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Ritalin to Roundup: Expanding the Pharmaceutical Industry Statutory Experimental Use Exception to Agriculture

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RITALIN TO ROUNDUP:
EXPANDING THE PHARMACEUTICAL INDUSTRY STATUTORY
EXPERIMENTAL USE EXCEPTION TO AGRICULTURE

*Jennifer Carter-Johnson**

Abstract

The modern agricultural biotechnology industry developed from a small cottage industry based on selective crop breeding into a multi-billion dollar industry based on the isolation and insertion of genes that code for commercially valuable crop traits. As it grew, the industry relied on patent protection to recoup its investment into new research and development of genetically engineered (GE) crops. A recent billion dollar patent infringement damage award to Monsanto based only on research activities of its competitors testifies to the importance of that patent protection.

Had the Monsanto patent infringement case been between two pharmaceutical companies creating genetics-based drugs, the outcome would have been different. Instead of a one billion dollar award, the patent verdict would have been one of noninfringement. The difference between the two patent infringement cases lies with the Hatch-Waxman Act's statutory experimental use exception.

The Hatch-Waxman Act controls the regulation of generic drugs by the Food and Drug Administration (FDA). Along with an abbreviated generic drug approval process, the Hatch-Waxman Act includes a statutory experimental use exception to patent infringement allowing pharmaceutical companies to conduct research on patented drugs if

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the research might be used in a regulatory submission to the FDA.

This Article explores the history of the statutory experimental use exception and argues that it should apply to the agricultural biotechnology industry's development of GE crops. The Supreme Court's interpretation of the statute has resulted in a very broad experimental use exception, limited only by whether an invention is regulated by the FDA. Since GE crops are regulated by the FDA, the statutory experimental use exception should apply to their development. Such a broadening of the experimental use exception would have potentially vast impacts on the patent valuations as well as the structure of the entire agricultural biotechnology industry.

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I. INTRODUCTION

In 2012, Monsanto Company and Monsanto Technology LLC (Monsanto) won a one billion dollar (\$1,000,000,000) award for patent infringement in its case against E.I. DuPont De Nemours and Company (DuPont) and Pioneer Hi-Bred International, Inc. (Pioneer).¹ What makes this judgment exceptional is not only the staggering damage award, but also the lack of any marketed product. There was no blockbuster drug, no pervasive technological gadget, not even a widely adopted genetically engineered (GE) crop. Rather, the award was based on Monsanto's evidence of the reasonable royalty it might have charged in order to conduct research using its patented technology.

Monsanto is one of the largest agricultural biotechnology companies in the world; it develops and produces GE crops among other products. At issue in the patent infringement suit was Monsanto's patented Roundup Ready soybean and corn traits. The Roundup Ready trait confers resistance to the herbicide glyphosate to those crops that express it.²

In 2002, Monsanto licensed the Roundup Ready traits to DuPont and Pioneer.³ The terms of the license allowed the companies to sell soybean and corn seeds expressing the patented traits. Four years later, the companies developed their own proprietary glyphosate resistant traits. In addition to the sales allowed by the license, DuPont and Pioneer had begun to conduct a research program to stack⁴ the Roundup Ready trait with their own proprietary traits. Monsanto sued for patent infringement for the unlicensed use of the Roundup Ready technology in the research program.⁵

Had such a patent-infringement case been between two pharmaceutical companies, the outcome would have been completely different. Instead of a one billion dollar award, the verdict would have been one of noninfringement. If patent law is supposed to be technologically neutral as to its protections, why is there such a difference in outcome between bio-agricultural and pharmaceutical research?

1. Reading of the Verdict for *Monsanto Co. v. E.I. DuPont De Nemours*, No. 4:09-CV-686 ERW, 2012 WL 3765059, (E.D. Mo. Aug. 1, 2012), 2012 WL 8438518.

2. Roundup is the brand of glyphosate herbicide that is marketed by Monsanto.

3. See Andrew Pollack, *Dispute Ends for Monsanto and DuPont*, N.Y. TIMES (Apr. 3, 2002), <http://www.nytimes.com/2002/04/03/business/03BIOT.html>.

4. Stacking is the process of combining the genes for multiple traits into one seed for expression. Isabelle E.J.A. François et al., *Different approaches for multi-transgene-stacking in plants*, 163 PLANT SCI. 281, 281 (2002).

5. *Monsanto Co. v. E.I. DuPont de Nemours*, No. 4:09CV00686 ERW, 2012 WL 5397601, at *1 (E.D. Mo. Nov. 2, 2012).

The key difference between *Monsanto* and the pharmaceutical hypothetical is application of the Hatch–Waxman Act.⁶ The Hatch–Waxman Act controls the approval and regulation of generic drugs by the Food and Drug Administration (FDA). Along with an abbreviated generic drug approval process, the Hatch–Waxman Act includes a statutory experimental use exception, allowing pharmaceutical companies to conduct research on patented technologies if the research might be used in a regulatory submission to the FDA.⁷

This Hatch–Waxman statutory experimental use exception has been expanded from its initial use for development of generic drugs to include newly developed and marketed drugs and medical devices which are marketed under a trademarked brand name (branded drugs).⁸ However, the *Monsanto* court was skeptical that the statutory experimental use exception could be expanded to include GE crops.⁹

The applicability of the statutory experimental use exception is important to the agricultural biotechnology industry in light of the industry's reliance on patent protection for GE crops. Application of an experimental use exception would allow for faster follow-on innovation; companies could begin to develop, but not market, new GE crops containing patented traits. On the other hand, implementation of an experimental use exception would represent a major loss of competitive advantage and licensing revenue to patent holders. Therefore, a clarification of the implementation of the Hatch–Waxman statutory experimental use exception to the agricultural biotechnology industry is needed.

This Article explores the development of the statutory experimental use exception of Hatch–Waxman and argues that the *Monsanto* court was wrong to not consider the defense. The experimental use exception should apply to the agricultural biotechnology industry's development

6. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.). In 2003, Congress amended this scheme in Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, tit. XI, subtit. A–B, 117 Stat. 2066, 2448–64 (codified at 21 U.S.C. § 355 (2006)).

7. 35 U.S.C. § 271(e)(1) (2010) states:

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 (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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.

8. See *infra* Part IV.B.

9. *Monsanto Co. v. E.I. DuPont de Nemours*, No. 4:09CV00686 ERW, 2010 WL 3039210, at *10-12 (E.D. Mo. July 30, 2010).

of GE crops. Part II describes the development and regulation of the modern agricultural biotechnology industry. Part III explains the regulation of the pharmaceutical industry as background for the development of the statutory experimental use exception. Part IV explains the evolution of the statutory experimental use exception through caselaw. Part V analyzes caselaw surrounding the statutory experimental use exception in light of GE crop regulations to argue why the experimental use exception might apply. Part VI concludes with a broader perspective of the application of the statutory experimental use exception in the agricultural biotechnology industry.

II. DEVELOPMENT AND REGULATION OF THE MODERN AGRICULTURAL BIOTECHNOLOGY INDUSTRY

The agricultural industry has changed radically over time. Man began to impact the genetic heritage of crops long before he understood the concept of DNA. Direct manipulation of crop DNA followed that understanding and led to the modern agricultural biotechnology industry and production of GE crops. In many ways, these changes in agricultural biotechnology products and the structure of the agriculture industry were ushered in due to the gradual application of intellectual property law associated with plants, particularly patents.¹⁰ This industry structure has been further supported by the need for regulatory approval of GE crops before marketing. Therefore, as this Article discusses the implementation of an experimental use exception to patent infringement by the agricultural biotechnology industry, it is important to understand the industry's history and the impact of patents and regulations on the industry.

A. History of the Development of Genetically Engineered Crops

1. Early Trait Selection and Traditional Breeding

Agriculture is very likely the oldest human industry. Evidence of domesticated wheat dating back 10,000 years has been found by archeologists in the area around southeastern Turkey.¹¹ Over the subsequent 2,000 years, humans domesticated other plants and animals,

10. See *infra* Part II.B.

11. See, e.g., Manfred Heun et al., *Site of Einkorn Wheat Domestication Identified by DNA Fingerprinting*, 278 SCI. 1312, 1312-13 (1997) and DANIEL ZOHARY ET AL., DOMESTICATION OF PLANTS IN THE OLD WORLD 1-3 (4th ed. 2012).

including barley, chickpeas, peas, beans, flax, sheep, goats, and pigs.¹² By 6800 B.C., rice, currently the world's most important food crop, was domesticated.¹³ This domestication of plants and animals was, broadly speaking, the first application of biotechnology to agriculture; as humans were breeding these plants and animals and selecting traits advantageous to humans.¹⁴ Such traits included larger seed size in plants, resistance to pests and diseases, and faster growth.¹⁵ Animals with the best traits were bred together and seeds from the best plants were saved for the next growing season.

Human skill at selecting crops and selectively breeding animals for advantageous traits continued to grow, but sexual reproduction in plants was not definitively identified until the late 1600s.¹⁶ With the identification of plant sexual reproduction, selective breeding of plants with advantageous traits and cross-breeding of related plants was suddenly possible. However, there was no true understanding of why selective breeding worked until the mid-1800s, when an Austrian monk by the name of Gregor Mendel began experimenting with breeding of the pea plant.¹⁷

While it was known that breeding of plants and animals with advantageous traits often resulted in offspring with similar traits, Mendel's studies revealed how these traits pass from parents to offspring.¹⁸ His experiments on the breeding of pea plants with certain traits revealed the rules of heredity.¹⁹ Mendel found in his studies of pea plants that some traits were "dominant" and would be passed through generations more frequently while other traits were "recessive" and were expressed less frequently in subsequent generations of the

12. See generally Melinda A. Zeder, *The Origins of Agriculture in the Near East*, 52 CURRENT ANTHROPOLOGY 221, 221-35 (2011).

13. See generally Dorian Q. Fuller et al., *The Domestication Process and Domestication Rate in Rice: Spikelet Bases from the Lower Yangtze*, 323 SCI. 1607, 1607-10 (2009).

14. See *id.*

15. Biotechnology has broadly been defined as "the use of living cells, bacteria, etc., to make useful products." MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/biotechnology> (last visited July 17, 2015). Recently, many authors have begun using the term biotechnology in its application to food production to specifically refer to the use of recombinant DNA technology to transfer genetic information from one organism to another.

16. Rudolf Jakob Camerarius (1665-1721) is thought to be the first researcher to demonstrate sexual reproduction in plants. DHARAM P. ABROL, *POLLINATION BIOLOGY* 26 (2012).

17. Gregor Johann Mendel (1822-1884) experimented on the breeding of pea plants between 1856 and 1863. His work was published in 1865 but mostly ignored until after his death. A translation of Mendel's presentation of his work, *Experiments in Plant Hybridization* (1865) can be found at <http://www.mendelweb.org/Mendel.html> (last visited Feb. 21, 2015). See also Daniel L. Hartl & Vitezslav Orel, *What Did Gregor Mendel Think He Discovered?*, 131 GENETICS 245, 245 (1992).

18. For an analysis of Mendel's experiments, see Hartl & Orel, *supra* note 17.

19. *Id.*

plant.²⁰ Importantly, Mendel found that these frequencies were very predictable, allowing for actual analysis in the breeding of specific traits.²¹ Mendel's elucidation of the principles of inheritance is the foundation of the science now known as genetics, though the importance of his work was not recognized until the beginning of the 20th century.²² Mendel's work in determining how heredity worked has had a profound impact on the agriculture industry.

2. The Rise of the Seed Companies

As understanding of the science underlying crop breeding developed, so too did the methods of production and distribution of seed. Through the 18th century in the United States, seed saving and local sharing was most common, with farmers saving the best seed from one year to plant in the next. Distribution of seed was generally local, though some wealthy landowners would collect seed while traveling and distribute it to their friends.²³

In the early 19th century, however, the U.S. government began to institute programs designed to distribute valuable plant varieties. In 1819, the Secretary of the Treasury requested that ambassadors and other foreign-stationed government officials collect seed from around the world and return it to the United States.²⁴ In 1839, the Commissioner of Patents obtained funding for the collection and free distribution of seed to farmers in order to increase crop diversity in the United States.²⁵ By 1855, the Patent Office was distributing over a million packages of seed to farmers each year, allowing farmers in different regions to examine new varieties that may have advantageous traits.²⁶ This effort by the U.S. federal government was enhanced with the establishment of the United States Department of Agriculture (USDA), which was charged by Congress with, among other tasks, the collection, propagation, and distribution of new and valuable seed stock

20. *Id.* at 249.

21. *Id.* at 249-50.

22. *Id.* at 245.

23. Benjamin Franklin and Thomas Jefferson are both known to have collected interesting crop seeds in their travels, sending those seeds back to the United States to be used in their own gardens and distributed to their friends. NELSON KLOSE, *AMERICA'S CROP HERITAGE: THE HISTORY OF FOREIGN PLANT INTRODUCTION BY THE FEDERAL GOVERNMENT 13-19* (1950).

24. *Id.* at 26.

25. *Id.* at 38. This source refers to the Commissioner of Patents as Oliver Ellsworth, though his name was Henry L. Ellsworth.

26. JACK RALPH KLOPPENBURG, JR., *FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY, 1492-2000*, 56 (Cambridge University Press, Cambridge 1998).

and plant varieties.²⁷

The seed distribution landscape began to change near the end of the 19th century. Private companies began to develop and distribute seed, and the USDA halted its free seed distribution program in 1924.²⁸ The rise of the private company as a seed producer coincided with two groundbreaking changes in the technology of plant-variety production—hybrid crops and induced mutations.

First, using the understanding of heredity gained from Gregor Mendel and other scientists, these companies began producing highly inbred strains of plants which strongly displayed some trait of interest.²⁹ Inbred plants are created by the repeated crossing of genetically related plants that possess some desired trait, such as drought resistance. If these plants are continually inbred over numerous generations, the resulting plants are nearly clones of each other; all will possess the desired trait and sometimes that trait is even enhanced by the process.³⁰

However, there was often a downside to these inbred lines in that many unwanted traits, such as slow growth, may also become enhanced. Indeed, unhealthy offspring resulting from inbreeding has been a long-recognized problem.³¹ Therefore, by themselves, these inbred plant varieties make poor material for crops due to an overall lack of health, though they may possess some trait or traits that are considered by the grower to be desirable.

This problem was overcome with the discovery that crossing two inbred lines of a plant such as corn often would result in the offspring displaying the advantageous traits, being much healthier than either of the inbred parental plants, and regaining the healthiness of the non-inbred plant type.³² This effect is known as hybrid vigor. It resulted in seed producing companies being able to systematically plan for and produce seeds that, in turn, would produce healthy crops that strongly displayed one or more desirable traits, such as drought resistance or large fruit production. The production of these highly inbred parental lines required dedicated specialists working at these private companies

27. Act of May 15, 1862, ch. 72, 12 Stat. 387, 37 Cong. Ch. 72.

28. KLOPPENBURG, *supra* note 26, at 71.

29. See Jorge Fernandez-Cornejo, *The Seed Industry in U.S. Agriculture: An Exploration of Crop Seed Markets, Regulation, Industry Structure, and Research and Development*, USDA-ECON. RESEARCH SERV. AGRIC. INFO. BULL. 786, 2-4 (2004); James Ming Chen, *An Agricultural Law Jeremiad: The Harvest Is Past, the Summer Is Ended, and the Seed is Not Saved*, 2014 WISC. L. REV. 235, 244 (2014) [hereinafter Chen, *Jeremiad*].

30. Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 133 (2005) [hereinafter, Chen, *The Parable*].

31. George H. Shull, *The Composition of a Field of Maize*, 4 AM. BREEDERS ASSOC. REP. 296, 296 (1908).

32. *Id.*

or in universities and was rarely accomplished by individual farmers.

For the seed companies, hybrid lines had the great advantage of requiring farmers to purchase new seed each year. While many of these hybrids produced viable offspring, hybrids do not breed true, meaning that only a percentage of the offspring actually would display the desired traits if the farmer tried to save the seeds produced by the hybrid plants for later replanting.³³ In order to maintain efficiency in crop production, the farmer would have to repurchase seed from the seed company each year rather than save seed from year to year. The seed company would breed a new batch of hybrid seed from the inbred parental lines for each growing season, necessitating that the seed producer maintain the inbred lines. These inbred lines are jealously guarded by seed companies and protected as trade secrets.³⁴

A second technological leap favoring the rise of seed companies was the method of producing new traits using induced mutation.³⁵ Naturally, mutations in the genes of plants and animals occur at a slow rate and, in fact, are the starting point for evolution and speciation. In the 1940s, scientists found that the rate of mutation could be enhanced using either radiation or chemicals to cause mutation in the genes of seeds.³⁶ Many of the resulting mutations would have adverse effects on the plants, but a very small minority of plants would demonstrate new, enhanced, or otherwise desirable characteristics that scientists could then reproduce as they would a traditional strain.³⁷ However, this method was labor intensive as every mutated seed had to be grown and evaluated. Also, the mutations that occurred were random in nature.³⁸ Despite these hurdles, induced mutation remained a popular method of producing new plant varieties through the 1970s, a decade that saw the beginning of the next groundbreaking technology in crop seed production—direct genetic modification using recombinant DNA³⁹.

33. Fernandez-Cornejo, *supra* note 29, at 42.

34. It is common to find a low percentage of inbred seeds contaminating a bag of hybrid seeds despite the many precautions taken by the seed producers to prevent this mixing. By planting a large number of hybrid seeds and isolating the slowest growing, the initial inbred lines can often be recovered by competitors. For an in-depth explanation of “chasing selfs,” see Chen, *The Parable*, *supra* note 30, at 133-34.

35. An induced mutation is “any alteration in the genetic material of an organism, a cell, or a virus, produced by exposure to a mutagen”. ROBERT C. KING ET AL., A DICTIONARY OF GENETICS 242 (8th ed. 2013).

36. See A. Micke et al., *Induced Mutations for Crop Improvement*, 7 MUTATION BREEDING REV. 1, 21-3 (1990); see also generally Ake Gustaffson, *Mutations in Agricultural Plants*, 33 HEREDITAS 1 (1947).

37. Micke, *supra* note 36, at 102.

38. *Id.*

39. *Id.* at 2-3; *infra* notes 42-44 and accompanying text.

3. The Development of Genetically Engineered Crops

Long before there was any knowledge of genetics or DNA, people unknowingly had been manipulating the genes of plants and animals through selective breeding and later through induced mutation. Only recently, however, advances in scientific knowledge have allowed direct and targeted manipulation of the genes of organisms, including crop plants. These advances, generically termed recombinant DNA technology, have allowed scientists directly to introduce foreign DNA into a plant's genome. Where before technologies such as crossbreeding were limited to related species, scientists easily now can introduce a bacterial gene into a crop plant such as corn.⁴⁰

Before the 1940s, the model of Mendelian inheritance taught that traits were controlled by one or more genes. However, the method by which the information represented by the gene was actually physically carried and passed on to progeny was a mystery. It was commonly thought that genes were made up of proteins, as proteins were a complex molecule produced in abundance in all plant and animal cells.⁴¹ It wasn't until 1944 that DNA was proposed as the actual information carrying molecule within cells.⁴² Less than a decade later, James Watson and Francis Crick proposed a double helix structure for DNA.⁴³ Over the next two decades, the way DNA was used to code for hereditary information and how DNA was copied into progeny was elucidated. By the beginning of the 1970s, the mechanism by which DNA worked in the cell was beginning to be understood. What remained was to figure out how to manipulate the DNA and, by extension, the cell's genes and resulting traits.

In the late 1960s and early 1970s, proteins were identified which could cut DNA and other proteins were found that could repair these cuts.⁴⁴ Using these newly discovered tools, scientists were able to insert

40. For example, Bt-corn is so named because it contains a gene from a bacterium *Bacillus thuringiensis*. The gene produces a protein that kills a major corn pest. Jennifer L. Price et al., *Insect Resistance Management for Bt Corn: An Assessment of Community Refuge Schemes*, 9(3) *AGBIOFORUM* 129, 129 (2006).

41. Maclyn McCarty, *Discovering Genes are Made of DNA*, 421 *NATURE* 406, 406 (2003).

42. Oswald Avery, Colin MacLeod, and Maclyn McCarty suggested in 1944 that DNA was the molecule within cells that carried information involved in heredity, *i.e.* the genes. Their work was not well received at first as proteins were thought to be much more complex (human proteins are made of chains of twenty-one different amino acids whereas DNA is made up of only four nucleic acids). See Oswald T. Avery et al., *Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types: Induction of Transformation by a Desoxyribonucleic Acid Fraction Isolated from Pneumococcus Type III*, 79 *J. OF EXPERIMENTAL MED.* 137 (1944); McCarty, *supra* note 41 at 406.

43. James D. Watson & Francis H. C. Crick, *A Structure for Deoxyribose Nucleic Acid*, 171 *NATURE* 737, 737 (1953).

44. Restriction endonucleases, or restriction enzymes, are proteins that recognize a specific DNA sequences and cut DNA at that site. The first identified restriction endonuclease, Hind II, was isolated

new stretches of DNA, and thus new genes, into an organism's genome. The first genetically modified organisms produced by recombinant DNA technology were created in the early 1970s when the laboratories of Herbert Boyer and Stanley Cohen conducted a series of experiments inserting genes that conferred resistance to antibiotics such as kanamycin and tetracycline into the genome of bacteria, resulting in new antibiotic-resistant strains of bacteria.⁴⁵

This technology would soon make its way into use for plants, allowing for the creation of transgenic varieties of crops.⁴⁶ Transgenic simply means that foreign DNA was inserted into the native genome.⁴⁷ This new technology allowed scientists to insert—relatively easily—genes producing traits of interest into crop plants. This method was much more efficient than older methods, such as induced mutation, that could not target the trait of interest and instead relied on analysis of many progeny in hopes of finding one that displayed the traits of interest.⁴⁸ Furthermore, recombinant DNA methods could move genes from one organism into a completely different species, a feat traditional crossbreeding could never hope to achieve.⁴⁹

These transgenic plants had a great advantage over inbred lines or induced mutations in that only the gene of interest became altered.⁵⁰ Inbred lines of plants enhanced numerous traits, often including disadvantageous ones resulting in overall poor health of the inbred line.⁵¹ To avoid this issue in the crop seed, hybrid strains were produced

from the *Haemophilus influenzae* bacterium. See Hamilton O. Smith & K. W. Wilcox, *A Restriction Enzyme from Hemophilus influenza: I. Purification and general properties*, 51(2) J. MOL. BIOL. 379, 379 (1970); Thomas J. Kelly & Hamilton O. Smith, *A restriction enzyme from Hemophilus influenza: II. Base Sequence of the Recognition Site*, 51 J. MOL. BIOL. 393 (1970). DNA ligases are proteins that help join cut DNA pieces back together. The first identified DNA ligase, T4 DNA Ligase, was identified by multiple laboratories in 1967. See e.g., Bernard Weiss & Charles C. Richardson, *Enzymatic breakage and joining of deoxyribonucleic acid, I. Repair of single-strand breaks in DNA by an enzyme system from Escherichia coli infected with T4 bacteriophage*, 57 PROCEEDINGS OF THE NATL. ACAD. SCI. U.S.A. 1021, 1021 (1967).

45. See generally, e.g., John Morrow et al., *Replication and Transcription of Eukaryotic DNA in Escherichia coli*, 71 PROCEEDINGS OF THE NAT. ACAD. SCI. U.S.A. 1743 (1974); Stanley N. Cohen et al., *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROCEEDINGS OF THE NATL. ACAD. SCI. U.S.A. 3240 (1973).

46. See generally, e.g., Robert T. Fraley et al., *Expression of Bacterial Genes in Plant Cells*, 80 PROCEEDINGS OF THE NATL. ACAD. SCI. U.S.A. 4803 (1983).

47. Transgenic is defined as “being or used to produce an organism or cell of one species into which one or more genes of another species have been incorporated.” MERRIAM-WEBSTER ONLINE DICTIONARY, <http://www.merriam-webster.com/dictionary/transgenic> (last visited July 17, 2015).

48. Micke, *supra* note 36, at 4.

49. See Gabrielle J. Persley & James N. Siedow, *Applications of Biotechnology to Crops: Benefits and Risks*, 12 COUNCIL FOR AGRIC. SCI. & TECH. 1, 1 (1999); see e.g., Price, *supra* note 40.

50. Persley & Siedow, *supra* note 49, at 2.

51. *Id.*

from the inbred lines, but hybrid plants do not breed true.⁵² The new transgenic plants, however, produced using recombinant DNA technology, breed true, alleviating the need for hybrids.⁵³ But this created another problem for the seed producers: these new seeds were self-replicating. Farmers once again could save seed from year to year with no decrease in crop production efficiency.⁵⁴ Unlike with a hybrid seed, all progeny of the transgenic plants carry the new traits.⁵⁵ Therefore, seed companies must rely on patent protection to prevent replication of their inventions.⁵⁶

B. The Impact of Intellectual Property on Commercial Seed Production

It has been hypothesized that one of the drivers of the sudden explosion of technological advances in the seed production side of the agriculture industry is expanding intellectual property protection.⁵⁷ Early seed companies relied on trade secret protections.⁵⁸ However, over time stronger types of intellectual property protection emerged until the agricultural biotechnology industry developed with reliance on patent protection. As this patent protection evolves, it will impact the structure of the entire industry.

1. Evolving Intellectual Property Protections for Plants

Between 1900 and 1970, the only intellectual property protection that applied to most crop plants was trade secret protection.⁵⁹ In that environment, many small, regional seed companies thrived, producing numerous inbred lines they jealously guarded and then bred together to form hybrid seed for sale to farmers.⁶⁰

52. See Fernandez-Cornejo, *supra* note 29; and Chen, *Jeremiad*, *supra* note 29, at 244.

53. Jeremy P. Oczeck, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Rights to Save and Replant Seed*, 41 BOSTON COL. L. REV. 627, 627-28 (2000).

54. See Jeremy N. Sheff, *Self-Replicating Technologies*, 16 STANFORD TECH. L. REV. 229 (2013).

55. This is true so long as the transgenic plants did not cross-pollinate with another variety that did not carry the trait of interest.

56. Genetic use restriction technologies (GURTs) designed to prevent self-replication of genetically engineered seeds have been proposed but have not, to this point, been commercially implemented. See, e.g., Yi Sang et al., *Gene Use Restriction Technologies for Transgenic Plant Bioconfinement*, 11 PLANT BIOTECH. J. 649, 649-50 (2013).

57. Elizabeth A. Rowe, *Patents, Genetically Modified Foods and IP Overreaching*, 64 SMU L. REV., 859, 862-63 (2011).

58. See Chen, *Jeremiad*, *supra* note 29, at 244-48.

59. *Id.* at 244.

60. See KLOPPENBURG, *supra* note 26, at 106; Donald N. Dubik, *Biotechnology in the 1930s: the Development of Hybrid Maize*, 2 NATURE REVIEWS: GENETICS 69, 72 (2001).

While the Plant Patent Act of 1930 allowed for a type of patent protection of asexually reproduced plants, most food-crop plants are sexually reproduced and thus are not eligible subject matter for a plant patent.⁶¹ Sexually reproduced plants were not provided with patent protection because, at the time, cultivators thought that sexual reproduction of the plant would destroy any special characteristics.⁶² Sexually reproduced plants were thought to not breed true to type, while asexually reproducing plants were thought to be much better for maintaining unique and identifiable characteristics of the variety.⁶³ As a result, seed producers relied on internal secrecy, trade secret laws, and the fact that hybrid plants do not breed true to protect their intellectual property from being copied.⁶⁴

Forty years later, however, Congress recognized that seed producers could indeed maintain stable characteristics in sexually reproducing plants and passed the Plant Variety Protection Act of 1970 (PVPA).⁶⁵ This Act provided a pathway to obtain a Certificate of Protection that gave patent-like protection to sexually reproduced plants, including most crop plants.⁶⁶ However, the PVPA contained a research exemption⁶⁷ and also a “farmer’s exemption,” which allowed farmers to save seed for replanting on their own farm.⁶⁸ While these farmers would not be able to sell this seed for replanting elsewhere, this exemption made protection under the PVPA much less valuable to the seed producers as they wanted to be able to sell their new transgenic seed types to the same farmers each growing season, much as they had

61. 35 U.S.C §§ 161-164. Section 161 reads:

Whoever 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, may obtain a patent therefor, subject to the conditions and requirements of this title.

62. Note that plants capable of sexual reproduction are eligible for plant patent protection if the plant is also asexually reproduced, such as by cuttings. United States Patent and Trademark Office, *Manual of Patent Examining Procedure*, § 1601, <http://www.uspto.gov/web/offices/pac/mppep/s1601.html> (last visited July 17, 2015).

63. Fernandez-Cornejo, *supra* note 29, at 20.

64. *See supra* notes 52 and 59 and accompanying text.

65. Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended in scattered sections of 7 and 28 U.S.C.)

66. *Id.* *See also* JOHN POEHLMAN & D. A. SLEPER, *BREEDING FIELD CROPS*, 20 (John Wiley & Sons 1995).

67. 7 U.S.C. § 2544 (1970). The research exemption reads “[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement.” *See also* Chen, *The Parable*, *supra* note 30.

68. 7 U.S.C. § 2543 (1970). The farmer’s exemption reads:

it shall not infringe any right hereunder for a person 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 for use on the farm of the person

done with hybrid seed strains.⁶⁹

Perhaps the most effective way to accomplish this goal would be to extend utility patent protection to plants and seed. However, the general understanding of the day prevented issuance of utility patents for living organisms such as plants that were considered products of nature, and in fact, the Plant Patent Act and PVPA had been passed in part due to that understanding.⁷⁰ This understanding changed with a series of Supreme Court cases beginning in 1980 with *Diamond v. Chakrabarty*.⁷¹

Chakrabarty was a microbiologist interested in finding new ways to clean oil spills.⁷² By inserting foreign DNA into a bacterium, he developed a transgenic strain of bacteria that was able to break down multiple components of crude oil.⁷³ He applied for a utility patent on his invention in which he claimed the transgenic bacteria itself.⁷⁴ The examiner for this patent application rejected his claims to the transgenic bacteria under the reasoning that bacteria, as living things and products of nature, are not patentable under 35 U.S.C. §101.⁷⁵

The rejection was appealed and eventually found its way to the Supreme Court. The Supreme Court determined that a live but human-made microorganism was patentable subject matter under 35 U.S.C. §101.⁷⁶ The Court held that the transgenic bacterium was a “manufacture” or a “composition of matter” not found in nature.⁷⁷ This reasoning was quickly adopted by the U.S. Patent and Trademark Office (USPTO) and expanded utility patent protection to transgenic plants as well as microorganisms.⁷⁸ Thus, the seed producing industry was provided with the ability to obtain strong utility patent protection for transgenic seeds and the USPTO issued approximately 1,800 utility

69. For a fuller discussion of the PVPA and its impact on the agricultural biotechnology industry, see Chen, *The Parable*, *supra* note 30, at 132-39.

70. *Diamond v. Chakrabarty*, 447 U.S. 303, 311 (1980). The Court stated: “Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law.”

71. 447 U.S. 303.

72. *Id.* at 303, 305.

73. *Id.* at 305.

74. *Id.* at 305-06.

75. *Id.* at 306. 35 U.S.C. § 101 reads “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

76. *Id.* at 305, 309.

77. *Id.* at 309-10.

78. See *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) USPQ 443, 447 (Bd. Pat. App. & Inter. 1985) (ruling that plants could be proper subject matter for a utility patent even though plants also may be protected under the Plant Patent Act or the Plant Variety Protection Act).

patents to seed companies over the next sixteen years.⁷⁹ Unlike a PVPA Certificate of Protection, utility patent protection does not include any exemptions for seed saving.⁸⁰ In 2001, the Supreme Court held in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred* that sexually reproduced plants eligible for protection under the PVPA also were eligible for protection under utility patents.⁸¹ This ruling confirmed the USPTO actions considering transgenic plants to be patentable subject matter for utility patents.

Under this new application of patent law, the industry moved quickly in producing transgenic food crops. In 1994, the FLAVR SAVR tomato became the first transgenic food crop destined for human consumption approved by the FDA.⁸² The FLAVR SAVR tomato had foreign DNA inserted into the tomato's genome that was designed to lengthen ripening time and, thus, shelf life.⁸³ The FDA determined that the transgenic tomato was as safe for human consumption as the equivalent nontransgenic tomatoes.⁸⁴

Herbicide-resistant food crops would be developed shortly thereafter with the 1996 introduction of the transgenic Roundup Ready soybean seeds and the 1998 introduction of Roundup Ready corn, both Monsanto creations.⁸⁵ Today in the U.S., nearly 90% of all soybeans and corn grown are transgenic.⁸⁶

2. The Changing Scope of Patent Protection

While patent protection was a clear boon to the burgeoning agriculture industry, the contours of that protection experienced change

79. E.J. Sease, *History and Trends in Agricultural Biotechnology Patent Law from a Litigator's Perspective*, 38, 40 in AGRICULTURAL BIOTECHNOLOGY AND INTELLECTUAL PROPERTY: SEEDS OF CHANGE, (Jay P. Kesan, ed. 2007) [hereinafter SEEDS OF CHANGE].

80. Chen, *The Parable*, *supra* note 30, at 133.

81. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001).

82. See FDA, *Agency Summary Memorandum Re: Consultation with Calgene, Inc., Concerning FLAVR SAVR™ Tomatoes* (May 17, 1994), <http://www.fda.gov/Food/FoodScienceResearch/GEPlants/Submissions/ucm225043.htm>; see also Rita Batista & Maria Margarida Oliveira, *Facts and Fiction of Genetically Engineered Food*, 27(5) TRENDS IN BIOTECHNOLOGY 277, 277 (2009).

83. FDA, *Agency Summary*, *supra* note 82.

84. *Id.*

85. MONSANTO, *Company History*, <http://www.monsanto.com/whoweare/pages/monsanto-history.aspx> (last visited Feb. 22, 2015).

86. See USDA, *Recent Trends in GE Adoption 1996-2014*, <http://www.ers.usda.gov/data-products/adoption-of-genetically-engineered-crops-in-the-us/recent-trends-in-ge-adoption.aspx> (last visited Feb. 22, 2015).

and will continue to change.⁸⁷ Judicial decisions have impacted intellectual property protection and the rights of GE crop producers. For example, only a few years after the expansion of patent protection to plants, the Federal Circuit significantly narrowed the application of the common law experimental use exception, favoring patent holders within the industry.⁸⁸ More recently, cases narrowing the conception of patent exhaustion as applied to seeds favored the industry.⁸⁹ This narrowing of available patentable subject matter left less protection for traits. Patents confer exclusive rights to inventors for limited periods of time⁹⁰, in order to incentivize the production of new inventions⁹¹. But patents are not without their limitations.

Beginning in the early 19th century, patent rights were interpreted to include a common law experimental use exception to infringement liability. This experimental use exception can be traced to the 1813 case of *Whittemore v. Cutter*, in which Justice Story established the experimental use exception as a defense to patent infringement if the infringement occurred during the process of scientific research.⁹² Justice Story recognized that the founding fathers had not intended patents to preclude scientific research when he wrote that “it could never have been the intention of the legislature to punish a man who [used a patented invention] . . . merely for philosophical experiments, or for the purpose of ascertaining the sufficiency . . . to produce its desired effects.”⁹³ This common law experimental use exception evolved to encompass uses in which the invention was not made for profit⁹⁴; moreover, use of a patented invention in order to improve the invention and procure an improvement patent was not considered to be a for-profit use.⁹⁵

The common law experimental use exception began shrinking in the late 1970s and early 1980s. Courts began to consider the commercial interests of the patent user and significantly narrowed the application of the common law experimental use exception. In *Pitcairn v. United*

87. Internationally, there is debate as to whether GE crops should have patent protection at all. Andrew Torrance, *Intellectual Property as the Third Dimension of GMO Regulation*, 16 KANSAS J. LAW & PUB. POL. 257, 260 (2007).

88. Roche Products v. Bolar Pharm. Co., Inc., 733 F.2d 858, 860 (Fed. Cir. 1984), *superseded by statute as recognized in* Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003).

89. *See, e.g.*, Bowman v. Monsanto Co., 133 S. Ct. 1761 (2013).

90. 35 U.S.C. § 101 (2000).

91. U.S. CONST. art. I, § 8, cl. 8.

92. *Whittemore v. Cutter*, 29 Fed. Cas. 1120 (C.C.D. Mass. 1813) (17,600).

93. *Id.*

94. *Swain v. Guild*, 21 F. Cas. 554 (C.C.D. Mass 1813) (No. 12,391).

95. *Chesterfield v. United States*, 159 F. Supp. 371, 375 (Ct. Cl. 1958).

*States*⁹⁶, manufacturers used patented technologies in building and testing helicopters. The *Pitcairn* Court rejected the argument that this use of the patented technology fell under the experimental use exception, holding instead that the infringing tests were required to prepare the helicopters for sale.⁹⁷ As a result, the experimental use exception was not available.⁹⁸

Subsequent decisions from the Federal Circuit further narrowed the application of the experimental use exception to the point of near extinction. In *Roche Products v. Bolar Pharmaceutical Co.*, a generic drug manufacturer was using a patented drug to perform experiments for submission to the Food and Drug Administration once the patents had expired.⁹⁹ The *Roche* court held that the use of the patented drug was not an experimental use when the activity is merely “in the guise of ‘scientific inquiry’” because the activity had “‘definite cognizable, and not insubstantial commerce prospects.’”¹⁰⁰ The Federal Circuit in *Embrex, Inc. v. Service Engineering Corp.* further noted that testing for a commercial purpose is infringing, even if commercialization proves unsuccessful.¹⁰¹ Judge Rader’s concurrence in *Embrex* went even further, saying that the Patent Act disallows the common law experimental use exception entirely.¹⁰² The death knell to practical use of the common law experimental use exception sounded in *Madey v. Duke University* when the Federal Circuit held that the non-profit or commercial status of an accused infringer did not matter as long as the infringing activity furthered a legitimate business interest.¹⁰³

The line of cases limiting the application of the common law experimental use exception occurred concurrently with the recognition that plants could be patented, the birth of the agricultural biotechnology industry, and the initial research and development of GE crops. The limitation on the common law experimental use exception strengthened the ability of patent holders to control a competitor’s use of patented technology to develop follow-on innovation and contributed to the industry structure discussed below in Part II.B.3.

More recently, the Supreme Court addressed the applicability of the patent exhaustion doctrine to patented seed in *Bowman v. Monsanto*.¹⁰⁴

96. *Pitcairn v. United States*, 547 F.2d 1106 (Ct. Cl. 1976).

97. *Id.* at 1125-26.

98. *Id.* at 1125-26.

99. *Roche Products v. Bolar Pharm. Co., Inc.*, 733 F.2d 858, 860 (Fed. Cir. 1984), *superseded by statute as recognized in Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

100. *Id.* at 863.

101. *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

102. *Id.* at 1352.

103. *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

104. *Bowman v. Monsanto Co.*, 133 S. Ct. 1761 (2013).

In doing so, the Court weighed in on an ongoing ambiguity in the law involving biological inventions, such as new kinds of seeds. Seeds represented an issue¹⁰⁵ because, unlike most inventions, they are self-replicating. This self-replication makes copying of the invention extremely easy¹⁰⁶. Furthermore, this intrinsic property of seeds potentially limited patent protection through the doctrine of patent exhaustion, which “provides that the initial authorized sale of a patented item terminates all patent rights to that item.”¹⁰⁷

The *Bowman* case centered on the farmer Bowman’s use of Monsanto’s Roundup Ready soybean seed. These genetically engineered seeds contain a gene that confers resistance to the herbicide glyphosate.¹⁰⁸ At the time of Bowman’s use of the seed, Monsanto held utility patents covering the gene and its use in crop plants, including soybeans.¹⁰⁹ Generally, an authorized purchase of seeds covered by these Monsanto patents would include licensing terms that forbid saving produced seed for replanting purposes.¹¹⁰ However, Bowman purchased “commodity” seed from a grain elevator that was intended for human or animal consumption.¹¹¹ By obtaining seed in this manner, Bowman avoided any licensing terms, which would have prevented him from saving seed for replanting. Due to the extreme prevalence of Roundup Ready soybean seed in the market, Bowman was able to treat the crop from this commodity seed with the herbicide glyphosate without killing the soybean plants.¹¹² Bowman saved the resulting soybean seed from this crop for future replanting.¹¹³

The Supreme Court found that, by planting the commodity seeds and harvesting seed from the resulting soybean plants, Bowman had “reproduced Monsanto’s patented invention.”¹¹⁴ The Court held that though Bowman could have used the purchased commodity seed as feed or even resell it, using it to produce more seed was not protected by the patent exhaustion doctrine.¹¹⁵ The Court was not swayed by Bowman’s argument that patent exhaustion should apply because the seeds are meant to be planted and replicated, finding instead that “[t]he exhaustion

105. *Id.* at 1768-69

106. *Id.*

107. *Quanta Computer Inc. v. LG Elec. Inc.*, 553 U.S. 617, 625 (2008).

108. *Id.* at 1764.

109. *Id.* See also U.S. Patent Nos. 5,352,605 and RE39,247E.

110. *Bowman*, 133 S. Ct. at 1764-65.

111. *Id.* at 1765.

112. *Id.*

113. *Id.*

114. *Id.* at 1767.

115. *Bowman*, 133 S. Ct. at 1766.

doctrine is limited to the ‘particular item’ sold’.¹¹⁶ Therefore, Bowman could use the seeds he purchased but could not copy them despite their inherently self-replicating nature. The *Bowman* decision strengthened patent protections surrounding GE crops by disallowing a line of arguments that would have reinvigorated seed saving among farmers to the detriment of GE crop seed sales.

In *Ass’n for Molecular Pathology v. Myriad Genetics Inc.*, however, the Supreme Court narrowed intellectual property protection for GE organisms.¹¹⁷ *Myriad* addressed whether isolated DNA sequences of naturally occurring genes were patentable subject matter. The Court held that merely isolating genes that are found in nature does not make them patentable subject matter.¹¹⁸ However, the Court also found that cDNA, the creation of which is a minor and routine laboratory alteration of a gene’s sequence, was patentable subject matter.¹¹⁹ This holding suggests that relatively minor alterations to otherwise naturally occurring genes may allow those genes to be patentable subject matter.¹²⁰

GE crops rely on the identification and transfer of genes for specific traits of interest.¹²¹ Companies seeking patent protection for GE crops file patents on the plant as well as the gene for the traits of interest. Therefore, *Myriad* necessarily limits some of the patent protections available within the agricultural biotechnology industry.

For the agricultural biotechnology industry, these cases help to delineate the metes and bounds of patent protection within the industry. *Roche* limited the ability of competitors to begin to work on competitive products using patented gene traits until the patents expire. *Bowman* effectively banned any remnant of seed saving left from farmers’ historical practices. On the other hand, *Myriad* prevents claims directed specifically at naturally occurring genes which may allow for traits to remain in the public domain. However, *Myriad* left open the possibility of claiming genes with laboratory-altered sequences and the transgenic organisms themselves.

116. *Id.* at 1767.

117. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

118. *Id.* at 2117-18.

119. *Id.* at 2119.

120. While cDNA passes the threshold requirement for patentable subject matter, the other requirements for obtaining a patent—novelty, non-obviousness and utility—still apply. Given the routine nature of cDNA conversion in modern laboratories, it is unclear that cDNA will continue to remain non-obvious in the eye of the USPTO.

121. *See supra* Part II.A.3.

3. Impact of Intellectual Property Law on Industry Structure

Coinciding with increased intellectual property protection and transgenic technology were major alterations in the structure of the agricultural seed-production industry.¹²² Over the last four decades, the industry shifted from one with a plethora of small, regional seed producers to an industry dominated by a small number of large, multinational corporations.¹²³ The seed industry is dominated by six large seed and chemical companies, with the largest three (Monsanto, Syngenta, and DuPont) controlling approximately half of the market.¹²⁴ This oligopolistic structure has resulted from rapid consolidation within the industry, with large corporations acquiring the majority of the small and mid-sized firms within the industry.¹²⁵

Strong intellectual property protections on bag-seed licenses and patent cross-licensing agreements among the dominant seed-producing corporations have served to maintain this structure by enhancing barriers to entry for smaller firms.¹²⁶ In the absence of a common law experimental use exception or application of the statutory experimental use exception, small companies that wish to develop GE crops with patented traits have been forced to negotiate with the large corporations for patent licenses.¹²⁷ These negotiations are required even if the resulting GE crops would not be ready for market until after the patent protection covering the underlying trait or crop had expired.

Not everyone is confident that the existing industry structure, based on such strong patent protections, is in the best interest of innovation or society.¹²⁸ In 2010, the U.S. Department of Justice instigated a two-year

122. Rowe, *supra* note 57, at 860.

123. Phillip H. Howard, *Visualizing Consolidation in the Global Seed Industry: 1996–2008*, 1 SUSTAINABILITY 1266, 1266–87 (2009); Jay P. Kesan, *Seeds of Change: A Link Among the Legal, Economic and Agricultural Communities*, xvii, xxii, in SEEDS OF CHANGE, *supra* note 79.

124. Howard, *supra* note 123, at 1274–79.

125. *Id.*

126. Andrew Pollack, *Monsanto and DuPont Settle Fight Over Patent Licensing*, N.Y. TIMES (MARCH 26, 2013), http://www.nytimes.com/2013/03/27/business/monsanto-and-dupont-settle-fight-over-roundup-ready-technology.html?_r=0; Elizabeth I. Winston, *What Ifs and Other Alternative Intellectual Property and Cyberlaw Story: If Seeds Were Not Patentable?*, 2008 MICH. ST. L. REV. 321, 330 (2008); Rowe, *supra* note 57, at 866; Jay P. Kesan, *Licensing Restrictions and Appropriating Market Benefits from Plant Innovation*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1081, 1084 (2006).

127. *See Monsanto Licensing Allows Farmers to Buy Traits from Folks They Know*, DELTA FARM PRESS (Oct. 19, 2001), <http://deltafarmpress.com/monsanto-licensing-allows-growers-buy-traits-folks-they-know>.

128. For a detailed argument that the industry structure is procompetitive, see F. Scott Kieff et al., *Comment on Intellectual Property, Concentration and the Limits of Antitrust in the Biotech Seed Industry* (Lewis & Clark Law Sch. Legal Studies Research Paper No. 2010-9; Geo. Mason Law & Econ. Research Paper No. 10-24), <http://ssm.com/abstract=1553064>.

antitrust investigation into Monsanto business practices due to the economic concentration of the industry.¹²⁹ At least one scholar has classified these barriers to entry as intellectual property overreaching because they do not leave room for experimentation during the patent term.¹³⁰ Similarly, Professor Mark Janis has suggested that the use of an experimental use exception would open the industry for sustainable agriculture.¹³¹ The application of the statutory experimental use exception would alleviate some of the concerns expressed by the DOJ and scholars and perhaps reshape the industry, as discussed in Part VI. These strong intellectual property protections, however, do not act in a vacuum. Rather, combined with complicated regulatory barriers, these constraints serve to keep the number of industry players small.

C. U.S. Federal Food Regulation

Federal food regulation in the U.S. began over a century ago with an emphasis on prevention of misbranding and adulteration of foodstuffs.¹³² Over time this regulatory structure expanded, resulting in a mosaic of “15 [federal] agencies that collectively administer at least 30 laws related to food safety.”¹³³ Primary among these agencies is the FDA, which is responsible for the regulation of most foods except poultry, meat, and some egg products, which are regulated by the USDA.¹³⁴

The FDA derives most of its power for food safety regulation from the federal Food Drug and Cosmetic Act (FDCA).¹³⁵ The FDCA does not provide authority for premarket approval of whole foods, such as fruits and vegetables, though the FDA has the ability to remove foods from the market if they are “adulterated”¹³⁶ or “misbranded.”¹³⁷ Under

129. Ian Berry & David Kesmodel, *U.S. Closes Antitrust Investigation Into Seed Industry, Monsanto*, WALL ST. J. (Nov. 16, 2012, 7:18 PM), <http://www.wsj.com/articles/SB10001424127887324735104578123631878019070>.

130. Rowe, *supra* note 57, at 874.

131. Mark Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEGAL STUDIES 91, 105, 106-08 (2001) [hereinafter Janis, *Sustainable Agriculture*].

132. For a short overview of early federal food and medicine regulation leading to the modern FDA, see FOOD & DRUG ADMINISTRATION, *FDA'S ORIGIN AND FUNCTIONS*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/default.htm> (last visited Sept. 14, 2015).

133. GOV'T ACCOUNTABILITY OFF., GAO-08-435T, *FEDERAL OVERSIGHT OF FOOD SAFETY 3* (2008).

134. GOV'T ACCOUNTABILITY OFF., GAO-15-290, *HIGH RISK SERIES 262* (2015).

135. 21 U.S.C. § 301.

136. The FDCA definition of an adulterated foods is found at 21 U.S.C. § 342 and generally indicates an unsafe, unwholesome, or impure food.

137. The FDCA definition of misbranded foods is found at 21 U.S.C. § 343.

the FDCA, however, the FDA does have premarket authority in the regulation of food additives.

1. Food Additive Regulations

The 1958 Food Additives Amendment gave the FDA more authority to examine the safety of food additives.¹³⁸ Currently, there are about 3,000 listed food additives including common additives such as salt and sugar.”¹³⁹ Under the FDCA, a food additive is

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food . . . if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures . . . to be safe under the conditions of its intended use¹⁴⁰

Therefore, a substance added to food that is generally recognized as safe (GRAS) is, by the FDCA’s definition, not a “food additive.”

Congress prohibits the “adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.”¹⁴¹ A food is “adulterated” if it contains “any food additive that is unsafe within the meaning of section 348[.]”¹⁴² and courts have held accordingly.¹⁴³ Anyone, including the FDA,¹⁴⁴ can file a petition regarding an intended use of a food additive that proposes a regulation outlining how a particular food additive may be used.¹⁴⁵ These petitions and the factors used to determine safety are exhaustive and require a huge amount of data.

The petition has several requirements. First, the petition must include “the name and all pertinent information concerning such food additive,

138. Food Additives Amendment of 1958, codified at 21 U.S.C. 321(s) (defining food additive); 21 U.S.C. 348(a) (defining unsafe food additive); section 409(b)-(h) (establishing a premarket approval process); 21 U.S.C. 342(a)(2)(C) (amending the food adulteration provisions).

139. FOOD & DRUG ADMINISTRATION, OVERVIEW OF FOOD INGREDIENTS, ADDITIVES & COLORS, U.S. DEP’T HEALTH & HUMAN SERVS., <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm094211.htm> (last visited Nov. 11, 2015) [hereinafter “FDA Food Additives”].

140. 21 U.S.C. § 321(s).

141. *Id.* § 331.

142. *Id.* § 342 (a)(2)(C)(i).

143. *See, e.g.,* United States v. Ewig Bros. Co., Inc., 502 F.2d 715, 725 (7th Cir. 1974); United States v. Articles of Food . . . Buffalo Jerky, 456 F. Supp. 207, 209 (D. Neb. 1978).

144. 21 U.S.C. § 348(d).

145. *Id.* § 348(b)(1).

including, where available, its chemical identity and composition.”¹⁴⁶ The petition shall also include “a statement of the conditions of the proposed use of such additive . . . ,”¹⁴⁷ including directions for the use of the additive, and examples of the proposed labeling.¹⁴⁸ Additionally, “all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect” must be included.¹⁴⁹

Other petition requirements include “a description of practicable methods for determining the quantity of such food additive in or on food, and any substance formed in or on food, because of its use” and full investigative reports regarding the safety of the additive.¹⁵⁰ These investigative reports should include all “information as to the methods and controls” employed in the investigations.¹⁵¹

Further, in the event that all of the enumerated requirements do not expressly require a certain group of information, § 348 contains a “catch-all” provision of sorts. Preceding all of the discussed requirements, § 348 states that the petition shall contain “any explanatory or supporting data.”¹⁵² Even more, the petitioner is required to give a “full description of the methods used in, and the facilities and controls used for, the production of such additive” and to provide “samples of the food additive involved, or articles used as components [of the food additive] and of the food in or on which the additive is proposed to be used” if the Secretary requests such information or samples.¹⁵³

Once the petition is filed, it is reviewed by the FDA. The FDCA sets forth a non-exhaustive list of factors that the FDA should consider when determining whether a proposed food additive is safe. The FDA should consider (1) “the probable consumption of the additive and any substance formed in or on food because of the use of the additive;”¹⁵⁴ (2) “the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet;”¹⁵⁵ and (3) “safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as

146. *Id.* § 348(b)(2)(A).

147. *Id.* § 348(b)(2)(B).

148. *Id.*

149. 21 U.S.C. § 348(b)(2)(C).

150. *Id.* § 348(b)(2)(D)-(E).

151. *Id.*

152. *Id.* § 348(b)(2).

153. *Id.* § 348(b)(3)-(4).

154. 21 U.S.C. § 348(c)(5)(A).

155. *Id.* § 348(c)(5)(B).

appropriate for the use of animal experimentation data.”¹⁵⁶ The FDA website adds that it will also consider “various safety factors.”¹⁵⁷ The FDA may also establish tolerance limits—i.e., limits on how much an additive may be used in order to assure safety.¹⁵⁸

2. Additives “Generally Recognized as Safe”

As noted above, under the FDCA, a substance that is added to food is not actually a food additive if it is GRAS.¹⁵⁹ General recognition of safety can be established by either scientific studies and evidence¹⁶⁰ or “common use in food prior to January 1, 1958.”¹⁶¹ However, where recognition of safety is based on scientific evidence there must be “the same quantity and quality of scientific evidence as is required to obtain [premarket] approval of a food additive regulation for the ingredient.”¹⁶² Additionally, any scientific procedures used to demonstrate recognition of safety shall “ordinarily be based upon published studies which may be corroborated by unpublished studies and other data”¹⁶³

The FDA has published a list of substances and their specified purposes that the agency has found to be GRAS.¹⁶⁴ However, this list is not exhaustive,¹⁶⁵ and in recent decades, the FDA has relied almost exclusively on companies themselves to make determinations as to whether a substance is GRAS. The FDA has stopped affirming GRAS status of substances and instead encourages the submission of a GRAS notification by companies, which the FDA can then respond to with any concerns the agency has.¹⁶⁶

D. Regulation of Biotechnology: The Coordinated Framework

The regulatory scheme directed towards the safety of biotechnology

156. *Id.* § 348(c)(5)(C).

157. FDA Food Additives, *supra* note 139.

158. 21 U.S.C. § 348(c)(4).

159. *Id.* § 321(s).

160. 21 C.F.R. § 170.30(b).

161. *Id.* § 170.30(c)(1)-(2).

162. *Id.* § 170.30(b).

163. *Id.*

164. 21 C.F.R. § 184.

165. FOOD & DRUG ADMINISTRATION, STATEMENT OF POLICY: FOODS DERIVED FROM NEW PLANT VARIETIES, U.S. DEP’T OF HEALTH AND HUMAN SERVS., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Biotechnology/ucm096095.htm> (last visited Sept. 15, 2015) [hereinafter “1992 Statement of Policy”].

166. FOOD & DRUG ADMINISTRATION, HOW U.S. FDA’S GRAS NOTIFICATION PROGRAM WORKS, U.S. DEP’T OF HEALTH & HUMAN SERVS., (Dec. 2005/Jan. 2006), <http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/ucm083022.htm>.

and its products, including food products and pesticides, is known as the Coordinated Framework.¹⁶⁷ The Coordinated Framework rests on the underlying premise that biotechnology can be adequately regulated through existing laws and regulatory structures, though it was recognized that some regulations and laws may have to adapt to rapidly changing technologies.¹⁶⁸ Further, the Coordinated Framework embodies the concept that genetically engineered products and organisms are not fundamentally different than those created by more traditional means such as selective breeding and induced mutation, and thus the agencies generally assess risk according to the individual product rather than the process used to create it.¹⁶⁹

For regulation of biotechnologically derived foods and food products such as GE crops, the Coordinated Framework relies primarily on three agencies: the FDA, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) and the Environmental Protection Agency (EPA).¹⁷⁰ A single product is often regulated by more than one agency and each agency operates under different, though sometimes overlapping, statutory authority. In the realm of agricultural biotechnology, the USDA-APHIS protects U.S. agriculture by regulating plant pests, diseases, and weeds via the Plant Protection Act.¹⁷¹ The EPA protects human health and the environment through regulation of pesticides and plant-incorporated protectants¹⁷² with the Pesticide Registration and Classification¹⁷³ system and experimental use permits¹⁷⁴ under authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the FDCA. The EPA also controls reporting review processes for intergeneric microorganisms pursuant to the Toxic Substances Control Act (TSCA).¹⁷⁵ The FDA protects the safety of the food and feed supply, primarily under the authority of the FDCA.¹⁷⁶

As stated previously, the USDA-APHIS is generally concerned with

167. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986) [hereinafter OSTP 1986]. For a full description of the Coordinated Framework, see PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, PEW, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS (2004), http://www.pewtrusts.org/~media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_and_biotechnology/hhsbiotech0901pdf.pdf [hereinafter PEW].

168. OSTP 1986, *supra* 167, at 3-4.

169. *Id.*

170. For an overview of the Coordinated Framework, see PEW, *supra* note 167.

171. 7 U.S.C. § 7701 and 7 C.F.R. § 340.0-9 (2013).

172. Such as Bt.

173. 40 C.F.R. § 152, 174 (2013).

174. *Id.* § 172.

175. *Id.* § 725.

176. *See generally* 21 U.S.C. § 301.

plant pests and diseases, working to prevent the release and spread of these agriculturally damaging agents.¹⁷⁷ USDA-APHIS regulates field tests and interstate shipping of most genetically engineered plants, and GE plants are considered to be “regulated articles” until a petition for deregulation is approved by the agency.¹⁷⁸ However, in the majority of situations the applicant needs only submit a notification to the USDA-APHIS before a field test or interstate shipment of a regulated article is performed.¹⁷⁹ The agency must then respond with an acknowledgement or denial of the notification.¹⁸⁰

Under USDA-APHIS regulations, a “regulated article” is “any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent” is known or believed to be a plant pest or if the classification of the organism is unknown.¹⁸¹ A “plant pest” is also extremely broadly defined as nearly any organism that can cause damage to a plant or a part of a plant.¹⁸² Currently, most genetic engineering methods for plants make use of organisms currently classified as plant pests, and so most GE plants come under USDA-APHIS regulation.¹⁸³ These definitions of a regulated article and plant pest gives the USDA-APHIS wide latitude in regulating initial transport and release into the environment of GE organisms, though the applicant can petition for deregulation with a showing of data of the effects of the GE organism on other plants, non-target organisms, and the environment.¹⁸⁴

As stated above, the EPA’s authority to regulate agricultural biotechnology is derived from the FIFRA, the FDCA, and the TSCA. Under FIFRA, the EPA regulates the use of pesticides.¹⁸⁵ Substances

177. See *supra* Part II.D.1.

178. 7 C.F.R. § 340.3.

179. *Id.*

180. 7 C.F.R. 340.3(d).

181. *Id.* § 340.1.

182. *Id.*

183. The first generations of genetically engineered plants often used transformation techniques (methods of moving the foreign DNA into the target plant cells), which relied on vectors such as *Agrobacterium tumefaciens* that are considered by USDA-APHIS to be plant pests. See Charles S. Gasser and Robert T. Fraley, *Genetically Engineering Plants for Crop Improvement*, 244 SCI. 1293, 1293 (1989). Newer methods of creating GE plants may not rely on known or suspected plant pests for transformation and so would not come under USDA-APHIS regulation. In 2011, USDA-APHIS confirmed that a GE Kentucky Bluegrass from Scott’s Miracle-Gro Company did not come under its regulation, as the “organisms used in generating Scotts’ variety of GE Kentucky bluegrass are not considered to be plant pests, and Scotts did not use a plant pest to genetically engineer the Kentucky bluegrass.” See U.S. DEP’T OF AGRICULTURE, NEWS RELEASE (July 1 2011), http://www.aphis.usda.gov/newsroom/2011/07/kentucky_bluegrass.shtml.

184. 7 C.F.R. § 340.6(c).

185. Pesticide is a broad term meaning:

falling under this definition of pesticide must be registered with the EPA before distribution or sale.¹⁸⁶ For registration to be successful, the substance must not cause “unreasonable adverse effects on the environment”¹⁸⁷ when used as intended or as is common practice.¹⁸⁸ Importantly for agricultural biotechnology, the EPA also regulates pesticides expressed by GE plants themselves (known as “plant-incorporated protectants”), such as crops expressing the Bt pesticide. The EPA is also responsible for regulating and establishing tolerance levels for pesticide residues in foods under the FDCA.¹⁸⁹

The FDA, the third agency in the Coordinated Framework, concerns its regulations with the safety of agricultural biotechnology for consumption.¹⁹⁰ Due to the language and caselaw¹⁹¹ surrounding the statutory experimental use exception, this Article focuses on those FDA regulations.

In 1992, the FDA published a policy (1992 Statement of Policy) that “clarified the agency’s interpretation of the application of the Federal Food, Drug, and Cosmetic Act with respect to human foods and animal feeds derived from new plant varieties and provided guidance to industry on scientific and regulatory issues related to these foods.”¹⁹² This policy “applied to all foods derived from all new plant varieties, including varieties that are developed using recombinant deoxyribonucleic acid (rDNA) technology.”¹⁹³ It basically provided that GE foods would be regulated as food additives under the Act.¹⁹⁴

(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, and (3) any nitrogen stabilizer, except that the term “pesticide” shall not include any article that is a “new animal drug”

7 U.S.C. 136(u).

186. *Id.* § 136a (a).

187. These “unreasonable adverse effects on the environment” include:

(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 346a of title 21. The Administrator shall consider the risks and benefits of public health pesticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this subchapter, the Administrator shall weigh any risks of the pesticide against the health risks such as the diseases transmitted by the vector to be controlled by the pesticide.

Id. § 136(bb).

188. *Id.* § 136a(c)(5)

189. 21 U.S.C. 346(a), 348.

190. *See* PEW, *supra* note 167.

191. *See infra* Part IV.

192. 1992 Statement of Policy, *supra* note 165.

193. *Id.*

194. GE crops are one type. GE animals for food consumption would be the other.

1. Regulation as Food Additives

In its 1992 Statement of Policy, the FDA did not create a new regulatory framework for GE crops and their food products. Instead, the FDA provided that “fruits, vegetables, grains, and their byproducts, derived from plant varieties developed by . . . new methods of genetic modification are regulated within the existing framework of the [Food, Drug, and Cosmetic Act].”¹⁹⁵ The FDA rationalized that this was the appropriate position because “[t]he regulatory status” of food is not dependent upon the method by which it is derived.¹⁹⁶ The “key factors in reviewing safety concerns should be the characteristics of the food product”¹⁹⁷ Accordingly, the FDA stated that GE foods would be regulated as food additives under § 402(a)(1) and § 409 of the FDCA.¹⁹⁸

According to the 1992 Statement of Policy, § 402(a)(1) applies to any “substance that occurs unexpectedly in the food at a level that may be injurious to health . . . includ[ing] a naturally occurring toxicant whose level is unintentionally increased by the genetic modification”¹⁹⁹ Moreover, the 1992 Statement of Policy places the burden on the producer of a new food to evaluate and determine safety and compliance with § 402(a)(1) of the FDCA.²⁰⁰

Section 409 of the FDCA “broadly encompasses any substance that has an intended use in food, unless the substance is [generally recognized as safe].”²⁰¹ The FDA felt that § 409’s broad scope indicated that the regulatory scheme in place would be sufficient to cover genetic material that is transferred.²⁰² Therefore, “in the case of foods derived from new plant varieties, it is the transferred genetic material and the intended expression product[s] . . . that could be subject to food additive regulation” if the genetic material is not GRAS.²⁰³ Thus, not all genetic materials would be evaluated under § 409. For example, nucleic acids would not be subject to food additive regulation because they “are present in the cells of every living organism,” and therefore, are “presumed to be [generally recognized as safe].”²⁰⁴

195. 1992 Statement of Policy, *supra* note 165.

196. *Id.*

197. *Id.*

198. *Id.*

199. *Id.* at § V.B.

200. 1992 Statement of Policy, *supra* note 165.

201. *Id.* at § V.C.

202. *Id.*

203. *Id.*

204. *Id.*

2. FDA Guidance on Regulatory Compliance

The FDA's 1992 Statement of Policy then set forth some guidance to the industry regarding foods that are derived from GE crops. The guidance is based around the idea that the "FDA believes that a scientific basis should exist to establish that new plant varieties do not exhibit unacceptable effects with respect to toxicants, nutritional value, or allergens."²⁰⁵ Moreover, the 1992 Statement of Policy set forth an "assessment scheme [that] focuses on characteristics of the new plant variety, . . . characteristics of the host and donor species, the nature of the genetic change, the identity and function of newly introduced substances, and unexpected or unintended effects that accompany the genetic change."²⁰⁶

As a general matter, the FDA then provides five major assessment considerations: (1) toxicants known to be characteristic of the host and donor species; (2) the potential that food allergens will be transferred from one food source to another; (3) the concentration and bioavailability of important nutrients for which a food crop is ordinarily consumed; (4) the safety and nutritional value of newly introduced proteins; and (5) the identity, composition, and nutritional value of modified carbohydrates, or fats and oils.²⁰⁷ Importantly, these are general considerations. The FDA also set forth specific, but similar, considerations for the safety assessment of the host plant,²⁰⁸ the donor plant,²⁰⁹ substances introduced into the host plant from the donor plant,²¹⁰ and toxicology.²¹¹

3. FDA-Developer Consultations

Since the 1992 Statement of Policy was issued, the FDA has encouraged developers to consult with the FDA regarding the development and marketing of new bioengineered products. These interactions take three forms: (1) biotechnology final consultations; (2) new protein consultations; and (3) establishment of a food master file or submission of a food additive petition.

In 2001, the FDA issued a proposed rule providing that "developers submit a scientific and regulatory assessment of the bioengineered food

205. 1992 Statement of Policy, *supra* note 165.

206. *Id.*

207. *Id.*

208. *See id.* at § VI.D.

209. *See id.* at § VI.E.

210. *See* 1992 Statement of Policy, *supra* note 165, at § VI.F. This category includes proteins, carbohydrates, fats, and oils.

211. *See id.* at § VI.G.

120 days before the bioengineered food is marketed.”²¹² The FDA also encourages developers to consult with the FDA before issuing a premarket notice.²¹³ During a final biotechnology consultation with the FDA, “a developer . . . may meet with the agency to identify and discuss relevant safety, nutritional, or other regulatory issues regarding the bioengineered food in an initial consultation.”²¹⁴ However, the developer may forgo the consultation and simply “submit to FDA a summary of its scientific and regulatory assessment of the food.”²¹⁵

New Protein Consultations (NPCs) and its corresponding documents were created to decrease the possibility that “new bioengineered plants could result in the inadvertent, intermittent, low-level presence in the food supply of proteins that have not been evaluated through FDA’s biotechnology consultation process.”²¹⁶ As NPCs take place, the FDA keeps and manages an inventory of completed NPCs.²¹⁷ This inventory includes the agency’s response and the developer’s actual submission.²¹⁸

The third category of submissions—food master files and petitions—are rare, and the FDA keeps an inventory of these as well.²¹⁹ A food petition and its corresponding master file of data is required only if the additive is not already regulated for the intended use.²²⁰

While the FDA has developed this extensive structure of consultations for GE crops, compliance is, from a legal standpoint, voluntary.²²¹ Since GE crops generally are considered GRAS, companies are free to declare the GE crop GRAS internally and market the seeds. Such internal GRAS declarations are quite common in the chemical food-additive space.²²² However, in the agricultural biotechnology industry, opting out of the voluntary process is quite rare. By the account of at least one former USDA official, all GE crops that

212. FOOD & DRUG ADMINISTRATION, SUBMISSIONS ON BIOENGINEERED NEW PLANT VARIETIES, U.S. DEP’T OF HEALTH AND HUMAN SERVS., <http://www.fda.gov/Food/FoodScienceResearch/GEPlants/Submissions/default.htm> (last visited June 2, 2016) [hereinafter “Submissions on Bioengineered Varieties”].

213. *Id.*

214. *Id.*

215. *Id.*

216. *Id.*

217. Submissions on Bioengineered Varieties, *supra* note 212.

218. *Id.*

219. *Id.*

220. FOOD & DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS ABOUT THE PETITION PROCESS, DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm253328.htm#answerA> (last visited Nov. 10, 2015).

221. PEW, *supra* note 167, at 20.

222. Tom Neltner & Maricel Maffini, *Generally Recognized as Secret: Chemicals Added to Food in the United States*, NAT. RESOURCES DEF. COUNCIL (Apr. 2014), <http://www.nrdc.org/food/files/safety-loophole-for-chemicals-in-food-report.pdf>.

have gone through the mandatory USDA-APHIS review also have gone through the FDA voluntary process.²²³

The context of the current contours of patent protection, industry structure, and the Coordinated Framework discussed above sets the stage for the analysis of the applicability of the statutory experimental use exception—an analysis based on FDA regulation. However, in order to consider the statutory experimental use exception, it is first necessary to understand the broad regulations of products in the health care industry and the development of abbreviated pathways of approval once patent protection has expired.

III. DEVELOPMENT AND REGULATION OF THE PHARMACEUTICAL INDUSTRY

Over time, the healthcare industry has evolved alongside the agriculture industry. Increased regulatory structure and patent protection have produced two dynamic, sophisticated industries similar in many ways. Like the agriculture industry, the pharmaceutical industry is focused on proprietary products that can be ushered through a regulatory process. However, patents have been explicitly directed at chemical drugs longer than plants. Therefore, consumers have come to expect cheaper, non-patent protected, generic versions of drugs to become available as patents on drugs expire.

As patents prohibit new entrants into a product marketplace until after expiration, consumers became concerned with the delay of entry of cheaper generics, especially with patent extensions being granted for delays in regulatory approval. In response, Congress developed an abbreviated approval pathway for generic drugs.²²⁴ This abbreviated pathway includes the statutory experimental use exception that is potentially applicable to the agricultural biotechnology industry.

A. Development and Regulation of New Drugs

While an article is not deemed a “drug” under the FDA merely by labeling it a drug, the FDA’s definition of drug is broad, encompassing four large categories of drugs. The first is any article “recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them.”²²⁵ The second is any article “intended

223. Nathanael Johnson, *The GM safety dance: What’s rule and what’s real*, GRIST (July 10, 2013), <http://grist.org/food/the-gm-safety-dance-whats-rule-and-whats-real/>.

224. See *infra* Part III.B.

225. 21 U.S.C. § 321(g)(1)(A) (1923).

for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.”²²⁶ The third is any article, other than food, “intended to affect the structure or any function of the body of man or other animals.”²²⁷ The fourth is any article “intended for use as a component of any article specified in” the previous categories.²²⁸

The regulation of drugs has evolved over time. Pre-Civil War, the only drug regulations involved protections against the importation of adulterated and misbranded drugs.²²⁹ It wasn’t until the passage of the 1902 Pure Food and Drug Act that Congress acted to regulate the interstate commerce of adulterated or misbranded domestic drugs.²³⁰ This Act also established the United States Pharmacopœia and National Formulary as the standard listings for approved drugs.²³¹ A series of deaths from untested drug formulations led to the passage of the FDCA of 1938, which established the requirement that companies prove the safety of any drug before it was marketed.²³² In 1962, Congress amended the FDCA to additionally require companies to submit proof of the drug’s efficacy for the marketed indication.²³³

1. FDA Approval Process for New Drugs

The regulatory process for FDA approval of new drugs is relatively straightforward but extremely expensive. The drug approval process begins with the company testing the new drug on animals.²³⁴ The purpose of this animal testing is to determine how the drug reacts and if

226. *Id.* § 321(g)(1)(B).

227. *Id.* § 321(g)(1)(C).

228. *Id.* § 321(g)(1)(D).

229. FOOD & DRUG ADMINISTRATION, BROCHURE: THE HISTORY OF DRUG REGULATION IN THE UNITED STATES, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/AboutFDA/WhatWeDo/History/FOrgsHistory/CDER/CenterforDrugEvaluationandResearchBrochureandChronology/ucm114470.htm> (last visited June 2, 2016) [hereinafter “Brochure”].

230. SUZANNE WHITE JUNOD, FDA AND CLINICAL DRUG TRIALS: A SHORT HISTORY, FOOD & DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm304485.htm> (last visited July 25, 2015).

231. Brochure, *supra* note 229.

232. FOOD & DRUG ADMINISTRATION, FDA’S ORIGIN AND FUNCTIONS – PART II: THE 1938 FOOD, DRUG, AND COSMETIC ACT, DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm054826.htm> (last visited June 2, 2016).

233. FOOD & DRUG ADMINISTRATION, FDA HISTORY – PART IV: REGULATING COSMETICS, DEVICES, AND VETERINARY MEDICINE AFTER 1938, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055137.htm> (last visited June 2, 2016).

234. FOOD & DRUG ADMINISTRATION, HOW FDA EVALUATES REGULATED PRODUCTS: DRUGS, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm> (last visited June 2, 2016) [hereinafter “FDA Drug Regulation”].

the drug is safe enough to be tested on humans.²³⁵ Once the animal testing is complete, the company must submit and get approved an Investigational New Drug Application (IND) to the FDA before any testing on humans can be conducted.²³⁶ When the FDA approves the IND, the company will then conduct testing of the drug on humans in clinical trials to determine the safety and efficacy of the drug.²³⁷ The company will then compile the data that it collects from the three-phased clinical trials and submit it to the FDA's Center for Drug Evaluation and Research (CDER) as part of its New Drug Application (NDA).²³⁸ The NDA, along with its included data and proposed labeling, will then be evaluated by the CDER team.²³⁹ If a drug's proposed benefits outweigh its known risks, the drug will be approved for sale.²⁴⁰ The cost of the approval process becomes apparent with the details of the approval process.

After animal testing indicates that a drug has a likelihood of success for use in humans, pharmaceutical companies must begin clinical trial testing in humans. Clinical trials occur in three basic stages. In Phase I of clinical trials, small groups of volunteers are given dosages of drugs in safety studies. The goal of a Phase I clinical trial is to determine initial drug safety, set a safe dosage range, and begin to identify potential side effects. Phase I clinical trials do not include tests for the efficacy of the drug. Phase II clinical trials involve a larger group of people, continue to evaluate safety, and also begin to collect data on the effectiveness of the drug. Phase III clinical trials are the final, most costly stage of drug testing. Large numbers of volunteers are needed in order to evaluate the drug's effectiveness and to monitor side effects. Also, Phase III clinical trials often compare the drug's effectiveness to commonly used treatments, if applicable, and collect information about side effects and counter-indications that will allow the drug to be used

235. *Id.* An independent Institutional Review Board (IRB) also will review the application to determine if human testing is appropriate. See FOOD & DRUG ADMINISTRATION, THE DRUG REVIEW PROCESS 1, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/UCM195671.pdf> (last visited June 2, 2016) [hereinafter "Drug Review Process"].

236. FDA Drug Regulation, *supra* note 234.

237. *Id.*

238. *Id.*

239. *Id.* This team is usually comprised of "physicians, statisticians, toxicologists, pharmacologists, chemists, and other scientists . . ." *Id.* If the CDER finds that the drug is unsafe and the FDA does not approve the drug, it will communicate its concerns regarding the drug to the company. Drug Review Process, *supra* note 235. The FDA, at this stage, also will evaluate and inspect the places where the drug will be made and how it will be made. *Id.*

240. FDA Drug Regulation, *supra* note 234. The FDA, at this stage, has sixty days to decide to approve and file an application or not. Drug Review Process, *supra* note 235.

safely.²⁴¹

Upon completion of the clinical trials, the pharmaceutical company still needs FDA approval to market the drug. The FDCA states that “[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to [FDCA provisions governing new drug applications or abbreviated new drug applications] of this section is effective with respect to such drug.”²⁴² Therefore, the pharmaceutical company must submit an NDA based on the results of the clinical trials.

Once the drug has been approved and is disseminated throughout the market, the FDA will then continue to passively monitor the drug’s performance.²⁴³ One way the FDA has indicated its surveillance is through MedWatch, “the agency’s safety information and adverse event reporting program.”²⁴⁴ However, this program is voluntary, and even the FDA notes that several serious adverse events go unreported.²⁴⁵ The FDA also conducts “postmarket requirement and commitment studies” after it has approved a product for marketing.²⁴⁶ If the FDA ultimately finds that a drug is unsafe once it has been released to the market, the FDA can take several steps, including issuing a Drug Safety Communication to consumers and healthcare professionals, adding a warning statement to the drug, or withdrawing an approved drug from the market.²⁴⁷

2. Importance of Patents in Drug Development

As mentioned, these testing protocols and regulations are costly. While the safety and efficacy requirements of the FDCA increase the safety of U.S. consumers, they increase the cost of drug development. Pharmaceutical companies on average invest millions of dollars into the development of one new drug.²⁴⁸ Additionally, approximately 90% of

241. U.S. NAT’L LIBR. OF MED., CLINICAL TRIAL PHASES, NAT’L INSTS. OF HEALTH, <https://www.nlm.nih.gov/services/ctphases.html> (last visited Sept. 16, 2015).

242. 21 U.S.C. § 355(a) (1984).

243. FDA Drug Regulation, *supra* note 234.

244. *Id.*

245. *Id.*

246. FOOD & DRUG ADMINISTRATION, THE FDA’S DRUG REVIEW PROCESS: ENSURING DRUGS ARE SAFE AND EFFECTIVE, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143534.htm> (last visited Sept. 16, 2015) [hereinafter “Drug Safety”].

247. FDA Drug Regulation, *supra* note 234.

248. This number is highly disputed. Some studies range from approximately one hundred million to eight hundred million or more. MERRILL GOOZNER, \$800 MILLION PILL: THE TRUTH BEHIND THE COST OF NEW DRUGS 239 (2004). But these studies often include capitalized costs of failed drug leads as well as opportunity costs. *Id.* at 9-10.

drugs in the clinical trial pipeline ultimately fail to gain FDA approval—often after Phase III data is obtained.²⁴⁹

In order to recoup the cost of development and generate a profit, pharmaceutical companies rely on patent protection for their approved products.²⁵⁰ A patent guarantees the pharmaceutical company a monopoly for the life of the patent. These patents typically cover the active ingredient of the drug but may also protect manufacturing practices or specialized uses of the drug.²⁵¹ These patented drugs are often called “branded drugs” because the pharmaceutical companies develop trademarked names for use in sales. For instance, the pain reliever ibuprofen is sold by Pfizer as the branded drug Advil.²⁵² Once the patent expires, other pharmaceutical companies are able to sell a drug previously covered by the patent. These formulations of the drug sold in direct competition with the branded drug are called generic drugs or just generics.

One consequence of the increased regulation of drugs and the resulting increased cost of development is an increased cost for the drug consumer. Pharmaceutical companies are able to command premium prices for branded drugs initially due to the monopoly power granted by the drug’s patent. Once other companies enter the market selling the same drug, competition almost immediately drives down the price of the drug.²⁵³

B. Pathway for Generic Drugs and the Implementation of Hatch-Waxman

Directly after the 1962 enactment of the FDCA, generic drug companies had to submit the same amount of safety and efficacy data as the branded drug company did in the initial filing. While generic companies did not have to invest in research for drugs unlikely to be approved, the cost of the clinical trials is enormous. As a result of the cost of regulation of drugs combined with the low selling price of drugs once competition began, generic drug manufacturers had little incentive

249. Michael Hay et al., *Clinical development success rates for investigational drugs*, 32 *NATURE BIOTECHNOLOGY* 40, 47 (2014).

250. Rebecca Eisenberg, *The Role of the FDA in Innovation Policy*, 13 *MICH. TELECOM. TECH. L. REV.* 345, 350-52 (2007).

251. For case studies describing the multiple patents covering a drug, see Lisa L. Ouellette, *How Many Patents Does It Take to Make a Drug - Follow-On Pharmaceutical Patents and University Licensing*, 17 *MICH. TELECOMM. & TECH. L. REV.* 299, 320-21 (2010).

252. See Joanna Shepard, *Biologic Drugs, Biosimilars, and Barriers to Entry* 6 (Emory Legal Studies Research Paper Series, Research Paper No. 14-284).

253. Gerald Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 *FOOD AND DRUG L.J.* 187, 187 (1999).

to bring competing drug formulations to market. Additionally, due to the patent protection, generic companies could not begin research on the generic form of the drug until patent protection ended. The resulting delay in approval of the generic often resulted in years of de facto monopoly for the branded drug manufacturer.²⁵⁴

Concerns over the availability of cheap generics for consumers after patent expiration led Congress to act. President Reagan signed the Drug Price Competition and Patent Term Restoration Act into law in 1984.²⁵⁵ The bill was sponsored in Congress by Congressmen Orrin Hatch and Henry Waxman and is known more commonly today as the Hatch-Waxman Act.²⁵⁶

The Hatch-Waxman Act addressed the concerns over generic availability by creating an abbreviated approval pathway by which generic drug manufacturers could gain FDA approval. Under Hatch-Waxman, a generic company can file an Abbreviated New Drug Application (ANDA). The ANDA must include a certification indicating one of four conditions: (1) there is no patent on the drug;²⁵⁷ (2) the patent has expired;²⁵⁸ (3) the date on which a patent will expire;²⁵⁹ or (4) that the patent is invalid or will not be infringed by the manufacture, sale, or use of the new drug.²⁶⁰ This certification delineates the earliest that the ANDA can be approved. Certifications under paragraphs 1 or 2 can be approved immediately while paragraph 3 certifications will be approved on the date the patent expires. Paragraph 4 certifications are essentially challenges to the validity of an existing patent and require a response from the branded drug manufacturer and potentially litigation before approval.

In addition to the ANDA itself, the generic drug manufacturer may take advantage of the data submitted by the branded drug manufacturer and submit only data to establish that the branded drug and the generic drug to be marketed are bioequivalent. According to the FDA, bioequivalency is defined as “the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar

254. *Id.* See also Eisenberg, *Innovation Policy*, *supra* note 250, at 357.

255. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15, 21, 35, and 42 U.S.C.).

256. *Id.*

257. 21 U.S.C. § 355(b)(2)(A)(i) (1984).

258. *Id.* § 355(b)(2)(A)(ii).

259. *Id.* § 355(b)(2)(A)(iii).

260. *Id.* § 355(b)(2)(A)(iv).

dose under similar conditions in an appropriately designed study.”²⁶¹

Chemical drugs tend to be small, low molecular weight compounds. This class of drugs is synthesized using well-controlled and highly reproducible reactions. As a result, the chemical compounds are replicated easily once the manufacturing process becomes known.²⁶² Under robust procedures, replication and production of highly pure substances can be presumed to be identical to the originals. Therefore, generic companies find it relatively cheap to conduct experiments establishing bioequivalency as compared to conducting the full range of required safety and efficacy studies.

Additionally, as a further incentive to file an ANDA, the first generic company to file an ANDA for a given drug receives 180 days of generic exclusivity before another ANDA can be filed.²⁶³ This generic exclusivity can be quite valuable to the generic manufacturer.²⁶⁴ During that 180 day period, the market for the drug contains only two competitors—the branded drug and the initial generic. Therefore, the generic manufacturer is able to obtain a premium over the generic price that will be set once others move into the market.

Finally, the Hatch-Waxman Act amended existing patent law by establishing a statutory experimental use exception to patent infringement for research on drugs still covered by a patent.²⁶⁵ Prior to 1984, companies that conducted research on patented inventions, but did not sell any infringing product, were thought to be exempt from patent infringement liability under a common law experimental use exception that traced its history from caselaw developed by Justice Story in *Whittemore v. Cutter*.²⁶⁶ However, in 1984, in the case of *Roche v. Bolar*, the Federal Circuit limited the use of the common law experimental use exception to noncommercial uses.²⁶⁷ Therefore, generic drug companies were prevented from conducting bioequivalency research using the patented drugs. In order to support quicker access to drugs, the Hatch-Waxman Act implemented a

261. CENTER FOR DRUG EVALUATION & RESEARCH, FOOD & DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES FOR ORALLY ADMINISTERED DRUG PRODUCTS — GENERAL CONSIDERATIONS (July 2002), <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM154838.pdf>.

262. Paul J. Declerck, *Biologicals and Biosimilars: a review of the science and its implications*, 1 GENOMICS & BIOSIMILARS INITIATIVE J. 13, 13 (2012).

263. 21 U.S.C. § 355(j)(5)(B)(iv)(I).

264. 21 U.S.C. § 355(j) (1984); C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 947 (2011).

265. 35 U.S.C § 271(e)(1) (1994).

266. *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600)

267. 733 F.2d 858 (Fed. Cir. 1984), *superseded by statute as recognized in Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).

statutory experimental use exception for generic drugs companies. As a result, research to establish bioequivalency is not an infringement of the patent covering the branded drug and can begin before the expiration of the patent. In light of this, consumers often enjoy the benefit of generics on the day that the patent expires.

IV. EVOLUTION OF THE STATUTORY EXPERIMENTAL USE EXCEPTION

The statutory experimental use exception as a defense to patent infringement began as a mechanism for generic drug companies to develop bioequivalency data for generic drug submissions before patent expiration. However, it quickly evolved into a more generalized research exception to patent infringement within the healthcare industry. The application of the statutory experimental use exception beyond the healthcare industry has not been addressed by either the Supreme Court or the Federal Circuit.

A. The Statute and Its Initial Application

The language of 35 U.S.C. § 271(e)(1) is the basis for the statutory experimental use exception. The language reads:

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* (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) *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.*²⁶⁸

As should be immediately evident, the language of the statutory experimental use exception is neither concise nor precise. In the words of the Supreme Court, “No interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship.”²⁶⁹

The statute was initially read by the pharmaceutical industry such that

²⁶⁸ . 35 U.S.C. § 271(e)(1) (emphasis added).

²⁶⁹ . Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661 (1990).

the language applied only to generic drug development. A “patented invention” was assumed to be a branded, patented drug. The “Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products” was interpreted as the provisions of the Food, Drug and Cosmetics Act that cover the abbreviated approval process for generic drugs. Finally, the use of the patented invention “solely for uses reasonably related to the development and submission of information” was understood to be the bioequivalency studies necessary for generic approval.²⁷⁰ While these interpretations make sense in the context of the development of the Hatch-Waxman Act of which the statute is a part, the language itself is actually quite broad. These ambiguities in the language of the statutory experimental use exception have led to a line of cases interpreting those provisions once thought to be applicable only to generic drugs.

B. Expansion of the Statutory Experimental Use Exception Beyond Generic Drugs

The Supreme Court struck down this narrow interpretation of the statutory experimental use exception in *Eli Lilly*.²⁷¹ Thereafter, the Supreme Court and the Federal Circuit weighed in several times as to the breadth of the application of the statutory experimental use exception in patent infringement cases involving drug and nondrug inventions.

1. *Eli Lilly* Expands the Statutory Experimental Use Exception

Eli Lilly sued Medtronic for patent infringement based on Medtronic’s use of *Eli Lilly*’s patented technology to develop Medtronic’s own cardiac defibrillator.²⁷² Medtronic asserted the statutory experimental use exception as a defense even though the product that was being developed was a medical device rather than a drug.²⁷³ Medtronic based its assertion on the idea that the Federal law at issue was the FDCA, albeit the provisions that regulate medical devices rather than drugs.²⁷⁴

270. See *id.* (arguments by made *Eli Lilly*).

271. *Eli Lilly*, 496 U.S. at 661.

272. *Id.* at 663.

273. *Id.* at 671.

274. *Id.*

a. Medical Device Regulation

Like drugs, medical devices are also regulated under the FDCA;²⁷⁵ however, the process is different from that of drugs in many ways. Medical devices are separated into three classes, with the amount of regulatory control increasing with each class—i.e., Class I medical devices are subject to the least amount of regulation; Class II are subject to more regulation; while Class III medical devices are subject to the most amount of regulation.²⁷⁶

Device classification is “risk-based” and “depends on the intended use of the device and also upon indications for use.”²⁷⁷ The Supreme Court has discussed the classification of devices.²⁷⁸ Class I devices are those that pose the least risk, while Class III devices pose the greatest risk.²⁷⁹ Specifically, Class I devices present no unreasonable risk of illness or injury.²⁸⁰ Examples of Class I devices include drainage catheters, saliva absorbers, wheelchair accessories, x-ray alignment devices, some dye and chemical solution stains, and liquid and elastic bandages.²⁸¹ Class II devices are potentially more harmful.²⁸² Some Class II devices include automated platelet aggregation systems, infusion pumps, blood access devices and accessories, tracheal tubes, blood pressure alarms, and blood pressure cuffs.²⁸³ Finally, Class III devices either “present a potential unreasonable risk of illness or injury,” or are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.”²⁸⁴ Class III devices include external cardiac compressors, defibrillators, female condoms,

275. 21 U.S.C. §§ 301–395 (1994).

276. FOOD & DRUG ADMINISTRATION, OVERVIEW OF DEVICE REGULATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/overview/default.htm> (last visited June 2, 2016) [hereinafter “Device Regulation”].

277. FOOD & DRUG ADMINISTRATION, CLASSIFY YOUR MEDICAL DEVICE, U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm> (last visited Sept. 20, 2015).

278. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

279. *Id.*

280. *Id.* (citing 21 U.S.C. § 360c(a)(1)(A) (2006)).

281. FOOD & DRUG ADMINISTRATION, PRODUCT CLASSIFICATION DATABASE, U.S. DEP’T OF HEALTH & HUMAN SERVS., http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/classification.cfm?start_search=1&Submission_Type_ID=&DeviceName=&ProductCode=&DeviceClass=1&ThirdParty=&Panel=&RegulationNumber=&PAGENUM=500 (last visited Mar. 20, 2013) [hereinafter “Product Classification Database”].

282. *Medtronic*, 518 U.S. at 477.

283. PRODUCT CLASSIFICATION DATABASE, *supra* note 281.

284. *Medtronic*, 518 U.S. at 477 (citing § 360c(a)(1)(C)).

intrauterine devices, and silicone and gel-filled breast prostheses.²⁸⁵

The FDA regulates medical devices with premarket notification and approval processes. Typically, Class I devices are exempt from any premarket requirements, whether it be notification or approval, instead they are subject only to minimal regulation by “general controls.”²⁸⁶ Although Class II devices may be marketed without advance approval, premarket notification is typically required.²⁸⁷ Class III devices typically require premarket notification and approval.²⁸⁸ Like drugs, Class III devices must apply for an investigational device exemption,²⁸⁹ which allows the devices to be used in order to collect data on safety and effectiveness in humans in preparation for the premarket approval application. Once approved, medical device reporting²⁹⁰ mandates reporting to the FDA any “[i]ncidents in which a medical device may have caused or contributed to a death or serious injury.”²⁹¹

b. *Eli Lilly Analysis*

In analyzing the application of the statutory experimental use exception to Class III medical devices, the *Eli Lilly* Court looked to various terms within the statute. First, the Supreme Court declared that “patented invention” applies to all types of inventions, not only drug-related inventions.²⁹² Thus, the statute potentially applies to any patented invention that satisfies its other requirements. The Supreme Court likely gave such a broad interpretation to the term “patented invention” because of the other qualifying language in the statute relating to the relevant law and types of submissions.

The *Eli Lilly* Court then identified what it viewed as a more complicated issue; the interpretation of the phrase “a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products.”²⁹³ *Eli Lilly* advocated for a narrow reading of the language limited to those provisions of the FDCA that regulates drugs, but the Supreme Court took a more expansive reading of the language, holding that it points to the entire statutory scheme of the regulation of the FDCA rather than individual provisions regulating drugs.²⁹⁴

285. PRODUCT CLASSIFICATION DATABASE, *supra* note 281.

286. *Id.*

287. Device Regulation, *supra* note 276.

288. *Id.*

289. *See generally* 21 C.F.R. § 812 (2011).

290. *See generally id.* § 803.

291. Device Regulation, *supra* note 276.

292. *Eli Lilly & Co. v. Metronic, Inc.*, 496 U.S. 661, 665 (1990).

293. *Id.*

294. *Id.* at 666.

In so holding, the *Eli Lilly* Court relied on both the language of the statute as well as the potential intent of Congress to offset patent term extensions granted due to delays in regulatory approval.²⁹⁵ For instance, drugs, medical devices, food additives, and color additives are all eligible for patent term extensions of up to five years if the product has been “subject to a regulatory review period before its commercial marketing or use,” and the “the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred.”²⁹⁶ Balancing that extension, the *Eli Lilly* Court noted, was the statutory experimental use exception that allowed competitors to engage in otherwise infringing activities before the patent ended.²⁹⁷

The *Eli Lilly* Court acknowledged that some products would not receive the extension but still suffer a loss in an infringement action, however, the Court was not persuaded by this because it could not “readily imagine such situations . . . except where there is good enough reason for the difference.”²⁹⁸ The Court further asserted that the likely reasons for a lack of extension would be a lack of an application for an extension or a follow-on version of a drug for which the extension would not apply. The *Eli Lilly* Court noted that all products eligible for a patent term extension under § 156(a)—“medical devices, food additives, color additives, new drugs, antibiotic drugs and human biological products”—are subject to the statutory experimental use exception because all of them “are subject to premarket approval under various provisions of the FDCA.”²⁹⁹

The *Eli Lilly* Court further acknowledged that this broad reading of invention, in conjunction with the interpretation of the statutory experimental use exception to apply to all products regulated under any provision of the FDCA, could result in a broad application of the statutory experimental use exception. However, the Court further noted a limitation on the application in that the use of the invention must be “reasonably related to the development and submission of information under” the FDCA.³⁰⁰

Not all products eligible for a patent extension require submission of

295. *Id.* at 666, 672.

296. 35 U.S.C. 156(a) (2006).

297. *Eli Lilly*, 496 U.S. at 672.

298. *Id.* It should be noted that the *Eli Lilly* opinion was issued in 1990, two years before the memo regarding the FDA’s regulatory scheme for GE crops. The Supreme Court could not have foreseen that regulatory schema at the time of the opinion.

299. *Id.* at 674.

300. *Id.* at 683 n. 6.

data under the FDCA. Producers of food and cosmetics do not need to develop and submit information to the FDA but merely meet “generally applicable standards.”³⁰¹ On the other hand, once Congress established a premarket approval requirement for infant formula, it was “automatically rendered” eligible for the statutory experimental use exception even though formula initially only needed to meet a set of standards.³⁰² This distinction implies that foods would not receive the benefit of the statutory experimental use exception because there are no regulatory submissions to the FDA. However, it is unclear where food additives designated as GRAS, such as GE crops, would fall on this spectrum of regulation.

While its decision greatly expanded the application of the statutory experimental use exception, the *Eli Lilly* Court left open a couple of questions pertinent to a determination of its application to GE crops. First, the Court did not explicitly state whether a product need be subject to § 156(a) premarket approval in order for the statutory experimental use exception to apply. Second, the definition of “reasonably related to the development and submission of information” was left open for further development.

2. No Need for Premarket Approval Under § 156(a) to Qualify for the Statutory Experimental Use Exception

While the *Eli Lilly* Court used very broad language in expanding the application of the statutory experimental use exception, it used much narrower reasoning to support broadening the experimental use exception beyond drugs. This narrow reasoning implied that inventions not subject to § 156(a) might not be subject to the statutory experimental use exception.

In *Abtox v. Exitron*,³⁰³ the Federal Circuit tackled the issue of whether the statutory experimental use exception applied to devices not covered under § 156(a).³⁰⁴ Prior to *Abtox*, district courts had applied the statutory experimental use exception only to Class III devices, since Class I and Class II devices are not subject to § 156(a).³⁰⁵

In *Abtox*, the patent covered a device used to sterilize medical instruments. Sterilization instruments are considered Class II medical

301. *Eli Lilly*, 496 U.S. at 683 n. 6.

302. *Id.*

303. *AbTox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997), *opinion amended on reh'g*, 131 F.3d 1009 (Fed. Cir. 1997).

304. *Id.*

305. The implantable cardiac defibrillators of *Eli Lilly* were Class III medical devices.

devices and not subject to § 156(a).³⁰⁶ Rather than premarket approval by the FDA, Class II devices require only a premarket notification before sales³⁰⁷. Therefore, the submissions to the FDA are quite different.

In expanding the application of the statutory experimental use exception beyond Class III devices, the Federal Circuit acknowledged the differences between the regulation of Class II and Class III devices.³⁰⁸ The *Abtox* court recognized that the Supreme Court had previously noted that the approval process for Class II devices “is by no means comparable” to the premarket approval necessary for Class III devices.³⁰⁹ Furthermore, the Federal Circuit acknowledged that Class III devices have a much more strict premarket approval process and are subject to “specific controls,” while Class I and II devices are only subject to “general controls.”³¹⁰

In spite of those differences in regulation, the Federal Circuit concluded that the statutory symmetry between § 156(a) and the experimental use exception discussed by the *Eli Lilly* Court was preferable but not required. Under a broad interpretation of *Eli Lilly*, the *Abtox* court reiterated that the “Federal Law” referred to the entire scheme of federal regulation and not just specific provisions.³¹¹ In doing so, the *Abtox* court noted that the statutory language did not limit the experimental use exception to drugs or a specific class of medical devices.³¹² Additionally the *Abtox* court held that an invention need not be subject to § 156 in order to be subject to the statutory experimental use exception.³¹³ In doing so, the Federal Circuit relied on the *Eli Lilly* Court’s acknowledgement of possible situations where “a patentee will obtain the advantage of the [§ 156] extension but not suffer the disadvantage of the [experimental use exception] non-infringement provision, and others in which he will suffer the disadvantage without the benefit.”³¹⁴ As a result of its holding, the *Abtox* court expanded the application of the statutory experimental use exception to every class of medical device and shifted the focus to whether the invention was used in a manner reasonably related to FDA submissions.

306. *AbTox, Inc.*, 122 F.3d at 1028.

307. *Id.*

308. *Id.*

309. *Id.*

310. *Id.*

311. *AbTox Inc.*, 122 F.3d at 1029.

312. *Id.*

313. *Id.*

314. *Id.*

3. Defining “Reasonably Related”

A separate line of cases dealt with how to define “uses reasonably related to the development and submission of information” to the FDA. Again, the Supreme Court broadly interpreted the statute, leaving much room for companies developing new products to invoke the statutory experimental use exception.

Merck KGaA v. Integra Lifesciences I, Ltd. is the leading Supreme Court case on the issue and established a broad definition of research that is “reasonably related” in the context of FDA submission.³¹⁵ In *Merck*, Integra Lifesciences (Integra) owned five patents that covered a set of peptides with a specific sequence (the RGD peptides).³¹⁶ Merck KGaA and Scripps Research Institute (collectively, Merck) conducted preclinical research on the RGD peptides without knowing which, if any, peptide eventually would lead to an FDA submission.³¹⁷ After eight years of research, Merck narrowed the RGD peptides to a few drug candidates, and an IND was filed on the lead candidate two years thereafter.³¹⁸ Integra sued for patent infringement; Merck defended using the statutory experimental use exception.

In reviewing Merck’s potentially infringing use of the RGD peptides, the Court held that preclinical research on patented inventions is protected under the statutory experimental use exception as long as there is a reasonable basis to believe that the invention could become part of a submission to the FDA.³¹⁹ The *Merck* Court noted that the statutory text “extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA.”³²⁰ The *Merck* Court’s emphasis on *any* information is potentially revealing as to how broadly the Supreme Court reads the statutory experimental use exception.

Furthermore, the *Merck* Court held that the data does not necessarily need to be included in a study submission.³²¹ The Court recognized the uncertainty inherent in research and drug development.³²² “[I]t will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it

315. 545 U.S. 193 (2005).

316. *Id.* at 199.

317. *Id.*

318. *Id.* at 199.

319. *Id.* at 202.

320. *Merck*, 545 U.S. at 202.

321. *Id.* at 207.

322. *Id.* at 207.

will take to win that agency's approval."³²³ Therefore, a narrow interpretation of "reasonably related" would leave companies in constant fear of being sued for patent infringement. Finally, the *Merck* Court did not limit the types of studies covered by the statutory experimental use exception to safety studies. However, basic research designed for information rather than the "intent to develop" a drug would not be covered because the Court saw such a connection to an FDA submission as too attenuated.³²⁴

Since *Merck*, the Federal Circuit has further developed the interpretation of "reasonably related." In *Telectronics Pacing Systems v. Ventritex*,³²⁵ Telectronics accused Ventritex of patent infringement on an implantable defibrillator. Ventritex sold the defibrillators at cost to obtain data on the device's operation and displayed the device at medical conferences to obtain clinical investigators.³²⁶ While Ventritex's CEO was attempting to raise money, he discussed the ongoing clinical trials and the defibrillators to investors and the press.³²⁷ The *Telectronics* court held that the demonstrations and conferences are a use "that is reasonably related to FDA approval because device sponsors are responsible for selecting qualified investigators and providing them with the necessary information to conduct clinical testing."³²⁸ Also, the presentation of information about the trials is not infringement because "dissemination of information" is not listed in the statute as an infringing activity.³²⁹ Finally, the *Telectronics* court clarified that the statute allows data resulting from the exempted infringement to also be used for non-FDA reporting purposes.³³⁰ *Telectronics* has been followed by other courts which have held that companies can use data gathered from exempted activities for many other purposes as long as the data is originally gathered via activities reasonably related to an FDA submission.³³¹

More recently, the Federal Circuit distinguished between mandated studies and the routinely reported information developed through nonrequired studies in post-marketing activities. In *Classen*

323. *Id.* at 207 (citing *Intermedics, Inc. v. Ventritex, Inc.*, 775 F. Supp. 1269, 1280 (N.D. Cal. 1991)), *aff'd by* 991 F.2d 808 (Fed. Cir. 1993).

324. *Id.* at 205.

325. 982 F.2d 1520 (Fed. Cir. 1992).

326. *Id.*

327. *Id.* at 1521.

328. *Id.* at 1523.

329. *Id.*

330. *Telectronics*, 982 F.2d at 1524.

331. *See, e.g.*, *Intermedics, Inc. v. Ventritex Co., Inc.*, No. 92-1076, 1993 WL 87405 (Fed. Cir. Feb. 22, 1993); *Nexell Therapeutics Inc., v. AmCell Corp.*, 143 F. Supp. 2d 407 (D. Del. 2001).

Immunotherapies, Inc. v. Biogen IDEC,³³² the court held that the statutory experimental use exception does not apply to infringing uses of a patented invention if the uses were not mandated, even if the data was routinely reported to the FDA.³³³ In *Classen*, Classen's patents were infringed during studies evaluating the timing of vaccinations and immune system disorders. While Classen was required to report the "adverse experience information" to the FDA,³³⁴ the studies themselves were not required by the FDA. In contrast, in *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, the infringing use was subject to the statutory experimental use exception even though the data was not actually submitted to the FDA. Rather, per 21 C.F.R. § 211.180(c), the records were required to be "readily available for authorized inspection" by the FDA at any time.³³⁵ In *Momenta*, the infringing use produced data for the FDA proving that each batch of Amphastar's product is the bioequivalent of the branded drug.³³⁶ The *Momenta* Court held that even if the FDA never inspects the records, the requirement to maintain such records equates to the information being submitted under the language of the statute.³³⁷

V. USAGE OF THE STATUTORY EXPERIMENTAL USE EXCEPTION BY THE AGRICULTURAL BIOTECHNOLOGY INDUSTRY

Application of the statutory experimental use exception to GE crop development is of utmost importance to the industry. As noted in the Introduction, the one billion dollar award against DuPont and Pioneer would have been a noninfringement verdict if the experimental use exception applied to GE crop development. An analysis of *Eli Lilly* and *Merck* indicate that the statutory experimental use exception should apply to GE crops. Furthermore, data from activities covered by the statutory experimental use exception can be used for other regulatory activities under the Coordinated Framework.

A. Application of the Statutory Experimental Use Exception to Genetically Engineered Crop Development

The industry consensus is that the statutory experimental use exception does not apply to its development of GE crops due to the

332. 659 F.3d 1057 (Fed. Cir. 2011).

333. *Id.* at 1070.

334. *See* 21 C.F.R. § 600.80 (2009).

335. *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, 686 F.3d 1348, 1357 (Fed. Cir. 2012).

336. *Id.*

337. *Id.*

statute's initial inclusion in a law directed toward human healthcare products.³³⁸ Unfortunately, caselaw has been less than clear as to whether the statutory experimental use exception applies to GE crops. GE crops, usually regulated as GRAS, fall into a gray area between food and food additives—each of which has a different outcome as to the applicability of the statutory experimental use exception.

As described in Part IV, both the Supreme Court and the Federal Circuit have broadly read and applied federal statutes to determine what “patented inventions” can take advantage of the experimental use exception. Clearly, GE crops and genetic traits are capable of being patented inventions under *Eli Lilly*. However, two main issues must be addressed before applying the statutory experimental use exception to GE crops—the applicability of § 156(a) and whether industry uses are “reasonably related” to submissions before the FDA. Unfortunately, neither issue is particularly clear cut, but both should be read to allow application of the statutory experimental use exception to GE crops.

1. Premarket Approval Under § 156(a)

It is tempting to declare that the applicability of § 156(a) to an invention does not matter for the use of the statutory experimental use exception. Federal Circuit caselaw interpreting *Eli Lilly* has applied the statutory experimental use exception beyond inventions subject to premarket approval under § 156(a). However, *Eli Lilly* predates the FDA development of the GE crop regulatory scheme. Therefore, courts are likely to look back to the statutory language as well as the current state of the caselaw. Arguments of statutory interpretation are either neutral or lean towards inclusion of GE crops under the statutory experimental use exception.

Initially, the caselaw seems quite clear that premarket approval is not required. In *Abtox*, the Federal Circuit held that manufacturers of Class II medical devices, which are not subject to § 156(a), can use the statutory experimental use exception.³³⁹ A similar parallel can be drawn to GRAS products. Food additives, like Class III medical devices, are subject to § 156(a). GRAS products—like Class II devices—go through a notification process before the FDA. Therefore, GRAS products should be subject to the statutory experimental use exception due to

338. See, e.g., M.D. Janis, *Rules versus Standards for Patent Law in the Plant Sciences*, in SEEDS OF CHANGE, *supra* note 79, at 50; cf., Christopher Holman, *District Court Rejects Argument that Hatch-Waxman Safe Harbor Applies to Genetically Modified Crops*, HOLMAN'S BIOTECH IP BLOG (Nov. 29, 2012), <http://holmansbiotechipblog.blogspot.com/2012/11/district-court-rejects-argument-that.html> (discussing the potential applicability of the statutory experimental use exception to agriculture).

339. *AbTox Inc. v. Exitron Corp.*, 122 F.3d 1019, 1028 (Fed. Cir. 1997).

Abtox's holding that "statutory symmetry is preferable but not required."³⁴⁰

However, the *Abtox* decision was not appealed, and the Supreme Court could disagree with such an analysis. The *Abtox* court recognized that its holding, while complying with the holding in *Eli Lilly*, was in conflict with the reasoning in that case. Specifically, the *Abtox* court noted that

under the broad holding of *Eli Lilly*, all classes of medical devices fall within the plain meaning of section 271(e)(1). Nevertheless, under the Court's narrower justification of statutory symmetry, only Class III devices fall within the section. Ultimately, this court must follow the Supreme Court's broader holding, which remains in force despite a potential conflict with its own narrower reasoning.³⁴¹

Why would the *Eli Lilly* Court issue such a broad holding based on its narrow reasoning of statutory symmetry? The Court answered this question in footnote 4 of the opinion. There, the *Eli Lilly* Court noted that it could not "readily imagine such situations [in which the patent holder would suffer the disadvantage of the statutory experimental use exception without the benefit of § 156(a)] . . . except where there is good enough reason for the difference."³⁴² Food, as GRAS products are considered by definition, has "generally applicable standards" to be met rather than a notification process.³⁴³

However, the *Eli Lilly* opinion was issued in 1990, two years before the 1992 Statement of Policy regarding the FDA's regulatory scheme for GE crops. The Supreme Court could not then have foreseen the regulatory schema that would include GE crops as GRAS products with FDA consultations. As a result, it is conceivable that the Supreme Court might take the view that the after-developed GE crop FDA regulatory scheme does not fall under the *Eli Lilly* holding regarding § 156(a) symmetry and should not be subject to the statutory experimental use exception.

A narrow application seems in line with Professor Chen's reasoning that statutory interpretation should result in a narrow construction of statutes to retain Congressional intent.³⁴⁴ However, Congress could have specifically excluded agricultural products as a class from the statutory experimental use exception if it had wished since a large part

340. *Id.* at 1029.

341. *Id.*

342. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 683 n. 4 (1990).

343. *Id.* at 683 n. 6.

344. Chen, *The Parable*, *supra* note 30, at 135.

of the FDA's job is food regulation. While Congress did not do so for agricultural products, veterinary drugs are excluded specifically from the statutory experimental use exception suggesting that agricultural crops were intended to be included by Congress.

Additionally, although application of the statutory experimental use exception to GE crops lacks the symmetry with § 156(a) present with certain inventions in the healthcare industry, application to GE crops does create a congruence with the PVPA discussed in Part II.B. The PVPA provides intellectual property protection for crops and contains a research exemption to patent infringement that is broader than the statutory experimental use exception at issue in this Article. In fact, the lack of a general experimental use exception for utility patents troubled the Supreme Court in *J.E.M. Ag Supply* and led to a dissent penned by Justice Breyer as to the patentability of plants.³⁴⁵ Therefore, it seems reasonable that the lack of § 156(a) symmetry would not bar application of the statutory experimental use exception.

However, at this point, the argument regarding § 156(a) symmetry is mere conjecture. There is no current indication from the Supreme Court that it might treat GE crops differently from other FDA regulated products. Therefore, under the Federal Circuit's *Abtox* opinion, GE crops should be eligible for the statutory experimental use exception as GRAS products even without § 156(a) premarket approval so long as the use by the potential infringer is "reasonably related" to a submission to the FDA.

2. "Reasonably Related"

While it seems highly likely that GE crops regulated as GRAS food additives would be products for the purposes of the statutory experimental use exception, the question as to whether the research conducted during their development is "reasonably related" to a submission to the FDA is less clear. The classification of GE crops as food additives with likely GRAS designations makes the analysis more complicated.

Food additives generally would be covered by the statutory experimental use exception. While there is no caselaw directed at food additives per se, dicta in *Eli Lilly* indicates food additives would be part of the expansion of the statutory experimental use exception beyond drugs. Food additives mirror the approval process of drugs and Class III medical devices. All three require FDA premarket approval and are

345. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 147-56 (2001).

subject to § 156(a).³⁴⁶ Indeed, food additives are listed along with drugs and medical devices in the reasoning of *Eli Lilly* in contradistinction to the categories excluded from coverage by the language of the statutory experimental use exception.³⁴⁷

While the FDA has stated its expectation that most GE crops will qualify as GRAS, the FDA has left open the possibility that some crops may need to be regulated as a food additive.³⁴⁸ If the data shows potential increases in allergenicity or toxicity, the GE crop will be regulated as a food additive rather than receiving premarket approval.³⁴⁹ Those GE crops regulated as food additives would clearly qualify for the statutory experimental use exception.

In contrast, food is unlikely to be covered by the statutory experimental use exception—and GRAS products are by definition food rather than food additives.³⁵⁰ The inapplicability of the statutory experimental use exception to food comes from footnote 6 of *Eli Lilly*.³⁵¹ There the Court discusses the broad application of the statutory experimental use exception to all products but counters that food, among other things, merely has “generally applicable standards” to be met rather than any sort of submission to the FDA.³⁵²

GE crops, as GRAS products, then inhabit a gray area between food additives and food. While GRAS products are technically food rather than food additives, manufacturers develop crops and data regarding safety and make their own determinations as to whether the GE crop qualifies for GRAS status. If the manufacturer believes a new GE crop is GRAS, the manufacturer initiates a voluntary consultation process to notify the FDA of the crop development and GRAS status.³⁵³ This voluntary consultation is different from the Class II medical devices of *Abtox*, which have a mandatory notification requirement.

It is the voluntary nature of this process that leads one to initially reject use of the statutory experimental use exception by the agricultural biotechnology industry. Indeed, in some ways, the voluntary consultation process looks like the “routinely reported data” of *Classen*. Neither the studies in *Classen* nor the consultation with the FDA are mandatory. In both cases, if a company opted to complete the studies or the consultation, then the reporting of the data would become required.

346. *Eli Lilly*, 496 U.S. at 672.

347. *Id.* at 674.

348. 1992 Statement of Policy, *supra* note 165, at § VII.

349. *Id.*

350. *See supra* note 159 (defining GRAS).

351. *Eli Lilly*, 496 U.S. at 674 n. 6.

352. *Id.*

353. 1992 Statement of Policy, *supra* note 165, at § V.

Therefore, the reasoning would be that neither is covered by the statutory experimental use exception.

In theory, a GE crop manufacturer could skip the consultation process and market the crop with only USDA and EPA approvals. However, in practice, every GE crop manufacturer has gone through the voluntary process. Since the FDA does have authority to remove a GE crop from the market if it has concerns over safety, no GE crop manufacturer has ever declined to go through the “voluntary” process.³⁵⁴ If the process is voluntary in theory, but mandatory in practice, perhaps a court would look to spirit rather than the letter of the law.

Additionally, while the consultation is voluntary, the development of data by the GE crop manufacturer is not. GRAS determination “require(s) the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient. [A GRAS determination] shall ordinarily be based upon published studies which may be corroborated by unpublished studies and other data and information.”³⁵⁵ In the case of a new GE crop consultation, the developing manufacturer must submit data regarding the newly developed crop to demonstrate that it does not differ significantly from non-GE crops in order to make the GRAS determination. This data must be developed even if the data is never submitted to the FDA. These privately held records for GRAS determination—records that a court could order be shared with the FDA if the agency suspected safety issues with a marketed GE crop—seem more in line with the holding in the *Momenta* case in which the statutory experimental use exception was applied where the FDA rarely bothered to inspect records but the generation of data and record availability were required.

Additionally, while *Classen* held routine, nonmandatory submissions were not covered by the statutory experimental use exception, the infringing activity in that case occurred post market approval. In contrast, the cases that deal with data submission in a premarket context take a broad view of the type of activity that qualifies as reasonably related to a submission. For example, in *Merck*, the Supreme Court noted the wide applicability of the statutory experimental use exception in “activities related to the federal regulatory process.”³⁵⁶ The Court further rejected the idea that information gathered should be excluded from the statutory experimental use exception based on “the particular submission in which it could be included.”³⁵⁷ Therefore, a submission

354. See Johnson, *supra* note 223, Interview with Val Giddings.

355. 21 C.F.R. § 170.30(b) (2012).

356. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005).

357. *Id.*

of data for a voluntary consultation process with the FDA should be “reasonably related to a submission” for purposes of the statutory experimental use exception.

Further bolstering the argument for the applicability of the statutory experimental use exception to GE crops is the uncertainty of the GRAS determination. If a manufacturer, after developing a GE crop, or the FDA determined that there were potentially heightened allergenicity or toxicity problems, the manufacturer would need to seek premarket approval of the GE crop as a food additive. The *Merck* Court used this uncertainty in the type of information needed to seek FDA approval as a basis for its broad reading of the application of the statutory experimental use exception to “submission of any information under the FDCA.”³⁵⁸ Therefore, as long as there is any reasonable potential that the data developed could be submitted to the FDA as part of a food additive premarket approval application or could be required by the FDA due to aftermarket safety concerns, the use of a patented trait or GE crops to develop the data should be covered by the statutory experimental use exception.

Thus, while the consensus of many in the legal world is that the statutory experimental use exception does not apply to the agricultural biotechnology industry’s development of GE crops, there are significant legal arguments as to why it should apply to research for submissions to the FDA. However, the tri-agency nature of the Coordinated Framework poses special considerations for the application of the statutory experimental use exception analysis.

B. Use of the Statutory Experimental Use Exception Under the Coordinated Framework

Using the statutory experimental use exception while being regulated under the Coordinated Framework will be fraught with difficult decisions. The Coordinated Framework regulating bioengineered foods complicates the development of GE crops. GE crop developers must comply with regulations from various agencies when the statutory experimental use exception has thus far only been applied to regulatory submissions to the FDA. Conversely, the Coordinated Framework yields some flexibility. By leaving the decision of whether to proceed as a GRAS product or a food additive in the purview of the developer, the Coordinated Framework allows a GE crop developer to relieve some uncertainty regarding the application of the statutory experimental use exception.

358. *Id.*

1. Exempted Activities Used for Non-FDA Purposes

Unlike pharmaceuticals, GE crops are regulated not solely by the FDA. Rather, GE crops are regulated under a Coordinated Framework that involves the FDA, USDA, and EPA working together to regulate different aspects of the GE crop.³⁵⁹ As a result, the developer of a new GE crop could potentially conduct infringing uses to develop submissions for the USDA or the EPA rather than the FDA.³⁶⁰

Even if the submission of data to the FDA exempts the activities to collect that data from patent infringement, it is important to remember that the USDA and EPA regulations generally have no experimental use exception for patent infringement. Importantly for a follow-on GE crop innovator, the *Telectronics* court clarified that the statute allows data resulting from exempted patent infringement to be also used for non-FDA reporting purposes.³⁶¹ Therefore, experimentation that results in data for FDA submission is exempt from patent infringement even if that data is also used for a submission to the USDA or EPA.³⁶² However, infringing activities not used to develop data for submissions to the FDA would not qualify for the statutory experimental use exception. Because of this, a GE crop developer might not be able to complete all regulatory requirements before patent expiration. Additionally, it may be quite difficult for a GE crop developer to keep the various uses separate, increasing risk of liability.

One caveat to this analysis could potentially expand the use of the statutory experimental use exception beyond submissions to the FDA. As discussed above,³⁶³ the EPA's authority to regulate GE crops is derived from the FIFRA, the TSCA, and the FDCA. The FDCA establishes the EPA's responsibility for regulating and establishing tolerance levels for pesticide residues in foods.³⁶⁴ Combining the EPA's authority under the FDCA with the *Eli Lilly* Court's holding that the language of the statute points to the entire statutory scheme of regulation by the FDCA,³⁶⁵ the mandatory regulatory submissions to the EPA regarding pesticides expressed by GE crops could be covered by the

359. See *supra* Part II.D.

360. See Jennifer Carter-Johnson, *Defining Limits to the Application of the Statutory Experimental Use Exception within the Agricultural Biotechnology Industry*, 2015 MICH. ST. L. REV. 509 (2015) [hereinafter Carter-Johnson, *Defining Limits*].

361. *Telectronics Pacing Sys. v. Ventitrex, Inc.*, 982 F.2d 1520, 1524 (Fed. Cir. 1992).

362. *Id.*

363. See *supra* notes 173-175 and accompanying text.

364. 21 U.S.C. §§ 346(a), 348 (2006). As noted above, the EPA regulates pesticides expressed by GE plants themselves (known as "plant-incorporated protectants"), such as crops expressing the Bt pesticide.

365. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990).

statutory experimental use exception. Such an expansion would be the first to apply the statutory experimental use exception outside of the FDA regulations.

2. Foregoing GRAS Determination

Until the ambiguities surrounding the application of the statutory experimental use exception to GRAS GE crops are resolved, perhaps the better choice for GE crop manufacturers is to forego GRAS determination and declare newly developed GE crops as food additives, due to food additives being far more likely to have the protection of the statutory experimental use exception based on *Eli Lilly* dicta. Additionally, there are several other benefits that make pursuing food additive designations the better alternative. Such benefits include cost, intellectual property protection, and public perception.

Counterintuitively, it may be cheaper to develop a GE crop as a food additive. Since similar data must be developed for GRAS products or food additives, the cost difference lies in the regulatory cost. While the food additive process likely is more expensive, that cost is likely offset by the decreased need to license every technology during development. If the *Monsanto* court was correct in its one billion dollar damage award, patent license savings could be significant. Of course, marketing of the GE crop would still require a license or patent expiration, but developing a crop with a patented trait would no longer require waiting until the patent expired.

A second consideration in choosing a food additive pathway is a limited amount of intellectual property protection during development. A GRAS application should include primarily public data and information while a food additive application can be based primarily on proprietary data. In a post-*Myriad* era where gene patent protections have been weakened, keeping genetic constructs used in GE crop development as trade secrets may be attractive. However, these trade secrets would last only until the crop is marketed. Once marketed, GE crops can be reverse engineered relatively easily to determine the trait and construct used in construction of the GE crop.

Finally, consumer perception of GE crops might be enhanced if the FDA were viewed as having more oversight. One of the complaints put forth by GE crop opponents is that there are no required safety studies. If a GE crop developer submitted to food additive regulations, the company could advertise its crops as having gone through a more intensive FDA oversight process. Such a benefit likely is less valuable to producers of commodity GE crops than for a crop that would be marketed directly to consumers, who may be choosing among GE and

non-GE versions.

VI. EXPERIMENTAL USE IN AGRICULTURAL BIOTECHNOLOGY— A BROADER PERSPECTIVE

In addition to the legal analysis of whether the statutory experimental use exception *can* be used in the agricultural biotechnology space, there is the question of whether an experimental use exception *should* be used. A high-level comparison of the pharmaceutical and agricultural biotechnology industries makes an experimental use exception attractive. However, such a radical change in infringement liability certainly would herald a change in business strategies and perhaps even in the structure of the agricultural biotechnology industry itself. Additionally, the near term expiration of many GE trait and crop patents makes now a good time to begin discussing whether applying the Hatch–Waxman Act within the agricultural biotechnology industry is a good decision because the development of a generic GE crop industry would be influenced by the availability of an experimental use exception.

A. Industry Structure and Innovation Incentives as Factors in Considering an Experimental Use Exception

While this Article focuses on an analysis of the Hatch–Waxman statutory experimental use exception, a brief discussion of whether any experimental use exception should be applied to the agricultural biotechnology industry is valuable. For example, the common law experimental use exception discussed in Part II.B.3. applies to all technologies. However, that common law experimental use exception has been narrowed by the courts, making it practically inapplicable to any industry.³⁶⁶ In order to analyze the application of an experimental use exception to GE crops, it is important to consider incentives to innovate and the resulting industry structure.³⁶⁷

The directive to “promote the Progress of Science and useful Arts” was

366. See *supra* Part II.B.2. Additionally, the history of the common law experimental use exception has been detailed before. See, e.g., Janis, *Sustainable Agriculture*, *supra* note 131, at 105, 106-08; Jennifer Carter-Johnson, *Unveiling the Distinction between the University and its Academic Researchers: Lessons for Patent Infringement and University Technology Transfer*, 12 VAND. J. ENT. & TECH. L. 473, 498 (2010) [hereinafter Carter-Johnson, *Unveiling the Distinction*].

367. This Article does not purport to make a full analysis of the economic incentives of the agricultural biotechnology industry. For a fuller treatment, see the authors cited herein. Rather, I merely want to establish a fuller context for any discussion of the implementation of the statutory experimental use exception.

important enough to enshrine in our Constitution.³⁶⁸ As a result, Congress enacted the laws creating the patent system.³⁶⁹ In light of this, any experimental use exception should be implemented only if promotes innovation rather than hinders it. However, the question of the extent to which strong patents promote rather than hinder progress is beyond the scope of this Article. Additionally, many scholars have debated the application of an experimental use exception in various contexts.³⁷⁰

A few scholars have argued for the use of an experimental use exception in agriculture.³⁷¹ For example, in her article on intellectual property overreaching in the agriculture industry, Professor Elizabeth Rowe suggested that an experimental use exception similar that of the pharmaceutical industry would be valuable³⁷² for innovation and regulatory decision making. As noted above, Mark Janis sees the experimental use exception as a means to promote sustainable agriculture.³⁷³ Others, however, have argued that innovation in the agricultural biotechnology industry is optimal and there is no need to adjust patent incentives.³⁷⁴

The industry structure seems to support Rowe and Janis. In the past forty years, the industry has continually consolidated based in part on the strong patent protection held by the major companies.³⁷⁵ Contrast this trend with that in the pharmaceutical biotechnology space where there are thousands of small companies striving to create the next new drug or biologic.³⁷⁶ While there are too many differences between the two industries to say that the availability of an experimental use exception is the key to diversifying research in the agricultural

368. U.S. CONST. art. I, § 8, cl. 8.

369. 35 U.S.C. § 101 (2000).

370. See Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000); Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457 (2004); Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); and Carter-Johnson, *Unveiling the Distinction*, *supra* note 366, at 498.

371. See e.g., Janis, *Sustainable Agriculture*, *supra* note 131, at 105; Rowe, *supra* note 57, at 889; DIANA L. MOSS, THE AM. ANTI-TRUST INST., *GENERIC COMPETITION IN TRANSGENIC SOYBEANS 10* (2011), <http://ssrn.com/abstract=1940150>.

372. Rowe, *supra* note 57, at 886.

373. Janis, *Sustainable Agriculture*, *supra* note 131, at 105.

374. F. Scott Kieff et al., *supra* note 128.

375. See Howard, *supra* note 123.

376. There were over three thousand companies working on drug candidates in the clinical pipeline in 2014. David Thomas & Chad Wessel, *Emerging Therapeutic Company Investment and Deal Trends*, BIO INDUSTRY ANALYSIS, 10 (2015), <https://www.bio.org/sites/default/files/BIO%20Emerging%20Therapeutic%20Company%20Report%20June%202011%202015.pdf>.

biotechnology industry, at least one scholar has indicated that Monsanto's patent protection on nearly all commercial transgenic traits was key in its ability to consolidate.³⁷⁷ The availability of an experimental use exception would have negated some of Monsanto's negotiation power since the long development timelines of GE crops would have allowed consolidation targets to continue research until Monsanto's patent expired.

Critics, such as Monsanto, might argue that implementation of a statutory experimental use exception to GE crops would decrease incentives to innovate, as licensing powers would be greatly lessened or that the statutory experimental use exception could amount to a governmental taking. Neither of these arguments is compelling.

While the license value of patents related to GE crops might decrease, it is unlikely to disappear altogether. Not all inventions created by the agricultural biotechnology industries are crops. Many are methods of creating crops or determining which genetic mutations to pursue. Such inventions are described as research tools and have been patented widely within the industry.³⁷⁸ Research tools are not subject to the statutory experimental use exception.³⁷⁹ Additionally, small companies still would need a license to the patents to the GE crop itself if they wanted to sell patent protected GE crops before the patent expires. Experimental use exceptions have never allowed for sales of infringing goods. Companies that desire to sell products before patent expiration would likely partner with Monsanto by licensing during development rather than be stuck with a product that could not be sold for years. An experimental use exception would merely prevent Monsanto from stalling follow-on research on its patented crops.

Monsanto also could argue that the implementation of an experimental use exception would be a taking under *Ruckelshaus v. Monsanto*.³⁸⁰ In *Ruckelshaus*, the EPA required disclosure and sharing of trade secret data protected under FIFRA.³⁸¹ Monsanto's trade secrets were held to be property protected by the Fifth Amendment Takings Clause.³⁸² While the implementation of an experimental use exception would change the contours of the patent protection available to Monsanto, such a change would be no different than the invalidation of

377. Howard, *supra* note 123, at 1274.

378. For a full discussion of the types of patented inventions created by agricultural biotechnology companies and the application of the statutory experimental use exception to research tools, see Carter-Johnson, *Defining Limits*, *supra* note 360.

379. *Id.*

380. 467 U.S. 986 (1984).

381. *Id.* at 994-95.

382. *Id.* at 1003-04.

any gene patents after the *Myriad* decision or the implementation of the Hatch-Waxman Act in the healthcare industry. This analysis is unlike that of *Ruckelshaus*, where the type of information at issue continued to be protected as a trade secret but a specific piece of information was taken from Monsanto alone. Instead, all GE crops would become subject to the statutory experimental use exception as the contours of patent protection change when courts interpret statutory language.

B. Technological Similarities and Regulatory Framework as Factors in Considering an Experimental Use Exception

Another question raised by GE traits and crops is whether the same basic technology used in different industries should have different patent protections. As noted in the Introduction, an experimental use exception can be a big deal if applied to patent rights valued at one billion dollars.

Patent law protection is generally considered to be technologically neutral.³⁸³ In spite of this theoretical technological neutrality, some scholars have questioned whether the application of patent law is actually technology specific.³⁸⁴ However, most scholarly work focuses on the different treatment of patent law in regards to different types of technology—such as the differences between software and biotechnology.³⁸⁵ Even Dan Burk and Mark Lemley's book, *The Patent Crisis and How The Courts Can Solve It*, which does explore proposed industry-specific patent applications,³⁸⁶ does not discuss the experimental use exception.³⁸⁷

Much like its pharmaceutical cousin, the agricultural biotechnology industry is a FDA regulated industry that is highly structured around patent-protected, biologically related products. Similarities between the two industries in the realm of technology—both development and final products—and regulation point to a need for the application of the statutory experimental use exception.

At their bases, GE crops and pharmaceuticals share several technological characteristics. Both types of products are human inputs—that is, both generally are ingested to support life and wellness.

383. See generally Dan Burk & Mark Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155 (2002) [hereinafter Burk & Lemley, *Technology-Specific*].

384. *Id.* Dan Burk & Mark Lemley, *Biotechnology's Uncertainty Principle*, 54 CASE W. RES. L. REV. 691, 691-92 (2004).

385. See generally Burk & Lemley, *Technology-Specific*, *supra* note 383.

386. DAN L. BURK & MARK A. LEMLEY, *THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT* (2009).

387. Katherine J. Strandburg, *Patent Fair Use 2.0*, 1 (NYU Center for Law, Economics, and Organization Law & Economic Research Paper Series, Working Paper No. 11-18), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1835007.

As such, these products have far more potential for immediate harm than other technologies and this is reflected in the regulatory structures discussed above.

More specifically, the technology used to produce GE crops mirrors the technology used to produce some pharmaceuticals, such as biologics. Biologics typically involve large molecular structures produced by living organisms.³⁸⁸ GE crops are entire living organisms in and of themselves. GE crops can be far more complicated than even the largest biologic. Additionally, the same molecular biology-based tools are used to produce biologics and GE crops. Both require direct manipulation at the genetic level to produce the product. GE crops require insertion of genetic traits into plants by definition. Biologic development often requires similar insertions into bacteria or other cells to produce the biologic of interest.³⁸⁹

The similarities in the technology underlying the products are further bolstered by the similarities in their research and development. Much as in the pharmaceutical industry, the initial expense of development and uncertainty of success leads investors to desire larger profits in order to invest. Additionally, both industries are plagued with long development time lines.³⁹⁰ Finally, similar to biologics, the ability to replicate or produce a bioequivalent may be uncertain. Inserting a genetic trait into a plant or bacteria is a fairly straightforward procedure technologically. However, the placement of the gene within the genome may impact its expression or may impact the expression of the endogenous surrounding genes.³⁹¹ These difficulties lead to further characterization problems for potential generics for both biologics and GE crops.

Similarities between the structure and regulation of the pharmaceutical and agricultural biotechnology industries also make the application of an experimental use exception to GE crop development attractive. First and foremost, both industries produce products that are heavily regulated. As described in depth in this Article, the FDA

388. Under the FDCA, biologics—or rather a biological product—“means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein . . . or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i)(1) (2012). See also Jason Kanter & Robin Feldman, *Understanding & Incentivizing Biosimilars*, 58 HASTINGS L.J. 57, 59 (2012).

389. See *supra* Part II.A.3.

390. MOSS, *supra* note 371, at 10.

391. Random insertion of a transgene into a plant’s genome may result in the inserted transgene disrupting sequences necessary for the proper regulatory control of endogenous genes. Furthermore, the actual location in the genome at which the transgene inserts may affect the expression of the transgene itself, a phenomena known as positional effects. See e.g., Christopher D. Day et al., *Transgene integration into the same chromosome can produce alleles that express at a predictable level, or alleles that are differentially silenced*, 14 GENES & DEV. 2869 (2000); Maïke Stam et al., *The Silence of Genes in Transgenic Plants*, 79 ANNALS OF BOTANY 3 (1997).

regulates both industries. To the extent that the voluntary nature of the FDA regulations is a concern, the agricultural biotechnology industry is also mandatorily regulated by the EPA and the USDA-APHIS. Extensive tests and submissions that increase the cost of developing products are required in both industries. As a way to recoup these costs, players in both industries rely on patent protection to establish monopoly pricing for their products and to control the development of competing products.

Following from that basic structure is the fact that the agricultural biotechnology industry must deal with the expiration of patents and competitor attempts to use and sell previously patent protected technology. The pharmaceutical industry has dealt with patent expiration and generics for years. However, the first GE-crop patents expired in 2014, and the agricultural biotechnology industry is struggling to deal with the resulting repercussions for the first time.

As patents expire, the agricultural biotechnology industry is facing similar pressures as the pharmaceutical industry with regards to pricing. Food prices are rising due to increased input costs such as seed, fuel, and irrigation.³⁹² The world's population is also increasing, putting additional demand pressure on pricing. Farmers are pressured to produce ever more food for less cost. One compromise is to use high-yielding generic GE traits for which there is no longer a patent-premium price tag.³⁹³ However, without an experimental use exception, regulatory hurdles may delay generic seed producers from entering the market.

C. Hatch–Waxmanizing the Agricultural Biotechnology Industry

A discussion about applying the Hatch–Waxman statutory experimental use exception in the agricultural biotechnology industry is merely the first step in a broader dialog. Monsanto's Roundup Ready patents expired in 2014, and more trait patents will expire soon.³⁹⁴ Next, it must be decided whether the agricultural biotechnology industry needs a Hatch–Waxman-esque abbreviated pathway for generic GE crop approval. It is also time for a discussion of how to define generic GE crops. Scholars are beginning to discuss both issues.³⁹⁵

392. Forty percent of the final seed price for patented GE crops is due to research and development. MOSS, *supra* note 371, at 8.

393. Norman W. Hawker, *Competition Issues Arising from Generic Biotech Crops*, 18 DRAKE J. OF AG. L. 137, 139 (2013).

394. *Id.* at 140.

395. *Id.* MOSS, *supra* note 371, at 8; Christopher Holman, *How Real Is the Concern That Seed Patents Will Turn Farmers into Inadvertent Infringers?*, 33 BIOTECH. L. REP. 165, 168 (2014).

The first question to be addressed is the definition of a generic GE crop, which may require a new nomenclature. In general, a generic Monsanto Roundup Ready soybean can be reproduced quickly and easily by planting a seed. Farmers have been saving seed for years, and the technology to do so is well settled. Abbreviated approval pathways are less helpful for such generics. But what of the development of new crops using generic glyphosate-resistant gene technology once the patents on the traits expire? Are those new crops considered generics—even if the patent-expired trait is stacked with a new patented trait? Without a statutory experimental use exception, the development of such crops can only begin after patent expiration. These follow-on crops using expired patent traits would most benefit from an abbreviated pathway.

For both sets of potential generic crops, data access is also an issue. Since GRAS data can be proprietary, follow-on crops using patent-expired traits would need access to approval documentation and data in order to prove some sort of bioequivalency.³⁹⁶ Furthermore, generic seeds saved from expired, branded GE crops will eventually need to renew regulatory approvals for export. Those approvals also require access to the initial development data.³⁹⁷

VII. CONCLUSION

The statutory experimental use exception potentially would change the face of the agricultural biotechnology industry. Its application to GE crops regulated as GRAS is unclear, but there is a valid legal argument for its use by the industry.

The breadth of the *Eli Lilly* Court's interpretation of "patented invention," combined with the *Abtox* court's decision to include inventions not subject to § 156(a) leaves open only the question of development activities being "reasonably related" to submissions to the FDA. Although the Coordinated Framework makes the FDA submissions technically voluntary, the Supreme Court's broad interpretation of a submission to the FDA, along with its desire to relieve uncertainties for the developer, make a strong case that the statutory experimental use exception should apply to the development of GE crops.

The application of the statutory experimental use exception has the potential to change the balance of power within the agricultural biotechnology industry. Currently, the industry is dominated by a few

396. Moss, *supra* note 371, at 8.

397. Hawker, *supra* note 393, at 144.

large companies that hold all the patents. New companies are locked out of developing GE crops until the existing patents expire, unless they are willing to enter into expensive limiting licenses with the current patent holders.

Even if courts decline to extend the statutory experimental use exception to GE crops, the development of an experimental use exception for the agricultural biotechnology industry is a viable idea. Whether developed as a stand-alone experimental use exception or as part of an entire system to encourage the development of a generic subset to the industry, the Hatch–Waxman Act’s statutory experimental use exception could play an important role in directing the discussion.