

Genetically Modified Seeds and the Patent Exhaustion Doctrine

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Introduction

In 2010, genetically modified (GM) seeds, mostly patented by Monsanto Company, were estimated to be used for 80% to 90% of all soybeans, maize and cotton production in the United States.¹ Millions of these seeds have been sold.² The most widely sold patented plants are GM crops engineered to be resistant to herbicides, such as glyphosates, and those engineered to produce pesticides, such as Bt toxins.³ The first approval of a GM product patented for food use and commercial sale was Calgene's Flavr-Savr tomato in the 1980's.⁴ GM seeds are an invention of the 20th century—a byproduct of the expanding commercial seed industry.⁵ This expansion was the result of the three factors: the termination of the federal government's seed program in 1924, the revival of Mendel's plant-genetics studies, and the rising popularity of plant hybridization.⁶

Patents owned by companies, most notably Monsanto and E. I. du Pont de Nemours and Company (DuPont), cover these GM plants.⁷ Patents for organisms are not new to the 21st century, but patents for self-replicating organisms, such as GM seeds, create novel complications for patent law. The laws surrounding the use of GM seeds have emerged into a combination of patent and contract law.⁸ The two critical aspects of patent law that affect GM seeds are the patent exhaustion doctrine and patent misuse. Patent exhaustion is “the legal principle that the

¹ Eric J. Rogers, *The Inexhaustible Right to Exclude Reproduction Doctrine*, 14 COLUM. SCI. & TECH. L. REV. 389, 401 (2013).

² *Id.* at 393.

³ *Id.* at 399.

⁴ *Id.* at 397.

⁵ Rita S. Heimes, *Post-Sale Restrictions on Patented Seeds: Which Law Governs?*, 10 WAKE FOREST INTELL. PROP. L.J. 98, 101 (2010).

⁶ *Id.* at 104.

⁷ Rogers, *supra* note 1, at 393.

⁸ *Id.* at 391.

authorized sale of an item exhausts certain patent rights with respect to that individual item.”⁹

Patent misuse is an “equitable doctrine that prevents a patentee with unclean hands from enforcing patent rights with respect to any misused patent.”¹⁰ The difference between these two patent doctrines has been called “the difference between law and equity” because “[p]atent exhaustion refers to when there exists no legal right to enforce, whereas patent misuse refers to when the legal right to enforce exists but is unavailable for reasons of equity.”¹¹

This paper discusses the application of patent law to GM seeds by analyzing the three different ways courts have interpreted patent law: the traditional patent exhaustion doctrine, the *Mallinckrodt* doctrine, and the inexhaustible right to reproduce doctrine. The paper also examines two case studies demonstrating the complications of the inexhaustible right to reproduce doctrine and its implications on patentees and purchasers of GM seeds.

Background

There are two main entities involved in GM seed patent issues: the companies producing GM seed technologies, such as Monsanto and DuPont, and the farmers actually growing the GM crops. From the perspective of the producers—the patentees—there is an incentive to acquire the full value afforded by the law for the purchase or licensing of their self-replicating technologies.¹² On the other hand, the purpose of the patent exhaustion doctrine is to prevent the “over-reward of patentee’s and the taxing of downstream users.”¹³ If the patent exhaustion doctrine were not enforced at all by the courts, patentees would continue to receive the benefits of their patents after they have been sold to the consumer—such as a farmer. However, a dilemma occurs when the law attempts to protect both the patentees with self-replicating products and the

⁹ Rogers, *supra* note 1, at 391.

¹⁰ *Id.*

¹¹ *Id.* at 431.

¹² *Id.* at 392.

¹³ *Id.*

concept of patent exhaustion. To solve this problem, the Supreme Court, in *Monsanto v. Bowman*,¹⁴ created a new doctrine of patent exhaustion: the inexhaustible right to exclude reproduction.¹⁵ This doctrine dutifully protects patentees of self-replicating technologies such as GM seeds.

The first issue is the intentional violation of GM patents. In this situation, like *Bowman*, farmers intentionally use GM seeds beyond their intended use by patentees. To do this, farmers may reproduce seeds by planting them for more than one generation, which violates the inexhaustible right to exclude reproduction doctrine. GM seed producers, like Monsanto and DuPont, would like to prevent farmers from committing patent infringement and using their seeds for multiple generations. In this situation, it is assumed that farmers desire to grow GM crops since they are putting effort into violating the patents, but that is not always the case.

The second issue is the unintentional contamination of conventional crops by GM seeds. Here, farmers do not desire to grow GM crops for a multitude of reasons, including a fear of tainting a crop's organic certification. Unintentional contamination can occur due to environmental factors like windblown seed drift and cross-pollination of GM pollen seeds to neighboring conventional crop fields.¹⁶ The contamination levels vary, but according to Monsanto's claims in *Organic Seed Growers & Trade Ass'n v. Monsanto*,¹⁷ contamination greater than one percent is unlikely.

In both cases, the patentees desire to keep their patent rights and ensure their seeds are accounted for. Additionally in both types of cases, the integrity of the farmers' seeds is at issue.

¹⁴ 133 S.Ct. 1761 (2013).

¹⁵ Rogers, *supra* note 1, at 392–93.

¹⁶ 718 F.3d 1350, 1357 (2d Cir. 2013).

¹⁷ *See id.*

The cases differ on whether the farmers raising the GM crops intend to and desire to grow GM plants or whether they would prefer to grow only conventional crops.

Applying Patent Law to GM Seeds

In *Diamond v. Chakrabarty*,¹⁸ the U.S. Patent and Trademark Office (USPTO) was faced with considering living organisms for patent eligibility.¹⁹ The USPTO originally ruled the genetically engineered bacterium²⁰ was not patent-eligible, but the Supreme Court, in a 5 to 4 decision held that living organism to be eligible subject matter for a patent.²¹ This living organism was considered eligible subject matter because it “did not exist in nature and it was a new and useful manufacture or composition of matter.”²² By the late twentieth century, the USPTO granted numerous utility patents²³ claiming living organisms such as (1) bacteria,²⁴ (2) cell lines,²⁵ (3) animals,²⁶ and (4) transgenic plants, such as the Flavr-Savr tomato plant.²⁷

Traditional Approach of Patent Exhaustion

During the early development of GM seeds, courts were following the traditional patent exhaustion doctrine laid out in 1942 by *United States v. Unis Lens Co.*²⁸ Under this doctrine, patentee’s rights are terminated when the item is sold, conferring the discretionary right to use on to the purchaser.²⁹ A caveat to this doctrine is that while it applies to the particular item being

¹⁸ 447 U.S. 303 (1980).

¹⁹ *See id.*

²⁰ The bacterium at issue was genetically engineered to metabolize the hydrocarbons that would be found in a typical oil spill.

²¹ Rogers, *supra* note 1, at 397.

²² *Id.*

²³ “A utility patent grants the owner for 20 years from the patent’s filing date the right to exclude others from 1) making, 2) using, 3) selling, 4) offering to sell or 5) importing the patented invention. Generally, patent exhaustion can occur for only the last four of the patent rights, but not the ‘right to make’.”

²⁴ Examples of self-replicating bacteria are oil eating *Pseudomonas* and ice-minus *Pseudomonas*.

²⁵ An example of a self-replicating cell line is human leukemia T-cells.

²⁶ Examples of a self-replicating animal are transgenic mammals expressing a human-made, activated oncogene covering the mice branded as the OncoMouse™.

²⁷ Rogers, *supra* note 1, at 413–14.

²⁸ 316 U.S. 241 (1942).

²⁹ *Bowman v. Monsanto*, 133 S.Ct. 1761, 1766 (2013).

purchased it still leaves the patentees ability to prevent a buyer from making new copies of the patented item.³⁰ Thus, patent exhaustion requires: “(1) an authorized and (2) unconditional (3) conveyance of tangible property that embodies patent rights, and (4) for which the patentee has been compensated for the patent right exhausted.”³¹ *Univis* described a two-prong test to determine whether a sold, non-infringing article exhausted any patent rights. First, the reasonable and intended use prong is an inquiry into “the intended use of the article, either explicitly or implicitly, manifested in the transaction of its sale.” The second, an essential features prong is an inquiry into “whether the article embodies any essential features of a patented invention.”³² Under the traditional approach of patent exhaustion, if this two prong test is fulfilled, the patent is exhausted and then patentee transfers the discretionary right to use the item onto the purchaser.

Mallinkrodt Doctrine and Bag Tags

In the 1990s, when the patenting of organisms became more widespread, the Federal Circuit narrowed the power of the patent exhaustion doctrine with the *Mallinckrodt* doctrine.³³ In 1992, the federal circuit in *Mallinckrodt, Inc v. Medipart Inc.*³⁴ held that “patent owners could condition the sale of patented goods with a restrictive notice and thereby restrict the disposition of the goods by the purchasers.”³⁵ Patent owners began using contracts in an effort to restrict the use of their patented organisms after sale.³⁶ Specifically, patentees in the patented seed industry began to rely on licensing agreements to maintain control over their GM seeds. Patentees did this in order to get the full value of their patented products, thus creating the ability to provide for future investment into research and development of new technologies. The licenses on GM seeds

³⁰ *See id.* at 1766.

³¹ *Rogers, supra* note 1, at 404.

³² *Id.*

³³ *Id.* at 421.

³⁴ 962 F.2d 700 (7th Cir. 1992).

³⁵ *Rogers, supra* note 1, at 421.

³⁶ *Id.*

are called “seedwrap licenses.” These licenses include a contract printed on a “bag tag” attached to the product and the contract is accepted by the purchase of the seed bag.³⁷ By introducing the *Mallinckrodt* doctrine, the courts expanded patentees’ power over patented items by giving them control over items even after they were purchased, and therefore narrowed the power of the patent exhaustion doctrine.

Since the *Mallinckrodt* doctrine was established in 1992, there has been discussion over its contended flaws. *Bowman* argues that *Mallinckrodt* “conflated post-sale restrictions that are enforceable by contract law (notwithstanding antitrust concerns) with a patentee's attempt to enforce post-sale restrictions through patent law.”³⁸ Commentators and scholars have described *Mallinckrodt* as inconsistent with long-standing precedent from the Federal Circuit and have view the decision as an improper expansion of the limited manufacturing license doctrine.³⁹ In *Mallinckrodt*, the court treated the principle of patent exhaustion as irrelevant if a sale is qualified or conditional, and thus, patent exhaustion could be legally avoided at the patentee's discretion using contract terms.⁴⁰ This approach allowed patentees to rely on contract law to define what constitutes an authorized sale, thereby avoiding patent exhaustion.⁴¹ The implications of this shift to contract law also effects jurisdiction of cases. State law generally applies to contract construction, even of agreements purporting to license rights arising under federal patent law, but federal common law may override state common law that interferes with purposes of the Patent Act. Specifically, several federal courts have held that federal common

³⁷ Rogers, *supra* note 1, at 421.

³⁸ *Monsanto Co. v. Bowman*, 657 U.S. 1341 (2011).

³⁹ *Id.* at 15.

⁴⁰ Rogers, *supra* note 1, at 408.

⁴¹ *Id.* at 409.

law governs the issue of assignability of nonexclusive patent licenses, preempting application of state law.⁴²

Current GM Seed Patent Law: Inexhaustible Right to Exclude Reproduction Doctrine

The most recent development in GM seed patent law is the inexhaustible right to exclude reproduction doctrine. The Supreme Court enacted this doctrine in *Bowman*, stating GM seed patents are able to claim that the purchaser of the patented seed is not allowed to replicate seeds or to use them in further generations of plants.⁴³ This ruling applies specifically to the patenting of self-replicating entities such as seeds, holding that each generation of a patented plant infringes the right to make or the right to manufacture.⁴⁴ Thus, “patented seeds conveyed into the stream of commerce are forever protected by patent rights such that using them to grow more than one generation is patent infringement.”⁴⁵

Some scholars believe that this new doctrine, like the *Mallinckrodt* doctrine, is flawed.⁴⁶ This argument points out that while the doctrine currently results in little harm to the public, this could change when other self-replicating patented products become part of the everyday consumers’ lives by being “mass marketed and purchased in ordinary channels of trade.”⁴⁷ The courts are compelled to solve controversies as they present themselves and cannot wait for Congress to amend the patent statute with “a sui generis rule for applying patent exhaustion to self-replicating products.” Therefore, the Court’s failure to consider every possible implication of the inexhaustible right to exclude reproduction doctrine results in little harm to the public, but

⁴² Heimes, *supra* note 5, at 141.

⁴³ See *Bowman*, 133 S.Ct. 1761.

⁴⁴ Rogers, *supra* note 1, at 422.

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.* at 483–84.

this could change when patented, self-replicating products become part of the ordinary pursuits of life by being mass marketed and purchased in ordinary channels of trade.”⁴⁸

Bowman v. Monsanto Case Study

*Bowman v. Monsanto*⁴⁹ is a keystone case for GM seed patent law. Vernon Bowman, an elderly farmer from Indiana, bought Roundup Ready® soybean seed (GM seed) and executed a Technology Agreement.⁵⁰ The Technology Agreement allowed users to sell second-generation crops as a commodity to grain elevators, which leads to grain elevators combining crops from multiple sellers—some crops being grown from GM seeds while others are not.⁵¹ Bowman first planted the originally purchased GM seeds, but then purchased additional soybeans from a grain elevator for a second harvest later in the season.⁵² Since the Technology Agreement considered the seeds from the grain elevator, they were not within the scope of the agreement.⁵³ Bowman used Roundup® on this second crop of soybeans and found that many were resistant—presumably because the grain elevator contained a mixture of Monsanto's patented soybeans and unpatented soybeans from various farms.⁵⁴ Bowman saved the Roundup® resistant seed from this second crop and replanted seeds for the growing seasons from 2000 to 2007.⁵⁵

Monsanto, the holder of the patents for GM soybean seeds in question, brought action against Bowman, a farmer, alleging farmer infringed patents by planting offspring of genetically altered seeds covered by patents.⁵⁶ Bowman raised the defense of patent exhaustion.⁵⁷ He argues that patent exhaustion should be applied to his case because he used seeds “in the normal way

⁴⁸ *Id.* at 483–84.

⁴⁹ *See Bowman*, 133 S. Ct. 1761.

⁵⁰ Rogers, *supra* note 1, at 427.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.* at 427–28.

⁵⁶ *See Bowman*, 133 S. Ct. 1761.

⁵⁷ *Id.* at 1763.

farmers do,” and therefore if the court allows Monsanto to interfere, it “would create an impermissible exception to the exhaustion doctrine for patented seeds.”⁵⁸ The court counters this argument by saying Bowman is actually the party asking for an exception because “exhaustion does not extend to the right to make new copies of the patented item.”⁵⁹ The court emphasizes that although soybeans naturally “self-replicate” unless stored in a controlled manner, it was Bowman, not the soybeans, which controlled reproduction of the patented invention.⁶⁰

The Court held the principle of patent exhaustion inapplicable and instead “made a broad holding that any second-generation replication of a patented plant is patent infringement.”⁶¹ In addition, Bowman was “clearly trying to exploit the glyphosate-resistance technology patented by Monsanto to grow a new generation of soybeans without paying any royalty to Monsanto.”⁶²

The Supreme Court held that “patent exhaustion does not permit a farmer to reproduce patented seeds through planting and harvesting without the patent holder’s permission.”⁶³ The *Bowman* decision solidified the inexhaustible right to exclude reproduction doctrine.⁶⁴ The doctrine relies on the concept that patent rights move forever with self-replicating products, like GM seeds, based on how the product is used.⁶⁵ The new doctrine means that each subsequent generation of a patented plant infringes the right to make.⁶⁶

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ Rogers, *supra* note 1, at 430.

⁶² *Id.*

⁶³ See *Bowman*, 133 S. Ct. 1761.

⁶⁴ Rogers, *supra* note 1, at 393.

⁶⁵ *Id.*

⁶⁶ *Id.* at 422.

Organic Seed Growers & Trade Ass'n v. Monsanto *Case Study*

In *Organic Seed Growers & Trade Ass'n v. Monsanto*,⁶⁷ the second issue of GM seed use is addressed—the unintentional contamination of conventional crops by GM seeds.⁶⁸ In this situation, farmers do not desire to grow GM crops, but rather are concerned that GM seeds will contaminate their crops and consequently, Monsanto will sue them for patent infringement.⁶⁹ In this case, the Organic Seed Growers & Trade Association et al. (“OSGTA”) argue for protection against legal action from Monsanto for unintentional GM seed contamination.⁷⁰ Specifically, the Appellants are concerned “if they do indeed become contaminated by transgenic seed, which may very well be inevitable given the proliferation of transgenic seed today, they could quite perversely also be accused of patent infringement by the company responsible for the transgenic seed that contaminates them.”⁷¹ Most of the plaintiffs in this case are certified organic producers, and do not support Monsanto’s transgenic seed technologies.⁷² The goal of the Appellants’ claim is to require Monsanto to “expressly waive any claim for patent infringement [Monsanto] may ever have against [appellants] and memorialize that waiver by providing a written covenant not to sue.”⁷³

OSGTA first sued Monsanto in Southern District of New York in March 2011 asking the Court to declare that, should Monsanto’s transgenic seed ever contaminate them, they need not fear a lawsuit for patent infringement.⁷⁴ The district court held that action failed to satisfy case or controversy requirement.⁷⁵ OSGTA appealed and in June 2013, the Court of Appeals held that

⁶⁷ 718 F.3d 1350 (Fed. Cir. 2013).

⁶⁸ *Id.* at 1353.

⁶⁹ *See id.*

⁷⁰ *See id.*

⁷¹ *Id.*

⁷² *Id.* at 1353

⁷³ *Id.* at 1354.

⁷⁴ Complaint at 4, *Organic Seed Growers & Trade Ass'n v. Monsanto*, 851 F.Supp.2d 544 (S.D. N.Y. 2011).

⁷⁵ *Organic Seed Growers & Trade Ass'n v. Monsanto*, 851 F.Supp.2d 544, 556 (S.D. N.Y. 2011).

action did not satisfy case or controversy requirement.⁷⁶ The Court of Appeals explains that the appellants have alleged no concrete plans or activities to use or sell greater than trace amounts of modified seed, and accordingly fail to show any risk of suit on that basis—the appellants therefore lack an essential element of standing.⁷⁷

Despite being dismissed from the case, appellants were granted protection from suits brought against them by Monsanto if their crops were contaminated with up to one percent of seeds carrying Monsanto's patented traits, based on Monsanto's disclaimers in court.⁷⁸ Monsanto's disclaimer is not a covenant not to sue, but the court asserts “those representations are binding as a matter of judicial estoppel.”⁷⁹ The Court explains that the reason Monsanto is legally bound to their assertion not to sue for contamination up to one percent is that “a party who successfully argues one position is estopped from later adopting a contrary position in a case involving the same patent.”⁸⁰ The main factors warranting judicial estoppel are (1) a party's later position is “clearly inconsistent” with its prior position, (2) the party successfully persuaded a court to accept its prior position, and (3) the party “would derive an unfair advantage or impose an unfair detriment on the opposing party if not estopped.”⁸¹ In the possibility that Monsanto should sue the appellants for future actions falling within the scope of this case, all three factors would warrant the application of judicial estoppel.⁸² At oral argument, Monsanto's counsel acknowledged this concept, but was careful never to represent that Monsanto would “forgo suit

⁷⁶ *Organic Seed Growers & Trade Ass'n v. Monsanto*, 718 F.3d 1350, 1361 (Fed. Cir. 2013).

⁷⁷ *Id.*

⁷⁸ “Monsanto has disclaimed any intent to sue inadvertent users or sellers of seeds that are inadvertently contaminated with up to one percent of seeds carrying Monsanto's patented traits.” *Id.* at 1357.

⁷⁹ *Id.* at 1357.

⁸⁰ *Id.* at 1358–59.

⁸¹ *Id.*

⁸² *Id.*

against a grower who harvested and replanted windblown seeds—even if that grower gained no advantage by doing so.”⁸³

The issue that is not discussed thoroughly in *Organic Seed Growers & Trade Ass’n*, is the possibility of contamination over one percent. Though plaintiffs state that they do not intend to infringe these patents and they would greatly dislike the contamination of over one percent, there is no explicit protection for plaintiffs’ crops that could inadvertently be contaminated over one percent. In early September 2013, petitioners Organic Seed Growers et al. filed an appeal to the Supreme Court asserting they risked contamination above one percent and thus have been forced to abandon full use of their land and perform genetic testing of their seed supplies in order to avoid being accused of patent infringement by Monsanto.⁸⁴ The petitioners are waiting for the Supreme Court to decide whether they will hear the case.⁸⁵

Conclusion

Patent law surrounding GM seeds has substantially developed over the past several decades—from the tradition approach of patent exhaustion, to the *Mallinckrodt* doctrine, to the most recent inexhaustible right to exclude reproduction doctrine. The evolution of patent law continues to adapt to the needs of patentees and patented product consumers. In the realm of GM seeds, the patent exhaustion doctrine continues to narrow, creating greater protection for patentee’s after GM seeds have been purchased. The *Bowman* and *Organic Seed Growers Trade Ass’n* show the dichotomy of issues patentees of GM seeds and farmers are facing in society today. Because the relationship these two entities have is both beneficial and controversial, the area of GM seed patent law may continue to see cases those discussed above, allowing for the potential further development of new aspects of patent law.

⁸³ *Id.* at 1359 n.6.

⁸⁴ *Id.* at 1350.