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## Patents, Hidden Novelty, and Food Safety

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## PATENTS, HIDDEN NOVELTY, AND FOOD SAFETY

*Jeanette M. Roorda* \*

## Abstract

This Note discusses how federal agency policy results in a lack of access to patent-protected genetically modified organisms (GMOs) for independent food safety testing. The U.S. GMO policy is a combination of biotechnology regulations and biotechnology intellectual property protections. Intellectual property protection for the developers of new organisms has increased as the technology has advanced from manual pollination to genetic modification methods. Initially the only protection available was in the form of trade secrets, but the protection has increased incrementally to now include full utility patent protection. This Note evaluates the interactions between U.S. Patent and Trademark Office (USPTO) GMO policy and Food and Drug Administration (FDA) GMO policy by comparing USPTO and FDA treatment of various human consumption products. GMO food products fall into a narrow “hidden novelty” exception created by the combination of the FDA’s GMO policy and the GMO manufacturers’ use of licensing enabled by utility patent protection. This Note emphasizes the necessity of access to human consumption products for independent safety testing and illustrates this necessity through a comparison to trans fats. Finally, this Note proposes a narrow research exemption to correct the “hidden novelty” exception while leaving patent law precedent undisturbed.

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INTRODUCTION

Genetically modified organisms (GMOs) are a growing part of the U.S. food supply. Biotechnology is rapidly advancing and potentially solving the many challenges of feeding the world’s growing population. The United States embraces innovation by allowing Congress “[t]o promote the Progress of Science and the useful Arts.”<sup>1</sup> Fantastic new discoveries come with many unknowns, and uncertainty is inherent in scientific discoveries. GMOs are no exception; they come with many potential benefits as well as many potential concerns.

One way Congress fulfills the constitutional mandate “[t]o promote the Progress of Science and the useful Arts” is by issuing utility patents to secure “for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>2</sup> A utility patent is intended to grant the owner “the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States” for the term of the patent.<sup>3</sup> In exchange for the inventor’s limited monopoly, the public receives the benefit of the invention itself and the knowledge gained through the invention.

GMOs have the potential to provide great benefits to the public. The potential benefits of GMOs include a more nutritious and abundant food supply for not only the United States but also the world.<sup>4</sup> Genetic

1. U.S. CONST. art. I, § 8, cl. 8.

2. U.S. CONST. art. I, § 8, cl. 8.

3. 35 U.S.C. § 154(a) (2012).

4. See JEFF SIMMONS, TECHNOLOGY’S ROLE IN THE 21ST CENTURY: MAKING SAFE,

modifications to food organisms can result in faster growth rates, increased yields, improved nutrition content, pest resistance, weed resistance, disease resistance, and other beneficial characteristics.<sup>5</sup> The development of such a potentially beneficial invention should be promoted, but at the same time, potential concerns must be adequately addressed.

The concerns regarding GMOs are related to their possible impact on human health and the environment. In the United States, the majority of processed foods contain at least one GMO ingredient.<sup>6</sup> Therefore, any adverse latent health effects from GMOs could have a widespread detrimental effect on the U.S. population. Additionally, because GMOs are living organisms, when a GMO is introduced into the environment, the genetically modified trait can spread into other related species through pollination or sexual reproduction.<sup>7</sup> Once a genetic modification has spread, it could be difficult or impossible to remove. While the risk of these concerns may be low, the severity of the potential impact warrants adequate research.

Many scholars have explored the various concerns surrounding GMOs. For example, Professor Mary Jane Angelo has analyzed the U.S. regulatory framework for GMOs.<sup>8</sup> Professors Lars Noah<sup>9</sup> and Katharine Van Tassel<sup>10</sup> have provided contrasting views related to tort liability concerns for GMOs. The concept of IP overreach, identified by Professor Elizabeth Rowe, provided the inspiration for this Note.<sup>11</sup>

This Note explores the U.S. regulatory framework for GMOs and the underlying policies for protecting the intellectual property of the developers of new organisms. It focuses on the interaction between U.S. Patent and Trademark Office (USPTO) GMO policy and Food and Drug

AFFORDABLE AND ABUNDANT FOOD A GLOBAL REALITY 7 (2011), <https://www.ncbiotech.org/sites/default/files/pages/Three-Rights-White-Paper-Revised.pdf>.

5. *Weighing the GMO Arguments: For*, FOOD & AGRIC. ORG. OF THE UNITED NATIONS, <http://www.fao.org/english/newsroom/focus/2003/gmo7.htm> (last visited June 25, 2016).

6. See *Genetically Modified Foods*, GENETIC SCI. LEARNING CTR. (June 22, 2014), <http://learn.genetics.utah.edu/content/science/gmfoods/>.

7. See R.L. Nielsen, *Minimizing Pollen Drift & Commingling of GMO and Non-GMO Corn Grain*, CHAT N<sup>7</sup> CHEW CAFE (Mar. 2000), [http://www.kingcorn.org/news/articles.00/GMO\\_Issues000307.html](http://www.kingcorn.org/news/articles.00/GMO_Issues000307.html).

8. Mary Jane Angelo, *Regulating Evolution for Sale: An Evolutionary Biology Model for Regulating the Unnatural Selection of Genetically Modified Organisms*, 42 WAKE FOREST L. REV. 93 (2007) (proposing a new evolutionary biology model for regulating GMOs).

9. Lars Noah, *Managing Biotechnology's [R]evolution: Has Guarded Enthusiasm Become Benign Neglect?*, 11 VA. J.L. & TECH. 1 (2006) (warning against inappropriate legal action and overregulation of new technology).

10. Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645 (2004).

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

Administration (FDA) GMO policy. This Note identifies a “hidden novelty” exception and discusses how this exception allows manufacturers to use the protective power of a utility patent to create a monopoly on the safety research of GMOs in the U.S. food supply. Finally, it explores why access to GMOs for independent food safety testing is a necessity and suggests a solution.

This Note presents its argument in four Parts. Part I explains the history of U.S. GMO policy, beginning with a description of the U.S. regulatory framework for biotechnology. Next, Part I explores the increasing levels of intellectual property protection available to the developers of new organisms. Part I provides the underlying logic that defines GMO policy.

Part II discusses the interaction between USPTO GMO policy and FDA GMO policy. It defines the roles of the USPTO and the FDA as well as identifies the purpose and responsibilities of each agency for GMO food products. Additionally, Part II explores examples to compare and highlight the varying treatment of different food products by the USPTO and the FDA.

Part III explains how independent researchers do not have access to GMOs for food safety testing as a result of the interaction of FDA policy and utility patent protection. Part III describes how the protective power of a utility patent and licensing restrictions shield from independent safety testing GMOs used as an ingredient or component of a processed food product, creating a narrow exception that this Note refers to as the special “hidden novelty” exception. The same protective power and licensing restrictions extend the monopoly of the manufacturer to include a monopoly on safety research of the patented GMO food product.

Part IV asserts the necessity of access to GMOs for independent research. It explores lessons from the history of trans fat—another man-made food product with many novel and useful characteristics—in the U.S. food supply. Part IV argues that patent policy should remain intact and that the FDA should enact regulations that create access to GMOs for independent research. This is the best solution to correct the special “hidden novelty” exception because it ensures that all food products in the U.S. food supply can be independently tested for safety without disturbing relevant patent law precedent.

GMO manufacturers combine the power of patent license protection with FDA policy to create a lack of access to GMO food products for independent food safety testing.<sup>12</sup> All other food products in the U.S. food supply are accessible for independent testing because they either lack patent protection, are sold rather than licensed, or can be easily identified

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12. See *Do Seed Companies Control GM Crop Research?*, SCI. AM. (July 20, 2009), <http://www.scientificamerican.com/article/do-seed-companies-control-gm-crop-research/> [hereinafter *Seed Companies*].

and isolated. Should a manufacturer be able to obtain utility patent protection, based on the novel and useful characteristics of a GMO that distinguish it from its non-modified counterpart, and then use the utility patent protection to prohibit any independent safety testing of the GMO as a food product?

## I. THE HISTORY OF U.S. GMO POLICY

Genetic modification of living organisms is a relatively new technological advancement. Congress has not passed any specialized legislation for GMOs.<sup>13</sup> As a result, the existing general statutory framework regulates GMOs.<sup>14</sup> Three federal agencies are responsible for the majority of GMO regulation issues: the U.S. Department of Agriculture (USDA), the FDA, and the Environmental Protection Agency (EPA).<sup>15</sup> This Part provides a brief overview of how the regulatory responsibility for GMOs is spread across these federal agencies. It also describes the increasing levels of intellectual property protection that developers of new organisms have received.

### A. *Regulating Biotechnology*

In 1986, the Office of Science and Technology Policy announced “the policy of the federal agencies involved with the review of biotechnology research and products” in the Coordinated Framework for Regulation of Biotechnology (Coordinated Framework).<sup>16</sup> The Coordinated Framework integrates multiple agencies’ regulations to cover all forms of biotechnology.<sup>17</sup> It details the federal regulatory policy intended to ensure the safety of biotechnology research and products.<sup>18</sup> Rather than create policy specific to GMOs, Congress determined that the existing statutory frameworks provide “adequate [regulation] to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”<sup>19</sup>

Under the existing statutory framework, a product’s use determines which federal agency has jurisdiction over that product, including

13. See LUIS ACOSTA, RESTRICTIONS ON GENETICALLY MODIFIED ORGANISMS: UNITED STATES, <http://www.loc.gov/law/help/restrictions-on-gmos/usa.php> (last updated June 9, 2015).

14. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,302–03 (June 26, 1986).

15. *Id.* at 23,303–06; ACOSTA, *supra* note 13; Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2216–17 (2004).

16. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302.

17. *Id.* at 23,302–03.

18. *Id.*; see also Mandel, *supra* note 15, at 2216 (outlining the intentions behind the federal regulatory policy).

19. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,302–03.

GMOs.<sup>20</sup> The FDA has jurisdiction over foods, food additives, human drugs, biologics and devices, and animal drugs.<sup>21</sup> The USDA's Food Safety Inspection Service has jurisdiction over domestic livestock and poultry.<sup>22</sup> The USDA's Animal and Plant Health Inspection Service has jurisdiction over the shipment or release of animal biologics and plant pests.<sup>23</sup> The EPA has jurisdiction over pesticides, including organisms genetically modified to produce their own pesticide.<sup>24</sup>

The Coordinated Framework recognizes that as scientific knowledge and understanding of possible risks of biotechnology increases, modification to the regulatory framework may be necessary.<sup>25</sup> The Coordinated Framework carefully notes that "there always can be potential problems and deficiencies in the regulatory apparatus in a fast moving field."<sup>26</sup> However, the Coordinated Framework has remained—without modification—the regulatory framework for biotechnology products since its establishment in 1986.<sup>27</sup>

The current statutory framework regulating GMOs is no longer adequate to ensure health and environmental safety. The current framework is deficient because it allows GMO manufacturers to use licensing restrictions to prevent access to GMO food products for independent food safety testing.<sup>28</sup> Under the current framework, GMO manufacturers, who profit financially from the inclusion of GMOs in the U.S. food supply, have sole control of the safety testing of their products.<sup>29</sup> This does not sufficiently ensure that the manufacturer's financial profit concerns will not overshadow health and environmental safety concerns. Federal agency policy must address these shortcomings to reduce the potential risk of any health and environmental harms while ensuring the intellectual property rights of manufacturers are protected.

### B. *Protecting the Developers of New Food Plants*

A growing population requires a growing food supply. Throughout history, mankind has sought better ways to produce food. As the history of agricultural advancements demonstrates, the level of intellectual

20. *See id.* at 23,303; Mandel, *supra* note 15, at 2216–17.

21. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. at 23,304.

22. *Id.*

23. *Id.*

24. *Id.* at 23,304–05.

25. *Id.* at 23,302, 23,306.

26. *Id.* at 23,306.

27. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989–90 (May 29, 1992); *Food from Genetically Engineered Plants*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/FoodScienceResearch/GEPlants/default.htm> (last updated Nov. 19, 2015).

28. *See Seed Companies*, *supra* note 12.

29. *Id.*

property protection has increased as more technology is employed with advancements.<sup>30</sup> The purpose of providing intellectual property protection to plants is to encourage the development of novel varieties with the end result of promoting agriculture in the public interest.<sup>31</sup> However, another purpose emerged when the USPTO introduced utility patents as intellectual property protection for GMOs. GMO manufacturers are now combining licensing with FDA policy to maintain full control and oversight of any safety testing of GMO food products.<sup>32</sup> This new purpose of preventing independent safety research conflicts with the fundamental purpose of promoting agriculture in the public interest. An overview of the history of intellectual property protection given to plants highlights the fundamental connection of intellectual property protection to the promotion of agriculture in the public interest.

### 1. Trade Secrets

The first advances in seed development were made through manual pollination.<sup>33</sup> In manual pollination, the seed producer selects two parent plants from different plant lines and cross-pollinates the parent plants.<sup>34</sup> The goal of manual pollination is to develop a plant with a combination of desired characteristics not exhibited in either of the parent plant lines.<sup>35</sup> The seed developed through this process is called a hybrid seed.<sup>36</sup> Typically, hybrid seeds only produce plants with the desired characteristics in the first generation of seed.<sup>37</sup> Subsequent generations of seed resulting from open pollination develop “inconsistent and undesirable characteristics.”<sup>38</sup>

The initial intellectual property protection for agricultural biotechnology came in the form of trade secret protection for hybrid seeds.<sup>39</sup> The hybrid seeds have built-in protection for the seed producer.<sup>40</sup> Because hybrid seeds are only useful for the first generation, seed

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30. See Rowe, *supra* note 11, at 862.

31. See Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542, 1542 (1970) (codified as amended at 7 U.S.C. §§ 2321–2583 (2012)), reprinted in 1 LEGISLATIVE HISTORY OF THE PLANT VARIETY PROTECTION ACT (1974); 8 DONALD S. CHISUM, CHISUM ON PATENTS § 24.03 (2014).

32. See *Seed Companies*, *supra* note 12.

33. Rowe, *supra* note 11, at 863.

34. Theresa Friday, *Heirloom or hybrid tomatoes, which to choose?*, UNIV. OF FLA. IFAS EXTENSION SANTA ROSA (Mar. 13, 2012), <http://santarosa.ifas.ufl.edu/blog/2012/03/13/heirloom-or-hybrid-tomatoes-which-to-choose/>.

35. *Id.*

36. *Id.*

37. *Id.*

38. Rowe, *supra* note 11, at 863. See Friday, *supra* note 34.

39. Rowe, *supra* note 11, at 862.

40. *Id.* at 863. See Friday, *supra* note 34.



producers can sell the first generation hybrid seed and do not have to be concerned about losing market share through the use or sale of the subsequent generations of seed produced by the buyer.<sup>41</sup> The seed producer can continue to profit each year with the sale of the first generation hybrid seeds by keeping the parent lines as a trade secret and only selling the first-generation hybrid seeds.<sup>42</sup> Independent parties are simply unable to reproduce a plant with the same characteristics using subsequent generations of the seed.

## 2. Plant Patent Act of 1930

The first patent protection for plants came when Congress passed the Townsend–Purnell Plant Patent Act of 1930 (PPA).<sup>43</sup> The intent behind the PPA was “to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry.”<sup>44</sup> The USPTO administers plant patents for those plants that meet the PPA’s specifications.<sup>45</sup> The PPA provides protection solely for plants asexually reproduced that also meet the general patent eligibility requirements of novelty, originality, and nonobviousness.<sup>46</sup> The asexual reproduction requirement means the plant must be reproduced by means such as cuttings or grafting and not by seeds.<sup>47</sup>

A plant patent is only infringed when others asexually reproduce the plant.<sup>48</sup> Therefore, the use of seeds to sexually reproduce a plant protected under the PPA does not constitute infringement.<sup>49</sup> Additionally, another plant producer is free to independently breed a similar variety.<sup>50</sup> Nothing restricts independent parties from growing or conducting research on any seeds produced by the plants; they are simply prohibited from asexually reproducing the plant. Thus, protection under the PPA is typically only beneficial for a plant variety that can only be reproduced asexually or is very difficult to reproduce sexually.<sup>51</sup> The purpose of intellectual property protection under the PPA is to encourage the preservation of a unique plant with desirable characteristics by providing a financial incentive to individuals who undertake the effort to preserve and asexually propagate a plant that would otherwise cease to exist when the parent plant died.

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41. Rowe, *supra* note 11, at 863. See Friday, *supra* note 34.

42. See Rowe, *supra* note 11, at 863.

43. Pub. L. No. 245, 46 Stat. 376 (1930); CHISUM, *supra* note 31, § 24.02(1).

44. CHISUM, *supra* note 31, § 24.02(1) (quoting S. REP. NO. 71-315 (1930)).

45. *Id.* § 24.01.

46. *Id.* § 24.02(2).

47. *Id.* § 24.02(2)(b).

48. *Id.* § 24.01.

49. *Id.*

50. *Id.*

51. *Id.* § 24.02.

### 3. Plant Variety Protection Act of 1970

Sexually reproduced plants did not receive any additional protection until Congress passed the Plant Variety Protection Act of 1970 (PVPA).<sup>52</sup> The PVPA provides protection for plants whose seeds produced heritable traits that are consistent and desirable through not only the first generation of seed but also in subsequent generations of seed.<sup>53</sup> The purpose of the PVPA is “[t]o encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest.”<sup>54</sup> A developer of a novel variety of plant who acquires a certificate of protection under the PVPA has the exclusive right for the patent term to “exclude others from selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing . . . a hybrid or different variety therefrom.”<sup>55</sup>

Although the PVPA provides protection similar to patent protection, the protection is distinctly different in two critical aspects.<sup>56</sup> First, the PVPA authorizes the USDA to issue certificates of plant variety protection (PVP certificates) rather than authorizing the USPTO to issue a patent.<sup>57</sup> Second, the PVPA provides exemptions for activities that could otherwise constitute infringement under a patent.<sup>58</sup> Two important exemptions are the research exemption and the crop exemption.<sup>59</sup> The research exemption states that “[t]he use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this chapter.”<sup>60</sup> The crop exemption originally allowed farmers to save seed for replanting their own crops and to sell limited quantities of saved seed to others for

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52. Pub. L. No. 91-577, 84 Stat. 1542, 1542 (1970) (codified as amended at 7 U.S.C. §§ 2321–2583).

53. 7 U.S.C. § 2541 (2012).

54. 84 Stat. at 1542.

55. 7 U.S.C. § 2483.

56. An interesting third distinct difference is beyond the scope of this Note. The PVPA allows a protected variety to be “open to use on a basis of equitable remuneration to the owner, not less than a reasonable royalty” if necessary “to insure an adequate supply of fiber, food, or feed in this country.” *Id.* § 2404. This provision protects the U.S. food supply by allowing the USDA to force the owner of a protected plant variety to allow the use of the protected variety at a reasonable price to ensure an adequate supply of food is available. See CHISUM, *supra* note 31, § 24.03(4)(a)(i).

57. 7 U.S.C. § 2323.

58. *Id.* §§ 2542–2545.

59. *Id.* § 2543 (Crop Exemption); *id.* § 2544 (Research Exemption). See Rowe, *supra* note 11, at 864–65.

60. 7 U.S.C. § 2544.

replanting.<sup>61</sup> However, in 1994, Congress amended the PVPA to eliminate the ability of farmers to sell saved seed to others for replanting, but it “[c]ontinues to allow farmers to save seed for replanting on their own farm.”<sup>62</sup>

#### 4. Utility Patents for Plants

The possibility of plants receiving the full protection of a utility patent arose with the landmark Supreme Court decision in *Diamond v. Chakrabarty*.<sup>63</sup> *Chakrabarty* involved the patent eligibility of a bacteria that was genetically modified to be capable of breaking down crude oil.<sup>64</sup> The question before the Supreme Court was “whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.”<sup>65</sup> The Supreme Court found that the “claim is not to a[n] . . . unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use.’”<sup>66</sup> Additionally, the Supreme Court observed that the applicant “ha[d] produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”<sup>67</sup> The Court held that genetically modified bacteria is patent-eligible subject matter, opening the door for the possibility of full utility patent protection for plants.<sup>68</sup>

In October 2001, the Supreme Court clarified any doubt as to whether sexually reproducing plants are patent-eligible subject matter.<sup>69</sup> In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Supreme Court considered whether “utility patents may be issued for plants under 35 U.S.C. § 101” or if “the Plant Variety Protection Act and the Plant Patent Act of 1930 are the exclusive means of obtaining a federal statutory right to exclude others from reproducing, selling, or using plants or plant varieties.”<sup>70</sup> *J.E.M. Ag Supply* involved the validity of utility patents covering the manufacture and use of Pioneer’s inbred and hybrid corn seed products.<sup>71</sup> The Supreme Court affirmed the lower court’s reliance

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61. See CHISUM, *supra* note 31, § 24.03(b)(ii).

62. H.R. REP. 103-349, at 11 (1994).

63. 447 U.S. 303 (1980).

64. *Id.* at 305.

65. *Id.*

66. *Id.* at 309–10 (alteration in original) (quoting *Hartranft v. Wiegmann*, 121 U.S. 609, 615 (1887)).

67. *Id.* at 310.

68. See *id.* at 318.

69. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001).

70. *Id.* at 127 (citations omitted).

71. *Id.*

on *Chakrabarty*'s broad construction of § 101 and held that the subject matter covered by § 101 clearly included plant life.<sup>72</sup> The Court observed that "advances in biological knowledge and breeding expertise have allowed plant breeders to satisfy § 101's demanding description requirement."<sup>73</sup> The Court also noted that "Congress ha[d] not only failed to pass legislation indicating that it disagree[d] with the [US]PTO's interpretation of § 101 [that plants are patent-eligible subject matter]; it has even recognized the availability of utility patents for plants."<sup>74</sup>

The decision in *J.E.M. Ag Supply* is where the current state of intellectual property protection for plants remains. If a plant meets the patent criteria of utility, novelty, and nonobviousness, it can receive the full protection of a utility patent.<sup>75</sup> A key difference is that the PPA and PVPA allow farmers to save their seeds for replanting and do not prohibit research.<sup>76</sup> A utility patent provides increased protection and gives the patent holder the power to exclude others from both saving their seeds for replanting and conducting research with the patented plant.<sup>77</sup>

## II. THE INTERACTION BETWEEN USPTO GMO POLICY AND FDA GMO POLICY

To analyze how USPTO GMO policy and FDA GMO policy interact, this Part begins by defining each agency's role. It then explains the underlying policy goals and the overall functions and responsibilities of each agency. An understanding of the purpose of each agency's actions again highlights the deficiency in the existing statutory framework. Examples comparing the varying treatment of different food products by the USPTO and the FDA illustrate this deficiency.

### A. *Defining the Roles of the USPTO and the FDA*

The USPTO and the FDA each have a separate and distinct role in U.S. GMO policy. The underlying policy considerations shed light on the unique roles that both the USPTO and the FDA play. Examining the overall functions and responsibilities of each agency clarifies the agency's role in GMO policy. The USPTO's role centers on granting patents which provide intellectual property protection. The FDA's role centers on ensuring the safety of the food supply and human health.

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72. *Id.* at 129.

73. *Id.* at 134.

74. *Id.* at 145.

75. See 35 U.S.C. §§ 101–103 (2012).

76. See 7 U.S.C. § 2541(a) (2012).

77. See 35 U.S.C. § 154(a)(1).

## 1. The Progress of Science

The USPTO serves to meet the constitutional mandate “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”<sup>78</sup> At a basic level, the USPTO’s impact on GMO policy is to “grant patents for the protection of inventions.”<sup>79</sup> Granting patents meets the constitutional mandate by promoting scientific progress “[t]hrough the preservation, classification, and dissemination of patent information” and by securing inventors exclusive rights to their discoveries for the limited term of the patent.<sup>80</sup> The USPTO evaluates each patent application under statutory provisions for subject matter eligibility as well as utility, novelty, and nonobviousness.<sup>81</sup>

The USPTO evaluates subject matter eligibility and utility under 35 U.S.C. § 101.<sup>82</sup> The statutory language provides that “[w]hoever 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.”<sup>83</sup> GMOs are patent-eligible subject matter under the Supreme Court precedent in *Chakrabarty* and *J.E.M. Ag Supply*.<sup>84</sup> *Chakrabarty* held that a living organism is patentable subject matter,<sup>85</sup> and *J.E.M. Ag Supply* affirmed that plants, both asexually and sexually reproducing, are patent-eligible subject matter for utility patents.<sup>86</sup> The utility for a GMO comes from the desirable trait incorporated into the GMO through genetic modification.<sup>87</sup> For example, a plant genetically modified to produce its own pesticide is a useful invention because of this new ability to repel insects.<sup>88</sup> Some possible utilities for GMO food products include faster growth rates, increased yields, resistance to pests and weeds, and decreased need for water.<sup>89</sup>

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78. U.S. CONST. art. I, § 8, cl. 8.

79. *Functions of the Patent and Trademark Office*, U.S. PAT. & TRADEMARK OFFICE, <http://www.uspto.gov/web/offices/pac/doc/general/function.htm> (last updated Nov. 14, 2015).

80. *Id.*

81. See 35 U.S.C. §§ 101–103. Each patent application is also evaluated for formalities, written description, enablement, best mode, and other requirements, however, those are beyond the scope of this Note. See MPEP Ch. 700 (9th ed., Mar. 2014) (providing guidance on the USPTO procedures for examination of applications).

82. See *id.* § 101.

83. See *id.*

84. See *supra* Subsection I.B.4.

85. *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

86. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 146 (2001).

87. See *Chakrabarty*, 447 U.S. at 313.

88. See U.S. Patent No. 6,340,593 col. 3 l. 36–40 (filed Oct. 21, 1999) (issued Jan. 22, 2002) (exemplifying plant-optimized polynucleotides encoding approximately 15 kDa and approximately 45 kDa pesticidal proteins).

89. *E.g.*, *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 169 (D.D.C. 2000).

After evaluating a GMO patent application for subject matter eligibility and utility, the USPTO evaluates the claimed invention for novelty and nonobviousness.<sup>90</sup> Novelty requires that the invention has not been “anticipated” by any prior art; in other words, the claimed GMO must be new.<sup>91</sup> A GMO will pass the novelty requirement unless it can be shown that the GMO is not a new invention.<sup>92</sup> Additionally, the nonobviousness requirement is likely the most challenging requirement a GMO faces. The statutory language provides as follows:

A patent for a claimed invention may not be obtained . . . if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious . . . to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.<sup>93</sup>

For a claimed invention of a GMO, the USPTO must determine if it would have been obvious to a person skilled in the art to combine the elements from the prior art to create the claimed invention.<sup>94</sup> A detailed analysis of the multiple variations of nonobviousness analysis possible for GMOs is beyond the scope of this Note.

The critical point to observe is that the more unnatural the genetic modification combination is, the more likely it is that the combination will be found nonobvious. The more likely it is that the combination is nonobvious, the more likely it is that the GMO will receive the protection of a utility patent. As genetic modification technology becomes increasingly common, there will likely be more patent application rejections based on “obviousness.” This possibility encourages GMO developers to make “less obvious” genetic combinations to obtain patent protection. “Less obvious” combinations will likely involve more transgenic GMOs and less intragenic GMOs.<sup>95</sup> For example, it might be obvious to genetically modify a red tomato with genes from a green tomato to increase bruising resistance, but it might be “less obvious” to

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90. 35 U.S.C. §§ 102–103 (2012).

91. MPEP § 2131 (9th ed., Mar. 2014) (providing guidance on how to analyze a patent application under 35 U.S.C. § 102).

92. *See id.*

93. 35 U.S.C. § 103.

94. *See* MPEP §§ 2141–2144 (providing guidance on how to analyze a patent application under 35 U.S.C. § 103).

95. Transgenic GMOs involve genetic modifications incorporating genes from different species, while intragenic GMOs involve genetic modifications incorporating genes from the same species. *See generally* Marlam Sticklen, *Transgenic, Cisgenic, Intragenic and Subgenic Crops*, *ADVANCES CROP SCI. & TECH.*, Apr. 2015, at 1, <http://www.esciencecentral.org/journals/transgenic-cisgenic-intragenic-and-subgenic-crops-2329-8863-1000e123.pdf>.

modify a red tomato with genes from a grasshopper to increase bruising resistance.

It is important to observe that the USPTO does not evaluate the safety of an invention receiving a patent. In the past, moral considerations played a role in the evaluation of the utility requirement.<sup>96</sup> However, the utility requirement's only modern moral restriction is that the invention must be capable of serving a lawful purpose.<sup>97</sup> The role of the USPTO in GMO policy is simply to promote the progress of science<sup>98</sup> by determining if the claimed GMO invention meets the statutory criteria to receive a patent without considering the safety of the claimed GMO.

## 2. Food Safety and Human Health

The origins of the FDA can be traced back to the passage of the Pure Food and Drugs Act in 1906.<sup>99</sup> Today, the FDA derives its authority from the Federal Food, Drug, and Cosmetic Act (FFDCA).<sup>100</sup> Essentially, the FDA regulates food safety and human health.<sup>101</sup> It “protect[s] the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, . . . [and the U.S.] food supply.”<sup>102</sup> Specifically, the “FDA regulates the safety of substances added to food . . . [and] how most food is processed, packaged, and labeled.”<sup>103</sup>

The FFDCA mandates a premarket approval safety assessment before a food enters the U.S. food supply.<sup>104</sup> The premarket approval process begins with a petition submitted by the applicant.<sup>105</sup> The petition must contain adequate data to allow the FDA to conduct a chemistry review, a toxicology review, and an environmental review prior to the FDA approval of the food product.<sup>106</sup> However, the FFDCA does not require

96. See *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8568), *abrogation recognized by In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005).

97. *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999).

98. U.S. CONST. art. I, § 8, cl. 8.

99. *History*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/> (last updated Mar. 23, 2015).

100. See 21 U.S.C. §§ 301, 393 (2012).

101. See *What We Do*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/whatwedo/> (last updated Dec. 7, 2015).

102. *Id.*

103. *Ingredients, Packaging & Labeling*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm> (last updated June 21, 2016).

104. See 21 C.F.R. § 171.1(h)(4) (2014) (detailing the FFDCA's safety assessment requirements).

105. *Guidance for Industry: Questions and Answers About the Petition Process*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm253328.htm#answerC> (last updated Mar. 23, 2015).

106. *Id.* (providing a basic overview of the petition requirements and process). The applicant-provided data includes the results from and the methodology of detailed safety studies. *Id.*

a premarket approval safety assessment if the food is classified as “generally recognized as safe” (GRAS).<sup>107</sup> Once a food substance qualifies as GRAS, it may enter directly into the U.S. food supply.<sup>108</sup>

In 1992, the FDA issued a policy statement regarding “Foods Derived from New Plant Varieties,” which it reiterated in 2001.<sup>109</sup> The policy states that “transferred genetic material can be presumed to be GRAS.”<sup>110</sup> The FDA also affirmed that it still holds the view that

there is unlikely to be a safety question sufficient to question the presumed GRAS status of proteins (typically enzymes) produced from the transferred genetic material, or of substances produced by the action of the introduced enzymes (such as carbohydrates, fats, and oils), when these proteins or other substances do not differ significantly from other substances commonly found in food and are already present at generally comparable or greater levels in currently consumed foods.<sup>111</sup>

Consistent with these policies, the FDA typically presumes food derived from genetically modified plants to be GRAS and therefore does not subject it to premarket approval safety testing.<sup>112</sup>

The FDA evaluates food additives under a more stringent safety standard than whole foods.<sup>113</sup> A food additive is “any substance that is not an inherent constituent of food or whose level in food has been increased by human intervention to be ‘added.’”<sup>114</sup> However, a food additive that is considered GRAS is excluded from the more stringent safety standard.<sup>115</sup> As a result, many food additives derived from natural sources are considered GRAS, which allows the food additives to bypass FDA review and enter the food supply.<sup>116</sup> The manufacturer of a new food product, not the FDA, makes the initial determination of whether

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107. See 21 C.F.R. § 170.30 (discussing various methods of determining whether a food substance qualifies as GRAS); *id.* §§ 182, 184, 186 (2014) (identifying food substances that have been generally recognized as safe).

108. See *id.* §§ 170.30, 182.1, 184.1, 186.1.

109. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989–90 (May 29, 1992). See Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4709 (Jan. 18, 2001) (reiterating the 1992 policy from the FDA Policy Statement regarding Foods Derived from New Plant Varieties).

110. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709.

111. *Id.*

112. See 21 C.F.R. § 170.30; FDA Proposed Rule, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. at 4709.

113. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. at 22,988–89.

114. *Id.* at 22,989.

115. *Id.*

116. See *id.*



the new food product is GRAS.<sup>117</sup>

The FDA also applies different standards of review for genetically modified plant food products and genetically modified animal food products. As discussed above, genetically modified plant food products are evaluated as a food substance and are presumed to be GRAS.<sup>118</sup> When confronted with the first genetically modified animal food product, the FDA determined that the appropriate standard of review was to treat the added genetic material as an animal drug, subjecting it to a much more extensive safety testing process.<sup>119</sup> However, the science and processes underlying genetic modification methods, such as recombinant DNA techniques or cell fusion techniques, are the same for both genetically modified plants and genetically modified animals.<sup>120</sup> The FDA stated that the reason for the different treatment is that animals can transmit diseases to humans, which leads to the increased safety testing requirement.<sup>121</sup> This differential treatment means that a strawberry modified to include fish genes could qualify as GRAS, while a fish modified to include strawberry genes would be evaluated under the animal drug regulations.

In addition to selecting a higher standard for safety evaluation of genetically modified animals as food products, the FDA approval process for the first genetically modified animal food product experienced multiple lengthy and unexplained delays.<sup>122</sup> AquaBounty first approached the FDA seeking approval for AquAdvantage Salmon in 1995 and did not receive approval until November 2015.<sup>123</sup> This is in contrast to the first genetically modified plant product, the Flavr Savr tomato, which Calgene first mentioned to the FDA in 1991 and which was in grocery stores by 1994.<sup>124</sup> Perhaps these differences are solely

117. *Id.*

118. *Id.* at 22,990.

119. U.S. FOOD & DRUG ADMIN., REGULATION OF GENETICALLY ENGINEERED ANIMALS 2 (2010), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048122.pdf>.

120. *Id.* at 1–2.

121. *Genetically Engineered Animals: General Q&A*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm113605.htm> (last updated Nov. 19, 2015).

122. Ron Stotish, *AquAdvantage Salmon: A Regulatory Odyssey*, BIOTECH NOW (Apr. 24, 2013), <http://www.biotech-now.org/food-and-agriculture/2013/04/aquadvantage-salmon-a-regulatory-odyssey>.

123. Heidi Ledford, *Transgenic Salmon Nears Approval: Slow US Regulatory Process Highlights Hurdles of Getting Engineered Food Animals to Dinner Tables*, 497 NATURE 17, 17 (2013), <http://www.nature.com/news/transgenic-salmon-nears-approval-1.12903>; *AquAdvantage Salmon Approval Letter and Appendix*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm466214.htm> (last updated Nov. 19, 2015) [hereinafter *AquAdvantage Approval Letter*].

124. Memorandum from Consumer Safety Officer, Biotechnology Policy Branch on Consultation with Calgene, Inc., Concerning FLAVR SAVR Tomatoes to Acting Dir., Office of

because of the ability of animals to spread disease to humans, or perhaps they are an indicator of the beginning of a shift in policy for the regulation of genetically modified foods by the FDA.

The FDA also has other responsibilities related to food safety and human health that are worth noting.<sup>125</sup> One of these responsibilities is advancing the public health “by helping to speed innovations that make medicines more effective, safer, and more affordable.”<sup>126</sup> Another responsibility is “helping the public get the accurate, science-based information . . . to use medicines and foods to maintain and improve their health.”<sup>127</sup> As a result, the FDA has promoted advances in biotechnology, including genetically modified plants.<sup>128</sup>

### B. USPTO and FDA Policy Comparisons

To better understand the GMO policy of the USPTO and the FDA, it is helpful to compare the way each agency evaluates various products for human consumption. New and naturally occurring food products, artificial and non-naturally occurring food products, and pharmaceuticals must typically undergo premarket approval safety testing by the FDA before entering the U.S. market.<sup>129</sup> This is in contrast to genetically modified plant food products, which typically bypass the premarket approval safety testing and enter directly into the U.S. food supply. As discussed above, the USPTO does not consider safety when determining whether a product is eligible for a patent. Interestingly, the FDA requires genetically modified animal food products to undergo a much more rigorous approval process than their genetically modified plant counterparts. The following examples illustrate how these policies operate in practice. For each example, assume the manufacturer is seeking a utility patent from the USPTO and entry into the U.S. food supply through the FDA.

#### 1. New and Naturally Occurring

Consider the treatment of two naturally occurring food products for which a company seeks both a patent from the USPTO and approval to enter the food supply from the FDA. For the first scenario, consider a newly discovered naturally occurring food product found in the wild. For the second scenario, consider a naturally occurring food product resulting from conventional crossbreeding of plants.

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Premarket Approval (May 17, 1994), <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/Submissions/ucm225043.htm>.

125. *What We Do*, *supra* note 101.

126. *Id.*

127. *Id.*

128. *See id.*

129. *See* 21 C.F.R. § 171.1(h)(4) (2014).

First, imagine a team of explorers discovering a new plant in the wild that produces yellow berries. The USPTO will determine that the plant and its yellow berries are not patentable, as the Supreme Court has held that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.”<sup>130</sup> The USPTO would not need to consider the criteria of utility, novelty, and nonobviousness because the discovery of the naturally occurring plant and yellow berries does not meet the initial subject matter eligibility requirements of 35 U.S.C. § 101.<sup>131</sup>

To receive FDA approval, the yellow berries must undergo premarket approval process.<sup>132</sup> The premarket approval process mandates a safety assessment of the food substance.<sup>133</sup> This safety assessment must show that the yellow berries are safe for human consumption before the yellow berries may enter the food supply.<sup>134</sup>

There are two important exemptions to the mandated food safety assessment.<sup>135</sup> If the naturally occurring food product has a history of extensive use in food prior to 1958 or published scientific evidence shows the safety of the food product for human consumption, then the food product can be considered GRAS.<sup>136</sup> A food substance classified as GRAS may enter the food supply without premarket approval safety testing.<sup>137</sup> In this example, neither exemption would apply because the newly discovered yellow berries are not substantially equivalent to an existing approved food substance.

Now, imagine a plant breeder uses manual pollination to crossbreed two varieties of strawberry plants and the resulting plant has a heritable trait that produces sweet purple berries. The USPTO will likely determine that the conventionally crossbred sweet purple berries are not utility patent eligible because they are still a product of nature, even though manual pollination aided nature.<sup>138</sup> Unlike the yellow berries newly discovered in the wild, the crossbred purple berries would likely be

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130. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (finding that “a new plant found in the wild is not patentable subject matter”).

131. See 35 U.S.C. § 101–103 (2012).

132. See *supra* Section II.B.

133. See 21 C.F.R. § 171.1(h)(4).

134. See *id.*

135. See INT’L FOOD INFO. COUNCIL FOUND. & U.S. FOOD & DRUG ADMIN., FOOD INGREDIENTS & COLORS 5 (2010), <http://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/ucm094249.pdf>.

136. *Id.*

137. *Id.*

138. See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132 (1948) (finding that no invention existed when several species of bacteria were mixed in a beneficial way). The plant could possibly obtain protection through the PVPA, but it would not be eligible for a plant patent because it has not been asexually reproduced. See *supra* Subsections I.B.2–3.

exempt from the FDA's premarket approval safety testing because they would likely be substantially equivalent to a typical strawberry and therefore classified as GRAS.

In summary, a naturally occurring food product would not be eligible for a patent but would be subjected to the FDA's premarket approval process, which includes safety testing. However, naturally occurring food products are classified as GRAS, and therefore bypass the premarket approval process, if the naturally occurring food product has a history of extensive use in food before 1958 or if published scientific evidence supports the safety of the food product.<sup>139</sup>

## 2. Artificial or Non-naturally Occurring

Now, consider the treatment of an artificial or non-naturally occurring food product for which a company seeks both a patent from the USPTO and approval to enter the food market from the FDA. As an example, consider the artificial sweetener sucralose.<sup>140</sup> Sucralose is used as a zero-calorie sweetener.<sup>141</sup> It is produced by subjecting naturally occurring sugar to a chlorination process.<sup>142</sup>

The USPTO has granted numerous patents for various forms of sucralose.<sup>143</sup> Sucralose meets all of the statutory requirements for patenting.<sup>144</sup> The artificial sweetener satisfies the subject matter eligibility requirement.<sup>145</sup> The utility requirement<sup>146</sup> is met by the zero-calorie characteristic of the sweetener, which makes it useful to individuals who want to reduce their caloric intake and to diabetics who are unable to consume natural sugar.<sup>147</sup> When sucralose was invented, it was new and met the novelty requirement.<sup>148</sup> Sucralose also passed the last hurdle presented by the nonobviousness requirement. At the time of the invention, it would not have been obvious that subjecting sugar to a chlorination process would result in a zero-calorie sweetener that is much sweeter than the original sugar.<sup>149</sup>

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139. INT'L FOOD INFO. COUNCIL FOUND. & U.S. FOOD & DRUG ADMIN., *supra* note 135, at 5.

140. See U.S. Patent No. 4,801,700 cols. 2 l. 65 to 3 l. 6 (filed Oct. 20, 1986) (issued Jan. 31, 1989) (describing patent claims for a sucralose process).

141. *What Is SPLENDA® Brand Sweetener (Sucralose)?*, SPLENDA, <http://www.splenda.com/faq/no-calorie-sweetener> (last visited June 25, 2016) [hereinafter *What Is Splenda*].

142. *Id.*

143. See U.S. Patent No. 6,646,121 col. 2 l. 45–48 (filed Nov. 16, 2001) (issued Nov. 11, 2003) (containing citations to additional granted U.S. patents for various forms of sucralose).

144. See *id.* cols. 3–8 (demonstrating the patentability of sucralose compositions).

145. See 35 U.S.C. § 101 (2012); MPEP § 2106 (9th ed., Mar. 2014).

146. See 35 U.S.C. § 101; MPEP § 2107.

147. *What Is Splenda*, *supra* note 141.

148. See 35 U.S.C. § 102; MPEP § 2131.

149. See 35 U.S.C. § 103; MPEP §§ 2141–2144.

The FDA classifies sucralose as a food additive.<sup>150</sup> During the approval process, the FDA reviewed more than 110 safety studies of sucralose.<sup>151</sup> The FDA notes that Sucralose has been extensively studied by others and is approved as a general-purpose sweetener in food under certain conditions of use.<sup>152</sup> Sucralose was not classified as GRAS because it was not substantially equivalent to sugar as indicated by the difference in caloric content and other characteristics.<sup>153</sup>

In summary, an artificial or non-naturally occurring food product is eligible for a patent but is subjected to the FDA's premarket approval process, which includes safety testing. The only exception to the premarket approval process is GRAS classification. An artificial or non-naturally occurring food product is less likely to be considered substantially equivalent and therefore less likely to be classified as GRAS.

### 3. New and Generic Pharmaceuticals

Consider the development of a new pharmaceutical. A new pharmaceutical typically is granted a utility patent if the pharmaceutical meets the criteria of novelty, nonobviousness, and utility. A manufacturer seeking approval to sell a new pharmaceutical must complete many steps to demonstrate the safety and effectiveness of the drug.<sup>154</sup> Initially, tests are conducted in the laboratory and on animals.<sup>155</sup> If these tests indicate the drug is safe enough to be tested in humans, the manufacturer submits an Investigational New Drug Application that the FDA reviews prior to the human testing.<sup>156</sup> The FDA monitors three phases of human clinical trials of the drug.<sup>157</sup> Finally, the records from all of the testing are submitted in a New Drug Application, which experts at the FDA review.<sup>158</sup> The FDA only approves the new pharmaceutical if the known benefits of its proposed use outweigh the known risks.<sup>159</sup>

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150. *Food Additives & Ingredients: High-Intensity Sweeteners*, U.S. FOOD & DRUG ADMIN. (May 19, 2014), <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm397716.htm>.

151. *Additional Information About High-Intensity Sweeteners Permitted for Use in Food in the United States*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/IngredientsPackagingLabeling/FoodAdditivesIngredients/ucm397725.htm> (last updated May 26, 2015).

152. *Id.*

153. *Id.*

154. *See How FDA Evaluates Regulated Products: Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm269834.htm> (last updated June 25, 2016).

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

159. *Id.*

By contrast, a generic pharmaceutical is ineligible for patent protection but enjoys an abbreviated FDA approval process. When a new pharmaceutical is developed, it typically has the protection of a utility patent.<sup>160</sup> Once the patent expires, generic versions of the pharmaceutical are made. Patent protection is not available for a generic pharmaceutical because the generic will fail the novelty requirement of patent eligibility. A generic pharmaceutical by its nature intends to be a copy of the original and not a new pharmaceutical.<sup>161</sup> The active ingredients must be the same in the original and the generic pharmaceuticals; however, the inactive ingredients may vary.<sup>162</sup> Additionally, to qualify as a generic pharmaceutical, the use indications must be the same as the original pharmaceutical.<sup>163</sup> The FDA only requires an abbreviated new drug application for approval to market a generic pharmaceutical.<sup>164</sup> The generic pharmaceutical manufacturer is not required to conduct the animal or clinical research on ingredients or dosage forms required of the original pharmaceutical manufacturer because those steps would be duplicative and unnecessary.<sup>165</sup>

#### 4. Genetically Modified Plants as Food

Now consider a plant that has been genetically modified using new methods, such as recombinant DNA techniques or cell fusion techniques, to include modification that would not be possible with traditional breeding methods. For example, a genetically modified plant created using recombinant DNA techniques to transfer genetic material from certain genes in fish, which encode proteins that increase resistance to cold, into an agricultural crop such as strawberries.<sup>166</sup> Clearly a fish and a strawberry are not sexually compatible and could not be crossbred using traditional methods. A strawberry genetically modified by inserting fish genetic material would be patent-eligible subject matter under the

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160. TONY ELLERY & NEAL HANSEN, *PHARMACEUTICAL LIFECYCLE MANAGEMENT: MAKING THE MOST OF EACH AND EVERY BRAND* § 8.10 (2012).

161. See *Generic Drugs: Questions and Answers*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm> (last updated Jan. 7, 2015).

162. *Id.*

163. *Id.*

164. *Id.*

165. *Id.*

166. In 1991, the DNA Plant Technology Corporation published a paper describing transgenic tomato plants that were modified by inserting a gene from the northern-hemisphere winter flounder to produce antifreeze proteins. See Robin Hightower et al., *Expression of Antifreeze Proteins in Transgenic Plants*, 17 *PLANT MOLECULAR BIOLOGY* 1013, 1013 (1991). The transgenic tomatoes never made it to the marketplace after further research was unsuccessful in developing a cold-resistant tomato. Peggy G. Lemaux, *Genetically Engineered Plants and Foods: A Scientist's Analysis of the Issues (Part I)*, 59 *ANN. REV. PLANT BIOLOGY* 771, 777, 779 (2008).

reasoning from *Chakrabarty*, which found that the genetic alteration by man was sufficient to overcome the restriction on patenting products of nature.<sup>167</sup> The new strawberry's increased resistance to cold is sufficient to meet the utility requirement.<sup>168</sup> The USPTO will grant a utility patent as long as the requirements of patentability, including novelty and nonobviousness, are met.<sup>169</sup>

The FDA has stated a presumption of GRAS status for foods derived from genetically modified plants.<sup>170</sup> As long as the new strawberry does not contain an increased level of a naturally occurring toxicant or a new unexpected toxicant and as long as it has a similar nutritional profile to a typical strawberry, the manufacturer is likely to determine that the new strawberry is GRAS.<sup>171</sup> No weight is given to the fact that it would be impossible to traditionally crossbreed a strawberry with a fish.<sup>172</sup> Once the new strawberry is determined to be GRAS, it bypasses the FDA review process and can enter the food supply.<sup>173</sup>

In summary, a food product derived from a genetically modified plant will likely obtain a utility patent, and the manufacturer will likely classify it as GRAS. The GRAS status allows the food product to bypass the FDA review process. The FDA states that it "has rarely had occasion to review the GRAS status of foods derived from new plant varieties because these foods have been widely recognized and accepted as safe."<sup>174</sup>

## 5. Genetically Modified Animals as Food

Now consider an animal that has been genetically modified using new methods, such as recombinant DNA techniques or cell fusion techniques, to include modification that would not be possible with traditional breeding methods. For this example, consider AquAdvantage Salmon, the first genetically modified animal for which a manufacturer has sought FDA approval.<sup>175</sup> AquAdvantage Salmon has genetic modifications that cause an Atlantic salmon to produce its growth hormone year-round rather than producing the growth hormone only during a short period each

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167. See *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

168. See 35 U.S.C. § 101 (2012).

169. See *id.* §§ 102–103.

170. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,989–90 (May 29, 1992).

171. See *id.* at 22,987, 22,990.

172. See *id.* at 22,990.

173. See *id.*

174. *Id.*

175. *An Overview of Atlantic Salmon*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222635.htm> (last updated Mar. 20, 2015).

year.<sup>176</sup> The result is AquAdvantage Salmon, which has the potential to grow to maturity in half the time as a naturally occurring Atlantic salmon.<sup>177</sup> Just as a genetically modified plant is eligible for a utility patent, a genetically modified animal is eligible for a utility patent.<sup>178</sup>

The FDA evaluates food derived from genetically modified animals differently than it evaluates food derived from genetically modified plants.<sup>179</sup> Genetically modified animals and food products derived from them are evaluated under a New Animal Drug Application (NADA).<sup>180</sup> Essentially, the inserted genetic material is treated as an “animal drug” for the animal being genetically modified.<sup>181</sup> This evaluation process requires a much more extensive safety review by the FDA.<sup>182</sup> If approved under a NADA, a post-market surveillance program is put in place to monitor for any unforeseen safety issues that arise.<sup>183</sup>

On November 19, 2015, the FDA announced the approval for AquAdvantage Salmon.<sup>184</sup> The FDA approval is subject to conditions of use which include specific manufacturing methods, facilities, and controls. Only two facilities, neither of which are located in United States, are approved to produce, raise, and harvest AquAdvantage Salmon.<sup>185</sup> The approval provides detailed specifications for physical containment, breeding procedures, testing requirements, and shipment logistics.<sup>186</sup> Additionally, the approval contains recordkeeping and reporting requirements which mandate the documentation of adverse events along with product and manufacturing defects, and require detailed periodic drug experience reports and special drug experience reports.<sup>187</sup>

In summary, a genetically modified animal as a food product is capable of receiving utility patent protection but is subject to a much more

176. *Frequently Asked Questions*, AQUABOUNTY TECHS., <http://aquabounty.com/press-room/frequently-asked-questions/> (last visited June 25, 2016).

177. *Id.*

178. *See* Transgenic Mice Expressing Human Insulin, U.S. Patent No. 6,018,097, at [57] (filed Apr. 11, 1995) (issued Jan. 25, 2000).

179. *See* U.S. FOOD & DRUG ADMIN. CTR. FOR VETERINARY MED., GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS 10–11 (2011), [http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/Guidancefor Industry/default.htm](http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm).

180. *Id.* at 6.

181. *See Genetically Engineered Animals: General Q&A*, *supra* note 121.

182. *See id.*

183. *Id.*

184. *See Genetically Engineered Animals: AquAdvantage Salmon*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/ucm280853.htm> (last updated Apr. 7, 2016) (stating the current status of the FDA approval process for AquAdvantage Salmon).

185. *AquAdvantage Approval Letter*, *supra* note 123.

186. *Id.*

187. *Id.*



extensive review by the FDA than a food derived from a genetically modified plant.<sup>188</sup> The review under NADA requires safety testing and a post-market surveillance program to evaluate the safety of a food derived from a genetically modified animal.<sup>189</sup> As demonstrated by the nearly two decade approval process and the detailed post-market conditions of use required for AquAdvantage Salmon, the FDA is clearly treating genetically modified animal food products differently from their genetically modified plant food product counterparts.

These examples illustrate the unique roles of the USPTO and FDA in GMO policy. The USPTO grants patent protection for novel inventions, such as GMOs, to promote scientific progress. The FDA protects human health through food safety regulations, which include the approval of food products entering the U.S. food supply. However, the FDA does not consider the impact of utility patent protection on a food product's availability for independent food safety testing.

### III. THE LACK OF INDEPENDENT FOOD SAFETY TESTING

FDA GMO policy, in combination with GMO manufacturer licensing restrictions, makes it very difficult to identify the end products containing specific genetically modified food products and nearly impossible to isolate a specific genetically modified food product for safety testing. This combination results in an effective block to independent food safety testing. This has created a special "hidden novelty" exception where the non-naturally occurring component of a manufactured food product not only makes the food product eligible for a utility patent but also results in the lack of access for independent food safety testing for which food products are otherwise available. Manufacturers use the protective power of the utility patent through license agreements to prevent any independent testing or safety research of the patented GMO.

#### A. *The Special "Hidden Novelty" Exception*

Many criticisms of the FDA's regulation of GMOs exist.<sup>190</sup> While critics have made many valid points, this Note limits its focus to the critical absence of independent food safety testing for GMOs protected by utility patents. One factor the FDA does not consider in its guidance for evaluating food safety is the accessibility of the food product for

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188. See *Genetically Engineered Animals: General Q&A*, *supra* note 121.

189. See *id.*

190. See, e.g., Maria R. Lee-Muramoto, *Reforming the "Uncoordinated" Framework for Regulation of Biotechnology*, 17 *DRAKE J. AGRIC. L.* 311, 313 (2012) (criticizing the regulation of GMOs); Mandel, *supra* note 15, at 2233 (same); see also Angelo, *supra* note 8, at 95–98 (proposing a new evolutionary biology model for regulating GMOs).

independent food safety research.<sup>191</sup> The current regulatory framework instead allows the manufacturer to determine the appropriate level of review for the food product that it seeks approval for based upon guidance issued by the FDA.<sup>192</sup> By ignoring the implications of utility patent protection, the FDA's current regulatory framework effectively removes the ability for most genetically modified foods to be independently tested for safety.

The missing food safety protection of independent safety testing is brought to light by considering the implications and interactions of the protection a utility patent provides a food product and the ability to identify the food product in the marketplace. In most instances, it is legal to conduct independent research and testing on a food product.<sup>193</sup> Independent testing is permissible in four general situations. First, it is permissible where a food product lacks utility patent protection. In this case, a manufacturer is unable to use the exclusion power of a utility patent to prevent an independent researcher from making, using, or testing the food product.<sup>194</sup> Second, it is permissible where a legal exemption for research exists. In this case, an independent researcher is able to conduct testing on a food product even if the testing would otherwise be prohibited.<sup>195</sup> Third, it is permissible where a food product is easily identifiable in the marketplace. For example, where a food product is either available as a whole food or clearly labeled, an independent researcher is able to identify and purchase the food product in the marketplace and conduct testing on the specific food product. Fourth, it is permissible where a food product is sold rather than licensed. In this case, an independent researcher is able to purchase and use the food product free of restrictions which allows for independent testing.<sup>196</sup>

However, when none of these situations exist, a food product is not available for independent testing. A utility patent granted to a food product provides the right to exclude others, does not provide a legal research exemption, and allows for the food product to be licensed rather than sold. When a utility patent protected food product is incorporated into a processed food product with multiple ingredients, in varying ratios, and without labeling, it is not easily identifiable in the marketplace. As a result, a utility patent protected food product is able to effectively "hide"

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191. Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,990 (May 29, 1992).

192. *Id.* at 22,989–91.

193. *See, e.g.*, Carey Gillam, *Fears over Roundup Herbicide Residues Prompt Private Testing*, REUTERS (Apr. 9, 2015), <http://www.reuters.com/article/us-food-agriculture-glyphosate-idUSKBN0N029H20150409>.

194. 35 U.S.C. § 154(a) (2012).

195. *See, e.g.*, 7 U.S.C. § 2544 (2012) (stating the research exemption provided in the Plant Variety Protection Act).

196. *See infra* Section III.B (discussing the power of patent licensing).

from independent safety testing.

The FDA's blindness to the implications of utility patent protection creates what this Note calls a "hidden novelty" exception. The "novel" feature of a food product results in utility patent protection. This novel feature is "hidden" from the FDA guidance and evaluation process. The FDA does not "see" a difference between the patented food product and its naturally occurring counterpart. The resulting "exception" allows the manufacturer to use the utility patent protection, through licensing restrictions, to prevent any independent food safety research while complying with FDA guidance and bypassing the premarket approval safety assessment. Therefore, the "hidden novelty" exception allows the manufacturer to use the novelty of its invention to maintain full control over any food safety testing of its patented product.

The narrowness of this special "hidden novelty" exception is exemplified by the previous examples comparing USPTO and FDA policy for various food product categories.<sup>197</sup> Naturally occurring food products will not have utility patent protection.<sup>198</sup> Additionally, if the PVPA protects a naturally occurring food product, there is a legal exemption specifically for independent research activities.<sup>199</sup> Non-naturally occurring food products, such as sucralose, typically have utility patent protection.<sup>200</sup> However, the product will be easily identifiable through food labeling in the marketplace, and the product is sold rather than licensed, making it available for independent testing. Utility patent-protected pharmaceuticals, which are subject to extensive testing requirements by the FDA,<sup>201</sup> are easily identified by labeling in the marketplace.

GMO manufacturers use the protection of a utility patent, including licensing,<sup>202</sup> combined with a lack of food labeling to identify the genetically modified products in the marketplace to prevent access to GMO food products for independent research. The narrow "hidden novelty" exception applies to GMOs. The utility patent gives the patent owner the right to exclude others from using or testing, including safety testing, the patented product. No legal exemption permits independent research for any reason. The lack of food labeling and the mixing of GMO food products in the food supply make it nearly impossible to identify a specific GMO food product in the marketplace. GMO manufacturers only

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197. *See supra* Section II.B.

198. *See supra* Subsection II.B.1.

199. 7 U.S.C. § 2544 (2012).

200. *See supra* Subsection II.B.2.

201. *See supra* Subsection II.B.3.

202. *See infra* Section III.B (explaining how a utility patent is used to block the ability of independent research on GMOs).

license the food producing organism to growers for commercial crops.<sup>203</sup>

The effect of this special “hidden novelty” exception from independent testing grows when a GMO food product is classified as GRAS. A manufacturer’s initial determination that its genetically modified plant food product is GRAS causes a three-fold effect. First, the food product can enter the food supply without going through the FDA’s premarket review process. Second, the FDA is unlikely to challenge the manufacturer’s GRAS determination because of the GRAS presumption. Third, the manufacturer can prevent any independent testing through its utility patent protection. The only safety testing that occurs is any testing the manufacturer grants permission for or voluntarily chooses to undertake.

### B. *The Power of Patent Licensing*

The power of utility patent protection, combined with the licensing agreements used by patent owners of genetically modified plant technology, has granted a monopoly not only over the patented technology but also over the research and testing of the raw ingredients in the U.S. food supply.<sup>204</sup> The license agreement, often called a “stewardship agreement,” requires the farmer to agree to several restrictions including: (1) to only use the seed products for a single commercial crop, (2) to not allow another person or entity to have any seed products for any purpose, (3) to not save any grain produced from seed products for planting by anyone, and (4) to not use or allow others to use the seed products, the grain produced, the licensed technologies, or any plant material containing the licensed technologies for crop breeding, research (including for testing or generating data to compare against similar non-licensed technologies), or seed production unless the patent owner has expressly authorized the activity through a written agreement.<sup>205</sup>

In 2013, the Supreme Court held in *Bowman v. Monsanto*<sup>206</sup> that the replanting of a patented seed without the patent holder’s permission constitutes patent infringement because the new plant replicates the patented invention.<sup>207</sup> This holding affirmed the patent owner’s right

203. See *infra* Section III.B.

204. See Rowe, *supra* note 11, at 882–87 (identifying the overreach of patent protection and discussing the implications of that overreach).

205. See, e.g., SYNGENTA SEEDS, INC., STEWARDSHIP AGREEMENT (June 5, 2013), <http://www3.syngenta.com/country/us/en/agriculture/Stewardship/Documents/SyngentaStewardshipAgreement.pdf>.

206. 133 S. Ct. 1761 (2013).

207. *Id.* at 1769. In *Bowman*, the Court noted that its holding was limited to a person taking an active step to make replicas of a patented product and not applicable to a case where the self-replication occurred outside the control of a person. *Id.*

prevent seed replanting but did not address the license's research restriction.<sup>208</sup> The Court has not had the opportunity to address the validity of the license provision prohibiting independent research.<sup>209</sup>

A license restriction that directly prohibits independent testing combined with a commercial crop limitation make it incredibly difficult, if not impossible, to use end food products for independent research. The commercial crop limitation results in genetically modified plant products mixing in with other crop strains at a grain mill before being sold for use in food products.<sup>210</sup> The FDA does not require labeling of food containing genetically modified plant products, adding to the difficulty of identifying the end food products containing a specific genetically modified plant product.<sup>211</sup> Genetically modified plant products are typically found in processed products containing multiple ingredients, making it practically impossible to identify and isolate a specific genetically modified food product to conduct reliable and high-quality independent research.<sup>212</sup>

The additional monopoly of the patent owner controlling the independent research of genetically modified plant products raises serious concerns. This monopoly, coupled with the difficulty of identifying genetically modified plant products in end food products, creates a tort liability issue.<sup>213</sup> Without the ability to identify which products contain a genetically modified plant product, an injured party would face an immense challenge in establishing causation for any injury attributed to genetically modified plant products.<sup>214</sup> Exploration of the tort liability issues is beyond the scope of this Note, but others have discussed it.<sup>215</sup>

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208. *See id.*

209. Rowe, *supra* note 1130, at 872–74.

210. *See* Van Tassel, *supra* note 10, 1662.

211. *Id.* at 1655.

212. *See id.* at 1662.

213. *See* Van Tassel, *supra* note 10, at 1645–48. Some simplified examples of the types of injuries that could result are health-related injuries, such as allergic reactions or the development of cancer. *Id.*

214. The injured party likely has no way of knowing how much or even if he ever consumed a specific GMO. The challenge of establishing causation increases for latent injuries such as cancer. *See* Albert C. Lin, *Beyond Tort: Compensating Victims of Environmental Toxic Injury*, 78 S. CAL. L. REV. 1439, 1446–47 (2004). The longer an injury takes to develop, the longer the victim is exposed to other possible causes. *See id.*

215. *See, e.g.,* Noah, *supra* note 9, at 53–60 (warning against inappropriate legal action and overregulation of new technology); Van Tassel, *supra* note 10, at 1646–47 (identifying and proposing a solution to a tort immunity problem); *see also* David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. 569, 572–73 (2010) (discussing the foreseeability of unexpected harmful consequences as science and technology rapidly advance).

#### IV. THE REQUIREMENT OF ACCESS

It is critical that the components of the U.S. food supply be accessible for independent safety testing. Discoveries that appear harmless and seem to be perfect solutions can in fact turn out to have dire consequences. It can take years before the harmful effects are fully realized or detectable. These latent and difficult-to-detect effects are why independent research is needed. Reliance on manufacturers to investigate and detect possible harmful effects of a food product for the length of a patent term is inefficient and not in the public interest. An access requirement for food safety testing on all food products and raw ingredients in the U.S. food supply is the best solution. It enables independent research while keeping patent law precedent intact and intrusion on a utility patent owner's intellectual property rights to a minimum.

##### A. *Trans Fat Historical Lesson*

Learning from past experiences can help avoid future mistakes. The new technological advances of genetic modification have the immense potential to be incredibly beneficial to society. Genetically modified food products promise higher crop yields and a more nutritious food supply to feed the world's ever-growing population—two advancements critical in the fight to end world hunger. The development of a product with such promise should be encouraged and supported. However, access for independent research must also be permitted as an added check on the safety of the food supply.

The United States has experience with a promising product that seemed to be the perfect solution to many problems but later proved very dangerous to human health. Trans fat was the first man-made fat included in the U.S. food supply.<sup>216</sup> The most common source of trans fat is partially hydrogenated vegetable oil.<sup>217</sup> Trans fat first entered the U.S. food supply in 1911 when Procter & Gamble introduced Crisco.<sup>218</sup> Trans fat became particularly important by the 1980s, when it was well established that saturated fats were unhealthy.<sup>219</sup> In response to consumer advocacy groups, food manufacturers and many fast-food restaurants switched from using saturated fats to using partially hydrogenated oils.<sup>220</sup>

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216. See David Schleifer, *The Perfect Solution: How Trans Fats Became the Healthy Replacement for Saturated Fats*, 53 *TECH. & CULTURE* 94, 100–01 (2012).

217. *Id.* at 94.

218. See *id.* at 100.

219. See *id.* at 109.

220. See *id.* at 109–15.

The FDA considered partially hydrogenated oil GRAS because it had a history of extensive use in food prior to 1958 with no known problems.<sup>221</sup>

Partially hydrogenated vegetable oil has many beneficial characteristics that produce desirable traits in food products.<sup>222</sup> For example, adding hydrogen atoms to an oil molecule increases the stability and solid characteristic of the oil.<sup>223</sup> The result is an oil that creates consistent texture, tenderness, and aeration in baked goods.<sup>224</sup> The oil also gives products a longer shelf life before the oil turns rancid.<sup>225</sup> The oil can be formulated to be a solid at room temperature, such as in a cake frosting to ensure the frosting adheres to the cake and yet literally melts in the consumer's mouth.<sup>226</sup> The oil has a higher smoke point than natural fats and oils, so when used as fryer oil, it reduces both smoke and the frequency that the fryer oil needs to be changed.<sup>227</sup> Additionally, the oil can be customized for many different uses, does not have a strong taste that affects flavor, and is kosher.<sup>228</sup> Partially hydrogenated vegetable oil seemed to be the perfect solution to common cooking problems in many ways.<sup>229</sup>

Trans fat was very useful in producing a wide variety of food products with desirable characteristics, but it was unclear what health effects trans fat would have over time. Independent research conducted in the 1990s, however, revealed a correlation between trans fat consumption and increased risk for heart disease.<sup>230</sup> In 2006, the FDA began requiring food labels to list the amount of trans fat in the product.<sup>231</sup> Previously, a consumer had to read the ingredient list in search of partially hydrogenated oil to determine if a food product contained any trans fat. The food industry responded by significantly reducing the use of partially hydrogenated oils in food products.<sup>232</sup> In November 2013, the FDA announced that it had “made a preliminary determination that partially hydrogenated oils . . . are no longer . . . GRAS.”<sup>233</sup> The Center for Disease Control estimated that eliminating partially hydrogenated oils

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221. See Dan Charles, *FDA Moves to Phase out Remaining Trans Fats in Food Supply*, NPR: THE SALT (Nov. 7, 2013, 3:48 PM), <http://www.npr.org/blogs/thesalt/2013/11/07/243730263/fda-moves-to-phase-out-remaining-trans-fats-in-food-supply>.

222. See *id.*; Schleifer, *supra* note 216, at 105–06.

223. Charles, *supra* note 221.

224. Schleifer, *supra* note 216, at 105.

225. *Id.*

226. See *id.* at 105–06.

227. *Id.* at 106.

228. *Id.* at 105–06.

229. *Id.* at 99.

230. See Charles, *supra* note 221.

231. *Id.*

232. *Id.*

233. U.S. FOOD & DRUG ADMIN, *FDA FACTS: QUESTIONS & ANSWERS REGARDING TRANS FATS 1* (2014), <http://www.fda.gov/downloads/Food/PopularTopics/UCM385846.pdf>.

“could prevent 10,000–20,000 heart attacks and 3,000–7,000 coronary heart disease deaths each year” in the United States.<sup>234</sup> In June 2015, the FDA made a final determination that partially hydrogenated oils are not GRAS and provided a three-year compliance period for manufacturers to eliminate the use of partially hydrogenated oils.<sup>235</sup>

Trans fat has many beneficial and wonderful characteristics for a chef working in a kitchen; however, what seemed to be the “perfect solution” in many ways was actually more harmful than the animal fats and oils it replaced.<sup>236</sup> The harmful effects of trans fat took decades to realize and may never have been identified without independent researchers. Even after researchers discovered the drawbacks of trans fat, it still took approximately another decade, the FDA requiring the addition of details on trans fat to food labels, and public awareness of trans fat health risks for the food manufacturers to significantly reduce their use of partially hydrogenated oil. More than eight years later, the FDA finally determined partially hydrogenated oil is not GRAS for any use in human food.

The independent researchers studying the effects of trans fat had the advantage of expired patents coupled with food labels listing the ingredient of partially hydrogenated oil. Consumers had the advantage of being able to avoid consuming partially hydrogenated oil by reading food labels if they had any concerns or uncertainty about its safety. The history of trans fat shows how it can take years to detect the harmful effects of a seemingly perfect food product.

Independent researchers face a much different scenario in conducting research on GMOs. Without the permission of the patent owner, researchers must wait until the patent term expires to begin any research on a food product in the U.S. food supply, creating up to a two-decade delay.<sup>237</sup> Technology is evolving rapidly, and newly patented GMOs will replace the older GMOs as they become available for research.<sup>238</sup> Any harmful effects from consumption of GMOs will likely be latent effects that take a long time to detect and identify.<sup>239</sup> The current utility patent protection and licensing agreements used by GMO manufacturers forces

234. U.S. CTR. FOR DISEASE CONTROL, TRANS FAT: THE FACTS 1 [http://www.cdc.gov/nutrition/downloads/trans\\_fat\\_final.pdf](http://www.cdc.gov/nutrition/downloads/trans_fat_final.pdf).

235. U.S. FOOD & DRUG ADMIN., FDA CUTS TRANS FAT IN PROCESSED FOOD 1 (2015), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm372915.htm>.

236. *Trans* fats were found to be more harmful than saturated fat because trans fat simultaneously increased the bad cholesterol and lowered the good cholesterol, whereas saturated fat only increased the bad cholesterol. *See id.* at 2.

237. *See* 35 U.S.C. 154(a)(2) (2012) (defining the patent term as twenty years).

238. *Roundup Ready Soybean Patent Expiration*, MONSANTO NEWSROOM, <http://www.monsanto.com/newsviews/pages/roundup-ready-patent-expiration.aspx> (last visited June 25, 2016).

239. The manufacturer will likely detect any immediate harmful effects, such as the production of a toxin, during development.



a nearly twenty-year delay on independent research on food products that make up raw ingredients in the U.S. food supply.

### B. Patent Law Policy

Plants should remain patent-eligible subject matter for utility patents. There is a strong line of support from Supreme Court decisions for the utility patent eligibility of plants, beginning with *Chakrabarty* in 1980, followed by *J.E.M. Ag Supply* in 2001, and most recently with *Bowman* in 2013. There is no need to disturb this line of precedent in addressing the issue of access to GMOs for independent research. History clearly demonstrates that GMOs deserve utility patent protection because they can meet the stringent requirements of utility patent eligibility. An entirely new and important use is incorporated into an existing food source. Rather than completely removing the protection of a utility patent, it is possible to enable access through other means such as a research exemption for independent food safety research.

A utility patent subject to a research exemption would still provide more protection to the patent owner than a PVP certificate issued under the PVPA. This proposal parallels the Court's reasoning in *J.E.M. Ag Supply* that "[b]ecause it is harder to qualify for a utility patent than for a Plant Variety Protection (PVP) certificate, it only makes sense that utility patents would confer a greater scope of protection."<sup>240</sup> The PVPA contains exemptions for saving seed and for research.<sup>241</sup> A utility patent subject to a research exemption would still provide the additional protection of prohibiting the saving of seed. This protection provides a significant financial incentive for the patent owner that is not available under the PVPA. The utility patent owner profits from the sale of the seed to each grower for every crop year rather than profiting only from the initial sale of seed to a grower, who then saves enough seed to replant crops the following year.

Access to GMOs for independent research can be achieved without disturbing the patent eligibility of GMOs. An access requirement for independent food safety research could be legislated or judicially created for patented food products. An access requirement would provide a great public benefit by providing an additional safety check for the U.S. food supply, and a utility patent would still provide more protection than a PVP certificate. The FDA is the ideal agency to implement an access requirement for independent food safety research.

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240. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 138 (2001).

241. *Id.* at 140.

### C. *FDA Policy*

The FDA should require any food product in the U.S. food supply to be available for independent food safety research. Allowing independent research on products in the U.S. food supply benefits public safety and does not significantly harm the intellectual property interests of the patent owners. FDA policy should create an access requirement for independent food safety research. The FDA must consider the implications of utility patent protection on the ability to conduct independent research on a food product.

At a minimum, the FDA could require access to a patented food product for independent food safety research in order for a food to qualify for GRAS status. By prohibiting GRAS status, the food product would then be subject to the premarket approval safety testing. While this would not create access for independent safety research, it would at least require the manufacturer to do significant additional testing before the food product could enter the food market. It is also possible that the manufacturer would voluntarily choose to make its product available for independent safety research to obtain GRAS status—perhaps through a limited use license allowing independent safety research that prohibits competitive research—to avoid the added time and expense of the premarket approval safety testing.

However, even if GMOs were subject to the FDA's premarket approval process, the patent owner can still block independent food safety research. The public is left to rely solely on the FDA for safety testing of the food product, and the FDA in turn relies on the manufacturer for safety testing. A manufacturer's concern for financial gain could be greater than its concern for food safety. A utility patent protecting the use of a food as a pesticide or herbicide should not make it illegal to test the food independently for safety.

The FDA should require any food product in the United States to be available for independent food safety research. In exchange for the benefit of the ability to sell the patented product or the food derived from it in the U.S. food market, the FDA should require a manufacturer to allow access to the patented product for independent food safety research. The FDA would not violate the patent owner's rights because the patent owner is free to choose not to participate in the U.S. food market. Implementation of an access requirement is a realistic solution that would allow independent researchers to access GMOs for safety testing.

### CONCLUSION

It is imperative that independent researchers have access to GMOs for food safety research. GMOs are an immensely promising technology with many possible benefits for not only the United States but also for the

world's food supply. However, the current combination of utility patent protection, licensing agreements, and the extreme difficulty in identifying a specific genetically modified ingredient in an end product has created a special "hidden novelty" exception for food products. This exception results in patent protected food products being unavailable for independent food safety testing. Ironically, the characteristics of a genetically modified food product must be different enough from the naturally occurring form of the food product to meet the stringent requirements of a utility patent, but the utility patent provides the power to prevent any independent testing of such a novel food product because the food product is considered GRAS.

The special "hidden novelty" exception that prevents access to GMOs for independent testing should be corrected. This exception creates a problematic and lengthy delay in the ability to conduct independent research on raw ingredients in the U.S. food supply. It places the control of safety testing solely in the hands of the manufacturer of the GMO for nearly two decades. Correction is easily accomplished with an access requirement for any food product in the U.S. food supply. The patent owner would still retain significantly more protection than through the PVPA by being able to prevent any seed replanting by farmers, Supreme Court precedent would remain intact, and GMOs would be available for independent research just like other products in the food supply.