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Roger A. McEowen

Iowa State University

6-4-2004

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DEVELOPMENTS IN GMO PATENT INFRINGEMENT CASES

— by Roger A. McEowen*

Overview

The ability to obtain a general utility patent on seed technology has led to cases in which farmers have been sued for misappropriation of the technology. Because seed is reproducible, any farmer that saves seed is a natural competitor of a company that sells seed. But, for seed that is patented, the saved seed exemption of the PVP is avoided, and the saving of seed can be prohibited. Indeed, under Technology Use Agreements for genetically modified seed presently in use, a farmer can use the seed for one-time planting, may not supply the seed to anyone else for planting, may not save any crop produced from the seed for replanting (or supply saved seed to anyone else for replanting) and must not use the seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production.

Clearly, a farmer signing a technology agreement is prohibited from saving seed subject to the agreement. But, what if the patented traits are present in the crops and/or resulting seed of a farmer that did not purchase or plant the patented seed? Has that farmer illegally infringed the patent even though having no intent to acquire the protected seed or infringe the patent? So far, courts have held that the process by which the patented seed arrives on a farmer’s land is irrelevant. But, the tide may be turning.

The Innocent Infringer Defense - The Advent of a Doctrine of Equitable Enforcement of Patent Laws?

The Canadian approach. In Monsanto Canada, Inc. v. Schmeiser, the Canadian Court of Appeals held that Schmeiser, a Canadian farmer, had infringed Monsanto’s patent on Roundup Ready canola by saving and replanting protected seed without a license. Schmeiser had not paid a license fee to use the technology and claimed that pollen drift from a neighbor’s fields or passing grain trucks had contaminated his fields. Schmeiser claimed that he did not knowingly acquire the technology or segregate the contaminated seeds nor spray his crop with Roundup. Indeed, Schmeiser had a long-standing farming practice of saving his own canola seed and replanting that saved seed the following year. Thus, the initial sources of contamination were an inadvertent, but nonetheless unavoidable, result of a normal farming practice. However, the appellate court held that Schmeiser had infringed Monsanto’s patent because he either knew or should have known that the subject seeds were glyphosate resistant.
After the appellate court’s opinion in Schmeiser,11 the Canadian Supreme Court rendered an opinion concerning the patentability of the so-called “Harvard Mouse.”12 In that case, the Court held that a mouse, as a higher life form, was not patentable under the specific wording of the Canadian Patent Act.13 The Court noted that the Canadian Patent Act provides for protection of intellectual property rights in the “making, constructing, and using [of an] invention and selling it to others to be used.”14 The Canadian Supreme Court agreed to hear the case, with the key questions being whether the genes and cells of seeds and plants are covered by the Patent Act in spite of the wording of the statute, and whether plants and seeds are patentable in light of the Court’s earlier opinion in Harvard Mouse.15

Upon review, the Canadian Supreme Court ruled that plants, as a higher life form, are not patentable subject matter, but that the Monsanto patent at issue applied to the gene and was valid.16 Schmeiser was found to have infringed the patent because his “use” of the patented invention deprived Monsanto of the full enjoyment of the monopoly conferred by the patent. The Court noted that mere possession of a patented invention creates a rebuttable presumption of “use,” and that the intent of the alleged infringer may be relevant to rebutting the presumption. The Court reasoned that Schmeiser failed to provide sufficient evidence to rebut the presumption of “use” and had infringed Monsanto’s patent. On the issue of damages, however, the court noted that the Patent Act only entitles the patentee whose patent has been infringed to the portion of the infringer’s profit which is casually attributable to the patented invention. Because Schmeiser earned no profit from infringing Monsanto’s patent,17 Monsanto was not entitled to damages. Thus, Schmeiser was not required to pay Monsanto any damages, penalties, court costs or the technology use fee of $15 per acre. Schmeiser, however, is barred from using Roundup Ready canola unless he pays a license fee, and must turn over any Roundup Ready seeds remaining in his possession.18

Key U.S. ruling. Three weeks before the Canadian Supreme Court’s opinion in Schmeiser,19 the United States Court of Appeals for the Federal Circuit, in Smithkline Beecham Corp. v. Apotex Corporation,20 invalidated a patent on a self-reproducing antidepressant drug because previous clinical trials constituted a prior use.21 In the 1970s, a British company invented and patented paroxetine, an antidepressant drug. Eventually, the company developed a process to produce the crystalline hydrochloride salt of paroxetine, paroxetine hydrochloride (PHC). In 1980, Smithkline Beecham (SB) received a license for the technology and began manufacturing it. In the mid-1980s, an SB chemist created a new crystalline form of PHC known as PHC hemihydrate.22 SB was awarded a patent for PHC hemihydrate in 1988 and began marketing it as Paxil in 1993. In 1998, Apotex sought approval from the Food and Drug Administration to market its own PHC antidepressant drug with PHC anhydrate as the active ingredient. SB brought an infringement action against Apotex in 1998 claiming that Apotex was infringing its PHC hemihydrate patent by manufacturing PHC anhydrate tablets that necessarily contain, by processes of nature, trace amounts of PHC hemihydrate.

The trial court23 found that the hemihydrate that SB created in 1984 had spread (i.e., seeded itself) to numerous manufacturing environments, including those of Apotex. As a result, under normal conditions in a seeded environment, some of the original anhydrate converted spontaneously into the patented hemihydrate crystals. The court upheld the patent’s validity, but ruled that Apotex had not infringed the patent because its production processes had resulted in small, commercially insignificant amounts of hemihydrate.24 The trial judge specifically noted that failing to limit the scope of the patent would lead to inevitable infringement, and opined that it is a defense to a charge of patent infringement that the patentee caused the infringement. In the agricultural setting, that could mean that the judge would not hold a conventional (or organic) crop farmer liable for patent infringement when the reason for the presence of the patented traits in growing or harvested crops is cross-pollination, contamination from passing grain trucks or machinery, or simply because trace amounts of the patented genes and cells appear in conventional seed stocks.25 However, by establishing a patent infringement test of commercial significance, the judge apparently would require any commercially significant amounts of the patented technology to be given back to the patentee.26

On appeal, the Federal Circuit Court of Appeals disagreed with the trial court by noting that any amount of hemihydrate PHC produced (whether commercially viable or not) infringed the patent.27 but agreed that Apotex had not infringed the patent because SB’s clinical trials constituted a prior use. As a result, the compound was already in the public domain, and SB’s patent was invalid.

A concurring opinion reasoned that the patent was invalid not because of prior use of the subject matter, but because the subject matter was not patentable. The concurrence noted that man-made products or processes are patentable, but products that result from natural processes are not patentable.28 Thus, PHC would qualify for a patent because it is a man-made product, but because the original paroxetine anhydrate could naturally convert itself into the hemihydrate, the resulting PHC is not patentable. The judge compared the seeding and conversion process of PHC to the spread of patented, biotech seed traits via cross-pollination, and concluded that, “[T]he implication – that the patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented . . . stalks – cannot possibly be correct.” The judge went on to state, “. . . In short, patent claims drawn broadly enough to encompass products that spread, appear, and ‘reproduce’ through natural processes cover subject matter unpatentable under Section 101 – and are therefore invalid.”

Future Implications

In any event, the trial judge’s comments in Smithkline Beecham,29 the Federal Circuit’s opinion (especially the concurrence) in the same case30 and, to a lesser extent, the Canadian Supreme Court’s opinion (particularly the dissent) in Schmeiser31 provide a framework for the development of
future cases and legislation supporting an equitable enforcement of patent laws respecting both the rights of patentees and the rights of innocent infringers.

FOOTNOTES

1 Se, e.g., Kloppenbarg, First The Seed: The Political Economy of Plant Biotechnology 1492-2000, at 280 (1988).
3 See Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004) (referring to 1998 version of “Monsanto Technology Agreement”).
7 Id. Schmeiser historically saved his own canola seed for replanting. Thus, the contamination carried into his next year’s crop for which patent infringement was alleged. Importantly, the initial sources of contamination were an inadvertent but unavoidable result of normal farming practices.
8 University of Manitoba tests confirmed that the presence of Roundup Ready canola ranged from nearly zero percent to sixty-eight percent. Monsanto claimed that the degree of contamination in Schmeiser’s 1998 crop ranged from ninety-five percent to ninety-eight percent.
9 The origin of the genetically altered plants on Schmeiser’s land was unclear. Schmeiser claimed that the plants resulted from genetically modified canola seed that blew onto his land or as a result of cross pollination of his conventional canola. During the 1997 growing season, Schmeiser sprayed Roundup near a canola field and some of the canola plants were unaffected. Schmeiser then sprayed a three-acre field and most of the canola did not die. After harvesting the 1997 canola crop, Schmeiser stored some of the seed from the acreage and used it to plant part of his 1998 crop. During the trial, a local Roundup Ready canola farmer testified that while hauling his grain to market past Schmeiser’s fields in 1997, a tarp came loose and “acted like a cyclone,” releasing considerable canola.
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14 Commissioner of Patents v. President & Fellows of Harvard College, [2002] S.C.C. 76. The patent application was for the process for preparing the affected mouse as well as the product of the process (the mouse itself).
15 [2004] S.C.C. 34. The dissent (the decision was 5-4) held that the cultivation of plants containing the patented gene and cell did not constitute infringement, and that to conclude otherwise would confer patent protection on the resulting plants. The dissent pointed out that the patent at issue made no claim for a glyphosate-resistant plant and all of its offspring. Thus, the dissent reasoned, the saving, planting or selling of seed from glyphosate-resistant plants does not constitute an infringement. Such restrictions, the dissent noted, can be handled through Monsanto’s licensing of seeds produced from the patented gene, and contractual obligations that prohibit the saving of the licensed seed.
16 No finding was made that Schmeiser sprayed his crops with Roundup herbicide to reduce weeds.
17 While Canadian legal opinions have no direct bearing on American courts, the opinion could have an impact on patent infringement claims by patentees of genetic seed traits against farmers in the United States. To the extent courts in the United States hold that patentees are not entitled to damages in situations where the alleged infringer has not profited from the misappropriated technology, it will reduce the economic incentive for patentees to pursue infringement claims against innocent infringers.
20 Under 35 U.S.C. § 102(b) (2000), a patent claim is not valid if “the invention was... in the public use... in this country, more than one year prior to the date of the application for patent in the United States.” “Public use” includes any use of the claimed invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor. See Netscape Communications Corp. v. Konrad, 295 F.3d 1315, 1321 (Fed. Cir. 2002).
21 The original patented form of PHC was anhydrous PHC (PHC anhydrate) that is made up of PHC without bound water molecules, whereas PHC hemihydrate is made up of PHC with one bound water molecule for every two PHC molecules.
24 Id. The court, instead of invalidating the patent, interpreted the patent claim as excluding hemihydrate produced by involuntary conversion of a proportion of an anhydrous mixture so small as to lack any commercial significance.
25 Clearly, the judge is recognizing the value of the conventional (or organic) crop farmer’s right to be free from unwanted genetic technology.
26 A question can be raised as to whether the judge would require the patentee to pay damages to the disaffected party for any costs incurred by reason of the unwanted patented genetic traits.