Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms

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Originally published in DRAKE JOURNAL OF AGRICULTURAL LAW
6 DRAKE J. AGRIC. L. 81 (2001)

LEGAL ISSUES SHAPING SOCIETY'S ACCEPTANCE OF BIOTECHNOLOGY AND GENETICALLY MODIFIED ORGANISMS

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I. INTRODUCTION: SETTING THE STAGE

The scientific development of biotechnology—particularly the transfer of genes between species and the movement of products derived from biotechnology

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into economic use—has the potential to transform many aspects of modern agriculture. However, the development and use of biotechnology raises a series of significant issues for society. Among the issues implicated by the development of biotechnology are:

- the role of science and our trust in it,
- the adequacy of regulatory mechanisms to identify and protect the public interest,
- the application of intellectual property protections to control ownership and use of products and allocate their economic returns,
- the effect of new technology and economic consolidation in promoting the industrialization of agriculture, and
- the ability of consumers to be informed about the foods they eat.

Helping society resolve the legal, economic, political, and social tensions associated with the issues emerging in connection with the use of biotechnology, in particular genetically modified organisms ("GMOs"), presents a significant challenge to the legal system. It also represents a considerable opportunity for lawyers, especially the agricultural and food lawyers who will counsel the parties and interests involved in these issues.[1]

American agriculture and the public are now embroiled in a growing controversy concerning the development and use of various forms of genetic modification technologies for seeds and plants.[2] In recent decades, American

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1. I have been fortunate through a series of accidents, opportunities, and good fortune to be in a position to gain insight on some of these issues. I serve on the National Genetic Resource Advisory Council, a body created by Congress and appointed by the Secretary of Agriculture, to advise the USDA and the nation on the policy for the National Genetic Resource System, which includes our seed banks. I also serve on the board of directors of the Seed Savers Exchange, the largest non-profit organization of people involved in collecting, preserving, and exchanging heirloom vegetable seeds, and on the board of *Diversity*, the leading journal of the international plant genetic resource community. In October 1999, I completed the intellectual property audit for the International Potato Center in Peru, one of sixteen centers administered collectively under the Consultative Group on International Agricultural Research, and affiliated with the Food and Agricultural Organization of the United Nations. I have participated in several national and international conferences addressing these issues, including a Rockefeller Foundation workshop in Bellagio, Italy, in March 2000. As a caveat, let me be clear, I am not a patent attorney nor an intellectual property expert and make no claim to be, but I am a student of agricultural law and an observer of how the policy choices we make influence the type of society and political economy we create. These remarks are written from that perspective.

2. *See, e.g.*, Barnaby J. Feder, *Plant Sterility Research Inflames Debate on Biotechnologies Role in Farming*, N.Y. TIMES, Apr. 19, 1999, at A18; Jennifer Kahn, *The Green Machine*, HARPER'S MAG., Apr. 1999, at 70, 71; Jeffrey Kluger, *The Suicide Seeds*, TIME, Feb. 1, 1999, at 44, 44; Colleen Krantz, *Activists Protest at Conference*, DES MOINES REG., Sept. 21, 2000, at B3; J. Madeleine Nash, *Grains of Hope*, TIME, July 31, 2000, at 39, 40-42; Carol Kaesuk Yoon, *When Biotechnology Crops and Their Wild Cousins Mingle*, N.Y. TIMES, Nov. 3, 1999, at A18.

companies—primarily in the seed and more recently in the chemical industry—and the public research sector through both the United States Department of Agriculture ("USDA") and the land grant university system, have invested millions of dollars developing a range of technologies that can be classified as biotechnology.[3] Many people involved in agriculture and food production, from farmers to government officials, and of course, the companies involved, place great faith in this "next generation" of technology to help agriculture meet its historic mission—to be more productive, to be more profitable, and to help "feed a hungry world."[4] These people, businesses, and institutions have invested considerable amounts of money, time, and political capital in this effort and have staked their futures on the value and profitability of biotechnology.[5]

On the other side of the debate are a range of individuals and organizations concerned about both the value and wisdom of depending on biotechnology as the future of agriculture.[6] Their concerns range from the potential unknown human health effects of some technologies—especially forms of genetic modification that could not happen in nature (for example transgenic transfers of material across species boundaries, such as moving genes from fish into fruit)—to the potential environmental risks from the release of genetically modified plants which could cross to wild populations.[7] Some people are concerned biotechnology is just one more step, perhaps the last, in the corporate domination of the food and agriculture system.[8] They see it as another part of the industrialization process that will make farmers and ultimately consumers dependent on a handful of companies using food production technologies that will be expensive and potentially unsafe.[9] When boiled

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3. *See* Julia Flynn et al., *Seeds of Discontent,* BUS. WK., Feb. 2, 1998, at 62, 62. *See also* Scott Kilman, *Biotech Industry Shivers at Threat to Seed Patents*, WALL ST. J., Mar. 3, 1999, at B1.

4. Reed Karaim, *Variety, the Vanishing Crop*, WASH. POST, Apr. 11, 1999, at B1 (quoting, in part, Agricultural Secretary Dan Glickman in a speech to the National Farmers' Union). *See also* David Barboza, *AstraZeneca to Sell a Genetically Engineered Strain of Rice*, N.Y. TIMES, May 16, 2000, at C8; Kluger, *supra* note 2, at 45 (claiming the use of "muscled-up crops" would increase harvest yields); Rick Weiss, *Sowing Dependency or Uprooting Hunger?*, WASH. POST, Feb. 8, 1999, at A9.

5. In addition to agriculture's traditional function of producing foods, many farmers are optimistic biotechnology will create new opportunities to produce beneficial drugs and medicines on farms. *See, e.g.*, Andrew Pollack, *New Ventures Aim to Put Farms in Vanguard of Drug Production,* N.Y TIMES, May 14, 2000, at A1 (detailing the scientific advances which might bring the production of agricultural crops genetically engineered to produce useful pharmaceutical products into actual application).

6. *See* Andrew Pollack, *Food Companies Urged to End Use of Biotechnology Products*, N.Y. TIMES, Oct. 4, 2000, at C18.

7. *See* Flynn et al., *supra* note 3, at 82-83.

8. *See generally* David Barboza, *In the Heartland, Genetic Promises*, N.Y. TIMES, Mar. 17, 2000, at C6 (stating that companies would lose millions if farmers and buyers abandoned biotechnology based crops). *See also* Scott Kilman, *Monsanto is Sued Over Genetically Altered Crops,* WALL ST. J., Dec. 15, 1999, at A3.

9. A significant part of the subtext of the GMO debate is the issue of control, in particular control over the supply of agricultural genetics and the impact on genetic diversity. Developments within the biotechnology sector have been a major factor in a series of business mergers. The mergers

down to its essence the issue is a conflict between American agriculture's traditional reliance on new technology—in this case, the long-promised and finally arriving commercial fruits of the "biotechnology revolution"—and the concerns of a range of other interests, both in the U.S. and abroad, that some technologies present inherent risks of unknown dimensions.[10]

My purpose in this Article is to give an overview of the legal issues associated with biotechnology and GMOs in order to provide a foundation for the more specific discussions that follow. The range and number of legal issues now in question relating to the ownership, control, and use of biotechnology and agricultural genetic resources and thus to the future of agriculture and food production—are amazing. From a legal perspective, it seems there are few dimensions of the use of biotechnology that do not trigger potential legal concerns. Much of the current policy debate is focused on the safety and use of GMOs.[11] This is well illustrated by the recent controversy over the discovery of a non-approved form of GMO corn in taco shells marketed by Kraft.[12] As the story evolved, it led to recall of the food, [13] renewed calls for better FDA regulations of GMOs,[14] and the removal of one type of

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serve as a way to increase capitalization and fund increased research capacity but can also buy access to and control over certain technologies. Intellectual property lawyers will also admit that one effect, if not purpose, of some business actions has been to resolve underlying legal fights over ownership of technologies. The result is former competitors may become cooperators in joint ventures and then ultimately merge, as happened between DuPont and Pioneer Hi-Bred. What started as the purchase of a 20% interest in Pioneer and formation of a joint venture, with built in limits on DuPont increasing its holdings, soon led to Pioneer's board and management agreeing to sell the whole company. But this decision was in part precipitated by the rumor DuPont might acquire Pioneer's rival Monsanto and split out the 20% share. The issue of control of the flow of genetic material into agriculture is an important part of the larger context of the GMO debate and is a concern that surfaces frequently in conversations with farmers.

10. Scientists are looking at other technologies that might not have the same type of social and political concerns to help agriculture produce more food. *See, e.g.*, Barnaby J. Feder, *New Method of Altering Plants Is Aimed at Sidestepping Critics*, N.Y. TIMES, Feb. 29, 2000, at F3 (detailing the scientific advancements of transgenomics which involves inducing genes present in a plant to express properties rather than transferring in genes from other sources); Andrew Pollack, *Looking for Crops That Clone Themselves*, N.Y. TIMES, Apr. 25, 2000, at F3 (discussing the research on apomixis, or self-cloning, and the potential value of the trait); Carol Kaesuk Yoon, *Simple Method Found to Increase Crop Yields Vastly*, N.Y. TIMES, Aug. 22, 2000, at F1 (concerning research relating to planting fields of mixed varieties and the related yield enhancement from disease suppression and other factors).

11. *See, e.g.*, Steven H. Yoshida, *The Safety of Genetically Modified Soybeans: Evidence and Regulation*, 55 FOOD & DRUG L.J. 193, 194 (2000).

12. *See* Marc Kaufman, *Test Detects Biotech Corn in Taco Shells*, DES MOINES REG., Sept. 18, 2000, at 1A. The concern was that the type of Bt corn detected, StarLink, had been cleared only for use in animal feeds but not for human use because a protein it produces may cause allergies. *See id.*

13. *See* Andrew Pollack, *Kraft Recalls Taco Shells With Bioengineered Corn*, N.Y. TIMES, Sept. 23, 2000, at C1.

14. *See, e.g.*, Marc Kaufman, *FDA Will Widen Probe of Biotech Corn Misuse*, WASH. POST, Oct. 3, 2000, at A13. The Kraft taco shell incident brought the issue of labeling foods produced with

GMO corn seed from the market.[15] But in reality the issue of food safety is just one of several fundamental legal policies implicated by the use of biotechnology. This Article will discuss ten different legal concerns associated with biotechnology. These ten issues stretch across legal practice and involve writing contracts, enforcing patents, applying food-labeling rules, negotiating and interpreting international treaties, implementing environmental regulations, and protecting individual property rights. In some ways, the issues are an intellectual grab bag with something in the debate for everyone.

You are no doubt aware the GMO debate is developing into one of the more controversial issues involving agriculture and our society. One finds many positions, perspectives, and views in the debate. Hopefully, one value of these remarks is they attempt to take a neutral or objective view on the issues. One obstacle to understanding the legal issues concerning biotechnology is most people stating positions or opinions have an economic or political interest in the outcome. As a result, it can be hard to find unbiased information. In addition, there is often little "middle" ground in the debates—at least according to the participants. I discovered this in 1993 after publishing *Who Owns Dinner: Evolving Legal Mechanism for Ownership of Plant Genetic Resources*,[16] and no doubt will experience it again as a result of this Article. The political dynamic seems to be "you are either for me or against me." This attitude is apparent in much of the current debate about biotechnology in the U.S. The choice is either you think GMOs are safe and the best thing ever to happen to agriculture, or you believe they are the work of Satan.[17] You either support the ability of the Monsantos of the world to develop, own, and market any technology created, or you are a Luddite. But things are not this simple. While there is a time and a need for lawyers and public officials to take positions, there is also little to be gained by denying that legitimate, good faith, differences of opinion—scientific, economic, legal, and political—exist relating to biotechnology.[18]

GMO grain into a new and sharper focus. *See also* Andrew Pollack, *Labeling Genetically Altered Food is Thorny Issue*, N.Y. TIMES, Sept. 26, 2000, at A1.

15. *See* Barnaby J. Feder, *Companies Act to Keep Bioengineered Corn Out of Food*, N.Y. TIMES, Sept. 27, 2000, at C2. *See also* Philip Brasher, *Firm Halts Biotech Corn Sale*, DES MOINES REG., Sept. 27, 2000, at D1.

16. *See* Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 587 (1993).

17. The technology required to engage in genetic engineering may not require either Satan or a well-funded research lab. *See* Fred Hapgood, *Garage Biotech is Here or Just Around the Corner*, CIVILIZATION, Apr.-May 2000, at 46, 49 (containing an interesting but disturbing discussion of the minimal equipment and scientific understanding necessary to conduct basic biotechnology experimentation, and concluding it is an accessible and potentially uncontrollable process).

18. *See, e.g.*, Carol Kaesuk Yoon, *Altered Salmon Leading Way to Dinner Plates, But Rules Lag*, N.Y. TIMES, Nov. 3, 1999, at A1 [hereinafter Yoon, *Salmon*] (discussing food safety and environmental threats of genetically engineered creatures "slip[ping] through a net of federal regulations"); Carol Kaesuk Yoon, *Squash With Altered Genes Raises Fears of 'Superweeds'* N.Y. TIMES, Nov. 3, 1999, at A1 [hereinafter Yoon, *Squash*] (presenting detailed examinations of some of the

As you no doubt recognize, the truth in this debate—as in most—rests somewhere in the middle. Hopefully these comments will help you consider just where you feel the truth might be.[19]

II. BASIC ASPECTS OF THE U.S. POSITION ON GMOS

To understand the position of the United States on biotechnology and GMOs it is helpful to consider eight fundamental features of American policy and culture relating to the technology. These are:

- American agriculture is historically technologically oriented and has been very successful relying on this approach;[20]
- GMOs are widely accepted by American farmers, which is evidence of how well the technologies fit into the current structure and style of commodity production;[21]
- American food companies and the U.S. Food and Drug Administration ("FDA") view the technology as safe and believe there is no evidence supporting health concerns from eating or using GMOs and no evidence of environmental harm;[22]

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scientific concerns about the American regulatory process relating to the actual field release and use of genetically modified squash).

19. Many issues related to the GMO debate show the power of language and the importance of controlling the terms of public discourse. For example, consider the term GMO, a label the biotechnology industry dislikes. The industry has essentially taken two approaches to deal with the term: change it or confuse the issue. The attempt to change the term is the effort to substitute genetically enhanced agriculture ("GEA") for GMO. This effort has found some following in the farm press but little popular support at the national level. The second effort, essentially an attempt to confuse the debate, is familiar to all of you. The argument goes something like this: "What is this term GMO, it doesn't mean anything because all foods are genetically modified. This is nothing different than what farmers and plant breeders have been doing for centuries. Hybrids are genetically modified so what is the worry?" This argument is subtle but essentially facile. It is true the history of crop improvement and plant breeding, whether done on the farm or by plant breeders, has involved genetic manipulation and improvement. But what is different with this set of technologies is that it involves genetic transfers across species boundaries that never could have been crossed in nature. One example is the transfer of flounder genes to strawberries to increase frost tolerance. While a flounder might eat a strawberry used as bait, they would not mate. The point is genetic engineering is not just the same old thing; it is a new technology, arguably a radical technology that raises legitimate questions about the unknown effects of introducing genes into new species. You do not have to be Chicken Little to believe there are many unknowns associated with biotechnology. And you do not have to be an extremist to believe caution may be in order as opposed to rushing headlong to release any genetic modification that can be developed. Further, biotechnology is not the precise or gentle technology some claim. Randomly blasting genetic material into cells to see what might happen or infecting them with transfer agents, common methods of gene transfer, are not gentle technologies. In thinking about the science of biotechnology, I am reminded of Henry A. Wallace's comment the most important trait in a plant breeder was "sympathy for the plant." JOHN C. CULVER & JOHN HYDE, AMERICAN DREAMER: THE LIFE AND TIMES OF HENRY A. WALLACE 518 (2000).

20. *See* Karaim, *supra* note 4, at B1.

21. *See* Nash, *supra* note 2, at 41.

- as a result, the FDA believes attacks on GMOs or even questions about their safety are based on other non-scientific objections or agendas;[23]
- the United States is a leader in biotechnology, essentially owning the science, and thus has a significant and valuable competitive advantage and opportunity;[24]
- the U.S. government believes the various international trade agreements and protocols support our position on using biotechnology and will resist any efforts to effectively modify the rules to constrain GMOs, such as mandatory labeling;[25]
- the U.S. government believes biotechnology will be important in "feeding the world" as reflected in the confidence placed in the next generation of products such as golden rice;[26] and
- American corporations and the U.S. government hope the issue will go away over time and is essentially in a race to achieve this objective by facilitating the planting of GMOs here and in other grain producing nations with the effect of making it increasingly difficult for national and international policies on GMO use and labeling to be effectively reversed.[27]

By keeping these fundamental issues in mind it is possible to consider how the United States came to the policy positions it has taken on GMOs and to predict how the policies might evolve.

III. THE LAW AND AGRICULTURAL BIOTECHNOLOGY: TEN ISSUES SHAPING THE LEGAL TERRAIN

There are many ways to arrange or analyze the various legal issues currently in play regarding biotechnology. Perhaps in simplest terms, the issues all relate to two subjects: ownership and safety. But the range of legal questions, the variety of interests at stake, and the number of legal institutions involved require a more detailed analytical format. For those reasons, this Article considers ten issues, each

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22. *See* Pollack, *supra* note 6 (generally, consumers in the United States have also expressed little concern about genetically modified foods).

23. *See Bond Calls on Administration to Clear up Public 'Hysteria and Fear' About GM Foods*, 2 FOOD SAFETY REP. (BNA), at 586 (May 10, 2000).

24. *See* David L. Levy & Peter Newell, *Oceans Apart? Business Responses to Global Environmental Issues in Europe and the United States*, 42 ENV'T, Nov. 2000, at 8, 13, 18.

25. *See* Karen A. Goldman, *Labeling of Genetically Modified Foods: Legal and Scientific Issues*, 12 GEO. INT'L ENVTL. L. REV. 717, 721-28 (2000).

26. *See id.* at 718-19; Jonathan H. Adler, *The Cartegena Protocol and Biological Diversity: Biosafe or Bio-Sorry?*, 12 GEO. INT'L ENVTL. L. REV. 761, 762 (2000) (stating golden rice, a product of agricultural technology, can improve global nutrition).

27. *See* Anthony DePalma & Simon Romero, *Crop Genetics On the Line in Brazil*, N.Y. TIMES, May 16, 2000, at C1; Anne Fitzgerald, *Biotech Crop Firms Launch Campaign*, DES MOINES REG., May 5, 2000, at D1; Robert Paarlberg, *Genetically Modified Crops in Developing Countries: Promise or Peril?*, 42 ENV'T, Jan.-Feb. 2000, at 19, 20.

presented with some textual exposition and sufficient references to find original source material.

A. *Application of Patents and Other Intellectual Property Claims to Agricultural Genetics and the Products of Biotechnology*

Without the ability to claim legal protection for inventions much of the economic incentive for private involvement in biotechnology would disappear—and arguably so would society's opportunity to gain whatever benefits are associated with its development. Recent cases in both the United States and Europe have upheld the idea that seeds and plant varieties are appropriate subjects for utility patents.[28] Clarifying the application of a broad range of intellectual property rights ("IPRs") to the products of biotechnology is essential for enabling development of the products.[29] Without these protections, private companies would be limited in their ability to capture the value they add to the product and thus fund the research needed to create the new traits.[30] While public institutions can exist without such reliance on IPRs, the reality of the U.S. system is the majority of biotechnology—and even traditional plant breeding—has moved to the private sector.[31] A second component of the application of IPRs to biotechnology relates to the proliferation of litigation between and among the private companies developing the technologies to clarify ownership and control of important technologies and to right alleged "infringements."[32]

A current lawsuit is testing the issue of whether Congress intended the Plant Variety Protection Act ("PVPA"), which was enacted in 1970, to be the exclusive

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28. *See European Patent Office Approves Novartis GM Patent*, LEGAL LETTER (AGRA/Industrial Biotechnology), Jan. 2000, at 1.

29. *See Patent Gives Pioneer Claims for Corn Transformation*, FEEDSTUFFS, Dec. 6, 1999, at 5 (concerning an announcement by Pioneer that it had received patent protection for "bombardment-mediated transformation" otherwise known as the "gene-gun" technology, which is one of the fundamental methods employed for genetic transformation).

30. For a well written and documented discussion of the role of intellectual property protection in the U.S. seed industry, see Debra L. Blair, Note, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297 (1999).

31. *See Biotechnology Research: Weighing the Options for a New Public-Private Balance*, AGRIC. OUTLOOK, Oct. 1999, at 22.

32. *See* Anne Fitzgerald, *Pioneer to be Paid $100M*, DES MOINES REG., May 17, 2000, at A1 (discussing an out-of-court settlement between Pioneer and Cargill concerning the alleged illegal use of Pioneer parent seed). However the shoe was on the other foot in August when a St. Louis federal court jury awarded Monsanto over $100 million in damages against Pioneer in a suit alleging illegal infringement and use of Monsanto proprietary biotechnology products. *See, e.g.*, Gene Erb, *Pioneer Plans to Appeal Verdict*, DES MOINES REG., Aug. 26, 2000, at D1. *See also Award in Corn Seed Dispute is Affirmed*, N.Y. TIMES, Feb. 22, 2000, at C2 (concerning a decision by a federal court affirming a $65 million damage award given to Aventis Crop Science in a suit against DeKalb Genetics, a division of Monsanto, relating to claims of patent infringement and misappropriation of technology).

way to obtain intellectual property rights for a plant variety.[33] In the case, a local agricultural supply company being sued by a major seed company challenged the validity of the company's seed corn patents.[34] The significance of the legal issue is that under the PVPA, farmers have the right to save seed for replanting and there is also a research exemption, neither of which exist under utility patents.[35] In the most recent decision, the Federal Circuit Court upheld the district court's action in favor of the seed company.[36] In the ruling, the circuit court determined that when Congress enacted the PVPA (even though done when it was believed living materials were not subject to patents, *i.e.*, prior to the U.S. Supreme Court's 1980 decision in *Diamond v. Chakrabarty*[37]) the law was not intended as an exclusive protection.[38] The case is still not resolved.[39] The agricultural supplier petitioned the U.S. Supreme Court to review the case, and in early October the Court requested the Department of Justice to provide input on the issue, indicating there is some sentiment on the Court to hear the case.[40]

While downplayed by the seed industry,[41] the case may expose a more fundamental issue relating to American attitudes toward biotechnology. The fact is the United States has never engaged in a social or political debate concerning the extension of patent protections to living materials. Instead, the Supreme Court's five-to-four decision in *Diamond v. Chakrabarty* is the somewhat slender stem upon which rests much of the economic and legal basis of the biotechnology sector, at least as to ownership of the intellectual property involved. Some of the social and political frustrations reflected in the controversy over GMOs, grow out of this reality.[42]

At this point, it is hard to imagine the courts or Congress trying to put the "gene patent" genie back in the bottle, but the residue from the lack of public involvement in the decision remains. It is also one of the factors distinguishing American public policy on biotechnology from some other nations, such as India,

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33. *See generally* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted*, 121 S. Ct. 1077 (2001) (rejecting the defendants claim that patents on plant varieties conflict with the provisions of the Plant Variety Protection Act and are illegal under U.S. law).

34. *See id.* at 1376.

35. *See* Hamilton, *supra* note 16, at 599.

36. *See Pioneer*, 200 F.3d at 1378.

37. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

38. *See id.* at 1376.

39. *See id., petition for cert. filed*, 68 U.S.L.W. 3775 (U.S. Jun. 12, 2000) (No. 99-1996).

40. *See* J.E.M. Ag Supply, Inc., v. Pioneer Hi-Bred Int'l Inc., 69 U.S.L.W. (BNA) 3224 (2000). "The Solicitor General is invited to file a brief in this case expressing the views of the United States." *Id. See also Court Struggles with Pioneer Case*, DES MOINES REG., Oct. 3, 2000, at D1. The potential economic and political impact of the Court examining, let alone invalidating, utility patents on plant varieties is significant. Even if the Court accepts the theory the PVPA does not leave room for variety patents, it is likely the biotechnology industry would seek congressional action to amend the law.

41. *See* Kilman, *supra* note 3.

42. *See* Barnaby J. Feder, *Rocky Outlook for Genetically Engineered Crops*, N.Y. TIMES, Dec. 20, 1999, at C8 (analyzing the post Seattle situation relating to GMOs).

where more fundamental moral and ethical issues concerning man's ability to own living materials are shaping public policy on the extension of intellectual property rights to agriculture and biotechnology.[43]

B. *Enforcing Seed Contracts Containing Limitations on Replanting*

One issue, which is essentially a subset of the larger intellectual property rights discussion, relates to the enforcement of private contracts or agreements restricting the use of seeds. The primary focus in this regard relates to Monsanto's aggressive enforcement of the "no saved seed" provisions in the "technology transfer" agreements or seed contracts growers sign to purchase Roundup Ready® products, such as soybean and canola seeds genetically modified to withstand higher doses of a popular weed killer.[44] The legal issue—contractual limits on the ability of farmers to save seed (or perhaps more accurately for the commercialization of biotechnology—the inability of farmers to save and reuse seed)—is central to understanding how biotechnology is leading to fundamental changes in marketing relations within agriculture.[45] For the most part, the legal issues involved in these disputes are simple and straightforward, involving claims of contract enforcement and interpretation of any applicable statutory exemptions.[46] The factual issues at the heart of cases that have been filed, such as one currently being litigated in Canada,[47] are often evidentiary. Similar cases revolve around questions such as: Is there a record of past purchases of protected seed? Does a signed contract exist limiting the grower's rights? What is the source of the "genetic material" alleged to show the contractual breach?

The farm sector has been a traditional supporter of the seed industry and to date has been supportive of the development of biotechnology;[48] however, this

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43. *See* David Downes & Matthew Stilwell, *The World Trade Organization's TRIPs Agreement and IPR: The Case Against Lifting the 'Life Patenting' Exception,* 15 DIVERSITY 25, 25 (1999).

44. *See* Christopher Leonard, *Monsanto Sues Midwest Farmers for Saving Soybean Seeds* (visited Apr. 1, 2001) <http://www.purefood.org/Monsanto/farmerssued.cfm>; *Saskatchewan Farmer Battles Monsanto, Sues Them Back* (visited Apr. 1, 2001) <http://www.infoshop.org/news4/monsanto2.html>.

45. *See generally* Kahn, *supra* note 2, at 70 (annotating the letter sent by Monsanto to growers concerning the legal obligation to not save and replant patented seed).

46. *See generally id.* (describing the contractual relationship Monsanto requires from U.S. farmers and resulting settlements when the crops fail). *See also* Leonard, *supra* note 44; *Saskatchewan Farmer Battles Monsanto, Sues Them Back, supra* note 44.

47. This case involves allegations the plaintiff illegally saved and replanted Roundup Ready® canola and a counter-claim by the producer his crops were contaminated with Roundup Ready® pollen that drifted in from neighboring fields. *See* John P. Mandler & Kristin R. Eads, *Potential Liability Exposure to Seed Companies from GMO Pollen Drift,* LEGAL LETTER (AGRA/Industrial Biotechnology), May 2000, at 1, 2.

48. *See* Flynn et al., *supra* note 3, at 62.

attitude could change if the terms or cost of access are perceived as unfair. As farmers become more fully aware of the extensive limitations on their personal rights and the additional costs associated with using some forms of biotechnology, resistance could develop.[49] While farmers may have some concern about "seed pirates" there is also the potential for farmers to develop a collective concern about having limited choices of seed products and higher costs.[50] The recent tension within the soybean community about the disparity between the cost and availability of Roundup Ready® soybeans to competitors in Argentina and the higher prices and planting restrictions faced by U.S. growers is a perfect example of how divisions can grow.[51] One result was for the American Soybean Association to ask Monsanto to drop the technology fee, something Monsanto refused to do.[52] If the fee is not dropped, one option could be for farmers to ask Congress to add a saved seed exemption to the law for patented varieties. It is also predictable that farmer support for biotechnology will diminish if market forces result in GMO crops being sold at a discount due to consumer resistance. This is one reason why the biotechnology industry strongly opposes any system of labeling GMO crops.[53] Any market resistance to labeled crops would likely be reflected in the market prices paid to farmers for such crops and could lead to reduced seed sales for GMO products.

C. *Class Action Against Monsanto Alleging Anti-Trust Violations in Marketing GMO Technology*

In December 1999 a national class action lawsuit was filed against Monsanto and other co-conspirators on behalf of six farmers relating to the development and marketing of GMO seeds.[54] The suit alleges, among other claims, a conspiracy to monopolize the seed industry and limit the technology options available for farmers.[55] The lawsuit involves an extensive array of claims, including price fixing, restraint of trade, failure to adequately test, destroying consumer confidence, as well as violations of customary international law.[56] Much of the media coverage of the lawsuit has related to the issues of whether GMO technology is safe and the

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49. *See, e.g.*, Leonard, *supra* note 44; Robert Schubert, *Monsanto Sues Nelson Farm: A North Dakota Family's Frustrations With Genetically Engineered Soybeans* (visited Apr. 1, 2001) <http://cropchoice.com/leadstry.asp?RecID=24>.

50. *See, e.g.*, Leonard, *supra* note 44; Schubert, *supra* note 49.

51. *See* U.S. GEN. ACCOUNTING. OFFICE, INFORMATION ON PRICES OF GENETICALLY MODIFIED SEEDS IN THE UNITED STATES AND ARGENTINA 12 (2000).

52. *See* American Soybean Association, *ASA Calls for Equitable Sales Practices for Soybean Seedstock* (last modified Feb. 20, 2001) <http://www.amsoy.org/news.htm>.

53. *See id.*

54. *See* Michael Howie, *Monsanto Sued Over GM Seed Sales*, FEEDSTUFFS, Dec. 20, 1999, at 3 (discussing the class action suit filed by a coalition alleging Monsanto and other seed companies conspired in marketing certain GMO technologies); Kilman, *supra* note 8.

55. *See* Pls.' Am. Pet. at 17-20, Higginbotham v. Monsanto Co., No. 1:99cv03337 (D.C.C. Dec. 14, 1999) (on file with author).

56. *See id.*

government's approval process adequate.[57] But from a farmer and legal perspective, the suit provides an interesting look at how Monsanto developed and marketed Roundup Ready® technology. A central theory of the case relates to how the decisions to commercialize the product through licensing agreements with other companies and use of a standard technology transfer agreement and fee for farmers allegedly violate anti-trust law.[58] Of course, the defendants have resisted these allegations[59] and there are two sides to every story. But what is interesting about the suit is that the complaint provides an informed, though slanted, historical lesson on how biotechnology is shaping the structure of both the agribusiness sector and farming.[60]

D. *Federal Regulation of Bio-Pesticides*

One form of biotechnology that raises a series of legal issues concerns bio-pesticides, which are seeds engineered to express pesticidal properties. This class of products involves the genetic transfer directly to seeds and plants of pesticidal properties, or "plant-expressed protectants," the term industry prefers.[61] The most well known and widely commercialized class of these products are the various Bt seeds, including cotton, potatoes, and corn.[62] In this technology, seeds are engineered so the plants express sufficient levels of Bt (Bacillus thuringiensis) toxin throughout the plant tissue so when a traditional insect pest, such as a Colorado potato beetle, European corn borer, or boll weevil, attacks the plant it consumes a sufficient level of Bt to sicken or die.[63] The products have found a relatively strong reception in the market although the range of concerns associated with their use is broad and growing. The concerns include:

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57. *See* Kilman, *supra* note 8; Melody Petersen, *U.S. to Keep a Closer Watch on Genetically Altered Crops*, N.Y. TIMES, May 4, 2000, at A23.

58. *See* Pls.' Am. Pet. at 21-25, *Higginbotham* (No. 1:99cv03337).

59. *See* Kilman, *supra* note 8.

60. *See* Pls.' Am. Pet. at 15-21, *Higginbotham* (No. 1:99cv03337).

61. The debate is partly over terminology as industry and researchers argue it is improper for the EPA to describe the seeds as "bio-pesticides" because there is no pesticide applied to the crop; instead the plant expresses the defense mechanism itself. *See* Ed Maixner, *EPA to Finalize Rule on Engineered Pest Resistance*, FEEDSTUFFS, Mar. 29, 1999, at 3. Apparently, the arguments of industry were persuasive because EPA recently announced in the draft final rule that it would refer to the products as "plant-incorporated protectants." *See* 65 Fed. Reg. 55,929, 55,929 (2000); *Draft of Final Plant Protectant Regulation Forwarded to Agriculture Department by EPA*, 2 FOOD SAFETY REP. (BNA), at 1107 (Sept. 20, 2000).

62. *See Organic Farmers, Greenpeace, Others Ask Court to Pull Bt Crop Registrations*, 1 FOOD SAFETY REP. (BNA), at 140 (Feb. 24, 1999).

63. *See generally id.* (discussing in part Bt crop effects on plants through animal intermediaries). *See also* Michael Pollan, *Playing God in the Garden*, N.Y. TIMES MAG., Oct. 25, 1998, at 44.

1. *Efficacy issues associated with using bio-pesticides.* This is an issue because some products, including Bt cotton and Roundup Ready® soybeans, have not worked as well as growers expected, resulting in situations where companies have had to "make good" with disgruntled users.[64]

2. *Delaying the development of pest resistance.* This is perhaps the most significant issue and it results from the scientific certainty that it is a question of when—not if—insects will develop resistance to the products.[65] The certainty of developed resistance has resulted in the next issue, which has a potential regulatory dimension.

3. *The required or recommended use of untreated field refuges.* The issue of field refuges is important because it means farmers may need to not plant portions of their fields in Bt products (and companies will need to resist the temptation to sell the products for use on the maximum acres).[66] The use of refuges is in an effort to delay the development of resistance in the target pests by creating areas where non-resistant insects can breed.[67] The field refuge issue has involved a scientific dispute between government officials and university and company researchers over the size of refuges necessary to delay resistance.[68] From a legal perspective, the question is whether the Environmental Protection Agency ("EPA") should "require" field refuges by regulation, or whether industry and corn growers should be responsible for a voluntary system of promised refuges.[69] The EPA has promulgated guidelines to require a form of refuge system patterned after the system developed and proposed by growers.[70] The policy issue revolves around the question of how the development of resistance can be delayed or managed in ways that maximizes the utility and life of the seed technology in question.[71] The challenge of managing insect resistance

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64. *See* Schubert, *supra* note 49.

65. *See* Rebecca Renner, *Will Bt-Based Pest Resistance Management Plans Work?*, 33 ENVTL. SCI. & TECH., Oct. 1, 1999, *available in* <http://pubs.acs.org/hotartcl/est/99/oct/ren.html>.

66. *See National Corn Growers Association Urges Members to Plant Non-Bt Refuges*, TOP PRODUCER, Dec. 1999, at 34.

67. *See id.*

68. *See id. See also* Carol Kaesuk Yoon, *E.P.A. Announces New Rules on Genetically Altered Corn*, N.Y. TIMES, Jan. 17, 2000, at A14 (announcing that the EPA would require at least 20% of farmers' crops to be planted as non-Bt).

69. *See, e.g.*, Michael Howie, *Companies Submit Plan to Prevent Bt Resistance*, FEEDSTUFFS, May 10, 1999, at 23 (maintaining a minimum of 20% of non-Bt corn in the Corn Belt states and a minimum of 50% of non-Bt corn would be required in southern corn/cotton growing region).

70. *See, e.g.*, Rick Weiss, *EPA Restricts Gene-Altered Corn in Response to Concerns: Farmers Must Plant Conventional 'Refuges' to Reduce Threat of Ecological Damage*, WASH. POST, Jan. 16, 2000, at A2 (discussing the EPA release of proposed guidelines relating to the use of mandatory field refuges with the planting of Bt corn and cotton and the letters the agency would require seed companies to send growers to implement the guidelines); Yoon, *supra* note 68.

71. To review what the EPA is requiring for biopesticides, visit the web site the EPA maintains on this topic (visited Feb. 13, 2000) <www.epa.gov/pesticides/biopesticides>.

raises questions of what standard of precaution or control should apply and who should be responsible for implementing and enforcing any resistance management plan.[72]

4. *Human health and safety issues from consuming foods with "biopesticides."* This issue is relevant because bio-pesticides are expressed in the plant tissues, including parts that may be eaten.[73] In this regard, the bio-pesticide issue is just one component of the larger debate about whether our food safety and regulatory system is adequate to protect the interests of consumers as it relates to GMOs. One of the most powerful stories yet written on the GMO issue focused on the regulatory approval of Bt potatoes.[74] In a *New York Times* magazine cover story, *Playing God in the Garden*, Michael Pollan documented the legitimacy of the "unknown" health concerns associated with eating the products, such as the New Leaf potato featured in the story.[75] This uncertainty largely results from what is perhaps best described as the regulatory fan dance done by the EPA and the FDA over whether to treat the products as a "food additive" (with the FDA regulating) or a "pesticide" (with the EPA regulating).[76] It appears each agency believes it is the other's responsibility. As a result neither has tested the "food safety" of eating the products.[77] Phillip Angell, a Monsanto representative, was quoted as saying, "Monsanto should not have to vouchsafe the safety of biotech food. Our interest is in selling as much of it

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72. The legal issue involves three central players: the companies selling the seeds, the producers who use them, and the agency responsible for regulating the product. As it relates to Bt technology, the basic approach to resistance management (other than not using the products) is to use refuges planted in other varieties, which function as sites where non-resistant insects can breed. *See National Corn Growers Association Urges Members to Plant Non-Bt Refuges*, *supra* note 66, at 34. The scientific issues are how rapidly resistance will develop and what size of refuge is needed. The legal issues are who will establish the size and how will their use be implemented. The idea the companies selling the product should play a role is apparent, but is counterintuitive because it involves marketing a product based on efficacy but then telling users they can only buy a portion of what they might want to use. The idea farmers will implement refuges voluntarily is also counterintuitive because it requires acting against one's self interest for the good of the community. The difficulty of making farmers responsible for maintaining individual farm level refuges is enhanced by the view the neighbor's property can always serve as a refuge. It was against this backdrop that the EPA had to develop regulatory approaches. This issue has involved several commodity organizations, most notably the National Corn Growers, in developing producer initiated efforts to implement refuge requirements. One value of doing so is to avoid the application of mandatory regulations imposing such refuges, in particular, larger ones than desired.

73. *See* Office of Pesticide Programs, United States Environmental Protection Agency, *What are Biopesticides* (visited Apr. 7, 2001) <http://www.epa.gov/pesticides/biopesticides/what_are_biopesticides.htm>.

74. *See* Pollan, *supra* note 63, at 44.

75. *See id.*

76. *See id.* at 50.

77. *See id.*

as possible. Assuring its safety is the FDA's job."[78] In a November 15, 1998 letter to the editor commenting on the story, Phillip Angell did not dispute his quote but did say his intent was to note food safety is too important to leave just to industry.[79]

5. *Environmental concerns from using bio-pesticides.* A recent study conducted by Cornell University reported the potentially harmful impact of Bt pollen on Monarch butterflies feeding on milkweeds.[80] The release of the Cornell study on the issue led to immediate action by the European Union to suspend importation of corn grown from several U.S. hybrids that had already been approved for sale in Europe.[81] The original Monarch butterfly study and subsequent ones, such as one completed by an Iowa State University researcher last summer, have been criticized by industry and other scientists who claim the studies do not represent real life field conditions and that Bt corn presents no threat to butterflies.[82] In late September 2000, the EPA released a draft report concluding Bt products do not present a serious threat to insects like Monarch butterflies.[83]

Even in light of this report, the possible environmental effect of GMOs such as Bt corn is perhaps the most significant public concern about biotechnology. This episode and the impact such "revelations" can have on commodity prices add to a growing fear about the future of GMO products. The uncertainty has caused farmers to wonder whether the sale of some GMO seeds might lead to a two-tiered marketing system where "unapproved products" sell domestically at a discount to exportable crops. As can be expected, any cloud on the economic promise of GMOs leads to grumbling among U.S. farmers. But as might be expected, to date most of the grumbling by companies, farmers, and the U.S. government has been aimed at the Europeans for their "unreasonable" actions and at the environmentalists who are using "unsound" science to raise unsubstantiated safety concerns.[84]

6. *Impact of widespread Bt crop use by organic farmers.* Because Bt is naturally occurring it has been one pesticide approved for use by organic growers, who may use it in emergency cases to treat insect problems.[85] This use is much more

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78. *Id.* at 51.

79. *See* Phillip Angell, *Letter to the Editor*, N.Y. TIMES MAG., Nov. 15, 1998, at 30, 30.

80. See Carol Kaesuk Yoon, *Altered Corn May Imperil Butterfly, Researchers Say*, N.Y. TIMES, May 20, 1999, at A1.

81. *See* Pollack, *supra* note 6.

82. *See* Anne Fitzgerald, *ISU Study Also Shows Bt Corn Kills Butterflies*, DES MOINES REG., Aug. 22, 2000, at A1.

83. *See* Carol Kaesuk Yoon, *Biotech Corn Isn't Serious Threat to Monarchs, Draft U.S. Report Finds*, N.Y. TIMES, Sept. 26, 2000, at F4.

84. *See* Scott Kilman & Helene Cooper, *Monsanto Falls Flat Trying to Sell Europe on Bioengineered Food*, WALL ST. J., May 11, 1999, at A1; Krantz, *supra* note 2 (quoting Doug Getter, executive director of the Biotechnology Association, as saying, "opponents are spreading fear about biotech crops by using unresolved issues as ammunition").

85. *See Organic Farmers, Greenpeace, Others Ask Court to Pull Bt Crop Registrations*, *supra* note 62, at 141

limited in time and area than the widespread use of Bt now found in plant expression.[86] One effect of the more extensive and persistent use of Bt is that once pests develop resistance, organic growers will no longer be able to rely on the treatment.[87] These concerns led a group of organic growers and environmental organizations to sue the EPA seeking withdrawal of approval for sale of all Bt seeds.[88] However, the plaintiffs recently withdrew the lawsuit.[89]

E. *Domestic Labeling of GMO Products*

1. *Food Labeling and the Consumer's Right-to-Know*

One central issue in the GMO debate concerns food safety.[90] The reality is that foods containing GMOs now predominate our food system, due largely to the widespread use of GMO seeds in soybean production and the almost ubiquitous nature of soybean products in our food supply.[91] But from a legal viewpoint, the issue involves two parts: food safety and food labeling, which is known as the food safety and consumer right-to-know dichotomy.[92] To make a clear distinction between two perspectives, the European approach to this dichotomy differs from the unitary approach taken in the United States.[93] In other words, in Europe you do not have to believe GMOs present a serious food safety concern or have evidence of the health risk to argue that consumers have a right to know about the processes and products used in producing their food.[94] This is the source of the European Union's "novel food" regulations and the basis for their efforts to prevent the sale of GMO products without adequate labeling.[95] However, in the United States we do not treat the two issues as distinct—our food labeling system is only designed to address food safety concerns, no matter how the food was developed.[96] Thus if you do not have evidence of a health risk or some other recognized basis for requiring a process or product to

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86. *See id.*

87. *See id.*

88. *See id.* at 140-41.

89. *See Greenpeace Drops Bt Lawsuit,* AG BIOTECH REP., Aug. 2000, at 16, 16.

90. *See, e.g.*, Yoshida, *supra* note 11, at 193.

91. *See generally id.* at 194 (explaining the scope of soybean agriculture in the United States).

92. *See* Goldman, *supra* note 25, at 720-21.

93. *See Intellectual Property Biotechnology Intellectual Property Explodes: What Are the Implications for Human Kind?*, LEGAL LETTER (AGRA/Industrial Biotechnology), May 2000, at 11-12 (describing the laws of various European nations, which range from all out bans to requiring permits before allowing farmers to grow GMOs).

94. *See* Frederick A. Degnan, *The Food Label and the Right-to-Know,* 52 FOOD AND DRUG L.J. 49, 56-57 (1997).

95. *See id.*

96. *See* Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 (1992).

be labeled, the weight of American food labeling law is against you. The United States' position is further reinforced by the FDA's 1992 decision that foods produced using genetic transformation are the substantial equivalent of other foods and do not require labeling.[97]

Another way of considering the issue is to acknowledge the United States does not have a food labeling system based on a consumer's right-to-know.[98] More accurately, our system involves a consumer's right-to-know only the minimum the law requires, or from the perspective of a food processors or marketers, a right not to tell consumers every little detail about the food they eat.[99] The litigation striking down state efforts to mandate labels relating to the use of bovine somatotropin ("BST") in milk production illustrates this.[100] These limitations on the performance or completeness of the food labeling system in part explain some of the growth in the demand for organic food—and especially for the proliferation of "eco-labels," which are essentially private brands based around some set of production or performance standards.[101] Marketing foods as "non-GMO" is a form of an eco-label type claim.[102]

It is interesting to note that even in those areas where there is the opportunity for "voluntary" labeling that would provide more information, the food industry is generally opposed to providing the information.[103] For example, consider the food industry's response to the FDA's recent proposal to allow voluntary labeling of non-GMO food.[104] Rather than respond with a plan for how this form of labeling can be facilitated, the food industry's response was to make it difficult for anyone to make such a claim.[105] Perhaps this was predictable if you believe consumers will in fact prefer non-GMO products and may choose them rather than foods silent on the issue (and implicitly made with GMO products).[106]

A final point to consider about the food labeling issue and GMOs is the argument that under the U.S. system we do not label the process whereby a food is

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97. *See id.* at 22,991. *See also* Degnan, *supra* note 94, at 49.

98. *See* Degnan, *supra* note 94, at 55 (stating food labeling policy in the United States is based on science and the Federal Food, Drug, and Cosmetic Act).

99. For an enlightening discussion of U.S. food labeling law, see Degnan, *supra* note 94, at 49.

100. *See generally* International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2nd Cir. 1996) (striking down the Vermont law requiring the labeling of dairy products produced with artificial BST).

101. For a discussion of some of the issues raised by eco-labeling initiatives, see Bart Driessen, *New Opportunities or Trade Barrier in Disguise? The EC Eco-Labeling Scheme*, 8 EUR. ENVT'L L. REP. 5 (1999).

102. *See generally Food Industry Groups Petition FDA for Guides on Biotechnology-Free Claims*, 2 FOOD SAFETY REP. (BNA), at 586 (May 10, 2000) (discussing guidelines for manufacturer claims of biotechnology food labels).

103. *See* David Safford, *Clinton Administration Outlines Policy: Mandatory Consultation, Voluntary Labeling*, 2 FOOD SAFETY REP. (BNA), at 584 (May 10, 2000).

104. *See id.*

105. *See id.* at 586

106. *See Food Industry Groups Petition FDA for Guides on Biotechnology-Free Claims*, *supra* note 102, at 586.

produced if the process is determined to be safe.[107] Thus, the claim is if GMO foods are the equivalent of non-GMO foods, then the manner by which the parent material (seed) was transformed is not relevant to the consumer—and to require this information on the label would be unprecedented in our food system.[108] For the most part this is accurate—we do not provide label information about how a food product was grown or processed.[109] However, there is at least one significant exception to the theory of not requiring labels for "safe" processing technologies. That exception is irradiation.[110] The FDA and USDA have determined irradiation of meat and other foods is safe but they still require this information to appear on label.[111] Why is that? Because they believe the information is of interest and relevant to a significant enough number of consumers that they will require it.[112] The point is the FDA could also require labeling for GMO foods if the agency wanted to. The refusal of the agency to require labeling was the subject of a lawsuit filed in 1998 by a coalition of scientists, clergy, and others concerned about the health risks of GMO foods.[113] In late September 2000, the U.S. District Court for the District of Columbia rejected the arguments and granted a summary judgment upholding the FDA's actions rejecting GMO labeling.[114]

2. *Features of the U.S. Regulation of GMO Foods*

An essential feature in appreciating America's approach to GMOs is to consider how the current regulatory process relating to food safety and environmental protection applies to the adoption of new GMO products.[115] The following discussion summarizes the various components of the system.

The USDA approves the field release and testing of GMO crops.[116] Approvals today are routine and based on safety information provided by the companies rather than independent evaluations made by the agency.[117] Examples of technologies approved for use and release include Bt corn, Roundup Ready®

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107. *See* International Dairy Foods Ass'n. v. Amestoy, 92 F.3d 67, 73-74 (2d Cir. 1996).

108. *See, e.g., id.*

109. *See* Pollack, *supra* note 14.

110. *See* Sarah Muirhead, *FDA Seeks Comments on Irradiation Labeling*, FEEDSTUFFS, Feb. 22, 1999, at 3.

111. *See id.*

112. *See id.*

113. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 170 (D.D.C. 2000) (challenging the FDA decision to allow the sale of GMO food without mandatory labeling).

114. *See, e.g.*, Andrew Pollack, *Judge Upholds F.D.A. Policy on Genetically Altered Foods*, N. Y. TIMES, Oct. 4, 2000, at C18.

115. *See generally* Judith E. Beach, *No "Killer Tomatoes:" Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181 (1998) (reviewing the GMO regulatory program).

116. *See id.* at 182.

117. *See* 7 C.F.R. §§ 340.4(b), (e) (2000).

soybeans, and virus resistant squash.[118] The primary concern of the USDA concerns plant health, the effect of field release and pollen drift, and resistance.[119]

The FDA approves the marketing of some foods and food related technologies.[120] In a key 1992 decision, the FDA determined there is no substantive difference between foods produced from GMO seeds and those produced from traditional plant breeding, which means no special labeling or approval process is required for most food products that contain GMOs.[121] The only exception is for products in which the genetic transformation includes known allergins.[122] The issue of when to notify the FDA of potential risks rests with the company, though the company also bears the risk of marketing a product that may turn out to be hazardous.[123] The FDA's determination means GMOs are not a food additive and as a result there are no special tests or labels required for foods made from GMOs.[124] There is also no FDA safety testing based on trials involving feeding or consumption of the products and there is no pre-market approval of the new GMO foods or those sold in their raw form.

The EPA is involved in the GMO debate only if a product is classified as a "bio-pesticide" such as Bt corn (though not Roundup Ready® soybeans).[125] In this situation, the EPA's primary concern has been the development of resistance, (as addressed in rules relating to mandatory refuges for use of Bt products), rather than safety testing or efficacy evaluation of the products.[126] The safety testing is done in reference to the safety of the product engineered into the seed (*i.e.*, if Bt applied as a traditional pesticide is safe then Bt engineered into seeds is considered safe).[127]

There are several results of this three-part regulatory approach. First, it creates the appearance of a detailed and comprehensive regulatory screen, so much so that promoters of biotechnology, like representatives of the Biotechnology Industry Organization ("BIO"), can argue these are the most heavily regulated foods in history.[128] Second, the reality may be somewhat less thorough however, because the division of responsibility creates the situation where it is not clear who is

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118. *See* Kilman, *Biotech Industry Shivers*, *supra* note 3; Yoon, *Biotech Corn*, *supra* note 83; Yoon, *Squash*, *supra* note 18.

119. *See* Petersen, *supra* note 57.

120. *See* 57 Fed. Reg. 22,984, 22,990 (1992).

121. *See id.* at 22,991. *See also* Beach, *supra* note 115, at 184-88.

122. *See* 57 Fed. Reg. 22,984, 22,991 (1992).

123. *See* Beach, *supra* note 115, at 185 (stating the FDA believes the best interest of the industry would be "to inform FDA prior to commercial distribution" about their food products).

124. *See id.* at 184.

125. *See id.* at 188-91; Weiss, *supra* note 70.

126. *See* Pollan, *supra* note 63, at 50.

127. *See id.* at 51.

128. *See* Megan Ladage, *The Biotech Battle Looms Large*, GROCERY HEADQUARTERS, May 1, 2000, at 70. *See also* Safford, *supra* note 103, at 585.

responsible for testing certain things, such as the safety of people actually eating foods made from GMO products.[129]

One final issue to consider is how the regulatory roles of the three agencies might change in the face of continuing public concerns about the safety of the products. As discussed below, recent actions by the agencies give some indication of the future. Secretary of Agriculture Glickman has noted a desire to have the agency responsible for doing more independent tests and verification of the information provided by companies, which will require additional capacity within the USDA.[130] The FDA has noted its intention to require pre-market notification and consultation before new GMO foods are brought to the market.[131] Finally, the EPA has signaled at least some willingness to be more directly involved in the process with its decision concerning field refuges for the use of bio-pesticides.[132]

F. *Biotechnology and International Trade: GMO Issues Will Test International Agreements*

Perhaps the most contentious international issue relating to America's production and sale of GMO grains and other foods has been the growing unwillingness of some foreign customers to purchase the products, at least without some type of labeling.[133] The growing international debate about the sale and labeling of GMO foods has reverberated throughout the international legal arena—from the failed World Trade Organization ("WTO") talks in Seattle,[134] to the CODEX negotiations,[135] to the recently completed talks on the Cartagena Biosafety Protocol.[136] The issue has led to tension between the United States and major trading partners such as Japan and Korea, has added new pressures to the already difficult trade relations with the European Union, and has added significant commercial

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129. For a discussion of how regulatory uncertainty might affect which foods come to the table, see Yoon, *Salmon*, *supra* note 18, detailing the production of genetically engineered salmon, the increased growth rate for the fish, and exploring the uncertain regulatory climate for the approval of such products. *See also* Editorial, *Coping With Supersalmon*, N.Y. TIMES, May 14, 2000, at A14. The administrative division of responsibility between the USDA, EPA, and FDA, and the uncertainty it creates was demonstrated in Michael Pollan's article. *See* Pollan, *supra* note 63, at 50-51.

130. *See id.* at 50-51.

131. *See* Safford, *supra* note 103, at 584.

132. *See* Weiss, *supra* note 70.

133. The examples of such actions taken by other nations are too numerous to mention, but see, e.g., *Australia, New Zealand Health Ministries Approve Resolution for Labeling GMO Foods*, 2 FOOD SAFETY REPORTER (BNA), at 961 (Aug. 9, 2000).

134. *See* Aarti Gupta, *Governing Trade in Genetically Modified Organisms: The Cartagena Protocol on Biosafety*, 42 ENV'T, at 23, 27 (May 2000).

135. *See* FOOD AND AGRIC. ORG. OF THE U.N. & WORLD HEALTH ORG., REPORT OF THE FIRST SESSION OF THE CODEX AD HOC INTERGOVERNMENTAL TASK FORCE ON FOODS DERIVED FROM BIOTECHNOLOGY 4 (2000).

136. *See* Gupta, *supra* note 134, at 23.

uncertainty about the economic returns from planting some GMO crops.[137] The uncertain foreign trade situation is developing into a major obstacle for the adoption of this generation of biotechnology.[138]

The human health concerns related to bio-pesticides make this form of GMO especially controversial in the trade arena and the subject of widespread international concern.[139] In the spring of 1999, the European Union refused to allow the import, even with labeling, of certain forms of Bt corn hybrids that had already being sold for planting in the United States.[140] The European Union's action led several major grain merchandisers and users in the United States to notify farmers they would not purchase grain from these hybrids and would require farmers to certify their crops did not contain the seeds.[141] This in turn necessitated a program by the seed companies involved to promise growers who purchased and planted the seeds that they would help find domestic markets for the crops.[142]

The U.S. dominance of the biotechnology sector and the presence of GMO grain in U.S. supplies will continue to create tensions with other nations both our customers and competitors. These issues will go beyond the traditional trade fights with the European Union over labeling and the precautionary principle because other major customer nations such as Japan will be involved. The availability and use of GMOs in other grain exporting nations creates interesting issues. For example, the widespread availability of Roundup Ready® soybeans in Argentina at prices substantially below U.S. prices has lead to schism within the agricultural sector.[143] The situation in Brazil is another source of possible concern.[144] Presently GMO seeds are not legally used in Brazil, which creates the potential for it to export soybeans as "GMO-free" to companies and nations desiring them. Whether in fact crop production in Brazil is GMO free or whether significant amounts of GMO seed come in from Argentina is in dispute.[145] The United States is concerned about the

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137. *See generally* Gupta, *supra* note 134, at 24-25 (delineating alliances formed at the Cartagena Protocol, with the U.S. in one group and Japan and Korea in another); Terence P. Stewart & Davis S. Johanson, *Policy in Flux: The European Union's Laws on Agricultural Biotechnology and Their Effects on International Trade*, 4 DRAKE J. AGRIC. L. 243 (1999) (discussing GMO issues in Europe).

138. *See* Stewart & Johanson, *supra* note 137, at 293-94.

139. *See, e.g.*, Flynn et al., *supra* note 3, at 62; Karaim, *supra* note 4; Kilman & Cooper, *supra* note 84.

140. *See* Feder, *supra* note 42.

141. *See, e.g.*, Michael Howie, *Confusion Abounds About GMO-Containing Seed, Grain*, FEEDSTUFFS, Apr. 26, 1999, at 1 [hereinafter Howie, *Confusion Abounds*]; Michael Howie, *Food Processors Keeping Close Eye on Biotech Grains*, FEEDSTUFFS, Apr. 26, 1999, at 8.

142. *See* Howie, *Confusion Abounds*, *supra* note 141, at 1.

143. *See* American Soybean Association, *supra* note 52.

144. *See generally* DePalma & Romero, *supra* note 27 (discussing the political situation in Brazil concerning legal access to GMO soybean seed and the growing concerns on the part of American farmers' use of GMO products in Brazil is creating potential for unfair or misleading trade competition in Europe).

145. *See id.*

unfair competitive advantage Brazil may attain by claiming its products are GMO free.[146] On the other hand, China is an example of a nation warmly embracing biotechnology and GMOs.[147] China sees biotechnology as providing a domestic production boost and an advantage in export sales.[148]

One final legal issue to consider is how well the international trade agreements, best reflected in the Sanitary and Phytosanitary Agreement[149] and the Trade Related Aspects of Intellectual Property Rights Agreement of the World Trade Organization[150] are functioning relative to the GMO debate. The short answer is the agreements help provide the context and much of the content of the international law against which disputes over use and marketing of biotechnology will be resolved.[151] The longer answer, which will not be detailed here, is the agreements may be only a starting point in providing guiding principles against which competing national and international interests will be resolved. The problems that arose in the Seattle WTO talks, some of which related to public demonstrations about the safety of GMO foods,[152] illustrate how international institutions will not be free of the social concerns that exist relative to biotechnology. If the hope of the U.S. is that the WTO will make the world safe for biotechnology and GMOs, our hope may be misplaced. This will occur only if the world in fact determines GMOs are safe for it. Given the broad range of legal issues and the variance of opinions both within and between nations, it is naïve to believe international law or agreements will provide the direction and answers not found at home.

G. *The Biosafety Protocol and the Relation to GMO Labeling and Promotion*

In January 2000 the countries party to the Convention on Biological Diversity ("CBD") finally struck an agreement on the terms of the Biosafety

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146. *See id.*

147. *See* Karby Leggett & Ian Johnson, *Up and Down 'Seed Street:' Chinese All Along the Food Chain Embrace Gene Altered Crops*, WALL ST. J. EUR., Mar. 31, 2000, at 25, *available in* 2000 WL-WSJE 2949378.

148. *See id.*

149. *See* Sanitary and Phytosanitary Agreement, Apr. 15, 1994 *reprinted in* Uruguay Round Trade Agreements, H.R. Doc. No. 103-316, at 1318, 1981 (1994).

150. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994).

151. *See* Kevin C. Kennedy, *Resolving International Sanitary and Phytosanitary Disputes in the WTO: Lessons and Future Directions*, 55 FOOD & DRUG L.J. 81, 81-104 (2000) (providing a thorough and valuable discussion of the application of various WTO provisions to the debate over the use and labeling of GMO products).

152. *See* Merrill Goozner, *Multicultural March Protests Genetically Altered Food, WTO Policies*, CHI. TRIB., Dec. 3, 1999, at 29N.

Protocol, known as the Cartegena Agreement.[153] While the United States is not a member of the CBD because Congress has refused to ratify the agreement, the United States was still able to play a dominant role in the negotiations, in part through the work of the Miami group of other grain exporting nations.[154] The most significant aspects of the agreement reached in Montreal relate to when labeling of GMO exports will be allowed and the process for informing importers of these products.[155] The exact effect of the agreement reached in Montreal is unclear and depends on whom you believe. On the one hand, the U.S. asserts that any effort at labeling has to be "scientifically based."[156] But other nations claim the agreement will allow nations to require labeling and pre-shipment approval based on precautionary principles.[157] The reality may be the Montreal agreement was just the next chapter in an ongoing and evolving international debate and disagreement. The United States acted on the belief that time favors our view. The more GMO products that can be sold and the larger the share of world grain trade made up of GMO products, then the less possible it will be for any effective segregation or labeling system to be implemented. It is hard to believe the United States would "agree" to any action in Montreal that actually threatened our ability to continue to export GMO grains free of labeling and segregation requirements. Stated another way, it is safe to assume the United States has a theory for either how the Montreal agreement does not restrict our actions or is confident actions taken in other forums, such as the WTO or the CODEX, will protect the U.S. position.[158]

H. *Genetic Pollution and Pollen Drift: How Evolving Legal Rules Will Shape the Adoption of Biotechnology*

Genetic pollution or "pollen drift" is perhaps the most intellectually interesting legal issue relating to biotechnology. It involves an intriguing mix of both traditional common law principles relating to property rights, contracts, and tort liability and the potential application of statutory or regulatory rules enacted to promote biotechnology.[159] A variety of legal theories will no doubt be used in the litigation likely to result from the conflicts relating to non-GMO crops being

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153. *See Final Draft of Biosafety Protocol Approved at Montreal Meeting on Biological Diversity Convention*, 2 FOOD SAFETY REP. (BNA), at 141 (Feb. 2, 2000).

154. For a discussion of the background on the Biosafety protocol and the U.S. position, see Gupta, *supra* note 134, at 23-25.

155. *See generally id.* at 23 (explaining how the Cartagena Agreement might apply to the use and sale of GMOs).

156. *See id.* at 25.

157. *See id.* at 25-26.

158. *See, e.g.*, Ian Elliot, *Purposely Vague UN Biosafety Protocol Not Expected to Disrupt Grain Trade*, FEEDSTUFFS, Feb. 7, 2000, at 1 (describing how the language agreed to in Montreal creates room for debate; and that there should be no immediate effect on U.S. grain trade or any real agreement on the need to label GMO exports).

159. *See* Mandler & Eads, *supra* note 47, at 1.

"contaminated" with GMO pollen. Whether the theory is based on nuisance, trespass, or by analogy to "pesticide drift" there is no shortage of legal arguments to make on behalf of growers who believe their crops are damaged by the action of neighbors or the companies selling the products. But on the other hand, claims of regulatory protections, contractual rights, and perhaps even statutory exemptions might be made on behalf of the growers of GMOs. Several states have proposed legislation to deal with the issue, with the fundamental questions being where to locate the presumption of right and which theory of liability to employ.[160]

The concerns of organic farmers are one component of the debate about genetic pollution caused by the movement of GMO pollen. At the present time, no private or governmental certification program for organic food allows use of GMO seeds.[161] This means from a consumer perspective, the "organic" label is one avenue (perhaps the only one) for purchasing GMO-free food. From the perspective of organic growers, the ability to market grain as "GMO-free" opens additional marketing opportunities. Of course, a producer does not need to be certified organic to enter a contract to sell non-GMO or "GMO-free" products if the producer can meet whatever standards are required to make such sale.[162] However, the issue of genetic pollution can arise in both situations because the actual testing for the presence of GMO material will be done somewhere later in the marketing or food processing chain. Producers who do not knowingly plant any form of GMO seed might still have crops yield positive tests if the crops are contaminated by GMO pollen that drifted in from neighboring fields. Such positive GMO tests might also result if the crop is otherwise "contaminated" with GMO seed after harvest or during shipping or processing. Even in cases where producers take extensive precautions, contamination can result from the actions of neighbors or others.

The problem of genetic pollution can also be an issue relating to seed purity, even for seed sold as GMO free. This issue was well illustrated in Europe in June 2000 when it was discovered a supply of canola seed grown in Canada and planted in a number of European Union countries was contaminated with GMO material.[163] The episode resulted in European nations taking action to destroy the planted crops

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160. *See, e.g.*, H.F. 2614, 81st Reg. Sess. (Minn. 2000) (an act relating to the use of genetically modified organisms); L.B. 959, 96th Leg., 2d Reg. Sess. (Neb. 2000) (an act relating to the use of genetically modified seed and providing a cause of action for certain crop damages).

161. *See, e.g.*, Mandler & Eads, *supra* note 47, at 2-3 (asserting that organic food growers may have legal grounds to hold GMO producers liable for damages resulting from cross-pollination because the crops would be rendered unmarketable).

162. For a discussion of some of the issues which can arise in making certified promises about crops relative to the GMO issue, see Neil Harl, *Genetically Modified Crops: Guidelines for Producers*, 10 AGRIC. L. DIG. 145, 145-46 (Oct. 1999).

163. *See* Donald G. McNeil, Jr., *Europeans Learn They're Growing Genetically Altered Plants*, N.Y. TIMES, May 19, 2000, at A5 (reporting that rape seed oil crops planted in several European Union nations, from seeds imported from Canada had been inadvertently contaminated with GMOs).

and compensate growers for the loss.[164] But it also brought into focus the issue of what liability rests with the seed company, a particularly interesting question in light of the fact the seed may not have violated existing seed trade standards concerning purity or contamination.[165]

The GMO debate provides several examples of the significance of controlling terms and language. One of the more interesting issues, and one with potentially significant legal consequences, is the fight over what to call plants engineered to act like chemicals and resist pests. The EPA has chosen to call this family of products bio-pesticides.[166] But industry officials and some scientists argue these products are not pesticides but instead are "plant-expressed protectants."[167] Why does it matter what terms are used? One possible example could be in a lawsuit by a farmer whose crops are contaminated with pollen from a neighboring field planted to GMOs.[168] Under traditional pesticide drift law, if the judge views the product as a pesticide then the person using it will be responsible and strictly liable for its movement of the property.[169] If it is seen as a natural product then the fact the crop expressed itself all over the neighbor's field may not result in liability.[170]

I. *International Disputes Over Ownership of Plant Genetic Resources*

One of the most politically loaded issues arising in connection with biotechnology relates to the ownership and control of the world's genetic resources. This issue has been a central feature in international debates and discussions over the last twenty years.[171] The issues are in some ways still unresolved, even after the agreements reached in the CBD[172] and in the TRIPs accord.[173] Ownership of plant genetic resources is significant in connection with biotechnology for several reasons. First, the technology is helping illustrate the value of genetic material as existing genetic stocks provide the source of materials for genetic engineering. But a second issue relates to the fact the actual possession of the seeds or plants, especially related materials, might not be as important for plant improvement as is access to individual genes that can be transferred into unrelated species. The continuing significance of international claims of ownership and how national laws may or may not respect

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164. *See id.*

165. *See id.*

166. *See U.S. EPA-Biopesticides* (last modified Jan. 17, 2001) <http://www.epa.gov/pesticides/biopesticides/>.

167. *See* Maixner, *supra* note 61, at 3.

168. *See* Mandler & Eads, *supra* note 47, at 1.

169. *See id.* at 3.

170. *See id.* at 5.

171. *See* Hamilton, *supra* note 16, at 592.

172. *See Final Draft of Biosafety Protocol Approved at Montreal on Biological Diversity Convention*, *supra* note 153, at 141.

173. *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 150, at 81.

them is illustrated by several recent controversies involving alleged "biopiracy" in which companies in developed nations have claimed intellectual property rights to traditional materials.[174] One case in particular illustrates the possible conflicts between the ability to claim intellectual property protection under U.S. law and the rights of traditional farmers.[175] The case involves a patent dispute under which a U.S. seed grower has claimed ownership of an "improved" variety of a Mexican yellow bean.[176] The grower has obtained both a Plant Variety Protection certificate and a utility patent on the "improved" variety and has used these protections to have the U.S. Custom Service block import of similar seeds from Mexico.[177] But Mexican officials contend the seeds claimed by the American grower are a traditional variety of bean long raised and exported by Mexican farmers.[178] The dispute has created tension between the nations and may test the adequacy of international agreements on the ownership of plant genetic resources.[179]

J. *Terminator Two: Ownership and Control of Gene Expression Control Technologies*

One of the newest classes of biotechnology that has generated considerable controversy is "Terminator seed" or more accurately "seed sterilization" (or alternatively "gene expression control") technology.[180] The current controversy involves a patent issued jointly to the USDA and Delta and Pine Land Company ("DPL").[181] The patent is for a technology that, in simplest terms, will allow a company to include an elite genetic trait in a parent seed and then treat the seed so it will grow and produce a crop, but the seeds from that crop will be sterile.[182] The

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174. *See* Andrew Pollack, *Biological Products Raise Genetic Ownership Issues: Governments are Demanding Share of Profits*, N.Y. TIMES, Nov. 26, 1999, at A1 (discussing the growing international controversy over ownership and control of genetic resources and recent disputes involving claims of "biopiracy" by western companies claiming patent protection for crops traditionally raised and used in developing nations).

175. *See* Jonathan Friedland, *As Two Men Vie to Sell Yellow Beans, Litigation Sprouts*, WALL ST. J., Mar. 20, 2000, at A1.

176. *See id.*

177. *See id.*

178. *See id.*

179. *See, e.g., id.* (detailing the controversy over alleged "biopiracy" by a U.S. seed producer patenting a traditional variety of Mexican yellow bean).

180. *See Biobit—Terminator Technology*, THE GENE EXCHANGE, Fall-Winter 1998, at 4.

181. *See id.*

182. *See id.* Monsanto announced plans to purchase DPL with the result that most of the political fury over "Terminator" focused on Monsanto, even though the company did not yet own the technology. In part as a result of the controversy and other financial set backs, Monsanto canceled plans to purchase DPL, which triggered a lawsuit for damages caused by the failure to pursue the merger. *See, e.g.*, Michael Howie, *Delta & Pine Land Sues Monsanto for Breach of Contract*, FEEDSTUFFS, Jan. 24, 2000, at 5.

actual science involved in the patent is a complicated three-gene process for inserting and then triggering the gene expression.[183] The idea of "technology protection" comes from the view that a company would not need to be concerned about farmers saving seed to replant or sell to others (known variously as seed saving, brown bagging, or seed piracy, depending on your perspective and the amount involved) without the company's approval.[184] From this perspective, the technology would allow the sale of improved seeds in markets or countries where the legal protections for intellectual property rights on plant genetics are seen as inadequate or non-existent.[185] It would also let companies avoid the necessity of requiring producers to sign contracts promising not to save seed and the related need to police farmers' actions, such as Monsanto's aggressive enforcement of "seed piracy" for Roundup Ready® soybeans.[186]

These traits allow the USDA and the companies involved to view the technology as a major development that will benefit agriculture at home and abroad.[187] Conversely, people and organizations concerned about biotechnology from a safety and environmental perspective, as well as from a corporate domination viewpoint, feel it is a threat to the food supply and to farmers in third world countries who rely on saved seed to plant next year's crops.[188] Fundamentally, they view the technology as antithetical to the idea of agronomic progress (*i.e.*, it is not designed to improve the expression of any seed trait; instead its purpose is to render sterile the seeds of the plant).[189] Viewed this way, critics see it as the ultimate expression of corporate control and domination of agriculture, farmers, and seeds.[190] Their penultimate fear is if the technology is placed into all seeds then farmers will have to go to the companies and buy new seed each year.[191] Their ultimate fear is somehow the technology will backfire and render other seeds sterile without the application of the trigger.[192] Defenders of the technology argue it is no different than hybridization, which brought great progress to corn farmers but also requires them to repurchase new seed each year.[193] Of course, one main difference between the technologies is the seeds from hybrids will grow, although at a different level of expression.[194]

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183. The actual technology is described quite well in two articles. *See* Feder, *supra* note 2; *Biobit—Terminator Technology*, *supra* note 180, at 4-5.

184. *See Biobit—Terminator Technology*, *supra* note 180, at 4.

185. *See* Kahn, *supra* note 2, at 73.

186. *See* DePalma & Romero, *supra* note 27.

187. *See* Weiss, *supra* note 4.

188. *See id.*

189. *See* Feder, *supra* note 2.

190. *See id.*

191. *See* Kluger, *supra* note 2, at 44.

192. *See* Weiss, *supra* note 4.

193. *See id.*

194. *See, e.g.*, Bill Lambrecht, *Critics Vilify New Seed Technology that Monsanto May Soon Control*, ST. LOUIS POST-DISPATCH, Nov. 1, 1998, at A1; Bill Lambrecht, *The St. Louis Company's Political Clout Has Turned the President and Cabinet Secretaries Into Pitchmen*, ST. LOUIS POST-

The Terminator issue has been used effectively by opponents of genetic engineering, most notably the Rural Advancement Foundation International ("RAFI"), which effectively dubbed the technology with its name, to draw attention to these issues and to criticize U.S. policy on the development and promotion of these technologies.[195] RAFI has been particularly successful in using the Internet to communicate across the world and in rallying opposition to the Terminator gene in the international arena where RAFI's long-time work on behalf on the interests of farmers in third world countries on plant genetic conservation and access have earned it substantial credibility.[196] This success and stature of RAFI is particularly galling to U.S. biotechnology companies and governmental officials who dismiss the organization as a non-profit group made up of a few people using this issue to generate foundation support.[197] Research conducted by RAFI after its discovery of the Terminator patent reveals that dozens of research projects and patent claims have been based on developing various forms of seed sterilization systems.[198]

The USDA finds itself in a difficult position because it is co-owner of the patent and thus is seen as the villain by critics of the technology.[199] USDA's discomfort is increased by the agency's view that under the terms of the Cooperative Research and Development Act ("CRADA") agreement used to fund the research between the Agricultural Research Service ("ARS") and DPL, it must offer the company an exclusive license.[200] As a result, the agency has taken a public relations beating.[201] The political controversy has resulted in internal review of the mechanism USDA uses to screen cooperative research proposals.[202] The USDA can be expected to continue supporting these technologies, both as a function of its predisposition to support development and use of biotechnology and because of the political influence of the companies involved. As a result, the agency is taking great pains to explain

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DISPATCH, Dec. 27, 1998, at A1 (discussing the controversy over the "Terminator gene" that resulted in a great deal of press coverage). *See also* Weiss, *supra* note 4 (discussing how the "Terminator gene" works to hinder reproduction and hybrid corn that will reproduce, but with poor seeds resulting in farmers buying new seeds every year).

195. *See, e.g.*, RAFI, *Suicide Seeds on the Fast Track* (visited Apr. 5, 2001) <http://64.4.69.14/web/allpub-one.shtml?d...play&rol=recNo&rfl=73&rt1=73&usebrs=true>. To review other materials prepared by RAFI on this issue and others, visit the web site at http://www.rafi.org. It should be noted that RAFI will soon undergo a name change, but at press time has not chosen a new name.

196. *See* Kluger, *supra* note 2, at 44.

197. *See id.*

198. *See, e.g.*, RAFI, *Seed Sterilization is Biotech 'Holy Grail'* (visited Apr. 1, 2001) <http://www.rafi.org/web/allnews-one.shtml?dfl=allnews.db&tfl=allnews-one-frag.ptml&operation=display&rol=recNo&rf1=22&rt1=22&usebrs=true>.

199. *See* Kluger, *supra* note 2, at 44.

200. *See* USDA-ARS, *The Control of Plant Gene Function* (visited Mar. 5, 2001) <http://www.ars.usda.gov/misc/fact.htm>.

201. *See, e.g.*, Kluger, *supra* note 2, at 44; Weiss, *supra* note 4.

202. *See* Petersen, *supra* note 57.

the positive benefits of gene expression control technology.[203] While some biotechnology companies responded to the Terminator controversy by making statements to disavow the technology, the reality is research on "gene expression control" technologies continues unabated today.[204]

IV. WHY BIOTECHNOLOGY LEGAL ISSUES ARE IMPORTANT FOR AGRICULTURAL LAWYERS AND SOCIETY

The legal issues discussed in the previous section are important to agricultural lawyers and society for many reasons. Some have a very practical real world application, most notably the development of legal guidance on the issue of "pollen drift" and the applicable legal theories of liability and responsibility. The development and refinement of legal principles on this issue will provide the basis for resolving disputes and establish the guidelines for influencing the conduct of farmers and companies alike. Because developing such legal rules may in essence allocate planting rights between neighbors and within society, the law will not just influence the adoption of some forms of biotechnology but it may alter traditional notions that landowners can plant whatever crops they desire. In so doing, the law will help shape the very face of agriculture by determining which crops dominant the landscape and by controlling the ability of individual landowners to use their property as they want.

A second legal issue with significant real world implications for shaping the business decisions of farmers relates to the rules on saving and replanting seeds from one crop to the next. Presently, a farmer's ability to do so depends on three factors: the form of intellectual property protection claimed for the seed, the extent of any statutory protection for seed saving, and any contractual obligations that may have been entered into.[205] There are still some minimal protections for seed saving by farmers, such as using the PVPA or by planting open pollinated or non-protected public varieties.[206] But in reality, the clear trends under both contract and intellectual property law for biotechnology are to limit this ability.[207]

Other legal issues discussed in the preceding sections have more systemic or structural implications. The range of IPR claims regarding agricultural genetics has a significant effect on the relative rights of plant breeders and seed companies, as well as on the farmers who buy the seed and grow the crops.[208] The significance of this fundamental tension is illustrated in lawsuits testing the Plant Variety Protection Act and patenting plant varieties.[209] But at a more fundamental level, the range and

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203. *See, e.g.*, USDA-ARS, *supra* note 200.
204. *See* RAFI, *Suicide Seeds on the Fast Track*, RAFI COMMUNIQUE, Feb-Mar. 2000, at 1, 2.
205. *See* Blair, *supra* note 30, at 307.
206. *See id.* at 312.
207. *See id.* at 330-31.
208. *See id.* at 320.
209. *See id.* at 313.

breadth of IPR claims authorized by a society—through its legal mechanisms—are the most significant determinants enabling the growth and privatization of technology and scientific advance.

Still other legal issues play out against a backdrop of international law, such as establishing rights and obligations for nations and their citizens, both businesses and individuals. In this regard, the resolution of some of the underlying disputes, including the labeling and marketing of GMO foods, will shape the very nature of the global marketplace. Clearly, while the issues will be debated and possibly resolved on an international level, the signals they send both socially and economically will be felt on farms and in grocery aisles, as well as in laboratories and boardrooms. The result may be that all of these issues will in some way impact the actions of American farmers and shape the food choices for the world's consumers. This final point, how the law on biotechnology will affect the interests of consumers, raises another feature that makes the issues significant. Because the products or technologies are used in the production of foods destined for eventual human consumption, the public's attitude, understanding, and acceptance of biotechnology will be critical in influencing the ultimate economic reality. We can develop refined legal systems for resolving disputes between parties concerning the ownership and use of biotechnology, but if consumers and the companies who supply their food do not want the technology used, its adoption will be limited.

V. RECENT DEVELOPMENTS IN BIOTECHNOLOGY IN THE UNITED STATES

In 2000 there were a series of significant developments in the United States that will influence the development and evolution of national policy on GMOs.[210] They are discussed in turn below.

In April, the National Research Council released a scientific study that concluded biotech foods are safe but the regulatory process needs to be tightened relating to the research and data provided by the companies marketing the products.[211]

The USDA has taken several actions, including Secretary Glickman appointing a thirty-seven member Biotechnology Advisory Committee to review the agency's policies, in particular the procedures for the testing and approval of new products.[212] The large and very diverse committee has met twice but has experienced

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210. *See generally* Safford, *supra* note 103, at 585 (discussing the administrative response to recent developments in biotechnology).

211. *See* Carol Kaesuk Yoon & Melody Peterson, *Cautious Support on Biotech Foods by Science Panel: But Tighter Rules Urged*, N.Y. TIMES, Apr. 6, 2000, at A1 (detailing the findings of the National Academy of Sciences report on GMO foods and explaining the recommendations made in the report supporting increased regulation).

212. *See USDA Advisory Committee on Agricultural Biotechnology*, 14 DIVERSITY 9, 9 (2000).

difficulty reaching any consensus.[213] In a May speech Secretary Glickman discussed a National Academy of Sciences project to assist the agency in developing and implementing policies to govern the approval of GMO foods.[214]

The FDA issued a set of long-awaited findings based on three field hearings held in the fall of 1999 relating to testing and labeling GMO foods.[215] The agency concluded: (a) biotech foods are safe and there is no reason to modify the 1992 decision; (b) the agency will not require mandatory labeling of the products but will endorse and establish guidelines for voluntary labeling of non-GMO products; and (c) the agency will require additional information from U.S. companies in the form of pre-market notification and safety testing.[216] The legality of the agency's action was upheld by a recent district court ruling.[217]

Legislation introduced in Congress to require labeling of GMO foods is in the early stages of consideration and there is little reason to expect congressional action.[218] Similar bills introduced in a number of state legislatures relate to liability, use, and labeling of GMOs,[219] but consideration of state legislation has been slow and significant legal questions exist concerning the legality of such state actions.

At the farm level, the demand for GMO seeds during the spring 2000 planting season leveled off.[220] Reports indicate the use of Bt corn declined by twenty-five percent and the use of Roundup Ready® soybeans grew slightly.[221] The explanation for these trends is probably a mixture of farmer concerns about possible marketing problems and the lack of insect pressure in some corn areas made it easier to not use more expensive Bt corn.

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213. *See USDA Biotechnology Committee is a Big Dud*, NUTRITION WK., Aug. 4, 2000, at 2 (describing the July meeting and the difficulty in deciding how to discuss the issues).

214. *See* David Stafford, *National Academy of Sciences to Help USDA Review Biotechnology Regulations*, 2 FOOD SAFETY REPORTER (BNA), at 585 (May 10, 2000).

215. *See* Petersen, *supra* note 57 (concerning the FDA announcement of new policies concerning the approval and labeling of GMO foods).

216. *See id.* As might be expected, the industry greeted the FDA action with relief and consumer advocates who argued for mandatory labeling greeted the action with concern. Part of the focus will now shift to establishing the standards for labeling non-GMO products. Predictably, the food industry is fighting this development and has proposed guidelines concerning accuracy and testing which will make use of the voluntary labels more difficult.

217. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 181 (D.D.C. 2000).

218. *See* H.R. 3377, 106th Cong. (1999); S. 2080, 106th Cong. (1999).

219. *See, e.g.*, H.F. 2614, 81st Reg. Sess. (Minn. 2000) (an act relating to the use of genetically modified organisms); L.B. 959, 96th Leg., 2d Reg. Sess. (Neb. 2000) (an act relating to the use of genetically modified seed and providing a cause of action for certain crop damages); *Hearings on Genetic Crops*, N.Y. TIMES, Oct. 2, 2000, at A26 (discussing a hearing held in the New York State Assembly on a bill to require a five year moratorium on the use of genetically engineered crops).

220. *See* Barboza, *supra* note 8.

221. *See id.* (discussing the situation in agricultural states during the 2000 planting season relating to farmers' decisions on whether to plant GMO crops and the actions taken by companies to reassure farmers there would be markets for the products).

For the most part, marketplace acceptance in the United States continues to be strong with little evidence of significant or organized consumer resistance.[222] Most of the concern in the United States continues to relate to environmental issues, such as the effect of Bt corn pollen on Monarch butterflies, as opposed to food safety.[223] The late breaking developments concerning the Kraft taco shells and the presence of a Bt corn variety not authorized for use in human foods has added renewed fuel to the debate.[224] But so far the most significant actions relating to use of GMOs are announcements by consumer food companies, such as McDonald's, Heinz, and others that they will avoid using GMO ingredients in their foods.[225] While there has been some consumer resistance on foods, there has been little opposition to use of GMO cotton products,[226] possibly showing the separation of concerns in consumers' minds. In the summer of 2000, a coalition of consumer and environmental groups announced a campaign focused at a limited number of food companies, most notably Campbell's, to force them to take a position on GMOs.[227] On the other side of the debate, the industry has funded a $50 million campaign with the Council for Biotechnology Information to influence public opinion favorably on the issues.[228]

Perhaps one of the most significant developments in 2000 was the economic performance of life sciences companies and the reaction of the financial markets to biotechnology in general.[229] For the most part, the stock market has shown limited interest and instead some fear about the future of the biotechnology and life sciences sector, at least as relates to agriculture.[230] This attitude is reflected in a number of developments. The difficulty experienced by Monsanto in several problematic merger attempts and the ultimate separation and partial sale of its agricultural division is one.[231] Another is the fact many "life sciences" companies decided to spin

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222. *See* Yoon, *supra* note 80.

223. *See id.*

224. *See* Kaufman, *supra* note 12.

225. *See, e.g.*, Andrew Pollack, *Novartis Ended Use of Gene-Altered Foods*, N.Y. TIMES, Aug. 4, 2000. at C4 (relating to the companies decision to end the use of GMO ingredients in its food lines, while at the same time another division of the company develops and markets GMO seeds).

226. *See* Yoon, *supra* note 2.

227. *See* Pollack, *supra* note 6 (concerning the new campaign by a consortium of consumer and environmental groups aimed at Campbell Soup Company).

228. *See* Fitzgerald, *supra* note 27 (detailing the launch of the $50 million education campaign sponsored by the Council for Biotechnology Information). For more information about the campaign and to receive copies of its materials, contact the Council for Biotechnology Information, P.O. Box 34380, Washington, DC 20043-0380, (202) 467-6565, or visit <http://www.whybiotech.com>.

229. *See* David J. Morrow, *Rise and Fall of 'Life Sciences:' Drugmakers Scramble to Unload Agricultural Units*, N.Y. TIMES, Jan. 20, 2000, at C1.

230. *See generally id.* (discussing the economic status and outlook for life sciences companies).

231. *See, e.g.*, Scott Kilman & Thomas M. Burton, *Farm and Pharma: Monsanto Boss's Vision of 'Life Sciences' Firm Now Confronts Reality*, WALL ST. J., Dec. 21, 1999, at A1 (describing the

off or sell their biotech divisions, including AstraZeneca and Novartis.[232] The depressed stock price of companies such as DuPont is additional evidence the market is uncertain about the future of biotechnology.[233] But even in the face of this downturn in market support companies heavily invested in biotechnology and GMOs are moving ahead with new products and technologies, and are actively fighting and defending their various intellectual property right claims to the technologies.[234]

The proliferation of litigation relating to biotechnology and its use is also a factor introducing uncertainty and risk into the future.[235] There are a variety of cases, many noted above, currently in the courts. It is important to note that several of the cases listed below have had recent decisions favoring use of biotechnology:

- the class action alleging anti-trust violations in the marketing of Roundup Ready® technology;[236]
- a lawsuit against the FDA for approving the safety of GMOs without adequate testing, the subject of a recent summary judgment for the government;[237]
- a suit filed by Greenpeace against the EPA for approving the use of Bt was recently voluntarily dismissed by the plaintiffs;[238]
- litigation involving Monsanto's enforcement of its seed technology use agreements;[239]
- litigation testing the relationship between the Plant Variety Protection Act and patent law and questioning the validity of patents on plant varieties;[240] and
- genetic pollution or drift cases which will result from claims of contamination.[241]

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financial problems facing the life sciences industry and in particular the "biotech backlash" affecting the financial health of Monsanto); Michael Specter, *The Pharmageddon Riddle*, THE NEW YORKER, Apr. 10, 2000, at 58, 58-71 (examining the personal and corporate motivations behind the efforts of Robert Shapiro, the chairman and CEO of Monsanto, relating to the development of biotechnology, life sciences and its relation to his vision of international sustainable agriculture).

232. *See, e.g.*, Morrow, *supra* note 229 (detailing the market response to efforts by drug companies to harness the perceived synergies between pharmaceuticals and agricultural biotechnology, with the economic reality of low returns and market risks associated leading most drug companies to sell their agricultural divisions).

233. *See* Feder, *supra* note 42.

234. *See* Barboza, *supra* note 8; Fitzgerald, *supra* note 27; Kilman, *supra* note 3.

235. *See* Kilman, *supra* note 3. *See also* Kilman, *supra* note 8.

236. *See* Kilman, *supra* note 8.

237. *See* Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 181 (D.D.C. 2000) (upholding FDA decision to allow the sale of GMO food without mandatory labeling).

238. *See Greenpeace Drops Bt Lawsuit, supra* note 89, at 16.

239. *See Award in Corn Seed Dispute is Affirmed, supra* note 32. *See also* Erb, *supra* note 32.

240. *See* Kilman, *supra* note 3.

241. *See* Pollack, *supra* note 13 (stating that the StarLink episode may have been caused by commingling or drift and has given new ammunition to those calling for stricter safety testing and labeling of bioengineered foods).

Each of these cases involves one or more legal challenges to the development, ownership or use of biotechnology. While the mere filing of a lawsuit does not mean any claimed result will occur, the existence of the cases is some measure of the social and legal friction associated with the manner in which biotechnology is being accepted by society.

VI. WHAT TO EXPECT FROM THE UNITED STATES ON GMO FOODS

As to future positions that may be taken by the U.S government, the biotechnology industry, and agriculture groups in the United States, there are several basic ideas to keep in mind.

- Companies, farmers, and officials continue to be surprised by consumer "resistance" to GMOs or at least the resistance reflected in the decisions of consumer food companies to avoid the technology.[242]
- For the most part, the U.S. biotechnology stakeholders will not admit or acknowledge there might be any legitimate health or environmental concerns associated with use of biotechnology.[243] This all or nothing approach appears to be based on a fear that to acknowledge even the slightest problem will provide justification for unwanted restrictions.[244] But the need for what is essentially ideological purity requires the United States to deny the existence of legitimate concerns even in the face of scientific evidence and threatens to place the U.S. at odds with public sentiment at home and in other nations.[245]
- The unwillingness to admit to any legitimate basis for concerns, in effect means the U.S. position instead views any opposition as either uneducated about the benefits (thus the expensive media education campaign funded by the biotechnology sector to "educate" consumers and policy makers) or as the proxy for other issues, such as social agendas or environmental goals. In particular, the United States appears willing to paint opposition to GMOs from abroad, especially in Europe, as essentially a form of non-tariff trade barrier designed to protect domestic producers and markets.[246] This political position if pursued will in effect turn the fight over GMOs into the basis for a trade war. While there are those who are confident the terms of international agreements such as the WTO agreement and the CODEX support our views, such an outcome is not a foregone conclusion. Further, the difficulty the United States has experienced in obtaining any effective economic or political "satisfaction" from our trading partners, such as the European Union, for

242. *See* Specter, *supra* note 231, at 58-61.
243. *See* Safford, *supra* note 103, at 584.
244. *See* Pollack, *supra* note 14 (stating that critics want labeling because it will scare consumers).
245. *See* Pollack, *supra* note 6.
246. *See* Specter, *supra* note 231, at 69.

past agricultural trade disputes, most notably the beef hormone case,[247] raise legitimate concerns about how productive another nasty trade war might be.

- The unwillingness of the U.S. government to acknowledge any health concerns and as a result, to require labeling for GMO foods is based on several premises, including: (1) industry and government research shows there are no health problems;[248] (2) there is no evidence of health problems after several years of use and consumption of GMOs;[249] (3) the significant financial investments in the technology make such admissions risky as they could only serve to set back the advancement and acceptance of the technology;[250] (4) the rapid uptake of GMO technology by farmers is evidence of the value of the products;[251] and (5) expanding the use of GMOs will make it increasingly difficult for any attempt to regulate or label to be effective, as reflected in the logistical difficulty of segregating non-GMO grains in the United States.[252]
- The rapid adoption of GMO technology by farmers[253] is evidence of how the products fit well into American grain production; however, if technological problems develop with the efficacy of the products (*i.e.*, they do not work, or more likely if there are marketing problems or costs associated with their use, for example price discounts for the presence of GMOs) farmers can and will abandon the technology.

VII. THE FUTURE OF BIOTECHNOLOGY AND INTERNATIONAL AGRICULTURE

At the international level, the real debate and focus in the GMO debate is shifting to the promise of the next generation of products—or at least the industry hopes it will. The industry very definitely needs some good news and some products that actually provide benefits to groups other than the farmers planting them or the companies selling the chemicals being promoted. This of course is where the development of "golden rice" is displayed as a prime example of the value and future of biotechnology.[254] The golden rice story is a valuable one, but there are at least two major problems on the way to getting golden rice into anyone's food bowl.[255] The first problem relates to the reason why most companies got into biotechnology in the first place—to make money. As it turns out, the technologies that enabled the

247. *See generally* Layla Hughes, *Limiting the Jurisdiction of Dispute Settlement Panels: The WTO Appellate Body Beef Hormone Decision*, 10 GEO. INT'L ENVTL. L. REV. 915, 916 (1998) (discussing beef hormone problem in England in the 1980s).

248. *See* Feder, *supra* note 42; Pollak, *supra* note 14.

249. *See, e.g.*, Yoon, *Squash*, *supra* note 18 ("Most Americans have probably eaten some food made with genetically modified soy or corn").

250. *See* Feder, *supra* note 42.

251. *See* Flynn et al., *supra* note 3, at 62.

252. *See* Pollack, *supra* note 14.

253. *See* Flynn et al., *supra* note 3, at 62.

254. *See* Nash, *supra* note 2, at 40 (detailing the scientific and political developments relating to "golden rice").

255. *See id.* at 41 (stating that such crops have a critical role to play in feeding the world).

development of golden rice are subject to dozens of different intellectual property claims owned by various companies.[256] While the researcher had a "research only" right to use the technologies now that a product with a commercial value exists, the reality of intellectual property law must be addressed. This will require either compensation for the owners or an action on their part to "contribute" the technology to the public good. The biotechnology industry recognizes that it needs a major public relations victory soon.[257] As a result, the cry has gone out to let golden rice be made available as a public good.[258] Gordon Conway, president of the Rockefeller Foundation, which has funded a great deal of public rice research, supports such an action.[259] And it will probably happen. But stop for a moment and think about what the intellectual property attorneys representing the biotechnology companies must think of this precedent. Once they develop a product of commercial value, the argument will be it is too important to sell for a profit but it must be released free of charge to countries in the developing world! Of course, the reality will be for technology owners to segment the world's market, that is to sell seeds to those who can afford them and give them to others. But this effort will be complicated by the fact seeds can replicate and they do not know who owns them. This helps explain the motivation behind technologies like Terminator seed that will allow the control of genetic expression.

The economic problem with golden rice also illustrates another problem with the promise that biotechnology will answer the hunger problems in the third world.[260] Assume for the moment golden rice works and is available commercially. If the technology is marketed like other GMO products, it will be priced at a premium above the market so the companies developing it can recoup their substantial investments and make a profit. The problem is whether the poor farmers of South Asia or other developing nations can afford to pay more for the products.[261] The problem here is not necessarily with the technology but instead with who developed and owns it. Rather than being created as a public good by public plant breeders such as those at the International Rice Research Institute in Manila, or any of the other Consultant Group on International Agricultural Research centers, most

256. *See id.* at 43 (stating that patents and proprietary rights encumbered the use of genes and bacteria transferred to make "golden rice").

257. *See* Barboza, *supra* note 4.

258. *See id.* (concerning the decision to market a strain of "golden rice" and related efforts to make the technology available in developing countries).

259. *See* Gordon Conway, *Food for All in the 21st Century*, 42 ENV'T Jan.-Feb. 2000, at 9, 9 (describing his vision for the future of agricultural development, trade, and research).

260. *See* Nash, *supra* note 2, at 41.

261. *See* Miguel A. Altieri, *Biotechnology: A Powerful Distraction from Solving World Hunger*, 15 DIVERSITY 24, 25 (2000).

biotechnology is being developed as private commodities.[262] The question arises: is it reasonable to expect the research agenda of private biotechnology firms to focus on the needs of customers who cannot afford to pay for the products?

262. *See In Search of Higher Ground: The Intellectual Property Challenge to Public Agricultural Research and Human Rights*, 6 THE OCCASIONAL PAPER SERIES No. 1 (RAFI/Rural Advancement Found. Int'l, Winnipeg, Canada), Sept. 2000, at 21-23.