NOTES

Monsanto Co. v. Scruggs: Has Federal Circuit Biotechnology Patent Scope Jurisprudence Gone to Seed?

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I. **OVERVIEW**

On appeal of a patent infringement lawsuit brought against Mississippi farmer Mitchell Scruggs by biotechnology giant Monsanto for the unauthorized replanting of seeds containing Monsanto's patented genetic traits, the United States Court of Appeals for the Federal Circuit rejected Scruggs' defenses of patent invalidity, patent exhaustion, implied license, antitrust, and patent misuse and upheld the United States District Court for the Northern District of Mississippi's summary judgment rulings in favor of Monsanto on August 16, 2006.1 Monsanto manufactures Roundup, a widely used herbicide, and Bollgard, a pesticide used to protect cotton crops.² In order to allow more comprehensive and convenient use of the products, Monsanto developed and patented methods for insertion of synthetic genetic traits into plants that provide resistance to Roundup and Bollgard.³ Monsanto granted limited licenses on the patents to seed producers to create and sell seeds with the synthetic traits.⁴ Under the terms of the patent licenses, seed producers must require buyers to sign separate seed grower license agreements with Monsanto, which in turn grant the grower the right to grow a single commercial crop in exchange for a technology fee.⁵ However, the seed grower license forbids the buyer to sell, transfer, or replant any seed produced and saved from the initial crop.⁶ Scruggs purchased the modified soybean and cotton seeds, but did not sign the required seed grower license agreement with Monsanto.⁷ Scruggs

7. Id.

Monsanto Co. v. Scruggs, 459 F.3d 1328, 1334, 1342 (Fed. Cir. 2006) (reh'g denied). 1.

^{2.} Id. at 1333.

^{3.} Id.

^{4.} Id. 5. Id.

Id. In addition, the license forbids research and experimentation on the seeds, and 6 requires growers to use Roundup Ready® seeds exclusively with Roundup and no other herbicide. Id.

proceeded to save seeds from the initial harvests and replanted them in subsequent crops.⁸ Monsanto sued Scruggs for patent infringement and was granted a preliminary injunction prohibiting Scruggs from using seeds containing Monsanto's technology.⁹

Scruggs admitted to replanting the seed, but argued that Monsanto's patents were technically invalid and that, alternatively, the patents only covered the synthetic traits and not the entire seed or the resulting plants.¹⁰ Scruggs therefore argued that Monsanto's license restrictions violated federal and state antitrust laws and amounted to patent misuse because the license terms impermissibly broadened the scope of Monsanto's patent rights.¹¹ The trial court granted Monsanto's summary judgment motions in favor of the patent infringement claims and against Scruggs' antitrust and patent-misuse defenses.¹² The trial court then issued a permanent injunction against Scruggs and entered final judgment.¹³

Scruggs appealed, again claiming that Monsanto's patents do not cover the crops he grew from the modified seeds he purchased, that Monsanto's patent rights were exhausted after the initial sale of the seeds to Scruggs, and that Scruggs had an implied license to use the technology from the purchase of the seeds from the seed producers.¹⁴ After vacating and remanding the permanent injunction order against Scruggs for additional scrutiny mandated by a recent United States Supreme Court ruling,¹⁵ the Federal Circuit reviewed the case de novo and *held* that (1) patents on embedded synthetic genetic traits read on not only the trait, but the seed in which the trait is embedded, the plants produced from the seed, and all subsequent generations of seeds; (2) the traditional "first sale" patent exhaustion doctrine does not extinguish a patent holder's rights in seed harvested subsequent to the initial planting of genetically altered seed because no unrestricted sale of the seed has

^{8.} *Id.*

^{9.} *Id.*

^{10.} Id. at 1333-34.

^{11.} *Id.* at 1333. Scruggs also brought a variety of common law counterclaims against Monsanto relating to the manner in which Monsanto investigated Scruggs activities, countersuing for invasion of privacy, trespass, tortious interference with contract or business relations, abuse of process, conversion, and unfair competition. *Id.*

^{12.} *Id.*

^{13.} Id. at 1334.

^{14.} *Id.*

^{15.} *Id.* at 1341-42; *see also* eBay v. MercExchange, L.L.C., 126 S. Ct. 1837, 1839, 1841 (2006) (holding that permanent injunctions are permissible only where the plaintiff can demonstrate an irreparable injury, where legal remedies do not suffice to compensate for the injury, where a remedy in equity is warranted by the balance of hardships between the parties, and where no harm to the public interest may occur).

yet occurred; (3) a prohibition on replanting seeds containing patented traits is within the scope of a patent holder's rights; and (4) patent misuse does not occur unless the act of tying the purchase of a patented product to another relevant product has demonstrable anticompetitive effects. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1335, 1340-41 (Fed. Cir. 2006).

II. BACKGROUND

The United States Constitution grants Congress the power "[t]o promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive right to their ... Discoveries."¹⁶ Accordingly, United States patent law grants a patent holder "the Right to exclude others from making, using, offering for sale, or selling the invention" as long as the patent is in force.¹⁷ A patent is, in essence, the grant of a legal monopoly amounting to almost complete control over the invention.¹⁸ In fact, no patent owner "shall be ... deemed guilty of misuse or illegal extension of the patent right by reason of his having . . . refused to license or use any rights to the patent."¹⁹ Types of restrictions that have been deemed within the scope of the patent grant include limited use licensing, royalty charges, and limitation of the use of the invention to specific purposes or areas of use.²⁰ Patent specifications must describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art ... to make and use the same" and must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."21

An individual is said to infringe on a patent when he "without authority makes, uses, offers to sell, or sells any patented invention."²² In order for a court to find infringement, at least one of the claims listed in the patent must read on the accused product.²³ Whether a claim reads on an allegedly infringing product is a question of proper claim

^{16.} U.S. CONST. art. I, § 8, cl. 8.

^{17. 35} U.S.C. § 154(a)(1) (2000).

^{18.} See Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 135 (1969).

^{19. 35} U.S.C. § 271(d).

^{20.} *Scruggs*, 459 F.3d at 1338 (citing Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 703 (Fed. Cir. 1992) (limited use licensing); Brulotte v. Thys Co., 379 U.S. 29, 33 (1964) (royalties); Gen. Talking Pictures Corp. v. W. Elec. Co., 305 U.S. 124, 127 (1938) (field of use restrictions)).

^{21. 35} U.S.C. § 112.

^{22.} *Id.* § 271(a).

^{23.} See Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1579 (Fed. Cir. 1984).

construction, and is a matter of law to be determined by the court.²⁴ affirmative defenses to patent infringement Possible include noninfringement, unenforceability, invalidity of the patent, patent misuse, patent exhaustion, and the existence of an implied license to use the patented technology.²⁵ A patent may be challenged as invalid if, for example, it fails to meet the written description and enablement requirements set out in 35 U.S.C. § 112.²⁶ The doctrine of patent misuse, however, implicates actions by the holder of a valid patent that attempt to impose conditions on licensees and purchasers of the invention that "impermissibly broaden[] the scope of the patent grant with anticompetitive effect."27 The doctrine of patent exhaustion comes into play when a patent holder sells an invention to a purchaser in an unrestricted sale.²⁸ When a patent holder has sold an invention "without any conditions ... the rule is well established that the patentee must be understood to have parted ... with all his exclusive right, and that he ceases to have any interest whatever" in the invention.²⁹ Finally, a purchaser can be said to have an implied license to use a patented invention if "the circumstances of the sale ... 'plainly indicate that the grant of a license should be inferred.""30

Given the express purpose of patent law to encourage innovation in furtherance of the public good, and given the breadth of monopoly rights conferred on patent holders, federal antitrust law serves as an essential backstop to competition-stifling practices that result from the abuse of patents.³¹ Under the Sherman Act, "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade ... is declared to be illegal.³² In addition, it is a felony to "monopolize, or

^{24.} Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996). The rationale behind this decision is that patent construction or interpretation is viewed as a special occupation requiring expertise beyond the cognitive reach of most potential jurors. *Id.* at 389. A patent claim construction hearing, most often prior to trial, wherein a judge reviews expert testimony to determine the legal scope of the claims in a patent is known as a "Markman" hearing. BLACK'S LAW DICTIONARY 991 (8th ed. 2004). This is especially important because, in the words of the same judge who issued the opinion in the noted case, "to decide what the claims mean is nearly always to decide the case." Markman v. Westview Instruments, Inc., 52 F.3d 967, 989 (Fed. Cir. 1995) (Mayer, J., concurring) (stating that the holding "jettison[ed] more than two hundred years of jurisprudence" and "eviscerat[ed]" the role of juries preserved by the Seventh Amendment).

^{25.} Scruggs, 459 F.3d at 1334.

^{26.} See 35 U.S.C. § 282.

^{27.} C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1372 (Fed. Cir. 1998).

^{28.} Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 707 (Fed. Cir. 1992).

^{29.} Mitchell v. Hawley, 83 U.S. 544, 546-47 (1873).

^{30.} LG Elecs., Inc. v. Bizcom Elecs., Inc., 453 F.3d 1364, 1369 (Fed. Cir. 2006) (quoting

Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686 (Fed. Cir. 1986)).

^{31.} See United States v. Line Material Co., 333 U.S. 287, 309-10 (1948).

^{32. 15} U.S.C. § 1 (2000).

attempt to monopolize, or combine or conspire ... to monopolize any part of the trade or commerce among the several States.³³³ Illegal monopolization occurs when a party gains or maintains monopoly power in a market through anticompetitive means.³⁴

A common form of antitrust violation is called a tying arrangement, wherein a seller conditions the sale of a product on the purchase of a second product.³⁵ This type of practice violates antitrust law if the seller has "appreciable economic power' in the tying product market" and where interstate trade in the product is substantial.³⁶ Engaging in conduct outside the rights granted by patent law may amount to a violation of the Sherman Act.³⁷ Accordingly, under patent law, if the seller has market power in the market for a patented product, it is a form of patent misuse to condition "the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product."³⁸

III. THE COURT'S DECISION

In the noted case, the Federal Circuit underscored its holding in *Monsanto Co. v. McFarling* regarding the claim construction of biotechnology patents involving embedded synthetic genetic traits.³⁹ In that decision, the Federal Circuit held that Monsanto's Roundup Ready® patent covers not just the synthetic trait, but the plant cells in which it is embedded, the plants grown from the seeds, and all future generations of seeds containing the trait.⁴⁰ As such, the patent holder retains all rights under patent law to restrict the use, sale, and distribution of the seeds.⁴¹ Once the Federal Circuit construed the scope of Monsanto's patent claim in this manner, all of Scruggs' defenses unraveled.⁴²

The majority rejected Scruggs' patent exhaustion defense by stating that because Monsanto expressly conditioned the use of the seed by seed

^{33.} Id. § 2.

^{34.} See Aspen Skiing Co. v. Aspen Highlands Skiing Corp., 472 U.S. 585, 596 n.19 (1985) (citing United States v. Grinnell Corp., 384 U.S. 563, 570-71 (1966)).

^{35.} Eastman Kodak Co. v. Image Tech. Serv., Inc., 504 U.S. 451, 461-62 (1992).

^{36.} Id. at 462.

^{37.} United States v. Line Material Co., 333 U.S. 287, 308 (1948).

^{38.} See 35 U.S.C. § 271(d)(5) (2000).

^{39.} See Monsanto Co. v. Scruggs, 459 F.3d 1328, 1336 (Fed. Cir. 2006); see also Monsanto Co. v. McFarling, 363 F.3d 1336, 1343 (Fed. Cir. 2004) (holding that the claim construction of Monsanto's patents reads on the seed, the plants, and the resulting crops).

^{40.} *McFarling*, 363 F.3d at 1343.

^{41.} *Id.*

^{42.} See Scruggs, 459 F.3d at 1338 (rejecting Scruggs' infringement and invalidity defenses).

growers on the signing of a license agreement with Monsanto, the sale of the seed to Scruggs was not unrestricted, and Scruggs therefore lacked the requisite statutory authority to use the invention.⁴³ The majority also reiterated its rationale in the McFarling decision, stating that ""[t]he "first sale" doctrine of exhaustion . . . is not implicated, as the new seeds grown from the original batch had never been sold."⁴⁴ The court stated that "[to apply] the first sale doctrine to ... self-replicating technology would eviscerate the rights of the patent holder."⁴⁵ The majority also rejected Scruggs implied license defense noting that his failure to sign the required license agreement did not eclipse the restrictions Monsanto lawfully imposed on its invention.⁴⁶ Scruggs could not dispute that Monsanto consistently required all licensees and purchasers of Roundup Ready® seed to sign a technology agreement, and that a notice of the license requirement was placed on every bag of Monsanto seed.⁴⁷ Under these circumstances, it was unreasonable for Scruggs to conclude that he had an implied license to use the seeds as he saw fit.⁴⁸ Therefore, Scruggs' purchase did not "plainly indicate that the grant of a license should be inferred."49

Addressing the alleged invalidity of Monsanto's patents, the majority held that Scruggs failed to demonstrate any deficiencies in the written description of the patent specification, and was convinced that Monsanto's patent met the enablement requirement allowing "any person skilled in the art... to make and use the [invention]."⁵⁰

The majority examined Scruggs' allegations that Monsanto's license restrictions amounted to anticompetitive misuse of its patents, and affirmed the trial court's finding that the no-replant policy was within Monsanto's patent rights because it simply prevented unauthorized distribution and uncontrolled proliferation of Monsanto's technology.⁵¹ The technology fee was viewed as an equivalent to a royalty on the invention and the rest of the license stipulations were included within the

^{43.} Id. at 1336; see 35 U.S.C. \S 271(a) (prohibiting use of a patented invention without authority).

^{44.} *Scruggs*, 459 F.3d at 1336 (quoting Monsanto Co. v. McFarling, 302 F.3d 1291, 1299 (Fed. Cir. 2002)).

^{45.} Scruggs, 459 F.3d at 1336.

^{46.} *Id.*

^{47.} *Id.* 48. *See id.*

^{46.} See Id.

^{49.} *Id.* (quoting Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684, 686 (Fed. Cir. 1986)).

^{50.} *Scruggs*, 459 F.3d at 1337-38 (quoting Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1253 (Fed. Cir. 2004)).

^{51.} Id. at 1340.

scope of patent protection.⁵² Finally, the majority held that Scruggs failed to present sufficient evidence to show that Monsanto's actions violated the Sherman Act's prohibitions against illegal tying.⁵³ It stated that there was no evidence of coercion of licensees or buyers, and that the Monsanto incentive programs were financial in nature and purely optional.⁵⁴

In response to Scruggs' assertion that requiring seed purchasers to use only Roundup herbicide on their Roundup Ready® crops amounted to an illegal tying arrangement, the court stated that Scruggs had to show that the tying had "an actual adverse effect on competition."⁵⁵ Monsanto's clout in the herbicide market notwithstanding, since the tied product Roundup was the only government-approved glyphosate-based herbicide on the market at the time the licenses were written, and since the Roundup Ready® seeds only had commercial value to buyers in relation to the use of Roundup, there was essentially no competition to adversely affect, no restraint of commerce, and therefore no patent misuse.⁵⁶

One judge filed an opinion dissenting from the majority's holding against Scruggs' antitrust and patent misuse claims.⁵⁷ Judge Dyk argued that Monsanto's grower license agreements requiring purchasers of Roundup Ready® seeds to use only Roundup herbicide over their crops constituted illegal tying.⁵⁸ Monsanto's assertion that Roundup was the only government-approved glyphosate-based herbicide on the market at the time the licenses were issued did not completely preclude the possibility of an anticompetitive effect on the herbicide market.⁵⁹ That the licenses stipulated the use of the Roundup brand specifically instead of merely the use of a government-approved herbicide posed a potentially significant disincentive for competitors to seek government approval for their products.⁶⁰ Judge Dyk recommended that the issue be remanded to

^{52.} *Id.*

^{53.} *Id.*

^{54.} *Id.*

^{55.} *Id.* at 1341.

^{56.} *Id.*

^{57.} Id. at 1342 (Dyk, J., dissenting).

^{58.} *Id.*

^{59.} *Id.* at 1343.

^{60.} *Id.* at 1343-44. The majority dismissed Judge Dyk's concerns, noting that as soon as new glyphosate-based products were introduced and approved, Monsanto altered its contracts to allow any government-approved herbicide to be used in combination with its Roundup Ready® seeds. *Id.* at 1341.

determine the extent of Monsanto's market power and whether patent misuse resulted.⁶¹

IV. ANALYSIS

Although Scruggs will likely appeal the decision to the United States Supreme Court, the central claim construction issue on the scope of the Roundup Ready® patent would probably not be overturned.⁶² This is so because the construction Scruggs requested (as seen in *McFarling* before him) requires an awkward semantic conception of the synthetic trait as a product somehow separable from the seed in which the trait is embedded.⁶³ Scruggs wanted the court to construe the claim in such a way that the illegal tying was between the Roundup Ready® trait and the seed.⁶⁴ In essence, the inseparability of the Monsanto trait and the naturally-occurring soybean germplasm forces the customer to buy the two together.

This is a novel conception of a tying arrangement, but one that collapses under the weight of its novelty. Of course, the trait by itself is useless. There is no market for it apart from its combination with the rest of the DNA of the plant. It is not separable, once embedded, and the patent must read on the entire seed, just as it would if Monsanto were to apply for patent protection under the Plant Variety Protection Act (PVPA).⁶⁵ Scruggs incorrectly conflated a patented invention with a marketable product. The likely reason the Roundup Ready® patent claimed only the synthetic trait is because Monsanto is sensitive to the fact that it does not own the vast amount of genetic information encoded in the rest of the germplasm.⁶⁶ In one sense, Monsanto greatly benefits from the semantic and scientific space between the way in which the law views a gene patent and a plant variety patent. From a farmer's perspective and viewed from the naked eye, there is no difference between a seed embedded with the Monsanto gene and a plant bred via

^{61.} See id. at 1344 (Dyk, J., dissenting).

^{62.} That the case would be granted certiorari on the claim construction issue is just as unlikely given that the court here did not choose to explicitly analyze its holding in *McFarling*, and did not address similar arguments raised in appellant's brief. *See id.* at 1336 (majority opinion); *cf.* Brief of Appellant at 25, *Scruggs*, 459 F.3d 1328 (Nos. 04-1532, 05-1120, 05-1121), 2005 WL 2796751.

^{63.} Monsanto Co. v. McFarling 302 F.3d 1291, 1299 (Fed. Cir. 2002).

^{64.} Scruggs, 459 F.3d at 1340.

^{65. 7} U.S.C. §§ 2541, 2543 (2000) (seed-saving exemption to infringement of protected plant variety).

^{66.} See N. Busch, Jack and the Beanstalk: Property Rights in Genetically Modified Plants, 3 MINN. INTELL. PROP. REV. 1, 101 (2002).

natural selection to resist glyphosate-based herbicides.⁶⁷ However, the PVPA does not allow plant variety patent holders to prohibit the saving of seed.⁶⁸ The law treats a naturally resistant soybean very differently from a synthetic one.

At its narrowest, the claim construction at issue here eliminates, at least in the agricultural sector, one of the basic ways in which patent law has traditionally been understood—the doctrine of patent exhaustion after first sale of the patented product (or a product containing the patented invention).⁶⁹ There is a real danger that downstream license restrictions on patented goods will become permanent because of the unique nature of self-replicating inventions: the patents will read on all future generations produced from the initial restricted license sale.⁷⁰ There is ample controversy as to whether this was Congress's intent.⁷¹

Patent claim construction controversy surrounding the Roundup Ready® trait aside, the court's analysis did not mention that the Roundup product itself went off-patent in 2000. At the time of the grower license agreements in question, Roundup was the only glyphosate-based herbicide on the market, specifically because it was still protected under Through its patents, Monsanto had legal monopolies on patent.⁷² glyphosate-based herbicides and on glyphosate-resistant soybean and cotton seeds.⁷³ The anticompetitive effect of the tying arrangement between the Roundup Ready® seeds and Roundup was even greater given that both were patented products, and should arguably have merited more attention from the court. In fact, the timing of the introduction of the Roundup Ready[®] seeds with the expiration of the Roundup patent is critical to understanding Monsanto's market strategy at the time. Scruggs' antitrust tying allegations were not so baseless as to merit dismissal on summary judgment, a point which is supported by Judge Dyk's dissent.74

Furthermore, the court did not allow for examination of how this type of patent operates in the context of the entire seed industry. When viewed horizontally across plant varieties, the Roundup Ready® gene will potentially allow Monsanto to gain control of almost all staple crops

^{67.} *Id.*

^{68. 7} U.S.C. § 2543.

^{69.} P. Carstensen, *Post-Sale Restraints via Patent Licensing: A "Seedcentric" Perspective*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1053, 1058 (2006).

^{70.} See id. at 1076.

^{71.} See id. at 1077.

^{72.} *Scruggs*, 459 F.3d at 1342 (Dyk, J., dissenting).

^{73.} *Id.*

^{74.} Id. at 1343-44.

in a very short period of time.⁷⁵ Through consolidation of control over an industry in a handful of large seed companies, by prohibiting small-scale independent research, and by forbidding farmer experimentation, patent protection has the potential to shut off innovation, and may significantly limit the "progress of Science and useful Arts."⁷⁶

The Federal Circuit tackled a novel issue in Scruggs with implications for intellectual property holders in agribusiness. pharmaceuticals, computer software, human and animal gene therapy applications, and nanotechnology-virtually any new technology with the ability to replicate itself. The uniqueness of this case and the manner in which the court chose to construe Monsanto's patent claims on the Roundup Ready[®] trait will serve as a platform on which agribusinesses will reap profits. However, the fact remains that the "public [has] a paramount interest in seeing that patent monopolies spring from backgrounds free from ... inequitable conduct and that such monopolies are kept within their legitimate scope."77 What is an unequivocally good decision for intellectual property rights holders is not necessarily in the best interest of society as a whole. The effects of Monsanto's no-replant policy on the agricultural industry, on farmers, and on consumers-held here to be within the bounds of Monsanto's patent rights-are unquantifiable in a brief legal analysis. Congress will likely need to respond to allegations of unfairness regarding the benefits conferred upon biotechnology patent holders by this decision.

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^{75.} Busch, *supra* note 66, at 120.

^{76.} U.S. CONST. art. I, § 8, cl. 8.

^{77.} Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945).

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