Marquette Law Review

Volume 97
Issue 4 *Summer 2014*

Article 7

Twenty Years In the Making: Transitioning Patented Seed Traits Into the Generic Market

Brianna M. Schonenberg
brianna.schonenberg@marquette.edu

TWENTY YEARS IN THE MAKING: TRANSITIONING PATENTED SEED TRAITS INTO THE GENERIC MARKET

Since the introduction of genetically modified seeds into the global market during the 1990s, there has been little need to prepare for the expiration of the patents related to the technologies. That is, until the expiration of the pioneer Roundup Ready seed-trait patent drew near. Now that Monsanto's Roundup Ready seed-trait patent is nearing expiration, seed-producing competitors, farmers, and the global food market have raised questions regarding how Monsanto will handle the unprecedented transition into a generic seed market. In response, Monsanto and other agricultural-biotechnology companies have created the Accord, comprised of two contractual agreements, which attempts to regulate the transition. However, this private-sector solution fails to address the needs of all interested parties in the same way that the Hatch-Waxman Act provides for the various parties in the pharmaceutical industry. For this reason, the legislature should act to provide a regime for the transition that ensures that the genetic traits with expiring patents stay available for public use and that crops grown with these seeds may continue to be exported. This Comment suggests a legislative solution that would meet these needs by delegating the regulation of the transition into the generic market to an administrative agency. The solution proposed in this Comment would provide for a regime similar to one enacted through the Hatch-Waxman Act that allows for competitors to develop products using the patented genetic trait prior to patent expiration to prepare for the generic market. At the same time, it provides a scheme to ensure the maintenance of the international regulation authorizations that are necessary for seeds and crops containing genetic modifications to be exported.

I. INTRODUCTION

The veil that has been in place between consumers and the food they eat began to lift following the 2009 documentary, *Food, Inc.*[1] The documentary exposed the expansive control small numbers of corporations have over the food people eat, including the control that Monsanto, a Missouri-based seed producer, has over the global grain market.[2] After receiving a nomination for an Academy Award and being praised by Oprah, *Food, Inc.* played nationwide in theaters for twenty-four weeks and grossed more than four million dollars, indicating that the general public is fascinated by what has been hiding behind the veil.[3] *Food, Inc.* is highly critical of Monsanto's patent protection practices, painting Monsanto as a bully that uses intimidation and money to keep farmers in line.[4] Now there is concern that these bully methods will continue and that they will be practiced over other seed producers to prevent competition in the upcoming market for generic seeds.[5]

In September 2014, an unprecedented event will occur in the agricultural-biotechnology industry: the first of the widely economically successful patents for genetic traits in seeds will expire.[6] This patent, for

---

1. FOOD, INC., 3:19–5:10 (Magnolia Pictures 2009) (alleging that a "deliberate" veil has been placed by the food industry between consumers and the food they eat). *Food, Inc.* has been described as "a powerful, startling indictment of industrial food production, revealing truths about what we eat, how it's produced, who we have become as a nation and where we are going from here." Food, Inc.*, A Robert Kenner Film: Film Description*, PBS, http://www.pbs.org/pov/foodinc/film_description.php (last visited Feb. 15, 2014).

2. FOOD, INC., *supra* note 1, at 3:28–3:40, 1:07:20–1:08:11 (noting Monsanto as the grain-industry leader).

3. *See* Bryan Alexander, *For "*Food, Inc.*" Oscar Nod Big, Oprah Bigger*, NBC WASH. (May 30, 2012, 2:45 PM), http://www.nbcwashington.com/blogs/popcornbiz/For-Food-Inc-Oscar-Nominations-Are-Big-Oprah-Bigger-83473987.html (noting that DVD sales for *Food, Inc.* have climbed since Oprah praised the documentary on her program); *supra* note 1 and accompanying text.

4. FOOD, INC., *supra* note 1, at 1:07:20–1:10:09 (claiming that Monsanto uses a staff of seventy-five people devoted to the investigation and prosecution of possible patent infringements, including private investigators, and that farmers now feel like they cannot defend themselves against such claims because of the monetary cost of doing so).

5. *See infra* Part III.A (discussing the recent antitrust litigation between Monsanto and DuPont, in which DuPont claimed that Monsanto forced independent seed companies to stop using the Roundup Ready trait associated with the expiring patent to prevent such companies from producing generic forms to be market ready once the patent expires).

6. *See* U.S. Patent No. RE39,247E (filed Sept. 13, 1994) (issued May 27, 1997); Roger Parloff, *Seeds of Discord*, FORTUNE, May 24, 2010, at 94. The 2014 expiration of Monsanto's patent is only the first of many, "another wave of gene patents are scheduled to expire around 2020, including those owned by [companies other than Monsanto.]" Daniel Grushkin, *Threat*

the transformation of plant cells into seeds with the Roundup Ready trait, is owned by industry-titan Monsanto.[7] The Roundup Ready trait enables plants to survive exposure to the active ingredients in herbicides—mainly, the Roundup Ready herbicide that Monsanto markets.[8] The agricultural-biotechnology industry, uncertain itself over how to handle the transition into the generic market for seed traits with expired patents, has attempted to contractually bind members of the industry with the Accord, a voluntary contractual agreement—that is unsurprisingly industry friendly—between industry members to control the transition into the generic seed market.[9] Absent governmental intervention, the future of the global food supply may be at risk due to the fact that regulation is necessary to ensure the maintenance of food exportation around the world and that restricting market access to seeds containing one of the most highly utilized genetic seed traits in the world will negatively impact the global crop yields.[10]

---

to Global GM Soybean Access as Patent Nears Expiry, 31 NATURE BIOTECHNOLOGY 10, 10 (2013).

7. '247E Patent (patenting the transformation of plant cells into Roundup Ready seeds; this patent is owned by Monsanto). The '247E Patent claims the transformation of "plant cells with novel protein-encoding gene sequences that encode for [glyphosate-tolerant 5-enolpyruvylshikimate-3-phosphate synthases], a glyphosate-tolerant enzyme." Monsanto Co. v. Bowman, 657 F.3d 1341, 1343–44 (Fed. Cir. 2011); *see also* '247E Patent. A plant containing the glyphosate-tolerant enzyme "enables . . . plants to survive exposure to glyphosate, the active ingredient in many herbicides (including Monsanto's own Roundup)." Bowman v. Monsanto Co., 133 S. Ct. 1761, 1764 (2013). The '247E Patent also claims the plants and plant seeds created through this transformation. *Monsanto Co.*, 657 F.3d at 1344; '247E Patent col. 164 l. 18–48. This technology may be used in a variety of crops. *Monsanto Co.*, 657 F.3d at 1344.

8. Parloff, *supra* note 6, at 98.

9. *See generally* THE AGACCORD: DATA USE AND COMPENSATION AGREEMENT (2013) [hereinafter DUCA], *available at* http://www.agaccord.org/include/DataUseandCompensationAgreement_10-9-13.pdf; THE ACCORD: GENERIC EVENT MARKETABILITY & ACCESS AGREEMENT (GEMAA) (2013) [hereinafter GEMAA], *available at* http://www.agaccord.org/include/gemaa_firstamendedMay9.pdf; *see also infra* Part II.C (outlining the provisions of the Accord).

10. *See* CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, EXECUTIVE SUMMARY: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2012, at 6–8 (2012), *available at* http://www.isaaa.org/resources/publications/briefs/44/executivesummary/pdf/Brief%2044%20-%20Executive%20Summary%20-%20English.pdf; REECE WALTERS, ECO CRIME AND GENETICALLY MODIFIED FOOD 30–34 (2011). In 2005, five corporations, including Monsanto, controlled ninety percent of the global grain market. *Monsanto's Big Deal*, FOOD FIRST (Feb. 9, 2005), https://www.foodfirst.org/fr/node/390. In 2009, the top ten seed companies controlled seventy-three percent of the global seed market, with Monsanto itself accounting for twenty-seven percent of the market. ETC GROUP, WHO WILL CONTROL THE GREEN ECONOMY 22 (2011), *available at* http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web

Instead of leaving the agricultural-biotechnology industry to regulate itself,[11] the legislature should take an active role in protecting farmers and small independent seed companies using seeds with expired or expiring genetic patents by adopting a regime similar to the safe harbor provision of the pharmaceutical industry's Hatch-Waxman Act of 1984 and the Accord, and by delegating the regulation of the generic transition to an administrative agency.[12] There is no basis in national or international law to provide for a transition from a patent-protected, privately created and owned, genetic-seed-trait monopoly into a generic marketplace.[13] While the private sector has attempted to regulate itself with a voluntary contract, the Accord, its attempt fails to address the needs of all interested participants, such as farmers and small seed companies.[14] In addition, the Hatch-Waxman Act's scope has been limited in that the development of seeds with stacked genetic traits prior to patent expiration has not been protected from infringement claims.[15]

_Dec2011.pdf. As recent as 2013, it was reported that most of the American-grown soy contains the Roundup Ready gene and that nearly sixty percent of this home-grown soy is exported abroad. Grushkin, *supra* note 6, at 10.

11. *About the AgAccord*, THE AGACCORD, http://www.agaccord.org/?p=about (last visited May 8, 2014).

12. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603 (codified as amended at 35 U.S.C. § 271(e)(1) (2006)) (Hatch-Waxman Act); *see also* Amanda Welters, Note, *Striking a Balance: Revising USDA Regulations to Promote Competition Without Stifling Innovation*, 13 MINN. J.L. SCI. & TECH. 407 (2012) (outlining the appropriateness of relying on the Hatch-Waxman Act to regulate the transition of patented seed traits into the generic market). While Welters provides a strong argument for relying on the Hatch-Waxman Act to regulate the patented seed trait transition because of the similarities in the pharmaceutical and seed industries, her Note was written prior to the full release of the Accord and thus lacks an analysis of the agreement. Welters, *supra*; *see also supra* note 9 and accompanying text. Additionally, Welters fails to propose a way to move forward and apply the Hatch-Waxman Act and appears to disregard the issue of international registrations that ensure the continued international trade of products containing genetically altered organisms. Welters, *supra*; *see also infra* Part IV; *infra* notes 127–33 and accompanying text.

13. J. THOMAS CARRATO & BRANDON W. NEUSCHAFER, FROM PROPRIETARY TO GENERIC: A PRIVATE CONTRACTUAL MECHANISM FOR BIOTECH SEED PRODUCTS 4 (2012), *available at* http://www.wlf.org/upload/legalstudies/legalbackgrounder/11-2-12Carrato_LegalBackgrounder.pdf.

14. *See* GEMAA, *supra* note 9, at 1–3; Grushkin, *supra* note 6, at 10.

15. Monsanto Co. v. E.I. Dupont De Nemours & Co., No. 4:09CV00686(ERW), 2012 U.S. Dist. LEXIS 163982, at *10 (E.D. Mo. Nov. 16, 2012) (referring to a court order from June 29, 2012, the "Hatch-Waxman Order"). Stacked seeds are seeds that have been inserted with more than one gene trait to allow farmers to purchase seeds that address multiple problems. *Sorting Out the Facts Behind Stacks*, MONSANTO, http://www.monsanto.com/newsviews/Pages/gene-stacks-facts.aspx (last visited Feb. 16, 2014). Stacking is supposed to

As such, the legislature should adopt a regime based on the safe harbor provision of the Hatch-Waxman Act and the Accord. Such a regime will allow for a smooth transition into the market for generic seeds by providing for the development of generic forms without the threat of infringement lawsuits, and will arrange the funding and mechanics necessary for maintaining international regulation authorizations.

This Comment proposes a framework for a law that would provide for a competitive market for generic genetically modified organisms based off of the Hatch-Waxman Act and the Accord. Part II begins with the history of patent protection for plants and seeds and then discusses the emergence of genetically modified seeds and the current concerns over Monsanto's soon expiring patent for seeds containing its Roundup Ready trait. Part II ends with a discussion of the agricultural-biotechnology industry's attempt to regulate itself with the drafting and signing of the Accord. Part III discusses the recent litigation between Monsanto and DuPont that arose in part due to uncertainty in how to prepare for the generic market for genetically modified seeds. In addition, Part III outlines the pharmaceutical industry's Hatch-Waxman Act, specifically its safe harbor provision, which allows for the preparation of generic drugs prior to patent expiration. Next, Part IV proposes the adoption of a law based off of the Accord, discussed in Part II, and the safe harbor provision of the Hatch-Waxman Act, outlined in Part III, that would balance the interests of both the patent holders and the small farmers. Finally, Part V offers concluding remarks.

II. BACKGROUND OF PLANT PATENTS, GENETICALLY MODIFIED ORGANISMS, AND THE ACCORD

The patentability of plant seeds, especially those of sexually reproducing plants, has long been debated.[16] At the heart of this issue is the common law exclusion to patentable subject matter for products of nature and the requirement of a full written description for a patent to

incrementally improve the quality of the seeds. *Id.* Seed companies cross-license their patented traits with each other to improve the quality of seeds that they provide. *Id.* (follow the "As you can see in this table" link) (indicating the various cross-licensed traits available in 2009 among the industry's largest companies).

16. Noting the years of the decisions, see, e.g., *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 124, 133 (2001); *Diamond v. Chakrabarty*, 447 U.S. 303, 303, 310–11, 313 (1980); *Ex parte Hibberd*, 227 USPQ 443, 443 (1985).

be issued.[17] By enacting the Plant Patent Act, Congress expressed its intent to allow patents to be issued for plants.[18] However, between the Plant Patent Act, the Plant Variety Protection Act, and the requirements for a utility patent under 35 U.S.C. § 101, confusion arose as to what protections were available to plants and how those protections fit together under the different laws.[19] In 2001, the Supreme Court addressed the issue and held that plants and plant seeds may be protected through all three statutory provisions, using either a plant patent, a plant variety protection certificate, or a utility patent.[20]

With the availability of patent protection for plant seeds, the market for genetically modified seeds grew.[21] Monsanto became the industry leader, finding market success with its patented herbicide Roundup and the patented gene trait that allows plants to be tolerant of the herbicide.[22] This gene trait, the first patented trait to receive widespread market success, was marketed as Roundup Ready; however, the patent for the Roundup Ready gene is set to expire in late 2014.[23] There have been growing concerns over how Monsanto will handle the transition of one of its most economically successful patents into the public domain, especially given its litigious history.[24] The expiration of the patent for

17. *Ex parte Hibberd*, 227 USPQ at 445.

18. *Id.*

19. *See, e.g.*, *J.E.M. Ag Supply, Inc.*, 534 U.S. at 127.

20. *See id.*

21. *See Recent Trends in GE Adoption*, USDA.GOV, http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx (last updated Jul. 9, 2013); *see also infra* notes 74–75 and accompanying text.

22. Parloff, *supra* note 6, at 96–97.

23. *See* '247E Patent (patenting the transformation of plant cells into Roundup Ready seeds; this patent is owned by Monsanto); Andrew Pollack, *As Patent Ends, a Seed's Use will Survive*, N.Y. TIMES, Dec. 18, 2009, at B3.

24. Parloff, *supra* note 6, at 98, 106. As of July 2009, Monsanto had filed lawsuits against farmers 138 times in the United States. *Pilot Grove Co-Op*, MONSANTO, http://www.monsanto.com/newsviews/Pages/pilot-grove-coop.aspx (last visited Feb. 16, 2014); *see also, e.g.*, Monsanto Co. v. Parr, 545 F. Supp. 2d 836, 836–37, 839 (N.D. Ind. 2008) (regarding a case where Monsanto sued Parr, a man who provided seed cleaning services to farmers to aid in seed replanting, for patent infringement and inducement to infringe a patent); Monsanto Co. v. Pilot Grove Coop. Elevator, Inc., No. 4:06CV1476(TIA), 2007 U.S. Dist. LEXIS 85522, at *1 (E.D. Mo. Nov. 19, 2007) (regarding a case where Monsanto sued Pilot Grove for patent infringement, inducement to infringe a patent, and breach of contract). However, the most famous suit brought by Monsanto occurred in Canada against farmer Percy Schmeiser, who still maintains that plants containing Monsanto's patented traits were not planted by him but were instead blown onto his fields or carried by birds. *See* Monsanto Can. Inc. v. Schmeiser, [2004] 1 S.C.R. 902, paras. 24, 27, 60, 86, 97 (Can.) (holding that Monsanto's patent is valid and that Schmeiser, though he claimed to have not planted seeds containing Monsanto's

the Roundup Ready gene is the first, but not the last, of the patents for seed traits to expire.[25]

In late 2012, the Biotech Industry Organization (BIO) and the American Seed Trade Association (ASTA) released their solution to the transition.[26] The two organizations, both "major trade groups for the seed and biotech industries," created the Accord, a contractual agreement between companies that chose to sign on, which is comprised of two separate agreements: the Generic Event Marketability and Access Agreement (GEMAA)[27] and the Data Use and Compensation Agreement (DUCA).[28] The GEMAA was released and opened for signatures in October of 2012, and the DUCA was released and opened for signatures in December of 2013.[29] While Monsanto has signed on to the GEMAA[30] and is thus contractually obligated to its terms, the Accord is limited to governing those companies that chose to agree to its terms.[31] As of May 2013, ten companies had signed on to the GEMAA; however, none of those ten companies are one of the roughly 600 small seed companies operating within the United States.[32]

---

patented traits, was infringing upon Monsanto's patent); *Percy Schmeiser*, MONSANTO, http://www.monsanto.com/newsviews/Pages/percy-schmeiser.aspx (last visited Feb. 16, 2014).

25. *See* AM. SEED TRADE ASS'N & BIOTECHNOLOGY INDUS. ORG., FACTSHEET: THE AGACCORD® IS NOW COMPLETED AS THE DATA USE AND COMPENSATION IS OPEN FOR SIGNATURE 1 (2013) [hereinafter *DUCA Factsheet*], *available at* http://www.agaccord.org/include/DUCAFACTSHEET.pdf.; Grushkin, *supra* note 6, at 10.

26. Press Release, Am. Seed Trade Ass'n & Biotechnology Indus. Org., The Accord: Generic Event Marketability and Access Agreement Is Now Effective (Nov. 15, 2012) [hereinafter GEMAA Is Now Effective], *available at* http://www.agaccord.org/include/press11152012.pdf.

27. Amanda Peterka, *Biotech: Industry Inks Agreement to Address Expiring Seed Patents*, GREENWIRE (Nov. 1, 2012, 1:05 PM), http://www.eenews.net/gw/2012/11/01.

28. *About the AgAccord*, *supra* note 11.

29. Press Release, Am. Seed Trade Ass'n & Biotechnology Indus. Org., The Accord: Generic Event Marketability and Access Agreement Is Open for Signature (Oct. 31, 2012) [hereinafter GEMAA Is Open for Signature], *available at* http://www.agaccord.org/include/press10312012.pdf; Press Release, Am. Seed Trade Ass'n & Biotechnology Indus. Org., The AgAccord®: Data Use and Compensation Agreement Is Open for Signature (Dec. 4, 2013) [hereinafter DUCA Is Open for Signature], *available at* http://www.agaccord.org/include/duca_press_release.pdf. Despite claims that the DUCA would be released in early 2013, it was not released until December 2013. *See* GEMAA Is Open for Signature, *supra*; DUCA Is Open for Signature, *supra*.

30. GEMAA Is Now Effective, *supra* note 26.

31. *About the AgAccord*, *supra* note 11.

32. *See* GEMAA, *supra* note 9, at 29 app. B; Grushkin, *supra* note 6, at 11.

A. The Path to the Patented Seed

Under Article I, Section 8, Clause 8 of the United States Constitution, Congress has the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[33] This clause allows Congress to issue patents, thus providing Congress the power to give the patent holder a monopoly for a limited time.[34] The first statute expressly giving plants patent protection came in 1930 with the Plant Patent Act.[35] This Act, recodified in 1952, allowed "plant patents" to be issued in addition to the already existing utility patents of 35 U.S.C. § 101 and design patents of 35 U.S.C. § 171.[36] Currently, the Plant Patent Act allows for the issuance of a plant patent to "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state."[37] After gaining a plant patent, the holder is given the exclusive right to asexually reproduce the plant, sell the reproduced plant, and import the plant into the United States.[38]

Forty years after Congress gave express patent protection to asexually reproducing plants with the Plant Patent Act,[39] Congress passed the Plant Variety Protection Act in 1970.[40] This Act provides "patent-like protection"[41] for "[t]he breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety" if the variety is new, distinct, uniform, and

33. U.S. CONST. art. I, § 8, cl. 8.

34. JANICE M. MUELLER, PATENT LAW 25–26 (4th ed. 2013).

35. Act of May 23, 1930, Pub. L. No. 71-245, 46 Stat. 376 (codified as amended at 35 U.S.C. §§ 161–164 (2006)).

36. Act of July 19, 1952, Pub. L. No. 82-593, § 161, 66 Stat. 792, 804 (codified as amended at 35 U.S.C. §§ 161–164 (2006)); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 124, 127, 133 & n.5, 145 (2001) (holding that newly developed plant breeds may be issued utility patents).

37. 35 U.S.C. § 161.

38. *Id.* § 163.

39. The first protection for asexually reproducing plants came with the 1930's Plant Patent Act. 46 Stat. at 376.

40. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended at 7 U.S.C. §§ 2321–2583 (2012)); *see also infra* notes 57–58 and accompanying text.

41. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 138.

stable.[42] Upon the issuance of a certificate, this protection includes the right to sell or market the plant, import and export the plant from the Unites States, and sexually reproduce the plant for purposes of marketing the plant.[43] These protections are strikingly similar to those given to holders of plant patents under the Plant Patent Act.[44] In addition to expressly providing these protections, Congress gave farmers the right "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 . . . or for sale."[45] In making this provision for seed saving to produce crops, Congress recognized farmers' interests in using protected plants.[46] Congress also limited the protections for plant varieties by expressly authorizing "[t]he use and reproduction of a protected variety for plant breeding or other bona fide research," with no requirement of authorization by the variety owner.[47] The term of the certificate is, in general, twenty years after the certificate is issued.[48] One exception to this twenty-year term is when the plant is a tree or vine, in which case the protection is extended to twenty-five years.[49]

The Supreme Court entered the debate in 1980, with *Diamond v. Chakrabarty*, which held that living things are patentable under 35 U.S.C. § 101.[50] In doing so, the Court found that "the relevant distinction" in determining whether something falls within the

42. 7 U.S.C. § 2402(a).

43. *Id.* § 2541(a).

44. *See id.*; 35 U.S.C. § 163 (2006).

45. 7 U.S.C. § 2543. The right to save seed first recognized in the Plant Variety Protection Act is now a far cry from the restrictions imposed on farmers under seed company license agreements. *See infra* notes 92–95 and accompanying text.

46. *See* 7 U.S.C. § 2543. Today, much of the criticism of Monsanto stems from its practice of suing farmers who save seeds for patent infringement. *See Why Does Monsanto Sue Farmers Who Save Seeds?*, MONSANTO, http://www.monsanto.com/newsviews/Pages/why-does-monsanto-sue-farmers-who-save-seeds.aspx (last visited Feb. 18, 2014) [hereinafter *Why Does Monsanto Sue Farmers*]; *see also supra* note 24.

47. This provision is commonly referred to as the research exception. 7 U.S.C. § 2544; Sidney B. Williams, Jr., *Protection of Plant Varieties and Parts as Intellectual Property*, SCI., July 6, 1984, at 18, 19, 21.

48. 7 U.S.C. § 2483(b)(1).

49. *Id.* § 2483(b)(1)(B).

50. Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980) (holding that a bacterium is patentable).

patentable subject matter of 35 U.S.C. § 101[51] is "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[52] In *Chakrabarty*, the Court said that a bacterium capable of breaking down components of crude oil was new, with "markedly different characteristics from any found in nature and one having the potential for significant utility," and that the bacterium was a result of the patentee's "handiwork."[53] As such, the bacterium fell within the patentable subject matter of 35 U.S.C. § 101.[54] This decision opened the door for other man-made living organisms to be patented with the traditional utility patent.

Using the opening the Supreme Court made in *Chakrabarty*, the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences issued an agency decision, *Ex parte Hibberd*, in 1985,[55] which led to the practice of the PTO to issue utility patents for plants.[56] In *Ex parte Hibberd*, the PTO Board of Patent Appeals and Interferences addressed the patentability of maize plant seeds that develop into sexually reproducing plants under 35 U.S.C. § 101.[57] Finding that the Plant Patent Act and the Plant Variety Protection Act are not the "exclusive forms of protection for plant life," the PTO Board of Patent Appeals said that plants can be patented under § 101.[58] The PTO Board of Patent Appeals held that plants are included in the meaning of "manufacture" or "composition of matter" and therefore can be issued a utility patent, for plants thus fall within patentable subject matter under 35 U.S.C. § 101.[59] This viewpoint was supported by the Supreme Court sixteen years later in the 2001 case *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*[60]

In *J.E.M. Ag Supply, Inc.*, the matter of what protection is offered to newly developed plant breeds came to a head when the Supreme Court

---

51. 35 U.S.C. § 101 (2006). Under § 101, patentable subject matter includes processes, machines, manufactures, or compositions of matter, and "any new and useful improvement thereof." *Id.*

52. *Chakrabarty*, 447 U.S. at 313.

53. *Id.* at 305, 310.

54. *Id.* at 310.

55. *Ex parte* Hibberd, 227 USPQ 443, 445–46 (1985) (holding that plants can be issued utility patents under 35 U.S.C. § 101).

56. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 131 (2001).

57. *Ex parte Hibberd*, 227 USPQ at 443–44.

58. *Id.* at 444.

59. *Id.*

60. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 131.

directly addressed the issue.[61] There, as in *Ex parte Hibberd*, the Court addressed the patentability of corn seeds that develop into sexually reproducing plants.[62] The Court held that newly developed plant breeds may be issued utility patents under 35 U.S.C. § 101,[63] despite the protections issued to plant varieties under the Plant Patent Act and the Plant Variety Protection Act.[64] In reviewing the Plant Patent Act, the Court determined that the Act's protection for asexually reproducing plants does not equate to "an affirmative decision by Congress to deny sexually reproduced plants patent protection under § 101."[65] Furthermore, the Court found that the Plant Variety Protection Act is not the "exclusive means for protecting sexually reproducing plants."[66] The Court left open the possibility that seeds may be protected by both the Plant Variety Protection Act and the Patent Act.[67] In issuing a patent for a plant, either a plant patent or a utility patent, the term of the patent is twenty years after the patent application is filed.[68] This twenty-year term is the same as the term generally provided by the Plant Variety Protection Act.[69]

Congress came back into the picture with the Leahy-Smith America Invents Act of 2011, which fully went into effect in March of 2013, and leaves the Plant Patent Act and the subject matter for utility patents under 35 U.S.C. § 101 unchanged (as relevant to plants and seed traits).[70] As such, there is no foreseeable change to the patent protections offered to plants.

---

61. *Id.* at 127 (holding that newly developed plant breeds may be issued utility patents).

62. *Id.* at 124.

63. *Id.* at 145.

64. 7 U.S.C. § 2402 (2012); 35 U.S.C. §§ 161–164 (2006); *J.E.M. Ag Supply, Inc.*, 534 U.S. at 127.

65. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 138.

66. *Id.* at 140–41.

67. *Id.* at 144.

68. 35 U.S.C. § 154(a)(2); MUELLER, *supra* note 34, at 20–21.

69. 7 U.S.C. § 2483(b)(1); *see also supra* notes 48–49 and accompanying text.

70. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified at 35 U.S.C. (Supp. V 2011)); MUELLER, *supra* note 34, at 20–21 & n.49. The Leahy-Smith America Invents Act of 2011 did add two new subject matter restrictions for utility patents: human organisms and tax strategies are now statutorily barred from receiving patents. § 14, 125 Stat. at 327–28 (tax strategies); § 33, 125 Stat. at 340 (human organisms). This change has no foreseeable implication on the patentability of seeds. *See generally* 125 Stat. 284.

B. The Emergence of the Patented Seed and the Development of Uncertainties in the Market

Companies such as Monsanto have been using gene-splicing technology to develop crops since the 1990s, but the manipulation of plant traits dates back to Gregor Mendel's work with peas in 1866.[71] The technology has been used to develop seeds for plants that are tolerant of herbicides[72] as well as plants that grow faster and healthier.[73] Companies may obtain plant patents, utility patents, or plant variety protection certificates for seed varieties that they develop using gene splicing.[74] These seeds are referred to as genetically modified organisms (GMOs), or GMO seeds.[75] The value of producing seeds with genetically modified traits can be seen in the wide use of the technology today. As of 2009, at least ninety percent of soybeans, sixty percent of corn, and sixty percent of cotton grown in the United States contained herbicide-tolerant traits.[76] Four years later, in 2013, ninety-three percent of the soybeans, eighty-five percent of corn, and eighty-two percent of cotton grown in the United States contained herbicide-tolerant traits.[77]

---

71. WALTERS, *supra* note 10, at 8–11 (outlining both the technical and legal history of GMOs and giving credit to Gregor Mendel as the pioneer in genetic manipulation of plants); Pollack, *supra* note 23. As early as 1996, about seven percent of the soybeans, two percent of the cotton, and three percent of the corn grown in the United States contained herbicide-resistant traits. *Recent Trends in GE Adoption*, *supra* note 21 (follow "Chart data" hyperlink under *Adoption of Genetically Engineered Crops in the United States, 1996–2013* chart).

72. Pollack, *supra* note 23.

73. *Traits, Technologies & Partnering*, MONSANTO, http://www.monsanto.com/products/Pages/plant-traits-technologies.aspx (last visited May 14, 2014).

74. *See* 7 U.S.C. §§ 2321–2583; 35 U.S.C. §§ 101, 161–164 (2006); J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 144 (2001); *see also supra* Part II.A (discussing the various protections that have become available for plants and seeds). Monsanto's soybean seeds that are tolerant of Monsanto's Roundup herbicide entered the market in 1996. Georgina Gustin, *Experts Question Monsanto Roundup Verdict; $1 Billion Patent Judgment Surprised Court Experts*, ST. LOUIS POST-DISPATCH, Aug. 10, 2012, at B1.

75. *Occupy Monsanto; Occupy Monsanto Stops GMO Seed Distribution*, ENG'G BUS. J., Sept. 26, 2012, at 86. A genetically modified organism, or a GMO, is defined as "[a]n organism produced through genetic modification." *Glossary of Agricultural Biotechnology Terms*, USDA.GOV, http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH_GLOSS&navtype=RT&parentnav=BIOTECH (last visited May 14, 2014). Genetic Modification is "[t]he production of heritable improvements in plants or animals for specific uses, via either genetic engineering or other more traditional methods." *Id.*

76. Pollack, *supra* note 23.

77. *Recent Trends in GE Adoption*, *supra* note 21. In addition to the high percentage of crops containing herbicide-tolerant traits, seventy-five percent of cotton and seventy-six percent of corn contain insect-resistant traits. *Id.* The trend of increasing percentages of crops being attributed to GMOs can be seen on a global level. JAMES, *supra* note 10, at 1.

Monsanto stated that about 275,000 farmers a year purchase seed varieties for which it holds patents.[78] Between Europe, Japan, and the United States, patents on plants and genes are increasing worldwide.[79]

In 2012, Monsanto was the largest producer of GMO seeds.[80] As the industry leader, Monsanto came under attack in an "Occupy" movement looking to force food producers to inform consumers through food labels when their food contains plants grown from GMO seeds.[81] The "Occupy Monsanto" protestors claimed that such plants "contain novel untested compounds that result in more weed killer sprayed on our food."[82] Some even referred to the food as "Frankenfoods."[83] Protestors hoped that their efforts would result in the United States joining Europe, Japan, and China in requiring labels on GMO-seed food products.[84] Such efforts have proven effective, as there have been movements in state legislatures throughout the country towards requiring GMO food product labeling.[85] Criticism against

78. *Why Does Monsanto Sue Farmers*, *supra* note 46.

79. John E. Haapala, Jr., *Patent Pools and Antitrust Concerns in Plant Biotechnology*, 19 J. ENVTL. L. & LITIG. 475, 476 (2004).

80. *Occupy Monsanto; Occupy Monsanto Stops GMO Seed Distribution*, *supra* note 75. In 2009, an agricultural economist at Iowa State University claimed that Monsanto controls as much as ninety percent of the seed genetics business. Christopher Leonard, *Monsanto Squeezes Out Seed Business Competition, AP Investigation Finds*, HUFFINGTON POST (Dec. 13, 2009, 1:45 PM) http://www.huffingtonpost.com/2009/12/13/monsanto-squeezes-out-see_n_390354.html?view=print&comm_ref=false. In addition to Monsanto, the other three chemical corporations that dominate the GMO food market are Sygenta, DuPont, and Bayer. WALTERS, *supra* note 10, at 12 (citing STEPHEN NOTTINGHAM, EAT YOUR GENES: HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET, at xi (2d ed. 2003)).

81. *Occupy Monsanto; Occupy Monsanto Stops GMO Seed Distribution*, *supra* note 75. In addition to movements against Monsanto itself, there has been an increasing amount of public opposition to GMO foods in general, "manifested in consumer boycotts, farmer resistance, street protests and de facto moratoriums." WALTERS, *supra* note 10, at 58–62.

82. *Occupy Monsanto: Occupy Monsanto Stops GMO Seed Distribution*, *supra* note 75. The effort to label foods containing GMOs for the public has been one of the main battles against Monsanto. FOOD, INC., *supra* note 1, at 1:18:14–1:19:38 (discussing the importance of labeling food containing GMOs); GENETIC ROULETTE: THE GAMBLE OF OUR LIVES, 1:11:30–1:17:33 (Institute for Responsible Technology 2012) (discussing the various efforts that have been made worldwide to label foods containing GMOs). Critics have argued that Monsanto's practice of genetically altering seeds equates to playing "roulette" with the "genetic integrity" of the world. GENETIC ROULETTE: THE GAMBLE OF OUR LIVES, *supra* at 11:18–11:25.

83. Parloff, *supra* note 6, at 96.

84. *Occupy Monsanto; Occupy Monsanto Stops GMO Seed Distribution*, *supra* note 75.

85. Benjamin Senauer, *Mandatory Labeling of Genetically Engineered (GE) Foods: The Showdown Begins*, CHOICES, 3d Quarter 2013, at 1. *See, e.g.*, CONN. GEN. STAT. ANN. § 21a-92c (West 2013).

Monsanto and GMO-seed food products came to the forefront of food health and environmental concerns in the 2009 documentary, *Food, Inc.*,[86] and has been present ever since.[87]

The debate over GMO seeds has not been limited to the United States. Pope Francis has recently taken an interest in the ongoing debate over the safety and the prevalence of GMO-seed food products globally.[88] The Pontifical Academy of Sciences came out in support of increasing global access to GMO-seed food products on the belief that there is "a moral imperative to make these technologies available to the poor."[89] Internationally, there is a wide disparity over the awareness of GMOs and disagreement over the safety of GMO-seed food products and the steps that should be taken to protect genetic diversity.[90] Some

86. FOOD, INC., *supra* note 1 (noting that major seed-producing companies have been lobbying against laws requiring food labels to indicate that the food contains GMOs). In the documentary, *Food, Inc.*, Monsanto is vilified for using allegedly intimidating techniques to investigate and enforce its patents and prevent farmers from seed saving, leading to a general feeling of acceptance by farmers that seed-saving practices are not allowed and that fighting a lawsuit against Monsanto would not be worth the money spent. *Id.*

87. *See, e.g.*, *Occupy Monsanto; Occupy Monsanto Stops GMO Seed Distribution*, *supra* note 75; Dyan Machan, *Planting the Seeds of Growth*, BARRON'S, Aug. 12, 2013, at 40.

88. Marcela Valente, *Latin America: Pope Francis Raises Hopes for an Ecological Church*, GLOBAL INFO. NETWORK, Mar. 22, 2013, *available at* ProQuest, Doc. No. 1319251760. For a brief overview of the interactions between the United States and the Vatican regarding GMO food products, see WALTERS, *supra* note 10, at 76–78.

89. Ingo Potrykus, *Lessons from the 'Humanitarian Golden Rice' Project: Regulation Prevents Development of Public Good Genetically Engineered Crop Products*, 27 NEW BIOTECHNOLOGY 466, 472 (2010); Anna Meldolesi, *Vatican Panel Backs GMOs*, 29 NATURE BIOTECHNOLOGY 11, 11 (2011); *see also* Albert Weale, *Ethical Arguments Relevant to the Use of GM Crops*, 27 NEW BIOTECHNOLOGY 582, 583–84 (2010) ("[T]here was a moral imperative for making such crops readily and economically available to those in developing countries who wanted them.").

90. WALTERS, *supra* note 10, at 54–58, 69–75 (noting that "the spread of anti-GM public sentiment extends beyond European boarders to include Australia, Asia and Africa"); Ryan Crawford, Note, *Did I Save My Seed for This? United States Intellectual Property Law, the Continuing Shift in Protection from Growers to Developers, and Some Potential Implications for Agriculture*, 14 SYRACUSE SCI. & TECH. L. REP. 35 (2006); Jeremy Grant & Raphael Minder, *Transatlantic Split Persists Over GM Food*, FIN. TIMES, Jan. 31, 2006, *available at* ProQuest, Doc. No. 228906957. In 2005, less than 0.5% of American consumers saw GMO-seed food products as a safety concern, but 54% of European Union consumers considered GMO food to be dangerous. *Id.* Peru became the first country in the Americas to ban GMO food in 2013 when it put a ten-year ban on GMO food. Annie Murphy, *Peru Says No to GMO*, CHRISTIAN SCI. MONITOR (April 25, 2013), http://www.csmonitor.com/World/Americas/2013/0425/Peru-says-no-to-GMO (attributing "food safety, a lack of long term research, and the potential for contaminating and even wiping out non-GMO species," and biosecurity, as justifications). Turkey also recently placed a ban on GMO food when it banned twenty-six GMO products. *Turkey Bans 26 Genetically Modified Organisms*, GREEN PROPHET (April

critics of the current U.S. agricultural policy argue that the policy is "directly at odds with the international goal of preserving genetic diversity."[91]

Despite the critics, GMO seeds have dominated the market since Monsanto introduced the Roundup Ready seed trait and set the industry standards in GMO seed use and licensing. Monsanto licenses its seed traits to various seed producers and farmers under the Monsanto Technology/Stewardship Agreement (MTSA), claiming that this practice allows farmers to "realize the benefits from these inventions through the brands they prefer to plant on their farm."[92] According to Monsanto, these licensing agreements allow seed companies to sell competitors' seed traits, as well as giving some competitors (who own their own seed traits) the right to stack traits together.[93] When purchasing seed varieties with patents belonging to Monsanto, farmers must enter into agreements stating "that they will not save and replant seeds produced from the seed they buy from [Monsanto]."[94] This means that farmers must buy new seed each year, which can be a costly burden on small farmers.[95] However, despite genetically engineered seeds costing more than conventional seeds by anywhere from thirty to eighty percent, farmers are typically willing to pay extra for the chance to make up for the difference in increased yield

29, 2013), http://www.greenprophet.com/2013/04/turkey-bans-26-genetically-modified-organisms/ (asserting food safety and genetic diversity as justifications for the ban). On the other side though, is China, which recently stated that it would allow three GMO soybean varieties to be imported into the country. Jin Zhu & Zhang Fan, *China Gives Approval to GM Soybeans*, CHINA DAILY USA, http://usa.chinadaily.com.cn/business/2013-06/14/content_16618175.htm (last updated June 14, 2013, 1:40 AM). As of 2012, China was one of the twenty-eight countries worldwide that produced GMO crops. JAMES, *supra* note 9, at 3 tbl.1.

91. Crawford, *supra* note 89.

92. *Licensing: The Facts on Monsanto's Approach to Licensing*, MONSANTO, http://www.monsanto.com/whoweare/Pages/seed-licensing.aspx (last visited May 14, 2014). The standard licensing agreement used by Monsanto is the Monsanto Technology/Stewardship Agreement (MTSA). Monsanto Co. v. Bowman, 657 F.3d 1341, 1344–45 (Fed. Cir. 2011); MONSANTO, 2014 MONSANTO TECHNOLOGY/STEWARDSHIP AGREEMENT 1 (2014) [hereinafter MTSA], *available at* http://www.siegers.com/pdfs/waivers/MonsantoTSA.pdf.

93. *Licensing: The Facts on Monsanto's Approach to Licensing*, *supra* note 92.

94. *Why Does Monsanto Sue Farmers*, *supra* note 46; *see also* MTSA, *supra* note 92, at 1. In the MTSA, farmers must agree "[n]ot to save or clean any crop produced from Seed for planting, not to supply Seed produced from Seed to anyone for planting, [and] not to plant Seed for production other than for Monsanto or a Monsanto licensed seed company under a seed production contract." MTSA, *supra* note 92, at 1.

95. MTSA, *supra* note 92, at 1; *see also* Pollack, *supra* note 23.

or other reduced maintenance costs.[96] Because the costs of Monsanto's products are on the rise, there is concern that the control Monsanto has over the market will prevent farmers from being able to avoid the increasing costs.[97] In the past, Monsanto has been strongly protective of its patents and violations of its licensing agreements, filing 145 lawsuits in the United States since 1997.[98]

Dow Chemical, another industry leader, also requires farmers and seed producers to sign a licensing agreement.[99] Under the Dow Agrosciences Technology Use Agreement, farmers may not "save or use any seed produced from Seed for planting by Grower or any other third party," or "use or allow others to use Seed or any plant material produced from Seed for crop breeding, seed production, research (including, without limitation, agronomic testing or generation of comparative data against seed containing Third-Party Trait Technology), or generation of regulatory approval data."[100] This express bar on using licensed and patented traits for research or to gain regulatory approval is exactly what this Comment proposes to prevent near the end of the patent's term.

The Supreme Court recently held that a farmer operating under the MTSA cannot actively replicate, for his own use or for sale, the patented seeds covered by the agreement.[101] In *Bowman v. Monsanto Co.*,

96. Parloff, *supra* note 6, at 100.

97. Leonard, *supra* note 80.

98. *Why Does Monsanto Sue Farmers*, *supra* note 46. To protect themselves against the high costs of patent infringement lawsuits, farmers have been advised to purchase insurance to protect against GMO contamination. Aviva Shen, *Farmers Told to Buy Insurance if They Don't Want to Get Sued by Corporations*, THINKPROGRESS (Nov. 21, 2012, 9:00 AM), http://thinkprogress.org/health/2012/11/21/1224761/farmers-insurance-sued-by-corporations/. *See generally* USDA ADVISORY COMM. ON BIOTECHNOLOGY AND 21ST CENTURY AGRIC., ENHANCING COEXISTENCE: A REPORT OF THE AC21 TO THE SECRETARY OF AGRICULTURE (2012), *available at* http://www.usda.gov/documents/ac21_report-enhancing-coexistence.pd f.

99. DOW ARGOSCIENCES, DOW AGROSCIENCES TECHNOLOGY USE AGREEMENT 1 (2012), *available at* http://msdssearch.dow.com/PublishedLiteratureDAS/dh_08bd/0901b803808bdce6.pdf?filepath=mycogen/pdfs/noreg/010-12440.pdf&fromPage=GetDoc. Like the MTSA, the Dow AgroSciences Technology Use Agreement prohibits farmers from saving seeds. *Id.* at 2.

100. *Id.* The "Third-Party Trait Technology" mentioned in the agreement refers to traits owned by Dow competitors, including the Roundup Ready trait owned by Monsanto. *Id.* at 1.

101. Bowman v. Monsanto Co., 133 S. Ct. 1761, 1764–65, 1769 (2013). "Bowman planted Monsanto's patented soybeans solely to make and market replicas of them, thus depriving the

Bowman unsuccessfully argued that the exhaustion doctrine, which "limits a patentee's right to control what others can do with an article embodying or containing an invention," protected him from infringement liability.[102] The Court noted a distinction between controlling the reproduction, or making, of Monsanto's patented invention, and controlling the "particular item" sold to Bowman.[103] The patent exhaustion doctrine limits only the patentee's control over the particular item, not the patentee's control over items that a purchaser subsequently makes.[104] The Court thus upheld the MTSA's limitation preventing farmers from saving and reproducing seeds where such practices are under the farmer's control.[105]

One of Monsanto's most successful traits, known as Roundup Ready,[106] which causes plant tolerance of the Roundup herbicide,[107] is attached to U.S. Patent RE39,247E.[108] This patent is set to expire in September of 2014; it is the first of such patents with widespread economic success to expire.[109] The '247E Patent will be the first of the patents that helped develop modern agriculture to reach expiration, and

company of the reward patent law provides for the sale of each article. Patent exhaustion provides no haven for that conduct." *Id.* at 1769.

102. *Id.* at 1766.

103. *See id.* at 1767.

104. *Id.* at 1767–68 ("[T]he patentee retains an undiminished right to prohibit others from making the thing his patent protects.").

105. *See id.* at 1764, 1769. The Court's holding is limited to technology that reproduces under purchaser control, as opposed to an item that is entirely self-replicating. *Id.* at 1769 ("[I]t was Bowman, and not the bean, who controlled the reproduction . . . of Monsanto's patented invention."). In *Bowman*, the Court noted that "Bowman was not a passive observer of his soybeans' multiplication; or put another way, the seeds he purchased (miraculous though they might be in other respects) did not spontaneously create eight successive soybean crops." *Id.* For more information on *Bowman*, see generally *Patent Act of 1952—Patent Exhaustion Doctrine*—Bowman v. Monsanto Co., 127 HARV. L. REV. 378 (2013).

106. Parloff, *supra* note 6, at 98. Monsanto developed this trait by transplanting a bacterium gene into a soybean genome. *Id.* at 100. For more on the development of the herbicide-resistant gene traits, see Jerry M. Green, *Evolution of Glyphosate-Resistant Crop Technology*, 57 WEED SCI. 108, 108 (2009).

107. *See supra* note 7. Monsanto began marketing the Roundup herbicide, composed mainly of a salt known as glyphosate, in 1974. Parloff, *supra* note 6, at 99. The patent on Roundup weed killer has expired. *See* U.S. Patent No. 3,799,758 (filed Aug. 9, 1971) (issued Mar. 26, 1974); Parloff, *supra* note 6, at 99.

108. '247E Patent; *see also supra* note 7.

109. *See* '247E Patent; Parloff, *supra* note 6, at 94, 97, 106.

several more are set to expire over the next fifteen years.[110] Once the '247E Patent expires, the technology will enter the public domain, allowing for a generic market to develop.[111] However, there is widespread concern that Monsanto's fierce protection of its patents has caused a wall to develop in the process of creating and internationally registering generic versions of the trait.[112] This block may result in Monsanto being able to extend its monopoly on the trait by years.[113] The ability to extend the term of a patent through the use of regulatory schemes that make it more difficult for competitors to enter the market quickly is reminiscent of the pharmaceutical industry's delay in getting generic drugs into the market after patent expiration, a driving factor in the enactment of the Hatch-Waxman Act.[114] Because the Roundup Ready trait is protected by a patent, the research exception of the Plant Variety Protection Act does not apply.[115] Thus, even taxpayer-funded researchers at universities are subject to Monsanto's licensing agreements.[116]

Monsanto has developed a second generation of its Roundup Ready trait, marketed as Roundup Ready 2 Yield.[117] Monsanto-rival DuPont alleged that this second generation is not worthy of a new patent because the difference between the two products is merely a change in the genome location of the trait.[118] Given the time required to develop and produce seeds, if Monsanto blocks the use of Roundup Ready before the '247E Patent expires, it may effectively force companies to use Roundup Ready 2 Yield, which lies under Monsanto's patent

110. Grushkin, *supra* note 6, at 10 ("[A]nother wave of gene patents are scheduled to expire around 2020."); Peterka, *supra* note 27.

111. Parloff, *supra* note 6, at 100.

112. *Id.* at 98, 104.

113. *Id.* at 98.

114. *See* KAYE SCHOLER LLP, PHARMACEUTICAL AND BIOTECH PATENT LAW § 8:1.1[A] (David K. Barr & Daniel L. Reisner eds., 2013) (discussing the historical background of the Hatch-Waxman Act).

115. 7 U.S.C. § 2544 (2012).

116. Leonard, *supra* note 80.

117. Parloff, *supra* note 6, at 102; *see also Roundup Ready Soybean Patent Expiration*, MONSANTO, http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx (last visited May 14, 2014).

118. *See* Michael Stumo, *Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits*, 15 DRAKE J. AGRIC. L. 137, 140–41 (2010) (discussing the differences between Roundup Ready and Roundup Ready 2 Yield and the economic implications of forcing an industry switch to Roundup Ready 2 Yield); *see also* Parloff, *supra* note 6, at 102.

protection and is more expensive than the original Roundup Ready.[119] In mid-2009, Hugh Grant, President and Chief Executive Officer of Monsanto, declared that:

> As we enter the next decade we'll stand alone in the technology arena that we alone have created. Our products will be fundamentally differentiated and thus we'll compete against our own older technologies. Our job then will be to replace every old biotech acre with a new one and gain lift the value proposition for growth.[120]

After this statement was made, Monsanto denied any attempt to force a conversion to Roundup Ready 2 Yield.[121] In December of 2009, Monsanto stated that "all existing Roundup Ready [] licenses would automatically be extended through the end of the product's patent life in 2014" and "no farmer would be barred from saving Roundup Ready [] seed in the last year of the patent term."[122] This sentiment was also expressed by Hugh Grant in early 2010:

> [F]or Roundup Ready 1 soybeans, our original soybean product will remain available through and beyond Monsanto's U.S. patent term, which expires in 2014. Global regulatory support for this product will be maintained for at least three years beyond that point. . . . [S]eed company licensees would be extended though the patent period to avoid any confusion regarding access to seed supply from multiple sources.
>
> . . . .

119. Stumo, *supra* note 118, at 140–43; *see also* Parloff, *supra* note 6, at 97.

120. Hugh Grant, Chairman of the Board, President, & Chief Executive Officer, Monsanto Company, F3Q09 (Qtr End 5/31/09) Earnings Call (June 24, 2009) (transcript available at http://seekingalpha.com/article/152631-monsanto-company-f3q09-qtr-end-5-31-09-earnings-call-transcript?part=single).

121. Parloff, *supra* note 6, at 104. Though Monsanto has claimed that it will not force a switch to Roundup Ready 2 Yield, DuPont claims that Monsanto is indeed forcing the transition to control the generic market for Roundup Ready before it has a chance to begin. Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Stay Discovery and for Separate Trial of Antitrust Counterclaims at 5, Monsanto Co. v. E.I. du Pont de Nemours & Co., No. 4:09-CV-00686(ERW), 2009 U.S. Dist. LEXIS 84512 (E.D. Mo. Sept. 16, 2009).

122. Parloff, *supra* note 6, at 104. While Monsanto has confirmed that a farmer may save certain seeds following the expiration of the Roundup Ready patent, it has made clear that the saving allowance only applies to farmers saving seeds "from their own farm back onto their own farm." *Roundup Ready Soybean Patent Expiration*, *supra* note 117. "It would be illegal to provide saved seed to others for replanting or to obtain saved seed from others and plant it on your own farm." *Id.*

> . . . [I]t remains clear that seed companies may choose to sell either or both the original soybean products or the new generation, higher yielding soy technologies.[123]

However, while Monsanto has pledged to extend license terms, it has not broadened the rights associated with them, such as allowing for increased stacking rights.[124] In fact, Monsanto recently sued DuPont for stacking beyond its license.[125] DuPont alleged that this conduct amounted to an antitrust violation.[126]

The role that international registration and licensing plays in the timeline of both allowing farmers to save seeds after the '247E Patent expiration and in providing market accessibility to those using the technology after the expiration is large.[127] In order for farmers to sell their product internationally, they must comply with the registration and licensing requirements of other countries if they want to export to those markets.[128] Currently, Monsanto itself maintains registrations and licenses for food products using its patented traits, not the farmers.[129] Monsanto has said that it will maintain the licenses through 2017, but after that time, farmers will not be able to sell crops with Roundup Ready in certain countries.[130] However, Roundup Ready 2 Yield will have active international licenses after 2017,[131] which will most likely serve as a strong inducement for farmers to purchase seeds containing traits under patent protection. There is no current way to ensure the

123. Hugh Grant, Chairman & Chief Executive Officer, Monsanto Company, F1Q10 (Qtr End 11/30/09) Earnings Call (Jan. 6, 2010) [hereinafter Monsanto F1Q10 Earnings Call] (transcript available at http://seekingalpha.com/article/181283-monsanto-company-f1q10-qtr-end-11-30-09-earnings-call-transcript).

124. *See* Parloff, *supra* note 6, at 104, 106.

125. Monsanto Co. v. E.I. Du Pont de Nemours & Co., No. 4:09CV00686(ERW), 2009 U.S. Dist. LEXIS 84512, at *3 (E.D. Mo. Sept. 16, 2009); Parloff, *supra* note 6, at 98. Monsanto claims that its licensing agreement with DuPont and Pioneer allowed for stacking any trait except other genes developed to give plants tolerance to glyphosate herbicides, which is what DuPont was attempting to do with its OGAT trait. *Id.* at 106.

126. *Monsanto Co.*, 2009 U.S. Dist. LEXIS 84512, at *3; Parloff, *supra* note 6, at 98.

127. GMO crops must be approved by a regulatory agency every three years in China, every five years in Korea, and every ten years in Japan and Europe. Grushkin, *supra* note 6, at 10. Once a patent expires, the financial incentive for maintaining international regulation authorizations is lost. *Id.* However, as of early 2013, about sixty percent of the American-grown soy is exported and thus subject to such international regulations. *Id.*

128. *Id.*; Pollack, *supra* note 23.

129. Pollack, *supra* note 23.

130. *See* Parloff, *supra* note 6, at 104; Pollack, *supra* note 23; Monsanto F1Q10 Earnings Call, *supra* note 123.

131. *See* Pollack, *supra* note 23.

maintenance of international licenses on a long term or permanent basis for seeds with traits no longer protected by expired patents.[132] The Accord addresses the issue of maintaining international regulation authorizations; however, the Accord is merely a contractual agreement that applies to signatories that chose to abide by its terms.[133]

Currently, the '247E Patent is used in sixteen of the twenty-six seed products marketed under patents by Monsanto.[134] The products include corn, soybeans, alfalfa, canola, sugar beets, and cotton.[135] Because the products also utilize other patents that are not expiring soon, Monsanto could continue enforcing patent protection on the seeds by pursuing patent infringement claims against farmers for those patented traits.[136] Monsanto has stated that it will not enforce these patents and that the farmers can save the seeds after the '247E Patent expires.[137] However, Monsanto is under no statutory obligation to do this, and its history of going after farmers for patent infringement may have farmers nervous.[138] The looming threat of an infringement lawsuit may be inducement enough to have farmers feel the need to switch over to seeds with Roundup Ready 2 Yield. Once the '247E Patent expires, other significant changes will occur with seed-producing companies that use various traits, or stack traits, to develop seeds.

---

132. *See* Grushkin, *supra* note 6, at 10.

133. *See About the Accord*, *supra* note 10; Peterka, *supra* note 27; *see also infra* Part II.C (discussing the various methods for the maintenance of covered authorizations, or international regulation authorizations, that the Accord provides for).

134. *Product Patents*, MONSANTO, http://www.monsanto.com/products/Pages/product-patents.aspx (last visited Oct. 30, 2012). These products include Roundup Ready® Corn 2, YieldGard® Corn Borer with Roundup Ready® Corn 2, YieldGard Rootworm with Roundup Ready® Corn 2, YieldGard® Plus with Roundup Ready® Corn 2, Genuity® VT Double PRO®, YieldGard VT Rootworm/RR2®, YeildGard VT Triple®, Genuity® VT Triple PRO® and Performance Series Sweet Corn, Genuity® SmartStax®, Roundup Ready® Soybeans, Genuity® Roundup Ready 2 Yield® Soybeans, Roundup Ready® Alfalfa, Genuity® Roundup Ready® Canola, Genuity® Roundup Ready® Sugarbeets, Genuity® Bollgard II® with Roundup Ready® Cotton, and Genuity® Bollgared II® with Roundup Ready® Flex Cotton. *Id.*

135. *Id.*

136. *Id.* For example, the Roundup Ready® Alfalfa is protected by several patents, including the '247E Patent and U.S. Patent No. 8,124,848 (filed Jan. 31, 2003) (issued Feb. 28, 2012), which will not expire until 2023. *Product Patents*, *supra* note 134.

137. Pollack, *supra* note 23. Monsanto has stated that it believes the patent expiration process will include farmers and licensees being free to plant and re-plant seeds, as well as allowing companies such as DuPont to stack the traits. Jack Kaskey, *Monsanto Won't Block Generic Seeds as Patent Ends (Update3)*, BLOOMBERG (Jan. 11, 2010, 4:40 PM), http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aFY8Uj4GAKOE.

138. *See supra* note 24.

After the '247E Patent expires, Monsanto will no longer be able to claim patent infringement for other's stacking practices utilizing Roundup Ready.[139] Seed-producing companies will be able to use the Roundup Ready trait without fees or licensing with Monsanto. This will allow competitors, such as DuPont, to combine their own herbicide-tolerant traits with the Roundup Ready trait to create seeds that are tolerant of new herbicides that have been developed to combat new weeds resulting from weed adaptations to resist herbicides now in use.[140] The Accord's DUCA addresses the issue of stacking traits, but this contractual agreement is not law.[141] Even under the DUCA, there is no right to use a patented trait for stacking purposes while the patent is still valid.[142]

C. The Accord

The Accord, "a private-sector driven mechanism that provides for the transition of regulatory and stewardship responsibilities for biotechnology events[] after patent expiration," is the result of years of work by BIO and the ASTA.[143] The Accord is comprised of two agreements: the Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA).[144] One of the main driving forces behind the development of the Accord was the concern over the maintenance of international licenses and authorizations for traits after patent expiration.[145] The first agreement to be released for signatures was the GEMAA, which was released in October of 2012.[146] The GEMAA provides for the

139. *See infra* Part III.A (discussing the recent litigation between Monsanto and DuPont).

140. Glyphosate-herbicide immune weeds have evolved around the world. WALTERS, *supra* note 10, at 37–38; Margaret Sova McCabe, *Superweeds and Suspect Seeds: Does the Genetically-Engineered Crop Deregulation Process Put American Agriculture at Risk?*, 1 U. BALT. J. LAND & DEV. 109, 111–12 (2012) (discussing how such weeds, described as "superweeds," have evolved).

141. DUCA, *supra* note 9, at 66; Peterka, *supra* note 27; *About the AgAccord*, *supra* note 11.

142. *See* DUCA, *supra* note 9, at 66.

143. AM. SEED TRADE ASS'N & BIOTECHNOLOGY INDUS. ORG., THE ACCORD: GENERIC EVENT MARKETABILITY AND ACCESS AGREEMENT IS OPEN FOR SIGNATURE 1 (2012), *available at* http://www.agaccord.org/include/facts.pdf.

144. *Id.* at 1–2.

145. *Id.*

146. GEMAA Is Open for Signature, *supra* note 29.

procedures to manage patent expiration.[147] The second agreement, the DUCA, was released for signatures in December of 2013.[148] The DUCA provides for access to data needed to maintain international regulation authorizations.[149]

1. The GEMAA

The GEMAA became effective in 2012 upon the signatures of five biotech companies, including Monsanto, DuPont Pioneer, and Dow Agro Sciences.[150] Under the GEMAA, a patent holder must notify the Administrator of Patent Expiration (who is appointed by and reports to the GEMAA Committee of Signatories) of any expiration three years prior to the expiration—a fact anyone could easily learn of through publicly available information.[151] At the time of the notification, the patent holder must choose one of three options in regards to "covered authorizations," which include international licenses.[152] The three options include independently maintaining and obtaining covered authorizations for its patented trait; seeking to share the responsibility of maintaining and obtaining covered authorizations for its patented trait; and giving notice of discontinuation of regulatory responsibilities for its patented trait.[153]

Under the GEMAA, if the patent holder decides to maintain and

147. *Id.*

148. *DUCA Factsheet*, *supra* note 25, at 1.

149. GEMAA Is Open for Signature, *supra* note 29. *See generally* DUCA, *supra* note 9 (maintaining international authorizations).

150. GEMAA Is Now Effective, *supra* note 26. The GEMAA became effective on November 15, 2012, a month and a half after its release, with the signatures of BASF Plant Science, Bayer Crop Science, Dow Agro Sciences, DuPont Pioneer, and Monsanto. *Id.* The agreement only needed four signatories to become effective. GEMAA, *supra* note 9, at 1.

151. GEMAA, *supra* note 9, at 2, 18. Because patents are publically disclosed, the notification of an expiring patent is merely a convenience. *See* Shubha Ghosh, *Patents and the Regulatory State: Rethinking the Patent Bargain Metaphor After* Eldred, 19 BERKELEY TECH. L.J. 1315, 1316–17 (2004) (describing the patent bargain, the idea that public disclosure of an invention is "the price paid for" a temporary monopoly on the invention).

152. *See* GEMAA, *supra* note 9, at 1, 4. Under the GEMAA, a "Covered Authorization" includes "[a]ll Authorizations necessary for the cultivation and sale of a single Covered or Generic Event in the United States, and all Authorizations necessary to permit undisrupted trade of material containing a Covered or Generic Event (Seed Products or grain, or any product thereof regulated as a result of the Event)." *Id.* at 1. An "Event" is "[a] genetic construct inserted into a specific site in a plant's genome." *Id.* at 2. The DUCA defines an "Event" as "[a] single insertion of a nucleic acid construct into a specific site in a plant's chromosome." DUCA, *supra* note 9, at 8.

153. GEMAA, *supra* note 9, at 4.

obtain covered authorizations independently, it agrees to bear the burden of all costs associated with covered authorizations, independent of those producing the trait generically, for seven years, beginning at the date of notification.[154] This means that the covered authorizations will be paid through a minimum of four years following the expiration of the patent.[155] Under this option, the patent holder does not need to provide market access to the trait until the patent expires and never needs to provide access for those stacking the trait.[156]

If the patent holder instead decides to try to share the responsibility of maintaining and obtaining covered authorizations for its patented trait, the patent holder and interested GEMAA signatories have sixteen months to negotiate a "joint responsibility agreement."[157] The joint responsibility agreement is required to include a provision that all parties executing the agreement shall have market access for all purposes to the patented trait, including stacking.[158] If a joint responsibility agreement is made, the costs of maintaining and obtaining covered authorizations are shared among the parties to the agreement.[159] It was expected that most genetic traits with expired patents would end up with this shared-cost method; however, in practice, the option to independently maintain covered authorizations has more often been selected.[160]

---

154. CARRATO & NEUSCHAFER, *supra* note 13, at 3; GEMAA, *supra* note 9, at 2, 4.

155. *See* CARRATO & NEUSCHAFER, *supra* note 13, at 3.

156. *Id.*

157. *Id.*; GEMAA, *supra* note 9, at 4–5.

158. CARRATO & NEUSCHAFER, *supra* note 13, at 3; GEMAA, *supra* note 9, at 5.

159. CARRATO & NEUSCHAFER, *supra* note 13, at 3; *see also* GEMAA, *supra* note 9, at 4–5.

160. Grushkin, *supra* note 6, at 11. As of May 2014, the only two notices that had been filed as a result of the GEMAA, both by Monsanto, called for independent maintenance of the covered authorizations, not the shared responsibility option. *GEMAA Notices*, THE AGACCORD, http://www.agaccord.org/?p=GEMAA (last visited May 15, 2014) (providing the full list of Notices of Patent Expiration that have been received); J. THOMAS CARRATO, MONSANTO CO., THE ACCORD: GENERIC EVENT MARKETABILITY & ACCESS AGREEMENT (GEMAA) NOTICE OF PATENT EXPIRATION FOR 40-3-2 SOYBEAN (2013), *available at* http://www.agaccord.org/include/NoticeofPatentExpiration40-3-2Soybean.pdf (selecting to independently maintain covered authorizations, Monsanto filed a Notice of Patent Expiration for a soybean trait); J. THOMAS CARRATO, MONSANTO CO., THE ACCORD: GENERIC EVENT MARKETABILITY & ACCESS AGREEMENT (GEMAA) NOTICE OF PATENT EXPIRATION FOR MON 810 CORN (2013), *available at* http://www.agaccord.org/include/NoticeofPatentExpirationMon810.pdf (selecting again to independently maintain covered authorizations, Monsanto followed the conditions of the Accord in filing a Notice of Patent Expiration for a corn trait).

Finally, if the patent holder decides to give notice of discontinuation of regulatory responsibilities for its patented trait, interested GEMAA signatories have sixteen months to negotiate a "transition agreement," under which interested signatories would take over the responsibility for maintaining and obtaining covered authorizations.[161] Like the joint responsibility agreement, the transition agreement is required to include a provision that the interested signatories executing the agreement shall have market access for all purposes to the patented trait, including stacking.[162] If no transition agreement is made, the patent holder and all others must stop selling the trait, including seeds containing the trait, four years prior to the date that the patent holder stops maintaining covered authorizations.[163]

To be a signatory of the GEMAA, one must "support[] access to, and availability of, Seed Products containing [patentable gene traits], including the growing, developing, marketing, selling, stewarding, processing, transporting, shipping, handling, or maintaining of such Seed Products."[164] As such, farmers are able to be signatories of the GEMAA. However, unless the farmer qualifies as a non-profit organization under the Internal Revenue Code or a small business entity under the Code of Federal Regulations, the farmer would be responsible for a percentage of the GEMAA operating costs equal to that of all other signatories.[165] Therefore, the cost of becoming a signatory may be a barrier for farmer participation. If a farmer cannot become a signatory, he loses the ability to enter into the negotiations for either a transition agreement or a joint responsibility agreement; thus, he is subject to the decisions of the corporations that are already signatories.[166] As of January of 2013, the GEMAA signatories only included "seed giants"—no small seed companies.[167]

---

161. CARRATO & NEUSCHAFER, *supra* note 13, at 3; GEMAA, *supra* note 9, at 5–6.

162. CARRATO & NEUSCHAFER, *supra* note 13, at 3; GEMAA, *supra* note 9, at 6.

163. GEMAA, *supra* note 9, at 6.

164. *Id.* at 3.

165. *Id.* at 22 (citing I.R.C. § 501(c)(3) (2006); 13 C.F.R. §§ 121.101–.108, 121.201 (2013)).

166. To participate in negotiations for either the transition agreement or the joint responsibility agreement, a party must be a GEMAA signatory. GEMAA, *supra* note 9, at 5–6.

167. Grushkin, *supra* note 6, at 11. As of May 2013, there were ten signatories to the GEMAA: American Farm Bureau Federation; American Seed Trade Association (ASTA); American Soybean Association; BASF Plant Science LP; Bayer CropScience; Dow Agro Sciences LLC; DuPont Pioneer; Gro Alliance, LLC; Monsanto Company; and National Corn

2. The DUCA

Despite suggestions that the DUCA would be released in early 2013, the DUCA was not released for signatures until December of 2013.[168] At patent expiration, the DUCA requires its signatories to share their data regarding crops using single gene traits and multiple gene traits, or stacked seeds, in return for the management of the data.[169] The crop data is required to be submitted periodically to maintain international regulation authorizations.[170] This unified data management system would be particularly beneficial to signatories because many of the stacked seeds contain genetic traits from multiple companies.[171] Such a system should "facilitate and expedite the development of new . . . 'stacked' seed products."[172] While the development of new stacked seeds would benefit farmers by combining companies' patented traits, the new seeds are more likely to contain newer traits, such as Roundup Ready 2 Yield, instead of traits with soon to be expired traits.[173]

The ability to sell GMO crops is heavily regulated throughout the world through international regulation authorizations.[174] In the United States, once the Department of Agriculture (USDA) "deregulates" the gene trait, the use of the trait in crops is indefinitely accepted.[175] However, other countries only approve the use of the gene in specific crops (and thus the importation of these specific crops) for specified time periods, requiring companies to reapply for subsequent time periods.[176] Countries worldwide vary in the duration of approvals.[177] In addition to the maintenance of international authorizations already in

---

Growners Association. GEMAA, *supra* note 9, at 29 app. B. There are roughly six hundred small seed companies in the United States that have yet to sign the GEMAA. Grushkin, *supra* note 6, at 11.

168. *DUCA Factsheet*, *supra* note 25, at 1; Grushkin, *supra* note 6, at 11.

169. Grushkin, *supra* note 6, at 11.

170. *Id.*

171. *Id.* Monsanto's Smartstax corn crop contains traits from Bayer Crop Science, Dow Agro Sciences, and Monsanto itself, developed through cross-licensing between the companies. *Id.*

172. CARRATO & NEUSCHAFER, *supra* note 13, at 3.

173. *Sorting Out the Facts Behind Stacks*, *supra* note 15, at 3.

174. *See* Grushkin, *supra* note 6, at 10.

175. *Id.*

176. *See id.*

177. *Id.* China allows for three years of approval per application; Korea allows for five years; and Japan and Europe extend the application period to ten years. *Id.*

place, new authorizations may need to be obtained both in countries with newly implemented authorization procedures and for new products utilizing the generic traits.[178] To obtain an international regulation authorization, one must undergo research and field testing and compile what is known as proprietary regulatory property (PRP), consisting of "studies, dossiers, data, and submissions."[179] PRP is owned by the seed companies and "is separately protected apart and distinct from . . . patent law."[180]

Without the maintenance of the international regulation authorizations, "[t]here could be a terrible trade disruption if [there were] a product that was no longer registered in a foreign country. It could lock down ships. It could disrupt the entire trade system."[181] The DUCA recognizes the risk that failure to maintain international regulation authorizations poses: "Without obtaining and maintaining these authorizations, the commercial marketability of Seed Products containing Generic [traits] will be jeopardized."[182] Because of the importance in maintaining international regulation authorization and the seed companies' interest in protecting their PRP, even after patents expire, there is a need for regulating access to PRP in a way that allows for authorizations involving seeds and crops containing generic traits. The DUCA provides an example of one way to fulfill this need.

---

178. DUCA, *supra* note 9, at 1–2 (noting that "even though all patents on [a trait] have expired, there still will be Continuing Maintenance Costs" associated with the "complex and costly" international authorizations). For more information on the various costs associated with obtaining and maintaining international regulatory authorizations, see DUCA, *supra* note 9, at app. H.

179. *Id.* at 1–2. The DUCA provides a specific definition for PRP:

> The data, studies, dossiers, submissions and Authorizations that enable the cultivation and sale of a Covered Event as a single Event in the United States and allow export and ex-United States use of material containing that Covered Event (*id est* Seed Products or grain) or any product regulated as a result of the Event. Proprietary Regulatory Property includes Regulatory Data, Regulatory Methods and Regulatory Correspondence.

Id. at 10. Whether a gene trait constitutes a "covered event" is determined under article V of the DUCA, but it generally includes commercialized gene traits for which the patent is within four years of expiration. *See id.* at 18–19. For purpose of this Comment, covered events will simply be referred to in general terms of gene traits.

180. *DUCA Factsheet*, *supra* note 25, at 3. PRP may be protected as intellectual property itself under law such as copyright, trade secret, or patent law. *See* DUCA, *supra* note 9, at 8.

181. Grushkin, *supra* note 6, at 10 (quoting Ray Gaesser, farmer and American Soybean Association Vice President).

182. DUCA, *supra* note 9, at 2.

Before the patent for a gene trait expires, the DUCA requires that the PRP owner (most likely also the patent holder) negotiate in good faith with any other DUCA signatory that requests access to the PRP and the gene trait in writing.[183] While the PRP owner is required to enter into negotiations, the DUCA does not impose any requirement or obligation to provide access to the PRP or trait before the patent's expiration or for either party to accept any offer.[184] Because of the inherent power disparity between the PRP owner and the party seeking access to the PRP, it is likely that the negotiations will be dominated by the PRP owner. Without implementing a system of guaranteed PRP sharing and protection from patent infringement claims during a specified pre-patent-expiration period, the DUCA fails to guarantee any method for creating a generic market for seeds containing gene traits just after patent expiration.

What the DUCA does provide is a system for organizing signatories who wish to continue to use gene traits after patent expiration and for maintaining international regulation authorizations as long as the signatories require. Outlined in the DUCA's Process Schedule, the DUCA procedure begins in the same way that the GEMAA's does, with an initial notice made to all DUCA signatories three years before a patent's expiration.[185] After receiving the initial notice from a PRP owner, a signatory has one month to execute a confidentiality agreement and send it to a signatory-appointed administrator, indicating an interest in maintaining the international authorizations for the trait.[186] Within three-and-a-half months of the initial notice, the administrator convenes a meeting of the signatories that executed confidentiality agreements to discuss the signatories' interest in becoming "verified."[187] To further participate in the DUCA procedure for a gene trait, the signatory must be verified.[188] In addition, the signatory must create a "Verification Fund," the size of which depends on the estimated costs of

183. *Id.* at 19.

184. *Id.*

185. *Id.* at 8, 23–24, app. G; *see also* GEMAA, *supra* note 9, at 2. The confidentiality agreement is attached to the DUCA in an appendix. DUCA, *supra* note 9, at app. D. After a signatory executes a confidentiality agreement, it will receive a "Confidential Notice." *Id.* at 24–25, app. G.

186. DUCA, *supra* note 9, at 24, app. G; *see also id.* at 5 (defining an administrator).

187. *Id.* at 25, app. G.

188. *Id.* at 25–27.

continued maintenance of international regulation authorizations.[189] The size of the fund does not take the signatory's identity or ability to pay into account, indicating that small companies or sole proprietorships may be prevented from participating in the process.[190]

After the verified signatories and the PRP owner are identified and all necessary funds are established, the parties enter into negotiations to develop terms and conditions for a "comprehensive agreement."[191] If the comprehensive agreement is not resolved within two years of the initial notice being sent out (i.e., one year prior to patent expiration), then the parties must enter into binding arbitration for the creation of the comprehensive agreement.[192] Generally, the comprehensive agreement will provide for an assessment of a portion of the costs for maintaining international regulation authorizations, appoint a party to be the "operator" that is responsible for maintaining authorizations, and provide access to the PRP for the verified signatories.[193] This limitation on access to the PRP information and control over the procedure should not limit non-parties to the comprehensive agreement from benefiting from the maintenance of the authorizations. The authorizations may be discontinued in a number of circumstances, but most notable is the ability for any party to the comprehensive agreement to give notice of the last sale of any product containing the gene trait at issue, which triggers the obligation to maintain authorizations for only four more years.[194]

While the GEMAA is already effective, the DUCA will not become effective until there are three non-PRP holder signatories and three other signatories who fall into one of two categories: PRP holders or petitioners of the USDA for the deregulation of a trait.[195] Because of the diversity and number of signatories that must be present for the DUCA to become effective, it may be a while before any of the

189. *Id.* at 27–30.

190. *See generally id.* at 27–30. In addition to the costs associated with maintaining international regulations, there are operating costs associated with the DUCA that are paid by the signatories by assessment. *Id.* at app. A at A11–A13.

191. *Id.* at 31–32.

192. *Id.* at 32. The DUCA provides for an arbitration and mediation procedure to handle the development of the comprehensive agreement as well as other issues between signatories. *Id.* at 50–52, app. C.

193. *See generally id.* at 31–47.

194. *Id.* at 47.

195. *Id.* at 1; DUCA Is Open for Signature, *supra* note 29.

agreement's measures come into effect.[196]

Due to the fact that it is a voluntary contractual agreement, the success of the Accord rests on the number of signatories that it is able to attract.[197] Even if the Accord does gain more signatories, the GEMAA provides for a fairly simple withdrawal process for signatories, merely requiring notice and a twelve-month period after such notice before the withdrawal becomes effective.[198] Like the GEMAA, the DUCA provides a fairly easy mechanism for a signatory to withdraw from the DUCA. The requirements for a signatory's withdrawal from the DUCA only include one-year notice in writing to the administrator and the identification of any gene traits that the signatory has obligations under the DUCA for.[199] While withdrawal is easy, it will not relieve the signatory from its obligations under any comprehensive agreement.[200] Without agreement throughout the industry to abide by the Accord, there is much left to the unknown. In addition, because there are three possible choices for patent holders to make under the GEMAA in regards to maintaining international regulation authorizations and only agreement signatories may play a role in negotiations for such maintenance, there are many players in the industry, such as farmers, who may be left out of the discussion.[201]

III. THE TRANSITION TO GENERIC, IN THE COURTS AND THE HATCH-WAXMAN ACT

Currently, there is no basis in national or international law to provide for a transition from a patent-protected, privately created and owned genetic trait to a generic marketplace.[202] Without an express model to follow, companies wishing to develop generic seeds have been left vulnerable to infringement lawsuits.[203] In response to such a lawsuit

196. AM. SEED TRADE ASS'N, AGACCORD: DATA USE AND COMPENSATION AGREEMENT 8 (2013), *available at* http://cdnseed.org/wp-content/uploads/2013/11/BiotechASTAAccord.pdf; *see also* DUCA, *supra* note 9, at 1; DUCA Is Open for Signature, *supra* note 29.

197. *See* Grushkin, *supra* note 6, at 10–11; GEMAA Is Open for Signature, *supra* note 29.

198. GEMAA, *supra* note 9, at 24–25.

199. DUCA, *supra* note 9, at 62.

200. *Id.* at 62–63.

201. *See* GEMAA, *supra* note 9, at 1, 29; Grushkin, *supra* note 6, at 10–11.

202. CARRATO & NEUSCHAFER, *supra* note 13, at 4.

203. *See, e.g.*, Monsanto Co. v. E.I. du Pont de Nemours & Co., No. 4:09CV00686(ERW), 2009 U.S. Dist. LEXIS 84512, at *3 (E.D. Mo. Sept. 16, 2009).

initiated by Monsanto, DuPont claimed that Monsanto committed antitrust violations in its attempt to block competitors from developing generic seeds.[204] A need to resort to antitrust claims could be avoided if the agricultural industry had a statutory framework for the transition to generic seeds similar to the pharmaceutical industry's Hatch-Waxman Act.[205] The Hatch-Waxman Act includes a safe harbor provision that allows competitors to begin developing generic forms of drugs prior to patent expiration.[206]

A. Monsanto v. DuPont*, the Anti-Trust Concerns*

For the past decade, Monsanto and DuPont have been involved in various legal battles.[207] The most recent string of litigation began in 2009 when Monsanto filed a lawsuit against DuPont, alleging patent infringement, breach of contract, and unjust enrichment.[208] In response, DuPont made seven antitrust counterclaims.[209] DuPont's relevant antitrust claims were that Monsanto's licensing agreements were based on a "switching strategy," designed to force independent seed companies using the Roundup Ready trait with the soon expiring patent to switch to Roundup Ready 2 Yield, to extend patent protection and "prevent generic entry into the market before the patent for

204. *Id.*; Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Stay Discovery and for Separate Trial of Antitrust Counterclaims, *supra* note 121, at 4–5.

205. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code) (Hatch-Waxman Act); Parloff, *supra* note 6, at 98.

206. *See* 35 U.S.C. § 271(e)(1); Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671 (1990).

207. Christopher Doering, *Seed Giants Clash Following $1 Billion Judgment in Patent Case*, GANNETT NEWS SERVICE, Aug. 2, 2012, at ARC. Monsanto and DuPont control two-thirds of the corn and soybean seed markets of North America. *Id.*

208. *Monsanto Co.*, 2009 U.S. Dist. LEXIS 84512, at *3. The claim was based off of a 2002 non-exclusive license agreement between Monsanto and DuPont, allowing DuPont to manufacture and sell corn and soybean seed with the Roundup Ready trait, a glyphosate-tolerant trait. Monsanto Co. v. E.I. Dupont De Nemours & Co., No. 4:09CV00686(ERW), 2012 U.S. Dist. LEXIS 157410, at *9–10 (E.D. Mo. Nov. 2, 2012). After DuPont created its own glyphosate-tolerant trait, known as Optimum GAT, or OGAT, in 2006, DuPont began stacking the Roundup Ready trait with OGAT. *Id.* at *10–11. Monsanto claimed that the stacking of its glyphosate-tolerant trait with DuPont's was done to hide the fact that OGAT did not work and that the practice was in violation of their license agreement. *Id.* at *9–11; Rich Keller, *Monsanto and DuPont Continue Litigation*, AG PROF. (Sept. 12, 2012), http://www.agprofessional.com/agprofessional-magazine/Monsanto-and-DuPont-continue-litigation-169510356.html?view=all.

209. *Monsanto Co.*, 2009 U.S. LEXIS 84512, at *3.

[Monsanto's] Roundup Ready[] trait seed line expires."[210] By requiring that independent seed companies switch from using Roundup Ready to Roundup Ready 2 Yield and destroy seed lines containing the Roundup Ready '247E Patent before it expires in 2014, Monsanto would block these companies from creating a generic version of Roundup Ready, foreclosing generic competition before it begins.[211] Ultimately, DuPont alleged that Monsanto sought "not only to unlawfully preserve its existing trait monopolies, but also to impede the entry of generics and to extend its monopoly power through exclusionary conduct into emerging markets for stacked traits and output traits."[212] In 2009, the claims of the lawsuit were bifurcated, with the patent infringement claims proceeding to a jury trial in favor of Monsanto in 2012, and the antitrust claims expected to go to trial in late 2013.[213] However, in March 2013, DuPont

---

210. *Id.* at *3–4. The other antitrust claims that DuPont brought include claims that depend on the validity and construction of the patents for Roundup Ready as well as claims that Monsanto has anticompetitive restrictions in its licensing agreements with independent seed companies. *Id.* at *3.

211. Defendants' Memorandum of Law in Opposition to Plaintiffs' Motion to Stay Discovery and for Separate Trial of Antitrust Counterclaims, *supra* note 121, at 4; Parloff, *supra* note 6, at 100, 104.

> By switching . . . to the Roundup Ready® 2 Yield trait, Monsanto seeks to remove the Roundup Ready® trait from the market prior to the time when competitors . . . will be able to market a generic product, thereby creating a bridge between its Roundup Ready® patent monopoly and its Roundup Ready® 2 Yield patent monopoly of longer duration.

Defendants' Amended Answer and Counterclaims at 23–24, Monsanto Co. v. E.I. du Pont de Nemours & Co., No. 4:09CV00686(ERW), 2009 U.S. Dist. LEXIS 84512 (E.D. Mo. Sept. 16, 2009).

212. Defendants' Amended Answer and Counterclaims, *supra* note 211, at 24.

213. *Monsanto Co.*, 2009 U.S. Dist. LEXIS 84512, at *3, *7; Doering, *supra* note 207. The jury trial for patent infringement ended in the jury awarding a surprising one billion dollars in damages to Monsanto, the largest verdict in Missouri history and one of the largest verdicts of 2012 in the United States. Gustin, *supra* note 74; *see also* Margaret Cronin Fisk, *Largest U.S. Jury Verdicts of 2012 (Table)*, BLOOMBERG (Jan. 17, 2013, 10:00 PM), http://www.bloomberg.com/news/2013-01-18/largest-u-s-jury-verdicts-of-2012-table-.html (showing the one billion dollar judgment to be the third largest jury award of 2012); Margaret Cronin Fisk, *U.S. Patent Jury Awards Soar with Some Big Ones Cut by Judges*, BLOOMBERG (Jan. 18, 2013, 12:00 AM), http://www.bloomberg.com/news/2013-01-18/patent-trial-awards-soar-with-some-big-ones-cut-by-judges.html. After a judge unsealed a sanction order, it was revealed that "DuPont executives and lawyers . . . knew the company didn't have an agreement allowing it to combine Monsanto's Roundup Ready soybeans with a second trait." Jack Kaskey & Susan Decker, *DuPont 'Fraud' in Monsanto Seed Case Unsealed by Judge*, BLOOMBERG (Nov. 30, 2012, 12:04 PM), http://www.bloomberg.com/news/2012-11-30/dupont-fraud-in-monsanto-seed-case-unsealed-by-judge.html. The antitrust case scheduled for late 2013 would have been before a new jury but the same judge who presided over the patent infringement case. *Id.*

and Monsanto announced that they had reached a settlement agreement, in which the billion-dollar verdict in favor of Monsanto for the patent infringement claims was thrown out and DuPont agreed to drop its antitrust lawsuit.[214] In conjunction with this settlement agreement, Monsanto and DuPont entered into technology license agreements that granted DuPont "regulatory access and maintenance support for [the] Roundup Ready" trait in soybeans *after* the '247E Patent expires.[215]

As a result of DuPont's antitrust claims against Monsanto, the Department of Justice began investigating possible antitrust practices in the seed industry.[216] After holding a series of workshops[217] and requesting information from seed companies, the formal investigation quietly ended after two years in November of 2012, with the agency stating that it would not take action against Monsanto.[218] Following the decision, DuPont did not initially back away from its antitrust claims, stating that "[t]he investigation by [the Department of Justice] is separate from the antitrust claims DuPont has brought against

214. E. I. du Pont de Nemours and Company, Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 (Form 10-Q) 25–26 (Oct. 22, 2013) ("[DuPont] agreed to dismiss with prejudice its antitrust claims against Monsanto in exchange for a dismissal with prejudice of Monsanto's patent infringement claims and the related damages verdict. Accordingly, as of the first quarter 2013 this matter was resolved, but for the court-ordered sanctions against the company for 'fraud against the court.' The court unsealed the order in November 2012. The parties agreed to present the sanctions and related rulings for immediate appeal and those matters are presently on appeal."); Andrew Pollack, *Monsanto and DuPont Settle Fight Over Patent Licensing*, N.Y. TIMES, Mar. 27, 2013, at B8.

215. E. I. du Pont de Nemours & Company, *supra* note 214, at 25–26.

216. Georgina Gustin, *Justice Dept. Ends Monsanto Antitrust Inquiry*, ST. LOUIS POST-DISPATCH, Nov. 20, 2012, at A10. Beginning in 2010, the Justice Department's investigation was "the first time US regulators scrutinized competition in the highly consolidated seed market." Rebecca Coons, *DOJ Drops Antitrust Inquiry into Seed Industry and Monsanto*, CHEMICAL WK., Nov. 26/Dec. 3, 2012, at 7.

217. U.S. DEP'T OF JUSTICE, COMPETITION AND AGRICULTURE: VOICES FROM THE WORKSHOPS ON AGRICULTURE AND ANTITRUST ENFORCEMENT IN OUR 21ST CENTURY ECONOMY AND THOUGHTS ON THE WAY FORWARD 2–4 (2012), *available at* http://www.justice.gov/atr/public/reports/283291.pdf.

218. Gustin, *supra* note 216; Tom Philpott, *DOJ Mysteriously Quits Monsanto Antitrust Investigation*, MOTHER JONES (Dec. 1, 2012, 3:03 AM), http://www.motherjones.com/tom-philpott/2012/11/dojs-monsantoseed-industry-investigation-ends-thud. The quiet manner in which the Department of Justice ended its inquiry into Monsanto, without even a press release, left the public wondering why. Philpott, *supra*.

Monsanto and is not an indication or a decision that Monsanto has not violated antitrust laws."[219]

As the investigation ended, the Department of Justice indicated that "many farmers say that the prices they're paying are indeed out of hand for seed," and "farmers say that their choice, their seed options, are dramatically reduced, especially in the way of conventional corn and soybean varieties."[220] In addition, the Department of Justice noted a fear among farmers "that the best and newest genetics will only be introduced with expensive patented traits stacked into them."[221] Over the years, there has been concern that farmers do not have access to low price seed options and that the price for seeds has grown faster than the prices farmers are paid for their crops.[222] Interestingly, the DUCA included a set of guidelines for its signatories to follow in regards to antitrust practices.[223]

While a formal regulation for the transition of genetic patents into a generic form will not necessarily help bring "the best and newest genetics" to farmers at reasonable prices, it would provide more low price seed options.[224] Now that DuPont's antitrust claims against Monsanto have been dropped, there is little hope that a legal solution regarding the transition into the public domain for patented seed traits will come into effect before the '247E Patent expires in late 2014.[225] Monsanto has stated that it will not prevent competitors from creating generic versions of traits once they lose patent protection, but this promise does not guarantee that generic versions will ever reach the

219. Gustin, *supra* note 216 (quoting DuPont spokesman, Daniel A. Turner). DuPont faced an uphill battle in pursuing its antitrust claims against Monsanto after the Department of Justice dropped its investigation into the seed industry. Kaskey & Decker, *supra* note 213 ("The [Department of Justice] decision may not bode well for DuPont's remaining antitrust claims against Monsanto." (quoting Attorney Greg Neppl)).

220. Coons, *supra* note 216 (quoting U.S. DEP'T OF JUSTICE, *supra* note 217, at 13).

221. *Id.*

222. Philpott, *supra* note 218 (citing a study done between 2000 and 2008 by the American Antitrust Institute indicating that the seed industry is increasing its prices on seeds higher than the prices farmers receive for their crops, and a 2010 survey by a University of Illinois researcher, indicating that a large percentage of farmers in Illinois claim to not have access to seeds that are not genetically modified); *see also supra* notes 95–97 and accompanying text.

223. *See generally* DUCA, *supra* note 9, at app. F.

224. Coons, *supra* note 216.

225. Parloff, *supra* note 6, at 94; Pollack, *supra* note 214; Keller, *supra* note 208.

market and does not prevent Monsanto from encouraging a switch to Roundup Ready 2 Yield.[226]

B. The Hatch-Waxman Act

In 1984, the Hatch-Waxman Act was enacted to protect "both the interests of drug manufacturers who produce new drugs and the interests of generic drug manufacturers and their consumers."[227] One of the Act's goals was to allow for economical production of generic forms of drugs.[228] To do this, the Act included a safe harbor provision,[229] providing that:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[230]

The premise behind this safe harbor provision "was to allow competitors to begin the regulatory approval process while the patent was still in force, followed by market entry immediately upon patent expiration."[231] However, there are limits to the safe harbor provision. Specifically, it does not allow a company to produce a pharmaceutical

---

226. Kaskey, *supra* note 137.

227. Abbott Labs. v. Young, 920 F.2d 984, 985 (D.C. Cir. 1990); *see* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code) (Hatch-Waxman Act).

228. Mead Johnson Pharm. Grp. v. Bowen, 838 F.2d 1332, 1333 (D.C. Cir. 1988). Prior to the enactment of the Hatch-Waxman Act, the term of a pharmaceutical patent was "distorted" to extend beyond the expiration of the patent due to the period of time it took for any generic drug to obtain FDA approval. *See* KAYE SCHOLER LLP, *supra* note 114, § 8:1.8 fig.8-1.

229. Pamela Fuentes, Comment, *Nipping the Bad in the Bud: Using Hatch-Waxman to Renew Monsanto's Crop*, 30 TEMP. J. SCI. TECH. & ENVTL. L. 81, 93 (2011).

230. 35 U.S.C. § 271(e)(1).

231. Proveris Scientific Corp. v. Innovasystems, Inc., 536 F.3d 1256, 1261, 1265–66 (Fed. Cir. 2008) (holding that a patented device is not subject to a FDCA approval process and thus not a "patented invention" under the terms of 35 U.S.C. § 271(e)(1), and is therefore not afforded the protection of the safe harbor provision). The provision thus "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671 (1990) (holding that the safe harbor provision may be extended to include medical devices, and not simply drugs).

for shipment to regulatory agencies abroad[232] or to stockpile the product just before FDA approval in anticipation of marketing.[233]

The scope of the safe harbor provision has been tested in regards to the patent infringement litigation between Monsanto and DuPont, with an order stating that the stacking of the Roundup Ready trait and DuPont's OGAT trait was not permitted under the safe harbor provision of the Hatch-Waxman Act.[234] Because the Hatch-Waxman Act does not appear to provide protection for seed companies developing generic seeds prior to patent expiration, these companies are not protected from infringement lawsuits during the patent term.[235]

Protection from infringement claims for the purposes of developing generic seeds is not addressed in the Accord.[236] By failing to include a provision providing for protection for generic development, the Accord falls short of its goal of promoting "continued innovation in the seed industry."[237] While the Accord has been developed and signed by industry leaders, it is not surprising that it appears to better protect the investments these companies have made in developing their products.[238] Balancing the promotion of innovation as well as protecting investments companies have made in developing their products is a function of the

232. KAYE SCHOLER LLP, *supra* note 114, § 8:1.8[G][4][b] (citing NeoRx Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 207 (D.N.J. 1994)).

233. KAYE SCHOLER LLP, *supra* note 114, § 8:1.8[G][4][b] (citing Biogen, Inc. v. Schering AG, 954 F. Supp. 391, 397 (D. Mass. 1996)).

234. Monsanto Co. v. E.I. Dupont De Nemours & Co., No. 4:09CV00686(ERW), 2012 U.S. Dist. LEXIS 163982, at *10 (E.D. Mo. Nov. 16, 2012) (referring to a court order from June 29, 2012, the "Hatch-Waxman Order").

235. *See id.*; Monsanto Co. v. E.I. du Pont de Nemours & Co., No. 4:09CV00686(ERW), 2009 U.S. Dist. LEXIS 84512, at *3 (E.D. Mo. Sept. 16, 2009). This vulnerability to infringement suits is similar to that felt by producers of generic drugs prior to the Hatch-Waxman Act. Fuentes, *supra* note 229, at 88–89.

236. *See* GEMAA, *supra* note 9, at 1.

237. AM. SEED TRADE ASS'N & BIOTECHNOLOGY INDUS. ORG., *supra* note 143, at 2 (stating that the goals of the Accord are to "promote continued innovation in the seed industry, preserve strong protection for intellectual property rights and potentially provide for new business opportunities").

238. *See generally* CARRATO & NEUSCHAFER, *supra* note 13, at 3–4 (outlining the various provisions of the Accord); GEMAA, *supra* note 9 (stopping short of creating a regime that enables the development and maintenance of a generic market for seed traits that have expired patents and thus protecting the development investments the patent owners have made towards the patent for an extended period of time); GEMAA Is Now Effective, *supra* note 26.

Hatch-Waxman Act that would be well placed in the agricultural industry.[239]

IV. USING THE HATCH-WAXMAN ACT AND THE ACCORD TO REGULATE THE TRANSITION TO GENERIC SEEDS

To promote innovation and protect the intellectual property rights of patent holders, various aspects of the Accord and the Hatch-Waxman Act should be adopted by the United States Legislature, providing a structure for seed companies to follow when transitioning from patent-protected traits into their generic forms while also delegating the regulation of the transition to an administrative agency.[240] Regulation based solely on the Accord, a private-sector contractual agreement, is not enough—the need for additional measures is evident.[241] While several have noted the need to adopt a regulation for the agricultural industry based on the Hatch-Waxman Act as a whole, it is the safe harbor provision that is the key to effectively protect large seed companies, small independent seed companies, and farmers.[242]

Amidst the concern over increasing seed prices,[243] infringement lawsuits resulting from the development of generics before patent expiration,[244] antitrust violation claims arising from the enforcement of

239. Welters, *supra* note 12, at 421–23 (explaining that the Hatch-Waxman Act would be an instructive model for the entrance of generic seeds into the market because of the similarity between the pharmaceutical and agricultural industry).

240. Such goals are in line with the stated goals for the Accord. AM. SEED TRADE ASS'N & BIOTECHNOLOGY INDUS. ORG., *supra* note 143, at 2; *see also supra* note 237 and accompanying text. Federal regulation of the agricultural-biotechnology industry should be permitted under the Commerce Clause and the Patent and Copyright Clause. U.S. CONST. art I, § 8, cl. 3 (Commerce Clause); U.S. CONST. art. I, § 8, cl. 8 (Patent and Copyright Clause).

241. *About the AgAccord*, *supra* note 11.

242. *See* Fuentes, *supra* note 229, at 82–83 (arguing that the agricultural-biotechnology industry would benefit from a regulation based on the Hatch-Waxman Act in a way that limits the protections of patent holders); Welters, *supra* note 12, at 421–23 (explaining that the Hatch-Waxman Act would be an instructive model for the entrance of generic seeds into the market because of the similarity between the pharmaceutical and agricultural industries); Parloff, *supra* note 6, at 98 (noting that there is no equivalent to the pharmaceutical industry's Hatch-Waxman Act in the agricultural-biotech industry).

243. Philpott, *supra* note 218 (citing a study done between 2000 and 2008 by the American Antitrust Institute indicating that the seed industry is increasing its prices on seeds higher than the prices farmers receive for their crops).

244. Monsanto Co. v. E.I. du Pont de Nemours & Co., No. 4:09CV00686(ERW), 2009 U.S. Dist. LEXIS 84512, at *3 (E.D. Mo. Sept. 16, 2009) (claiming that DuPont violated their licensing agreement by stacking genes, Monsanto sued DuPont for patent infringement).

limiting licensing agreements,[245] and the maintenance of international regulation authorization for seeds with expiring patents,[246] the adoption of the agricultural biotechnology equivalent of the Hatch-Waxman Act's safe harbor provision may provide the answer.[247] While some may call for more regulation on the industry by removing the right of patent holders to restrict farmers from re-planting seeds through licensing agreements, such an encroachment on the rights of patent holders would not provide for an equitable solution to this problem.[248] If the right of patent holders to restrict farmers from re-planting seeds is removed, the goal of promoting innovation would not be met, for it would lead to decreased seed sales and thus less funding for research.[249] An agricultural-biotechnology safe harbor provision, based off of the Hatch-Waxman Act's provision, should read:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States, import into the United States, or export from the United States a patented invention solely for uses reasonably related to the development and submission of information under a Federal or International law which regulates the manufacture, use, or sale of genetically modified organisms.[250]

By including an express provision protecting the export of seeds and crops, as well as a provision allowing for use of a patented invention to meet international laws, this law would incorporate the important international concerns that have arisen.[251] Additionally, allowing "competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval" permits companies to prepare for patent expiration by developing their own generic forms, including forms that use stacking technology, thereby promoting innovation.[252] In turn, the law would not overly encroach

245. *Id.* at *5–6 (holding that DuPont's counterclaim against Monsanto for antitrust violations should be bifurcated from Monsanto's patent infringement claims).

246. Grushkin, *supra* note 6, at 10.

247. 35 U.S.C. § 271(e)(1) (2006).

248. Fuentes, *supra* note 229, at 104 (proposing a statute that would allow farmers to re-plant seeds containing patented traits on their property).

249. *See supra* note 237 and accompanying text.

250. *See generally* 35 U.S.C. § 271(e)(1).

251. *See* Grushkin, *supra* note 6, at 10.

252. Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 671 (1990) (holding that the Hatch-Waxman Act's safe harbor provision may be extended to include medical devices, and not simply drugs).

upon the patent holder's legal monopoly, for the generic forms of seeds could not be sold in the market until the patent had expired and patent holders would still be able to bring infringement suits for those using the seeds improperly. In a way, such a statute would be a revival and an expansion of the Plant Variety Protection Act's research exception.[253] However, instead of limiting the allowable research to those with "bona fide research" purposes, it would be broadened to include those with the purpose of creating a commercial product.[254] By allowing for the development and manufacture of generic seeds prior to patent expiration, a competitive market for generic seeds may begin immediately following the expiration, minimizing the antitrust concerns as well as the concerns over rising seed prices.[255] Some may argue that allowing the use of stacking technology prior to patent expiration will be difficult to regulate where the traits are being used properly to create generic forms, as opposed to improperly for sale prior to patent expiration. This is something that would most likely have to be monitored by the patent holders themselves and expressly provided for in licensing agreements.

To avoid a finding that a safe harbor provision modeled after the Hatch-Waxman Act would also include the limitation of the Act that prevents a company from producing a pharmaceutical for shipment to regulatory agencies abroad,[256] the agricultural-biotechnology safe harbor provision should also include an explicit allowance of the shipment of GMOs for the purpose of obtaining foreign regulation authorizations. Such a provision would read:

> It shall not be an act of infringement to make, use, offer to sell, or sell any genetically modified organism in the United States or another country for the purpose of obtaining or maintaining regulatory authorization in the United States or another country for the sale or importation of the genetically modified organism.

This provision would specifically allow for the protection of international seed trade and prevent any gap in authorizations. While

253. 7 U.S.C. § 2544 (2012).

254. *Id.*

255. *See generally* Philpott, *supra* note 218 (noting the antitrust concerns that have arisen due to the coming expiration of the Roundup Ready trait and citing a study done between 2000 and 2008 by the American Antitrust Institute indicating that the seed industry is increasing its prices on seeds higher than the prices farmers receive for their crops).

256. KAYE SCHOLER LLP, *supra* note 114, § 8:1.8[G][4][b] (citing NeoRx Corp. v. Immunomedics, Inc., 877 F. Supp. 202, 207 (D.N.J. 1994)).

this provision would be beneficial for those who can afford to independently obtain international regulation authorizations, it would fail to protect small companies or sole proprietorships in the same way that the DUCA fails to protect such entities for lack of funding.[257] Additionally, it does not provide access to the PRP that is necessary for obtaining the international regulation authorizations.[258] Because of these shortfalls, there needs to be a mechanism for maintaining and obtaining these authorizations for everyone, as opposed to the comprehensive agreements of the DUCA that provide access to entities with sufficient funding.[259]

In creating a competitive market for generic seeds, the next questions that must be addressed are who will bear the costs for maintaining international regulation authorizations for the gene traits and how will the PRP be managed. These are areas where the agricultural industry, through the Accord, has proposed an equitable solution in its GEMAA shared responsibility option, in which interested parties may elect to share the costs of maintaining the authorizations by entering into a joint agreement.[260] The DUCA also provides a useful model in allowing for all interested parties to make their interest in maintaining the international authorizations known to others.[261] A provision addressing the financial implications in maintaining international regulation authorizations should read:

> Three years prior to the expiration of a patent for genetic traits of a genetically modified organism, the patent holder shall provide notification to all interested parties reasonably known to the patent holder of the impending expiration. Such notification will include information regarding how long the patent holder intends to maintain international regulation authorizations, as well as an accounting of the costs associated with maintaining such authorizations over the ten years prior to the notification. The patent holder will also submit this notification to a committee developed to oversee the expiration process within the USDA.[262]

---

257. *See supra* notes 189–90 and accompanying text.

258. *See supra* notes 183–84 and accompanying text.

259. *See supra* notes 192–93 and accompanying text.

260. CARRATO & NEUSCHAFER, *supra* note 13, at 3; GEMAA, *supra* note 9, at 4–5.

261. *See supra* notes 185–86 and accompanying text.

262. The USDA was selected here because of its role in the regulation of GMOs within the United States. *See supra* notes 174–75 and accompanying text.

> All interested parties will have six months to notify the committee of their genuine intent to use the relevant genetic trait in its generic form following patent expiration. If the committee receives at least one interest notification, the patent holder will be required to maintain international regulation authorizations up to the patent expiration date.
>
> All parties that do use the genetic trait in its generic form following patent expiration shall report such use to the committee on an annual basis. The committee will bear the initial costs and responsibility of maintaining the authorizations and then allocate the costs on a market share ratio to those using the genetic traits. If a party qualifies as a non-profit organization under the Internal Revenue Code or a small business entity under the Code of Federal Regulations, the party will be absolved of its portion of the costs. Maintenance of international regulation authorizations will continue until there is no reported use of the genetic traits.
>
> Once the committee gains the responsibility of maintaining the international regulation authorizations, the expired patent holder will turn over all proprietary regulatory property to the committee. The committee will maintain the confidentiality of the proprietary regulatory property if it is protected by law and will only release the proprietary regulatory property upon the consent of the proprietary regulatory property owner.

Spreading the costs among parties that are most likely to be able to afford the expenditures mitigates the costs to small farmers and other entities. The maintenance of international regulation authorizations costs between $1 million and $2 million per year for each trait, a cost beyond the means of small farmers.[263] The proposal to require patent holders to maintain international authorizations through the end of a patent's life due to other parties' interests in the patent is clearly a debatable requirement.[264] Instead of mandating the maintenance of the

---

263. ROGER A. MCEOWEN, EXPIRATION OF BIOTECH CROP PATENTS—ISSUES FOR GROWERS 3–4 (2011), *available at* http://www.calt.iastate.edu/system/files/CALT%20Legal%20Brief%20-%20Expiration%20of%20Biotech%20Crop%20Patents%20-%20Issues%20for%20Growers.pdf.

264. Such a requirement to purchase an authorization internationally would surely produce arguments similar to the uproar over the individual health insurance mandate. *See generally* Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012); Sheryl Gay Stolberg, *Obama's Shift on Mandate May Be Health Law's Undoing*, N.Y. TIMES, Nov. 16, 2011, at A22.

authorizations, the proposed framework could suggest that if the patent holder decides to discontinue the authorizations at any time, the committee will begin allocating the associated costs to all interested parties. However, this proposal has a greater probability of being abused by patent owners, for if they can unilaterally decide to discontinue the authorizations and absolve themselves of the associated costs while still maintaining the benefits of patent monopoly, the patent owner will significantly increase its profits.

The management of the PRP necessary for international regulation authorizations is a difficult issue because it may be protected information itself.[265] In an effort to respect the property rights associated with the PRP, the committee should be under an obligation to keep the information confidential. Ideally, the sharing of the PRP with the committee and the interested agricultural community may be seen as a trade-off for the PRP owner being able to share the financial burden associated with maintaining international regulation authorizations.

Putting a formal administrative agency in charge of policing the authorization process removes the power from the hands of the large company patent holders, while at the same time removing the monetary burden on them in maintaining the authorizations independently.[266]

---

265. *See supra* notes 179–80 and accompanying text.

266. While some may argue that there are serious conflict of interest concerns for governmental agencies regulating the agricultural industry, with a number of the top USDA and FDA officials being former private-sector executives from companies like Monsanto, this problem is beyond the scope of this Comment. FOOD, INC., *supra* note 1, at 1:16:10–1:17:57 (noting several examples of people who have filled both high level private-sector positions as well as top regulatory positions); Jeremy Bloom, *Should Monsanto Be Able to Patent Genes? Supreme Court May Take Up the Case, in Part*, OCCUPY MONSANTO (Apr. 12, 2012) http://www.occupymonsanto360.org/Occupy,Monsanto,GMO,Genetic,Engineering,Modified, Organism,Food,Sustainable,Local,Locavore,Organic,RoundUp/clarence-thomas/ (discussing fifteen people involved in the government with Monsanto ties). A conflict of interest along this same line is currently present on the bench of the United States Supreme Court in Justice Clarence Thomas, a former lawyer for Monsanto, who has refused to recuse himself from cases involving and affecting Monsanto, such as *Monsanto Co. v. Bowman*, 133 S. Ct. 1761, 1764 (2013), where the question presented to the Supreme Court was "whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission"; *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010); and *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 126, 145 (2001), where the Court, with Justice Thomas writing the majority opinion, held that utility patents may be issued to newly developed plant breeds. *See* FOOD, INC., *supra* note 1 (noting that Justice Thomas wrote the majority opinion for *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001)); Doug Snodgrass, *Ex Monsanto Lawyer Clarence Thomas to Hear Major Monsanto Case*, CELSIAS (Mar. 11, 2010), http://www.celsias.com/article/ex-monsanto-lawyer-

Arguably, it may prove difficult to keep track of "all interested parties." However, the licensing agreements that seed companies already have with other seed producers and farmers would be a good starting point. In addition, by standardizing the transition process, any interested party unknown to the patent holder would know where to express its intent to use the trait, regardless of it being known to the patent holder. Through the enactment of a law that balances the interests of both the patent holder and the small farmers and companies, the future of the global food supply may be protected.[267]

V. CONCLUSION

The United States Legislature should adopt a regime based off of the safe harbor provision of the Hatch-Waxman Act and the Accord. This will provide for a smooth transition into the market for generic GMOs by providing for the development of generic forms without the threat of infringement lawsuits as well as the funding for maintaining international regulation authorizations, while also delegating the regulation of the generic transition to an administrative agency.[268] Plant and seed varieties have had a long history of statutory protection, with the types of protection available to them gradually increasing throughout the past eighty years.[269] Since the 1990s, gene-splicing technology has been used to create genetically modified organisms, which now make up the majority of the United States' corn and soybean crops.[270] Monsanto, the leading company behind this agricultural-biotechnology industry, is set to have its first economically successful seed patent expire in September 2014.[271] In anticipation of this unprecedented event, the industry created the Accord, a voluntary private-sector contractual agreement that aims to regulate both the transition into the generic market for seeds and the management of the

clarence-thomas-hear-major-mons/ (noting that Justice Thomas, who worked as a lawyer for Monsanto between 1976 and 1979, was not recusing himself from *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743 (2010), where the Court held that the district court was incorrect in issuing an injunction preventing the Animal and Plant Health Inspection Service from deregulating Roundup Ready Alfalfa for environmental concerns, *id.* at 2750, 2762–63).

267. *See supra* note 10 and accompanying text.

268. *See supra* Part IV (outlining the proposed law that would balance the interests of both the patent holders and the small farmers).

269. *See supra* Part II.A (discussing the history of protections offered to plant and seed varieties).

270. *See* Pollack, *supra* note 23; *see also supra* notes 71, 76 and accompanying text.

271. *See supra* notes 106–10 and accompanying text.

data used for international regulation authorizations.[272] Despite this industry effort to provide for a predictable system and company assertions that seed saving will be allowed after the Roundup Ready gene trait patent expires, farmers continue to be suspicious and nervous about testing the system and opening themselves up to infringement liability.[273] The importance of creating a method for a transition to the generic market is highlighted by the fact that the agricultural-biotechnology industry itself is attempting to regulate the transition through contracts.[274] The pharmaceutical industry has a statutory regime for the transition of patented drugs into the generic market with the Hatch-Waxman Act, specifically with the safe harbor provision of the Act.[275] In light of the antitrust concerns regarding the transition,[276] the global impact of the transition (due in part to the control Monsanto has over the global food supply),[277] and the international regulation authorizations that must be maintained to sell domestic crops overseas,[278] the Federal Government should take control of the situation.

BRIANNA M. SCHONENBERG*

272. *See supra* Part II.C (outlining the provisions of the Accord).

273. *See* INST. OF AG PROF'LS., PROCEEDINGS OF THE 2013 CROP PEST MANAGEMENT SHORTCOURSE & MINNESOTA CROP PRODUCTION RETAILERS ASSOCIATION TRADE SHOW 28–39 (2013), *available at* http://www.extension.umn.edu/agriculture/ag-professionals/cpm/2013/docs/UMN-Ext-CPM13-Orf.pdf; Grant Gerlock, *Generic Seeds Could Have a Short Life Span*, NETNEBRASKA.ORG (Feb. 19, 2013, 6:30 AM), http://www.netnebraska.org/article/news/generic-seeds-could-have-short-life-span.

274. *See supra* note 9 and accompanying text.

275. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of the U.S. Code) (Hatch-Waxman Act); *supra* Part III.B (discussing the Hatch-Waxman Act).

276. *See supra* Part III.A (regarding the antitrust litigation between Monsanto and DuPont).

277. *See supra* note 10.

278. *See supra* notes 127–33 and accompanying text (describing the importance of maintaining international regulation authorizations).

*Candidate for J.D., 2014, Marquette University; B.S., 2009, University of Wisconsin, Madison. Thank you to the staff of the *Marquette Law Review* for their hard work and support in editing this Comment. Specifically, I would like to thank Professor Kali Murray and Steven Kruzel for their help in inspiring and shaping this Comment. Finally, I would like to thank my family for their unwavering support.