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## Who Owns Your Dinner? A Discussion of America's Patented Genetically Engineered Food Sources, and Why Reform is Necessary

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# WHO OWNS YOUR DINNER? A DISCUSSION OF AMERICA'S PATENTED GENETICALLY ENGINEERED FOOD SOURCES, AND WHY REFORM IS NECESSARY

*Madison Smith\**

## *I. Introduction*

The United States Code provides that “a live human-made micro-organism is patentable,” and further provides for issuance of patents to persons who invent or discover new or useful “manufacture” or “composition of matter;” micro-organisms constitute “composition of matter” or “manufacture” within meaning of the code.<sup>1</sup> Thus, since the landmark 1980 Supreme Court case *Diamond v. Chakrabarty*, thousands of patents on living organisms have been granted to genetically modified food products for human consumption.

This Note will briefly introduce patent law and its application to genetically engineered living organisms in the courts, analyzing critical case law from *Diamond v. Chakrabarty* to the present. Furthermore, this Note will describe the process of genetic engineering and how it is used in our American food crops, as well as current regulatory procedure regarding these foods. Part II will introduce the genetic engineering seed giant Monsanto, whose aggressive patent protection and sizeable market share of genetically engineered seeds has greatly affected and transformed American crops. Part III will introduce AquaBounty's genetically modified salmon, currently awaiting approval from the Food and Drug Administration (“FDA”) to

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<sup>1</sup> See 35 U.S.C. § 101 (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 309-16 (1980).

become the first genetically engineered animal food source available for human consumption. Part IV will discuss the impact these patent protected food sources have on our nation's food supply, analyzing their positive and negative effects on both the marketplace and the consumer. In addition, it will address current trends in Congress and current events that may result in seismic changes in the regulatory structure. Finally, Part V proposes two solutions to the negative aspects of genetically engineered foods: the first is the creation of a single regulatory body; and the second - more important solution - is patent law reform for genetically modified food products.

### A. Brief History of Patents

Patents were developed to ensure that inventors would be compensated for their inventions; such compensation is accomplished by granting inventors the exclusive right to their inventions for a limited period of time.<sup>2</sup> Patents give the patent holder a form of monopoly control for twenty years from the date of filing, thus limiting competition.<sup>3</sup>

The United States grants patents for "any new and useful process, machine, manufacture, or composition of matter, of any new and useful improvement thereof."<sup>4</sup> The United States Code section on plant patents states that any person who invents or discovers a new variety of plant (*and* asexually reproduces it) may obtain a patent for that plant.<sup>5</sup> In order to receive a patent, the patented plant must have a distinct characteristic that is different from other plants.<sup>6</sup> Furthermore, the Supreme Court has interpreted this legislation's purpose as being one that encourages the plant breeding industry.<sup>7</sup>

Under patent laws, a patentee has the right to exclude others from making, using, or selling a patented invention.<sup>8</sup> The

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<sup>2</sup> The Council for Responsible Genetics, *DNA Patents Create Monopolies on Living Organisms*, ACTION BIOSCIENCE (Apr. 2000), <http://www.actionbioscience.org/genomic/crg.html>.

<sup>3</sup> *Id.*

<sup>4</sup> 35 U.S.C. § 101 (2010).

<sup>5</sup> 35 U.S.C. § 161 (2010).

<sup>6</sup> *Id.*

<sup>7</sup> See *Diamond*, 447 U.S. at 319-23.

<sup>8</sup> 35 U.S.C. § 154(a)(1) (2010); see also *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1338 (Fed. Cir. 2006).

patent holder also enjoys the right to license the invention for a limited period of time,<sup>9</sup> charge royalties,<sup>10</sup> and restrict the invention's use in some fields – while permitting it in others – and all at the sole discretion of the patent holder.<sup>11</sup> Given the many benefits bestowed upon patent holders by patent law, it is no surprise that they are also treated favorably in the court system.

## B. History of Patent Protection

The Constitution grants Congress the broad power to “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>12</sup> This authority of Congress is exercised with the hope that “[the] productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.”<sup>13</sup> In *Diamond v. Chakrabarty*, the Supreme Court stated that “Congress plainly contemplated that the patent laws would be given wide scope.”<sup>14</sup>

Legislative history also shows a penchant for broad interpretation.<sup>15</sup> The Patent Act of 1793, written by Thomas Jefferson, defined statutory subject matter as “any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof].”<sup>16</sup> Congress intended patent statutes to “include anything under the sun that is made by man.”<sup>17</sup>

However, initially the laws of nature, physical phenomena, and abstract ideas were not patentable.<sup>18</sup> After the ruling in *Diamond*, all that changed. The Supreme Court held that a micro-organism capable of breaking down oil compounds was not a product of nature but the result of human ingenuity

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<sup>9</sup> *Scruggs*, 459 F.3d at 1338; see also *Mallinckrodt, Inc. v. Medipart, Inc.* 976 F.2d 700, 703 (Fed. Cir. 1992).

<sup>10</sup> *Scruggs*, 459 F.3d at 1338.

<sup>11</sup> *Id.*

<sup>12</sup> U.S. CONST. art. I, § 8, cl. 8.

<sup>13</sup> *Diamond*, 447 U.S. at 307.

<sup>14</sup> *Id.* at 308.

<sup>15</sup> *Id.*

<sup>16</sup> Act of Feb. 21, 1793 § 1, 1 Stat. 319.

<sup>17</sup> S. REP. NO. 82-1979, at 5 (1952), reprinted in 1952 U.S.C.C.A.N. 2394, 2399; H. R. REP. NO. 82-1923, at 6 (1952).

<sup>18</sup> See 35 U.S.C. § 101 (2010); see also *Diamond*, 447 U.S. at 313.

and research, and thus was held to be patentable.<sup>19</sup> Seven years later, in 1987, the United States Patent and Trademark Office (“USPTO”) declared that multi-cellular, non-human life forms are patentable subject matter.<sup>20</sup> As a result, between years 1996 and 2000, over 4,200 agricultural biotechnology patents were granted to private industry.<sup>21</sup>

Since this landmark decision, and subsequent patent legislation, courts have often ruled in favor of granting patents to scientifically modified life forms. *Monsanto v. Bowman* provides an example of how modern courts view genetic modification of life. The court, referring to genetic modification of the soybean plant, stated that, “[W]hile this type of genetic modification... may be considered controversial in other parts of the world, its widespread use in the United States indicates that it has been widely accepted here.”<sup>22</sup> This is indicative of the generally positive treatment courts give to corporations that own patent protected technology.

### C. History of Patented Genetic Engineering in the United States

In 1973, scientists first used the technology behind genetic engineering successfully.<sup>23</sup> In 1996, this technology was used to produce commercial food sources.<sup>24</sup> The first patent granted on a genetically modified living micro-organism came about as a result of *Diamond v. Chakrabarty*.<sup>25</sup>

Genetic engineering is a term used to describe the process by which recombinant DNA (“rDNA”) is placed into an

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<sup>19</sup> *Diamond*, 447 U.S. at 313.

<sup>20</sup> Barry S. Edwards, “. . . and on his farm he had a geep”: *Patenting Transgenic Animals*, 2 MINN. INTELL. PROP. REV. 89, 90 (2001); see generally Patent and Trademark Office Notice: Animals-Patentability, 1077 Official Gazette U.S. Pat. & Trademark Off. 24 (Apr. 21, 1987).

<sup>21</sup> Jorge Fernandez-Cornejo & Margaret Caswell, *The First Decade of Genetically Engineered Crops in the United States*, USDA ECON. RESEARCH SERV., 2 (Apr. 2006), available at <http://www.ers.usda.gov/publications/eib11/eib11.pdf>.

<sup>22</sup> *Monsanto Co. v. Bowman*, 686 F. Supp. 2d. 834, 837 (S.D. Ind. 2009).

<sup>23</sup> Robert Paarlberg, *The Global Food Fight*, 79 FOREIGN AFF. 24, 25 (2000).

<sup>24</sup> Cornejo & Caswell, *supra* note 21, at 8.

<sup>25</sup> *Diamond*, 447 U.S. at 309.

organism.<sup>26</sup> When scientists splice together pieces of DNA and then introduce that modified DNA into an organism, it is referred to as "rDNA technology."<sup>27</sup> A genetically engineered ("GE") plant or animal contains this rDNA construct, thus changing the organism by giving it a new trait or characteristic.<sup>28</sup> Once this new plant or animal is "invented," the biotech company that produced it may apply for a patent.

In 1994, the first GE food item approved for human consumption, the Flavr Savr tomato, a tomato genetically modified to ripen slowly, was introduced into the market.<sup>29</sup> In 1996, GE soybeans, corn, and cotton became commercially available, and other use of GE items by farmers has dramatically increased since then.<sup>30</sup> In fact, by 2005, herbicide-tolerant GE soybean seeds accounted for 87% of total U.S. soybean acreage, while GE cotton accounted for 60%.<sup>31</sup>

The GE seed industry itself has also grown significantly since 1996, when commercial seeds were first introduced. Many smaller companies merged to form larger ones, resulting in a heavily concentrated market of GE seed producers.<sup>32</sup>

The types of GE seeds that are generally patented are ones resistant to either herbicides or pesticides.<sup>33</sup> Herbicide-tolerant GE seeds make the plant resistant to herbicides that are sprayed on it, thus simultaneously killing the weed while also protecting the plant. GE seeds resistant to pesticides do the same thing, but instead kill bugs that may attack the plant.

#### D. How Are GE Foods Regulated?

The FDA is the government body that has been given the

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<sup>26</sup> FOOD & DRUG ADMIN., BACKGROUND DOCUMENT: PUBLIC HEARING ON THE LABELING OF FOOD MADE FROM THE AQUADVANTAGE SALMON (Aug. 2010), available at <http://www.fda.gov/Food/LabelingNutrition/FoodLabelingGuidanceRegulatoryInformation/Topic-SpecificLabelingInformation/ucm222608.htm> [hereinafter FDA BACKGROUND DOCUMENT].

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2176 (2004).

<sup>30</sup> Cornejo and Caswell, *supra* note 21, at 8.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.* at 2.

<sup>33</sup> *Id.* at 8.

power to regulate the rDNA construct because it is considered an animal drug under the Federal Food, Drug, and Cosmetic Act (“FDCA”).<sup>34</sup> However, this is not the only regulatory agency responsible for GE food regulation. There are currently three different agencies responsible for this task: The FDA, as stated, regulates the rDNA construct and is responsible for food safety issues surrounding GE plants and animals; the Environmental Protection Agency (“EPA”) is responsible for the health and environmental effects of pest-protected plants; and lastly, the United States Department of Agriculture (“USDA”) regulates the effects of GE plants on other plants and animals in both agricultural and non-agricultural environments.<sup>35</sup> Clearly, this is a convoluted system, and while many feel that there may be a more efficient way to regulate GE products, especially those approved for human consumption, this three-prong framework has seen little change since its introduction in 1986.<sup>36</sup>

The FDA’s primary role is to ensure that any GE food introduced in the market is safe for human consumption prior to sale to the public.<sup>37</sup> On May 29, 1992, the FDA published a *Statement of Policy: Foods Derived from New Plant Varieties* (“New Plant Policy”), announcing that it would presume all GE foods were “generally recognized as safe” (“GRAS”) under the FDCA, and therefore not subject to regulation as food additives.<sup>38</sup>

*Alliance for Bio-Integrity v. Shalala* provides an excellent explanation of FDA policies concerning GE foods and the courts’ favorable rulings on such matters. This case was brought by a coalition of groups and individuals, including scientists concerned about the safety and marketing of GE foods, against the FDA and their policies regarding such foods.<sup>39</sup> They challenged the New Plant Policy on several grounds, including a violation of the National Environmental Protection Act (“NEPA”), the FDA’s presumption that GE foods are GRAS, and the FDA’s refusal to label foods as GE.<sup>40</sup>

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<sup>34</sup> FDA BACKGROUND DOCUMENT, *supra* note 26, at 2.

<sup>35</sup> Mandel, *supra* note 29, at 2216-17.

<sup>36</sup> See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,309 (June 26, 1986).

<sup>37</sup> Mandel, *supra* note 29, at 2218.

<sup>38</sup> See *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 170 (D.D.C. 2000); see also 21 U.S.C. § 321(s) (2010).

<sup>39</sup> See *Alliance*, 116 F. Supp. 2d at 170.

<sup>40</sup> *Id.*

The NEPA requires that all agencies of the federal government include a detailed statement on the environmental impact of every major proposed federal action affecting the quality of the human environment.<sup>41</sup> A major federal action includes actions like the “adoption of official policy. . . adoption of programs. . . and approval of specific projects.”<sup>42</sup> The FDA is free to decide what constitutes a major federal action under the NEPA. Agencies like the FDA have wide discretion in interpreting regulations, and the FDA’s interpretation will be upheld in a court of law unless found to be arbitrary and capricious.<sup>43</sup> The court in *Alliance* found that the FDA’s determination that the New Plant Policy was not a major federal action was justified, and was neither arbitrary nor capricious.<sup>44</sup>

The second pertinent claim in *Alliance* was that the FDA’s presumption that all GE foods are GRAS violated the FDCA.<sup>45</sup> The FDCA provides that any substance which may “[become] a component or otherwise [affect] the characteristics of any food” shall be deemed a food additive.<sup>46</sup> More specifically;

‘[F]ood additive’ means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food . . .), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures. . . to be safe under the conditions of its intended use. . .<sup>47</sup>

If the food is found to be an additive, then the producer of such additive must submit a petition to the FDA for approval, unless the producer determines the additive is GRAS.<sup>48</sup> Thus, since the FDA, through the New Plant Policy, has determined

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<sup>41</sup> *Id.* at 173-74; *see also* 42 U.S.C. § 4332(2)(c)(i) (2010).

<sup>42</sup> 40 C.F.R. § 1508.18(b)(1-4) (2010).

<sup>43</sup> *Alliance*, 116 F. Supp. 2d at 174.

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 175.

<sup>46</sup> 21 U.S.C. § 321(s) (2010).

<sup>47</sup> *Id.*

<sup>48</sup> *Alliance*, 116 F. Supp. 2d at 175.



that GE foods are GRAS, GE foods do not require regulation as a food additive.<sup>49</sup> In order for courts to evaluate whether the FDA's interpretation of legislation is legitimate, they must first determine whether Congress has spoken directly to the issue at hand, and if so, courts will follow Congress.<sup>50</sup> If the agency's discretion in its application is also at issue, courts then determine whether the FDA's construction of the statute is faithful to its plain meaning or is a permissible construction of the statute.<sup>51</sup> In *Alliance*, the court found that when Congress passed the Food Additives Amendment in 1958, it obviously could not account for GE food technologies, therefore the FDA's interpretation was a permissible construction.<sup>52</sup> The court thus held that the plaintiffs failed to prove that the GRAS presumption was a violation of the statutory requirements.<sup>53</sup>

In order for the FDA to pronounce a product as GRAS, it must meet two criteria: (1) it must have technical evidence of safety, usually in published scientific studies; and (2) this technical evidence must be generally known and accepted in the scientific community.<sup>54</sup> Furthermore, "a severe conflict among experts [. . .] precludes a finding of general recognition."<sup>55</sup> Even though the plaintiffs presented several documents showing significant disagreements among expert scientists, the court only considered what was on the FDA's record at the time the decision was made.<sup>56</sup> Thus, the court held that the plaintiffs did not present sufficient evidence that GE foods are not GRAS.<sup>57</sup>

Finally, the plaintiffs challenged the FDA's New Plant Policy, in that it did not require labeling of GE foods. The FDCA grants the FDA limited authority to require labeling on food products.<sup>58</sup> In general, foods are considered misbranded if their labeling "fails to reveal facts. . . material with respect to consequences which may result from the use of the article to which the labeling. . . relates under the conditions of use

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<sup>49</sup> *Id.*

<sup>50</sup> *Id.* at 176.

<sup>51</sup> *Id.*

<sup>52</sup> *Id.* at 177.

<sup>53</sup> *Id.*

<sup>54</sup> *Id.* See also 21 C.F.R. § 170.30(a-b) (2010).

<sup>55</sup> *Alliance*, 116 F. Supp. 2d at 175.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 178.

<sup>58</sup> *Id.* See also 21 U.S.C. § 321(n) (2009).

prescribed in the labeling . . . or under such conditions of use as are customary or usual.<sup>59</sup>

Plaintiffs contended that GE foods are materially different than their natural counterparts while the FDA argued otherwise.<sup>60</sup> Courts give deference to agency interpretations of these statutes, especially in cases where Congress has not spoken directly to the issue.<sup>61</sup> The court only needs to determine whether the interpretation by the agency was reasonable.<sup>62</sup> The court held that GE foods, as a class, are not established as being inherently dangerous or that they differ in some material way from their natural counterparts, and thus the FDA is not required to label them differently.<sup>63</sup> Moreover, even though the plaintiffs presented evidence that consumer opinion is overwhelmingly in favor of mandatory labeling, the court held that, until a material difference between GE and natural foods is established, the FDA does not need to consider consumer opinions.<sup>64</sup> The court in *Alliance* rejected all of the plaintiff's claims and ruled in favor of the FDA.<sup>65</sup>

This case illustrates the extremely favorable treatment that agencies like the FDA receive in the courts. However, this does not necessarily reflect current consumer opinion on these matters. In *Alliance*, the court also referenced a 1999 act, the Genetically Engineered Food Right to Know Act that was introduced in the House of Representatives.<sup>66</sup> This act proposed to amend the FDCA, the Federal Meat Inspection Act, and the Poultry Products Inspection Act to require food that contains genetically engineered material be labeled accordingly.<sup>67</sup> Despite being introduced again in 2006, this bill has never passed.<sup>68</sup>

Recently, in September 2010, Rep. Rosa DeLauro introduced legislation that would mandate labeling on genetically engineered salmon and cloned animal products, titled the

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<sup>59</sup> *Alliance*, 116 F. Supp. 2d at 178; *see also* 21 U.S.C. § 321(n).

<sup>60</sup> *Alliance*, 116 F. Supp. 2d at 178.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 179.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 180.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> Genetically Engineered Food Right to Know Act, H.R. 5269, 109th Cong. (2006), *available at* <http://www.govtrack.us/congress/bill.xpd?bill=h109-5269>.

Consumers Right to Know Food Labeling Act.<sup>69</sup> These bills represent widespread dissatisfaction with current regulatory procedure, and an interest in reform, regulation, and labeling. Yet so far, these concerns have largely fallen on deaf ears.

## II. Monsanto

The Monsanto Company owns the patent for and manufactures the Roundup Ready soybean, which is resistant to the common herbicide, Roundup – also manufactured and patent protected<sup>70</sup> by Monsanto.<sup>71</sup> In 1997, the market share of genetically manufactured soybeans in the United States by any company was only 8%.<sup>72</sup> Today, Monsanto has its patented genes in about 96% of the soybean crop in the United States through licensing agreements with various seed companies around the country.<sup>73</sup>

Monsanto's Roundup Ready patented soybean trait is now thirteen years old and, thus, close to expiration. Monsanto has come up with a solution, however: it has been using new licensing requirements with its farmers and independent seed companies that now include its Roundup Ready 2 Yield, a new patent that will extend patent protection until 2020, further preventing generic entry into the market.<sup>74</sup> This new Roundup Ready 2 Yield soybean is also resistant to Roundup like the old patent, but Monsanto claims this new patented seed is a new invention because it also boosts per-acre yield by 7 to 11%.<sup>75</sup> This newly patented seed is the first product in what Monsanto hopes will be

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<sup>69</sup> Sara Ditta, *DeLauro Proposes Mandated GE Salmon, Cloned Animal Food Labeling*, 16 FDA WEEK, Oct. 1, 2010, available at <http://healthpolicynewsstand.com/FDA-Week/FDA-Week-10/01/2010/menu-id-315.html>.

<sup>70</sup> Until recently, when its patent expired and generics entered into the market.

<sup>71</sup> *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1333 (Fed. Cir. 2006).

<sup>72</sup> *Monsanto Co. v. Bowman*, 686 F. Supp. 2d. 834, 836 (S.D. Ind. 2009).

<sup>73</sup> *Monsanto Focus of Antitrust Investigation: Justice Department Looking into Marketing Tactics in the Biotech Seed Industry*, CBS NEWS, Oct. 8, 2009, available at <http://www.cbsnews.com/stories/2009/10/08/business/main5372772.shtml> [hereinafter *Monsanto Antitrust Investigation*].

<sup>74</sup> *Monsanto Co. v. E.I. Du Pont De Nemours and Co.*, No. 4:09CV00686 ERW, 2009 WL 3012584, at 1 (E.D. Mo. 2009).

<sup>75</sup> Rachel Melcher, *Monsanto Gains go-ahead for 2nd Generation Soy Seed*, ST. LOUIS POST-DISPATCH, Aug. 1, 2007, at C1.

a long line of GE soybean production.<sup>76</sup> Indeed, Monsanto views it as the basis for seeds that feature several genetic traits at once, instead of just one.<sup>77</sup> Monsanto also has Roundup Ready patents on GE alfalfa,<sup>78</sup> canola, corn, cotton, sorghum, sugar beets, and wheat, making it the leading producer of GE seeds.<sup>79</sup>

Monsanto has been remarkably aggressive in its patent protection, hiring people to investigate farmers to expose possible patent infringement, and has brought suit against several farmers and independent seed companies.<sup>80</sup> Monsanto places four main restrictions on its seed growers, which include: (1) requiring growers to use only seed containing Monsanto's patented biotechnology for planting a single crop; (2) prohibiting transfer or re-use of seed containing the biotechnology for replanting; (3) prohibiting research or experimentation; and (4) requiring payment of a "technology fee."<sup>81</sup> In *Monsanto v. Scruggs*, Monsanto accused a farmer of illegally using its Roundup Ready technology, without properly compensating Monsanto.<sup>82</sup> Scruggs argued that he purchased the seeds without ever signing a licensing agreement, and thus, under the doctrine of patent exhaustion, he had the right to use the seeds free from patent restriction.<sup>83</sup> The doctrine of patent exhaustion states that the unrestricted first sale by a patentee of his patented article exhausts his patent rights in the article.<sup>84</sup> However, the court found that the doctrine of patent exhaustion was inapplicable, stating, "[t]he fact that a patented technology can replicate itself does not give a purchaser the right to use replicated copies of the technology, [and furthermore] [a]pplying the first sale doctrine to subsequent generations of self-replicating technology would

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<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

<sup>78</sup> Until recently, Monsanto was not allowed to sell or plant their Roundup Ready Alfalfa seeds because of the Supreme Court decision *Monsanto v. Geertson Seed Farms*, *infra* note 136 (where the Court granted an injunction on Monsanto that was recently lifted).

<sup>79</sup> Monsanto Products Page, Agricultural Seeds, <http://www.monsanto.com/products/Pages/monsanto-agricultural-seeds.aspx> (last visited Oct. 1, 2010).

<sup>80</sup> *Scruggs*, 459 F.3d at 1333.

<sup>81</sup> *Id.* at 1333.

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 1335-36.

<sup>84</sup> *Id.* See also *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 701 (Fed. Cir. 1992).

eviscerate the rights of the patent holder.<sup>85</sup> Because of strict and protective patent laws, this is the result of many of the cases that Monsanto brings against farmers around the country. The courts have no choice but to rule for Monsanto, since it owns these patents, and as such, has the complete rights to them.

### III. The AquaBounty Salmon

The company AquaBounty Technologies has developed a genetically modified salmon that grows twice as fast as conventional salmon.<sup>86</sup> The AquaBounty salmon's DNA has been altered by adding a growth hormone found in Chinook salmon that allows the fish to produce their growth hormone all year long; as opposed to conventional salmon, which only produce the hormone some of the time.<sup>87</sup> This new type of genetically modified salmon, labeled the AquAdvantage salmon, may soon be approved by the FDA for retail sale, thereby becoming the first genetically modified animal approved for human consumption.<sup>88</sup> The FDA considers the AquAdvantage salmon a New Animal Drug Application ("NADA"). If the FDA approves the salmon as a NADA – essentially deeming the animal safe – it will be approved.<sup>89</sup> If approved, the AquAdvantage salmon could appear on supermarket shelves within the next two years.<sup>90</sup>

If the AquAdvantage salmon is eventually approved, it would open the door for several other genetically modified animals for human consumption, including an environmentally friendly pig from Canada or cattle resistant to mad cow disease.<sup>91</sup>

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<sup>85</sup> *Scruggs*, 459 F.3d at 1336.

<sup>86</sup> Mary Clara Jalonick, *Super Salmon or 'Frankenfish'? FDA to decide: Officials mull whether to approve sale of genetically engineered animal for human consumption*, MSNBC, Sept. 20, 2010, available at [http://www.msnbc.msn.com/id/39265727/ns/health-food\\_safety/](http://www.msnbc.msn.com/id/39265727/ns/health-food_safety/).

<sup>87</sup> *Id.*

<sup>88</sup> *Id.*

<sup>89</sup> FOOD & DRUG ADMIN, GUIDANCE FOR INDUSTRY: REGULATION OF GENETICALLY ENGINEERED ANIMALS CONTAINING HERITABLE RECOMBINANT DNA CONSTRUCTS, FOOD AND DRUG ADMINISTRATION, Jan. 15, 2009, available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf> [hereinafter FDA GUIDANCE FOR INDUSTRY]

<sup>90</sup> Jalonick, *supra* note 86.

<sup>91</sup> *Id.*

Proponents argue that the AquAdvantage salmon is a revolutionary new food source that would have a groundbreaking impact on both the environment and the battle against world hunger.<sup>92</sup>

Opponents, on the other hand, argue that the salmon is an untested “frankenfish” that could cause unknown allergic reactions, and harm the environment by eliminating an already depleted wild salmon population.<sup>93</sup> Furthermore, many argue that even if the FDA approves the salmon, the current process used by the FDA is inadequate because it allows the company to keep some proprietary information private,<sup>94</sup> and that modified foods should not be regulated under the same process used for animal drugs.<sup>95</sup> AquaBounty’s reluctance to label its salmon as a GE product has given rise to critical consumer and political outcries for more required disclosure centered upon the right to know what is and what is not in our food supply.<sup>96</sup>

AquaBounty has attempted to quash concerns in several ways. In response to concerns over the decimation of the wild salmon population, it claims that all the fish would be bred female and sterile – though if nature has taught us anything, a small percentage may be *able* to breed.<sup>97</sup> Indeed, even AquaBounty has conceded that merely 5% may be able to breed.<sup>98</sup> If so, the salmon would be bred in confined pools where the potential for escape would be minimal.<sup>99</sup> The FDA has determined, in fact, that there are enough safety mechanisms in place.<sup>100</sup> The chief executive of AquaBounty, Ron Stotish, claims that the fish would be bred in better conditions than many of the world’s other farmed fish, and could be located closer to populous areas, thus feeding more people.<sup>101</sup> The company counters the environmental claim by arguing that the increase in its genetically engineered salmon could help relieve endangered wild salmon populations, although it has provided little to no information as to how that would actually happen.<sup>102</sup>

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<sup>92</sup> FDA BACKGROUND DOCUMENT, *supra* note 26.

<sup>93</sup> Jalonick, *supra* note 86.

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

Furthermore, if AquaBounty's salmon is allowed into grocery stores, the company does not want them to be labeled as genetically modified.<sup>103</sup> AquaBounty argues that such a label would be misleading to the consumer, and presumably harmful to profit margins, because it would highlight a difference that AquaBounty argues does not exist.<sup>104</sup>

The FDA is also concerned about the negative public image they may receive should they approve the NADA relating to the AquaBounty salmon. To help allay public concerns, the FDA allowed the public to participate in the hearing, and released a preemptive informational background document in August 2010 to better prepare the public for what it would hear. The FDA has stated that if it does approve the AquaAdvantage salmon NADA, the approval will include a label that identifies the different types of rDNA constructs that accompany the separate forms of the fish to the growers.<sup>105</sup> These different types include the fish eggs, the young fish, called fry, and the more mature fish that are sold to growers who then bring the fish to market for sale.<sup>106</sup> However, the FDA has made it clear that these labels are much different than the labels that would be placed on the actual food in the marketplace, and the decision to label has not yet been made.<sup>107</sup>

When deciding whether to label GE foods, the FDA requires name changes on labels only when the food from the GE plant is significantly different from its natural counterpart.<sup>108</sup> A significant difference, according to the FDA, is one that is so distinctive that its common name would not adequately describe the GE food.<sup>109</sup> For example, the FDA required different labeling for a variety of GE soybeans that produced larger amounts of acid than naturally occurring soybeans.<sup>110</sup> The FDA concluded that this difference in acid content was significant enough to warrant a new name on its label.<sup>111</sup> On the other hand, the milk from cows that had been altered with recombinant Bovine

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<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> FDA BACKGROUND DOCUMENT, *supra* note 26, at 2.

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

<sup>108</sup> *Id.* at 4.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

Somatropin, which caused them to increase milk production, was not found to be significantly different from the milk produced by unaltered cows (and so required no additional labeling).<sup>112</sup>

#### *IV. The Current GE Food Supply and What the Future Holds for American Food*

Between 1997 and 1999, genetically engineered ingredients appeared in two-thirds of all processed foods in the United States, and this fraction has only increased over time.<sup>113</sup> As stated, Monsanto's Roundup Ready is present in approximately 96% of the soybean crop in the United States.<sup>114</sup> Sixty percent of all processed foods including bread, pasta, candy, ice cream, pie, margarine, meat products, and vegetarian meat substitutes contain soy.<sup>115</sup> Thus, every person that eats processed foods in this country has eaten GE food products on a consistent basis. While there are several potential benefits of GE foods, the negative side effects are too great to ignore.

##### A. Benefits of GE Foods in the United States

Although there are many critics of GE foods, they do have the possibility of providing many benefits to our society. These include agricultural benefits, consumer benefits, environmental benefits, and scientific progress for the future.

Using GE technology, crops can often be grown on a larger scale, leading to larger output and cheaper costs.<sup>116</sup> This larger output is also due to the fact that many GE crops are grown to resist harsh weather conditions, herbicides, and plant pests; hence, more can be harvested for human consumption.<sup>117</sup> It has been suggested that use of herbicide tolerant crops can reduce total production costs by 6% in some cases.<sup>118</sup> Furthermore, with the GE crops' resistance to weather fluctuations, they can be grown in more varied climates, increasing output around the

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<sup>112</sup> *Id.*

<sup>113</sup> Cynthia D. Fisher, Comment, *The Genie is Out of the Bottle: Consumers Demand Mandatory Labeling on Genetically Engineered Foods*, 4 J. LEGAL ADVOC. & PRAC. 88, 94 (2002).

<sup>114</sup> *Monsanto Antitrust Investigation*, *supra* note 73.

<sup>115</sup> Fisher, *supra* note 113, at 94.

<sup>116</sup> Mandel, *supra* note 29, at 2180.

<sup>117</sup> *Id.* at 2181.

<sup>118</sup> *Id.*



world.<sup>119</sup> Increased output leads to decreased prices, which benefits the consumer.

There is also an argument that GE food crops may allow for more nutritious and better tasting food.<sup>120</sup> GE crops usually stay fresh longer, look aesthetically better, and have less damage.<sup>121</sup> Furthermore, some GE foods may be used to reduce allergenic risks associated with certain food products.<sup>122</sup> A higher level of nutrition is also a benefit to the consumer, and to humanity as a whole.

Another common proponent argument is that GE crops will actually help the environment, instead of harming it as many predict. It is argued that, because so many GE crops include natural pesticides within them, the use of harmful pesticides will no longer be necessary and, as such, there will be less pesticide residue run-off left in the environment.<sup>123</sup> Because habitat loss continues to be a growing threat to biodiversity, proponents of GE crops argue that, because crops are more efficient and produce larger output, the pressure to develop currently undeveloped natural habitats would decrease as farmers would require less land.<sup>124</sup>

Finally, many argue that the benefits of GE technology itself are simply too large and varied to ignore. Scientists are working on producing GE plants that may decrease the levels of toxic heavy metals in contaminated water and soil.<sup>125</sup> There is also significant progress being made in the medical field. Specifically, GE technology can produce new medicines, and may provide cures for diseases such as non-Hodgkins lymphoma, cystic fibrosis, and *E. coli*.<sup>126</sup>

The purported benefits of GE technologies used in food and medicine production should not be ignored. However, there are also many problems and concerns that must be addressed.

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<sup>119</sup> *Id.*

<sup>120</sup> *Id.* at 2183.

<sup>121</sup> *Id.*

<sup>122</sup> *Id.* at 2184.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at 2185-86.

<sup>125</sup> *Id.* at 2186.

<sup>126</sup> *Id.* at 2187.

## B. Problems with GE Foods in the United States

A substantial problem with GE foods is the lack of scientific certainty concerning safety and nutrition for human consumption. Genetic engineering of our nation's food supply is still a very confusing and complex science experiment that has not been fully tested or analyzed. Opponents of GE foods argue that there is insufficient proof to conclude with absolute certainty that these products are safe for human consumption, yet they continue to be marketed (and purchased) in supermarkets across the country.<sup>127</sup> GE food technology transfers material between species that do not interbreed naturally and are not closely related, in some cases splicing genetic material from animals into plants.<sup>128</sup> When GE is used to produce plant and animal foods for human consumption, then new proteins are suddenly introduced into our diet, with unknown effects.<sup>129</sup> Perhaps this will have no effect, or perhaps they will cause unknown allergies or digestion issues in the body. Scientists have suggested that the introduction of foreign genes into plants and animals may cause that gene to mutate or behave differently than it normally would, with potentially disastrous effects.<sup>130</sup> Unless extensive scientific testing is done by laboratories without incentivized agendas stemming from their connection to the patent holding companies, we will not know for sure.

Another serious issue with GE foods is the lack of required labeling, leaving the consumer in the dark about what they are actually eating. Studies have shown that consumers are generally not opposed to GE foods, but are vehemently against allowing those foods to be sold without proper labeling.<sup>131</sup> The United States is one of the only countries that refuse to label GE foods. While GE foods are widespread in supermarkets in the United States, most European Union ("EU") supermarket chains refuse to sell GE foods.<sup>132</sup> When GE goods are sold in EU shops, they are clearly labeled.<sup>133</sup> In Britain, restaurants and pubs are required to label any items on their menus that contain GE

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<sup>127</sup> Fisher, *supra* note 113, at 94-96.

<sup>128</sup> *Id.* at 92.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 97.

<sup>131</sup> *Id.* at 88.

<sup>132</sup> *Id.* See also Fernandez-Cornejo & Caswell, *supra* note 21, at 6.

<sup>133</sup> Fisher, *supra* note 113, at 88-89. See also Fernandez-Cornejo & Caswell, *supra* note 21, at 6.

ingredients or risk facing large fines.<sup>134</sup> In contrast, some private companies in the United States have attempted to place “GE Free” labels on their products, only to face litigation.<sup>135</sup>

In *Geertson Seed Farms v. Johanns*, the court noted that, “[a] federal action that eliminates a farmer’s choice to grow non-genetically engineered crops, or a consumer’s choice to eat non-genetically engineered food, is an undesirable consequence.”<sup>136</sup> Because GE foods may now include genetic materials from both animals and plants in certain products, accurate labeling is critical for vegetarian and vegan consumers, not to mention those with religious dietary restrictions.<sup>137</sup> Surveys of the American public in 2003 and 2004 found that 47% of people oppose GE foods altogether, while only 27% favor them.<sup>138</sup> Other surveys indicated that approximately half of the people polled would likely not buy GE food products that were modified to taste better or fresher.<sup>139</sup> Alternatively, half of those polled said they would be open to purchasing such products.<sup>140</sup> In fact, studies have shown that many American consumers would be willing to pay a premium to *avoid* certain GE food products.<sup>141</sup> These studies provide proof that consumers have a significant interest in labeling GE products so that they can avoid them if they desire. While American consumers may not wish to ban GE foods altogether, they do, however, want to be given the right to choose to eat them or not.

Lack of proper regulation of GE foods is another concern for the modern consumer. As described above, there are currently three separate government agencies charged with the regulation of GE foods: the FDA; the EPA; and the USDA.

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<sup>134</sup> Fisher, *supra* note 113, at 89.

<sup>135</sup> *Id.* at 112. See also *Ben & Jerry's Homemade, Inc. v. Lumpkin*, 1996 WL 495554, at 1 (N.D. Ill. Aug. 28, 1996) (eventually this case settled, and the Illinois Department of Public Health agreed to allow a disclaimer that reads, ‘the family farmers who supply our milk and cream pledge not to treat their cows with rBGH’).

<sup>136</sup> *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 U.S. Dist. LEXIS 14533, at \*26 (N.D. Cal. Feb. 13, 2007).

<sup>137</sup> Sarah L. Kirby, *Genetically Modified Foods: More Reasons to Label Than Not*, 6 *DRAKE J. AGRIC. L.* 351, 357 (2001).

<sup>138</sup> Fernandez-Cornejo & Caswell, *supra* note 21, at 16.

<sup>139</sup> *Id.*

<sup>140</sup> *Id.*

<sup>141</sup> *Id.* at 17.

The FDA ensures the safety of all foods other than meat and poultry.<sup>142</sup> In order to achieve this goal, the FDA provides *voluntary* premarket consultations with food companies, seed companies, and plant developers regarding the safety of GE foods.<sup>143</sup> In January 2009, the FDA released an industry guidance document, *Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* ("GE Animal Guidance"), yet the first paragraph made it clear that the document was not binding.<sup>144</sup>

This guidance document presented the FDA's views on the topic:<sup>145</sup> "[I]t [did] not create or confer any rights for or on any person and [did] not operate to bind FDA or the public."<sup>146</sup> Alternative approaches were deemed acceptable if such approaches satisfied the requirements set forth in applicable statutes and regulations.<sup>147</sup>

The GE Animal Guidance document essentially stated that if a producer of a GE animal wishes to get that food into the marketplace, the FDA must first approve it.<sup>148</sup> In order to do so, the FDA will first decide whether it is a new animal drug.<sup>149</sup> If it is, then the FDA will decide whether to approve a NADA for that particular use.<sup>150</sup> If so, then it is deemed safe, and the producer may proceed.<sup>151</sup> It is clear that the FDA's process is rife with holes. There is very little scientific proof required before the FDA will deem a food product NADA and hence safe for human consumption.

The EPA is charged with regulating both the environmental and human health impact of plants genetically modified to produce their own pesticides.<sup>152</sup> This authority comes from its authority to regulate pesticide use and pesticide residue in food products.<sup>153</sup> In order to prevent insects from becoming resistant to insecticides in GE crops, the EPA mandates that seed producers and farmers follow insect resistance management

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<sup>142</sup> Mandel, *supra* note 29, at 2218.

<sup>143</sup> *Id.* at 2219.

<sup>144</sup> FDA GUIDANCE FOR INDUSTRY, *supra* note 89.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> Mandel, *supra* note 29, at 2211.

<sup>153</sup> *Id.* at 2223.

("IRM") plans.<sup>154</sup> However, compliance has been an issue because these IRM plans are often administered by the biotech-seed companies themselves.<sup>155</sup> For example, between 2002 and 2007, Monsanto neglected to inform Texas farmers of IRM planting restrictions, and illegally distributed its GE cotton seeds to these farmers.<sup>156</sup> For these actions, Monsanto was subsequently fined \$2.5 million.<sup>157</sup> IRM plans should be administered and regulated by the EPA itself, not by the biotech companies. Otherwise, there will continue to be opportunities to abuse the system and few incentives to encourage compliance. Fines like the one imposed on Monsanto, however, are a positive step to enforcing regulation and keeping these companies honest.

The USDA regulates the agricultural safety of the movement, importation, and field-testing of GE plants.<sup>158</sup> To grow GE plants outside of a laboratory, approval must first be obtained from the Animal and Plant Health Inspection Service ("APHIS").<sup>159</sup> APHIS gets this regulatory responsibility from the Plant Protection Act ("PPA").<sup>160</sup> The PPA was enacted in 2000, and is essentially a combination of the Federal Plant Pest Act from 1957 and the Federal Plant Quarantine Act of 1912.<sup>161</sup> The USDA has received much criticism in its approval of new GE plants. In some cases, APHIS relied on misinformation provided by pesticide-industry funded groups when making its approval decisions.<sup>162</sup> In other cases, the USDA cited pesticide usage data that was over ten years old.<sup>163</sup> In recent years, APHIS has allowed companies, like Monsanto, that are petitioning for deregulation of their crops to submit the results of observation trials that do not even involve application of Roundup to the crop.<sup>164</sup> This

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<sup>154</sup> *Problem of Superweeds: Before the Domestic Policy Subcomm. of the H. Oversight and Gov't Reform Comm.*, 111th Cong. (2010) (statement of William Freese, Science Policy Analyst, Center for Food Safety), available at <http://truefoodnow.files.wordpress.com/2010/09/oversight-hearing-9-30-2010-freese-oral-final.pdf> [hereinafter *Problem of Superweeds*].

<sup>155</sup> *Id.*

<sup>156</sup> *Id.*

<sup>157</sup> *Id.*

<sup>158</sup> Mandel, *supra* note 29, at 2223-24.

<sup>159</sup> *Id.* at 2224.

<sup>160</sup> *Id.*

<sup>161</sup> *Id.*

<sup>162</sup> *Problem of Superweeds, supra* note 154.

<sup>163</sup> *Id.*

<sup>164</sup> *Id.*

essentially means that when a GE crop resistant to Roundup is deregulated, the applicant has provided virtually no information on susceptibility to disease, which potentially leads to infected crops that are available for human consumption.<sup>165</sup>

It is apparent that this is a complicated system based upon outdated legislation that was enacted long before GE technology was possible. One can easily see how there are inevitable overlaps and inconsistencies among the three agencies, resulting in a possible dangerous situation for the American consumer. In fact, potentially dangerous situations associated with deficiencies in the regulation of GE foods have already occurred. In 1997, Aventis, the manufacturer and patent owner of StarLink corn, a GE food product, sought the EPA's approval of its product for both animal and human consumption.<sup>166</sup> The EPA<sup>167</sup> approved the product for animal consumption, but denied approval for human consumption because of the possibility that it may cause allergies in humans.<sup>168</sup> In September 2000, scientists discovered the unapproved corn in Kraft Foods Taco Bell taco shells, causing a widespread recall.<sup>169</sup> Since then, StarLink corn has been detected in as many as 300 different foods around the country.<sup>170</sup> Overall, it was determined that over nine million bushels of the corn were dumped into grain elevators.<sup>171</sup> Interestingly, the only excuse Aventis advanced in defense of what occurred was that it might have failed to notify a number of its customers about the EPA restrictions.<sup>172</sup> Because the EPA and FDA obviously cannot monitor every bushel, stricter regulations are needed to prevent these sorts of 'mix-ups' in the future.

Furthermore, "drift" has become a major problem for the non-GE and organic farmer. "Drift" occurs when a seed from a GE crop blows into a field of non-GE crops of the same or related species and the GE crops cross pollinate with the non-GE crops.<sup>173</sup> GE plant seeds and pollen can easily be carried by the wind, animals, or insects into fields growing natural foods, thus

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<sup>165</sup> *Id.*

<sup>166</sup> Fisher, *supra* note 113, at 99.

<sup>167</sup> While the FDA is primarily responsible for the regulation of GE Foods, the EPA regulates the genetic material inserted into transgenic pest-protected plants, like the StarLink corn. See Mandel, *supra* note 29, at 2221.

<sup>168</sup> *Id.*

<sup>169</sup> *Id.*

<sup>170</sup> *Id.*

<sup>171</sup> *Id.*

<sup>172</sup> Fisher, *supra* note 113, at 99.

<sup>173</sup> Kirby, *supra* note 137, at 362.

contaminating those crops with GE crops.<sup>174</sup> Pollen from GE plants can travel extremely far. A bee specialist from the United Kingdom found that GE pollen was able to travel over two and a half miles from the field that it originated.<sup>175</sup> To combat this, some farmers have purchased GE seeds not because they want them, but to defend against drift from neighbors.<sup>176</sup> Farmers cannot possibly control the wind or animals from bringing the seed into their land, and so it seems inevitable that cross contamination will occur, and organic farming will no longer be guaranteed. Because non-GE crops are so easily contaminated, both organic and non-GE farmers are less able to ensure that their product is truly natural, or organic.<sup>177</sup>

An organic tortilla producer, Terra Prima, provides an example of how economically devastating this problem can be. After sending a \$500,000 shipment of corn tortilla chips to Europe, scientific testing proved that GE corn was found in the chips, causing the shipment to be refused and returned.<sup>178</sup> Terra Prima later concluded that pollen from a nearby GE corn farm was the probable cause of the contamination.<sup>179</sup>

Drift is especially dangerous for organic farmers, as it could result in their expulsion from the organic market.<sup>180</sup> Both North Dakota and Montana have found that virtually all seeds in their states are potentially contaminated with GE product due to drift, and, in fact, 2002 was the last year that they officially guaranteed pure seed.<sup>181</sup>

Some worry that the patenting of GE plants and animals may lead to universal 'bioserfdom' in which farmers lease their plant and animal patents from biotech conglomerates like Monsanto and pay royalties on the seeds and offspring.<sup>182</sup> Although this may sound farfetched, the legal aspects of such practices are already being litigated in current court cases. For example, in the 2009 case *Monsanto v. Bowman*, the defendant farmer contended that Monsanto should be required to include

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<sup>174</sup> *Id.* at 362-63.

<sup>175</sup> *Id.* at 363.

<sup>176</sup> *Problem of Superweeds, supra* note 154.

<sup>177</sup> Kirby, *supra* note 137, at 362.

<sup>178</sup> *Id.*

<sup>179</sup> *Id.*

<sup>180</sup> *Id.* at 363.

<sup>181</sup> Fisher, *supra* note 113, at 107.

<sup>182</sup> *Id.* at 105-06.

with its license to plant their soybean seed a mandatory requirement that the resulting crop be segregated from the non-Monsanto crops going forward, so that commodity soybean planting is not eliminated as an option for farmers.<sup>183</sup> The court refused to consider this public policy argument, ruling against Bowman, and thus no such requirement has been imposed.<sup>184</sup>

### C. Recent Backlash Against GE Foods

Recently, many of the concerns over GE foods cited in this Note have been voiced by both Senate and House lawmakers. Congressmen Dennis Kucinich, Peter DeFazio, and Mike Thompson, along with seventeen other members of Congress, recently sent a letter to Margaret Hamburg, Commissioner of the FDA, asking her to halt the approval process of the AquaBounty salmon.<sup>185</sup> The letter outlined four major concerns: (1) the review method is deficient; (2) there is a serious lack of data on whether the salmon is safe to eat; (3) irreversible environmental effects are likely; and (4) the FDA needs to require a label.<sup>186</sup>

In arguing that the review process is inadequate, the letter stated that the FDA should develop an appropriate evaluation method, rather than relying upon the current process used to review a new drug meant for animals.<sup>187</sup> Furthermore, even though AquaBounty filed a NADA for the AquaAdvantage salmon with the FDA in 2001, the letter claimed that the environmental assessment compiled by AquaBounty was flawed and does not consider the *totality* impact the salmon could have on the environment.<sup>188</sup> The letter also contended that the FDA should have initiated an environmental impact statement to determine the effect these new GE salmon would have on endangered fish populations.<sup>189</sup> Finally, the letter stated that the data the FDA provided to the public was deficient and untenable not only because it was compiled by AquaBounty itself, but also because the sample size for the studies conducted to determine

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<sup>183</sup> *Monsanto Co. v. Bowman*, 686 F. Supp. 2d. 834, 837 (S.D. Ind. 2009).

<sup>184</sup> *Id.*

<sup>185</sup> Nathan White, *House Letter Urges FDA to Protect Consumers and the Environment from Potential Dangers of GE Salmon*, FED. INFO. & NEWS DISPATCH, INC. (Sept. 28, 2010).

<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> *Id.*

<sup>189</sup> *Id.*



the salmon's morphology as well as possible allergic reactions was merely twelve.<sup>190</sup> Thus, the letter argued that this data provided by AquaBounty is hardly sufficient for a substantive evaluation of a full range of health and safety concerns.<sup>191</sup>

The letter also addressed some Congress members' concerns with how the AquaBounty fish will affect the environment. As stated above, AquaBounty claims that its salmon poses "less risk" to wild endangered salmon populations due to sterility, yet it also acknowledges that 5% of their fish could remain fertile and able to naturally procreate with wild salmon.<sup>192</sup> If these GE salmon do escape, they will easily out-compete wild salmon for food, territory, and reproductive access because they are more than twice the size of naturally-reproduced salmon.<sup>193</sup> In addition, the members of Congress argued that, because AquaBounty plans to raise the fish at an egg hatchery facility on Prince Edward Island, Canada, the possibility for contamination of the wild population is extremely high.<sup>194</sup>

This was not the only letter from Congress addressing concerns about AquaBounty's salmon. Rep. Frank Pallone also sent a letter to the agency.<sup>195</sup> Additionally, eleven Senate lawmakers sent a letter stating that the FDA has no sufficient procedure to review GE animals designed for human consumption.<sup>196</sup> These letters are a clear indication that lawmakers in the United States consider the introduction of genetically engineered animals into the public market to be an important issue that deserves Congress' and the regulatory agencies' attention (and scrutiny). The future of the AquaBounty salmon is uncertain, but these September 2010 letters provide clear evidence of a need and desire for change.

There has also been backlash against GE crops. Recent congressional testimony from the Center for Food Safety's policy analyst, William Freese, speaks to the growing problem of "superweeds" that has resulted from the widespread use of Monsanto's Roundup Ready crops. In 1997, at the introduction of

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<sup>190</sup> *Id.*

<sup>191</sup> *Id.*

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> Ditta, *supra* note 69.

<sup>196</sup> *Id.*

the first Roundup Ready crops, Monsanto's scientists published a paper in which they presented several reasons why weeds were not likely to evolve resistance to the active ingredient in Roundup, glyphosate.<sup>197</sup> As expected, Monsanto's scientists were disastrously wrong, and as a result, an epidemic of Roundup-resistant weeds has infested over ten million acres of farmland.<sup>198</sup> In turn, this has substantially increased the amount of herbicide use,<sup>199</sup> as well as soil eroding tillage, raising costs and placing more chemicals into our crops.<sup>200</sup> Chuck Foresman, an employee of agri-business leader Syngenta, projects a 40% annual increase in these superweeds, infesting thirty-eight million acres by 2013.<sup>201</sup> Monsanto believes that the solution is to develop new GE crops, resistant to more varieties of toxic herbicides. Such herbicides have been proven to have significant adverse effects on animals in clinical trials, including low sperm count and sluggish brain development, among other effects.<sup>202</sup>

Monsanto's solution is clearly the wrong response to superweeds; more resistant seeds and stronger chemicals are not the answer. If weeds have adapted to Roundup, there is reason to believe that this vicious cycle will continue, and these weeds will similarly become resistant to more toxic herbicides, resulting in even more powerful and dangerous superweeds, and necessitating the use of even more potent and dangerous herbicides.<sup>203</sup> Prior to the introduction of Roundup resistant seeds, there were virtually no weeds resistant to Roundup, proving a direct correlation between the epidemic of superweeds and the introduction of Roundup resistant seeds.<sup>204</sup> This proves how much of an impact GE seeds have had on the environment in twenty short years, and no one knows what the future has in store.

It appears that much of this negative press has finally caught up to Monsanto, as its stock has dropped about 42% since the beginning of the year.<sup>205</sup> Furthermore, sales of Roundup have

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<sup>197</sup> *Problem of Superweeds*, *supra* note 154.

<sup>198</sup> *Id.*

<sup>199</sup> Completely refuting the contention advanced by those in favor of GE foods that GE crops will actually decrease chemical use.

<sup>200</sup> *Problem of Superweeds*, *supra* note 154.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

<sup>203</sup> *Id.*

<sup>204</sup> *Id.*

<sup>205</sup> Andrew Pollack, *After Growth, Fortunes Turn for Monsanto*, NEW YORK TIMES REPRINTS (Oct. 4, 2010), available at

plummeted, as Chinese generics have entered the market.<sup>206</sup> Sales on its Roundup Ready 2 Yield soybean seeds have not sold as Monsanto projected, resulting in sharp price cuts.<sup>207</sup> Many farmers and investors that once were in Monsanto's camp have become skeptical of the benefits of its products.<sup>208</sup> Many of its new products with several inserted genes have produced far below the expectations of farmers, causing Monsanto to offer credits to its unsatisfied customers.<sup>209</sup> Farmers are also unhappy with the amount of genes in each seed, as they often do not need or want such modified seeds.<sup>210</sup> Clearly, the seed giant is not as powerful as it once was. Perhaps the winds of change are blowing.

#### V. Single-Body Regulation and Patent Reform

In *Monsanto v. Bowman*, the District Court stated, “[T]he court is not the appropriate venue for raising a policy argument with respect to conditions which should be placed upon an award of a utility patent for genetically altered seed.”<sup>211</sup> The farmer in the case further questioned whether the Monsanto soybean can really be considered a soybean at all, but instead a new variety of plant.<sup>212</sup> The court dismissed this point entirely, stating that, “[R]esolution of such an issue is beyond the realm of this court.”<sup>213</sup> Furthermore, they stated that, “[T]he court may disagree with the decision to award unconditional patent protection to Monsanto for its genetically altered soybeans . . . but this court does not make policy; . . . it interprets and enforces the law.”<sup>214</sup> It is evident that the courts are not the proper venue for reform and change to the GE food issue. While many argue that GE foods should be banned entirely, this proposition is no longer feasible. GE compounds are already in the majority of foods consumed in this country. At this point, there is no way to completely eradicate

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[http://www.nytimes.com/2010/10/05/business/05monsanto.html?\\_r=1](http://www.nytimes.com/2010/10/05/business/05monsanto.html?_r=1)

<sup>206</sup> *Id.*

<sup>207</sup> *Id.*

<sup>208</sup> *Id.*

<sup>209</sup> *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> *Monsanto Co. v. Bowman*, 686 F. Supp. 2d. 834, 837 (S.D. Ind. 2009).

<sup>212</sup> *Id.*

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*

their presence from our foods, even if we wanted to. Therefore, this section does not discuss a ban on GE foods, but will instead posit two possible solutions for many of the current criticisms of GE foods, taking a look at each, and how the solutions may aid in solving the problems by working toward a more safe, trustworthy, and less monopolized food culture in the United States. That is, a food culture in which both natural and GE foods can co-exist harmoniously.

### A. Single-Body Regulatory Control

As described, the current three-prong regulatory structure of GE foods is outdated and confusing. The legislation on which these regulatory bodies rely was penned during a time when rDNA technology was beyond comprehension. It results in overlap, redundancy, and confusion, and thus leaves gaping holes in the regulation of GE food sources that have not been proven safe for consumers. As evidenced by the recent letters to the FDA from many Senate and House members, a change is greatly needed.

Thus, a single-body regulatory control format should be created. Obviously, creating a completely new government agency is not an easy task, and the agency would have to rely upon legislation that is specifically tailored towards GE foods. Therefore, this Note advocates for a new regulatory body under the assumption that Congress will also enact comprehensive, pro-consumer legislation<sup>215</sup> on GE food products. The new agency would have to employ persons familiar with GE technology and the safety, environmental, and economic challenges that come with it. A team of scientists not in any way involved with biotech corporations must be the backbone of this new agency. By keeping this body independent and focused on science, the inevitable political pressure would be greatly decreased, allowing for more accurate and honest scientific findings on the safety of these food products for both consumers and the environment. One of the shortcomings of the current system is the lack of communication between the three regulatory agencies dealing with GE food. A single agency would help to relieve this problem.

This proposed regulatory body must also insist upon

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<sup>215</sup> An extremely unlikely proposition, *see* discussion of the strength of the GE lobby in Part IV.A *infra*.

special labeling requirements designed for GE food products. Europeans label, so why can't America? Our current labeling requirements send a message to the rest of the world that what our agribusiness cares about is money, and not its products. Regardless of whether this is true, without labels American consumers also have no right to choose what they want to eat. Moreover, lack of labeling keeps GE food producers dishonest, as they have no incentive to disclose what is in their products. Thus, they have little or no reason to make sure that what they are putting out is safe, as the profits enter regardless.

Another positive side effect of a single agency would be that the approval process would take longer, affording scientists more time to research the human and environmental impact of new GE foods and more time to assess their safety concerns. Longer time researching the effects of these food products would translate to unbiased decisions based on concrete research, whose objective is to find a definitive answer to the question of whether certain GE products for the general public should be approved for the market.

Admittedly, from an environmental perspective, there is simply no workable method to regulate GE foods at this point. There is no way that any regulatory body of any type could possibly control GE pollen from blowing into non-GE and organic fields. This is the bed we have made, so we must lie in it. Unless all GE food crops were somehow moved indoors, or giant walls were built surrounding every field - which is clearly impossible - there is no way to stop cross contamination of GE and non-GE crops. The same may be said of the AquaBounty salmon, if it gets approved.<sup>216</sup> There is just no way to stop every single fish from escaping and reproducing with a natural counterpart; nature will find a way, as it always does.

Moreover, the GE food lobby is incredibly powerful, rendering the likelihood of pro-consumer GE legislation being passed by Congress slim. In fact, among former President George W. Bush's cabinet, the secretaries of defense, health, and agriculture all had connections with either Monsanto or the biotech industry, as well as the attorney general and the chairman

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<sup>216</sup> If AquaBounty is denied approval, it is only a matter of time before another GE animal is approved.

of the House Agriculture Committee.<sup>217</sup> And although President Obama promised to stand up to agribusiness, it appears he is giving us more of the same: the FDA Deputy Commissioner for Foods is the former Monsanto Vice President; the director of the USDA National Institute of Food and Agriculture is the former director of the Monsanto-funded Danforth Plant Science Center; and the Agriculture Negotiator for the U.S. Trade Representative is the Vice President of CropLife, the Monsanto and Dupont<sup>218</sup>-funded pesticide-promoting lobbying group.<sup>219</sup>

Regulation is a great idea in theory, but as the FDA, USDA, and EPA have proven time and again, there is simply no way to control every plant and animal in the world. Pollen from GE crops will inevitably carry into non-GE and organic fields; GE fish will escape and reproduce with the native salmon population; and as of now, there is no way to say for certain that these foods are safe, for only time will tell. One cannot regulate the wind from blowing or bees from flying, fish from swimming, and life from reproducing. Furthermore, since the biotechnology lobby's influence in our government is so strong, unless the current culture of bullying and greed changes, reform of any kind is far off. Therefore, the second proposed solution is not only more plausible, but more necessary.

### B. GE Patent Law Reform

A second, and in all likelihood, more feasible solution is immediate and requires tough reform of current patent law. As discussed above, solving the environmental issue is likely impossible as there is no turning back on our choices now. Therefore, this section will address why patent law reform is not only the most viable, but the most likely to enact real change, while helping to solve many of the current issues facing GE food. Furthermore, it will argue that patents on GE food products are not - and should not be - considered the same as patents on everyday inventions under the law.

Under current law, biotechnology giants that hold patents (e.g., Monsanto) can continue to monopolize the GE seed

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<sup>217</sup> Robert Cohen, *Monsanto and G.W. Bush Administration: Who Will Own The Store?* ORGANIC CONSUMERS ASS'N. (Jan. 21, 2001), available at <http://www.organicconsumers.org/monsanto/MonBushAdmin.cfm>

<sup>218</sup> The world's second-largest chemical producing company.

<sup>219</sup> *Millions Against Monsanto Campaign*, ORGANIC CONSUMERS ASS'N. (n.d.), available at <http://www.organicconsumers.org/monlink.cfm>

industry, driving out all competition, preventing generics, and bullying anyone stepping in their path. Granting a twenty year monopoly to a company that produces a significant portion of our nation's food supply is not the same as granting the patent on non-food inventions like Velcro. One cannot eat Velcro, it is not relied upon for survival, nor are there hundreds of cases of patent infringement due to the unintended, and in many cases totally innocent,<sup>220</sup> uses of Velcro.

As mentioned, patents are given to encourage invention, innovation, and progress within modern society. These are all admirable goals, but they do not apply in the GE world as they do to inventions unconnected with our nation's food sources. When *Diamond v. Chakrabarty* was decided, the Court allowed a patent for a *microorganism* that would be used to absorb oil, helping in many admirable instances such as oil spills.<sup>221</sup> It is highly unlikely that the *Diamond* Court would have felt the same about a super-sized salmon or a soybean seed able to withstand huge loads of pesticide with seemingly no effect (despite reports to the contrary).

Furthermore, a twenty year period is entirely too long, especially in the biotechnology industry where the proffered goals are medical research for the good of mankind, and an increased food supply for our nation that is more nutritious, delicious, and economical. If human invention and innovation for the betterment of mankind are the goals, why would a lack of competition be the best method to reach them? This only seems like a method preferred by the large corporations which profit off of government-granted monopolies, while retarding honest, ethical, and progressive scientific research that serves a master other than the bottom line. Competition is the driving force behind new products and ideas, so without it, why would anyone try to improve on old techniques or advance scientific research? Why would anyone attempt to improve upon someone else's work if they had no opportunity to try? Without competition our society would stagnate and plateau.

The new grant of a patent on Monsanto's Roundup Ready 2 Yield soybean that essentially increases their monopoly until

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<sup>220</sup> *Monsanto Co. v. Bowman*, 686 F. Supp. 2d. 834, 840 (S.D. Ind. 2009). (“[I]t was certainly within reason for Bowman to reach a conclusion that what he was doing was within legal bounds”).

<sup>221</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309-16 (1980).

2020 is an abomination. Generics should have been allowed into the GE seed market years ago. Many biotech corporations argue that their patented food technology makes food cheaper and more accessible to the people. Instead, it merely funnels the profit straight into their bank accounts, crippling the family farming industry that has been an integral part of our nation's historical economy. Extending monopoly power on Monsanto's Roundup Ready soybean is not only preventing others from entering the market, but also making the American consumer more reliant on Monsanto's products than ever. What if it was discovered that Roundup Ready soybeans cause cancer, or a virus without a known cure? The resulting epidemic would be of a scale the world has not seen since the Black Plague. While that may sound hyperbolic, the American consumer is so reliant upon GE food sources whose safety is wholly unknown that if these sources were found to be dangerous or toxic, a very small minority would be unaffected. For these reasons, competition absolutely should be encouraged in the seed industry, to promote both healthy competition and scientific research.

Patents granted on GE foods, or on properties that will be used in GE foods, should have a reduced protection period of five to ten years maximum. Adding a minor new property to an existing product and calling it an invention is a hoax that the USPTO should not entertain.<sup>222</sup> If the period were reduced to five to ten years, sorely needed competition in the GE food industry would exist, and there would thus be a larger share of companies involved, thereby increasing the amounts of scientific research and equalizing bargaining power between the American farmer and GE seed producer. The more companies involved, the more the American consumer is informed. The few dominant seed corporations have hidden in the shadows long enough. The issue of the American consumer's right to food is an important one, and with more players in the game, the more likely consumers are to find out information about what is really going on with our food and - more importantly - where it comes from.

Patent-holding biotech corporations will argue that the lack of monopoly will hurt their businesses. This argument is shallow at best. As a business, there is no reason that they cannot charge a competitive market price for their GE seeds and make a profit. In fact, charging market price will not only make them

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<sup>222</sup> For example, consider Monsanto's new Roundup Ready Yield 2 soybean.



more profitable, but also seeks to incentivize these companies to produce better products, thereby encouraging innovation and invention as much as a patent would, and arguably more. As it stands, large corporations will continue to exploit current patent laws to their advantage, increasing patent protection long after their time is up, unless something is done to make them more honest.

Patent reform is crucial to increasing competition, scientific study, and conversation. At the end of the day, the American consumer wants to feel they are part of the discussion, not like a child kept in the dark. Reform is critical to establishing accountability between the large corporations, keeping their scientists unbiased and honest, and letting Americans eat the food they choose.

### *VI. Conclusion*

GE plant, and soon, animal, food sources are here to stay - there is no turning back the clock. There are benefits and cautions on both sides, and they make up a significant portion of the food supply in the United States. The American consumer will likely eat a GE food product at some point every day. Lack of respect for human safety and the environment, bolstered by patent protection, as well as legislative and judicial support, has allowed the GE food industry to hide behind its humanitarian rhetoric long enough. While there can be important benefits found in GE food production, it has not been thoroughly tested, so no scientist can say for certain whether it is safe (and in fact, many argue that it is not). Furthermore, the consumer has no choice in deciding whether to eat these products because of lack of labeling. With the imminent introduction of GE animal products into our food supply, this issue has been pushed to the forefront, and hopefully people will begin to listen. Given the recent letters to the FDA, in addition to proposed legislation, it appears they have.

While irreversible environmental contamination has already happened, there are solutions to many of the GE food problems. Correcting the current lack of regulation would be a significant step, yet, unless a miracle occurs and Congress drafts pro-consumer legislation on GE food products, notable regulatory change is unlikely to occur. In its absence, patent reform must happen, and soon.

The USPTO must realize that patents on non-edible inventions and GE foods are not the same, nor should they be treated as such. The lifespan of patents granted on GE food products should be greatly reduced, to five or ten years at a maximum. This approach will still encourage companies and individuals alike to make discoveries in the GE food industry, as they will still be granted a limited monopoly. The GE food industry remains controversial, and therefore competition is necessary to improve overall efficiency and quality of the foods. GE foods cannot be avoided; hence they must be scientifically tested for the safety of American consumers. Granting companies monopoly control over our nation's food supply for over twenty years, as current laws allow, is not only adverse to innovation, but impedes competition and results in little choice for the farmer, scientist, and consumer. Therefore, to eradicate many of these problems, the patent period must be greatly reduced. We live in a country where GE foods are a daily occurrence on our plates. In order to ensure that food is safer, let's increase competition, limit patent protection, and become a part of the discussion.