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PATENT CONTROLS ON GM CROP FARMING

Janice M. Mueller[1]

I. INTRODUCTION

Patents on genetically modified (GM) crop technology arm their owners with powerful control over farmers' ability to grow, harvest, distribute, and profit from GM crops. No clearer example exists than the April 2004 decision of the U.S. Court of Appeals for the Federal Circuit in *Monsanto Co. v. McFarling* (*McFarling II*),[2] in which the court upheld Monsanto's patent licensing practice of forbidding farmers to save seed from GM crops for replanting. *McFarling II* thus confirms the illegality of a custom engaged in by farmers for centuries.[3] The Federal Circuit's

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[2] *See* Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004), *cert. denied*, 125 S. Ct. 2956 (2005) [hereinafter *McFarling II*] (opinion authored by Circuit Judge Clevenger for a panel also including Circuit Judge Lourie and Senior Circuit Judge Plager). An earlier Federal Circuit decision in the same matter upheld a district court's preliminary injunction of *McFarling*. *See* Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002) [hereinafter *McFarling I*].

[3] The saving and replanting of seed is a custom of ancient lineage. *See* Jeremy P. Oczek, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. REV. 627, 647 (2000) (noting that "[e]ver since humans began the transition from nomadic herders to farmers, saving seed for planting the following year's crop has been a basic tenet in the practice of agriculture.") (citing Laurent Belsie, *Plants Without Seeds Challenge Historic Farming Practices*, CHRISTIAN SCI. MONITOR, July 30, 1998, at B4). This custom is reflected in the exemption for seed-saving included in the U.S. Plant Variety Protection Act (PVPA) of 1970. *See* 7 U.S.C. § 2543 (2005) (providing in part that "[e]xcept to the extent that such action may constitute an infringement under subsections (3) and (4) of section 111 [7 U.S.C.S. § 2541(3) and (4)], it shall not infringe any right hereunder for a person to save seed produced by the person from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seeding purposes and use such saved seed in the production of a crop for use on the farm of the person, or for sale as provided in this section.").

conclusion that Monsanto's restriction on planting saved seed does not violate the antitrust laws nor amount to patent misuse deserves further scrutiny, as demonstrated by the Supreme Court's invitation to the Acting Solicitor General to file an *amicus* brief in *McFarling II*.[4] This paper details the facts of *McFarling II* and critiques the Federal Circuit's analysis of the unique patent and antitrust law issues raised thereby.

II. Facts of *Monsanto v. McFarling*

Homan McFarling, a Mississippi soybean farmer, obtained 1000 bags of Monsanto's Roundup Ready® (RR) soybean seed from his local seed store.[5] This seed is genetically modified so that the soybean plants

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The 1985 advent of U.S. utility patent protection for seeds and plants provided a stronger form of protection than the PVPA that was particularly useful for genetically engineered crops. *See Ex parte* Hibberd, 227 U.S.P.Q. 443 (Bd.Pat.App. & Int. 1985) (rejecting USPTO examiner's position that plants and seeds protectable under the PVPA or the Plant Patent Act (PPA) of 1930 could not also qualify as subject matter eligible for utility patent protection under 35 U.S.C. § 101). In *McFarling II*, the Federal Circuit confirmed that U.S. utility patent protection of seeds is not subject to the seed-saving exemption found in the PVPA. *See McFarling II*, 363 F.3d at 1344 (concluding that in light of Supreme Court's interpretation in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001), of Congress's intent in enacting the PVPA, "Congress did not intend to prohibit owners of utility patents from enforcing seed-saving prohibitions in their licenses"); *see also* Mark D. Janis, *Supplemental Forms of Intellectual Property Protection for Plants*, 6 MINN. J. L. SCI. & TECH. 305, 311 (2004).

[4] McFarling filed a petition for *certiorari* in the Supreme Court on July 6, 2004. *See* Petition for Writ of Certiorari, McFarling v. Monsanto Co., No. 04-31, 2004 WL 1535852 (S. Ct. July 6, 2004). The Supreme Court thereafter invited the Acting Solicitor General to file a brief in the case expressing the views of the United States. McFarling v. Monsanto Co., 125 S. Ct. 348 (2004). The United States recommended denial of *certiorari*, primarily on the ground that the Federal Circuit's decision "involve[d] a narrow application of established legal principles to a specific factual context involving a self-replicating product." Brief for the U.S. as Amicus Curiae at 10, McFarling v. Monsanto Co., No. 04-31, 2005 WL 1277857 (S. Ct. May 27, 2005). The Supreme Court subsequently denied *certiorari*. McFarling v. Monsanto Co., 125 S. Ct. 2956 (2005).

[5] The transaction is arranged such that instead of purchasing the seeds outright, the farmer merely obtains a license to use the seeds subject to certain restrictions on that use. Software manufacturers similarly use "shrink-wrap" licenses to convey software to users

grown therefrom will be resistant to Monsanto's Roundup® herbicide.[6] Monsanto owns several patents directed to the gene modification technology[7] and licenses the patents to approximately 200 seed manufacturers (denominated Monsanto's "seed partners"), which insert the patented trait (glyphosate resistance) into unmodified soybeans. As a condition of obtaining the resulting GM seed, McFarling had to sign Monsanto's Technology Agreement. In exchange for the "opportunity to purchase and plant seed containing" the RR technology, a farmer signing the Technology Agreement agrees *inter alia* "to not save any crop produced from this seed for replanting."[8] Because he cannot save the "second-generation" seed and use it for the following season's planting,

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without "selling" the software to them. If these transactions involved true sales, the exhaustion of rights and/or first sale doctrines would otherwise prohibit the vendor's imposition of post-sale restrictions.

[6] Currently, 60% of all soybeans grown are transgenic. Herbicide tolerant soybeans are the most dominant of all biotech crops, accounting for 48.4 million hectares worldwide. International Service for the Acquisition of Agri-Biotech Applications, Dominant Biotech Crops, 2004 (chart), http://www.isaaa.org/kc/CBTNews/press_release/briefs32/figures/dominant_crops.jpg (last visited Sept. 17, 2005).

[7] Two patents directed to various aspects of the RR seed technology are at issue in *McFarling II*. Monsanto's U.S. Pat. No. 5,633,435 ('435 patent) relates to the gene encoding a modified form of the enzyme 5-enolpyruvyl-shikimate-3-phosphate synthase (EPSPS). Naturally-occurring, unmodified EPSPS is inhibited by glyphosate, the active ingredient in Roundup® herbicide. The modified form of EPSPS is not affected by the presence of glyphosate, and performs the same sugar-conversion function, necessary for plant growth, that is carried out by naturally occurring EPSPS. The '435 patent claims the isolated DNA molecule encoding the modified EPSPS; a glyphosate-tolerant plant cell comprising that DNA molecule; a glyphosate- tolerant plant comprising that plant cell; a seed of a glyphosate-tolerant plant; a particular transgenic soybean plant; and a method of producing genetically transformed plants which are tolerant toward glyphosate herbicide. *See McFarling II*, 363 F.3d at 1338-39.

Monsanto's U.S. Pat. No. 5,352,605 ('605 patent) relates to the use of a particular promoter in genetically modified plant cells. The '605 patent claims *inter alia* DNA sequences and plant cells containing the promoter (a promoter sequence is a DNA sequence located in proximity to the DNA sequence that encodes a protein and that, in part, tells the cellular machinery how much of the protein to make). *Id*.

[8] *McFarling II*, 363 F.3d at 1339.

the farmer must purchase new "first-generation" RR seed for planting each season (so long as he wants to continue growing RR soybeans).

Contrary to the terms of the Technology Agreement, during two successive growing seasons McFarling saved the second-generation seed from his soybean crop and replanted it. This generated new soybean plants having the patented genetic makeup and herbicide resistance.[9] Monsanto sued McFarling, alleging that in saving and replanting he had infringed Monsanto's '435 and '605 patents and had breached the Technology Agreement. Siding with Monsanto, a federal district court granted summary judgment on the breach of contract claim, imposed liquidated damages on McFarling in the amount of $780,000, and rejected McFarling's counterclaims and defenses that the Technology Agreement provisions violated the antitrust laws and constituted patent misuse by Monsanto.

On appeal to the Federal Circuit, McFarling argued that the Technology Agreement's prohibition on saving and replanting seeds was a form of illegal tying,[10] which constituted both a violation of the antitrust laws[11] and patent misuse.[12] McFarling took the position that illegal tying

[9] *Cf. id*. at 1343 (noting that first- and second-generation seeds "are nearly identical copies").

[10] A tying arrangement is "an agreement by a party to sell one product . . . on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that [tied] product from any other supplier." *See* Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 461 (1992). The "essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms. When such 'forcing' is present, competition on the merits in the market for the tied item is restrained and the Sherman Act is violated." Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 12 (1984).

[11] Section One of the Sherman Act declares illegal "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations." 15 U.S.C. § 1 (2004). The courts have construed

occurred when Monsanto required that farmers purchase new RR seed (the "tied" product) as a condition of obtaining a license under the Monsanto patents to "use" the patented technology (i.e., the Roundup® herbicide resistance trait) in growing their soybean crop. In other words, by asserting its patent-based dominance in the market for the patented genetic modification, Monsanto was improperly dampening competition in the market for the seed.

McFarling urged that Monsanto could have chosen a less restrictive alternative to the tying arrangement. This alternative would have allowed farmers to save the second-generation seed and replant it, so long as the farmers paid Monsanto the appropriate technology fee for the amount of seed saved each season. Instead, Monsanto's Technology Agreement forced the farmers to buy new RR seed each season, which (according to McFarling) was much more expensive than replanting and resulted in subsidizing the seed companies.

The Federal Circuit rejected McFarling's tying theory. McFarling had not raised a "typical" tying allegation, in which a patentee conditions the grant of a patent license on a licensee's purchase of an unpatented material for use in the invention; in this case the second-generation RR seed was also the subject of the licensed Monsanto patents.[13] According to the Federal Circuit, McFarling's proposed less restrictive alternative of saving/replanting the second-generation seed and paying a commensurate

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§ 1 as prohibiting only *unreasonable* restraints of trade, rather than interpreting the statutory language in its fullest, literal extent.

[12] The Federal Circuit observed that in determining whether a patentee has committed patent misuse, "the key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect." *McFarling II*, 363 F.3d at 1341.

[13] *Id*. at 1342.

technology fee would amount to granting him a compulsory license to use the patent rights in conjunction with the second-generation seed.[14] Reaffirming its earlier broad pronouncements concerning a patent owner's right to refuse to license patented material,[15] the Federal Circuit "declined to hold that Monsanto's raw exercise of its right to exclude from the patented invention by itself is a 'tying' arrangement that exceeds the scope of the patent grant."[16]

While rejecting McFarling's tying theory, the Federal Circuit also took issue with certain of Monsanto's characterizations of its licensing practices. Monsanto had urged that its prohibition on saving and replanting the second-generation seed was a permissible "field of use" restriction on the patented first-generation seed.[17] The Federal Circuit disagreed, explaining that Monsanto's Technology Agreement did not impose a restriction on the *use of the product purchased* under the license

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[14] *Id*.

[15] *See* CSU, L.L.C. v. Xerox Corp., 203 F.3d 1322, 1327-28 (Fed. Cir. 2000) (refusing to inquire into patentee's "subjective motivation for exerting his statutory rights, even though his refusal to sell or license his patented invention may have an anticompetitive effect, so long as that anticompetitive effect is not illegally extended beyond the statutory patent grant.").

[16] *McFarling II*, 363 F.3d at 1342.

[17] A typical field of use restriction in a patent license is a restraint on the licensee's freedom to use the patented technology for particular purposes. For example, a license for technology to produce a GM crop might limit the licensee to use of the patented technology in the growing of a particular crop, such as soybeans or corn. Territorial (geographic) restrictions on a licensee's use of a patented invention are also frequently encountered. Generally, so long as the field of use and territorial restrictions appear in a vertical licensing arrangement (where the patent owner and licensee are not competitors), and where the licensee is not prohibited from using alternative noninfringing technology or developing its own noninfringing technology, the restrictions will not be deemed anticompetitive restraints of trade. *See* U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, ANTITRUST GUIDELINES FOR THE LICENSING OF INTELLECTUAL PROPERTY § 2.3 (1995) [hereinafter *Licensing Guidelines*], *available at* http://www.usdoj.gov/atr/public/guidelines/0558.pdf.

(i.e., the first-generation seed), as would a conventional field of use restriction, but rather imposed a restriction on the *use of the goods made by the licensed product* (i.e., the second-generation seed). The Federal Circuit admitted that the propriety of such a restraint in a patent license was an open question, for its case law had "not addressed in general terms the status of such restrictions placed on goods made by, yet not incorporating, the licensed good under the patent misuse doctrine."[18]

Monsanto's licensing restriction was saved in the Federal Circuit's view, however, by the unique facts of this case; namely, that the licensed and patented product (the first-generation seed) and the goods made by the licensed product (the second-generation seed) were "nearly identical copies" that were both within the literal scope of Monsanto's '435 patent. According to the Federal Circuit, this unique circumstance meant that the licensing restrictions on the use of goods produced by the licensed product were not beyond the scope of the patent grant at issue.[19] Therefore, patent misuse was not established.

Having dismissed McFarling's patent misuse defense, the Federal Circuit quickly rejected his antitrust counterclaim. "[B]ecause we have found McFarling's allegations insufficient to present a genuine issue of material fact concerning whether Monsanto's licensing restrictions went beyond the boundaries of its patent grant, McFarling's antitrust counterclaim also fails."[20] In this case, the Federal Circuit concluded, "the anticompetitive effect of which McFarling complains is part and parcel of the patent system's role in creating incentives for potential inventors."[21]

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[18] *McFarling II*, 363 F.3d at 1343.

[19] *Id*.

[20] *Id*.

[21] *Id*.

To establish illegal tying under the antitrust laws, the claimant must establish that the tying and tied products are in fact separate products.[22] The Federal Circuit agreed with McFarling that the district court had erred by failing to consider consumer demand in the course of concluding that the tying product (the patented trait) and the tied product (the seed) were not two separate markets. However, the Federal Circuit observed, "the district court's finding concerning the unified nature of the market for the trait and the seed is not relevant to our holding, so we expressly decline to reach or review it."[23]

Although it sustained McFarling's liability for breach of the Technology Agreement, the Federal Circuit did vacate the district court's award of $780,000 in damages to Monsanto.[24] The liquidated damages clause in the Technology Agreement was invalid and unenforceable under Missouri law as applied to McFarling's breach of replanting of saved seed. The Federal Circuit remanded the case to the district court for determination of actual damages.

III. McFarling's Petition for *Certiorari*

McFarling filed a petition for *certiorari* in the U.S. Supreme Court on July 6, 2004.[25] The Questions Presented were as follows:

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[22] *See* Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 21 (1984) (explaining that "a tying arrangement cannot exist unless two separate product markets have been linked.").

[23] *McFarling II*, 363 F.3d at 1344.

[24] *Id*. at 1344-52.

[25] Petition for Writ of Certiorari, McFarling v. Monsanto Co., No. 04-31, 2004 WL 1535852 (S. Ct. July 6, 2004).

> 1. May a patent holder lawfully prohibit farmers from saving and replanting seed as a condition to the purchase of patented technology?
>
> 2. Does obtaining patents on products which are the subject of licensing agreements afford an absolute defense to any claim that the licensing agreements violate the Sherman Act?[26]

McFarling's arguments for grant of *certiorari* focused largely on the economic impact of Monsanto's licensing practices, which McFarling asserted the Federal Circuit had erroneously failed to consider:

> The heart of McFarling's argument is that agreements to prohibit seed-saving are an unreasonable restraint of trade, since the farmer is not allowed to purchase the Monsanto technology without also agreeing to buy overpriced new seed. Monsanto ties unwanted new seed to the right to purchase the patented technology. This tying is not for the benefit only of Monsanto. Instead, its seed company licensees derive a financial windfall since farmers have to buy overpriced new seed from the seed companies each year. A farmer cannot purchase the technology unless he also agrees to purchase new seed each year.[27]

Disputing the Federal Circuit's statement that the anticompetitive effect of Monsanto's policy was "part and parcel of the patent system's role in creating incentives for potential inventors," McFarling contended

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[26] *Id*. at *1.

[27] *Id*. at *9.

that the beneficiaries of Monsanto's licensing scheme were not primarily Monsanto but rather the seed companies, which did not invent the patented technology. McFarling cited record evidence that when a U.S. soybean farmer purchases a 50-pound bag of RR seed, he is paying not only a $6.50 technology fee (patent royalty) to Monsanto but also an additional $18.00 to the seed company for the seed germplasm. In contrast, a farmer who saves and replants the second-generation seed will have invested only about $7.00 per bag of seed.[28] According to McFarling, the Technology Agreement ensured that "the purchase of new seed is 'bundled' with the technology as a way to extract monopoly profits from farmers, who would otherwise simply pay the technology fee to Monsanto and use saved seeds." Moreover, "farmers consider saved seed to be superior in quality" over new purchased seed."[29]

McFarling's *certiorari* petition also challenged the validity of Monsanto's patents, charging the Federal Circuit with "radically extend[ing] the previous reach of the patent laws as this Court has defined them." McFarling noted that Monsanto's '435 patent claimed both the genetically-altered seed and its progeny; that is, both the first- and second-generation seed. According to McFarling, the "second generation of genetically-altered soybeans is not a 'human-made' invention," as required by the Court's decisions such as *Diamond v. Chakrabarty*,[30] but rather is a product of nature "created by God."[31]

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[28] *Id*. at *5.

[29] *Id*. at *7.

[30] *See* Diamond v. Chakrabarty, 447 U.S. 303, 313 (1980) ("the relevant distinction [i]s not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.").

[31] *See* Petition for Writ of Certiorari, *McFarling*, No. 04-31, 2004 WL 1535852, at *13-*14.

In an order issued October 12, 2004, the Supreme Court invited the Acting Solicitor General to file a brief in the case expressing the views of the United States.[32] The government recommended denial of *certiorari*, primarily on the ground that the Federal Circuit's decision did not merit review because it "involve[d] a narrow application of established legal principles to a specific factual context involving a self-replicating product."[33] The government admitted that McFarling's initial pleadings had appeared to raise a "novel question" concerning whether the patent exhaustion doctrine[34] limited Monsanto's ability to enforce post-sale restrictions on the use of its patented seed,[35] but contended that McFarling had failed to properly preserve that issue for review by the Supreme

[32] McFarling v. Monsanto Co., 125 S. Ct. 348 (2004).

[33] Brief for the U.S. as Amicus Curiae at 10, McFarling v. Monsanto Co., No. 04-31, 2005 WL 1277857 (S. Ct. May 27, 2005). The determinative inquiry for patent misuse is whether a patentee's challenged practice has "'impermissibly broadened the scope of the patent grant.'" *Id.* (quoting C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998)). Here, both the first-generation seed sold by Monsanto and its partners and the second-generation seed produced by the first-generation seed were within the scope of the Monsanto patents in suit, and thus patent misuse was not made out. *See id.*

[34] The patent exhaustion doctrine provides that "sale of [a patented product] exhausts the monopoly in that article and the patentee may not thereafter, by virtue of his patent, control the use or disposition of the article." United States v. Univis Lens Co., 316 U.S. 241, 250 (1942).

[35] *See* Brief for the U.S. as Amicus Curiae at 11, *McFarling,* No. 04-31, 2005 WL 1277857 (observing that Federal Circuit's earlier rejection of McFarling's patent exhaustion defense at preliminary injunction stage involved "the novel question whether (and, if so, to what extent) the patent-exhaustion doctrine applies to restrictions on the use of a materially identical patented product that was produced by the patented product sold by the patentee."). In the government's view, such a question "may not recur with any frequency, and it would be beneficial to have a fully considered resolution of that question in the lower courts." *Id.*

Court.[36] The Supreme Court followed the government's recommendation and denied *certiorari* on June 27, 2005.[37]

IV. Discussion

Those who oppose the farming of GM crops may applaud the result, if not the reasoning, of the Federal Circuit's decision in *McFarling II*. Allowing Monsanto to prohibit the saving and replanting of second-generation seed and forcing farmers to buy new GM seed each season may limit the amount of GM crop grown; farmers will simply not be able to afford to grow as much as if they were permitted to save seed. Whether Monsanto's practices actually have a chilling effect on the planting of GM crops is questionable, however, in light of the fact that 75% of the soybeans grown in the U.S. today are genetically modified.[38] The practical result of Monsanto's licensing practices may disproportionately impact small farmers, concentrating GM crop growth among larger farming operations which are better able to bear the financial burden.

In this regard McFarling's challenge to Monsanto's licensing practices resonates well beyond the U.S. and other industrialized economies that dominate agribusiness. Despite McFarling's protest, the added financial burden of having to buy new seed each season is not a novel problem in the U.S., where many farmers have done so since the

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[36] *See id.*

[37] McFarling v. Monsanto Co., 125 S. Ct. 2956 (2005). Another reason why *certiorari* was denied in *McFarling II* may be that review was recently granted in another patent/antitrust case discussed *infra* Part IV, *Illinois Tool Works, Inc. v. Independent Ink, Inc.*, 125 S. Ct. 2937 (2005). It is relatively rare for the Supreme Court to grant *certiorari* in patent cases and even more unlikely that the Court would accept two patent cases involving antitrust issues for review at the same time.

[38] *See* PETER PRINGLE, FOOD, INC.: MENDEL TO MONSANTO–THE PROMISE AND PERILS OF THE BIOTECH HARVEST 189 (2003) (stating that by 2003, in America 75% of the soybean crop was GM).

introduction of hybrid varieties in the 1920s and 1930s.[39] The longer-term and potentially much more onerous impact of seed-saving prohibitions is seen by comparing the plight of subsistence farmers in developing countries. In these countries, about 80 percent of farmers save seed for replanting in order to reduce costs.[40] It is unclear how or when developing country farmers will share in the promise of GM crops. As concluded by the 2004 annual report of the United Nations Food and Agriculture Organization (FAO), the real problem with GM crops is not safety, but rather access to the benefits of the technology.[41] Research and development into GM crops has not yet been sufficiently aimed at helping establish food security in the poorest countries of the world. The poor have been left at the sidelines of the "gene revolution," and seed-saving prohibitions contribute to their exclusion.

The Federal Circuit in *McFarling II* rejected as tantamount to compulsory licensing McFarling's proposal for a "less restrictive alternative," that farmers should be allowed to save seed and replant it while paying a technology fee to Monsanto for the amount of seed

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[39] *See* FELICIA WU & WILLIAM P. BUTZ, THE FUTURE OF GENETICALLY MODIFIED CROPS: LESSONS FROM THE GREEN REVOLUTION 52 (Rand Corp. 2004); *id*. at 50 (noting that hybrid corn was first grown on U.S. farms in the 1920s and 1930s). "[B]y its nature, hybrid seed precludes farmers from saving their own seed for planting. . . . [I]f a farmer achieves good results with hybrid XYZ, and wants to grow more of the same hybrid the following year, he must again obtain hybrid seed produced by the controlled crossing of the same two or more parental lines used to produce the hybrid in prior years. . . . Only those who control the parent lines from which a hybrid is made can reproduce it." William L. Brown, *Plant Genetic Resources: A View from the Seed Industry*, *in* SEEDS AND SOVEREIGNTY: THE USE AND CONTROL OF PLANT GENETIC RESOURCES 218, 224 (Jack R. Kloppenburg, Jr., ed., Duke Univ. Press 1988).

[40] *See* WU & BUTZ, *supra* note 39, at 52.

[41] Editorial, *A Call for a Gene Revolution,* N.Y. TIMES, May 24, 2004, at A26.

saved.[42] The court likely viewed the proposal as one that would effectively compel Monsanto to give the farmers permission to "use" the patented trait in raising a new crop, rather than allowing Monsanto to exercise its statutory right to exclude others from that use.[43] From a *patent law* perspective, the Federal Circuit's rejection of McFarling's proposal is not surprising. United States courts have historically disfavored compulsory licensing and any remedy considered tantamount thereto.[44]

However, the Federal Circuit did not address the *antitrust* consequences of the existence of less restrictive alternatives. Restraints in patent licenses between parties in a vertical arrangement (such as Monsanto and McFarling) are generally analyzed under the antitrust rule of reason,[45] which considers not just anticompetitive effect but also the antitrust defendant's pro-competitive justifications for the restraint. For an apparently anticompetitive restraint to be redeemed, it must not only promote a legitimate objective (as in this case, maintaining incentives for innovation through recouping of R&D investment), but must also do so significantly better than the less restrictive alternatives.[46] As McFarling's

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[42] Monsanto Co. v. McFarling, 363 F.3d 1336, 1342 (Fed. Cir. 2004), *cert. denied*, 125 S. Ct. 2956 (2005).

[43] *See* 35 U.S.C. § 271(a) (2005).

[44] *E.g.*, Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (describing compulsory licensing as "rarity" in U.S. patent system); *see also* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 172 (1951) (explaining that compulsory licensing has been "violently opposed" in the U.S. because it "can be such a serious derogation of the monopoly 'rights' of the patentee"); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 911 (1990) (describing compulsory licensing as "anathema" to U.S. patent law). The U.S. Congress considered but ultimately dropped the idea of compulsory licensing as part of the 1952 Patent Act. *See Dawson Chem. Co.*, 448 U.S. at 215 n.21.

[45] *See Licensing Guidelines*, *supra* note 17, at § 3.4.

[46] *See* PHILLIP E. AREEDA, ANTITRUST LAW ¶ 1505 (2002). *See also Licensing Guidelines*, s*upra* note 17, at § 4.2 (stating that "[t]he existence of practical and

certiorari petition points out, Monsanto has in fact exercised less restrictive alternatives outside the U.S. market. In Argentina, Monsanto permits soybean farmers to save and replant patented varieties upon payment of an annual fee.[47] Among the 17 countries that now permit the growing of GM crops, Argentina is second only to the U.S. in terms of acreage.[48]

Is Monsanto's seed saving prohibition a legitimate field of use restriction on its patented GM technology? The Federal Circuit's decision strongly suggests that absent the unique fact that the progeny of the patented seed is genetically identical and thus also within the '435 patent's scope, Monsanto's field of use restriction would not pass antitrust muster. The court left unresolved the question of whether a patent licensor may properly impose license restrictions on goods made by, yet not incorporating, the licensed good, limiting its decision to the unique facts

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significantly less restrictive alternatives is relevant to a determination of whether a restraint is reasonably necessary.").

[47] Roger A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 WASHBURN L.J. 611, 652 n.244 (2004) (citing David Dechant, *Monsanto Wants Extended Seed Royalties*, CROPCHOICE, May 22, 2003, *available at* http://www.mindfully.org/GE/2003/Monsanto-Seed-Royalties22may03.htm). Dechant's article translates a Monsanto Argentina website as providing the following terms to farmers: "Following the purchase of the seed and before the next crop year begins, the producer needs to make a sworn statement attesting to the amount of seed saved for planting. After turning over the sworn statement, Monsanto will emit a debit note for royalties of the value of US $1.50 for every 25 kilos (55 pounds) of seed. This mechanism will repeat itself every time the farmer saves seed bought under this system." *Id*.

[48] *See* International Service for the Acquisition of Agri-Biotech Applications, Global Status of Biotech Crops in 2004 (chart), http://www.isaaa.org/kc/CBTNews/press_release/briefs32/figures/Biotech_map_acreage.jpg (last visited Sept. 17, 2005) (reporting that in 2004 the U.S. had 117.6 million acres of biotech crops while Argentina had 40 million acres; Canada, Brazil, and China round out the top five countries in terms of biotech crop acreage).

of *McFarling II*.[49] But given the rapid advances in agricultural biotechnology, such a scenario is not unlikely to come before the court in the future. Consider a hypothetical genetic modification of a crop that would result in the production of second-generation seeds sufficiently different in genetic makeup that the patent on the first-generation seed does not read on them.

Expanding the hypothetical beyond the GM crop sector, consider a patent on a transgenic mouse that may potentially serve as an important laboratory research tool in the development of a new drug for treating cancer. A license granted to permit use of the patented mouse might properly restrict the licensee's use of the mouse to solely research applications, or alternatively to commercial-only applications. But what if the license further imposed restrictions on the use of any new drug product developed through testing with the mouse? Consider a hypothetical patent license that included a provision barring the use of any resulting new drug for diseases other than cancer, or one that limited the nationality of the patients that could receive the drug, or that imposed geographic restrictions on the distribution of the drug. Such restrictions would seem clearly beyond the scope of the patent on the transgenic mouse and presumably would be treated by the courts as an unreasonable restraint of trade in violation of the antitrust laws.[50] Should the unique fact of

[49] Monsanto Co. v. McFarling, 363 F.3d 1336, 1343 (Fed. Cir. 2004), *cert. denied*, 125 S. Ct. 2956 (2005) (stating that "[o]ur case law has not addressed in general terms the status of such restrictions placed on goods made by, yet not incorporating, the licensed good under the patent misuse doctrine. . . . [b]ecause the '435 patent would read on all generations of soybeans produced, we hold that the restrictions in the Technology Agreement prohibiting the replanting of the second generation of ROUNDUP READY® soybeans do not extend Monsanto's rights under the patent statute.").

[50] These seemingly anticompetitive restrictions on the use of a product made by the patented invention should be distinguished from a patentee's ability to recover royalties based on the commercial value of that product. Many patent licenses in the life sciences impose "reach-through" royalties. The propriety of such royalties is the subject of

genetically identical progeny in *McFarling II* justify more favorable treatment?

Although it was not clearly preserved on appeal,[51] McFarling's additional argument that Monsanto's patents cover "products of nature" not patentable under 35 U.S.C. § 101 also raises interesting questions. The argument parallels a position recently adopted by Federal Circuit Judge Gajarsa in his concurrence in *SmithKline Beecham Corp. v. Apotex Corp*.[52] In that case, the patent claim at issue broadly recited "crystalline paroxetine hydrochloride hemihydrate." A structurally similar compound, paroxetine anhydrate, which was not the subject of any patents, had a tendency to spontaneously transform itself into the patented paroxetine hemihydrate, without the intent of the accused infringer (a manufacturer of the unpatented paroxetine anhydrate). Rejecting the notion of "inevitable infringement" liability, Judge Gajarsa took the position that "patent claims drawn broadly enough to encompass products that spread, appear, and 'reproduce' through natural processes cover subject matter not patentable under Section 101--and are therefore invalid."[53] In future cases of this sort, Judge Gajarsa suggested, "[i]inventors wishing to claim

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ongoing debate and has not yet been squarely addressed by the Federal Circuit. *Cf.* Integra Lifesciences I, Ltd. v. Merck KGaA, 02-1052, 02-1065, 2003 U.S. App. LEXIS 27796, at *31 (Fed. Cir. June 6, 2003) (noting that "[w]hile this court does not opine on the applicability of a reach-through royalty in this case, the presence or absence of stacking royalties for research tools may color the character of a hypothetical negotiation between Merck and Integra for access to the RGD peptide technology.").

[51] The Federal Circuit's decision noted that McFarling had not challenged the validity of Monsanto's patents at the trial court level. *See McFarling II*, 363 F.3d at 1340 (noting that McFarling "failed to raise or argue the alleged invalidity of the '435 patent as a defense to the breach of the Technology Agreement claim or as an element of its patent misuse defense, and at this stage of the proceedings we deem the argument to have been waived for purposes of deciding this appeal.").

[52] *See* SmithKline Beecham Corp. v. Apotex Corp., 365 F.3d 1306 (Fed. Cir. 2004).

[53] *Id*. at 1331 (Gajarasa, J., concurring).

products that can either be synthesized in laboratories or generated by natural processes may protect themselves by incorporating negative limitation terms like 'non-natural' or 'non-human' into the claims that they submit for examination."

Monsanto's '435 patent claims do not contain such limitations.[54] If the Supreme Court were to view the patent claims to second-generation seed as encompassing subject matter that is not patentable, this would transform McFarling's tying claim into a "conventional" one, by which the patentee is forcing a licensee to purchase unpatented material as a condition for receiving the license. The Supreme Court has recently shown a rather unexpected interest in the limits of patentable subject matter,[55] which may have contributed to the Court's initial interest in *McFarling II*.[56]

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[54] *See* U.S. Patent No. 5,633,435, claim 79 (filed Sept. 13, 1994) ("A seed of a glyphosate-tolerant plant of claim 28").

[55] Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 125 S. Ct. 1413, 1413 (2005) (Order inviting the Acting Solicitor General to file a brief expressing the views of the United States limited to following question:

> Respondent's patent claims a method for detecting a form of vitamin B deficiency, which focuses upon a correlation in the human body between elevated levels of certain amino acids and deficient levels of vitamin B. The method consists of the following: First, measure the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice whether the amino acid level is elevated and, if so, conclude that a vitamin B deficiency exists. Is the patent invalid because one cannot patent "laws of nature, natural phenomena, and abstract ideas"? Diamond v. Diehr, 450 U.S. 175, 185, 101 S. Ct. 1048, 67 L. Ed.2d 155 (1981)).

[56] A similar argument of non-patentability was raised, without success, by Canadian farmer Perry Schmeiser in his battle with Monsanto over the right to save and replant RR canola seeds. The Canadian Supreme Court upheld the patentability of Monsanto's Canadian patent claims directed to genes conferring herbicide resistance and plant cells transformed with such genes. *See* Monsanto Can. Inc. v. Schmeiser, 2004 Can. Sup. Ct.

Lastly, with respect to McFarling's tying claim, recent changes in the Federal Circuit's law on patent tying may also make that claim more feasible. The Federal Circuit decided *McFarling II* several months prior to its ruling in *Independent Ink, Inc. v. Illinois Tools Works, Inc.*[57] The court held in *Independent Ink* that in the patent tying context, a patent owner is presumed to have market power and the burden of rebutting this presumption is placed on the patentee. Although the Federal Circuit's holding in *Independent Ink* is contrary to modern economic thought[58] and has resulted in a grant of *certiorari* by the Supreme Court,[59] as long as the decision stands it makes the challenge to a tying arrangement before the Federal Circuit substantially easier. In *McFarling II*, however, the Federal Circuit never reached the issue of whether Monsanto had power in the relevant market for its patented inventions; rather, it rejected McFarling's threshold argument that the Technology Agreement's seed saving and replanting prohibition constituted a tying arrangement.

LEXIS 32, at *26-*27 (2004). The *Schmeiser* majority interpreted the claims as encompassing practice of the patented invention in plants regenerated from the patented cells, whether the plants were located inside a laboratory or in the field, *id*. at *27, and rejected the dissent's narrow construction that would have limited the claims to the recited genes and plant cells only when in isolated laboratory form. *Id*. at *24. The majority concluded that "[w]hether or not patent protection for the gene and the cell extends to activities involving the plant is not relevant to the patent's validity [but rather] relates only to the factual circumstances in which infringement will be found to have taken place . . . ." *Id*. at *27.

[57] Indep. Ink, Inc. v. Ill. Tool Works, Inc., 396 F.3d 1342 (Fed. Cir. 2005), *cert. granted*, 125 S. Ct. 2937 (2005).

[58] The new economic learning of antitrust law teaches that ownership of a patent does not necessarily confer market power due to the possibility of consumers turning to noninfringing alternatives in the event of a price increase for the patented invention. *See, e.g. Licensing Guidelines*, *supra* note 17, at § 5.3 (stating with respect to tying that the antitrust agencies "will not presume that a patent, copyright, or trade secret necessarily confers market power upon its owner.").

[59] Ill. Tool Works, Inc. v. Indep. Ink, Inc., 125 S. Ct. 2937 (2005).

V. Conclusion

As a matter of patent law, the Federal Circuit's decision in *McFarling II* is unremarkable. The court has not shown a propensity to find patent owners guilty of patent misuse.[60] But the Federal Circuit's relatively summary dismissal of the antitrust challenges raised by McFarling bears further scrutiny. A recognized "dissonance" exists at the intersection of the patent and antitrust laws,[61] which has only been exacerbated by conflicts between the Federal Circuit's patent and antitrust decisions and those of the regional circuits.[62] *McFarling II* presented the Supreme Court with an attractive vehicle for imparting some much needed clarity at the intersection of these two increasingly intertwined legal regimes. Although the Court declined to review *McFarling II*, the issues raised by the case are likely to recur with increasing frequency as Monsanto and other agribusiness giants continue their use of patents to control the growth and distribution of GM crops.

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[60] *See, e.g.*, CSU, L.L.C. v. Xerox Corp., 203 F.3d 1322, 1328 n.2 (Fed. Cir. 2000); C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372-73 (Fed. Cir. 1998); Va. Panel Corp. v. MAC Panel Co., 133 F.3d 860, 868-71 (Fed. Cir. 1997).

[61] *See* Image Tech. Servs. v. Eastman Kodak Co., 125 F.3d 1195, 1217 (9th Cir. 1997) (observing that "[a]t the border of intellectual property monopolies and antitrust markets lies a field of dissonance yet to be harmonized by statute or the Supreme Court.").

[62] *Compare id*. at 1219 (holding that ownership of patents was presumptively valid reason for refusal to sell or license patented parts to independent repair services, but that presumption was rebuttable where patent ownership was mere pretext for masking anticompetitive behavior), *with CSU, L.L.C.*, 203 F.3d at 1327 (explicitly rejecting Ninth Circuit's "pretext" approach and refusing to inquire into a patent owner's subjective motivations for refusing to license.).