

PLANTED OBSOLESCENCE: SYNAGRICULTURE AND THE LAW

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DR. ANDREW W. TORRANCE*

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I. INTRODUCTION

Few applications of biology have engendered more controversy than the genetic engineering of agricultural organisms, whether crops or livestock. Proponents of genetically-modified (GM) organisms (GMOs) often justify their development and use on such bases as increased efficiency, larger yields, reduced environmental pollution from pesticides or herbicides, and the creation of new food sources. Opponents often respond by warning of introgression of engineered genetic traits from GMOs into non-GM wild or domesticated populations, safety or purity concerns sur-

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rounding GM food, or dominant ownership of GM technologies by large agribusiness at the expense of family farmers. In the meantime, adoption of GM agriculture has increased rapidly around the world. Yet, this version of GM agriculture that has experienced such success may soon be superseded by a much more radical version based upon synthetic biology.

The advent of synthetic biology offers the simultaneous possibility of two substantial sources of divergence from the current trajectory of agriculture: (1) precise and efficient *de novo* engineering of agricultural organisms and (2) democratization of their design and production. The pedigree of synthetic biology incorporates important influences from the engineering sciences. Instead of tinkering around the edges of existing organisms, a dominant goal of synthetic biology is to design organisms, and their substituent components and systems, from scratch. This approach avoids the need to depend upon existing, and often constrained, biological systems. Starting afresh allows the possibility of optimizing synthetic biological organisms in new ways and for new purposes. Furthermore, the prevailing ethic in synthetic biology is one of openness and collaboration. Rather than rely on patent, copyright, trademark, and trade secrecy for protection of inventions, many in the synthetic biology community celebrate the sharing, spread, and pooling of innovative biotechnologies. Under this open and collaborative model of innovation, concentration of expertise, ownership, and control is replaced by widespread dispersion of synthetic biotechnologies that allow anyone with sufficient interest, motivation, and skill to design and build new agricultural organisms. For better or worse, synthetic biology could create a new paradigm of open, engineered, and distributed agriculture.

This article attempts to trace the progression from GM agriculture to synthetic agriculture (“synagriculture”). Part II surveys the origins of GM agriculture and the controversies that have surrounded it. Part III discusses how the law has grappled with, and come to terms with, GM agriculture. Part IV attempts to map the science and ethos of synthetic biology, and the related Do-It-Yourself biology (“DIYbio”) movement, onto modern agriculture. Part V concludes by evaluating the promise, perils, and ironies of synagriculture, and suggesting renewed vigilance by the law to ensure that society benefits from this brave new world of synthetic biological agriculture.

II. A HISTORY OF GM AGRICULTURE

A. Genetic Engineering

For millennia, farmers have been selectively breeding organisms to enhance the phenotypic expression of useful hereditary traits.¹ Individual crop plants with higher yields, individual cattle with more nutri-

1. See JARED DIAMOND, GUNS, GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES 115–16, 158–75 (1997).

tious milk, and individual wolves with more docile and trainable natures were all favored over conspecifics with less beneficial traits as breeding stock for the next generation. This sometimes involved the careful production of purebred lineages, or, at other times, the hybridization of distinct lineages. All major crop plants and domesticated animals can trace their origins to this early form of genetic engineering.

As the techniques of molecular genetics progressed during the 20th Century, biologists developed new, more precise, methods for enhancing the genetic traits of organisms. By introducing DNA from one organism into the genetic complement of another, genetic engineering was born. An earlier method of genetic engineering involved transferring small circlets of DNA (that is, “plasmids”) between eubacteria. For example, in 1972, Dr. Ananda M. Chakrabarty, a General Electric Company staff biologist, filed a patent application claiming a “bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids.”² Once successfully incorporated into a host cell, the genes within a plasmid may be expressed by that host cell, often resulting in the expression of new phenotypic traits.

A further advance in genetic engineering involved the insertion of foreign DNA directly into the genomic DNA of a recipient cell. Known as “recombinant DNA,” this form of gene transfer rapidly became the gold standard of genetic engineering because it offered “a simple method for isolating and amplifying any gene or DNA segment and moving it with controlled precision, allowing analysis of gene structure and function in simple and complex organisms.”³ Invented and developed between 1972 and 1974 by molecular biologists Stanley Cohen (Stanford University) and Herbert Boyer (University of California San Francisco), recombinant DNA sparked a revolution in genetic engineering.⁴ Cohen, Boyer, and their universities filed a patent application in November 1974, claiming their methods of recombinant DNA,⁵ which issued as a U.S. patent in 1980. The great flexibility of the method could be used even to insert human genes into eubacterial cells, with human somatostatin having been successfully expressed within the eubacterium, *Escherichia coli*, by 1977.⁶

B. Scientific Controversies

Genetically-modified organisms have inspired safety anxieties since their development began several decades ago. Alleged concerns have

2. U.S. Patent No. 4,259,444 col.16 ll.23–25 (filed June 7, 1972).

3. Sally Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology*, 1974-1980, 92 *ISIS* 541, 541–42 (2001).

4. *Id.*

5. See U.S. Patent No. 4,237,224 (filed Dec. 2, 1980). Stanford University and UCSF filed parent patent application 520,691, which matured into patent application 06/001,021, and ultimately issued as U.S. Patent No. 4,237,224.

6. See Keiichi Itakura et al., *Expression in Escherichia Coli of a Chemically Synthesized Gene for the Hormone Somatostatin*, 198 *SCIENCE* 1056, 1056–63 (1977).

ranged from threats to human health from ingestion of toxic “Frankenfoods,”⁷ to dangers to biodiversity from the escape of GM crops into the environment,⁸ and to contamination of organic crops by GM crop pollen.⁹ Although scientific evidence to support these worries has been elusive, three scientific articles (and events surrounding them) have made an indelible impression on public opinion surrounding GMOs.

The first of this trio of controversial publications involved Dr. Árpád Pusztai, a biochemist at the Rowlett Research Institute in Scotland who is known as a world expert on lectin,¹⁰ a protein involved in binding carbohydrates and glycoproteins to the surfaces of cells. Pusztai transferred into potato cells a gene encoding lectin, which he had derived from Snowdrop, a flowering plant of genus *Galanthus*, and then assessed the dietary safety of the resulting transgenic potatoes by feeding them to laboratory mice.¹¹ On June 22, 1998, in an interview on the British television program *World in Action*, Pusztai warned that his GM potatoes had caused adverse health effects in mice who had ingested them, and that “[i]f I had the choice I would certainly not eat it.”¹² Nevertheless, when he later published the results of his experiments in *The Lancet*, a prestigious, peer reviewed British medical journal, his conclusions had become much more circumspect:

Diets containing genetically modified (GM) potatoes expressing the lectin *Galanthus nivalis* agglutinin (GNA) had variable effects on different parts of the rat gastrointestinal tract. Some effects, such as the proliferation of the gastric mucosa, were mainly due to the expression of the GNA transgene. However, other parts of the construct or the genetic transformation (or both) could also have contributed to the overall biological effects of the GNA-GM potatoes, particularly on the small intestine and caecum.¹³

7. Andrew W. Torrance, *Intellectual Property as the Third Dimension of GMO Regulation*, 16 KAN. J.L. & PUB. POL’Y 257, 269–73 (2007).

8. *Id.* at 270–71.

9. The value of organic crops depends, at least in part, on assurances that they are not genetically modified. See generally, Matthew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153 (2000). The United States has witnessed some litigation by organic farmers alleging harm to their crops due to contamination by GM pollen. See, e.g., *In re Starlink Corn Products Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

10. Les Levidow et al., *Recasting Substantial Equivalence: Transatlantic Governance of GM Food*, 32 SCI. TECH. & HUMAN VALUES 26 (2007).

11. Stanley W. B. Ewen & Árpád Pusztai, *Effect of Diets Containing Genetically Modified Potatoes Expressing Galanthus Nivalis Lectin on Rat Small Intestine*, 354 LANCET 1353 (1999).

12. James Randerson, *Arpad Pusztai: Biological Divide*, THE GUARDIAN, Jan. 14, 2008, <http://www.guardian.co.uk/education/2008/jan/15/academicexperts.highereducationprofile>.

13. Ewen & Pusztai, *supra* note 11, at 1353.

In the same issue of *The Lancet*, an editorial cast doubt on Pusztai's data analysis,¹⁴ and another article reinterpreted the data, finding therein little evidence of toxicity.¹⁵ However, the *World in Action* interview had already contributed to a strong negative impression of GM foods among European consumers.

A year later, in 1999, controversy over GMOs was stoked further when *Nature*, another prestigious scientific journal, published an article in which entomologist John Losey and two colleagues suggested that pollen from GM corn genetically engineered to express *Bt* toxin, a potent insecticide derived from *Bacillus thuringiensis* (*Bt*) eubacteria, could poison Monarch butterfly larvae in the wild.¹⁶ Then, in 2001, another *Nature* article, by David Quist and Ignacio Chapela, reported data suggesting that genes from GM corn had introgressed into diverse native maize varieties in Mexico.¹⁷ Opponents of GMOs cited both scientific reports as vindicating fears that GM crops posed serious threats to human health, biodiversity, and genetic diversity in native crop stocks. As had occurred in the Pusztai affair, the accuracy of the results reported in both *Nature* articles was soon questioned. Studying Monarch butterfly caterpillars in the wild, Mark K. Sears and several colleagues concluded that "[t]his 2-year study suggests that the impact of Bt corn pollen from current commercial hybrids on monarch butterfly populations is negligible."¹⁸ And, in an extraordinary action, *Nature* published a special editorial on the Quist and Chapela study, concluding that "the evidence available is not sufficient to justify the publication of the original paper."¹⁹ Nonetheless, despite serious doubts having been raised about all three studies, much damage to public perceptions of GM crops lingered, especially in Europe.

C. Evidence of Harm or Safety

Little evidence has yet emerged that GMOs pose significant health or environmental dangers not also posed by conventional organisms.²⁰ Such evidence may still emerge in time, and the pervasive adoption of GM food should provide sample sizes massive enough to reveal even ra-

14. Richard Horton, Editorial, *Genetically Modified Foods: "Absurd" Concern or Welcome Dialogue?*, 354 LANCET 1314 (1999).

15. Harry A. Kuiper et al., *Adequacy of Methods for Testing the Safety of Genetically Modified Foods*, 354 LANCET 1315 (1999).

16. John E. Losey et al., *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999).

17. David Quist & Ignacio Chapela, *Transgenic DNA Introgressed into Traditional Maize Landraces in Oaxaca, Mexico*, 414 NATURE 541 (2001).

18. Mark K. Sears et al., *Impact of Bt Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, 98 PROC. NAT'L ACAD. SCI. 11937 (2001).

19. Editorial Note, 416 NATURE 567, 600 (2002).

20. See, e.g., Philip J. Dale et al., *Potential for the Environmental Impact of Transgenic Crops*, 20 NATURE BIOTECHNOLOGY 567 (2002).

re and subtle effects on human health.²¹ With respect to environmental damage, evolutionary theory suggests that wild organisms should generally outcompete human-designed organisms, as the former have resulted from millions of years of rigorous natural selective pressures. Similarly, genes designed by humans should tend to confer disadvantages, not advantages, to populations into which they introgress. Natural selection should tend to sweep aside GM organisms and any foreign genes they might spread.

A number of governmental investigations have failed to find notable evidence of harm posed by GMOs or GM food. In 2004, the National Academy of Sciences (NAS), a private nonprofit organization composed of respected scientific experts who provide independent advice the United States government, published a report based on a review of the available scientific evidence about GMOs. The NAS concluded that, “[t]o date, no adverse health effects attributed to genetic engineering have been documented in the human population.”²² In 2006, the United States Food and Drug Administration (FDA) published a report concluding that cloned livestock for which data were available posed no unique threats to human health:

Extensive evaluation of the available data has not identified any subtle hazards that might indicate food consumption risks in healthy clones of cattle, swine, or goats . . . [Edible] products from healthy clones that meet existing requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals . . . Edible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals based on underlying biological assumptions, evidence from model systems, and consistent empirical observations.²³

Other countries have also embarked on similar studies. The United Kingdom government, in its “Science Review” of more than 600 published scientific studies of GMOs published in 2003, concluded that “[on] balance . . . the risks to human health are very low for GM crops currently on the market.”²⁴ The British Royal Society, the United King-

21. In fact, one might argue that, given the long period of time over which GMOs have already been used in, and their pervasiveness as a part of, human agriculture, adverse health and environmental safety effects should have become apparent to science by now.

22. COMM’N ON IDENTIFYING AND ASSESSING UNINTENDED EFFECTS OF GENETICALLY ENGINEERED FOODS ON HUMAN HEALTH, INST. OF MED., SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 180 (2004).

23. U.S. FOOD & DRUG ADMIN., ANIMAL CLONING: A RISK ASSESSMENT 332 (2008), <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AnimalCloning/UCM124756.pdf>.

24. THE GM SCIENCE REVIEW PANEL, GM SCIENCE REVIEW—FIRST REPORT 23 (2003), <http://image.guardian.co.uk/sys-files/Guardian/documents/2003/07/21/gmsci-report1-full.pdf>. (“Detailed field experiments on several GM crops . . . in a range of environments have demonstrated that they are very unlikely to invade our countryside or become problematic

dom's equivalent of the NAS, concurred with the conclusions of the Science Review, and criticized the press for "ignoring the scientific evidence [about GMO safety]."²⁵ Furthermore, the Nuffield Council on Bioethics, an independent British institute devoted to the study and reporting of bioethical issues raised by biology and medicine, characterized the scientific evidence surrounding GM food and human health as benign: "A number of recent authoritative reviews have concluded that there are no proven health damages arising from the consumption of GM crop products on the market as yet."²⁶

The remarkable lack of evidence demonstrating malign effects of GMOs and GM food, either on human health or the environment, prompted Paul F. Lurquin, a prominent plant geneticist, to conclude that

[t]he projected threats of plant biotechnology against humanity have not come to pass. There is no scientific evidence that engineered corn, soybean, or canola have had a detrimental impact on humans and the environment. Americans and Canadians are not suffering short-term or medium-term effects from the consumption of these transgenic foods.²⁷

In short, the community of biological experts is approaching a consensus that neither GMOs nor food derived from them represent dangers to human health or the environment above the levels posed by conventional organisms or food. Such a consensus would strongly undermine both human health and environmental safety concerns as policy rationales for restrictively regulating GMOs and GM food. A distinct ground for concern—alleged overconcentration of ownership and zealous enforcement of restrictive patents and contracts—has at least partially filled the vacuum created by this lack of scientific evidence indicating harm to either humans or the environment.²⁸

D. Rapid Spread

The adoption of GM crops around the world has proceeded at a rapid rate since the initial commercialization of such crops began in 1996.²⁹

plants . . . Nor are they likely to be toxic to wildlife or to perturb soil structure in such a way that the functioning of soil communities is substantially affected.").

25. Shaoni Bhattacharya, *GM Food Risk to Humans "Very Low,"* NEW SCIENTIST, July 21, 2003, <http://www.newscientist.com/article/dn3959-gm-food-risk-to-humans-very-low.html>.

26. NUFFIELD COUNCIL ON BIOETHICS, THE USE OF GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES—A FOLLOW-UP DISCUSSION PAPER 61 (2004), available at <http://www.nuffieldbioethics.org/sites/default/files/GM%20Crops%20Discussion%20Paper%202004.pdf>.

27. PAUL F. LURQUIN, HIGH TECH HARVEST—UNDERSTANDING GENETICALLY MODIFIED FOOD PLANTS 162 (2002).

28. Torrance, *supra* note 7, 275–76.

29. CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRIBIOTECH APPLICATIONS, BRIEF NO. 42, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2010, at 1 (2010), <http://www.isaaa.org/resources/publications/briefs/42/executivesummary/p>

Crops having GM variants include alfalfa, canola, corn, cotton, papaya, rice, soybean, squash, sugar cane, sugar beet, sweet pepper, and tomato.³⁰ The most common genetic traits engineered into GM crops are *Bt* toxins against insect pests and herbicide resistance.³¹ The global hectareage of GM crops has exploded, from 1.7 million ha (hectares) in 1996,³² to 44.2 million ha in 2000, to 90.0 million ha in 2005,³³ and to 148 million ha in 2010.³⁴ This extraordinarily rapid rate of global adoption has few documented parallels among other new technologies. The ten countries having the largest planted areas of GM crops, in order from largest to smallest, are the United States, Brazil, Argentina, India, Canada, China, Paraguay, Pakistan, South Africa, and Uruguay.³⁵ Although the developed world adopted GM crops earlier than did the developing world, the latter drew almost equal with the developed world in planted hectareage by 2010.

III. LAW AND GM AGRICULTURE

A. The Asilomar Conference

In 1975, biologists involved in the nascent method of recombinant DNA met together at the Asilomar Conference Center in Pacific Grove, California.³⁶ The Asilomar Conference on Recombinant DNA (Asilomar Conference) was largely motivated by growing fears that genetic engineering could release dangerous novel organisms into the world.³⁷ The Conference was organized by Paul Berg, a Stanford University biochemistry professor, who was an early leader in recombinant DNA methods.³⁸ Berg had been conducting experiments on mixing together the genes of two viruses, SV40 and bacteriophage λ , when colleagues prevailed upon him not to complete the final genetic recombination step for fear of producing a novel, highly infectious carcinogenic virus.³⁹ In response, he and other biologists instituted a voluntary moratorium on further recombinant DNA experiments until experts in the field had had an opportunity to meet and discuss issues of biosafety.⁴⁰

The Asilomar Conference gathered together biologists, physicians, and attorneys, who attempted to evaluate the risks posed by recombi-

df/Brief%2042%20-%20Executive%20Summary%20-%20English.pdf.

30. *Id.* at 3.

31. *Id.* at 8.

32. *Id.* at 1.

33. *Id.* at cover fig. "Global Area of Biotech Crops."

34. *Id.* at 1.

35. *Id.* at 2.

36. Paul Berg & Maxine F. Singer, *The Recombinant DNA Controversy: Twenty Years Later*, 92 PROC. NAT'L ACAD. SCI. USA 9011, 9011 (1995).

37. *Id.* at 9011.

38. Paul Berg, *Autobiography*, NOBEL PRIZE (March 2004), http://www.nobelprize.org/nobel_prizes/chemistry/laureates/1980/berg-autobio.html.

39. Susan Wright, *Recombinant DNA Technology and Its Social Transformation, 1972-1982*, 2 OSIRIS 305, 311-12 (1986) [hereinafter *Recombinant DNA Technology*].

40. *See id.* at 318-19.

nant DNA methods, and to recommend safety procedures for the future conduct of such research.⁴¹ The resulting guidelines agreed on two major principles to minimize the biosafety risks of recombinant DNA research: (1) containment measures should constitute essential features of experimental design and (2) the effectiveness of containment measures should be proportional to the estimated risk of the experiment.⁴² The guidelines recommended the use of biological barriers (that is, fragile host bacteria and fragile and nontransmissible plasmid, bacteriophage, and viral vectors), effective physical containment (for example, use of fume hoods and negative pressure laboratories), rigorous adherence to proper microbiological practices, and thorough training and education of research personnel.⁴³ Four levels of containment were proposed: minimal, low, moderate, and high risk.⁴⁴ Furthermore, the guidelines prohibited certain categories of experiments entirely (for example, recombining DNA from highly pathogenic organisms or engineering organisms that make potentially harmful chemical products).⁴⁵

One of the enduring legacies of the Asilomar Conference was the paradigm it suggested for managing potentially hazardous scientific research: those with the greatest expertise in that field of research should attempt rigorously and thoughtfully to govern themselves.⁴⁶ The resulting self-governance of recombinant DNA, specifically, and molecular biology, more generally, is widely judged as successful, and perhaps even exemplary. In addition, the perception that this self-governance is effective may have circumvented the imposition by governments of draconian regulations that might have harmed the nascent field of genetic engineering.

B. *Diamond v. Chakrabarty*

Only a few short years after recombinant DNA methods had been invented, the United States Supreme Court considered the patentability of GMOs in *Diamond v. Chakrabarty*.⁴⁷ In this 1980 case, the Supreme Court addressed whether or not a “human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil,” constituted patentable subject matter.⁴⁸ The Court viewed its task as having to “determine whether respondent’s micro-organism consti-

41. Paul Berg et al., *Summary Statement of the Asilomar Conference on Recombinant DNA Molecules*, 72 PROC. NAT’L ACAD. SCI. USA 1981, 1981–84 (1975).

42. *Id.*

43. *Id.* at 1982.

44. *Id.*

45. *Id.* at 1983.

46. See *Recombinant DNA Technology*, *supra* note 39. See also Susan Wright, *Molecular Biology or Molecular Politics? The Production of Scientific Consensus on the Hazards of Recombinant DNA Technology*, 16 SOC. STUD. SCI. 593, 595–96 (1986); Berg & Singer, *supra* note 36.

47. 447 U.S. 303, 305 (1980).

48. *Id.* at 305.

tutes a 'manufacture' or 'composition of matter' within the meaning of the statute."⁴⁹

In its majority opinion, the Court evaluated the categories of patentable subject matter specifically enumerated in the Patent Act at 35 U.S.C. § 101, and decided that, "[i]n choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope."⁵⁰ Citing the legislative history of the 1952 Patent Act, it noted that "[t]he Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"⁵¹ However, the broad ambit of patentability in 35 U.S.C. § 101 did not extend to "[the] laws of nature, physical phenomena, and abstract ideas."⁵² The Court answered the question of whether the claimed recombinant eubacterium constituted statutory subject matter in the affirmative, deciding that

[Chakrabarty's] micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter . . . The patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter.⁵³

The Court majority classified the claimed GM eubacterium itself as a "composition of matter," and rejected the notion that it fell within any of the prohibited categories of unpatentable subject matter.⁵⁴ In short, whole living organisms themselves constituted eligible subject matter for patent protection.⁵⁵ Having decided that "anything under the sun that is made by man" could include living organisms,⁵⁶ the Court majority cleared the way for the patentability of diverse GMOs, including macroscopic plants,⁵⁷ animals,⁵⁸ and even mammals.⁵⁹ Of particular relevance to GM crops, the Supreme Court specifically held whole living

49. *Id.* at 307.

50. *Id.* at 308.

51. *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952); H.R. REP. NO. 1923, at 6 (1952)).

52. *Id.* at 309.

53. *Id.* at 309–10.

54. *Id.* at 309.

55. *Id.*

56. *Id.* at 309 (quoting S. REP. NO. 1979, at 5 (1952)).

57. *See* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145–46 (2001); *Ex parte* Hibberd, No. 645-91, 227 U.S.P.Q. 443, 443 (B.P.A.I. 1985).

58. *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (B.P.A.I. 1987).

59. U.S. Patent No. 4,736,866 (filed June 22, 1984) (Transgenic Non-Human Mammal).

plants to be utility patent-eligible in its 2001 decision, *JEM v. Pioneer Hi-Bred*.⁶⁰

Since *Diamond v. Chakrabarty*, patent protection has played a vital role in crop plant innovation, which is now firmly centered on GM crops. The European Patent Office (EPO) provides a vivid illustration of this. Every year but one since 1996, the EPO has published at least 800 patent applications related to plants.⁶¹ Since 1990, The European Patent Office has granted 1,690 patents on plants, of which 1,602 have claimed GM plants and only 88 have claimed non-GM plants.⁶² As discussed below, patent protection for GM crops may allow patent owners a degree of control over agriculture and agricultural innovation that has not historically been possible.

C. *J.E.M. v. Pioneer Hi-Bred*

In 2001, twenty years after the landmark decision in *Diamond v. Chakrabarty*, the Supreme Court revisited the issue of the patent eligibility of GMOs. In this case, the organism in question was the corn plant (*Zea mays*). Pioneer Hi-Bred International, Inc. (Pioneer), is a seed company that sold hybrid seeds under a limited label license.⁶³ Pioneer owned seventeen patents covering the inbred and hybrid corn seed at issue in the litigation.⁶⁴ Furthermore, the limited label license under which the seed was sold restricted purchasers to growing the corn for “grain” or “forage;” it prohibited other uses, such as reselling, seed production and saving, and further breeding of the corn plants.⁶⁵

J.E.M. Ag Supply, Inc. (J.E.M.) purchased Pioneer’s patented seed in bags having the license, and then resold the bags, despite the terms of the license.⁶⁶ Pioneer sued J.E.M. for patent infringement.⁶⁷ J.E.M. filed counterclaims alleging that the Pioneer patents claiming sexually-reproducing plants were invalid as constituting subject matter ineligible for patent protection.⁶⁸ J.E.M. based its contention, at least in part, on the existence of specific statutory protection for asexually reproducing plant inventions under the Plant Patent Act (PPA) and for sexually reproducing plant inventions under the Plant Variety Protection Act (PVPA).⁶⁹

The Supreme Court sided with Pioneer, holding that all plants, whether sexually or asexually reproducing, are eligible for utility patent

60. *J.E.M. Ag Supply*, 534 U.S. at 132.

61. THE “MELON PATENT” CASE-FAQ, EUROPEAN PATENT OFFICE, <http://www.epo.org/news-issues/issues/melon.html> (last updated Feb. 14, 2012).

62. *Id.*

63. *J.E.M. Ag Supply*, 534 U.S. at 128.

64. *Id.* at 127.

65. *Id.* at 128.

66. *Id.*

67. *Id.*

68. *Id.* at 129.

69. *Id.*

protection.⁷⁰ The Court also noted that the same plant invention might be entitled to simultaneous protection under either the PPA or the PVPA.⁷¹ Furthermore, the majority opinion had the support of six Supreme Court justices, including a concurring opinion, and there was but a single dissent.⁷² This result reflected a shift in favor of the patent-eligibility of living organisms because the majority opinion in *Diamond v. Chakrabarty* had managed to attract the support of a bare majority: five of nine justices.⁷³ Having held that non-GM plants constitute patentable subject matter, it is logical to conclude that the Supreme Court would consider GM plants at least as patent-eligible, if not more so, as more conventional hybrid and inbred plant varieties. After *J.E.M. v. Pioneer Hi-Bred*, there has been little doubt that GM crops are eligible for patent protection.

D. Terminator Technology

Andrew W. Torrance has suggested that, over the lifetime of the GM crop controversy, criticisms of GM crops as threats to human or environmental safety have latterly been joined or, in some cases, replaced, by criticisms that corporations, often wielding patents, possess too much control over beneficial GM crops.⁷⁴ These two classes of criticism are in logical tension: the first critique, “safety,” suggests that no one should grow GM crops because they are dangerous, whereas the second critique, “control,” implies that access to GM crops should be more widespread so that more people can share their benefits. “Terminator technology” provides a vivid illustration of the issue of control over GM crops.

Patent rights have often been difficult to enforce in many developing nations. As a consequence, agricultural companies have often avoided introducing their most advanced GM crops in the developing world to avoid misappropriation of these crops in the absence of effective legal remedies. “Terminator” technology or Genetic Use Restriction Technology (GURT), has been proposed as an alternative to patent protection. Terminator technology would involve the introduction of “suicide genes” into crop plants so that, once the crop has been harvested, the plant and

70. *Id.* at 144.

71. *Id.*

72. Justice Thomas delivered the opinion of the Court, with Chief Justice Rehnquist and Justices Scalia, Kennedy, Souter, and Ginsburg joining. *J.E.M. Ag Supply*, 534 U.S. at 126. Justice Scalia filed a concurring opinion. *Id.* Justice Breyer filed a dissenting opinion. *Id.* And, Justice O'Connor did not participate in either the consideration or the decision of the case. *Id.*

73. Chief Justice Burger delivered the opinion of the Court, and was joined by Justices Stewart, Blackmun, Rehnquist, and Stevens. *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980). Justice Brennan, joined by Justices White, Marshall, and Powell, dissented. *Id.* at 318.

74. Torrance, *supra* note 7, at 259.

its seeds would be biologically unviable.⁷⁵ Some have expressed worries that such terminator plants or genes could spread into the wild. However, it is difficult to envision such a scenario, since the technology itself is self-eliminating.

Both the United States Department of Agriculture (USDA) and Monsanto Corporation (Monsanto)⁷⁶ attempted to develop terminator technology for crop plants during the 1990s.⁷⁷ Patents claiming aspects of terminator technology have been issued by the USPTO.⁷⁸ These issuances ignited controversy around the world. Terminator technology was criticized by nongovernmental organizations and others as a threat to global agricultural and food security.⁷⁹ India banned the import of seeds incorporating terminator genes.⁸⁰ The influential former leader of the United Nations Conference on the Environment and Development, Maurice Strong condemned the technology:

If the owners of technology, such as big companies, used [biotechnology] to victimize people through methods such as promotion of 'terminator genes,' the state should intervene and not leave the task to the market mechanism.⁸¹

In the face of this controversy, the Clinton administration even ordered USDA to discourage further development of terminator technology.⁸² And, in 1999, Monsanto publicly pledged that, if allowed to acquire the Delta Pine and Land Company (the company that had most actively pursued the development of terminator technology), it would forego use of terminator technology unless its safety had been convincingly demonstrated.⁸³

At the international level, opposition to terminator technology coalesced at the Fifth Conference of the Parties (COP) of the Convention on Biological Diversity (CBD), in 2000, where members of the CBD success-

75. NUFFIELD COUNCIL ON BIOETHICS, THE USE OF GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES—A FOLLOW-UP DISCUSSION PAPER 50 (2004), <http://www.nuffieldbioethics.org/sites/default/files/GM%20Crops%20Discussion%20Paper%202004.pdf>.

76. See Torrance, *supra* note 7, at 276. The corporation that actually pursued this technology was the Delta and Pine Land Company, which was acquired by Monsanto in 2007. Sutton, *infra* note 77; Andrew Pollack, *Monsanto Buys Delta and Pine Land, Top Supplier of Cotton Seeds in the U.S.*, N.Y. TIMES, Aug. 16, 2006, <http://www.nytimes.com/2006/08/16/business/16seed.html>.

77. See generally Jason Sutton, 'Terminator' Technology, TRANSGENIC CROPS: AN INTRODUCTION AND RESOURCE GUIDE, <http://cls.casa.colostate.edu/TransgenicCrops/terminator.html> (last updated Feb. 2, 2004).

78. U.S. Patent No. 5,977,441 (filed Nov. 2, 1999); U.S. Patent No. 5,925,808 (filed July 20, 1999); U.S. Patent No. 5,723,765 (filed Mar. 3, 1998).

79. See generally Ricarda A. Steinbrecher & Pat Roy Mooney, *Terminator Technology: The Threat to World Food Security*, 28 THE ECOLOGIST 276 (1998). Nigel Hawkes, *War on Killer Seed*, TIMES (LONDON), Nov. 4, 1998.

80. Rob Edwards, *US Officials Fear a Backlash Over 'Terminator Technology'*, NEW SCIENTIST 2121, 2121 (1998).

81. *Adopt Agenda-21 for Sustainable Future*, THE HINDU, Apr. 8, 1999, at article 5.

82. Edwards, *supra* note 80, at 2121.

83. *Terminator Gene Halt a 'Major U-Turn'*, BBC NEWS, Oct. 5, 1999, <http://news.bbc.co.uk/2/hi/science/nature/465222.stm>.

fully passed a moratorium on all field trials of terminator crops until scientific evidence assured they could proceed safely.⁸⁴ This vote to successfully ban field trials of terminator crops was influenced by a letter sent to the Fifth COP by more than 300 scientists, which made the following request:

We call . . . for the immediate suspension of [all environmental releases] of [terminator] crops and products, both commercially and in open field trials, for at least five years, for patents on living processes, organisms, seeds, cell lines and genes to be revoked and banned, and for a comprehensive public enquiry into the future of agriculture and food security for all.⁸⁵

In 2006, the Eighth COP voted to extend the moratorium, although several developed nations—Australia, Canada, and New Zealand—opposed extension of the complete ban.⁸⁶

It appears that terminator technology has yet to be used commercially. However, the fever pitch of controversy it inspired strongly suggests that issues of monopoly control over GM crops compete vigorously with concerns that GM crops are unsafe.

E. Monsanto Canada v. Schmeiser

In 1993, Monsanto Canada received Canadian Letters Patent No. 1,313,830 (the “830 patent”), entitled “Glyphosate-Resistant Plants.”⁸⁷ Among other inventions, the patent claimed genes and cells present in a variety of canola genetically engineered to resist glyphosate herbicides.⁸⁸ At the time, Monsanto sold in Canada both glyphosate herbicide, named “Roundup,” and “Roundup Ready” GM canola capable of withstanding

84. Conference of the Parties to the Convention on Biological Diversity, Decision V/5 Agricultural Biodiversity: Review of Phase I of the Programme of Work and Adoption of a Multi-Year Work Programme, UNEP/CBD/COP/5/23, at 88, para. 23 (May 2000).

[I]n the current absence of reliable data on genetic use restriction technologies without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, *inter alia*, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated. In order to enhance the capacity of all countries to address these issues, Parties should widely disseminate information on scientific assessments, including through the clearing-house mechanism, and share their expertise in this regard.

85. Letter from Institute of Science in Society & World Scientists to All Governments Concerning Genetically Modified Organisms (GMOs) (Jan. 9, 2000), <http://www.issis.org.uk/list.php>.

86. Mario Osava, *Ban on Terminator Seed Field Trials Continues*, INTER PRESS SERVICE, Mar. 24, 2006.

87. *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, para. 8 (Can.).

88. *Id.* at para. 9.

field application of glyphosate herbicide.⁸⁹ Monsanto Canada sued a Saskatchewan farmer named Percy Schmeiser and the corporation that officially owned his farm (together, “Schmeiser”) in the Trial Division of the Federal Court of Canada for allegedly infringing the ‘830 patent by growing Roundup Ready canola on his fields without a license or other permission.⁹⁰

Schmeiser defended by claiming that he had neither purchased nor intentionally planted Roundup Ready canola, but admitted that he may have planted Roundup Ready canola inadvertently by saving and subsequently replanting seed from his 1997 harvest.⁹¹ Furthermore, he argued that, (1) by allowing its canola to be grown in fields, Monsanto had ceased to exercise adequate control of its canola genes; (2) since he had not used Roundup herbicide, he had consequently not used Roundup Ready canola, which two products he claimed were inextricably linked together; and (3) the ‘830 patent claimed unpatentable subject matter, such as plants, cells, and genes.⁹²

The Trial Division held that the ‘830 patent was valid because it claimed genetic sequences and cells, not higher organisms,⁹³ and that Schmeiser had infringed claims of the patent.⁹⁴ Importantly, the court noted that intent was not an element of patent infringement.⁹⁵ The Trial Division awarded Monsanto both lost profits and injunctive relief against further infringement by Schmeiser.⁹⁶

The Federal Court dismissed appeals by both Schmeiser and Monsanto,⁹⁷ while noting that even if Monsanto’s canola seeds had drifted onto Schmeiser’s property by themselves, their growth there could still trigger liability for patent infringement.⁹⁸ Although the court did suggest it might not be fair to hold a farmer liable for involuntary patent infringement,⁹⁹ it considered that Schmeiser did know, or should have known, that the saved seed from 1997 was glyphosate-resistant, and might infringe patent rights if grown.¹⁰⁰

The Supreme Court of Canada agreed to accept an appeal, by Schmeiser, of the decision of the Federal Court. Aside from reducing the amount owed by Schmeiser, the court largely affirmed the decision of

89. *Id.*

90. *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, paras. 4–8 (Can.).

91. *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, paras. 60–63, 66 (Can.).

92. *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, paras. 11–13 (Can.). There were also a number of arguments between the parties concerning admissibility of evidence from testing by the parties and others, as well as about remedies. Costs, including attorneys’ fees, were the subject of a separate decision. *See Monsanto Canada Inc. v. Schmeiser*, 2002 FCT 439 (Ca.).

93. *Monsanto Canada Inc. v. Schmeiser*, 2001 FCT 256, paras. 88, 90 (Can.).

94. *Id.* at para. 127.

95. *Id.* at para. 115.

96. *Id.* at paras. 130–40.

97. *Monsanto Canada Inc. v. Schmeiser*, 2002 FCA 309, para. 89 (Can.).

98. *Id.* at para. 51.

99. *Id.* at paras. 56–57. The Court of Appeal made this assessment even though the issue of intent was not before it. *Id.* at para. 57.

100. *Id.* at para. 58.

the Trial Division.¹⁰¹ The court pointed out that the '830 patent claimed genes and cells, but not a plant *per se*: "Everyone agrees that Monsanto did not claim protection for the genetically modified plant itself, but rather for the genes and the modified cells that make up the plant."¹⁰² The dissent would also have considered the use of the claimed DNA or cells to constitute patent infringement, but would not have found patent infringement for the growing of canola plants containing the patented DNA or cells.¹⁰³ By contrast the court majority stated that "the law holds that a defendant infringes a patent when the defendant . . . uses a patented part that is contained within something that is not patented, provided the patented part is significant or important."¹⁰⁴ The majority noted that the canola plants grown by Schmeiser were composed of patented cells.¹⁰⁵ Ironically, even though the Supreme Court of Canada had previously denied the patentability of whole "higher" organisms, such as mice,¹⁰⁶ its decision in *Monsanto Canada v. Schmeiser* effectively rewarded patent owners with even broader patent protection, over the constituent recombinant DNA and GM cells of such "higher" organisms.

The *Monsanto Canada v. Schmeiser* case illustrates vividly the control that a patent can confer over the behavior of farmers. As the Supreme Court of Canada confirmed, Monsanto and other holders of patents that claim GM crops, or substituent parts thereof, can exert strong control over agriculture. For example, the owner of a patent claiming a GM crop, or a substituent part, may prevent a farmer not only from growing the plant in the first generation, but in subsequent generations as well.¹⁰⁷

F. *Geertson v. Monsanto*

Alfalfa (*Medicago sativa*) is the most commonly cultivated legume crop in the world, and is useful both as human food and livestock forage. Monsanto developed and patented a GM Roundup Ready alfalfa re-

101. *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, para. 106. Note that the Supreme Court of Canada decided the *Harvard College* case after the Federal Court of Appeals' *Monsanto* decision.

102. *Id.* at para. 17.

103. *Id.* at paras. 161–62 (Arbour, J., dissenting in part).

104. *Id.* at para. 42.

105. *Id.*

106. *See* *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76 (Can.).

107. Multigenerational patent rights in self-replicating GMO inventions would appear to challenge the exhaustion, or first-sale, doctrine in patent law. In *Monsanto v. Bowman*, the U.S. Court of Appeals for the Federal Circuit held that the exhaustion doctrine did not apply to "commodity" soybeans that an Indiana farmer named Vernon Bowman had bought from a local grain elevator for use in a second-crop planting, *Monsanto Co. v. Bowman*, 657 F.3d 1341, 1349 (Fed. Cir. 2011). However, the U.S. Supreme Court is considering whether to grant certiorari in an appeal of this decision, *Petition for Writ of Certiorari, Bowman v. Monsanto Co.*, No. 11-796 (U.S. Dec. 20, 2011); the Court has already asked invited the Solicitor General to file briefs indicating the opinions of the United States in this dispute. See *Orders in Pending Cases*, U.S. Supreme Court (April 2, 2012), <http://www.supremecourt.gov/orders/courtorders/040212zor.pdf>.

sistant to Roundup herbicide—that is, glyphosate (N-(phosphonomethyl) glycine). However, Monsanto required approval from the USDA under the Plant Protection Act (the Act)¹⁰⁸ to cultivate Roundup Ready alfalfa commercially.

The USDA describes the Act as “necessary because of the major impact plant pests currently have and could have on the agriculture, environment, economy, and commerce of the United States.”¹⁰⁹ In practical terms, the Animal and Plant Health Inspection Service (APHIS) enforces the Act, endeavoring “to prohibit or restrict the importation, exportation, and the interstate movement of plants, plant products, certain biological control organisms, noxious weeds and plant pests.”¹¹⁰ Under the regulations implementing the Act, APHIS makes a default assumption that GM crops qualify as plant pests.¹¹¹ Nevertheless, APHIS has established a procedure by which GM crop owners may have their crops deregulated by demonstrating that these crops are not, in fact, plant pests.

In 2004, Monsanto petitioned APHIS for the deregulation of two of its varieties of GM Roundup Ready alfalfa. Having drafted an environmental assessment (EA) and solicited public comment on deregulation, APHIS made a “Finding of No Significant Impact,” granted these petitions, and unconditionally deregulated the two varieties.¹¹²

A number of seed farms and environmental organizations opposed the deregulation decisions, and sued in the Northern District of California to have the decisions overturned. They were granted injunctive relief that essentially banned any cultivation of Roundup Ready alfalfa due to APHIS’s violation of the National Environmental Policy Act (NEPA)¹¹³ by failing to prepare a full environmental impact statement (EIS) on the effects of full deregulation of the GM alfalfa varieties.¹¹⁴ The Ninth Circuit Court of Appeals affirmed the decision of the district court, and held that the latter had not abused its discretion.¹¹⁵

On June 21, 2010, the Supreme Court issued a nearly unanimous decision in *Monsanto v. Geertson Seed Farms* that reversed the decision of the Ninth Circuit.¹¹⁶ The Court held that “the District Court abused its discretion in enjoining APHIS from effecting a partial deregulation

108. Plant Protection Act, 7 U.S.C. §§ 7701–86 (2006).

109. ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, THE PLANT PROTECTION ACT: PLANT AND PROTECTION AND QUARANTINE FACTSHEET 1 (2002), http://www.aphis.usda.gov/lpa/pubs/fsheet_faq_notice/fs_phproact.pdf.

110. *Id.*

111. 7 C.F.R. § 340 (2011).

112. ANIMAL & PLANT HEALTH INSPECTION SERV., USDA, ENVTL. ASSESSMENT & FINDING OF NO SIGNIFICANT IMPACT (2005), http://www.aphis.usda.gov/brs/aphisdocs2/04_11_001p_com.pdf.

113. National Environmental Policy Act, 42 U.S.C. §§ 4321–70 (2006).

114. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2751 (2010).

115. *Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1139, 1141 (9th Cir. 2009), *rev’d*, 130 S. Ct. 2743 (2010).

116. *Geertson Seed Farms*, 130 S. Ct. 2743. Only Justice Stevens dissented. Justice Breyer took no part in the decision.

and in prohibiting the possibility of planting [RRAs] in accordance with the terms of such a deregulation."¹¹⁷ The case was then remanded for further proceedings consistent with the Court's opinion.¹¹⁸

Later, in December 2010, APHIS published its final EIS, in which it found that Roundup Ready alfalfa was substantially equivalent to non-GM alfalfa.¹¹⁹ In the EIS, APHIS identified two "preferred" alternative dispositions: either grant deregulated status to GM alfalfa, or partially deregulate GM alfalfa, subject to "isolation distances and geographic restrictions."¹²⁰ These recommendations were made against the backdrop of two court cases, *In re Starlink Corn Products Liability Litigation*¹²¹ and *Monsanto Canada v. Schmeiser*,¹²² in which the contamination of non-GM crops by genes from GM crops had triggered legal action.

There are echoes in the growing disputes over the incompatibility of neighboring GM and non-GM crops of the nineteenth century disputes between the owners of the then-new railways and those landowners through whose properties these railways ran, in part because sparks from steam engines often set adjacent fields afire. In response to this danger of fire, Britain passed the English Railway Fires Acts to compensate farmers whose properties were damaged by passing trains, while also limiting tort liability of railway owners, and thus providing a degree of legal protection for the continued expansion of railways.¹²³ The deregulation pathway in the Act has the potential to serve a similar purpose, by allowing the deregulation of GM crops, but conditioning deregulation on reasonable and not unduly onerous safeguards. The Wall Street Journal excoriated the conditions APHIS imposed on the deregulation of the alfalfa varieties as being unscientific: "[i]f non-science criteria are introduced as considerations for allowing the sale of biotech crops, the effect would be disastrous for the USDA's regulatory reputation."¹²⁴ Several weeks later, on January 19, 2011, U.S. Representative Frank Lucas (R-Okla.) and U.S. Senators Saxby Chambliss (R-Ga.) and Pat Roberts (R-Kan.) sent a letter of complaint to USDA Secretary Tom Vilsack, warning him that the Act did not grant the USDA the authority to rely on non-scientific factors in deciding how to regulate GM crops:

117. *Id.* at 2761.

118. *Id.* at 2762.

119. Animal & Plant Health Inspection Serv., USDA, Final Env'tl. Impact Statement, Glyphosate-Tolerant Alfalfa Events J101 & J163: Request for Nonregulated Status, at iv-viii (Dec. 2010), http://www.aphis.usda.gov/biotechnology/downloads/alfalfa/gt_alfalfa%20_feis.pdf.

120. *Id.* at 11.

121. *In re Starlink Corn Products Liab. Litig.*, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

122. *Monsanto Canada, Inc. v. Schmeiser*, 2004 SCC 34 (Can.).

123. 1918A THE LAWYERS REPORTS ANNOTATED 941 (Burdett A. Rich, Henry P. Farnham & George H. Parmele eds., 1918).

124. Editorial, *Ag Department Uproots Science; Vilsack Seeks out Politically Congenial Scientific Opinion*, WALL ST. J., Dec. 26, 2010.

It is unfortunate that those critical of the technology have decided to litigate and as you rightly point out that courts may unwisely interfere in normal commerce. However, the alternative you propose and include in the EIS is equally disturbing since it politicizes the regulatory process and goes beyond your statutory authority and indeed Congress' intent in the [Act]. The [Act] requires the Secretary to make a scientific determination if the product under review is a plant pest (7 U.S.C. 7711(c)(3)). If the final decision is that the product is not a plant pest, nor would the movement of the product in question impose the risk of dissemination of a plant pest, then USDA has no authority to impose further restrictions (7 U.S.C. 7712(a)).¹²⁵

Finally, on January 27, 2011, the USDA announced in a press release that it had opted for full deregulation of Roundup Ready Alfalfa, and would place no special restrictions on Monsanto's GM alfalfa varieties. The press release quoted Secretary Vilsack as saying that, "[a]fter conducting a thorough and transparent examination of alfalfa through a multi-alternative environmental impact statement (EIS) and several public comment opportunities, APHIS has determined that Roundup Ready alfalfa is as safe as traditionally bred alfalfa."¹²⁶ Further legal challenges to the deregulation of GM crops will certainly be made. Like many other cases of conflicting land use, the law will have to adjudicate between the colliding interests of supporters and opponents of GM crops.

The USDA has recognized the growing importance of these conflicting agricultural uses. In fact, the agency resurrected both the Advisory Committee on Biotechnology and twenty-first century Agriculture and the National Genetic Resources Advisory Committee to help it "tackle a broad range of issues, from ensuring the availability of high quality seed, to helping ensure that growers have access to the best tools available to support their production choices, to whether risk management and indemnification options can play a role."¹²⁷ Legislatures and courts will be busy for years attempting to find the proper legal and regulatory framework within which GM agriculture can thrive without unreasonably imperiling the property or activities of others.

125. Press Release, Lucas, Chambliss, Roberts: USDA Sending Mixed Signals on Genetically Engineered Alfalfa (Jan. 19, 2011), <http://agriculture.house.gov/press/PRArticle.aspx?NewsID=1293> (quoting Letter from Saxby Chambliss, U.S. Senator; Pat Roberts, U.S. Senator; and, Frank Lucas, U.S. Representative, to Tom Vilsack, Secretary, USDA).

126. Press Release, U.S. Dep't of Agric., USDA Announces Decision to Fully Deregulate Roundup Ready Alfalfa (Jan. 27, 2011), <http://www.usda.gov/wps/portal/usda/usdahome?contentidonly=true&contentid=2011/01/0035.xml>.

127. *Id.*

IV. THE DAWN OF SYNAGRICULTURE

A. Biology as Engineering

In 1958, yeast geneticist Edward L. Tatum used the occasion of his Nobel Prize acceptance speech to predict a future in which biology would become an engineering discipline:

With a more complete understanding of the functioning and regulation of gene activity in development and differentiation, these processes may be more efficiently controlled and regulated, not only to avoid structural or metabolic errors in the developing organism, but also to produce better organisms.

. . . [Understanding the genetic code] may permit the improvement of all living organisms by processes which we might call biological engineering.¹²⁸

With the advent of recombinant DNA methods in the 1970s, Tatum's "biological engineering" began to take form as "genetic engineering."¹²⁹ Nevertheless, genetic engineering's capabilities remained rather modest compared to those of other fields of engineering; genetic engineering often denoted nothing more ambitious than the modification of several nucleotide bases in single genes within host organisms. Today, a nascent field called "synthetic biology" aims to transform traditional biology and genetic engineering into a more rigorous and powerful engineering discipline.¹³⁰

To make biological engineering a reality, synthetic biology is attempting to import an engineering approach and ethos into biology.¹³¹ Synthetic biologists hope that biological systems, such as genes, genomes, cells, and organisms, will prove to be predictable and replicable.¹³² This contrasts with the conventional view that biological systems are hopelessly complex and inherently unpredictable. A leading synthetic biologist at Stanford University, Drew Endy,¹³³ has portrayed the question of which of these two views is more accurate as an empirical question.¹³⁴ Prodigious time and effort will likely be necessary to determine if, how, and to what extent biological systems can be tamed by engineering approaches.

128. Edward Tatum, Nobel Lecture (Dec. 11, 1958), http://nobelprize.org/nobel_prizes/medicine/laureates/1958/tatum-lecture.html.

129. See W. FRENCH ANDERSON, HUMAN GENE THERAPY: THE INITIAL CONCEPTS 1–2, 6, <http://cmbi.bjmu.edu.cn/cmbidata/therapy/about/PDF/pre1980.pdf>.

130. See EUROPEAN COMM'N, SYNTHETIC BIOLOGY: APPLYING ENGINEERING TO BIOLOGY 5–7 (2005), ftp://ftp.cordis.europa.eu/pub/nest/docs/syntheticbiology_b5_eur21796_en.pdf.

131. See *id.*

132. *Id.*

133. Stanford University School of Medicine and School of Engineering Department of Bioengineering Faculty Page, <http://bioengineering.stanford.edu/faculty/> (last visited March 26, 2012).

134. Drew Endy, *Foundations for Engineering Biology*, 438 NATURE 449, 449 (2005).

In 2005, Endy published *Foundations for Engineering Biology*, in which he offered an optimistic vision of synthetic biology.¹³⁵ His vision included the need for biology to adopt three general engineering principles: (1) standardization, (2) decoupling, and (3) abstraction.¹³⁶ Standardization requires “the definition, description and characterization of the basic biological parts, as well as standard conditions that support the use of parts in combination and overall system operation.”¹³⁷ Decoupling requires the systematic reduction of large problems into smaller, specialized modules, each of which is amenable to independent solutions by different specialists.¹³⁸ For example, a synthetic, multi-gene metabolic pathway might be constructed in such a way that each individual gene could be designed and built independently, and the metabolic pathway itself could be built by systematically aggregating the resultant genes. Abstraction requires that a biological engineering problem be considered from distinct hierarchical levels of complexity (“abstraction hierarchies”), and that basic components of engineered biological systems be designed to allow easier modeling.¹³⁹ One benefit of this engineering approach to biology could be the generation of standard biological “parts,” whose ready availability would facilitate the construction of biological “devices” that could, in turn, be used to construct biological “systems.”¹⁴⁰

B. An Open Biology Ethos

Among the leaders of the synthetic biology field there is a pervasive ethos of open standards, open access, and open innovation. A prevalent goal of the field is to foster free sharing of standard biological parts and synthetic biological methods in order to foster wide participation in synthetic biology by users. These users would be encouraged to make, use, copy, alter, and combine standard biological parts in new and unexpected ways, and for new and unexpected purposes. User innovation would, in turn, drive an increase in the number of available standard biological parts.

Champions of open synthetic biology worry that robust intellectual property rights, especially patents, could stand in the way of fostering a community of user innovators. For example, Heller and Eisenberg identified a “tragedy of the anticommons” in biotechnology that they feared overzealous patenting might cause.¹⁴¹ Instead of proprietary models of innovation, advocates of open synthetic biology often point to open

135. *Id.* at 450–52.

136. *Id.*

137. *Id.* at 450.

138. *Id.* at 451.

139. *Id.* at 451–52.

140. *Id.*

141. See, e.g., Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 *SCI.* 698, 698–701 (1998).

source and free software as models for spurring innovation and ensuring access in open synthetic biology.

There is considerable evidence that user, collaborative, and open paradigms of innovation are capable of generating prodigious amounts of new technology.¹⁴² Furthermore, patent protection may not be the spur to innovation that it has been commonly assumed to be. Eric von Hippel, a leading innovation scholar, has pointed out that “[s]tudies find that innovators in many fields view patents as having only limited value,” and that “most innovators do not judge patents to be very effective, and that the availability of patent grant protection does not appear to increase innovation investment in most fields.”¹⁴³ In their comprehensive economic analysis of the patent system, *Patent Failure*, Bessen and Meurer “suggest that much innovation is not dependent on patenting,” and that, “[o]n average, patents make a rather small contribution in this regard.”¹⁴⁴ Furthermore, a series of experimental studies directly comparing proxies of innovation, productivity, and social utility in simulated patent systems, combination patent/open source systems, and patentless commons, found that the commons systematically outperformed proprietary systems.¹⁴⁵

Several models of open biological innovation exist. One is CAMBIA, an Australian organization led by Richard Jefferson, which attempted to develop an open source GM crops platform to encourage agricultural biotechnological innovation without fears of patent infringement.¹⁴⁶ Another is the International HapMap Project (IHMP), which is a “partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom, and the United States to develop a public resource that will help researchers find genes associated with human disease and response to pharmaceuticals.”¹⁴⁷ The public resource in question is the HapMap, “a catalog of common genetic variants that occur in human beings” with potential uses in diagnosing and treating genetic diseases.¹⁴⁸ Several initiatives have been specifically organized to foster openness in synthetic biology. Notable among these are the Bi-

142. ERIC VON HIPPEL, ET AL., COMPARING BUSINESS AND HOUSEHOLD SECTOR INNOVATION IN CONSUMER PRODUCTS: FINDINGS FROM A REPRESENTATIVE STUDY IN THE UK 11–18 (2011).

143. ERIC VON HIPPEL, DEMOCRATIZING INNOVATION 10, 112 (2005).

144. JAMES BESSEN & MICHAEL JAMES MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK 90, 118 (2008).

145. See generally Andrew W. Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 131, 160–62 (2009); Andrew W. Torrance & Bill Tomlinson, *Property Rules, Liability Rules, and Patents: One Experimental View of the Cathedral*, 14 YALE J.L. & TECH. 138 (2011).

146. CAMBIA, <http://www.cambia.org/daisy/cambia/home.html> (last visited Mar. 26, 2012).

147. INTERNATIONAL HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov/> (last visited Apr. 16, 2012).

148. *What is the HapMap?*, INTERNATIONAL HAPMAP PROJECT, <http://hapmap.ncbi.nlm.nih.gov/whatishapmap.html> (last visited Apr. 4, 2012).

oBricks Foundation (BBF) and the annual International Genetically Engineered Machines (iGEM) competition.¹⁴⁹

C. Open Synthetic Biology Institutions

Three institutions have played a fundamental role in promoting open synthetic biology. These are the BBF, the Registry of Standard Biological Parts (Registry), and the annual iGEM competition. These institutions have historically shared some of the same leaders.

The BBF is a non-profit foundation whose mission is “to ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet.”¹⁵⁰ Formerly, its mission was defined more narrowly as “the development and responsible use of technologies based on BioBrick standard DNA parts that encode basic biological functions.”¹⁵¹ BioBricks may be combined and inserted into living cells in a manner analogous to how Lego pieces may be combined to build structures.¹⁵² The BBF has suggested that BioBricks may be used to “program living organisms in the same way a computer scientist can program a computer.”¹⁵³ The Registry is a collection of BioBricks, along with detailed technical information about how to make and use them.¹⁵⁴ The Registry accepts contributions of new BioBricks, but it prefers that they match BBF technical standards and are well described so that others can use them with relative ease.¹⁵⁵ In the broader synthetic biology community, the Registry provides the technical standards and processes for creating BioBricks, and provides direction for other technical matters relevant to the field.¹⁵⁶

The Registry serves several purposes. First, it acts as a resource for biologists who wish to gain access to standard biological parts.¹⁵⁷ Second, it provides sets of BioBricks to teams participating in the iGEM competition.¹⁵⁸ These BioBricks may be modified or combined with other BioBricks or other DNA molecules. And third, the BBF encourages users

149. Kristian M. Müller & Katja M. Arndt, *Standardization in Synthetic Biology*, in SYNTHETIC GENE NETWORKS: METHODS AND PROTOCOLS 31, 33 (W. Weber & M. Fussenegger eds., 2012).

150. BIOBRICKS FOUNDATION, <http://biobricks.org> (last visited Apr. 16, 2012).

151. *Synthetic Biology 4.0*, BIOBRICKS FOUNDATION, <http://sb4.biobricks.org/biobrick/s/> (last visited Apr. 4, 2012).

152. See *Help: An Introduction to BioBricks*, REGISTRY STANDARD BIOLOGICAL PARTS, http://partsregistry.org/Help:An_Introduction_to_BioBricks (last visited April 24, 2012).

153. BRUCE JONES ET AL., POWER & RESPONSIBILITY: BUILDING INTERNATIONAL ORDER IN AN ERA OF TRANSNATIONAL THREATS 141 (2009) (quoting the BioBricks Foundation website).

154. REGISTRY OF STANDARD BIOLOGICAL PARTS, http://partsregistry.org/wiki/index.php/Main_Page (last visited Apr. 16, 2012).

155. *DNA Submission Instructions*, REGISTRY OF STANDARD BIOLOGICAL PARTS, http://partsregistry.org/wiki/index.php/DNA_Submission_Instructions (last visited Apr. 16, 2012).

156. *Id.*

157. REGISTRY OF STANDARD BIOLOGICAL PARTS, http://partsregistry.org/wiki/index.php/Main_Page (last visited Apr. 4, 2012).

158. *About*, iGEM, <http://igem.org/About> (last visited Apr. 4, 2012).

to submit to the Registry new parts and devices that result from modification or combination of existing BioBricks. This helps the Registry grow, and makes new biological innovations available to others.¹⁵⁹

The BBF explicitly champions an “open-source ethic.”¹⁶⁰ The organization is “dedicated to advancing synthetic biology to benefit all people and the planet” through “ensuring that the fundamental building blocks of synthetic biology are freely available for open innovation; creating community, common values and shared standards; and promoting biotechnology for all constructive interests.”¹⁶¹ Furthermore, the BBF leads efforts to set and maintain open technical standards.¹⁶²

The Registry has successfully amassed an expansive, and ever-expanding, collection of BioBricks. Currently, there are more than 7,000 available for order by iGEM competition teams and academic laboratories.¹⁶³ By comparison, the human genome is comprised of approximately 20,000 genes.¹⁶⁴ The massive number of BioBricks available from the Registry has created a substantial, and accelerating, network effect incentive for synthetic biologists to comply with Registry standards for the sake of interoperability.

Since 2003, teams of students have been competing in the iGEM competition held annually at the Massachusetts Institute of Technology (MIT).¹⁶⁵ By 2011, iGEM had grown from humble beginnings to 165 teams, representing universities in dozens of countries, and even including several teams composed of high school students.¹⁶⁶ Teams begin their projects with identical kits of BioBricks, and compete to create new BioBricks, as well as novel genetic devices and systems built of BioBricks.¹⁶⁷ Teams invent new genes, polypeptides, proteins, metabolic pathways, cells, and even organisms, in the hope of winning awards in these Olympic Games of synthetic biology.¹⁶⁸ Teams are encouraged to resubmit new BioBricks they have developed back into the Registry for others to learn from and use.¹⁶⁹ Winning projects have ranged from “a rainbow of pigmented bacteria, to banana and wintergreen smelling bacteria, an arsenic biosensor, Bactoblood, and buoyant bacteria.”¹⁷⁰ The fact that these and other inventions have been created by undergradu-

159. *See id.*

160. BIOBRICKS FOUNDATION, <http://biobricks.org/> (last visited Apr. 4, 2012); *see also* Jon Mooallem, *Do-It-Yourself Genetic Engineering*, N.Y. TIMES, Feb. 10, 2010, at 6, available at <http://www.nytimes.com/2010/02/14/magazine/14Biology-t.html?scp=1&sq=mooallem%20open%20source%20ethic&st=cse>.

161. BIOBRICKS FOUNDATION, <http://biobricks.org/> (last visited Apr. 4, 2012).

162. *Id.*

163. REGISTRY OF STANDARD BIOLOGICAL PARTS, http://partsregistry.org/wiki/index.php/Main_Page (last visited Mar. 26, 2012).

164. JAMES D. WATSON ET AL., MOLECULAR BIOLOGY OF THE GENE 636 (5th ed. 2004).

165. *See About*, IGEM, <http://igem.org/About> (last visited Apr. 4, 2012).

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.*

ate or high school students has helped illustrate the accessibility and potential power of synthetic biology as a technology.

D. Here Comes Everybiologist

The DIYbio movement has arisen in parallel with the field of synthetic biology. A prominent and pioneering DIYbio organization, DIYbio.org, which has been active since 2008,¹⁷¹ describes its goals as follows:

[M]aking biology an accessible pursuit for citizen scientists, amateur biologists and biological engineers who value openness and safety. This will require mechanisms for amateurs to increase their knowledge and skills, access to a community of experts, the development of a code of ethics, responsible oversight, and leadership on issues that are unique to doing biology outside of traditional professional settings.¹⁷²

Another example is BioCurious, a DIYbio organization with a community biotechnology laboratory in Sunnyvale, California,¹⁷³ which states its mission as follows:

We believe that innovations in biology should be accessible, affordable, and open to everyone. We're building a community biology lab for amateurs, inventors, entrepreneurs, and anyone who wants to experiment with friends.¹⁷⁴

An earlier community laboratory, called "Genspace," opened in 2010 in Brooklyn, New York.¹⁷⁵

A number of trends have fostered participation in DIYbio. The growth of biotechnology, and its notable successes—such as the full nucleotide sequence of the human genome, on-demand DNA synthesis, availability of inexpensive genetic diagnostic tests, and even saliva-sample ancestry testing—has led to a large population of trained biologists and a receptive audience for their research breakthroughs. A spike in bankruptcies in the biotechnology industry has resulted in abundant laboratory equipment available for purchase at steep discounts. And, a growing perception by high school and undergraduate students that studying biology might lead to enhanced employment prospects has led

171. Ritchie S. King, *When Breakthroughs Begin at Home*, N.Y. TIMES, Jan. 16, 2012, at D4, available at <http://www.nytimes.com/2012/01/17/science/for-bio-hackers-lab-work-often-begins-at-home.html>.

172. *An Institution for the Do-It-Yourself Biologist*, DIYBIO, <http://diybio.org/> (last visited Mar. 26, 2012).

173. Pui-Wing Tam, *'Biohackers' Get Their Own Space to Create*, WALL ST. J., Jan. 12, 2012, <http://online.wsj.com/article/SB10001424052970204124204577150801888929704.html>.

174. *About*, BIOCURIOUS.ORG, <http://biocurious.org/about/> (last visited March 26, 2012).

175. King, *supra* note 171, at D4.

to greater demand for biological science courses in educational institutions at all levels.

The availability of well-provisioned biology laboratories for anyone interested in “biohacking” has attracted much attention, and burgeoning participation.¹⁷⁶ The science journal, *Nature*, gave its 2010 editorial about DIYbio the encouraging headline, “*Garage biology – Amateur scientists who experiment at home should be welcomed by the professionals,*” though it went on to note that “[m]ost biohackers are hobbyists who delight in crafting their own equipment and who tackle projects no more sophisticated than those found in an advanced high-school biology lab.”¹⁷⁷ Nevertheless, not everyone dismisses the potential of amateur biologists to make significant contributions to biology; the United States Federal Bureau of Investigation’s Weapons of Mass Destruction Directorate has already begun to monitor DIYbio activity.¹⁷⁸ The DIYbio movement has the potential to spur mass participation in synthetic biology, and, by doing so, to help democratize this new approach to biological science.

E. Synagriculture

A confluence of scientific and legal trends heralds the arrival of a new paradigm in agriculture: the democratization of GM crop and livestock development. The growing global participation in biotechnology, from iGEM to DIYbio, will cause the migration of at least some biological innovation out of professional contexts, such as universities, governments, institutions, and corporate research facilities, and into garages, basements, high schools, and community laboratories. In addition, whereas sophisticated biotechnological research was previously the exclusive domain of highly-trained biologists, it is increasingly becoming a pastime shared by uncredentialed, yet enthusiastic, ambitious, and talented amateurs. It is inevitable that these changes to biological science herald similar changes to GM agriculture.

For millennia, farmers have selectively bred their crops, livestock, and companion animals. Every major crop plant and livestock breed is the result of this relentless genetic modification. Although large corporations have recently become the locus for crop innovation, due largely to economies of scale in plant science research and development achievable with greater financial resources, synthetic biology and DIYbio will allow farmers to engage in their own genetic engineering research programs to improve their own crops. Even large agricultural crop firms, such as Monsanto and Pioneer Hi-Bred, may find themselves unable to maintain control over crop innovation when faced with thousands, or even millions, of farmers tinkering in their own crop genetics laboratories, and collaborating with their fellow citizen innovators around the

176. Tam, *supra* note 173; King, *supra* note 171, at D4.

177. *Garage Biology*, 467 NATURE 633, 634 (2010).

178. *Id.*

globe. As Eric von Hippel has demonstrated, the aggregate amount of innovation generated by individual users can dwarf that generated even in the research laboratories of large firms with teams of professional researchers.¹⁷⁹

If synthetic biology and DIYbio lead to a decentralization of GM agricultural innovation, the phenomenon will necessarily become more difficult to regulate. For example, the USDA, FDA, and Environmental Protection Agency (EPA) can much more easily regulate GM crop and livestock innovation by monitoring a modest number of relatively large agricultural corporations and universities than it can if it must monitor the innovations and collaborations of myriad individual farmers and other user innovators. Monitoring the latter innovators effectively would necessitate a vast increase in USDA, FDA, and EPA inspection personnel, which is a highly unlikely scenario given governmental strictures. A more likely outcome would be a form of effective regulatory capitulation by the agencies, which might have to settle for prosecution actions restricted to cases of egregious misconduct or negligence.

One salutary outcome of democratized agricultural innovation might be less dependence by farmers on large agricultural firms as monopoly suppliers of GM crops and livestock. Another benefit might be a decline in dependence on one-size-fits-all crops purchased from agricultural firms, due to increased availability of GM crops optimized by local farmers to local environmental conditions. Society would likely be better off if this led to increased crop yields, lower resultant crop prices, and a greater diversity of available agricultural products.

Democratized synagricultural innovation would not avoid the problems of patent infringement. In fact, increased innovation by farmers would almost certainly lead to more instances of infringement, whether deliberate or unintentional, by existing GM crop and livestock patents, many of which are owned by large agricultural firms.¹⁸⁰ Firms with GM agricultural patents would be most likely to sue farmer innovators whose GM crops or livestock threatened the firms' own markets. Because of their relative penury, most farmers and their GM agricultural innovations would likely be safe from patent litigation, even when their innovations did infringe patents owned by others. However, there is a possibility that agricultural firms, fearing the loss of their markets, might decide to sue individual farmer innovators in order to make examples of them, just as the Recording Industry Association of America (RIAA) pursued even modest individuals who had violated corporate copyrights by making unauthorized digital copies of music.¹⁸¹

179. ERIC VON HIPPEL ET AL., COMPARING BUSINESS AND HOUSEHOLD SECTOR INNOVATION IN CONSUMER PRODUCTS: FINDINGS FROM A REPRESENTATIVE STUDY IN THE UK 1–2 (2011).

180. Rajesh Chhabara, *Climate Ready GM Crops: The Patent Race*, CLIMATECHANGE.CORP.COM (Sept. 17, 2008), <http://www.climatechangecorp.com/content.asp?ContentID=5644>.

181. See, e.g., *12-Year-Old Sued for Music Download*, FOXNEWS.COM (Sept. 9, 2003), <http://www.foxnews.com/story/0,2933,96797,00.html>.

There is a substantial irony in the recent trend, both in the law and among the citizenry, towards comfort with GMOs. Consider the relevant United States and Canadian Supreme Court cases. *Diamond v. Chakrabarty* began the trend by legitimizing patents claiming GMOs.¹⁸² *J.E.M. v. Pioneer Hi-Bred* specifically recognized the patentability of GM crops, as well as the ability to combine utility patent and PPA or PVPA protection for the same GM plant.¹⁸³ *Monsanto Canada v. Schmeiser* reinforced the strength of GM crop patents by imposing liability for infringement even when infringement may have been inadvertent.¹⁸⁴ Finally, *Monsanto v. Geertson* reflected a growing accommodation with the complete deregulation of GM crops.¹⁸⁵ Together, these cases would seem to indicate that GM crops and livestock have become normal facts of agricultural life in North America, and no longer carry the taint of being considered either exotic or dangerous. However, this sense of comfort with GM agriculture is based on two important characteristics of current GM crops and livestock. First, experience with GM crops and livestock thus far has been with those having a single or small number of modified genetic traits. Second, the locus of innovation in, and resulting patent control of, GM crops and livestock has heretofore been dominated by a relatively small number of easily-monitored agricultural firms. Synthetic biology and DIYbio directly challenge both of these characteristics. The biological engineering approach of synthetic biology strongly suggests the wholesale redesign and reengineering of GM crops and livestock, from the genome up, rather than the traditional approach of minor tinkering among a small number of genes. The open ethos that pervades many in the field of synthetic biology, and serves as the very foundation of DIYbio, promises to shift the locus of GM agricultural innovation away from corporate concentration and control, and toward farmers and their fellow genetic tinkerers everywhere. Thus, just as law and society have begun to accept simple GM crops and livestock as normal, safe, and regulable, synthetic biology and DIYbio may be about to create much more complex GM crops and livestock that lack closely-related and comparable natural analogs. Moreover, synagriculture threatens to accomplish this not in a small number of large centralized laboratories that are relatively easy to monitor and regulate, but, instead, in myriad small, local laboratories occupied by individual farmers and other innovators who share and collaborate, and whose sheer weight of numbers make them difficult, if not impossible, to monitor or regulate. A brave new world of synagricultural innovation beckons.

V. CONCLUSION

Supporters of GM agriculture have had a long row to hoe in achieving public acceptance for the safety of this important technology. Con-

182. 447 U.S. 303 (1980).

183. 534 U.S. 124 (2001).

184. 2004 SCC 34 (Can.).

185. 130 S. Ct. 2743 (2010).

troverly has surrounded the foundational technology of recombinant DNA methods, the application of genetic engineering to crop plants and livestock, the safety of GM “Frankenfoods” as sources as human and animal nutrition, the potential environmental threats posed by the possible development of GM “superweeds,” and the corporate control over GM agriculture exercised by a relatively small number of agricultural companies armed with vast financial resources and powerful patent portfolios.¹⁸⁶ Nevertheless, as exemplified by the United States and Canadian Supreme Court cases, *Diamond v. Chakrabarty*, *J.E.M. v. Pioneer Hi-Bred*, *Monsanto Canada v. Schmeiser*, and *Monsanto v. Geertson*, the law, and the society it reflects, have finally managed to accommodate the important technology of GM agriculture.

However, a new paradigm in biological science—synthetic biology—has begun to remake the face of GM agriculture. Synthetic biology seeks to purge biology of some of its fundamental inefficiencies through the rigorous application of engineering principles. Rather than tinkering around the edges, biological engineering would remake living organisms from first principles, and employ standard parts to make qualitatively new biological devices and systems. Traditional arguments that GM crops and livestock are simply slightly-modified versions of their conventional counterparts may no longer be either appropriate or accurate in the face of synthetic biological approaches to engineering new plants. Moreover, both synthetic biology and DIYbio seek to shift biological research and development out of traditional laboratories and the hands of credentialed biologists, and instead allow any interested and motivated user to become a research biologist, biotinkerer, or synthetic biological engineer. Home and community laboratories are already springing up at a rapid rate, and farm laboratories are sure to follow, as participation in this new, open, and democratized movement burgeons. In short, large numbers of individual and collaborating users, spread over many small and local laboratories, are beginning fundamentally to reengineer genes, cells, organisms, and systems composed of organisms or their substituent parts. The comfortable acceptance of GMOs at which society has only recently begun to arrive may soon be misplaced in the face of both fundamentally new scientific approaches and the democratization of innovation.

The results for agriculture may be beneficial: enhanced rates of agricultural innovation through new biological approaches and wide participation. Moreover, synagriculture may prove to be as safe as GM agriculture or even conventional agriculture. However, assumptions about current GM crops and livestock may not easily apply to synthetic versions, nor may the current paradigm of GM regulation be possible when innovation becomes atomized among millions of farmers. Some of the “settled” legal issues surrounding GM crops and livestock may have to be revisited as new perceived or actual threats and benefits arise.

186. William Neuman & Andrew Pollack, *Farmers Cope With Roundup-Resistant Weeds*, N.Y. TIMES, May 3, 2010, at B1.

One irony may be that the same patent system that has so often been criticized in the past for providing agricultural companies with too much control over farmers may soon represent one of the most effective methods for monitoring and regulating GM agricultural innovation. Although some farmer innovators may eschew patent coverage for their agricultural inventions, others may opt to seek patent protection for their innovative new synthetic crops and livestock. Because the USPTO will have to examine any new GM crop inventions prior to issuing letters patent, disclosures to the USPTO synthetic biological inventors who opt for patent protection may become a vital centralized locus for monitoring and regulating otherwise highly decentralized synagricultural innovation.

New methods of biological engineering and new models of user, collaborative, and open innovation are soon to affect the trajectory of GM agricultural innovation. Even if such changes turn out to be salutary, they will be changes nevertheless. To ensure that society receives the full benefits of open and democratized synthetic biological innovation in crops and livestock, it would be well and wise for the law to prepare itself to reexamine the brave new world of synagriculture with brand new eyes.