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PATENTS, GENETICALLY MODIFIED FOODS, AND IP OVERREACHING

Elizabeth A. Rowe*

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I. INTRODUCTION

GENETICALLY engineered plants and animals have become a large part of the food we consume. The United States is the world's largest producer of genetically modified foods, making American consumers the most exposed population to these products.¹ Patent law is one of the main contributors to this phenomenon that has affected not only the kinds of food we eat but also the nature of the agribusiness industry that produces these foods. Ultimately, agricultural biotechnology patents permit the handful of companies that own the patented technologies to determine what will end up on consumers' plates.² The patenting of food has led to concerns about the effects on individual farmers around the world. This issue has been thoroughly explored by other commentators³ and will not be addressed here.

This Article, however, will take on another area of concern that has remained unexplored—the effect of these patents on independent research and scientific inquiry. There is currently a void in the scientific knowledge relating to the effects of genetically modified foods on human health and the environment.⁴ Patent law perpetuates that void by allowing patent holders to control and restrict independent research in the area. This is facilitated mostly through no-research clauses in license agreements with farmers. This further exacerbates the problem of incomplete information about genetically modified foods and may ultimately threaten public health and safety.

As the editors of *Scientific American Magazine* have argued, “when scientists are prevented from examining the raw ingredients in our nation's food supply or from testing the plant material that covers a large portion of the country's agricultural land, the restrictions on free inquiry become dangerous.”⁵ While even without the involvement of the patent law companies have economic and other incentives to perpetuate infor-

1. *Agricultural Biotechnology Continues to Increase Crop Yield and Farmer Income Worldwide While Supporting the Environment*, CBS INTERACTIVE BUSINESS NETWORK (Feb. 13, 2008), http://findarticles.com/p/articles/mi_m0EIN/is_2008_Feb_13/ai_n24260354; see also *Global Status of Commercialized Biotech/GM Crops: 2007*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, <http://www.isaaa.org/resources/publications/briefs/37/executivesummary/default.html> (last visited Nov. 6, 2010).

2. See PETER PRINGLE, FOOD, INC.: MENDEL TO MONSANTO—THE PROMISES AND PERILS OF THE BIOTECH HARVEST 5–6 (2003).

3. See, e.g., Keith Aoki, *Malthus, Mendel, and Monsanto*, 19 J. ENVTL. L. & LITIG. 397, 408–13, 428–30, 446–47 (2004); Vincent G. Buehler, *Chapter 424: Terminating Pesticide Litigation, or a Paper Pesticide?*, 40 MCGEORGE L. REV. 355, 356–58 (2009); Dennis S. Karjala, *Biotech Patents and Indigenous Peoples*, 7 MINN. J. L. SCI. & TECH. 483, 490–92, 517–18 (2006); Roger A. McEowen, *Agricultural Law Developments Shaping the Sector and Legal Practice*, 14 DRAKE J. AGRIC. L. 1, 9–10 (2009).

4. Deborah B. Whitman, *Genetically Modified Foods: Harmful or Helpful?*, PRO-QUEST (Apr. 2000), <http://www.csa.com/discoveryguides/gmfood/review.pdf>.

5. *A Seedy Practice*, SCI. AM., Aug. 13, 2009, at 28.

mation gaps regarding their products,⁶ patent law's specific involvement provides an even easier and more direct way to "exclude" negative information.

Accordingly, this Article explores whether these research restrictions are contrary to the public interest and inconsistent with the underlying goals of patent law. If we accept that patents support innovation, then we must not overlook the unintended consequences of the innovation that is supported and perpetuated by the patent laws. Using genetically modified foods as a case study for exploring this issue, this Article will raise questions about whether the patent system bears any social responsibility to consumers. As the gatekeepers to new technologies, should the patent law concern itself with the consequences of the innovation it fosters? The broader public policy issue at the backdrop of this problem represents the struggle to reconcile the rights of patent owners with the public interest, when such patent rights may endanger public health and safety. This tension has been explored in other contexts. The patenting of human genes, for instance, raises similar questions and has received much attention in the literature.⁷

The research restrictions associated with the patenting of genetically modified foods, however, have not been explored. This Article not only introduces and analyzes the specific problems caused by the no-research restrictions but situates the issue in the larger context of intellectual property overreaching. As the Supreme Court has recognized, "Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby."⁸ Accordingly, to the extent the license restrictions at issue here are supported by or grounded in patent law, it becomes the responsibility of courts interpreting the law to take a more equitable approach in balancing these overarching patent policy tensions.

The next Part discusses the interconnection between and among agriculture, technology, and intellectual property. It provides relevant background on the evolution of the patenting of genetically modified foods as well as the public concerns regarding these foods. Part III identifies the specific patent policies that are implicated as well as the nature of the research restrictions and regulatory shortcomings associated with geneti-

6. See Wendy E. Wagner, *Commons Ignorance: The Failure of Environmental Law to Produce Needed Information on Health and the Environment*, 53 DUKE L.J. 1619, 1634–41 (2004).

7. See, e.g., Russel Lawrence Barsh, *Pharmacogenomics and Indigenous Peoples: Real Issues and Actors*, 11 CARDOZO J. INT'L & COMP. L. 365, 365–66 (2003); Timothy Caulfield, *Human Gene Patents: Proof of Problems?*, 84 CHI-KENT L. REV. 133, 133 (2009); Eileen M. Kane, *Molecules and Conflict: Cancer, Patents, and Women's Health*, 15 AM. U. J. GENDER SOC. POL'Y & L. 305, 307 (2007); Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG L.J. 133, 137–34 (2004).

8. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5–6 (1966).

cally modified foods. It compares the treatment of pharmaceuticals to that of genetically modified foods to underscore the greater potential for harm that arises from restricting research on genetically modified foods. Part IV argues that the patent law's role in limiting access and restricting research goes too far, contrary to the public interest and the underlying goals of patent law. It suggests that courts use a "patent overreach" doctrine to rein in these restrictions. Finally, the Article concludes in Part V that, on balance, the public interest in promoting independent research on the health and safety effects of foods should outweigh the patent holder's interest in controlling the state of adverse information available about its product.

II. AGRICULTURE, TECHNOLOGY, AND INTELLECTUAL PROPERTY

Technological innovations in agriculture have led to many advances that have helped make farming more efficient and productive. They have, for instance, enabled the use of less land to produce more food and the use of fewer pesticides sprayed directly onto crops.⁹ The first biotech food appeared in the United States market in 1995.¹⁰ Today, almost the entire crop of corn and soybeans in the United States is genetically modified.¹¹ However, this development did not happen overnight, and the involvement of science, intellectual property protection, and government regulation is an important part of the story of its evolution.

A. BRIEF HISTORY

A brief history of the progression of agricultural biotechnology to today shows the increasing involvement of intellectual property protection with each step in scientific advancement. As the remainder of this Part will discuss, during the open-pollination period, when the wind and insects did the work,¹² there was little need for protection. Later, as hybrid seeds were introduced, trade secret law allowed seed producers to protect their proprietary information.¹³ In 1930, Congress recognized the impor-

9. *A Seedy Practice*, *supra* note 5, at 28.

10. *Factsheet: Genetically Modified Crops in the United States*, PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY (Aug. 2004), http://www.pewtrusts.org/uploadedFiles/www.pewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Genetically_Modified_Crops_Factsheet0804.pdf.

11. Bruce Stutz, *Companies Put Restrictions on Research into GM Crops*, YALE ENV'T 360 (May 13, 2010), <http://www.e360.yale.edu/content/print.msp?id=2273>.

12. Debra L. Blair, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 304 n.72 (1999).

13. McEowen, *supra* note 3, at 9; see Jeremy P. Oczek, Note, *In the Aftermath of the "Terminator" Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seed*, 41 B.C. L. REV. 627, 632 (2000) ("Breeding plants through the hybridization process involves selecting and reproducing plants with favorable characteristics while rejecting plants with undesirable traits. Using hybrid crosses between various inbred lines, seed developers can sell seed that produces hybrid plants, but which in turn does not reproduce hybrids.")

tance of affording patent-like protection to plants.¹⁴ Finally, in 2001, plants were deemed entitled to full patent protection in the form of utility patents.¹⁵ Today, the technological advancements that create genetically modified foods are protected by utility patents.¹⁶ It is the bundle of rights associated with these patents that has helped shape the agribusiness industry as well as the level of control exerted over the production and the state of knowledge surrounding genetically modified foods.

1. Hybrid Seeds and Trade Secrets

In the beginning, seed production did not involve technology. Crops were pollinated by nature using wind or insects.¹⁷ Over time, seed producers were able to produce hybrid seeds using manual pollination.¹⁸ Plants grown from these hybrid seeds exhibited enhanced characteristics such as greater yield or disease resistance not exhibited in either of the parent-inbred lines.¹⁹ However, while the first generation of hybrid seeds consistently produced plants with desired characteristics, the subsequent generations that were the product of open pollination in the farmers' fields produced inconsistent and undesirable characteristics.²⁰ Thus, hybrid seeds were only useful for the first generation, and farmers had to buy new hybrid seeds each planting season from the seed producers.²¹ The ability to sell hybrid seeds to farmers without releasing the parent inbred lines allowed private seed producers to keep the parent inbred lines as trade secrets, thus conducting business and research under the protection of trade secret law.²²

The first hybrid corn seed was marketed in 1926 by Hi-Bred Corn Company (which later became Pioneer Hi-Bred International Inc.) in Des Moines, Iowa.²³ During the 1930s, hybrid seed corn gained increasing acceptance among farmers, "and by 1943, virtually one hundred percent of the corn planted in Iowa and ninety percent of the corn planted in

14. Benjamin Ikuta, *Genetically Modified Plants, Patents, and Terminator Technology: The Destruction of the Tradition of Seed Sharing*, 35 OHIO N.U. L. REV. 731, 734-35 (2009).

15. Keith Aoki, *Seeds of Dispute: Intellectual-Property Rights and Agricultural Biodiversity*, 3 GOLDEN GATE U. ENVTL. L.J. 79, 102-03 (2009).

16. *Id.* at 103.

17. Blair, *supra* note 12, at 304 n.72 (quoting JOHN MILTON POEHLMAN, BREEDING FIELD CROPS 20 (3d ed. 1987) ("Open-pollination, also known as natural cross pollination, is the transfer of pollen by such means as the wind or insects from the anther on one plant to the stigma or silk of another plant.")).

18. See Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 269 (2003); see Blair, *supra* note 12, at 305.

19. See Aoki, *supra* note 18, at 270; Blair, *supra* note 12, at 305 (noting that these inbred lines were homozygous and thus would produce nearly identical plants generation after generation through self pollination).

20. See Aoki, *supra* note 18, at 271; Blair, *supra* note 12, at 305.

21. See Aoki, *supra* note 18, at 271.

22. See Aoki, *supra* note 18, at 281; Blair, *supra* note 12, at 306-10; see also Keith D. Parr, *Developments in Agricultural Biotechnology*, 19 WM. MITCHELL L. REV. 457, 469-72 (1993) (discussing Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc., No. 81-60-E, 1987 WL 341211 (S.D. Iowa Oct. 30, 1987)).

23. Blair, *supra* note 12, at 305.

the U.S. Corn Belt was hybrid seed corn.”²⁴ Representing a \$70 million market by 1944, corn seed was established “as the core business of the U.S. seed industry.”²⁵

2. *Introduction of Patent-Like Protection for Plants*

In 1930, Congress passed the Townsend-Purnell Plant Patent Act of 1930 (PPA)²⁶ to provide a patent-like system for protecting plants.²⁷ The PPA was the first legislation of its kind in the world to grant intellectual property rights to breeders²⁸ who had “invented or discovered and asexually reproduced any distinct and new variety of plant, other than a tuber-propagated [sic] plant.”²⁹ The Act defines asexual reproduction to include reproduction “by means other than from seeds, such as by the rooting of cuttings, by layering, budding, grafting, in-arching, etc.”³⁰ Congress created the PPA to provide breeders of new asexually propagated plant varieties with incentives and protections similar to those provided by utility patents.³¹ Infringement occurs when the accused plant “is a direct or indirect asexual reproduction of the patentee’s original patented parent plant.”³² There is no infringement when one sexually reproduces the patented plant.³³

In 1970, Congress expanded the intellectual property protection afforded to plants by enacting the Plant Variety Protection Act (PVPA).³⁴ Prior to the enactment of the PVPA, hybrid-seed companies enjoyed trade-secret protection over the plant varieties they developed but, as discussed above, were not eligible for the patent-like protection of the PPA.³⁵ The PVPA, through the issuance of a plant variety certificate, confers exclusive rights to “[t]he breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety”³⁶ PVP certificates are issued by the Department of Agriculture—not the PTO.³⁷

Unlike the earlier Plant Patent Act, the PVPA contained two signifi-

24. *Id.*

25. JORGE FERNANDEZ-CORNEJO, U.S. DEP’T OF AGRIC., *THE SEED INDUSTRY IN U.S. AGRICULTURE: AN EXPLORATION OF DATA AND INFORMATION ON CROP SEED MARKETS, REGULATION, INDUSTRY STRUCTURE, AND RESEARCH AND DEVELOPMENT* 25 (ERS Agric. Info. Bull. No. 786, 2004), available at <http://www.ers.usda.gov/publications/aib786/aib786.pdf>.

26. 35 U.S.C. § 161 (2006).

27. Aoki, *supra* note 15, at 96.

28. *Id.*

29. 8 DONALD S. CHISUM, *CHISUM ON PATENTS* § 24.02(1) (2010).

30. *Id.* § 24.02(2)(b).

31. See Aoki, *supra* note 15, at 96–97.

32. *Id.*

33. CHISUM, *supra* note 29, § 24.02(4).

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

35. FERNANDEZ-CORNEJO, *supra* note 25, at 25–26.

36. 7 U.S.C. § 2402(a) (2006).

37. FERNANDEZ-CORNEJO, *supra* note 25, at 21.

cant exemptions: one for crops and the other for research.³⁸ The crop exemption allows crops grown from protected varieties to be sold as food, feed, fiber, or for other nonreproductive purposes.³⁹ Additionally, the crop exemption allows farmers to save seed produced from protected varieties for replanting the next season on their own farm.⁴⁰ Between its enactment in 1970 and 1994, the crop exemption also allowed farmers whose primary farming business was growing crops for nonreproductive purposes to sell saved seed grown from protected varieties for reproductive purposes.⁴¹ In 1994, Congress repealed the provisions of the PVPA's crop exemption that allowed farmers to sell their saved seed to others.⁴² In its current form, the crop exemption allows farmers to sell seed for nonreproductive purposes and to save seed for planting on their own farms.⁴³ Notably, the PVP certificate contains a research exemption, explicitly providing 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."⁴⁴ It is interesting that, unlike the crop exemption, Congress has chosen not to repeal or amend this provision.

3. Enter Genetically Modified Seeds and Utility Patents

In 1980, the United States Supreme Court recognized the patentability of living organisms in its landmark case *Diamond v. Chakrabarty*.⁴⁵ The Court ruled in *Chakrabarty* that a living bacterium "was patentable subject matter because (1) it was a product of creative human agency containing characteristics 'markedly different' from those found in nature, and (2) it possessed potential for significant utility."⁴⁶ In light of the decision in *Chakrabarty*, the U.S. Patent Office wrestled with whether utility patents could cover sexually reproduced plants.⁴⁷ The U.S. Board of Patent Appeals and Interferences concluded that the PVPA did not prevent application of patent protection to such plants.⁴⁸ Finally, in 2001, the U.S. Supreme Court confirmed that utility-patent protection extended to sexually and asexually reproduced plants.⁴⁹ These cases paved the way for the introduction and patenting of genetically modified seed in agriculture.

38. Jim Chen, *The Parable of the Seeds: Interpreting the Plant Variety Protection Act in Furtherance of Innovation Policy*, 81 NOTRE DAME L. REV. 105, 124 (2005) (discussing the PVPA research exemption).

39. *Id.* at 127.

40. *Id.*

41. *Id.* at 128.

42. *Id.* at 129.

43. *Id.* at 131.

44. 7 U.S.C. § 2544 (2000); see also Chen, *supra* note 38, at 132–39.

45. 447 U.S. 303, 310 (1980).

46. Aoki, *supra* note 15, at 102 (citing *Chakrabarty*, 447 U.S. at 310).

47. See *Ex parte* Hibberd, No. 645-91, 227 U.S.P.Q. (BNA) 443, 444 (B.P.A.I. 1985).

48. *Id.* at 444–45.

49. *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145–46 (2001).

B. FROM PATENTS TO SUPERMARKETS

About seventy percent of the food available in American supermarkets contains genetically modified substances.⁵⁰ The United States is the top producer of genetically modified crops, followed by Brazil, Argentina, India, and Canada.⁵¹ The vast majority of corn grown in the United States, eighty percent, is genetically modified,⁵² and about a quarter of the products in the supermarket contain corn.⁵³ These corn-containing products span an array that may surprise most consumers—from high-fructose corn syrup in beverages to ketchup, cake mixes, syrups, margarine, salad dressing, and vitamins.⁵⁴

The three companies leading the biotech food products industry are Monsanto, DuPont's Pioneer Hi-Bred, and Syngenta.⁵⁵ "These three companies develop most of the new [genetic cross bred] traits [in the industry] and license them to each other, smaller seed companies, and public breeding programs."⁵⁶ Monsanto alone sold \$7.3 billion of seeds and seed genes in 2009, placing first among its competitors.⁵⁷ Indeed, Monsanto seeds dominate. "Ninety percent of the U.S. soybean crop and 80% of the corn crop and cotton crop are grown with seeds containing Monsanto's technology."⁵⁸ The company focuses largely on corn, cotton, and soybean crops rather than on a wider variety of crops because these are more likely to generate a large enough return on its investment in biotechnology.⁵⁹ While traditionally, genetic material was transferred between the same species (e.g., plant to plant), genetic engineering technology now permits transfers between and among any genus or species.⁶⁰

50. *How Consumers Process Information at the Heart of Debate Over Labeling of Genetically Modified Foods*, PEW CHARITABLE TRUSTS (June 27, 2002), http://www.pewtrusts.org/news_room_detail.aspx?id=33460.

51. See James Kanter, *In Europe, a Move to Ease Curbs on Growing Biotech Crops*, N.Y. TIMES, July 8, 2010, at B4.

52. NAT'L AGRIC. STATISTICS SERV., U.S. DEP'T OF AGRIC., ACREAGE 32 (June 30, 2008), available at <http://usda.mannlib.cornell.edu/usda/current/Acre/2000s/2008/Acre-06-30-2010.pdf>. In 2008, 92% of soybeans grown in the United States are genetically modified. *Id.* at 34.

53. MICHAEL POLLAN, *THE OMNIVORE'S DILEMMA: A NATURAL HISTORY OF FOUR MEALS* 19 (2006).

54. *Id.* at 18–19.

55. Elizabeth I. Winston, *What Ifs and Other Alternative Intellectual Property and Cyberlaw Story: If Seeds Were Not Patentable?*, 2008 MICH. ST. L. REV. 321, 329 n.45 (2008).

56. *Id.*

57. Robert Langreth & Matthew Herper, *The Planet Versus Monsanto*, FORBES, Jan. 18, 2010, at 64.

58. *Id.*

59. *Id.* at 69. Because genetically modified corn and soybeans are not often sold directly to consumers they are "less controversial." *Id.*

60. See, e.g., *Statement of Policy: Foods Derived from New Plant Varieties*, 57 Fed. Reg. 22,984, 22,986 (May 29, 1992); Charles W. Schmidt, *Genetically Modified Foods: Breeding Uncertainty*, ENVTL. HEALTH PERSP. (Aug. 1, 2005), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1280366/pdf/ehp0113-a00526.pdf>.

Thus, for example, both a tomato⁶¹ and a pig⁶² can contain genes from a fish. The crossing of traits carries many benefits that before now were not possible. It can increase nutritional value⁶³ (e.g., rice containing beta-carotene),⁶⁴ freshness for storage (e.g., tomatoes containing a fish gene to reduce rotting),⁶⁵ and resistance to insects and pests.⁶⁶

In the early 1980s,⁶⁷ researchers at Monsanto discovered a breakthrough method for producing biotech crops. Rather than inserting new genes into plant cells with a gene gun, they discovered that bacteria (inserted with the desired genes) mixed in a Petri dish with plant cells was a more effective method.⁶⁸ That method is still widely used today.⁶⁹ Roundup Ready® soybeans were developed and patented by Monsanto.⁷⁰ These soybeans have been genetically altered to resist the herbicide Roundup.⁷¹ The advantage of the Roundup Ready® soybeans is that spraying the field to kill weeds will not kill the soybean plants.⁷² Corn has also been genetically engineered to carry genes from *Bacillus thuringiensis* (BT), a naturally occurring soil bacterium that produces a protein toxic to some insects.⁷³

The advancements continue. Monsanto is currently working on a genetically modified soybean that would contain high levels of omega-3 fatty acids; these fish-based fatty acids have been shown to promote a healthy heart.⁷⁴ Additionally, on a more aesthetic note, in Israel, gene technology is being used to create exotic “designer” fruits and vegetables to entice consumers: tomatoes that smell like lemons, carrots shaped like potatoes, strawberries shaped like carrots, and blue bananas.⁷⁵ It probably will not be long before these products land in United States supermarkets.

Beyond genetically engineered crops, as this Article is being prepared, the Food and Drug Administration (FDA) is in the process of reviewing

61. Schmidt, *supra* note 60.

62. See Liangxue Lai et al., *Generation of Cloned Transgenic Pigs Rich In Omega-3 Fatty Acids*, 24 NATURE BIOTECHNOLOGY 435–36 (Apr. 2006), available at <http://www.nature.com/nbt/journal/v24/n4/pdf/nbt1198.pdf>.

63. See, e.g., NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 35 (2000).

64. *Biotech Crop Roundup: Stars—and Failures—in the Field of Genetically Modified Crops*, NPR (Nov. 15, 2001), <http://www.npr.org/programs/morning/features/2001/nov/biotech/011115.crops.html>.

65. *Id.*

66. John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, 810–11 (2001).

67. Langreth & Herper, *supra* note 57, at 64.

68. *Id.*

69. *Id.*

70. See *Monsanto Co. v. McFarling (McFarling II)*, 363 F.3d 1336, 1338–39 (Fed. Cir. 2004) (holding that the soybeans are covered by U.S. Patent Nos. 5,633,435 and 5,352,605).

71. Jay P. Kesan, *Licensing Restrictions and Appropriating Market Benefits from Plant Innovation*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 1081, 1082–83 (2006).

72. *Id.* at 1083.

73. Langreth & Herper, *supra* note 57, at 67.

74. *Id.*

75. Edmund Sanders, *Yes, We Have Blue Bananas*, L.A. TIMES, May 29, 2010, at A1.

the first genetically altered animal for our kitchens—salmon.⁷⁶ AquaBounty Technologies, the salmon's developer, wishes to create and sell eggs that have been genetically modified to produce salmon that grow twice as fast as conventional Atlantic salmon.⁷⁷ It contains a growth hormone from a Chinook salmon and genetic material from another kind of fish, the ocean pout, that permits the growth hormone to be released year round, unlike nonengineered salmon, which do not produce growth hormone in cold weather.⁷⁸ Not surprisingly, this salmon appears to be patented.⁷⁹ While its nutritional content is claimed to be identical to its naturally occurring counterpart, the genetically modified salmon takes eighteen months to grow and mature rather than the usual three years.⁸⁰ Interestingly, it is not entirely clear whether the FDA, under the current regulations, has the authority to review this genetically altered salmon, and it is possible that its authority could be challenged.⁸¹ Nevertheless, if this salmon is approved, it would be the first genetically modified animal approved for human consumption.⁸² However, like genetically modified corn and other crops, it will not be labeled.⁸³

C. PUBLIC HEALTH CONCERNS AND THE UNKNOWN

The possible health consequences of genetically modified foods are currently unknown. While many possible concerns have been identified, the state of research is incomplete and inconclusive. When DNA from a donor food is added to a host food, the DNA also adds a foreign protein to the host food product.⁸⁴ This could mean, for instance, that genetic engineering can transfer allergens from a food to which someone is allergic (e.g., nuts) to a food to which she has no known allergies (e.g., soybeans) without her being aware of the change, and thus may cause her to

76. Editorial, *First, Grill Robo-Salmon's Producers—and the FDA*, THE OREGONIAN (July 7, 2010, 6:23 PM), http://www.oregonlive.com/opinion/index.ssf/2010/07/first_grill_robosalmons_produ.html.

77. *Id.*

78. Andrew Pollack, *Genetically Altered Salmon Set to Move Closer to Dinner Table*, N.Y. TIMES, June 26, 2010, at A1.

79. See U.S. Patent No. 5,545,808 (filed Mar. 10, 1994) (Transgenic salmonid fish expressing exogenous salmonid growth hormone); U.S. Patent No. 5,480,774 (filed Oct. 14, 1993) (Determination of genomic sex in salmonids).

80. Pollack, *supra* note 78, at A1.

81. See Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2209 (2004). Because the genetic modification of the salmon involves increased production of its growth hormone it would seem that, consistent with the FDA's position on the insertion of genetic material, it should be treated as GRAS and not require approval. However, in this instance the FDA is treating it as a "new animal drug" under the Food, Drug, and Cosmetic Act. *Id.*; see also discussion *infra* at Part III.C.

82. Editorial, *supra* note 76.

83. See *id.*; see also Pollack, *supra* note 78, at A1.

84. See LUCA BUCCHINI & LYNN R. GOLDMAN, A SNAPSHOT OF FEDERAL RESEARCH ON FOOD ALLERGY: IMPLICATIONS FOR GENETICALLY MODIFIED FOOD (2002), http://www.pewtrusts.org/uploadedfiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_snapshot.pdf.

suffer serious, potentially life-threatening reactions.⁸⁵ The incidence of food allergies is reportedly on the rise.⁸⁶ However, there is insufficient data to determine the relationship between the increase in allergies and the use of biotech foods.⁸⁷

Part of the challenge in identifying possible links to health consequences is that given the nature of these genetically modified products and how they are used, it is more difficult to identify and measure consequences and to correlate them to the source.⁸⁸ If a consumer eats a genetically modified food and becomes ill or has an allergic reaction to it, he or she is unlikely to even be aware that he or she consumed a genetically modified product (given the absence of labeling), and the incident may never be connected to the consumption.⁸⁹ This means that it will probably require a longer span of time over which to quantify and determine health consequences. Accordingly, the current state of affairs is probably best described as an “information void” where we do not have enough information to determine the extent of unintended health and environmental consequences.⁹⁰

The use of genetic engineering does not in itself create inherent health risks.⁹¹ However, the possibility of health hazards cannot yet be ruled out, and there is a lot that we simply do not know. A few studies that have been performed on animals reveal potentially negative health outcomes in rats from genetically modified foods.⁹² For instance, genetically modified potatoes have reportedly damaged rats’ organs, including their brains, livers, and testicles.⁹³ Similarly, rats fed genetically modified tomatoes and corn also developed multiple negative reactions.⁹⁴ High fructose corn syrup, which is found in most beverages that Americans consume and which is mostly made from genetically modified corn, has

85. See Julie A. Nordlee et al., *Identification of a Brazil-Nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688, 688 (1996). On the flip side, genetic engineering may allow for the removal of allergens from food products. See Andrew Pollack, *Gene Jugglers Take to Fields for Food Allergy Vanishing Act*, N.Y. TIMES, Oct. 15, 2002, at F2 (discussing the possibility of actually deleting allergens from foods like wheat and peanuts).

86. Hugh A. Sampson et al., *Fatal and Near-Fatal Anaphylactic Reactions to Food in Children and Adolescents*, 327 NEW ENG. J. MED. 380, 384 (1992) (“It is our belief and that of other investigators studying food allergy that the frequency of fatal and near-fatal food-induced [allergic] reactions has risen over the past several years.”); Susan Dominus, *The Allergy Prison*, N.Y. TIMES, June 10, 2001, § 6 (Magazine), at 63.

87. See BUCCHINI & GOLDMAN, *supra* note 84, at 9.

88. See Katharine A. Van Tassel, *Genetically Modified Plants Used for Food, Risk Assessment and Uncertainty Principles: Does the Transition from Ignorance to Indeterminacy Trigger the Need for Post-Market Surveillance?*, 15 B.U. J. SCI. & TECH. L. 220, 246 (2009).

89. *Id.*

90. *Id.* at 229.

91. PRINGLE, *supra* note 2, at 5.

92. See generally Jeffrey M. Smith, *GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS* (2007).

93. *Id.* at 23.

94. *Id.* at 25–29; Katherine Goldstein & Gazelle Emami, *Monsanto’s GMO Corn Linked to Organ Failure, Study Reveals*, HUFFINGTON POST (Mar. 18, 2010, 5:12 AM), http://www.huffingtonpost.com/2010/01/12/monsantos-gmo-corn-linked_n_420365.html.

also recently been linked to potential liver problems in humans.⁹⁵ However, because each of these studies was limited, further research and investigation is required to better determine health risks.

There are also concerns about possible harm to the environment from genetically modified crops. There is a risk that genetically engineered plants containing insecticides may cause the insect population to become resistant to these pesticides.⁹⁶ Furthermore, genetically modified herbicide-resistant plants may cause farmers to use more toxic chemicals as they increase the amount of herbicides sprayed on weeds, knowing that the herbicide will not affect the plants.⁹⁷ Cross-contamination is also a potential problem as genetically modified crops can contaminate non-genetically modified crops,⁹⁸ and genetically modified products not meant for human consumption can inadvertently enter the food supply.⁹⁹ In September 2000, for instance, StarLink corn, a genetically engineered strain of corn not approved for human consumption, was found in Taco Bell-brand taco shells as well as in other human food products, and all of the shells had to be recalled.¹⁰⁰

III. PATENT RESTRICTIONS, FOOD, AND THE CONSUMER

Patent law supports innovation. That is the mantra that justifies the power of a patent and the resulting monopoly associated with it.¹⁰¹ While some scholars disagree about the extent to which innovation would be stifled without a strong patent system, patenting and innovation go hand in hand. This phenomenon has wide-reaching effects that move beyond

95. Melissa Healy, *High-Fructose Corn Syrup Consumption May Push Fatty Livers to the Brink*, L.A. TIMES (Mar. 18, 2010, 6:12 PM), http://latimesblogs.latimes.com/booster_shots/2010/03/high-fructose-corn-syrup-consumption-may-push-fatty-livers-to-the-brink.html?

96. See *First Documented Case of Pest Resistance to Biotech Cotton*, SCIENCE DAILY (Feb. 8, 2008), <http://www.sciencedaily.com/releases/2008/02/080207140803.htm> (discussing the bollworm's developed resistance to Bt cotton).

97. Michael A. Whittaker, Comment, *Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods*, 35 SAN DIEGO L. REV. 1215, 1220 (1998).

98. See GREENPEACE INT'L, GM CONTAMINATION REGISTER REPORT 2007, at 5 (2008), <http://www.greenpeace.org/international/en/publications/reports/gym-contamination-register-2007/> (follow "Download document" hyperlink).

99. In the last ten years, over two hundred incidents have been recorded involving this kind of contamination into the food supply. *Id.* at 11. In one incident, piglets modified with cow genes to increase milk production and a synthetic gene were accidentally sold for use in consumer pork products. Shelley Smithson, *Eat, Drink and Be Wary: Genetically Modified Animals Could Make It to Your Plate with Minimal Testing—and No Public Input*, GRIST (July 30, 2003, 9:00 AM), <http://www.grist.org/article/and3>.

100. See Barnaby J. Feder, *Companies Act to Keep Bioengineered Corn Out of Food*, N.Y. TIMES, Sept. 27, 2000, at C2; Andrew Pollack, *Kraft Recalls Taco Shells with Bioengineered Corn*, N.Y. TIMES, Sept. 23, 2000, at C1. See generally ALEJANDRO E. SEGARRA & JEAN M. RAWSON, STARLINK™ CORN CONTROVERSY: BACKGROUND (Jan. 10, 2001), available at <http://www.ncseonline.org/nle/crsreports/agriculture/ag-101.cfm>.

101. See ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE 127 (rev. 4th ed. 2006).

intellectual property and into the business arena.¹⁰² Patents are tied to our economic development, and the ownership of patents has strong implications for companies large and small and the industries in which they operate.¹⁰³ Because patenting has such a strong influence on business and industry, and ultimately on consumers, patent law and policy should not be viewed in isolation or as a discrete field belonging only to intellectual property laws but in a larger context that takes into consideration the broader effect of patents after they have been granted.

Under § 101 of the Patent Act, “[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 therefore, subject to the conditions and requirements [of the Act].”¹⁰⁴ According to the Constitution, the patent system is meant to promote the progress of science.¹⁰⁵ It does so by providing an incentive to invest in innovation.¹⁰⁶ Patents allow the patent holder to exclude others from practicing an invention unless permission has been granted, often through a license. Monsanto, for instance, receives an estimated \$500 million in royalties from licensing its Roundup Ready® soybean seed.¹⁰⁷

In determining whether an invention has met the many requirements of the Patent Act, there is no place for considering possible consequences of using the invention.¹⁰⁸ The closest category might be the consideration of utility or usefulness.¹⁰⁹ However, for most inventions the utility requirement does not make value judgments or moral judgments nor does it present much of a hurdle as the courts have interpreted it to be satisfied as long as the invention can be put to some lawful purpose.¹¹⁰

A. RESTRICTIONS ON SAVING SEEDS

It used to be that companies had to rely on the Plant Variety Protection Act (PVPA) for protection.¹¹¹ The PVPA offered patent-like protection for sexually reproduced seeds, but it allowed farmers to save seeds for replanting.¹¹² In *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Court held that plant materials could be protected by utility patents, which offer stronger protection, and thus the PVPA was no

102. See Steve LeVine, *IBM May Not Be the Patent King After All*, BLOOMBERG BUSINESSWEEK (Jan. 13, 2010, 6:12 PM), http://www.businessweek.com/magazine/content/10_04/b4164051608050.htm.

103. See *id.*

104. 35 U.S.C. § 101 (2006).

105. U.S. CONST. art. I, § 8, cl. 8.

106. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480–81 (1974); *MERGES ET AL.*, *supra* note 101, at 127.

107. Langreth & Herper, *supra* note 57, at 69.

108. See Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 490–93 (2003) (noting that the U.S. patent system does not consider moral utility for biotech inventions).

109. *Id.*

110. See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367–68 (Fed. Cir. 1999).

111. See *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.* 534 U.S. 124, 127 (2001).

112. Plant Variety Protection Act, 7 U.S.C. § 2543 (2006).

longer the exclusive means of protection.¹¹³ Accordingly, when seeds are covered by a utility patent, a farmer who saves seeds in violation of an agreement with the manufacturer is infringing the patent.¹¹⁴

Seed producers use license restrictions called “bag tag” or “seed wrap licenses” on bags of seed.¹¹⁵ They often require farmers to sign a technology agreement in which, among other things, they acknowledge that the seeds are protected by a patent and that saving or reselling them is prohibited.¹¹⁶ A Pioneer “bag tag” license reads:

[I]f the tag indicates this product or the parental lines used in producing this product are protected under one or more US patents, Purchaser agrees that it is granted a limited license thereunder only to produce forage, or grain for feeding or processing. Resale of this seed or supply of saved seed to anyone, including Purchaser, for planting is strictly prohibited under this license.¹¹⁷

Monsanto’s seeds are distributed through authorized seed distributors who have signed contracts containing restrictions including that the distributor can only license the seed to the grower but not sell it.¹¹⁸ Monsanto requires seed companies to enter into licenses or technology agreements with each purchaser or farmer.¹¹⁹ Under the Monsanto agreement, the farmers must agree:

To use the seed containing the Monsanto gene technologies for planting a commercial crop only in a single season. To not supply any of this seed to any other person or entity for planting, and to not save any crop produced from this seed for replanting, or supply saved seed to anyone for replanting. To not use [the] seed or provide it to anyone for crop breeding, research, generation of herbicide registration data or seed production.¹²⁰

Sometimes these “agreements” are mere notices on the products rather than a document that the licensee has to sign, acknowledging the terms and granting consent.¹²¹ However, the Court of Appeals for the Federal Circuit has upheld the validity of these license notices unless they were “objected to within a reasonable time.”¹²² However, note that these

113. *J.E.M. AG Supply, Inc.*, 534 U.S. at 129, 143 (“Utility patents issued for plants do not contain such [seed saving] exemptions” and “utility patent holders receive greater rights of exclusion” for having met “more stringent requirements.”).

114. *See McFarling II*, 363 F.3d 1336, 1342–43 (Fed. Cir. 2004).

115. Mark D. Janis & Jay P. Kesan, *Intellectual Property Protection for Plant Innovation: Unresolved Issues After J.E.M. v. Pioneer*, 20 NATURE BIOTECHNOLOGY 1161, 1163 (2002).

116. *Id.*

117. *Id.*

118. Winston, *supra* note 55, at 331.

119. *McFarling II*, 363 F.3d at 1339.

120. *Id.*

121. *See, e.g., Pioneer Hi-Bred Int’l, Inc. v. Ottawa Plant Food, Inc.*, 283 F. Supp. 2d 1018, 1024 (N.D. Iowa 2003) (notice on bags of corn).

122. *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 n.7 (Fed. Cir. 1992) (relying on the Uniform Commercial Code, which provides that a restriction may become a term of the sale without explicit assent under certain circumstances). For some very sound argu-

cases address the seed saving provision but not the research restriction discussed below. Accordingly, it is unclear whether the validity of the research restrictions would be similarly upheld.

Because the companies invest millions of dollars in the production of genetically modified seeds, they view these intellectual property restrictions as critical to preserving their investment.¹²³ Otherwise, because seeds self-replicate, if farmers were allowed to keep them there would be very little need to purchase additional seeds, thus threatening the companies' ability to recoup their investments.¹²⁴ One court noted that

[w]ithout the prohibition against the saving of seed for replanting or resale, Monsanto's patent would soon be rendered useless by virtue of the potential for exponential multiplication of the seed containing its patented technology. Given the risk of Monsanto's thus losing control of its technology, the limited license of its technology was the only reasonable alternative available to it if it hoped to garner a reasonable return on its sizeable investment.¹²⁵

Lawsuits against farmers for saving seeds have been successful. For instance, in two prominent cases, Monsanto sued Mississippi farmers who planted Roundup Ready® soybean seeds and retained seeds for replanting.¹²⁶ The Court of Appeals for the Federal Circuit affirmed the lower court's grant of summary judgment in favor of Monsanto, rejecting the argument that Monsanto's patent rights had expired after the farmers purchased the initial bags of seed.¹²⁷

B. RESTRICTIONS ON RESEARCH

The licenses also prohibit research or experimentation and the growing of these crops for research purposes.¹²⁸ The Court of Appeals for the Federal Circuit appears to have found that these no-research policies are "within the protection of the patent laws."¹²⁹ However, because the issues before the court focused on challenges to other aspects of the license agreement and as part of an anticompetitive and antitrust analysis, it is

ments why the court's reliance on the UCC is misguided in these types of cases, see Mark R. Patterson, *Contractual Expansion of the Scope of Patent Infringement through Field-of-Use Licensing*, 49 WM. & MARY L. REV. 157, 186-88 (2007).

123. A survey by the American Seed Trade Association in 2005 showed that companies invested more than \$554 million in research and development of seed technologies. Brief Amicus Curiae of the American Seed Trade Association in Support of Neither Party at 12, *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008) (No. 06-937), 2007 WL 3353100 at *12.

124. See Jason Savich, Note, *Monsanto v. Scruggs: The Negative Impact of Patent Exhaustion on Self-Replicating Technology*, 22 BERKELEY TECH. L.J. 115-16 (2007).

125. *Monsanto Co. v. Scruggs*, 249 F. Supp. 2d 746, 753 (N.D. Miss. 2001).

126. See, e.g., *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1333 (Fed. Cir. 2006); *McFarling II*, 363 F.3d 1336, 1340 (Fed. Cir. 2004).

127. *Scruggs*, 459 F.3d at 1336 (noting that "[a]pplying the first sale doctrine to subsequent generations of self-replicating technology would eviscerate the rights of the patent holder").

128. See, e.g., *Monsanto Co. v. Scruggs*, 342 F. Supp. 2d 568, 575 (N.D. Miss. 2004).

129. *Scruggs*, 459 F.3d at 1340 (citing district court's finding on summary judgment).

unclear whether a specific and more rigorous challenge to the research restriction itself would yield a similar result.¹³⁰ This Article takes the position that such research restrictions violate public policy given the unique problems created by genetically modified foods. Moreover, it is questionable whether these restrictions would fall within the scope of the patent claims. The use of the license term arguably allows the patent holder to reach those who are not a party to the agreement.¹³¹

Beyond the license restrictions, there are additional and broader limitations on researchers' access to the necessary patent materials and data with which to conduct research.¹³² Scientists have complained that their access to patented genetically modified plants for research is restricted and that companies such as Monsanto, Pioneer, and Syngenta exert too much control over independent researchers.¹³³ Thus, these scientists argue that they cannot test seeds, compare one company's seeds to another's, or investigate the environmental effects of genetically modified crops.¹³⁴ To do so requires permission from each patent holder of the seed or gene required for testing; access to data and the publication of data would also need to be negotiated.¹³⁵ Sometimes, in exchange for receiving permission to do research on the seeds, the researcher must submit any findings to the company for review prior to publication.¹³⁶ These requirements and restrictions are inconsistent with scientists' obligations to publish the results of publicly funded research.¹³⁷ Prior to the advent of patent protection in this area, researchers could purchase and test these products if they were commercially available,¹³⁸ just as they continue to do for conventional seeds.¹³⁹

Indeed, a group of twenty-four scientists representing public research institutions in seventeen states recently submitted a statement to the Environmental Protection Agency (EPA),¹⁴⁰ complaining that "[a]s a result of restricted access, no truly independent research can be legally con-

130. *Id.* at 1341.

131. *See, e.g., Monsanto Co.*, 342 F. Supp. 2d at 575 (holding restrictions on research fell within the scope of the patent monopoly and were lawful).

132. *See A Seedy Practice*, *supra* note 5, at 28.

133. *See id.*

134. *Id.*; *see also* Emily Waltz, *Under Wraps*, 27 NATURE BIOTECHNOLOGY 880, 880 (2009) ("Syngenta recently implemented a rule prohibiting any study that compares its commercial crops to other companies' crops . . .").

135. Stutz, *supra* note 11.

136. Andrew Pollack, *Crop Scientists Say Biotechnology Seed Companies Are Thwarting Research*, N.Y. TIMES, Feb. 20, 2009, at B3.

137. Waltz, *supra* note 134, at 881 ("Negotiations in 2008 between Monsanto and two universities—North Dakota State University and the University of Minnesota—broke down when Monsanto insisted on approving publication of any data on its newly commercialized transgenic sugar beets . . .").

138. Thomas W. Sappington et al., Commentary, *Conducting Public-Sector Research on Commercialized Transgenic Seed: In Search of a Paradigm That Works*, GM CROPS, Mar.–Apr. 2010, at 55, 56 (2009).

139. Pollack, *supra* note 136, at B3.

140. Stutz, *supra* note 11.

ducted on many critical questions regarding the technology.”¹⁴¹ The scientists submitted their statement anonymously, mindful that they were criticizing an industry from which they require cooperation in order to conduct their research.¹⁴²

However, the identities of several of the participants have since been revealed, and they include entomologists from the University of Minnesota, Cornell University, Purdue University, and North Dakota State University, among others.¹⁴³ The heart of the frustration felt by the scientists is reflected in a comment by Professor Elson J. Shields of Cornell, who stated that as a result of these research restrictions the industry has “the potential to launder the data,” and “[i]f your sole job is to work on corn insects and you need the latest corn varieties and the companies decide not to give it to you, you can’t do your job.”¹⁴⁴ Separately, there are also reports that scientists are intimidated by the industry, and that some have been personally and professionally threatened for publishing data with which the industry did not agree.¹⁴⁵

The companies, on the other hand, take a different view. They assert that they support academic research.¹⁴⁶ Monsanto, for instance, uses an academic research license that permits certain kinds of research.¹⁴⁷ The companies defend their need to manage public sector research in light of government regulations relating to exports, experiments with precommercial products, and protection of their substantial investments and intellectual property.¹⁴⁸ They acknowledge that it is important to maintain good relationships with academics because the companies rely on their expertise and often engage them to conduct certain studies.¹⁴⁹ The scientists argue that these justifications are not credible and are largely the producer’s effort to minimize the chances that negative data or information will be released about their products.¹⁵⁰

141. Anonymous Public Comment to Meeting Notice, 73 Fed. Reg. 75,099–75,101 (Dec. 10, 2008), Docket No. EPA-HQ-OPP-2008-0836-0043 (Feb. 9, 2009, 1:54 PM), <http://www.regulations.gov/#!documentDetailD=EPA-HQ-OPP-2008-0836-0043>. The text of the statement reads as follows: “Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited.” *Id.*

142. *Id.*

143. Pollack, *supra* note 136, at B3.

144. *Id.*

145. Stutz, *supra* note 11.

146. See Waltz, *supra* note 134, at 882.

147. *Id.* at 881.

148. *Id.*; Pollack, *supra* note 136, at B3.

149. Waltz, *supra* note 134, at 882.

150. Pollack, *supra* note 136, at B3. See generally Wagner, *supra* note 6.

C. REGULATORY SHORTCOMINGS

If patent law and its license restrictions permit producers of genetically modified crops to restrict and control research on the health effects of genetically modified foods, one may expect that there are checks in other areas of the government to protect consumers. Unfortunately, that does not appear to be the case. Outside of patent law, the regulatory policy choices on genetically modified products represent the belief that these products are not significantly different from their non-genetically engineered counterparts and that they are not inherently dangerous.¹⁵¹ Thus, their regulation occurs under statutes that were already in existence before the arrival of genetically modified technology.¹⁵² Scientists have assumed that the genes from one organism can be extracted and moved into another organism and that the gene will continue to operate exactly the same way that it did in the original organism.¹⁵³ The underlying assumption is that the mere fact that these products were created using biotechnology does not in itself create any unusual risks.¹⁵⁴ Accordingly, the approach was to focus on the ultimate product created and not the process that was used to create it.¹⁵⁵ But what if these assumptions are inaccurate? Recent evidence suggests, for instance, that a gene may express itself differently in a new organism than it did in the donor organism and that the context and environment in which a gene has been transferred may trigger certain unexpected reactions.¹⁵⁶

The three main agencies involved in the regulation of genetically modified foods are the Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA).¹⁵⁷ The FDA regulates genetically modified organisms (GMOs) that become food or drugs, the USDA regulates GMOs where they are existing crops, and the EPA regulates genetically modified pesticide products.¹⁵⁸ The shortcomings of the existing regulatory framework governing genetically modified products have been well documented and analyzed by other commentators.¹⁵⁹ As such, this Article will only pro-

151. See Mandel, *supra* note 81, at 2242.

152. *Id.* at 2242–43.

153. Mark B. Gerstein et al., *What is a Gene, post-ENCODE? History and Updated Definition*, 17 GENOME RES. 669, 672 (2007).

154. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, GUIDE TO U.S. REGULATION OF GENETICALLY MODIFIED FOOD AND AGRICULTURAL BIOTECHNOLOGY PRODUCTS, at i (Sept. 2001), http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_0901.pdf.

155. *Id.*

156. See Van Tassel, *supra* note 88, at 222; see also Vanessa E. Prescott et al., *Transgenic Expression of Bean α -Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity*, 53 J. AGRIC. FOOD CHEM. 9023, 9029 (2005) (describing genetically modified peas where animal testing revealed that the added protein was allergenic).

157. Mandel, *supra* note 81, at 2173.

158. *Id.* at 2216–17.

159. See, e.g., 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, 141–47 (2007); Mandel, *supra* note 81, at 2231–33.

vide a brief overview of the regulatory scheme to orient the reader.

Regulation of transgenic plants is divided into two areas: (1) regulation of the transgenic plant itself and (2) regulation of products derived from the transgenic plant.¹⁶⁰ The first consideration under regulation of the transgenic plant is whether it has been modified to produce a plant-incorporated protectant (PIP).¹⁶¹ A plant that produces a PIP is a plant that has been engineered to produce its own pesticide, such as Bt corn.¹⁶² Even if each of the agencies reviews a particular genetically modified plant, as it currently stands, their evaluations are not focused on overall human health.¹⁶³ Instead, for instance, the EPA and the USDA are evaluating the amount of pesticide residue in the plant, whether the plant is a plant pest, and whether the amount of pesticide is at or below the level deemed safe for consumption.¹⁶⁴ The producers of genetically modified products submit data to the respective agencies when required, and much of it is designated as confidential or trade secret information and not shared with the public or with researchers.¹⁶⁵ Accordingly, some argue that it is difficult to verify data that has been submitted to the government in support of approvals.¹⁶⁶

1. USDA

All transgenic plants are subject to regulation as a potential plant pest by the U.S. Department of Agriculture-Animal and Plant Health Inspection Service (APHIS). Anyone who wants to import, transport interstate, or release into the environment a “regulated article”¹⁶⁷ must apply for a permit or notify APHIS that an introduction will be made.¹⁶⁸ If a permit is sought, the applicant must submit an application with specific information about the proposed release.¹⁶⁹ APHIS then reviews the application to evaluate the potential risks.¹⁷⁰ APHIS can then issue the permit or

160. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 2.

161. *Id.* at 8.

162. *Id.* at 12.

163. *Id.*

164. *Id.* at iii.

165. Waltz, *supra* note 134, at 882.

166. See THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 9–10.

167. “‘Regulated articles’ are defined as any organism which has been altered or produced through genetic engineering . . . which [USDA] determines is a plant pest or has reason to believe is a plant pest.” *Id.* at 9 (alteration in original) (citing 7 C.F.R. § 340.1 (2009)).

“Section 403 of the PPA defines a plant pest as ‘a protozoan; a nonhuman animal; a parasitic plant; a bacterium; a fungus; a virus or viroid; an infectious agent or other pathogen,’ or similar articles that injure, damage, or cause disease in any plant or plant product.” *Id.*

168. *Id.* at 9–10.

169. Information required on a permit application includes the following: (1) donor organism(s); (2) recipient organism(s); (3) vector or vector agent(s); (4) description of the molecular biological mechanisms involved in the production of the regulated article; (5) description of the activity of the modified genetic material in the regulated article; (6) description of the purpose of the introduction; and (7) steps to control the article and associated biologic materials. *Id.* at 10 (citing 7 C.F.R. § 340.4 (2009)).

170. APHIS evaluates whether the transgenic plant will “(1) expose other plants to pathogens; (2) harm other organisms, including agriculturally beneficial organisms,

deny it.¹⁷¹ When the plant is ready for commercial release, a person may petition APHIS for nonregulated status.¹⁷² APHIS, based on accumulated evidence from the field trials, can make a determination that the regulated article does not pose a risk as a plant pest and that the previously regulated article will no longer be regulated.¹⁷³

In several instances, the USDA has been accused of not observing its regulations with sufficient rigor.¹⁷⁴ In a series of cases, the Agency has been criticized for deregulating genetically modified plants without first conducting a proper assessment of the risks or for finding that there will be no significant impact on the environment and obviating the need to prepare an environmental impact statement.¹⁷⁵ Just recently, the Supreme Court ruled on a case where the USDA had not prepared an environmental assessment before deregulating the growth of biotech alfalfa.¹⁷⁶ While the district court had entered an injunction banning the growth of biotech alfalfa because of this violation, the Supreme Court ruled that the genetically engineered alfalfa seeds could be planted on an interim basis while the agency completed its environmental impact statement.¹⁷⁷

2. EPA

If a plant produces a PIP it will be regulated by both EPA, under the Federal Fungicide Insecticide and Rodenticide Act (FIFRA),¹⁷⁸ and the USDA-APHIS, under the Plant Protection Act (PPA).¹⁷⁹ If the plant does not produce a PIP it will be regulated only by the USDA-APHIS.¹⁸⁰ The EPA is concerned with the plant's pesticidal properties while the USDA-APHIS is concerned with whether the plant is a "plant pest."¹⁸¹ Under FIFRA, the EPA regulates to ensure that the pesticide will not cause "unreasonable adverse effects on the environment,"¹⁸² which are defined as:

threatened and endangered species, and, in the case of plants that produce pesticides, organisms that are not the intended target of the pesticide (non-target organisms); (3) increase weediness in another species with which it might cross; (4) have an adverse effect on the handling, processing or storing of commodities; or (5) threaten biodiversity." *Id.*

171. *See id.* at 11.

172. *Id.* at 11–12.

173. *Id.* (citing 7 C.F.R. § 340.6 (2009)).

174. Mandel, *supra* note 81, at 2232.

175. *See, e.g.*, Ctr. for Food Safety v. Vilsack, No. C 08-00484 JSW, 2009 WL 3047227, at *9 (N.D. Cal. Sept. 21, 2009) (finding that APHIS failed to prepare an environmental impact statement before deregulating a genetically engineered sugar beet); Int'l Ctr. for Tech. Assessment v. Johanns, 473 F. Supp. 2d 9, 27–29 (D.D.C. 2007) (finding that APHIS failed to, among other things, list genetically engineered bluegrass as a noxious weed and ignored its own regulations).

176. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2750–51 (2010).

177. *Id.* at 2759–60.

178. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 12.

179. Mandel, *supra* note 81, at 2229 tbl. 1.

180. *Id.*

181. *Id.* at 2237 tbl. 2.

182. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 12 (citing 7 U.S.C. § 136a(c)(5) (2000)).

(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [standard under the] Federal Food, Drug, and Cosmetic Act.¹⁸³

EPA regulation of transgenic plants that produce PIPs starts during the developmental stage.¹⁸⁴ Prior to approval for commercial release, the EPA regulates pesticides through either the notification process or experimental use permits (EUP).¹⁸⁵ The size of a proposed field test will determine whether notification or an EUP is required.¹⁸⁶ When the product is ready for commercial release, it must go through the EPA's pesticide registration process¹⁸⁷ unless it qualifies for an exemption from registration.¹⁸⁸ Finally, if residue from the pesticide produced by the plant presents a human dietary risk resulting from its use on or in food, the EPA is charged, under the Federal Food, Drug, and Cosmetic Act (FFDCA), with setting tolerance levels for that pesticide.¹⁸⁹

3. FDA

Under the FFDCA, the FDA categorizes substances that are added to foods as either food additives or "generally recognized as safe" (GRAS).¹⁹⁰ This distinction bears significance because, while food additives require premarket review and approval by the FDA,¹⁹¹ those cate-

183. *Id.* (alteration in original) (citing 7 U.S.C. § 136(bb) (2000)).

184. Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37,772, 37,785 (July 19, 2001) (to be codified at 40 C.F.R. pts. 152, 174).

185. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 12.

186. Notification is required for a field test of less than ten acres of land or one acre of water, an EUP is required for a field test up to 5,000 acres, and field tests larger than 5,000 acres generally require full registration. *Id.* (citing 7 U.S.C. § 136(c) (2000)).

187. *Id.* at 13. To obtain a registration "the applicant must show that the pesticide 'when used in accordance with widespread and commonly recognized practice, . . . will not generally cause unreasonable adverse effects on the environment.'" *Id.* (alteration in original) (citing 7 U.S.C. § 136a(c)(5) (2000)). "EPA's evaluation includes an assessment of data from tests done by the producer of the pesticide according to EPA guidelines, and an evaluation of whether a pesticide has the potential to cause adverse effects on humans, wildlife, fish and plants." *Id.*

188. "FIFRA allows EPA to exempt from registration requirements a pesticide or category of pesticides for which registration is not necessary to meet the goal of environmental protection." *Id.* (citing 7 U.S.C. § 136w(b)(2) (2000)). "To qualify for an exemption . . . a pesticide must pose a low probability of risk to the environment . . . and be unlikely to cause unreasonable adverse effects to the environment even in the absence of regulatory oversight." *Id.* (citing 40 C.F.R. § 152.25 (2000)). "If a pesticide or its chemical residue may appear in food, then it can only meet exemption criteria if it also meets the food safety standard under the FFDCA that 'there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'" *Id.* (citing 21 U.S.C. § 346a(c)(2)(A) (2000)).

189. *Id.* (citing 21 U.S.C. § 356a(a)(1) (2000)).

190. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 20.

191. *Id.* (alteration in original) (citing 21 C.F.R. § 170.3(i) (2000)).

gorized as GRAS require no FDA approval.”¹⁹² The FDA treats genetically modified foods, which are not expressly provided for in the FFDCA, as GRAS; as such, they are not subject to FDA approval.¹⁹³ It is the manufacturer that determines whether a product is GRAS, without review by the FDA.¹⁹⁴ There is, however, a voluntary process by which the manufacturer can seek guidance from the FDA on whether a substance is GRAS.¹⁹⁵ Under this voluntary process, the determination of safety rests with the manufacturer.¹⁹⁶

In short, neither premarket testing nor FDA approval is required before genetically modified plant foods are sold to consumers.¹⁹⁷ Furthermore, genetically modified foods are not required to be labeled because they are not considered substantially different from their conventional counterparts.¹⁹⁸ Incidentally, this also raises a question about how a product could be substantially equivalent to its non-genetically modified counterpart for FDA purposes, yet it had to have been substantially different to receive a patent.¹⁹⁹

D. TREATMENT OF GENETICALLY MODIFIED FOODS VERSUS DRUGS

The approach that the United States has taken to regulating genetically modified foods stands in stark contrast to the regulation of drugs, which are also ingested by most American consumers. The pharmaceutical industry is also an appropriate analogous point of reference because it too relies heavily on patenting.²⁰⁰ Unlike genetically modified foods, after the patent issues on a drug (and in usual fashion the patent prosecution process does not take into consideration the consequences of use of the invention), there is a regulatory regime in place to approve drugs before they reach the consumer.²⁰¹ While not without its shortfalls,²⁰² FDA oversight exists while tort law, through products liability actions, also helps to identify those drugs that cause injury to consumers.²⁰³

Before a drug is approved, its manufacturer must establish to the FDA

192. *Id.* (citing 21 U.S.C. § 321(s) (2000); 21 CFR § 170.30 (2000)).

193. 21 U.S.C. § 321(s) (2000).

194. THE PEW INITIATIVE ON FOOD AND BIOTECHNOLOGY, *supra* note 154, at 21.

195. *Id.* (citing 21 C.F.R. § 107.35(c)(4) (2000)).

196. *Id.* at 20–21.

197. Van Tassel, *supra* note 88, at 241.

198. Mandel, *supra* note 81, at 2219.

199. Analysis of this question is beyond the scope of this Article. However, consideration of the various standards involved would lead to a better understanding of how it may be possible to reconcile these apparent contradictions. See *supra* note 81 and accompanying text; see also MERGES ET AL., *supra* note 101, at 209 (noting that to meet the novelty requirement under the Patent Act an invention must be different from that which already exists).

200. See Christine D. Galbraith, *Dying to know: A Demand for Genuine Public Access to Clinical Trial Results Data*, 78 Miss. L.J. 705, 757–58 (2009).

201. Victor E. Schwartz & Phil Goldberg, *A Prescription for Drug Liability and Regulation*, 58 OKLA. L. REV. 135, 141–31 (2005).

202. See Galbraith, *supra* note 200, at 712 (arguing that the results of clinical trial data should be public).

203. *Wyeth v. Levine*, 129 S. Ct. 1187, 1200 (2009).

that it is safe and effective for humans.²⁰⁴ Thus, the pharmaceutical company must file an Investigational New Drug Application (IND) prior to conducting clinical trials with humans.²⁰⁵ The IND provides information about earlier studies conducted with the drug in the laboratory and on animals.²⁰⁶ This is then followed by three stages of clinical trials using human subjects.²⁰⁷ If the results of these trials indicate that the drug is likely to be approved, the company will then file a New Drug Application (NDA) with the FDA, providing the data and results from the clinical trials.²⁰⁸ Upon reviewing all of this data, the FDA will determine whether the drug is safe, effective, and worthy of approval.²⁰⁹ While these clinical trial results are generally treated as trade secrets by the FDA and are not revealed to the public,²¹⁰ there is some level of assurance in knowing that the FDA has reviewed the positive and negative data about a drug before it is made available for public consumption.²¹¹ Such is not the case, however, with genetically modified products.²¹²

Moreover, to the extent that there are flaws in the FDA process that would permit approval of drugs that are nonetheless harmful to patients, tort and criminal laws serve as a check on pharmaceuticals that may cause harm. For instance, in 2004, the New York Attorney General filed suit against the maker of Paxil® for misrepresenting the safety of the drug for use in children and adolescents.²¹³ Thousands of products liability lawsuits were also filed accusing Merck & Co.'s Vioxx® of increasing the risks of myocardial infarctions and stroke.²¹⁴ The discovery of these side effects was supported by a number of studies and publications in the scientific literature.²¹⁵ Several diet drugs have also been the subject of similar claims, resulting in class actions.²¹⁶

With genetically modified foods, however, the tort system is not a feasible option. Since consumers are generally unaware that they have even consumed a genetically modified food, it becomes very difficult to estab-

204. 21 U.S.C. § 355(d)(2), (5) (2006).

205. 21 C.F.R. § 312.20(b) (2008); *see also* Schwartz & Goldberg, *supra* note 201, at 142.

206. 21 C.F.R. § 312.22(c) (2008).

207. 21 C.F.R. § 312.21 (2008).

208. 21 U.S.C. § 355(b)(1) (2006); 21 C.F.R. § 314 (2008).

209. 21 U.S.C. § 355(d) (2006); 21 C.F.R. § 314.125(a) (2009).

210. Availability of Records and Information, 42 Fed. Reg. 3094 (Jan. 14, 1977).

211. *But see* Galbraith, *supra* note 200, at 705, 710–13 (identifying weaknesses in the FDA review process).

212. Mandel, *supra* note 81, at 2218–21.

213. Complaint at 1, *State v. GlaxoSmithKline, P.L.C.*, No. 905-03 (N.Y. Sup. Ct. filed Feb. 13, 2003), 2003 WL 22023372.

214. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 571 (E.D. La. 2005); *see also Merck Agrees to Settlement over Vioxx Ads*, N.Y. TIMES, May 21, 2008, at C3.

215. *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d at 571.

216. *See, e.g., In re Diet Drugs Prods. Liab. Litig.*, 282 F.3d 220, 225 (3d Cir. 2002); *Vioxx Clinical Study*, CLINICAL STUDY RESULTS.ORG, http://www.clinicalstudyresults.org/search/?company_id=40&-drug_name_id=438-r=1&submitted=1&page=1 (last visited Oct. 31, 2010); *Wyeth Seeks to Delay Payments to Some in Fen-Phen Settlement*, N.Y. TIMES, May 6, 2004, at C8.

lish a causal connection between the product and any resulting injury.²¹⁷ Moreover, without the requisite research to evaluate genetically modified foods, it is almost impossible for a plaintiff to show that the risk of harm was foreseeable,²¹⁸ or conversely, independent research could also reveal that the products pose very little risk. Further drawing on the food versus drug comparison, in a subsequent section this Article draws an analogy between regulatory treatment of generic drugs and genetically modified foods, suggesting that the FDA's assumptions about the equivalence of genetically modified foods, at best, does not alleviate the need for independent research on these substances and, at worst, could be faulty.²¹⁹

E. COMPARISON TO THE EUROPEAN APPROACH

Other countries have taken a different approach from the United States in light of the lack of knowledge about genetically modified foods.²²⁰ European patent law, for instance, considers the morality of the invention in assessing suitability for patenting.²²¹ The European approach to genetically modified products has also been much more cautious. Indeed, many European countries have banned the planting of genetically modified crops²²² and restricted importation of products such as bioengineered corn from American companies like Monsanto, Dow AgroSciences, Pioneer Hi-Bred, and Syngenta.²²³ European countries tend to view genetically modified foods as "Frankenstein food."²²⁴ The French government, for instance, banned genetically modified crops in 2008.²²⁵ The European Commission is now considering a proposal to allow individual member countries to decide whether they wish to grow genetically modified crops.²²⁶

IV. PATENT OVERREACHING

While the predominant narrative supporting the patent system is that patents exist to encourage innovation, we often overlook the fact that the

217. For a thoughtful analysis of genetically modified products and the tort system see Katharine Van Tassel, *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Identify*, 72 U. CIN. L. REV. 1645, 1678–85 (2004).

218. *Id.* at 1684–86.

219. See *infra* Part IV.B.

220. Japan has chosen to heavily regulate genetically modified foods because of their unknown consequences. See Paul J. Heald & James Charles Smith, *The Problem of Social Cost in a Genetically Modified Age*, 58 HASTINGS L.J. 87, 88 (2006). Similar to South Korea, Australia, and New Zealand, Japan requires labeling for food products containing genetically modified foods. *Id.* at 112.

221. Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 103, 202 (2002).

222. Langreth & Herper, *supra* note 57, at 66.

223. Kanter, *supra* note 51, at B4.

224. David G. Owen, *Bending Nature, Bending Law*, 62 FLA. L. REV. 569, 575–76 (2010).

225. Kanter, *supra* note 51, at B4.

226. *Id.*

primary concern of the patent system is the public interest.²²⁷ The constitutional clause granting Congress the power to establish the patent laws recognizes the importance of “promot[ing] the [p]rogress of [s]cience.”²²⁸ This underlying premise is consistent with intellectual property principles that preserve information in the public domain unless it can specifically be claimed under one of the branches of intellectual property law, support incentives for investments in research, and recognize the full disclosure of information to the public as a worthy exchange in the patent bargain with an inventor.²²⁹

As part of that bargain, Congress (and the Founding Fathers) could not have intended that the public benefit received from disclosure on a patent would be less than the value of the patent.²³⁰ If that were the case, the inventor would receive a windfall. As a court has noted, “[t]he far-reaching social and economic consequences of a patent . . . give the public a paramount interest in seeing that patent monopolies . . . are kept within their legitimate scope.”²³¹ Accordingly, patents on genetically modified plants that not only grant a monopoly to the patent holder but also restrict any research that may identify risks to the public health from use of these patented materials go too far. According to the Supreme Court: “[i]nnovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system . . . [t]his is the standard expressed in the Constitution and it may not be ignored.”²³² If patent laws are intended to promote the progress of science, then it seems intuitive that active discouragement of independent research does not support scientific advancement and, ultimately, is inconsistent with the underlying goals of patent law and policy. If the goal is to encourage innovation, there cannot be innovation without scientific inquiry and research.

A. PROTECTING OR OVERREACHING?

It is important to be mindful of overreaching intellectual property laws that provide “protection” above and beyond that which was intended. While in other contexts this may be considered abuse by the individual rights holder, here, however, the system—the courts and the legislature—has created and sanctioned the conduct. Accordingly, it is not the indi-

227. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330–31 (1945) (“The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure.”); see also *United States v. Line Material Co.*, 333 U.S. 287, 320 (1948) (Douglas, J., concurring).

228. U.S. CONST. art. I, § 8, cl. 8.

229. James Bradshaw, *Gene Patent Policy: Does Issuing Gene Patents Accord with the Purposes of the U.S. Patent System?*, 37 WILLAMETTE L. REV. 637, 645 (2001).

230. See, e.g., *In re Fisher*, 427 F.2d 833, 839 (C.C.P.A. 1970) (noting that the scope of a patent must be commensurate with the scope of what the patentee has given the public).

231. *Mayo Clinic Jacksonville v. Alzheimer’s Inst. of Am., Inc.*, 683 F. Supp. 2d 1292, 1295 (M.D. Fla. 2009).

232. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 6 (1966).

vidual corporations that are to be blamed for protecting their interests but rather the laws that serve as the thumb on the scale in their favor and to the potential detriment of the public interest. In the case of genetically modified foods, the license agreements, in addition to the patent rights, create cause for concern and reflect another example of intellectual property laws providing far greater protection than contract law alone would provide in a typical license.

The “bag tag” licenses with the seeds are similar to “shrink-wrap” licenses used on software. The terms of the license are on the product, and the consumer impliedly accepts the terms of the license by purchasing and using the product.²³³ In copyright law, courts have upheld “shrink-wrap” and “click-wrap” licenses.²³⁴ Often these cases rely on the fact that the consumer was made aware of the terms at the time of sale, acknowledged that awareness, and had an opportunity to decline the terms by, for instance, returning the product.²³⁵ It is not clear that these terms are met when a notice is posted on a bag of corn seeds.²³⁶ Furthermore, it is now nearly impossible for a commodity farmer to avoid using seeds from any of the companies that require these licenses.²³⁷

It is therefore not unusual that intellectual property laws are used to restrict consumers or shield information from the public. Granted, there are often legitimate reasons to do so, and trade secret law in conjunction with a complicated regulatory scheme allows companies to keep proprietary information from public view.²³⁸ Indeed, before it was acceptable to protect plants with patents, producers used trade secret law to protect their innovations.²³⁹ In another example involving copyright law, the Digital Millennium Copyright Act (DMCA) declares it copyright infringement to “circumvent a technological measure” that is used to encrypt or protect information in digital form.²⁴⁰ This meant, for instance, that a college professor may not make a one-minute clip from a movie on a DVD to teach a class, even though without the legislation that kind of use would probably be permissible fair use. Accordingly, the DMCA has been criticized for going too far to protect copyright owners at the expense of the public.²⁴¹ Recognizing that the DMCA anticircumvention

233. *Specht v. Netscape Commc'ns Corp.*, 306 F.3d 17, 22 n.4 (2d Cir. 2002); *see also* *Bowers v. Baystate Techs., Inc.*, 320 F.3d 1317, 1324 (Fed. Cir. 2003) (upholding the validity of shrinkwrap licenses).

234. *See, e.g., ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1952–53 (7th Cir. 1996); *see also* *Patterson*, *supra* note 122, at 189.

235. *Patterson*, *supra* note 122, at 189–90.

236. *See id.*

237. *See, e.g., supra* notes 3, 55–58 and accompanying text.

238. *See* Elizabeth A. Rowe, *Striking a Balance: When Should Trade-Secret Law Shield Disclosures to the Government?*, 96 IOWA L. REV. 791, 807–15 (2011).

239. *See supra* Part II.A.2.

240. 17 U.S.C. § 1201(a)(1)(A) (2006).

241. Christina Bohannon, *Reclaiming Copyright*, 23 CARDOZO ARTS & ENT. L.J. 567, 591 (2006); John B. Clark, *Copyright Law and the Digital Millennium Copyright Act: Do the Penalties Fit the Crime?*, 32 NEW ENG. J. ON CRIM. & CIV. CONFINEMENT 373, 402–03 (2006); Kevin C. Earle, *No-Copy Technology and the Copyright Act: Has the Music Industry Been Allowed to Go Too Far in Diminishing the Consumers' Personal Use Rights in the*

provisions go too far in reaching otherwise noninfringing conduct, the Copyright Office has recently issued certain exemptions to the provisions; thus, a college professor may now create the clip, and a cell phone user can “unlock” his or her phone to be used with a network carrier of his or her choice.²⁴²

B. FORBIDDING RESEARCH—CROSSING THE LINE?

The research restrictions that are the focus of this Article are even more troubling than the kinds of limitations imposed under copyright law. The fact that these no-research clauses could pose a direct threat to public health and safety and because they involve our food supply, it makes the call for action all the more compelling. These licenses provide greater restrictions than patent law itself allows. Some commentators have argued, for instance, that the license terms are inconsistent with the patent exhaustion doctrine, which allows the purchaser of a patented product to use it without owing further duties to the patent owner.²⁴³ Why is it that one can purchase a car with patented components, take it apart, repair it, and sell it, but a farmer cannot do the same with his or her seeds? As the editors of *Scientific American Magazine* have argued, “when scientists are prevented from examining the raw ingredients in our nation’s food supply or from testing the plant material that covers a large portion of the country’s agricultural land, the restrictions on free inquiry become dangerous.”²⁴⁴ It should be apparent that knowledge restrictions involving food and its safety ought to receive closer scrutiny than other consumer commodities, or at least as much as that received by pharmaceuticals.

In the analogous context of pharmaceuticals, congressional action²⁴⁵ and current Supreme Court jurisprudence allow others to conduct research on patented drugs and medical devices as long as it is the kind of research that is reasonably related to a submission to the FDA.²⁴⁶ Since this exemption allows even commercial competitors to experiment without infringing, it probably also allows academic researchers to do so and

Digital World?, 2 J. MARSHALL REV. INTELL. PROP. L. 337, 352 (2003); Thomas A. Mitchell, Note, *Copyright, Congress, and Constitutionality: How the Digital Millennium Copyright Act Goes too Far*, 79 NOTRE DAME L. REV. 2115, 2133 (2004).

242. Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 75 Fed. Reg. 43,825 (July 27, 2010) (to be codified at 37 C.F.R. pt. 201).

243. See, e.g., Kevin Rodkey, *Exhaustion and Validity of Single-Use Licenses for Transgenic Seeds in the Wake of Quanta v. LG Electronics*, 19 FED. CIR. B.J. 579, 603–04 (2010); Jon Sievers, Note, *Not So Fast My Friend: What the Patent Exhaustion Doctrine Means to the Seed Industry After Quanta v. LG Electronics*, 14 DRAKE J. AGRIC. L. 355, 371–74 (2009).

244. *A Seedy Practice*, supra note 5, at 28.

245. 35 U.S.C. § 271(e)(1) (1994) (creating a “safe harbor” exemption for research).

246. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (interpreting section 271’s safe harbor provision to extend to “all uses of patented inventions that are reasonably related to the development and submission of any information to [to the FDA]”).

takes away a patent holder's ability to claim infringement on such activities.²⁴⁷ If Congress and the Court have seen fit to issue this kind of exemption for patented pharmaceuticals, a similar move for genetically modified foods seems logical. Indeed, it appears that the pharmaceutical exemption has already been interpreted broadly to reach beyond drugs.²⁴⁸

This suggests that the research conduct that is prohibited through the license agreements and patent law may be otherwise permissible, given the broad interpretation of the Supreme Court's holding in *Merck v. Integra*. These restrictions may be ripe for congressional legislation that would make them void as a matter of public policy.²⁴⁹ Alternatively, *Merck* and the direction that we are headed with drug research suggest that courts (even without congressional action) may consider, on a case-by-case basis, how to deal with research restrictive licenses in cases involving genetically modified foods. One could, for instance, envision litigation similar to the Myriad case involving BRACA1 where a group of academic researcher plaintiffs (such as the group that submitted the anonymous statement to the EPA) challenge their inability to conduct basic research to determine whether genetically modified foods are safe to consume.²⁵⁰

Restricting research has far-reaching consequences that go beyond merely protecting the patent holder's intellectual property rights and also insulates the patent holder from the potentially harmful consequences of his or her invention. Without sufficient research to expand the state of knowledge about genetically modified products that enter consumers' bodies, consumers and legislators are unable to make choices about whether and to what extent to consume or regulate these products. Furthermore, unlike with pharmaceuticals, if injury were to occur, potential plaintiffs are, in effect, locked out of the tort system.²⁵¹ Without research, the state of knowledge cannot establish foreseeability of harm, and because plaintiffs bear the burden of proving foreseeability, the patent-holding manufacturer is insulated from liability.²⁵² Thus, the results are failures in the system where checks and balances are eliminated, and the power of a patent does not serve the progress of science or enrich the public knowledge, but instead enriches and insulates a patent holder at the expense of the public.

247. See Christina M. Gagnier, Comment, *Running Cases Through a Merck Sieve: Biopharmaceutical Research in the Wake of Merck v. Integra*, 12 INTELL. PROP. L. BULL. 159, 172-73 (2008).

248. See, e.g., *Classen Immunotherapies, Inc. v. King Pharm., Inc.*, 466 F. Supp. 2d 621, 625 n.2 (D. Md. 2006) (applying exemption to "research tools"); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 381 F. Supp. 2d 452, 456 (D. Md. 2005) (protecting the gathering of vaccine data after the vaccine has been approved by FDA); *Genentech, Inc. v. Insmad, Inc.*, 436 F. Supp. 2d 1080, 1094 (N.D. Cal. 2006) (protecting activities conducted for commercial purposes where the results were used to get FDA approval).

249. See discussion *infra* notes 279-82 and accompanying text.

250. See discussion *infra* notes 286-91 and accompanying text.

251. See Van Tassel, *supra* note 217, at 1678-85.

252. See *id.*

Even without patent law and contractual research restrictions, it has already been suggested that scientific research and results made public by manufacturers can be questionable.²⁵³ For example, when required to produce studies, manufacturers sometimes contract with university scientists or other laboratories, and these contracts generally allow the manufacturer to retain ownership of the results and to control its publication.²⁵⁴ This allows for adverse research findings to be concealed or for further studies to be commissioned that will produce more positive results.²⁵⁵ This practice is consistent with some of the complaints that have already been lodged by academic scientists against the industry.²⁵⁶ Further, it makes the case for much more research, by a wider group of scientists, in an area about which we know so little, even more persuasive.

Finally, another example from the pharmaceutical industry provides further reason to question regulators' assumptions about genetically modified foods. As noted earlier, these products are not required to be labeled because they are assumed to be "essentially the same" as their non-genetically modified counterparts.²⁵⁷ Similarly, generic drugs are assumed to be the same as their branded counterparts as long as they contain bioequivalent levels of the active ingredient.²⁵⁸ However, researchers have noted that generic drugs are not the same as the brand-name drug because, for example, they have different inactive ingredients and patients sometimes have different reactions to the generic drug than to the brand-name drug.²⁵⁹ Accordingly, this suggests a further threat to public health from the information void surrounding genetically modified foods.²⁶⁰ Not only might the assumption of equivalence between the genetically modified and non-genetically modified foods be faulty but, unlike with a generic drug, the consumer is not aware that he or she is consuming the genetically modified (generic) version of a food and cannot make an informed decision about whether to switch to the non-genetically modified (branded) version in case of a negative outcome.²⁶¹

253. See *supra* notes 138–46 and accompanying text.

254. See, e.g., Gail Charnley & Jacqueline Patterson, *Use of Human Subjects Data for Regulating Chemical Exposures*, 33 ENVTL. L. REP. 10,923, 10,927 (2003) (referring to pesticide manufacturers' use of contract laboratories to conduct testing).

255. See, e.g., David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence from a National Survey of Faculty*, 277 J. AM. MED. ASS'N 1224, 1224 (1997); Drummond Rennie, Editorial, *Thyroid Storm*, 277 J. AM. MED. ASS'N 1238, 1242–43 (1997); Steven A. Rosenberg, *Secrecy in Medical Research*, 334 N. ENG. J. MED. 392 (1996); Wagner, *supra* note 6, at 1707–08.

256. See *supra* notes 140–45 and accompanying text.

257. See *supra* notes 151–52, 198 and accompanying text.

258. See Susan J. Shaw & Adam L. Hartman, *The Controversy Over Generic Antiepileptic Drugs*, 15 J. PEDIATRIC PHARMACOLOGY & THERAPEUTICS 81, 82 (2010).

259. See *id.* at 87; see also Lesley Alderman, *A New Disquiet About Generic Drugs*, N.Y. TIMES, Dec. 19, 2009, at B6.

260. See *supra* notes 90, 153–56 and accompanying text.

261. See *supra* notes 90, 153–56 and accompanying text.

C. PROPOSING A "PATENT OVERREACH" DOCTRINE AND GREATER ACCESS

Professor Margo Bagley has argued that the "patent first, ask questions later" approach used in the United States is bad policy.²⁶² The issues that arise with patenting genetically modified foods support her argument. Indeed, it illustrates an extreme angle on the problem because it represents patenting first, asking questions later, and *shutting off* the research necessary to answering the question. While patent law generally does not concern itself with morality, if it exists to serve (or at least not harm) the public interest, then we ought to be troubled by the implications of this new direction.

The Supreme Court has recognized that "Congress in the exercise of the patent power may not overreach the restraints imposed by the stated constitutional purpose. Nor may it enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby."²⁶³ The patent system should therefore be imbued with a sense of social responsibility, such that the powers granted under a patent are not stretched to such an extent that the public interest is subjugated to a point where public health and safety may be compromised. This is a broader consideration than moral utility or other such considerations that are specific to the grant of a patent to an inventor.

One way to ensure that the public interest is directly considered would be to create a judicial doctrine to be used by courts when determining whether certain restrictions are within a patent right. It would serve as a limiting principle to avoid undue expansion of a patent's power to exclude. This Article thus suggests and coins a "patent overreach" doctrine that courts could rely on in refusing to enforce license agreements that restrict research. This outcome is justified where, on balance, the public interest in access to more information about the effects of genetically modified products outweighs any legitimate interest in enforcement of these agreements. Such agreements, at worst, may have the effect of concealing substantial health and safety dangers and, at best, limit or control the body of independent research available on genetically modified foods.

The patent overreach doctrine is consistent with the existing doctrine of patent misuse that forbids an impermissible broadening of a patent beyond the scope of the patent rights.²⁶⁴ While generally used in the antitrust context, the patent misuse doctrine has some flexibility to restrain practices that go beyond anticompetitive conduct and to broader violations of public policy.²⁶⁵ Thus, one possible iteration of the patent over-

262. Bagley, *supra* note 108, at 474-75.

263. *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 5-6 (1966).

264. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1339 (Fed. Cir. 2006); *Va. Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992).

265. See *SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1047 (N.D. Ill. 2003) (Posner, J.), *aff'd*, 365 F.3d 1306 (Fed. Cir. 2004), *vacated en banc*, 403 F.3d 1328

reach doctrine could be an expansion of the patent misuse doctrine to cover conduct that goes beyond the scope of a patent and which is contrary to the public interest, such as undue restrictions on scientific research or inquiry. Where patent overreaching violates our sensibilities about justice and fairness and potentially threatens public health and safety, courts (and the legislators in their own context) should take notice in order to protect the public interest. As several members of the Supreme Court have noted, sometimes too much patent protection can obstruct rather than promote scientific progress.²⁶⁶

Beyond addressing enforcement of the license restrictions, the greater problem of researchers' access to the patented genetically modified products will also need to be addressed in a meaningful way. PVP certificates specifically provide an exemption for bona fide research.²⁶⁷ A similar exemption for plant utility patents is worth considering, as it would both allow the patent holder to exclude others yet permit independent research. Similar exemption schemes are already recognized and in place under the patent law for analogous inventions that involve public health and safety.²⁶⁸ Congress has created exemptions from patent infringement for germplasm in the PVPA,²⁶⁹ for development of generic drugs,²⁷⁰ and for doctors using patented surgical procedures.²⁷¹ The research exemption for pharmaceuticals and medical devices, for instance, permits the balancing of the same kinds of public interests that are at issue here.²⁷²

While easing the license restrictions would mean that scientists can access the products through farmers without either party being liable for patent infringement, direct access from the companies may continue to be an issue unless private arrangements can be made. So far, the seed companies will not agree to remove the "bag tag" restrictions on research. However, they have expressed a willingness to enter into academic licenses with researchers.²⁷³ A public repository could be another option as a source of seeds for bona fide research. Indeed, the PVPA requires applicants for plant variety protection to deposit seeds or other reproduc-

(Fed. Cir. 2005); *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1372 (Fed. Cir. 1998) ("Patent misuse is viewed as a broader wrong than antitrust violation . . ."); *Mallinckrodt, Inc.*, 976 F.2d at 704 ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that drew anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.")

266. *See, e.g.*, *Bilski v. Kappos*, 130 S. Ct. 3218, 3254–55 (2010) (Stevens, J. concurring); *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 127 (2006).

267. 7 U.S.C. § 2544 (2006).

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

269. *Id.*

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

271. 35 U.S.C. § 287(c)(1) (2006) (exempting health care professionals from infringement of certain patented medical techniques).

272. *Id.*

273. In response to the complaint to the EPA, the seed companies have expressed an interest in being more cooperative with researchers. However, researchers are skeptical about the nature and extent of the companies' true commitment to sharing. *See Stutz, supra* note 11.

tive material in a public repository.²⁷⁴ However, the Supreme Court, in dicta, has stated that the public has no right to seeds deposited in connection with applications for plant variety protection during the term of protection.²⁷⁵ Examination of operations at these public repositories confirms the Supreme Court's statement that seeds deposited under certification are not released to the public without the consent of the certificate holder.²⁷⁶ Thus, options to create access are not without hurdles and will require thoughtful and balanced consideration.

Finally, even if the end-products containing the genetically modified substances may be commercially available and thus accessible to researchers, this does not solve the problem. Because genetically modified products are not labeled,²⁷⁷ a researcher walking into the supermarket to purchase the product is presumably in the same position as other consumers in that he or she is unable to identify the genetically modified foods. Perhaps, unlike the consumer, the researcher could perform tests after making the purchase to identify the components of the food product. However, this nonetheless creates a hurdle and a burden. Furthermore, because the end-product will be a combination of substances, it may be difficult to sufficiently isolate the genetically modified material and its effect.²⁷⁸ Accordingly, this option does not provide a viable substitute for access to genetically modified materials that may be subject to the no-research restrictions.

D. THE LARGER ISSUE OF PUBLIC POLICY AND PATENTING

The protection of public health and safety may be the most important in the hierarchy of public policies. Several states have recognized, for instance, that it is against the public interest to enter into settlement agreements that shield information about dangers to the public's health and safety.²⁷⁹ Similar public policy carve-outs have also been made in the employment law area to permit whistle-blowing by employees despite their having signed confidentiality agreements.²⁸⁰ One legislative option would be for Congress to rule these kinds of contracts that restrict research void as a matter of public policy. However, until that happens courts could, relying on the patent overreach doctrine, find that these contracts violate the public interest.

274. Chen, *supra* note 38, at 140–41.

275. *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143 (2001) (stating that the PVPA “requires a deposit of seed in a public depository . . . but neither the statute nor the applicable regulation mandates that such material be accessible to the general public during the term of the PVP certificate”).

276. Chen, *supra* note 38, at 140–41.

277. *See supra* note 257 and accompanying text.

278. *See supra* notes 98–99 and accompanying text.

279. *See* Elizabeth E. Spainhour, *Unsealing Settlements: Recent Efforts to Expose Settlement Agreements That Conceal Public Hazards*, 82 N.C. L. REV. 2155, 2158–61 (2004) (discussing state laws, like Florida's, that declare private settlements that conceal public hazards void as a matter of public policy).

280. *See* EMPLOYMENT LAW § 8.9, at 262 (Mark A. Rothstein et al. eds., 2d ed. 1999) (discussing the erosion of the employment at will doctrine).

According to the Second Restatement of Contracts, a contract is unenforceable for public policy reasons if either “legislation provides that it is unenforceable or the interest in its enforcement is clearly outweighed in the circumstances by a public policy against the enforcement of such terms.”²⁸¹ Thus, in this instance, the public interest in promoting independent research on the health and safety effects of foods should outweigh the producer’s interest in controlling the state of adverse information available about its product. Indeed, the last time Congress considered and debated the balance between protection for seed producers and the public, under the PVPFA, it demonstrated a clear preference for and recognition of the importance of research.²⁸²

The problem identified in this Article illustrates a larger question in patent policy: how do we reconcile patent rights with the public interest when the patent rights may threaten public health and safety? Similar concerns have been raised about the patenting of human genes.²⁸³ The genes associated with breast cancer, BRACA1 and BRACA2, are owned and patented by Myriad Genetics.²⁸⁴ Myriad’s control over these genes have been widely criticized for prohibiting independent research on the genes, thus interfering with women’s health and physician’s treatment practices.²⁸⁵ Indeed, a few months ago, a New York district court granted a victory to the American Civil Liberties Union and other researcher–plaintiffs²⁸⁶ who challenged the validity of Myriad’s patents.²⁸⁷ The case exemplifies the concern, as with the genetically modified products, that a patent holder has the power to impede research that could potentially harm the public.²⁸⁸

This Article recommends a solution-based approach focused on the larger, macro issues about obligations and policies of the patent system, rather than the more specific questions about the propriety of issuing patents on specific inventions or the class of inventions comprising genetically modified substances. It is important to recognize and balance the interests of all the stakeholders involved here. Inventors and businesses need to protect their investment in research and development. Accordingly, this is by no means a call to eliminate these patents. However,

281. RESTATEMENT (SECOND) OF CONTRACTS § 178 (1981).

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

283. See, e.g., Eric D. Zard, Comment, *Patentability of Human Genetic Information: Exploring Ethical Dilemmas Within the Patent Office and Biotechnology’s Clash with the Public Good*, 6 U. ST. THOMAS L.J. 486, 504–11 (2009) (discussing opposing sides of the controversy on gene patenting); Brian Zadorozny, Comment, *The Advent of Gene Patenting: Putting the Great Debate in Perspective*, 13 SMU SCI. & TECH. L. REV. 89, 104–13 (2009) (same).

284. *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 181 (S.D.N.Y. 2010).

285. Complaint at 29, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181 (No. 09-CV-04515), 2009 WL 1343027, at *29.

286. These plaintiffs are researchers who received cease and desist letters from Myriad for conducting research using the genes. *Id.*

287. *Ass’n for Molecular Pathology*, 702 F. Supp. 2d at 238 (granting summary judgment in favor of plaintiffs and against Myriad).

288. See *id.* at 206–11.

because the public's interest must also be safeguarded, one would, at a minimum, see the logic in removing research restrictions.

Some commentators have suggested that perhaps we should change the way patents are issued in these cases by, for instance, tightening the utility standard.²⁸⁹ However, this problem requires a larger scale policy prescription. For one thing, it is not merely the issuance of the patents that contribute to the problem, but the licenses as well. Further, the nature of these products also crosses over from the patent law and policy into other regulatory arenas, and beyond law to science.²⁹⁰ The call to modify the existing regulatory scheme²⁹¹ is also likely to be a politically difficult route.²⁹² However, Congress has at times revised the patent laws to respond to particular problems,²⁹³ indicating that such a path is indeed feasible when there is congressional will.²⁹⁴

V. CONCLUSION

There is currently a void in the scientific knowledge relating to the effects of genetically modified foods on human health and the environment. Patent law perpetuates that void by allowing patent holders to control and restrict independent research in the area. Accordingly, this Article analyzes how these research restrictions are contrary to the public interest and inconsistent with the underlying goals of patent law. The Article concludes that, on balance, the public interest in promoting independent research on the health and safety effects of foods should outweigh the patent holder's interest in controlling the state of adverse information available about its product. It recommends that courts use a "patent overreach" doctrine to rein in these restrictions where public health and safety may be threatened. This would serve as a limiting principle to avoid undue expansion of a patent's power to exclude.

289. See, e.g., Zachary Lerner, Comment, *Rethinking What Agriculture Could Use: A Proposed Heightened Utility Standard for Genetically Modified Food Patents*, 55 U. KAN. L. REV. 991, 1014–20 (2007).

290. Thus, among the many possible approaches to this problem, one could consider requiring additional regulatory input or involvement before and after patent issuance. The patent system as it currently exists, with patent examiners as the gatekeepers, is not equipped to make determinations about whether a genetically modified invention will not only meet the patenting standards but also the effect of the invention on environmental safety and public health. Another consideration may be an EPA requirement that all seeds be available to independent researchers prior to approving their sale.

291. See, e.g., Mandel, *supra* note 81, at 2258–59 (arguing in favor of new regulations).

292. See, e.g., Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 188 (2006) ("Congress does not appear to be supporting initiatives to address food safety concerns and to tighten the regulatory process for bioengineered food in the United States.")

293. See, e.g., Biotechnological Process Patent, Pub. L. No. 104-41, 109 Stat. 351 (codified as amended at 35 U.S.C. § 103(b) (2006)) (revising process for biotechnology patents); see also 35 U.S.C. § 273 (2006) (creating defense to patent infringement).

294. Accordingly, one modification of the existing patent law framework could require that these types of plant inventions be eligible only for plant patents, not utility patents. Of course, a complicating factor would be treatment of genetically modified animals as food that would also need to be part of any comprehensive schematic solution in this area.

The Article also calls for continuing discourse and consideration of the larger questions about reconciling patenting with public policy, and patenting with science and research. Congress and the courts must begin to pay attention to the role of patenting in limiting, rather than promoting, the progress of science, especially when public health and safety is implicated.

