July, 2013

GM Crops in the Courts: Three Recent US Patent Decisions

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GM Crops and Food: Biotechnology in Agriculture and the Food Chain 4:3, 1–4; July/August/September 2013; © 2013 Landes Bioscience

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Note from the editors of *GM Crops and Food*

In recent months there has been increasing recourse to the courts in various countries by people and organizations who wish in various ways to influence or prevent the application of agricultural biotechnology in those lands. As part of the editorial policy of *GM Crops and Food* to consider from time to time all aspects of relevant activity, we have introduced another feature which will appear often but not in every issue of the journal: GM crops in the courts.

We are very fortunate that Professor Drew Kershen, Earl Sneed Centennial Professor of Law (Emeritus) at the University of Oklahoma, College of Law, has agreed to contribute the benefits of his thinking and experience. He has very wide experience of regulatory and legal issues pertaining to GM-technology, focusing his attention on agricultural biotechnology law and policy since 1997. This is the first of his contributions.

Introduction

This article reflects on three recent US patent decisions involving biotechnology: *Association for Molecular Pathology v. Myriad Genetics, Inc*[1]; *Bowman v. Monsanto Company*[2]; and *Organic Seed Growers and Trade Association v. Monsanto Company*[3] (commonly referred to as the OSGATA case).

The Myriad Genetics case

In the early 1990s, Myriad Genetics, Inc. discovered the chromosomal location and genetic sequence of the genes called BRCA1 and BRCA2. Myriad Genetics then proceeded to isolate these two genes, linked to increased risk of breast cancer in women, and to develop a diagnostic test for this risk. With this scientific work completed, Myriad Genetics applied for and obtained US patents, giving the company the exclusive right to use and commercialize the claimed inventions in the patents for a period of 20 y. Myriad Genetics enforced these patents by bringing patent infringement actions against other physicians, researchers, and companies that tested women for the BRAC1 and BRAC2 genes.

The Association for Molecular Pathology, joined by medical doctors and patient advocacy groups, filed this lawsuit seeking a judicial declaration that Myriad Genetics' patents were invalid and unenforceable under US patent law. The Association was the plaintiff in this lawsuit; Myriad Genetics was the defendant in this law suit.

In deciding the case, the Supreme Court of the United States focused on four claims as representative among the Myriad Genetics patents. Claim 1 asserted a patent on the DNA code that produces a string of BRCA1 amino acids in a particular described sequence. Claim 2 asserted a patent on a DNA code, lacking the introns, that produces a string of BRCA1 amino acids that codes for the typical BRCA1 gene. Claim 5 asserted a patent on a subset of data in Claim 1—a series of 15 nucleotides existing in the typical BRCA1 gene. Claim 6 asserted a patent on a subsection of data in Claim 2—a series having a least 15 nucleotides from the claim 2 DNA. The Supreme Court identified Claim 1 and Claim 5 as being claims in DNA; it identified Claim 2 and Claim 6 as being claims in cDNA (complimentary DNA).

To highlight the legal issue that the Supreme Court decided and the ruling that they rendered, it is best to quote directly from the Court's opinion:

> *This case involves claims from three [Myriad Genetics patents] and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 [the subject matter eligible for protection in the patent statutes] by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA) which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. For the reasons that follow we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.*[4]

The Supreme Court decision applied to Myriad Genetics the long-standing judicial precedents holding that laws of nature, natural phenomenon, and abstract ideas are not within the statutory eligibility language of § 101. The Supreme Court justified these exclusions from patentability on the grounds that laws of nature, natural phenomenon, and abstract ideas

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Submitted: 08/13/2013; Accepted: 08/13/2013
http://dx.doi.org/10.4161/gmcr.26251

are foundational information meant to be available to everyone as part of the common goods of the physical environment. If foundational information could become subject to the patent monopoly, others would be excluded from the common goods and, furthermore, society would lose, thereby, the innovative creativity of everyone using this foundational information.

By contrast, the Supreme Court has consistently upheld patents that involve inventions and discoveries resulting in human-made compositions of matter and manufacture. As explained by the Supreme Court, patents provide an incentive for those who create new, useful, and non-obvious human-made compositions of matter and manufacture. Without the incentive of patents, those interested in creating new, useful human-made items would not be willing to invest the time, money, and effort needed to create these new, useful human-made items.

Applying these abstract principles of patent law to the specifics of Myriad Genetics' patent, the Supreme Court distinguished between the patent eligibility of Claims 1 and 5 (denied) and the patent eligibility of Claims 2 and 6 (allowed).

With respect to Claims 1 and 5, the Supreme Court emphasized that Myriad Genetics claimed only the genetic information that already existed in the human genome. While Myriad Genetics had isolated the genetic information, the Supreme Court ruled that the act of isolation did not change a natural phenomenon into a human-made item—the genetic information was identical before or after the isolation. Even though Myriad Genetics had spent considerable time, effort, and money in locating, sequencing, and isolating BRAC1 and BRAC2, the Supreme Court said that these facts do not bring a natural phenomenon within patent eligibility.

With respect to Claims 2 and 6, the Supreme Court emphasized that Myriad Genetics had used laboratory techniques to create a human-made item (cDNA) that did not exist in the human genome. As cDNA for BRAC1 and BRAC2 were human-made items, the Supreme Court held that Myriad Genetics had met the patent eligibility requirements and should earn the patents providing Myriad Genetics with the incentive reward for their scientific creativity.

In distinguishing natural phenomenon from human-made items, the Supreme Court referred to two prior Supreme Court decisions specifically involving agricultural inventions. These two prior cases were *Diamond v. Chakrabarty*,[5] (human-made oil-eating bacteria, that did not exist in nature, created by using modern biotechnology laboratory techniques) and *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,[6] (human-made variety of soybean seed created by advanced conventional breeding techniques.) In both the *Chakrabarty* and the *J.E.M. Ag. Supply* decisions, the Supreme Court upheld the patent eligibility of these human-made items.

The Bowman Case

Bowman bought soybean seeds from an elevator intending to plant them in order to grow a crop. As almost all neighboring farmers grew RoundupReady (RR)-glyphosate tolerant soybeans, Bowman surmised that the seed he purchased from the elevator would also be herbicide-tolerant. He confirmed his surmise when he sprayed the planted seeds with glyphosate to kill weeds and confirmed that almost all the planted seeds survived. Bowman then saved seeds from those purchased at the elevator to grow a crop in the following year. He repeated seven times this pattern of saving seeds to produce a new crop.

Monsanto Company has patents on RR-soybeans and sells these patented seeds to farmers through licensed dealers. Under the license, farmers purchasing the seeds must sign a technology use agreement in which the they agree that the seed can be planted to produce one crop which must be used for food or feed either on the farmer's farm or by sale to an elevator or to a food processor. When Monsanto learned that Bowman, having purchased soybean seeds intended solely for food or feed, had planted them for a crop, and saved seeds from the harvested crop for additional crops, Monsanto sued Bowman for patent infringement.

Highlighting the legal issue that the Supreme Court decided and the ruling that the Supreme Court rendered are best achieved by quoting directly from the Court's opinion:

> *Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention. The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission. We hold that he may not.*[7]

In the *Bowman* case, the Supreme Court faced the issue of the reach of the doctrine of patent exhaustion. Courts have long held that patent exhaustion means that if a patent owner sells its patented article, the purchaser of that article acquires rights of ownership in the item. With those rights of ownership, the purchaser may sell the item to another person, discard the item or give it to another person. However, at the same time, the courts have held that patent exhaustion does not give the purchaser any of the intellectual property rights (e.g., patents in this instance) in the purchased item. Consequently, the purchaser cannot make a second copy of the purchased item because doing so would use the intellectual property rights of the patent owner and would undermine the strength of the patent owner's patent monopoly that exists for 20 y.

Bowman did not challenge the validity of Monsanto Company's patents because that had been clearly established in prior judicial decisions. Bowman argued that the patent exhaustion doctrine protected his actions because he had purchased the seeds from an elevator after the original purchaser (a farmer) had harvested a crop and sold that crop to the elevator for food or feed. He argued that the patent became exhausted with the sale to the elevator, allowing him to purchase the soybean seeds free and clear of any patent rights by Monsanto.

The Supreme Court rejected Bowman's argument because the patent exhaustion applies to the original item (the initial seed purchased by farmers). The patent exhaustion doctrine does not allow the making of additional copies of the original item except

as allowed by the patent holder's license. Under the Monsanto license, the farmer can reproduce the seeds to produce a bountiful harvest so long as that bountiful harvest is used solely for food or feed. The Monsanto license does not allow saving of seed for planting to produce a new crop. Moreover, the Supreme Court said that patent law affirms the Monsanto license restriction because failure to affirm the restriction would mean effectively that Monsanto would receive compensation from only one sale of the seed—the first sale.

Bowman argued also that seeds are meant to be planted and that he did not "make" new seeds. Bowman stated that he only planted seeds that reproduce themselves into multiple copies of a bountiful harvest.

The Supreme Court rejected this argument by noting that Bowman was not a passive observer of soybean growth. He took active steps to buy the commodity seeds, condition the commodity seeds, plant the seeds, tend the seeds prior to harvest, and save seeds for a coming crop year. As the Supreme Court wrote, "In all this the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto's patented invention."[8]

The OSGATA Case

The OSGATA plaintiffs sought a declaratory judgment against Monsanto Company that Monsanto's patents were unenforceable and invalid. In order to reach these substantive issues of the validity and enforceability of Monsanto's patents, the OSGATA plaintiffs were required to establish that their allegations (the plaintiff's pleading—the formal complaint to bring a lawsuit) showed a justiciable case or controversy to pursue a declaratory judgment legal action. In a procedural motion to dismiss the case, Monsanto Company argued that the judge should dismiss the case because the OSGATA plaintiffs failed to prove that their pleadings showed a justiciable case or controversy. In the United States, courts lack jurisdiction to decide hypothetical, abstract, or intellectually interesting legal issues; there must be a justiciable case or controversy between the plaintiff bringing the lawsuit and the defendant defending in the lawsuit.

Quoting the court's opinion is again the best way for the reader to understand the court's view of the case and its holding in the case:

> *[Plaintiffs], a coalition of farmers, seed sellers, and agricultural organizations, sought declaratory judgments of non-infringement and invalidity with respect to twenty-three patents owned by Monsanto Co. ... The district court concluded that there was no justiciable case or controversy and dismissed for lack of jurisdiction. Because Monsanto has made binding assurances that it will not "take legal action against growers whose crops might inadvertently contain traces of Monsanto biotech genes (because, for example, some transgenic seed or pollen blew onto the grower's land)," ... and [plaintiffs] have not alleged any circumstances placing them beyond the scope of those assurances, we agree that there is no justiciable case or controversy. We affirm [the decision of the district court].*[9]

For a lawsuit to present a justiciable case or controversy under the Declaratory Judgment Act of the United States, the plaintiff's allegations must (1) allege an affirmative act by the patent owner related to the enforcement of the patent against plaintiff or persons similarly situated to plaintiff and (2) allege actions by the plaintiff that show meaningful preparation to engage in infringing activity.

With respect to affirmative actions by the patent owner (Monsanto Company), the court accepted the evidence that Monsanto does bring infringement law suits against farmers and seed dealers. The court stated that the evidence showed 144 law suits and 700 settlements in the period of 1997 to April 2010 (the date the OSGATA plaintiff's filed this lawsuit). But the court noted that all the evidence showed that Monsanto pursued these lawsuits and settlements against farmers or seed dealers who intentionally infringed or did so when they should have known that their actions were actions of infringement. The court said that there was no evidence that Monsanto had brought a lawsuit or sought settlement against a farmer or seed company with inadvertent traces of its patented seeds or traits among a harvest or a seed supply.

The court then noted that Monsanto Company had pledged to the court the following:

> *"[Monsanto] policy has never been nor will it be Monsanto policy to exercise its patent rights where trace amounts of our patented seeds or traits are present in farmers' fields as a result of inadvertent means."*[10]

The plaintiff's argued, and Monsanto did not contest, that "trace amounts" is up to one percent of the seeds—i.e., the voluntary seed and product certification standards existing in the United States. (The United States government has not adopted a legal definition of "trace amounts" in any statute or regulation.) Consequently, the court accepted Monsanto's pledge as a binding promise to the courts (called judicial estoppel) that would legally preclude Monsanto from bringing a patent infringement lawsuit against anyone for a "trace amount" of up to one percent.

With respect to OSGATA plaintiff's preparation to engage in infringing actions, the OSGATA plaintiffs had consistently alleged and argued to the court that they did not want nor seek to have any transgenic seed or transgenic traits in any seed or crop or harvest. OSGATA plaintiffs presented evidence to the court that they took specific actions (rejection of purchased seed, testing of seeds and harvests) to assure that they had no transgenic seed or traits in their seeds, crops, and harvests. In light of these OSGATA allegations and arguments, the court found as a matter of the evidence that the plaintiffs clearly were not engaged in any activity preparatory to infringing Monsanto's patents.

Finally, the OSGATA plaintiffs argued to the court that, although they took affirmative actions to preclude the presence of transgenic seeds or traits, that they were afraid that their best efforts might fail. The OSGATA plaintiffs argued that they were

afraid that they might not only have trace amounts but that, at times, they factually might have more than trace amounts. The OSGATA plaintiffs argued that their subjective fears meant that they had established a justiciable case or controversy.

The court ruled that, the plaintiff's avoidance combined with Monsanto's pledge meant that the OSGATA plaintiffs did not face any substantial risk of a patent infringement lawsuit. While the court acknowledged that subjective fears existed, they ruled that these fears were not sufficient to establish a justiciable case or controversy. As the court wrote, "[OSGATA plaintiffs] 'cannot manufacture [a justiciable case or controversy] merely by inflicting harm on themselves based on their fears of hypothetical future harm.' 568 U.S. at 1151"[11]

Brief Comments

Biotechnology, particularly agricultural biotechnology, fared well in these three US patent cases.

In the *Myriad Genetics* case, the Supreme Court expressly affirmed the foundational cases allowing patents in agricultural biotechnology. Moreover, the Court ruled that cDNA inventions are patentable subject matter. Although the Court did not address synthetic biology, it is a fair reading of the Myriad Genetics decision to think that the Supreme Court will also decide that the inventions from synthetic biology are patentable subject matter.

In the *Bowman* case, the Supreme Court explained the doctrine of patent exhaustion in a manner that gave robust protection to patents in agricultural seeds. However, the Court made clear that the application of the patent exhaustion doctrine to other factual patterns involving self-replications technologies (e.g., stem cells in medicine, animal biotechnology) awaits future cases.

In the *OSGATA* case, the federal appellate court set a standard for patent infringement through the doctrine of judicial estoppel. At the same time, however, the federal appellate court protected biotechnology companies from lawsuits whose arguments and tactics the lower federal district court had labeled as "baseless," "groundless," "not to be tolerated" and "unacceptable."

References

1. Association for Molecular Pathology v. Myriad Genetics, Inc., Slip Opinion, # 12-398 (Supreme Court U.S.A. (Sup. Ct.) decided June 15, 2013).
2. Bowman v. Monsanto Company, Slip Opinion, # 11-796 (Sup. Ct. decided May 13, 2013).
3. Organic Seed Growers and Trade Association v. Monsanto Company, 718 F.3d 1350 (U.S. Ct. App., Fed. Cir., June 10, 2013) *affirming* 851 F. Supp.2d 544 (U.S. Dist. Ct., So. Dist. N.Y., Feb. 24, 2012).

4 Myriad Genetics at Slip Opinion, p. 1, # 12-398.

5. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
6. J.E.M. Ag. Supply, Inc., v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).

7 Bowman at Slip Opinion, p.1, # 11-796.

8 Bowman at Slip Opinion, p. 10, # 11-796.

9 OSGATA at 718 F.3d 1353.

10 OSGATA at 718 F.3d 1358.

11. OSGATA at 718 F.3d 1360, quoting from the U.S. Supreme Court opinion in *Clapper v. Amnesty Int'l USA*.