

Note

Striking a Balance:

Revising USDA Regulations to Promote Competition Without Stifling Innovation

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Genetically modified organisms. For some, these words may conjure images of Frankenstein and wild-haired scientists modifying living things with reckless abandon.¹ For others, the image is of teams of scientists synthesizing forward-thinking science in an attempt to enhance an organism's potential. These scientists have changed the world of agriculture as crops—like soybeans—are modified for improved performance. In 2014, the agriculture industry will be facing for the first time the expiration of a patent for an enormously popular crop—Roundup Ready soybeans. “While the pharmaceutical industry has the Hatch-Waxman Act of 1984 to tell its players exactly how to transition seamlessly from patent monopolies to generic competition, agricultural biotech has no equivalent.”²

In 2010, 93 percent of soybeans planted in the United

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1. See, e.g., Yann Devos et al., *Ethics in the Societal Debate on Genetically Modified Organisms: (Re)Quest for Sense and Sensibility*, 21 J. AGRIC. & ENVTL. ETHICS 29, 33 (2008), available at <http://www.springerlink.com/content/h8322712ng142735/fulltext.pdf>.

2. Roger Parloff, *Monsanto's Seeds of Discord: Full Version*, FORTUNE 500 (May 11, 2010, 2:31 PM), http://money.cnn.com/2010/05/06/news/companies/monsanto_patent_full.fortune/index.htm. But see Andrew A. Caffrey, III & Jonathan M. Rotter, *Consumer Protection, Patents and Procedure: Generic Drug Market Entry and the Need to Reform the Hatch-Waxman Act*, 9 VA J. L. & TECH. 1, 28 (2004) (illustrating that the transition to generics in the pharmaceutical industry was not so “seamless” with an FTC study that showed the Hatch-Waxman Act resulted in increased litigation and extended patent stays).

States were herbicide-resistant.³ This percentage is largely attributable to one company—Monsanto—with its Roundup Ready (RR) soybeans.⁴ Since Monsanto first introduced its RR soybean in 1996,⁵ the company has enjoyed a strong hold on the soybean market.⁶ Monsanto's patent on the RR technology expires in 2014, which will enable companies to begin manufacturing a generic version of the RR soybean.⁷ Current legislation, however, cannot adequately oversee the transition to the generic use of genetically modified organisms (GMOs). The United States Department of Agriculture (USDA) is responsible for overseeing the regulation of GMOs—like RR soybeans.⁸ Recent court cases questioning the USDA's effectiveness in overseeing name brand GMOs raises concerns over the USDA's ability to monitor generic GMOs.⁹ Moreover, legislation is needed to ensure the availability of generic GMOs as name brand manufacturers like Monsanto attempt to use patent protections to slow the emergence of generic versions.¹⁰

3. NAT'L AGRIC. STATISTICS SERVICES, AGRIC. STAT. BOARD, ACREAGE 25 (2010), available at <http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf>.

4. Alison Fitzgerald, *Monsanto 7-State Probe Threatens Profit from 93% Soybean Share*, BLOOMBERG (Mar. 10, 2010, 12:01 AM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aCK4Q3XZCpy>.

5. Jennifer M. Latzke, *Roundup Ready Soybean Trait Nears Expiration in 2014*, HIGH PLAINS/MIDWEST AG J., at 1 (Aug. 2, 2010), available at <http://www.hpj.com/archives/2010/aug10/aug2/0716SeedMACOAug2sr.cfm>.

6. See *Monsanto, the Government, Monopoly Claims*, MONSANTO, <http://www.monsanto.com/food-inc/Pages/monsanto-revolving-door.aspx> (last visited Aug. 28, 2011) (recognizing that the majority of soybeans planted contain the Roundup Ready gene); see also Jack Kaskey, *Monsanto's Roundup Ready Soybeans Probed by Justice (Update4)*, BLOOMBERG (Jan. 14, 2010, 5:09 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=a.17BeOtaDpU> (examining the U.S. Justice Department's probe into possible anti-competitive practices by Monsanto).

7. Kaskey, *supra* note 6.

8. See *Frequently Asked Questions About Biotechnology*, U.S. DEPT. OF AGRIC., <http://www.usda.gov/wps/portal/usda/usdahome?contentid=BiotechnologyFAQs.xml&navid=AGRICULTURE> (last visited Sept. 9, 2011) [hereinafter *USDA FAQs*].

9. See Jack Kaskey, *Monsanto Won't Block Generic Seeds as Patents End (Update3)*, BLOOMBERG (Jan. 11, 2010, 4:40 PM), <http://www.bloomberg.com/apps/news?pid=newsarchive&sid=aU3lBepsCb68> [hereinafter *Monsanto Won't Block Generic Seeds*]; see also Parloff, *supra* note 2 (discussing Monsanto competitor Dupont's claims that "Monsanto is using abusive patent license provisions").

10. *Monsanto Won't Block Generic Seeds*, *supra* note 9.

This Note outlines current issues surrounding the regulation of generic GMOs and proposes changes to existing USDA regulations. Part I provides an overview of the current regulatory issues and patent protections used in the agriculture industry that impact the availability of generic GMOs. Part II briefly compares the agriculture industry to the pharmaceutical industry and then contemplates how the pharmaceutical industry may be instructive in establishing USDA regulations that are more effective while ensuring an efficient transition to the use of generic GMOs. This Note concludes that the USDA should adopt a regulation similar to the Hatch-Waxman Act to facilitate the entrance of generic GMOs in the market.

I. OVERVIEW OF GENETICALLY MODIFIED ORGANISMS, REGULATIONS, AND PATENT PROTECTIONS

A. GENETICALLY MODIFIED ORGANISMS

A genetically modified organism is an “organism where the genetic material is altered unnaturally through fertilization and/or recombination.”¹¹ An organism’s genetic material is typically altered to confer some benefit—usually economic in nature.¹² One variation of a GMO is genetically engineered crops, which are engineered to provide various benefits to farmers ranging from weed and insect resistance to enhanced drought tolerance.¹³ Monsanto’s RR soybeans are a genetically engineered crop because the company has modified the soybean to build a tolerance to glyphosate.¹⁴ Glyphosate is an active ingre-

11. Debdatta Dobe & Rohini Sen, *Genetically Modified Organisms Trade Route and Biosafety—Is it a Failing Synthesis?*, 1 AM. J. OF ECON. & BUS. ADMIN. 206, 206 (2009), available at <http://thescipub.com/html/10.3844/ajebasp.2009.206.212>.

12. See *Genetically Modified Food: What are Genetically Modified Foods?*, NAT. HEALTH GUIDE, <http://www.natural-health-guide.com/genetically-modified-food.html>, (last visited Aug. 28, 2011).

13. See *USDA FAQs*, *supra* note 8. The USDA defines genetic engineering as the “[m]anipulation of an organism’s genes using the methods of modern molecular biology.” *Biotechnology: Glossary of Agricultural Biotechnology Terms*, U.S. DEP’T OF AGRIC., <http://www.usda.gov/wps/portal/usda/usda/home?contentid=BiotechnologyGlosary.xml&navid=AGRICULTURE> (last visited Sept. 11, 2011).

14. *Safety Assessment of Roundup Ready Soybean Event 40-3-2*, MONSANTO (Sept. 2002), http://www.monsanto.com/products/Documents/safety-summaries/soybean_es.pdf [hereinafter *Safety Assessment*].

dient in Monsanto's Roundup herbicides.¹⁵ By engineering the soybean to have a tolerance to glyphosate, farmers are able to spray fields with Monsanto's herbicides without killing the soybeans.¹⁶ Moreover, the Roundup herbicide is effective against several types of weeds and grasses, which allow the farmers to spray less often.¹⁷ Since farmers do not need to spray as often, Roundup herbicides enable farmers to save money on fertilizer, implement effective weed management programs, and be more environmentally friendly.¹⁸

B. THE GREAT DEBATE: DO THE BENEFITS OF GMOs OUTWEIGH THE RISKS?

In addition to the various benefits attributed to Monsanto's RR soybeans, there are also several concerns about their use.¹⁹ One concern is that RR soybeans build herbicide resistance in weeds.²⁰ Studies have shown that weed resistance to glyphosate has increased since the introduction of RR crops.²¹ If the weeds are less resistant to the Roundup herbicide, more herbicide is required to effectively eradicate the weeds; thus, removing some of the benefits associated with the use of RR soybeans.²²

The controversy surrounding the use of RR soybeans is just one example of the larger debate regarding the use of GMOs in general.²³ The various advantages of GMOs that proponents point to include: drought tolerance, disease resistance, and pest

15. *Id.*

16. See Barry A. Palevitz, *DNA Surprise: Monsanto Discovers Extra Sequences in its Roundup Ready Soybeans*, 14 THE SCIENTIST 20 (2000), available at <http://classic.the-scientist.com/article/display/11963>.

17. *Safety Assessment*, *supra* note 14.

18. *Id.*

19. See Deborah Whitman, *Genetically Modified Foods: Harmful or Helpful*, CSA DISCOVERY GUIDES, at 5 (Apr. 2000), <http://www.csa.com/discoveryguides/gmfood/review.pdf>.

20. *Id.* at 6.

21. Terrance Hurley et al., *Effects of Weed-Resistance Concerns and Resistance-Management Practices on the Value of Roundup Ready Crops*, 12 J. AGROBIOTECH. MGMT. & ECON. 291, 291 (2009), available at <http://www.agbioforum.org/v12n34/v12n34a05-mitchell.pdf>.

22. See *Monsanto and the Roundup Ready Controversy*, SOURCEWATCH.ORG, http://www.sourcewatch.org/index.php?title=Monsanto_and_the_Roundup_Ready_Controversy (last modified May 13, 2010, 12:30 AM).

23. Whitman, *supra* note 19, at 1.

resistance.²⁴ GMOs may also improve nutrition, especially in developing countries.²⁵ In addition, scientists are beginning to modify plants to have pharmaceutical value with the goal of making medicine more accessible, especially to those in developing countries.²⁶

For all the benefits associated with the use of GMOs, critics point out that there are also downsides.²⁷ Critics of GMOs cannot be easily categorized—ranging from members of religious organizations and environmental activists to scientists and government officials.²⁸ These critics claim the potential risks and drawbacks to GMOs outweigh the potential benefits.²⁹ In addition to environmental concerns, such as transferring genes to unintended species, there are also human health risks and economic concerns.³⁰ One persistent health concern is that the use of GMOs may create new allergies or that a gene introduced in a plant may cause an allergic reaction.³¹ For example, many Americans have an allergy to peanuts. If a scientist introduces a gene from a peanut into soybeans, the gene may cause an allergic reaction in an unsuspecting person.³²

One economic concern regarding GMOs is the potential to marginalize the poor.³³ GMOs require extensive research and development before they may be commercialized.³⁴ As a result, companies seek protective patents on their products in order to recoup their initial investments.³⁵ However, critics worry that the protective patents will allow companies to raise prices so high that developing countries and smaller farmers will be unable to purchase the seeds and benefit from them, “thus widen-

24. *Id.* at 2–4.

25. *Id.* at 3. For example, some developing countries rely on rice for food, but rice by itself contains small amounts of nutritional value. Therefore, if the rice can be modified to add vitamins and minerals, it could ameliorate the malnutrition problem in some developing countries. *Id.*

26. *Id.*

27. *See generally id.* (outlining several positive and negative aspects associated with the use of GMOs).

28. *Id.* at 5.

29. *E.g., Genetically Modified Food, supra* note 12.

30. Whitman, *supra* note 19, at 7–8.

31. *Id.* at 7.

32. *See, e.g., id.*

33. *Id.*

34. *Id.*

35. *Id.*

ing the gap between the wealthy and the poor.”³⁶

The debate surrounding the use of GMOs is not limited to the United States.³⁷ Countries around the world are divided on the use of GMOs.³⁸ The international dispute over GMOs involves issues such as the “technical aspects of GMOs and their international impacts” as well as “consumer education related to GMOs.”³⁹

C. REGULATING GMOS

1. Food Safety in the United States: A Coordinated Framework

The U.S. Government places the responsibility of policing GMOs with three primary agencies: the Food & Drug Administration (FDA), the Environmental Protection Agency (EPA), and the USDA.⁴⁰ The agency that regulates a specific GMO depends on the intended use of the product.⁴¹ The FDA generally regulates foods in interstate commerce that are eaten by animals or humans, such as a bowl of cornflakes.⁴² Meanwhile, the EPA determines the environmental risks of pesticides and genetically engineered plants containing altered pesticide properties.⁴³ The EPA conducts risk assessments on pesticides that pose a potential harm to humans or the environment. There are strict guidelines regarding the amount of pesticides that may be present while the crop is growing, in addition to the level of pesticide retained in the food. Farmers must ensure they are

36. *Id.*

37. *See* Dobe & Sen, *supra* note 11, at 208.

38. *Id.* Countries like Japan, the United Kingdom, and Taiwan are more reluctant to use GMOs than the United States. *Id.* Some of this reluctance may stem from mistrust in governmental regulatory oversight for food. *See id.* For example, in the United Kingdom, part of this mistrust arguably arises from recent food scares. Sally Eden, et al., *The Sceptical Consumer? Exploring Views About Food Assurance*, 33 FOOD POL’Y 624, 624 (2008).

39. Dobe & Sen, *supra* note 11, at 208.

40. *USDA FAQs*, *supra* note 13.

41. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986) (“Jurisdiction over the varied biotechnology products is determined by their use”); *USDA FAQs*, *supra* note 13.

42. Whitman, *supra* note 19 (noting that the FDA regulates cornflakes because it is considered a “food product” and not a “whole food”); *see also* Alan McHughen, *Plant Genetic Engineering and Regulation in the United States*, UNIV. OF CAL. DIVISION OF AGRIC. & NAT. RESOURCES, at 3, <http://ucanr.org/freepubs/docs/8179.pdf> (last visited Aug. 28, 2011).

43. McHughen, *supra* note 42, at 3.

adhering to the EPA's safety standards.⁴⁴

The USDA—the third agency in the coordinated framework—assesses how safe it is to grow the genetically engineered plant.⁴⁵ For example, while the FDA regulates cornflakes, the USDA regulates the corn that was a raw material in producing the cornflakes.⁴⁶ The USDA monitors for various environmental problems, such as insects developing resistance to certain genetically engineered crops, and conducts studies to determine the relative safety of genetically engineered plants, animals, and microorganisms.⁴⁷ Specifically, the USDA's Animal and Plant Health Inspection Service (APHIS) division is responsible for ensuring that U.S. crops are free of pests and disease.⁴⁸

Monsanto's Roundup Ready soybeans are regulated by both the USDA and the EPA. Soybeans are like corn in that they are considered a "whole food," so the USDA is responsible for ensuring that the modified soybean plant is safe to grow and will not adversely affect other agriculture and the environment.⁴⁹ The EPA is responsible for assessing whether the RR soybean crops are safe to use.⁵⁰

2. The Inner-Workings of Current and Proposed USDA Regulations

The USDA derives its regulatory power over GMOs—like RR soybeans—from the Plant Protection Act (PPA).⁵¹ The PPA

44. See Whitman, *supra* note 19, at 10 ("The USDA is concerned with potential hazards of the plant itself. Does it harbor insects? Is it a noxious weed? Will it cause harm to indigenous species . . . ?").

45. See *id.*

46. See *id.*

47. *Id.*

48. *USDA FAQs*, *supra* note 13.

49. See McHughen, *supra* note 42, at 3; Whittman, *supra* note 19; see, e.g., Louise Prance, *USDA Grants New Soybean Deregulation*, FOODNAVIGATOR.COM (Aug. 6, 2007), <http://www.foodnavigator-usa.com/Regulation/USDA-grants-new-soybean-deregulation> (noting that the USDA regulates Monsanto's RR soybeans).

50. Maggie Delano, *Key Players*, ROUNDUP READY CROPS, <http://web.mit.edu/demoscience/Monsanto/players.html> (last visited Aug. 28, 2011).

51. Plant Protection Act, 7 U.S.C. § 7711 (2006). Prior to the enactment of the PPA in 2000, APHIS derived its regulatory power from two acts: the Plant Quarantine Act (PQA) and the Federal Plant Pest Act (FPPA). Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV.

grants the USDA the authority to “prohibit or restrict . . . any plant . . . if [the Secretary of Agriculture] determines that the prohibition or restriction is necessary to prevent . . . the dissemination of a plant pest or noxious weed within the United States.”⁵² The PPA defines “plant pest” broadly, which results in the USDA having the authority to regulate GMOs.⁵³ The USDA then delegates to APHIS the task of ensuring compliance with the PPA.⁵⁴

The PPA requires developers of a GMO to first evaluate the risk of the plant, and then follow either a notification or permit process.⁵⁵ The goal of both processes is to prevent the escape of harmful GMOs into the environment.⁵⁶ The notification process, however, is shorter and simpler than the permit process.⁵⁷

A developer can follow the notification process so long as it meets the following six standards: (1) the plant is not a “noxious weed”; (2) the genetic material is “stably integrated”; (3) the function of the genetic material is known and will not result in plant disease; (4) the genetic material does not cause “production of an infection entity,” encode substances that will “be toxic to non-target organisms,” or “encode products intended for pharmaceutical or industrial use”; (5) plant virus-derived genetic material must be “noncoding regulatory sequences of known function, or . . . prevalent and endemic in the area where introduction will occur”; and (6) the plant cannot be modified to contain certain “genetic material[s] from animal or human pathogens.”⁵⁸

2167, 2224 (2004).

52. Plant Protection Act, 7 U.S.C. § 7712(a) (2006).

53. See 7 C.F.R. § 340.1 (2010) (defining “plant pests” as “[a]ny living stage of . . . invertebrate animals, bacteria, fungi, other parasitic plants . . . or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants . . . or any processed, manufactured, or other products of plants”).

54. See Mandel, *supra* note 51, at 2224.

55. *Id.* at 2225.

56. *Id.* at 2225–26.

57. See *id.* at 2226. “Nearly 99% of all field tests, importations, and interstate movement of genetically engineered plants take place under the notification system.” *Id.*

58. 7 C.F.R. § 340.3(b)(1)–(6). If the six standards are met then the developer needs to only mail notification to APHIS with contact information for the developer, identifying information for the “regulated article,” the location of where the environmental release will take place, the date of the release, and a

If, however, the GMO is unable to meet all six criteria then the developer must follow the longer permit process.⁵⁹ Two versions of the permit application must be submitted.⁶⁰ The first copy should contain confidential information and trade secrets, but those pages containing this information should be marked “CBI copy,”⁶¹ and the second copy of the application should have the confidential information redacted with “CBI deleted” on those pages.⁶² Additionally, developers can ask that their genetically engineered plant be granted “nonregulated status.”⁶³ The developer must prepare a complete statement supporting why the GMO should be granted non-regulatory status.⁶⁴ Moreover, APHIS must prepare a detailed environmental impact statement (EIS) when it takes “major Federal actions significantly affecting the quality of the human environment.”⁶⁵ If the GMO will not have a substantial environmental impact, the shorter environmental assessment (EA) suffices.⁶⁶ Typically only one APHIS employee determines whether the notification process is sufficient to approve the genetically engineered plant without any public or scientific expert comment.⁶⁷ Further—as currently applied—once a plant has been granted non-regulated status, the plant’s status is “absolute” and the agency will not have “further oversight of the plant or its progeny and descendants.”⁶⁸

APHIS is currently in the process of revising its regulations for GMOs.⁶⁹ The goal of the revisions is to improve trans-

statement certifying that the six standards are met. 7 C.F.R. § 340.3(d).

59. 7 C.F.R. § 340.3(e). The permit application must be filed at least 120 days before the contemplated release of the plant as compared to only 30 days under the notification process. 7 C.F.R. § 340.4(b).

60. 7 C.F.R. § 340.4(a).

61. CBI stands for “confidential business information.” *Id.*

62. *Id.*

63. 7 C.F.R. § 340.6(a).

64. 7 C.F.R. § 340.6(b). The developer must “include copies of scientific literature, copies of unpublished studies . . . and data from tests performed . . .” *Id.*

65. 42 U.S.C. § 4332(2)(c) (2006).

66. *See* 40 C.F.R. § 1508.13 (2010).

67. COMM. ON ENVTL. IMPACTS ASSOC. WITH COMMERCIALIZATION OF TRANSGENIC PLANTS ET AL., ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 9 (2002), available at http://books.nap.edu/openbook.php?record_id=10258&page=1.

68. *Id.* at 10.

69. *See Proposed Revisions to APHIS Regulation of Genetically Engineered Organisms*, U.S. DEPT OF AGRIC., <http://www.aphis.usda.gov/biotechnology/>

parency, eliminate unnecessary regulations, and enhance clarity of regulations.⁷⁰ Under the proposed regulations, the notification process would be removed⁷¹ and replaced with three types of permits: interstate movement, importation, and environmental release.⁷² Permits for an environmental release would include a multiple category system.⁷³ The categories would be based on the risk associated with the genetically engineered plant as well as the ability of the unmodified version of the plant to survive with the introduction of the modified plant.⁷⁴ The proposed regulations would purportedly clarify the process and standard used to determine approval for nonregulated status.⁷⁵ Further, a procedure may be included that allows APHIS to revoke nonregulated status.⁷⁶ Those genetically engineered plants currently non-regulated will be grandfathered in and continue to have such status.⁷⁷

Changes to the regulations, however, have been slow in coming.⁷⁸ In July 2007, APHIS issued a Draft Environmental Issue Statement summarizing the issues APHIS was contemplating while making the changes.⁷⁹ One of the significant

340/340_index.shtml (last modified Mar. 22, 2011) [hereinafter *Proposed Revisions to APHIS*].

70. See Transcript of a Media Call on the Proposed Regulatory Revisions, FTS-USDA-APHIS (Oct. 6, 2008), available at http://www.aphis.usda.gov/newsroom/content/2008/10/content/printable/brs_transcript_340_10608.pdf [hereinafter Transcript of a Media Call].

71. *Questions and Answers: Proposed Revisions to Biotechnology Regulations*, USDA-APHIS (Oct. 2008), http://www.aphis.usda.gov/publications/biotechnology/content/printable_version/faq_brs340.pdf [hereinafter *Questions and Answers*].

72. Martha E. Marrapese, *USDA APHIS Proposes Amendments to Regulations Regarding Genetically Engineered Organisms*, MARTINDALE.COM (July 31, 2009), http://www.martindale.com/technology-science-law/article_Keller-Heckman-LLP_763758.htm.

73. *Questions and Answers*, *supra* note 71.

74. Marrapese, *supra* note 72. All other genetically engineered organisms besides genetically engineered plants “would be placed into a single category and reviewed on a case-by-case basis.” *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. See *Proposed Revisions to APHIS*, *supra* note 69 (showing that changes to the USDA regulations for biotechnology were first considered in 2007, but no revisions have been forthcoming since the public comment period ended mid-2009).

79. *Lessons Learned and Revisions Under Consideration APHIS' Biotechnology Framework*, USDA 1, <http://www.aphis.usda.gov/newsroom/content/>

changes proposed is replacing the current notification system with the previously discussed multi-permit system.⁸⁰ The proposed revisions were open for public comment on October 9, 2008 and reopened for public comment on January 16, 2009, which was extended until June 29, 2009.⁸¹ Since the end of the comment period in June 2009, APHIS has not made further publications to indicate the strides it is making with the revisions.⁸² Noticeably absent in USDA regulations, as well as in the proposed revisions, is the procedure for regulating generic GMOs.⁸³

3. Current USDA Regulations Leave Much To Be Desired

Despite the USDA's attempts to effectively regulate genetically engineered crops, problems still exist. First, the USDA's current GMO regulations are inadequate for effective regulation.⁸⁴ The PPA only covers those GMOs classified as "plant pests."⁸⁵ As a result, the PPA does not cover those organisms that are beneficial to plants, nor nonparasitic plants, nor vertebrate animals.⁸⁶ Therefore, many biological species remain unregulated, even though environmental risks may exist.⁸⁷

Second, recent cases demonstrate that APHIS has not dili-

2007/10/content/printable/LessonsLearned10-2007.pdf (last visited Aug. 28, 2011). The purpose of the Draft Environmental Issue Statement is to assess the environmental impact proposed changes would have. *Proposed Revisions to APHIS*, *supra* note 69.

80. See Transcript of a Media Call, *supra* note 70.

81. *Proposed Revisions to APHIS*, *supra* note 69.

82. *Id.*

83. See Parloff, *supra* note 2 (noting that there is a "legislative void" in transitioning products from patented protection to generic competition).

84. William Allen, *The Current Federal Regulatory Framework for Release of Genetically Altered Organisms into the Environment*, 42 FLA. L. REV. 531, 545 (1990).

85. *Id.*

86. *Id.*

87. *Id.* For example, the FDA, rather than the USDA, determines whether genetically modified salmon should be approved for human consumption. Kim Carollo, *Surprise: FDA Panel Unable to Reach Conclusion on Genetically Modified Salmon*, ABC NEWS (Sept. 20, 2010), <http://abcnews.go.com/Health/WellnessNews/fda-unable-reach-conclusion-genetically-modified-salmon/story?id=11682586>. While the Federal Food and Drug Cosmetic Act may be seen as giving the FDA regulatory authority over animals, like salmon, its authority has not been clearly established. *Guides to U.S. Regulation of Genetically Modified Food and Agricultural Biotechnology Products*, PEW INITIATIVE ON FOOD & BIOTECH. 22, available at http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf.

gently followed the procedures required by the PPA.⁸⁸ For example, the USDA has failed to prepare an EIS in several instances.⁸⁹ In 2005, APHIS deregulated RR alfalfa but failed to first prepare an EIS, allegedly in violation of 42 U.S.C. § 4332(2)(c).⁹⁰ Even though APHIS received over 500 comments opposing the deregulation of RR alfalfa and despite APHIS's own internal documents warning that contamination could occur, APHIS still granted RR alfalfa deregulated status.⁹¹

APHIS again failed to complete an EIS before deregulating genetically engineered sugar beets.⁹² The California District Court ruled that APHIS violated the law by not first preparing an EIS and prohibited future plantings of genetically engineered sugar beets until an EIS was prepared.⁹³

C. PREVENTING GENERIC COMPETITION THROUGH GMO PATENTS

Even though Monsanto has announced that it will not impede manufacturers from making a generic version of the RR soybean once its patent expires in 2014,⁹⁴ farmers and Monsanto's competitors still worry that the company will use various tactics to prevent the market entrance of a generic version.⁹⁵ Some of this fear stems from hard-line tactics Monsanto has previously used to protect its RR soybean patents as well as from concerns regarding the recent development of its Roundup Ready 2 (RR2) soybean.

88. Deniza Gertsberg, *Internal Reports Finds USDA's Failure to Effectively Regulate GMOs*, GMO J. (Jan. 28, 2010), <http://gmo-journal.com/index.php/2010/01/28/internal-report-finds-usdas-failure-to-effectively-regulate-gmos>. A 2005 Inspector General report found that the USDA at times was unaware of the specific location where a GMO was to be planted; the agency failed to adequately document its reasons for approving "initial field test applications" and the agency did not always require a report of what was to be done with the GM crops after the trial was complete. *Id.*

89. *E.g.*, *Monsanto Co. v. Geerston Seed Farms*, 130 S. Ct. 2743, 2758 (2010).

90. *Id.*

91. *Id.* at 2762–63 (Stevens, J., dissenting).

92. *Center for Food Safety v. Vilsack*, 734 F. Supp. 2d 948, 950 (N.D. Cal. 2010).

93. *Id.* at 952–53.

94. Kaskey, *supra* note 6; see *Roundup Ready Soybean Patent Expiration*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/roundup-ready-patent-expiration.aspx> (last visited Aug. 28, 2011).

95. Kaskey, *supra* note 6.

One significant way Monsanto defends its RR soybean patent is by prohibiting farmers from saving the seeds of RR soybeans. A farmer that purchases RR soybeans is required to sign a written document agreeing not to save or replant seeds produced from a grown RR soybean plant.⁹⁶ Monsanto's rationale behind the prohibition is that a farmer has not paid for the soybeans featuring Monsanto technology if they are grown from the saved seeds.⁹⁷ Accordingly, Monsanto has sued farmers who have violated the agreement.⁹⁸ Farmers meanwhile have criticized Monsanto for employing this tactic.⁹⁹

Even though farmers will be able to save and replant seeds grown from their own crop once the RR soybean patent expires in 2014, farmers still fear that Monsanto's introduction of the RR2 soybean is another tactic the company will use to impede the development of a generic version of the soybean.¹⁰⁰ It is feared that in an effort to induce the market to adopt the RR2 soybeans, Monsanto could force farmers to begin purchasing the new RR2 variety before a generic version of the older RR soybean is widely adopted.¹⁰¹ As a result, the generic RR soybean, set to go off patent in 2014, would no longer be as desirable and there would be less incentive for generic manufacturers to duplicate the RR soybean.¹⁰²

The concerns regarding the forced adoption of a similar GMO and aggressive patent protections are just two examples of tactics used by companies to protect their patented products.¹⁰³ Critics believe, however, that these tactics lead to higher prices and limit the public's ability to purchase and benefit

96. *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 Aug. 28, 2011).

97. *See id.*

98. *Id.* Between 1997 and April 2010, Monsanto filed lawsuits against 144 farmers. *Id.*

99. *Monsanto Won't Block Generic Seeds*, *supra* note 9 ("Farmers criticized Monsanto in the 2008 documentary 'Food Inc.' for its contracts to keep them from saving seeds after a harvest."). The criticisms have included suing farmers at all for having saved seeds, "suing a small farmer for cleaning seeds," and fear of suing farmers for genetically engineered crops that blew into a farmer's field. *Food, Inc. Movie*, MONSANTO, <http://www.monsanto.com/food-inc/Pages/default.aspx> (last visited Nov. 1, 2011).

100. *See Monsanto and the Roundup Ready Controversy*, *supra* note 22.

101. Michael Stumo, *Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits*, 15 DRAKE J. AGRIC. L. 137, 140-41 (2010).

102. *See id.* at 142.

103. *See Stumo*, *supra* note 101, at 140-43.

from genetically engineered crops.¹⁰⁴

D. THE NEED FOR CHANGE

The entrance of generics into the market will magnify the problems currently seen with respect to GMOs—inadequate and ineffective administration of current GMO regulations as well as the hard-line patent protection policies used by name brand companies.¹⁰⁵ The lower prices from the sale of generics will likely result in increased demand.¹⁰⁶ If demand increases, the negative health and environmental effects will be exacerbated as more people use GMOs.¹⁰⁷ In addition, name brand companies will engage in more tactics to protect their patents and maintain their market share.¹⁰⁸ On the other hand, there are various benefits associated with the use of GMOs, and the use of generic GMOs will also lead to more people realizing

104. See Kaskey, *supra* note 6; see also Whitman, *supra* note 19, at 7 (“[C]onsumer advocates are worried that patenting these new plant varieties will raise the price of seeds so high that small farmers and third world countries will not be able to afford seeds from GM crops . . .”).

105. See *supra* notes 94–104 and accompanying text.

106. Cf. *Economics Basics: Demand and Supply*, INVESTOPEDIA, <http://www.investopedia.com/university/economics/economics3.asp> (last visited Aug. 28, 2011). The pharmaceutical industry, for example, has seen the effect that lower prices have on demand. The decreased pricing associated with generics is caused by the influx of generic brands hitting the market after the expiration of a patent. See CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 28 (1998). As a result, the different competitors try to differentiate themselves by dropping prices to incentivize consumers to purchase their version of a drug. *Id.* at 32. The manufacturers of generic drugs are able to set lower prices because they do not have the initial investment costs of brand-name manufacturers. Cf. *id.* at 14–16 (explaining the costs incurred by drug manufacturers during new drug development). A Federal Trade Commission report found that after a pharmaceutical drug’s patent expires and two generic companies begin immediately selling a generic version of the drug, the price is 6.5% lower on average as compared to only 4.5% lower on average if only one generic manufacturer enters the market. Daniel B. Moskowitz, *FTC: Authorized Generics Lead to Lower Prices*, DRUG BENEFIT TRENDS (Aug. 1, 2009), <http://dbt.consultantlive.com/generics/content/article/1145628/1465515>. Moreover, even Monsanto recognizes that a benefit of generic RR soybeans is the increased availability of the technology to the public. *Roundup Ready Soybean Patent Expiration*, *supra* note 94.

107. “Farmers and seed companies, having paid dearly for Roundup Ready’s benefits throughout its patent life, are now eager to begin enjoying their half of the patent bargain—the point when Monsanto’s legal monopoly expires and Roundup Ready enters the public domain.” Parloff, *supra* note 2.

108. Stumo, *supra* note 101, at 140.

these advantages.¹⁰⁹ One of the possible advantages of a generic RR soybean is the possibility that it might address the economic concerns of small farmers who are unable to afford genetically engineered crops such as RR soybeans.¹¹⁰ With the entrance of generic genetically engineered crops into the market and the resulting lower prices, more farmers will be able to afford the technology.¹¹¹

Given the magnification of advantages that may result from the increased availability of generic GMOs, the USDA-APHIS should revise its regulations to facilitate the market entrance of generic GMOs in order to realize the various benefits from their use. With any increase in the use of GMOs the disadvantages attributed to their use will also be magnified, so regulatory oversight of generic GMOs is still necessary in order to limit these concerns.

II. ANALYSIS

While the USDA-APHIS is currently revising its regulations for GMOs, we should also consider striking a proper balance between ensuring that generic GMOs are safe, spurring innovation, and promoting competition. To help strike the proper balance, the USDA can look to the pharmaceutical industry and the Hatch-Waxman Act. The Hatch-Waxman Act is a useful regulatory structure that supports the entrance of generic drugs while protecting name brand companies that originally developed the drugs. In addition, the recently passed Biosimilar Act further supports the adoption of an act similar to the Hatch-Waxman Act by the agriculture industry.

A. AN INDUSTRY COMPARISON

The agriculture industry and pharmaceutical industry are similar in various ways. First, both industries require significant initial costs in development, either of a genetically engineered crop or a new drug, and then in bringing the new product to market. Monsanto has stated that it typically takes an

109. Whitman, *supra* note 19, at 2–4 (listing the potential benefits of GMOs). If the disadvantages of using generic GMOs are magnified as more people gain access to the technology, there should also be an increase in the benefits associated with the use of GMOs as well. *See generally id.* at 7–8 (explaining that small farmers do not have the financial ability to take advantage of GMOs).

110. *See generally id.* at 7–8.

111. *See id.* at 7.

average of ten years and \$100 million to bring a new product to market,¹¹² and the Congressional Budget Office notes that pharmaceutical companies can spend more than \$800 million to develop an innovative pharmaceutical drug.¹¹³ Second, each industry utilizes mergers and acquisitions to reduce costs, augment product offerings, and increase the number of patents.¹¹⁴ In the agriculture industry, there has been an upward trend in mergers and acquisitions since the late 1990s¹¹⁵ and “by 2002, 95[%] of patents originally held by seed or small ag-biotech firms had been acquired by large chemical or multinational corporations.”¹¹⁶ The pharmaceutical industry has also had numerous restructurings through mergers and acquisitions resulting in the ten largest companies accounting for approximately fifty percent of worldwide sales in 2002 as compared to only twelve percent in 1987.

Third, besides using acquisitions to offset the substantial investment costs, both industries have utilized various patent protections to protect their investments. One of agriculture industry’s largest firms—Monsanto—has employed patent pro-

112. Jeffrey Tomich, *Monsanto Growth Falters as SmartStax Yields, Pricing Raise Questions*, STLtoday.COM (Oct. 6, 2010, 12:05 AM), http://www.stltoday.com/business/article_b0c5044b-c54d-5a84-a92a-042b3f7ef7da.html; see also *Why Does Monsanto Sue Farmers Who Save Seeds?*, *supra* note 96 (“[Monsanto] currently invest[s] over \$2.6 million per day to develop and bring new products to market.”).

113. CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2 (2006), available at <http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D>. However, there is research suggesting that the \$800 million research and development estimate is too low and that the cost actually is closer to \$1 billion. *Cost of Drug Development: \$1 Billion*, HEALTHCARE ECONOMIST (Feb. 16, 2010), <http://healthcare-economist.com/2010/02/16/cost-of-drug-development-1-billion> (citing Christopher Paul Adams & Van Vu Brantner, *Spending on New Drug Development*, 19 HEALTH ECON. 130,138 (2010)).

114. See Margaret Brennan, et. al., *An Innovation Market Approach to Analyzing Impacts of Mergers and Acquisitions in the Plant Biotechnology Industry*, 8 J. AGROBIOTECH. MGMT. & ECON. 2&3, 89, 89 (2005), available at <http://agbioforum.org/v8n23/v8n23a05-pray.pdf><http://agbioforum.org/v8n23/v8n23a05-pray.htm>; Natasha Singer & Duff Wilson, *Drug Firms Dreaming of Deals*, N.Y. TIMES, Feb. 25, 2009, at B1, available at http://www.nytimes.com/2009/02/25/business/25place.html?_r=1&ref=busines.

115. UNITED NATIONS CONFERENCE ON TRADE AND DEV., TRACKING THE TREND TOWARDS MARKET CONCENTRATION: THE CASE OF THE AGRICULTURAL INPUT 26 (2006) [hereinafter UNCTAD], available at http://www.unctad.org/en/docs/ditccom200516_en.pdf.

116. *Id.* at 26.

tections ranging from refusing to allow farmers to save seeds to allegedly contemplating requiring farmers to purchase its new RR2 soybean, while discontinuing the original version of its RR soybean. Similarly, the pharmaceutical industry has been criticized for “product hopping,” where a pharmaceutical company switches the formulation of its patented drug and removes the “old version” as soon as the generic company files its Abbreviated New Drug Application (ANDA), which forces the generic company to either start the regulatory procedures over or refrain from entering the market for that drug.¹¹⁷

B. THE HATCH-WAXMAN ACT

The Hatch-Waxman Act is a viable regulatory framework for the agricultural industry. The similarities between the pharmaceutical and agriculture industries¹¹⁸ and the effectiveness of the Hatch-Waxman Act in the pharmaceutical industry,¹¹⁹ suggest that use of such a framework would be successful. Specifically, Hatch-Waxman is instructive on how to structure regulation for the entrance of generic GMOs into the market while still protecting the investments companies made in developing the name brand GMOs.

1. The Inner Workings of the Hatch-Waxman Act

Pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA), new drugs must be shown to be safe before they may be sold.¹²⁰ Meanwhile, drug research and development is a risky venture because development requires much investment with low rates of success.¹²¹ As a result, name brand drug manufacturers rely on patents to recoup their investments in developing the drug. Before the enactment of the Hatch-Waxman Act, name brand pharmaceutical companies lobbied for a more

117. Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Context*, 2007 MICH. ST. L. REV. 631, 657–58.

118. See *supra* notes 112–117 and accompanying text.

119. Aaron F. Barkoff, *Patent Litigation Under a Future Biosimilars Act*, 6 SNIPPETS 1, 1 (May 2008), available at http://www.mbhb.com/resources/documents/Snippets_Vol_6_Issue_1.pdf.

120. 21 U.S.C. § 355(b)(1) (2006); FDA, A HISTORY OF THE FDA AND DRUG REGULATION IN THE UNITED STATES 2 (n.d.), available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/ucm093550.pdf>.

121. James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 449 (1986).

efficient approval process to receive greater benefit from their patents because the longer review periods reduced the effective length of patent protection.¹²² In addition, generic drug companies claimed that requiring “generic equivalents” to undergo the same lengthy process required of name brand manufacturers “unfairly delayed drug price competition.”¹²³

Responding to claims from both name brand and generic drug manufacturers,¹²⁴ Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act.¹²⁵ The Act first allowed pharmaceutical companies to apply for a patent extension of up to five years if the patent life was less than fourteen years after FDA approval.¹²⁶ The Act also provided for an ANDA. An ANDA is “abbreviated” because preclinical and clinical trials are not typically required for FDA approval of the drug.¹²⁷ Instead, the generic manufacturer must only prove that the generic drug is bio-equivalent to the name brand one.¹²⁸

When a generic manufacturer applies for an ANDA, the manufacturer must certify that to the best of its knowledge it meets one of four paragraph certifications as related to the listed drug—(I) no patent exists that covers the product; (II) the patent has expired; (III) the generic manufacturer will not seek FDA approval until the patent expires; or (IV) the patent is invalid or will not be infringed if the generic drug company produces the drug.¹²⁹

122. *Id.* at 435.

123. *Id.*

124. *Id.*

125. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585 (codified as amended 21 U.S.C. § 355 (2006)).

126. Wheaton, *supra* note 121, at 435.

127. *Abbreviated New Drug Application (ANDA): Generics*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/default.htm> (last updated Mar. 21, 2011).

128. *Id.* Bioequivalence means that the generic drug performs in the same way as the name brand drug. *Id.* Bioequivalence is shown by measuring the time it takes the generic drug to reach the blood stream. The resulting absorption rate is known as the bioavailability of the generic drug. *Id.* “The generic version must deliver the same amount of active ingredients into a patient’s bloodstream in the same amount of time as the innovator drug.” *Id.*

129. Drug Price Competition and Patent Term Restoration Act § 101(2)(A)(vii)(I)–(IV).

If, however, the patent holder does not bring a lawsuit within forty-five days of notice, the FDA may approve the ANDA and/or the generic manufacturer can sue.¹³⁰ In addition, the generic manufacturer(s) that first file(s) an application with a paragraph IV certification will receive 180-days of market exclusivity beginning the “date of first commercial marketing.”¹³¹ The 180-day market exclusivity period, however, may be forfeited in various ways, including the “fail[ure] to market the drug within seventy-five days of approval or within thirty-months after submission of the ANDA.”¹³²

2. Applying the Hatch-Waxman Act in the Agriculture Industry

As discussed earlier in this Note, the agriculture industry is similar to the pharmaceutical industry in several ways, including substantial investment costs.¹³³ Given the high investment costs, it is important to ensure that the manufacturers of name brand GMOs, like Monsanto, continue to be incentivized to develop novel products. Therefore, patent protection is necessary. The agriculture industry appears to be facing the same concerns the pharmaceutical industry faced prior to enactment of the Hatch-Waxman Act: name brand manufacturers wanted reduced review periods to effectively lengthen the patent period, while generic manufacturers wanted a shortened review process when producing a generic equivalent. However, the need for patent protection must be balanced against the need for additional competition in the form of generic GMOs. The Hatch-Waxman Act is instrumental in accomplishing both these goals.

The Hatch-Waxman Act provides access to data, and in return the name brand company receives patent protection. The Act, as applied to the agriculture industry, could work much like it does in the pharmaceutical industry. Under the Act, name brand manufacturers could extend the patent life depending upon the years remaining on the patent after USDA

130. *Id.* at 614. The 180-day market exclusivity period provides that the FDA may not approve ANDAs for the same drug by other generic manufacturers. *Id.*

131. *Id.* at 619.

132. D. Christopher Ohly, *The Hatch-Waxman Act: Prescriptions for Innovative and Inexpensive Medicines*, SCHIFFHARDIN LLP, at 18 (Spring 2010), http://www.schiffhardin.com/binary/ohly-Hatch_Waxman_Prescriptions-42010.pdf.

133. See *supra* notes 112–117 and accompanying text.

approval, while generic manufacturers could follow an abbreviated application process if able to show generic equivalence to the name brand version of the crop.

When it comes to generic versions of genetically engineered crops, there are two access points from which a “generic” version of the seed may be obtained: (1) by purchasing seed from a generic manufacturer or (2) reusing seed from a previously grown RR soybean plant.¹³⁴ With respect to access point (1)—purchasing seeds from a generic manufacturer—an act similar to the Hatch-Waxman Act is important in ensuring that data is available to produce a generic version of the RR soybean. Due to current regulations, a generic manufacturer will need proprietary information from Monsanto to receive federal approval and the technical data needed to update licenses in areas like the European Union (EU) and China,¹³⁵ where regulations tend to be stricter.¹³⁶ If the agriculture industry adopted an act similar to the Hatch-Waxman Act, a generic manufacturer could develop a generic version based on the data provided in Monsanto’s patent and receive USDA approval through an abbreviated process. The generic manufacturer would only need to show that the generic RR soybean is equivalent to the name brand soybean.¹³⁷ In addition, an act like the Hatch-Waxman Act would allow generic manufacturers to begin developing generic versions sooner and also receive the benefit of an exclusivity period.¹³⁸

134. See Parloff, *supra* note 2.

135. Frank Morris, *Monsanto GMO Ignites Big Seed War*, NPR (Jan. 12, 2010), <http://www.npr.org/templates/story/story.php?storyId=122498255>.

136. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. OF EUR. L. 525, 537–38 (1998) (explaining that the EU requires not only governmental approval (similar to the FDA and USDA in the U.S.) but also Member State approval of GMOs, while the U.S. requires no special approval); see Dobe & Sen, *supra* note 11, at 208 (noting that China has published comprehensive new laws).

137. The way in which equivalence between the generic product and name brand one is determined is outside the scope of this Note. However, equivalence should be established to show that the generic GMO performs in the same way as the name brand one and is not a “plant pest or noxious weed”—in that the generic version does not violate the Plant Protection Act. 7 U.S.C.A. § 7712(a) (West 2010).

138. Currently, a generic manufacturer in the agriculture industry must wait until the patent expires to begin producing a generic version, which can result in the loss of market appeal for the generic product. For example, Pioneer explains that areas like the EU and China require regulatory approval

Monsanto claims that a regulation like Hatch-Waxman Act is unnecessary because through access point (2)—reusing seeds—the farmer is able to grow the RR soybean without having to purchase a generic version;¹³⁹ therefore, a specific act facilitating approval of generic GMOs is unnecessary. While farmers may realize the benefit of RR soybeans by simply saving seeds, most farmers will not want to do so due as the “quality of its ‘germplasm,’” or the quality of the plants genetic material, is reduced, thus adversely affecting the crop yield.¹⁴⁰ Developers work to improve the germplasm of seeds through breeding, which can improve crop yields.¹⁴¹ However, when a farmer reuses seeds from a previously grown plant, he will not receive these benefits.¹⁴² It is thus in the farmer’s best interest not to reuse seeds, but to purchase those that continually have higher quality germplasm. In addition, while a farmer may be able to reuse his seeds and continue planting RR soybeans, he will be unable to “stack”¹⁴³ the RR soybean with any other trait, such as drought resistance. The RR soybean has only one benefit—herbicide resistance¹⁴⁴—so the farmer will forego any additional benefits that could be paired with the RR trait if the farmer relies solely on saved seeds.

Adopting a version of the Hatch-Waxman Act is an effective way to ensure market competition while still protecting a name brand company’s patent. Legislation similar to the Hatch-Waxman Act would allow companies like Monsanto to extend the length of their patent up to five additional years if

before genetically engineered soybeans will be imported; however, it can take years for a generic manufacturer to complete and submit the required data for approval in these countries. *Comments of DuPont/Pioneer Hi-Bred International Regarding Agriculture and Antitrust Enforcement Issues in Our 21st Century*, JUSTICE.GOV, at 18, <http://www.justice.gov/atr/public/workshops/ag2010/comments/254990.pdf> (last visited Aug. 28, 2011).

139. Parloff, *supra* note 2.

140. *Id.*

141. *Id.*

142. *Id.* A germplasm developer could use the seeds from a RR soybean plant when the patent is up in 2014, but DuPont claims that Monsanto is incentivizing germplasm developers to “drop[] their Roundup Ready 1 seed lines . . .” *Id.*

143. “Stacking” refers to when more than one gene is inserted into a plant in order to obtain certain characteristics, such as weed control or insect resistance. *Sorting Out the Facts Behind Stacks*, MONSANTO, <http://www.monsanto.com/newsviews/Pages/gene-stacks-facts.aspx#q1> (last visited Aug. 28, 2011).

144. Parloff, *supra* note 2.

the time remaining on the patent after regulatory approval is less than fourteen years. This ensures that the company still has time remaining on its patent to recoup its investment. Moreover, the name brand manufacturer still receives protection in the face of litigation—in cases where the manufacturer is contesting an application filed with a paragraph IV certification—because the name brand manufacturer can receive one thirty-month stay.

Critics of the Hatch-Waxman Act claim the Act burdens the judiciary with patent disputes. The 180-day market exclusivity period encourages generic manufacturers to file ANDAs, while the thirty-month stay encourages name brand manufacturers to file lawsuits opposing ANDAs.¹⁴⁵ Nonetheless, the changes to the Hatch-Waxman Act following the Medicare Prescription Drug and Improvement Act of 2003 are helpful in limiting the amount of litigation. The Medicare Prescription Drug and Improvement Act of 2003 amended the 180-day market exclusivity period in that it may be forfeited by the generic manufacturer,¹⁴⁶ thereby limiting the number of generic manufacturers benefiting from the 180-day exclusivity period. On the other hand, those generic manufacturers that do benefit from the market exclusivity period must bring the product to market within a certain timeframe, thus promoting competition and reduced pricing. In addition, the Medicare Prescription Drug and Improvement Act of 2003 provides for only one thirty-month stay for a name brand manufacturer, so there is less incentive for the manufacturer to continue filing lawsuits for the same product.¹⁴⁷ One lawsuit in response to an ANDA filed will suffice in triggering the thirty-month stay. As a result, there is less incentive to bring numerous lawsuits.

Despite these criticisms, the Hatch-Waxman Act is shown to be effective. The overall sale of pharmaceuticals has increased, and the average price of a prescription has fallen as

145. Laba Karki, *Review of FDA Law Related to Pharmaceuticals: The Hatch-Waxman Act, Regulatory Amendments and Implications for Drug Patent Enforcement*, 87 J. PAT. & TRADEMARK OFF. SOC'Y 602, 615 (2005).

146. Ohly, *supra* note 132, at 18. For example, a generic manufacturer will forfeit the 180-day market exclusivity period if it "fails to market the drug within 75 days of approval or within 30 months after submission of the ANDA." *Id.*

147. *Id.*

more generic manufacturers enter the market.¹⁴⁸ The Hatch-Waxman Act is considered to have encouraged innovation while “facilitat[ing] the growth of a robust generic pharmaceutical manufacturing industry, both in the US and around the globe.”¹⁴⁹ With Hatch-Waxman’s success in lowering prescription prices through generic competition and increasing public access to drugs, the Act is a good foundation on which to base the regulation of generic GMOs.

C. THE BIOSIMILAR ACT

The Hatch-Waxman Act is an effective structure for setting up a regulation that allows for generic GMOs to enter the market without having to go through repetitious testing—thus delaying market entry—while protecting companies that spent millions of dollars on developing the product. The recently passed Biosimilar Act expands on the Hatch-Waxman Act¹⁵⁰ and further supports that a regulatory structure like Hatch-Waxman is appropriate for the agriculture industry and regulation of generic GMOs.

1. The Inner-Workings of the Biosimilar Act

The Biologics Price Competition and Innovation Act of 2009 (the Biosimilar Act) was passed in March 2010¹⁵¹ with the purpose of lowering prices via increased competition as a result of a more efficient FDA approval process.¹⁵² The Biosimilar Act regulates biologic drugs that are typically created from living organisms. Biologic drugs are larger and more complex than traditional small molecule drugs. The Hatch-Waxman Act regulates the traditional—generally chemically-created small mole-

148. *Id.* at 28.

149. *Id.* at 29.

150. The Biosimilars Act includes features similar to the Hatch-Waxman Act such as abbreviated procedures for approving drugs that are “highly similar” and have “no clinically meaningful differences;” a period of exclusivity for the name brand manufacturer; and a market exclusivity period for the biosimilar product manufacturer. See JAMES N. CZABAN, KARIN A. HESSLER & MATTHEW J. DOWD, BNA PHARMACEUTICAL L. & INDUSTRY REP. PANACEA OR POISON PILL? MAKING SENSE OF THE NEW BIOSIMILARS LAW 2 (May 28, 2010), available at http://www.wileyrein.com/resources/documents/BNA_Czaban_May2010.pdf. Since the Biosimilar Act seems to be a modified extrapolation of the Hatch-Waxman Act, it further suggests the success of the Hatch-Waxman Act and the belief that a similar approach would be beneficial with more complex products.

151. *Id.*

152. *Id.*

cule—drugs.¹⁵³

Under the Biosimilar Act, a drug is considered a biosimilar of a reference product (i.e., the name brand drug) if the biosimilar drug is demonstrated to be “highly similar to the reference product notwithstanding minor differences in clinically inactive components.”¹⁵⁴ In addition, there must be “no clinically meaningful differences between the biologic product and the reference product in terms of the safety, purity, and potency of the product.”¹⁵⁵ A biologic product may be “interchangeable” with the reference product if the “biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.”¹⁵⁶ To meet the requirements of biosimilarity, the applicant must submit with its application data from analytical, animal, and clinical studies supporting a “high similarity” and “no clinically meaningful differences.”¹⁵⁷ If a manufacturer is able to show that the biologic product is a biosimilar of the reference product, then the approval process is shortened.¹⁵⁸

In return for the abbreviated process, the FDA grants name brand manufacturers an additional period of twelve years of patent protection.¹⁵⁹ During this time, a competitor is unable to receive approval based on data that was originally collected by the name brand manufacturer.¹⁶⁰ In addition, similar to how the Hatch-Waxman Act grants the first filer of an ANDA a 180-day market exclusivity period, the Biosimilar Act also provides for an exclusivity period.¹⁶¹

153. *Id.*

154. 42 U.S.C.A. § 262(i)(2)(A) (West 2010).

155. 42 U.S.C.A. § 262(i)(2)(B) (West 2010).

156. 42 U.S.C.A. § 262(i)(3) (West 2010).

157. 42 U.S.C.A. § 262(k)(2)(A)(i)(I)(a)–(c) (West 2010).

158. The approval process is abbreviated because full clinical testing is not required. ROPES & GREY, CONGRESS AUTHORIZES ABBREVIATED REGULATORY PATHWAY FOR FDA APPROVAL OF BIOLOGICAL DRUGS, ROPES & GRAY (Mar. 30, 2010), available at <http://www.ropesgray.com/healthreformbiosimilars>.

159. CZABAN, *supra* note 150, at 3–4. Compare to the Hatch-Waxman Act, which only grants a “five-year data exclusivity barrier to the submission of abbreviated new drug applications (ANDAs) for generic versions.” *Id.* at 4.

160. *Id.* at 3–4.

161. *Id.* at 4. Under the Biosimilar Act, if a previous biosimilar product is already determined to be interchangeable with the reference product, then the FDA is temporarily prevented from approving another biosimilar product. *Id.* The exclusivity period depends on various circumstances including whether there is patent litigation pending or concluded in addition to when the first

2. The Biosimilar Act and the Agriculture Industry

GMOs and biologic drugs have various similarities including their complexity and substantial development costs for name brand manufacturers. In addition, some GMOs are also derived from living organisms.¹⁶² Despite these similarities the agriculture industry should adopt an approach more similar to the Hatch-Waxman Act than the Biosimilar Act.

First, the application process under the Hatch-Waxman Act is better suited for the agriculture industry. When an applicant submits an ANDA certifying which of paragraphs (I) through (IV) are true, the length of the approval process varies. With the Biosimilar Act, while it is assumed that fewer studies will be required to demonstrate a biologic drug is biosimilar to, or interchangeable with, the reference product, this has yet to be verified.¹⁶³ Moreover, debates have already ensued regarding the application of the Biosimilar Act.¹⁶⁴ Potential issues are likely to include how similar the proposed product must be to the reference product, and what it means to be “highly similar” and to have “no clinically significant difference.” As a result, the entrance of generic competitors will most likely be slowed. With respect to the agriculture industry, a standard should be adopted where if an applicant is able to show equivalence¹⁶⁵ between the generic and the name brand GMO, then additional studies are not required—similar to the Hatch-Waxman Act. Further, with the current debate surrounding the use of GMOs,

interchangeable product was commercialized. *Id.* at 4.

162. For example, Monsanto’s Roundup Ready soybean, which is glyphosate-tolerant, is derived from inserting a gene encoded from *Agrobacterium tumefaciens* CP4, a soil bacterium. *GM Crop Database*, CENTER FOR ENVTL. RISK ASSESSMENT, [http://cera-gmc.org/index.php?hstIDXCode\[\]=8&auDate1=&auDate2=&action=gm_crop_database&mode=Submit](http://cera-gmc.org/index.php?hstIDXCode[]=8&auDate1=&auDate2=&action=gm_crop_database&mode=Submit) (last visited Aug. 28, 2011).

163. CZABAN, *supra* note 150, at 3. Moreover, the requirement that an applicant provide analytical, animal, and clinical studies seems to indicate that a significant amount of data is required to support biosimilarity between the reference drug and the biologic one. The applicant filing for biosimilarity also has a higher burden in proving interchangeability under the Biosimilar Act than under the Hatch-Waxman Act because the FDA must determine that the risks of diminished efficacy and safety from switching to the biosimilar product are not greater than that of the reference product if there was no switch. *Id.*

164. See, e.g., *Biosimilars—FDA Speaks for the First Time About Challenges of Biosimilars Act at DIA 2011 in Chicago*, FDA LAWYERS BLOG (July 1, 2011), <http://www.fdalawyersblog.com/2011/07/biosimilars-fda-speaks-for-fi.html>.

165. See *supra* note 138 and accompanying text.

it is better to have a term more readily understandable (i.e., “bioequivalent” rather than “highly similar”) when determining whether the generic GMO should be approved.

Second, the agriculture industry should also adopt a market exclusivity period similar to the shorter exclusivity period under the Hatch-Waxman Act. The Hatch-Waxman Act provides the generic applicant with 180-days (or approximately six months) market exclusivity when it begins commercially marketing the product.¹⁶⁶ In comparison, the Biosimilar Act has an exclusivity period that varies depending upon the circumstances—ranging from twelve months to forty-two months.¹⁶⁷ The agriculture industry should adopt the shorter 180-day market exclusivity period because it allows for more competitors to enter the market sooner, thus furthering the goal of increased competition and decreased pricing.

And third, the Hatch-Waxman Act is considered successful overall,¹⁶⁸ while the newly passed Biosimilar Act is both complex and ill-defined.¹⁶⁹ As a result, the courts, Congress, and the FDA will be busy interpreting various components of the Act and closing any loopholes.¹⁷⁰ Therefore, it is better to base legislation to be used in the agriculture industry on an act that has gone through numerous revisions over the past twenty-five years in an attempt to make improvements rather than new legislation subject to much reform.

D. FILLING IN THE DETAILS

Both the Hatch-Waxman Act and the Biosimilar Act are instructive on the structure of regulation the agriculture industry should adopt. In addition to adopting a standard more similar to the Hatch-Waxman Act, the agriculture industry needs to ensure a regulatory provision for establishing that the generic

166. Ohly, *supra* note 132, at 18.

167. CZABAN, *supra* note 150, at 4.

168. See *supra* notes 146–148 and accompanying text. But see Martha Rumore, *The Hatch-Waxman Act—25 Years Later: Keeping the Pharmaceutical Scales Balanced*, PHARMACY TIMES (Aug. 15, 2009), <http://www.pharmacytimes.com/publications/supplement/2009/genericsupplement0809/generic-hatchwaxman-0809> (explaining that while the Hatch-Waxman Act has benefited consumers through increased entry of generic drugs in the market, the Act is riddled with loopholes and gives rise to various anticompetitive strategies).

169. CZABAN, *supra* note 150, at 1.

170. See *id.*

GMO is truly the equivalent of the name brand version. A generic GMO must be equivalent to the name brand by performing in the same way as the name brand version and must maintain conformity with the Plant Protection Act—in that the generic GMO is not a “plant pest or noxious weed.”¹⁷¹ The proposed revisions to the USDA regulations may be sufficient to ensure the equivalence of the generic GMO; however, that is outside the scope of this Note. Nevertheless, a procedure for determining equivalence must be established. If the USDA determines that simply comparing the properties of the generic GMO and the name brand is insufficient, it should consider adopting a more thorough approach that conducts various studies and includes the results in the application process.

In addition, the USDA needs to ensure that its agents are strictly complying with regulations. As discussed earlier in this Note, cases have arisen where the agency has not complied with the regulations for approval of new GMOs. With the introduction of generic GMOs and the magnification it will have on both the benefits and concerns currently surrounding the use of GMOs, the regulations for generic GMOs must be strictly followed.

CONCLUSION

The expiration of the patent for Monsanto’s RR soybeans in 2014 will mark one of the first times in the agriculture industry that a widely used GMO will soon have a generic version available. There are advantages and disadvantages associated with the use of GMOs, and the availability of a generic GMO will magnify both the benefits and risks surrounding use as more people will have access to a generic GMO due to the lower price.

Revised regulations are necessary to ensure a proper transition to generic GMOs and to limit the risks associated with GMOs. The pharmaceutical industry is instructive on how to handle the entrance of a generic GMO. The Hatch-Waxman Act is a useful foundation for encouraging generic competition through a more streamlined approval process, while still ensuring that name brand companies are incentivized to continue developing innovative GMOs. The recent Biosimilar Act, which appears to expand on the Hatch-Waxman Act, is helpful in showing that the Hatch-Waxman Act is a good regulatory

171. Plant Protection Act, 7 U.S.C. § 7712(a) (2006).

framework for more complicated products as well. While both the Biosimilar and Hatch-Waxman Acts are good regulatory frameworks to facilitate of market entry by generic GMO manufacturers, a strict regulatory framework is needed to ensure that the generic GMO is the same as its name brand counterpart.