).¹⁵ Similarly, plant patents protect only against unauthorized asexual propagation of protected plants. Accordingly, plant patent protection has been of little value in the seed industry.

Trade Secrets

There is no comprehensive federal law on trade secrets, but most states have adopted trade secrets statutes. Those statutes generally recognize trade secret protection in a variety of types of information (technical information, sales and marketing data, etc.), as long as that information derives its value from the fact that it is secret, and is the subject of reasonable efforts to maintain it as a secret. Trade secret laws prohibit trade secret “misappropriation”

11.7 U.S.C. §2541(c).

12.7 U.S.C. §§2541; 2543.

13.7 U.S.C. §2404.

14. For additional information on the Plant Variety Protection Act and its foreign counterparts, see Mark D. Janis & Jay P. Kesan, *U.S. Plant Variety Protection: Sound and Fury. . .?*, U. HOUSTON L. REV. (forthcoming 2002)

15. For the relevant statutory provisions, see 35 U.S.C. §§161-63.

(acquiring a trade secret improperly or in breach of a confidential relationship), but do not prohibit independent development, nor do they prevent reverse engineering (reconstructing the trade secret through publicly disclosed materials).

Trade secret protection has commonly been used in the seed industry. For example, a seed company might protect the identity and genealogy of the inbred parents of a commercially successful hybrid corn line.¹⁶

In this context, questions may arise over whether the practice of “chasing the selfs” would constitute permissible reverse engineering, or would otherwise lead a court to conclude that trade secret protection had been lost. “Chasing the selfs” is a technique to identify a hybrid’s parents by, for example, sifting through seeds in a bag of hybrid seed to find self-pollinated parent seed that may accidentally have been included. If selfing is deemed to be an act of uncovering the trade secret through legitimate, publicly available means, it may fit within the scope of permissible reverse engineering. If selfing is characterized as taking advantage of a mistaken or accidental disclosure of the secret, where all reasonable precautions against disclosure were taken, then trade secret protection might be preserved notwithstanding the potential for deriving the trade secret information by way of selfing.

In either case, the potential for loss of protection through the inadvertent disclosure of “selfs” suggests that trade secret protection is an especially vulnerable form of intellectual property protection for plant-related innovation.

Technology Agreements

Most intellectual property owners collect returns on their intellectual property by way of licensing arrangements. A license is an agreement between an intellectual property owner (licensor) and a licensee, typically providing that (1) the licensor agrees not to sue the licensee for undertaking acts that would otherwise constitute intellectual property infringement; and (2) the licensee agrees to pay fees to the licensor, often calculated as royalties on sales of products made or sold by the licensee under the license agreement.

License agreements may arise even in the absence of a formal, written document. For example, a consumer might purchase a DVD player at a retail electronics store. In all likelihood, the DVD player is covered by one or more patents. Technically, the consumer needs a license under those patents to use (or resell) the DVD player, yet typical retail sales transactions do not include express patent licenses. Accordingly, the intellectual property law provides that when an intellectual property owner makes an unconditional sale of protected products, the purchaser takes an “implied” license, the license’s “terms” being fixed by default rules of intellectual property and contract law. The principle that an unconditional sale triggers an “implied license” is sometimes referred to as “exhaustion” of rights.

16. Pioneer Hi-Bred Int’l v. Holden Foundation Seeds, 35 F.3d 1226 (8th Cir. 1994).

In some areas of technology – particularly those characterized by easy duplication – intellectual property owners prefer to supply their own license terms rather than relying on the “terms” of an “implied” license. For example, in the distribution of software, it has become customary for distributors to require purchasers to agree to express written license restrictions either printed on the software’s packaging or embedded in its installation programming (and therefore called “shrink-wrap” or “click-wrap” licenses).

The seed industry has followed suit. Major seed producers typically include express license restrictions on seed bags (called “bag tag” or “seed-wrap” licenses, or, more conventionally, “technology agreements”). A representative Pioneer bag tag license, for example, provides, in relevant part, that

“If the tag indicates this product or the parental lines used in producing this product are protected under one or more U.S. patents, Purchaser agrees that it is granted a limited license thereunder only to produce forage, or grain for feeding or processing. Resale of this seed or supply of saved seed to anyone, including Purchaser, for planting is strictly prohibited under this license.”

Similarly, a Monsanto technology agreement appearing on 50-lb. bags of Roundup Ready soybeans in the late 1990's required payment of a \$6.50 per bag license fee and restricted use of the seed. It expressly provided that seeds must be used “for planting a commercial crop only in a single season” and directed farmers not to “save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting.”

In an important recent decision, the Court of Appeals for the Federal Circuit upheld Monsanto’s Roundup Ready technology agreement against a challenge mounted by a Mississippi farmer, McFarling.¹⁷ McFarling had purchased Roundup Ready soybeans from Monsanto and had signed the technology agreement. Notwithstanding the restrictions in the agreement, McFarling saved 1500 bushels of Roundup Ready soybeans from one harvest and replanted them during the next season. He then repeated the practice, and indicated that he intended to continue despite conceding that his actions violated the technology agreement. According to McFarling, the agreement violated the antitrust and patent laws, and was improper in view of the PVPA.¹⁸

The Federal Circuit rejected each of McFarling’s arguments. Two of those arguments merit brief mention here. McFarling argued that his seed saving practice should be shielded by the doctrine of “exhaustion.” The Federal Circuit disagreed. According to the court, McFarling’s purchase of a bag of seed did not exhaust Monsanto’s rights in new seed

17. *Monsanto Co. v. McFarling*, No. 01-1390 (Fed. Cir. Aug. 23, 2002). See also *Monsanto Co. v. Trantham*, 156 F.Supp.2d 855 (W.D. Tenn. 2001) (discussing similar issues at trial court level).

18. McFarling also challenged whether the Federal District Court for the Eastern District of Missouri properly had jurisdiction.

generated from the purchased seed. Alternatively, the court could simply have pointed out that the exhaustion doctrine only applies to *unconditional* sales, and the sales at issue were accompanied by the express license conditions in the technology agreement -- so those sales were not unconditional. Another way to make the same point is to say that the express license restrictions trump any implied license “terms.”

McFarling also argued that the technology agreement should not be enforced because it conflicted with the “saved seed” exemption of the PVP. The court rejected this argument as well, noting that utility patent protection and PVPA protection are “complementary” and concluding that “the right to save seed of plants registered under the PVPA does not impart the right to save seed of plants patented under the Patent Act.” Here, again, the court might have used a different analytical route to reach the same result. The court might have pointed out that the “saved seed” provision is simply an exception from liability under the PVPA; it does not (and cannot) create any affirmative “right” to save seed. That is, the fact that Congress chose to exempt certain behavior from one federal statute surely does not mean that Congress intended to exempt that behavior from all other federal statutes.

Conclusion

Intellectual property protection can stimulate investments in plant-related innovation, particularly in the area of plant biotechnology. But intellectual property protection must be shaped properly to balance competing needs of plant breeders, growers, and others who depend upon the health of the farm economy. The task of achieving the proper balance will fall largely to Congress, the federal courts, and policymakers. Those who care about the farm economy – and that surely includes Midwesterners – should pay careful attention to this debate.