An Agricultural Law Research Article

Intellectual Property As the Third Dimension of GMO Regulation

by

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Originally published in KANSAS JOURNAL OF LAW AND PUBLIC POLICY
16 KAN. J. L. & PUB. POL'Y 257 (2007)

INTELLECTUAL PROPERTY AS THE THIRD DIMENSION OF GMO REGULATION

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I. INTRODUCTION

Genetic engineering has rapidly become one of the most controversial technologies at both the domestic and international levels. Predictably, such controversy has attracted much legal attention, as governments, intergovernmental organizations (IGOs), nongovernmental organizations (NGOs), and citizens grapple with decisions about appropriate regulatory responses. Genetic engineering is a transformative technology that forces scientists to integrate prodigious scientific complexities and uncertainties on behalf of lawmakers hoping to regulate it in ways that are effective, ensure safety, and are politically justifiable.

One especially controversial application of genetic engineering has been the creation of genetically modified (GM) organisms (GMOs)—and products derived from them, such as foods, pharmaceuticals, and industrial chemicals. Infamously disparaged as "superweeds" and "Frankenfoods" by critics, GMOs and their GM food derivatives pose difficult regulatory challenges for jurisdictions wishing to capture their economic advantages while simultaneously ensuring human health, environmental safety, and dispersed ownership. A crescendo of anxiety around the turn of the millennium over the perceived risks of GMOs and GM foods resulted in an international agreement to regulate their transboundary trade: the Cartagena Protocol on Biosafety (CPB), a protocol under the Convention on Biological Diversity (CBD), which entered into force in 2003.[1] As GMOs have increased their share of world agriculture, controversy around the world over these fruits of genetic engineering has proven to be persistent.

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1. *See* Convention on Biological Diversity, Cartagena Protocol on Biosafety: Status on Ratification and Entry into Force (2000), http://www.biodiv.org/biosafety/signinglist.aspx?sts=rtf&ord=dt.

Genetically modified crops are increasing that share at an extraordinary—and possibly unprecedented—rate. In early 2007, the International Service for the Acquisition of Agri-Biotech Applications (ISAAA) summarized the rapid worldwide adoption of GM crops:

> In 2006, the first year of the second decade of commercialization of biotech crops 2006-2015, the global area of biotech crops continued to climb for the tenth consecutive year at a sustained double-digit growth rate of 13%, or 12 million hectares (30 million acres), reaching 102 million hectares (252 million acres). This is a historical landmark in that it is the first time for more than 100 million hectares of biotech crops to be grown in any one year.[2]

By the end of 2006, more than 10 million farmers around the globe were growing GM crops.[3] Worldwide, the area of farmland on which GM crops are cultivated had increased by sixty times from 1996 to 2006.[4] Even after this prodigious decade of growth, the amount of agricultural land cultivated with GM crops continues to increase at double-digit rates.[5] In a remarkable example of the pervasive and rapid adoption of GM crops, even in India, a country often viewed as a focus of anti-GM crop sentiment, the area of agricultural land devoted to GM crops rocketed upwards by approximately 200% between 2005 and 2006, outpacing increases in every other country.[6] Even Europe—another jurisdiction more notably associated with opposition to rather than acceptance of GMOs and GM crops—has shown substantial growth in the area of agricultural land planted with GM crops. Seven European countries now cultivate GM crops commercially, and, across Europe, future growth in the total area devoted to GM crops is projected to be rapid.[7] In fact, so quick has been the advance of GM crops worldwide that the ISAAA claims they represent the most rapidly adopted novel technology in recorded history.[8]

Since the advent of GM crops and livestock, jurisdictions have tended to focus their regulatory efforts on two perceived risks: (1) human health and (2) environmental safety. Anxieties regarding whether foods derived from GM crops or livestock present unique risks to human health (that is, human health risks not also posed by conventional foods) have led many governments both to review the scientific evidence pertaining to GM food and to regulate GM foods more restrictively than conventional foods. Similarly, worries that GM crops could escape domestic cultivation and spread into nature, and that their modified genes introgress into existing populations of wild organisms, thus harming biodiversity, have led to strict regulation of field trials by many

2. INTERNATIONAL SERVICE FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS (ISSAA), ISAAA BRIEF 35-2006, EXECUTIVE SUMMARY (2006), http://www.isaaa.org/Resources/Publications/briefs/35/executivesummary/default.html (last visited Apr. 19, 2007).

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

governments.

If one imagines a spectrum stretching on one end from acceptance of GMOs and GM food to rejection of GMOs and GM food on the other, different jurisdictions have situated themselves at different locations along the spectrum. For example, the European Union (known in some contexts as the "European Communities") and its constituent countries (collectively "Europe") have been situated towards the rejection end of the spectrum, whereas the United States has been situated towards the acceptance side of the spectrum. Predictably, this has resulted in a tendency for Europe to regulate GMOs and GM foods restrictively, while the United States has tended to regulate GMOs and GM foods much more permissively. Canada, a country influenced by strong cultural and economic ties with both the United States and Europe (especially colonial founders, the United Kingdom and France), has tended to occupy an overall regulatory position closer to that of the United States. A comparison of policies toward GMOs and GM food in these three jurisdictions brings legal choices each jurisdiction has made regarding GMOs and GM food into high relief.

Recently, a new locus of GMO and GM food regulation has been emerging. Human health and environmental safety have traditionally been the dominant concerns motivating legal regulation of GMOs and GM food. However, the large and growing body of scientific evidence assessing potential threats uniquely posed by GMOs and GM food to human health and environmental safety has thus far overwhelmingly failed to substantiate such threats. As the scientific understanding of GMOs and GM food has undermined human health and environmental safety as regulatory justifications, anxieties over GMOs have been shifting towards patent monopoly control over new and useful varieties of GM food.

Concerns over monopoly ownership of GM food have been acquiring growing salience in concert with the rapid increase in GM crops and livestock worldwide. Governments, IGOs, and NGOs have begun to pronounce their misgivings about a future in which food supplies become controlled by corporations who own the patents covering the GM crops and livestock from which food supplies are derived.[9]

The rationale underlying fears over monopoly control of GM food conflicts starkly with the rationales of human health and environmental safety. Fears over human health and environmental safety suggest the need for legal policies limiting the development and cultivation of GM crops and livestock because they threaten society with serious dangers and significant costs. By

9. Fears about monopoly or oligopoly ownership over new food technologies date back at least to the Green Revolution, when many in developing countries opposed the adoption of Green Revolution food technologies on the grounds that a small group of large, multinational agricultural companies might come to control the means of agricultural production. *See, e.g.*, Vernon W. Ruttan, CONTROVERSY ABOUT AGRICULTURAL TECHNOLOGY: LESSONS FROM THE GREEN REVOLUTION, 43-54 (2002) (forthcoming in INT'L J. BIOTECH.).

contrast, the fears about monopoly patent control over GM crops and livestock suggest that these innovations are of such great potential benefit to society that access to them should not be legally restricted by patent owners; rather, access should be legally assured by preventing concentrated ownership and tempering the monopoly control that patents confer upon their owners. In other words, whereas anxieties about human health and environmental safety counsel strict legal restrictions on GM agriculture, anxieties about patent monopoly control counsel legal policies to assure easy and widespread access to the very same technology. Perhaps facilitated by the dearth of scientific evidence of threats to human health and environmental safety, justifications for legal regulation of GM agriculture may be shifting away from limitations on cultivation and towards ensuring access.

Significant dispute exists over whether GMOs should be eligible for patent protection at all.[10] Article 27 of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) mandates that member countries offer patent protection for inventions arising in all fields of technology, though exceptions are allowed for plants and animals (including genetically engineered varieties).[11] Jurisdictions in the developed world have tended to offer patent protection for GMOs, including GM plants and animals, with the United States having pioneered such protection, and Europe having later followed suit. However, Canada has been a notable exception to this pattern, refusing patent protection for GM animals and plants.

As the debate over GMOs has shifted toward concerns over monopoly control of food, the legacies of past patent policies have been placed into high relief. A patent gives its owner the right to exclude others from practicing inventions claimed in the patent. Such an exclusionary right confers significant power to patent owners. Both the United States and Europe offer patent protection for GM crops and livestock, thus limiting their ability to prevent monopoly control of GM food. Because GMOs have been comparatively well accepted in the United States, light regulation on human health, environmental safety, and monopoly control have presented few public policy challenges. By contrast, Europe currently finds its regulatory flexibility limited by a strong legacy of regulating GMOs for purposes of protecting human health and environmental safety—rationales that appear increasingly unjustifiable in light of the scientific evidence—but without the regulatory tools to prevent monopoly ownership of new and useful GM foods because of earlier legal decisions to allow the patentability of such inventions. Unlike the

10. A related concern is whether ownership of patents covering GM food will be concentrated in the hands of too few companies, threatening secure access to future food supplies.

11. World Trade Organization, The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS): Patents, http://www.wto.org/english/docs_e/legal_e/27-trips_04c e.htm (last visited Apr. 19, 2007). Note that developed countries currently offering patent protection for GM plants and animals are currently arguing for weakening or elimination of this exception from TRIPS.

United States and Europe, Canada has avoided strict regulation of GM agriculture, while still maintaining its legal capacity to limit patent monopoly ownership of GM crops and livestock by denying patents claiming GM plants and animals.

Ironically, Canada appears to be beginning a transition towards legal availability of patent protection for GM plants and animals. This transition may be driven, at least in part, by such influences as an epistemic community of biotechnology experts largely shared with the United States, legal positions Canada would like to promote in the international arena but that are inconsistent with current domestic patent law, and a desire to avoid international shaming. As Europe continues to struggle with the calculus of perceived, yet scientifically unproven, human health and environmental safety concerns posed by GMOs and GM food versus the tremendous economic, health, and environmental benefits GM agriculture may offer, it may look to Canada for an alternative regulatory strategy just as Canada begins to abandon that strategy.

II. REGULATION OF GMOS FOR HUMAN HEALTH AND ENVIRONMENTAL SAFETY

A. Domestic Legal Approaches to Regulation of GMOs

The loci of legal regulation of GMOs and GM food in the United States, Europe, and Canada can be divided into three major categories: (1) human health, (2) environment safety, and (3) availability of patent protection. With respect to human health, both the United States and Canada have tended to regulate GM foods by applying or adapting existing requirements of their food and drug laws.[12] Similarly, concerns about the environmental impacts of GM foods have tended to be regulated by applying or adapting existing provisions of environmental law.[13] Europe, by contrast, has applied a heightened level of

12. Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 182 (2006) ("U.S. regulation of biotechnology food products does not differ fundamentally from the regulation of conventional food products. The United States uses health and safety laws written prior to the development of modern biotechnology to review genetically engineered products. To date, the United States has not issued any new legislation for these products." (citing United States Regulatory Agencies Unified Biotechnology Website, Frequently Asked Questions, http://usbiotechreg.nbii.gov/FAQRecord.asp?qryGUID=2 and 1986 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (June 26, 1986))). *See also* Sara J. MacLaughlin, Note, *Food for the Twenty-First Century: An Analysis of Regulations for Genetically Engineered Food in the United States, Canada, and the European Union*, 14 IND. INT'L & COMP. L. REV. 375, 382-83 (2003) ("In 1993, Canada issued the Federal Regulatory Framework for Biotechnology (Framework), which . . . provides that novel products will be regulated under the same regulations as traditional products. Further, it provides that existing regulations would govern novel products rather than creating new regulations.").

13. Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2216,

regulatory scrutiny to GMOs and GM food on the assumption they pose threats to human health and environmental safety not posed by conventional crops and livestock. The Organization of Economic Cooperation and Development (OECD) has suggested that the comparative criterion of "substantial equivalence" be used in making decisions about the legal regulation of GMOs and their products.[14] The United States and Canada regulate GMOs and GM food using the substantial equivalence criterion, while European regulation tends to assume non-equivalence.[15]

In the United States, the current regulatory framework for GM products, including food, is largely a legacy of legislation and regulations enacted before genetic engineering became a common method for altering organisms. The 1986 Coordinated Framework for Biotechnology categorizes GM foods based upon their objective characteristics instead of on the basis of any methods that may have been used to produce those foods.[16] Three agencies divide the principal regulatory responsibility for monitoring and ensuring the safety of GMOs and GM foods: the Food and Drug Agency (FDA), the Department of Agriculture (USDA), and the Environmental Protection Agency (EPA).[17] These federal agencies derive most of their regulatory authority over GMOs and GM foods from the Federal Food, Drug, and Cosmetics Act (FFDCA), the Plant Protection Act (PPA), and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), respectively.[18] The federal laws governing each of the three agencies continue to evolve as the use of GMOs and GM food becomes more familiar and widespread.

The legal regulation of GM food is indicative of the general regulatory approach toward GMOs in the United States. According to the FDA, GM foods raise the same categories of scientific and regulatory concerns as do conventional foods.[19] Consequently, the FDA uses the same regulatory scheme for conventional and GM foods, and evaluates foods by their objective characteristics rather than on the basis of any methods that may have been

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2221-30 (2004) (describing the Coordinated Framework and the role of the EPA and the USDA). *See also* MacLaughlin, *supra* note 12, at 385-88 (focusing on Canada's regulation of GMOs with respect to environmental concerns).

14. *See, e.g.*, Henry I. Miller, *Substantial Equivalence: Its Uses and Abuses*, 17 NATURE BIOTECH. 1042, 1042-43 (1999); *see also* Peter Kearns & Paul Meyers, *Correspondence: Substantial Equivalence Is a Useful Tool*, 401 NATURE: INT'L WKLY. J. SCI. 640, 640-41 (1999).

15. COUNCIL FOR BIOTECHNOLOGY INFORMATION, SUBSTANTIAL EQUIVALENCE IN FOOD SAFETY ASSESSMENT (2001).

16. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

17. United States Department of Agriculture, Agricultural Biotechnology—Laws and Regulations, http://www.usda.gov/agencies/biotech/laws.html (last visited Apr. 19, 2007).

18. United States Department of Agriculture, U.S. Biotechnology Product Query Results, http://www.usda.gov/agencies/biotech/laws.html (last visited Apr. 19, 2007).

19. DONNA U. VOGT & MICKEY PARISH, FOOD BIOTECHNOLOGY IN THE UNITED STATES: SCIENCE, REGULATION, AND ISSUES (2001), *available at* http://www.ncseonline.org/nle/crsreports/science/st-41.pdf at 10.

employed to produce those foods.[20]

The Canadian regulatory regime for GMOs and GM food is broadly similar to that of the United States, Canada's most significant competitor in agricultural markets worldwide. Legal regulation of GMOs and GM food resides largely in three Canadian federal agencies: Health Canada, the Canadian Food Inspection Agency (CFIA), and Environment Canada.[21] While these three agencies serve distinct functions in regulating GMOs and GM food, their activities overlap to a significant degree. For example, Health Canada and the CFIA both regulate the labeling of GM foods, and the CFIA and Environment Canada both conduct environmental safety assessments.[22] Despite this overlap, Health Canada holds primary responsibility for ensuring public health and food safety, the CFIA holds primary responsibility for agricultural issues, such as "the importation (Plant Protection Act), environmental release (Seeds Act), variety registration (Seeds Act) and use in livestock feeds (Feeds Act) of plants with novel traits (PNTs)," and Environment Canada is responsible for regulating new substances outside the purview of either Health Canada or the CFIA and also performs environmental assessments of possible toxic substances.[23] These agencies coordinate their activities in an effort to ensure the health and safety of humans, animals, and the environment from risks associated with the ingestion, environmental release, and commercial use of novel plants, food, and feed, including GM varieties.[24]

As in the United States, GM food does not tend to be regulated on the basis of their methods of production.[25] Rather, all novel food products, regardless of production method, are subject to similar risk assessment procedures and are authorized for environmental release and commercialization only after assessment of any novel traits.[26] There is no legal assumption in the Canadian regulatory regime that GMOs, GM crops, or GM livestock are inherently more dangerous than their conventional equivalents.

The European regulatory approach to GMOs and GM food stands in stark

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20. *Id.*

21. Canadian Biotechnology Advisory Committee, http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00186e.html#sec2d (last visited Apr. 19, 2007).

22. *Id.*

23. *Id.*

24. Health Canada, Health and the Environment, http://www.hc-sc.gc.ca/sr-sr/biotech/environ/index_e.html (last visited Apr. 29, 2007) (listing the joint responsibilities of Health Canada and Environment Canada regarding biotechnology regulation and noting that Health Canada works with other agencies); Health Canada, Food, http://www.hc-sc.gc.ca/fn-an/gmf-agm/index_e.html (last visited Apr. 29, 2007) (overview of regulation of food biotechnology).

25. John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 207, 232-37 (2001).

26. *Id.*

contrast to the North American approaches. The regulatory regime in Europe is characterized by abundant caution. It does distinguish between GMOs and GM food based upon their methods of production, and it employs an extreme version of the precautionary principle to justify limitations on GMOs and GM food that might implicate human health or environmental safety. Genetically modified organisms and GM foods are regulated differently from their conventional equivalents simply because they are products of genetic engineering.

In 2004, the EU enacted a "fundamentally revised legal system [for regulating GMOs that made the] essential foundations of the EU's policies . . . tight safety standards and freedom of choice for consumers and farmers."[27] Prior to this revision there had been a "*de facto* moratorium" on approval of new GMOs and GM foods, absent the satisfaction of very strict requirements for tracing and labeling food ingredients.[28] Although the previous regulatory regime only officially authorized member countries to enact a "safeguard clause [that] allowed for a temporary ban of a GM product on a state's territory if there was substantial evidence that it imposed risks to human health or the environment," in practice, this safeguard clause was implemented in a manner tantamount to a total ban on commercial testing and marketing of GM crops and livestock throughout the EU.[29] In contrast to this *de facto* ban, the new regulatory regime has three major laws[30] intended to enable the commercialization of GM crops and livestock: two pertains to authorization requirements and one to labeling and traceability requirements.[31] Directive 2001/18 regulates the use of GM crops and their possible release into the wild, Directive 1829/2003 regulates the use of food and feed derived from GM plants, and Directive 1830/2003 sets labeling standards for GM foods.[32] Unlike the system of voluntary pre-market safety evaluation implemented in the United States, the EU requires authorization of every GM food prior to its entry onto the market.[33]

In addition to legal regulatory regimes directed at ensuring human health

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27. *Genetic Engineering, Plants, and Food: The European Regulatory System,* GMO COMPASS, Jan. 10, 2006, http://www.gmo-compass.org/eng/regulation/regulatory_process/156.european_regulatory_system_genetic_engineering.html.

28. *EU Lifts de Facto Moratorium on GMOs*, FOOD & DRINK WEEKLY, May 24, 2004, *available at* http://www.findarticles.com/p/articles/mi_m0EUY/is_19_10/ai_n6367969.

29. *Genetically Modified Organisms*, EURACTIV, Aug. 17, 2004, http://www.euractiv.com/en/biotech/genetically-modified-organisms/article-117498.

30. The three major laws are known in the European Union as "directives."

31. *EU-Law Overview: The Two Laws Governing Genetically Modified Plants*, GMO COMPASS, Feb. 15, 2006, http://www.gmo-compass.org/eng/regulation/regulatory_process/158.two_laws_governing_genetically_modified_plants.html.

32. *Id. See also* Europa—Food Safety: From the Farm to the Fork, http://ec.europa.eu/food/food/biotechnology/index_en.htm (describing the directives and also mentioning Directive 90/219 (EC) on the contained use of GM micro-organisms and Regulation 1946/2003 (EC) for the transboundary movement of GMOs between member countries).

33. *Id. See also Genetically Modified Organisms*, EURACTIV, Aug. 17, 2004, http://www.euractiv.com/en/biotech/genetically-modified-organisms/article-117498.

and environmental safety, the United States, Canada, and Europe all have relatively efficient and well-enforced intellectual property systems. Their intellectual property systems include readily available patent rights to protect new inventions of qualifying subject matter. The United States and Europe both allow patent protection on GM animals and plants. Rare among industrialized countries, Canada does not consider animals and plants—GM or otherwise—to constitute statutory subject matter eligible for patent protection.

B. International Legal Approaches to Regulation of GMOs

As with their domestic legal approaches, the United States and Canada have taken similar legal approaches to the regulation of GMOs and GM food in the international sphere. In keeping with its restrictive domestic legal regulatory regime, Europe has supported international legal restrictions on GMOs and GM food.

Although Canada was the second country to ratify the CBD, it signed, but did not ratify, the CPB,[34] which authorizes member countries to regulate trade in GMOs and GM food.[35] The United States is one of only seven countries yet to have ratified the CBD, and it has not signed the CPB.[36] The European Union and most of its constituent members have both signed and ratified or approved both the CBD and its CPB.[37] Neither the United States, Canada, nor Europe (with a few exceptions) have signed or ratified the Statutes of the International Centre for Genetic Engineering and Biotechnology, its Protocol, or its amendments, which propose legal circumscriptions on genetic engineering.[38] The United States, Canada, and Europe are all members of the World Trade Organization (WTO) and its Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).[39]

The United States and Canada have long been aggressively pressing Europe to accept imports of their GM agricultural products. On May 13, 2003, both the United States and Canada announced their desire to negotiate with Europe to end "certain measures taken by the EC and its member States affecting imports of agricultural and food imports from the United States and Canada."[40] The complaints arose from policies adopted by both Europe and its

34. Convention on Biological Diversity, Parties to the Convention on Biological Diversity: Cartagena Protocol on Biosafety, http://www.biodiv.org/world/parties.asp (last visited Apr. 19, 2007) [hereinafter "Convention on Biological Diversity", "Parties"]. Note that this and other statements regarding the signing and ratification of international treaties were true as of the writing of this article.

35. *Id.*

36. *Id.*

37. *Id.*

38. *Id.*

39. World Trade Organization, Understanding the WTO: The Organization, Members and Observers (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Apr. 20, 2007).

40. World Trade Organization, Dispute Settlement: DS291, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, http://www.wto.org/

member countries:

> Regarding EC-level measures, the US and Canada asserted that the moratorium applied by the EC since October 1998 on the approval of biotech products has restricted imports of agricultural and food products from the US and Canada. Regarding member State-level measures, the US and Canada asserted that a number of EC member States maintain national marketing and import bans on biotech products even though those products have already been approved by the EC for import and marketing in the EC.[41]

The WTO appointed a panel to adjudicate the trade complaints lodged by the United States (WTO DS 291), Canada (WTO DS 292), and a number of other countries, including Argentina (WTO DS 293).[42] After three years, the panel circulated its reports on September 29, 2006.[43] The panel largely sided with the United States, Canada, and the other complainants, finding that Europe:

> applied a general de facto moratorium on the approval of biotech products between June 1999 and August 2003, which is when the Panel was established. Before the Panel, the European Communities had categorically denied the existence of such a moratorium. The Panel further found that, by applying this moratorium, the European Communities had acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement[44] because the de facto moratorium led to undue delays in the completion of EC approval procedures . . . . With regard to the product-specific EC measures, the Panel found that the European Communities has acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement in respect of the approval procedures concerning 24 out of 27 biotech products identified by the complaining parties because there were undue delays in the completion of the approval procedures for each of these products.[45]

Significantly, the panel found that Europe, and its member countries, had misapplied risk assessments and misused scientific evidence:

> With regard to the EC member States safeguard measures, the Panel found that the European Communities acted inconsistently with its obligations under Articles 5.1 and 2.2 of the SPS Agreement with regard to all of the safeguard measures at issue, because these measures were not based on risk assessments satisfying the definition of the SPS Agreement and hence could be presumed to be

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english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Apr. 19, 2007).

41. *Id.*

42. *Id.*

43. *Id.*

44. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures, http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm

45. World Trade Organization, Dispute Settlement: DS291, *supra* note 40. Note that the United States and Canada did not prevail on all of their claims against Europe. Rather, the panel identified a significant number of WTO provisions that Europe did, in fact, apply correctly.

maintained without sufficient scientific evidence.[46]

On November 21, 2006, the panel reports were adopted by the Dispute Settlement Body (DSB).[47]

Europe decided not to challenge the findings of the WTO panel. On December 19, 2006, at the DSB meeting, Europe "announced its intention to implement the recommendations and rulings of the DSB in a manner consistent with its WTO obligations."[48] However, Europe also announced that proper implementation of the recommendations would take a substantial period of time "due to the complexity and sensitivity of the issues involved."[49]

III. THE SCIENCE AND RISKS OF GENETICALLY MODIFIED ORGANISMS

A. Genetic Engineering

Genetic engineering (also known as recombinant DNA technology) encompasses a set of chemical methods by which means "[the] genetic endowment of organisms can now be precisely changed in designed ways."[50] Genetic modification "allows selected individual genes to be transferred from one organism into another, including genes from unrelated species."[51] Specific methods of genetic engineering and modification include transgenics (transferring genetic material from organism to organism), genetic alteration (altering the genetic material in an organism), and cloning (creating a genetic duplicate of an existing organism).

B. Genetically Modified Organisms and Modern Agriculture

Since the dawn of agriculture, humans have been deliberately modifying the genetic material of crop plants and livestock by selectively breeding for favored traits having genetic bases. Genetic engineering "can be used to promote a desirable . . . character or to suppress an undesirable trait,"[52] and has allowed genetic modification to be achieved more precisely, efficiently, and rapidly than previously possible. Genetic engineering allows the creation of high fidelity genetic modifications within a single generation, where traditional breeding methods required many generations and achieved relatively low success rates. Genetic engineering technologies have produced agricultural

46. *Id.*

47. *Id.* The DSB is the specific organ of the WTO that oversees dispute settlement between member countries.

48. *Id.*

49. *Id.*

50. JEREMY M. BERG ET AL., BIOCHEMISTRY 134 (6th ed. 2007).

51. NUFFIELD COUNCIL ON BIOETHICS, THE USE OF GENETICALLY MODIFIED CROPS IN DEVELOPING COUNTRIES—A FOLLOW-UP DISCUSSION PAPER 61 (2004), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/GM_Crops_Discussion_Paper_2004.pdf [hereinafter "NUFFIELD COUNCIL"].

52. *Id.*

crops with greatly expanded yields and greatly reduced needs for nutrients, water, fertilizer, herbicides, and pesticides, as well as livestock with similarly beneficial genetic traits.

The example of Golden Rice illustrates the great promise for agriculture of genetic engineering. Much of the world's population relies upon rice as a staple food. For example, in Southeast Asia, rice is an important source of calories, especially to the rural poor, who may derive more than 80% of daily calories from it.[53] However, grains of rice lack beta-carotene (also known as provitamin A), which is a vital nutrient in the human diet. With support from the Rockefeller Foundation, two biologists—Ingo Potrykus, Professor *emeritus* from the Swiss Federal Institute of Technology, and Peter Beyer, Professor at the University of Freiburg—set out to create a breed of rice rich in beta-carotene to improve nutrition and health for people in countries dependent on rice.[54] A biological problem precluded the use of traditional genetic techniques: beta-carotene is not produced in the rice endosperm (that is, the edible tissue of rice).[55] Without a genetic basis for increasing the amount of beta-carotene in the endosperm through selective breeding of the rice plant (with those that possessed relatively greater amounts of beta-carotene in their endosperm), traditional selective breeding was not an option. Instead, genetic engineering was necessary to introduce genetic traits where they previously did not exist.

Potrykus and Beyer discovered that the addition of only two transgenes (that is, genes from organisms other than rice) to the rice genome led to the production of beta-carotene in the endosperm.[56] Each transgene allowed rice to produce a distinct chemical product:

> The first transgene encodes phytoene synthase (PSY), which utilises the endogenously synthesised geranylgeranyl-diphosphate to form phytoene, a colorless carotene with a triene chromophore (Burkhardt et al., 1997). The second encodes a bacterial carotene desaturase (CRTI) that introduces conjugation by adding four double bonds. The combined activity of PSY and CRTI leads to the formation of lycopene, which is a red compound due to its undecaene chromophore.[57]

Fortified by these transgenes, the metabolic machinery already present in rice endosperm is able to produce beta-carotene in significant amounts.[58] The first generation of Golden Rice contained a PSY gene derived from daffodil and a CRTI gene derived from a bacterium, *Erwinia uredovora*.[59] However, in

53. GOLDEN RICE, THE SCIENCE BEHIND GOLDEN RICE (2005), http://www.goldenrice.org/Content2-How/how1_sci.html.

54. GOLDEN RICE, HISTORY OF GOLDEN RICE PROGRAM (2006), http://www.goldenrice.org/Content1-Who/who2_history.html.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

order to enhance the level of beta-carotene to satisfy the nutritional needs of children in developing countries, it was later discovered that the PSY gene from maize and rice led to greater production of beta-carotene.[60] As of 2005, the Golden Rice genetically engineered by Potrykus and Beyer produced sufficient beta-carotene to meet even the ambitious recommended daily allowances for children in rich, developed countries.[61]

The example of Golden Rice puts into high relief a crucial difference, and important advantage, of genetic engineering. Where traditional methods of selective breeding cannot create organisms with new traits, genetic engineering can. Furthermore, even where successful selective breeding augments a pre-existing characteristic of a plant or animal, this method can require many generations. By contrast, genetic engineering has the potential to achieve the same—or a better—genetic endpoint in a single generation.

C. Risk Assessment of Genetically Modified Organisms

Many critics of genetic engineering worry that GMOs represent a significant danger to human health and the environment. Nightmare scenarios range from GM "superweeds," armed with superior genetic characteristics that escape the confines of farmers' fields to harm the environment, to GM "Frankenfoods", containing ingredients harmful to human health.[62] Despite such worries, credible scientific evidence of harmful effects of GMOs and GM foods has so far proved elusive.

Three published scientific studies, in particular, have been cited as evidence for adverse effects of GMOs. The first was conducted by Dr. Árpád Pusztai, a research scientist at the Rowlett Research Institute in Scotland.[63] Dr. Pusztai introduced a gene from Snowdrop, a flowering plant in the genus *Galanthus*, into potatoes.[64] The Snowdrop transgene produces lectin, a protein or glycoprotein involved in binding carbohydrates to the surface of cells.[65] The potatoes were then fed to laboratory mice to assess their dietary safety.[66] Prior to publication of his results in *The Lancet*, a prestigious, peer-reviewed

60. *Id.*

61. *Id.*

62. Beyond potential threats to human health and the environment, more prosaic worries have included the possibility that GM pollen will pollinate non-GM crops in neighboring fields, thus causing genetic contamination. These concerns are particularly relevant to organic farmers, the value of whose crops depend, at least in part, on assurances that they are not genetically modified. In the United States such concerns have recently begun to spur litigation. *See, e.g., In re* Starlink Corn Prods. Liab. Litig, 212 F. Supp. 2d 828 (N.D. Ill. 2002).

63. Geoffrey Lean, *GM: When Fed to Rats It Affected Their Kidneys and Blood Counts. So What Might It Do to Humans? We Think You Should Be Told; The Secret Research We Reveal Today Raises the Potential Health Risks*, THE INDEPENDENT ON SUNDAY, May 22, 2005, at 6.

64. Stanley WB Ewen & Árpád Pusztai, *Effect of Diets Containing Genetically Modified Potatoes Expressing Galanthus Nivalis Lectin on Rat Small Intestine*, THE LANCET, Oct. 16, 1999, at 1353.

65. *Id.*

66. *Id.*

British medical journal, Dr. Pusztai spoke about the results of his research in a televised interview, and suggested that ingestion of the GM potatoes had caused serious ill health effects in the mice.[67] However, his published results were more equivocal:

> Diets containing genetically modified (GM) potatoes expressing the lectin *Galanthus nivalis* agglutinin (GNA) had variable effects on different parts of the rat gastrointestinal tract. Some effects, such as the proliferation of the gastric mucosa, were mainly due to the expression of the GNA transgene. However, other parts of the construct or the genetic transformation (or both) could also have contributed to the overall biological effects of the GNA-GM potatoes, particularly on the small intestine and caecum.[68]

The Lancet distanced itself from Dr. Pusztai's interpretations of his data in an accompanying editorial[69]. In the same issue, *The Lancet* published an alternative interpretation of the data that failed to support Dr. Pusztai's conclusions about toxicity.[70] The latter interpretations proved consistent with later scientific studies of the health effects of GM food, which have overwhelmingly failed to identify health threats unique to GM food.[71] Nevertheless, the effect of Dr. Pusztai's allegations of toxic GM potatoes may have soured a European citizenry already distrustful of food safety in the wake of the outbreak of Bovine spongiform encephalopathy (BSE), or mad cow disease, to the palatability of GM food.

Soon after, a study published in 1999 in the scientific journal *Nature*[72], caused an uproar after suggesting that Monarch butterfly larvae might be poisoned in the wild by exposure to pollen from GM corn genetically engineered to express *Bt* toxin, a potent insecticide derived from *Bacillus thuringiensis* (*Bt*) bacteria.[73] Two years later, a second study in *Nature* suggested that genetic material from GM crops had leaked into indigenous Mexican varieties of maize, highly valued as natural repositories of genetic diversity.[74] These two studies were widely cited in the popular press and by NGOs as demonstrating serious health and environmental threats posed by GMOs. However, both scientific studies were quickly revealed to suffer from

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67. Lean, *supra* note 63, at 6.

68. Ewen & Pusztai, *supra* note 64, at 1353.

69. Richard Horton, *Genetically Modified Foods: "Absurd" Concern or Welcome Dialogue?*, THE LANCET, Oct. 16, 1999, at 1314.

70. Harry A. Kuiper et al., *Adequacy of Methods for Testing the Safety of Genetically Modified Foods*, THE LANCET, Oct. 16, 1999, at 1315.

71. *E.g.*, Shaoni Bhattacharya, *GM Food Risk to Humans "Very Low,"* NEW SCIENTIST, July 21, 2003, http://www.newscientist.com/channel/health/gm-food/dn3959 (last visited on Apr. 20, 2007).

72. *Nature* is considered by scientists to be one of the most prestigious and rigorously peer-reviewed scientific journals.

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

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

serious scientific flaws. The Monarch butterfly study was carried out only in the laboratory, and subsequent studies characterized the threats of *Bt* toxin to larvae in the wild as negligible.[75] The Mexican maize study was determined to be so deeply flawed scientifically that, a mere four months after its initial publication, *Nature* stated in a special editorial that "the evidence available is not sufficient to justify the publication of the original paper."[76]

No conclusive scientific evidence has surfaced since these two studies to indicate significant health or environmental threats represented uniquely by GMOs.[77] This has wrong-footed governments and NGOs whose opposition was based on scientific evidence, especially where these same governments and NGOs rely on scientific evidence to back their policies on other environmental and health issues, such as global climate change, loss of the ozone layer, biodiversity, and the environmental and health effects of chemical toxins.[78] To rely on science to inform policy on some issues, while discounting it on others, invites the appearance of inconsistency and hypocrisy.

Governments have been active in trying to assess the risks posed by GMOs and GM food to human health and environmental safety through science. To date, they have found little evidence of harm. The United States government requested that the National Academies of Science (NAS), a semi-independent organization whose members tend to be prominent and well-respected scientists in their fields, investigate the risks of GMOs. After reviewing the totality of available scientific evidence, the NAS concluded that "[t]o date, no adverse health effects attributed to genetic engineering have been documented in the human population."[79] Similarly, the FDA recently released a draft report concluding that, with the exception of sheep (for which there

75. *See, e.g.*, Mark K. Sears et al., *Impact of* Bt *Corn Pollen on Monarch Butterfly Populations: A Risk Assessment*, 98 PNAS 11937 (2001) ("This 2-year study suggests that the impact of *Bt* corn pollen from current commercial hybrids on monarch butterfly populations is negligible.").

76. *Editorial Note*, 416 NATURE 600 (2002).

77. *See, e.g.*, Philip J. Dale et al., *Potential for the Environmental Impact of Transgenic Crops*, 20 NATURE BIOTECH. 567 (2002). Evolutionary theory suggests that the probabilities of GM organisms spreading their genes into natural populations are very low. Given the rigors of natural selection, and the unlikelihood that human tinkering will be superior to millions of years of evolution at selecting genetic traits advantageous for survival and reproduction, GM organisms will tend to be less, rather than more, likely to survive in the wild than their unmodified wild cousins. By corollary, any wild organism to which GM genes do spread will tend to survive less well because of those GM genes than their purely non-GM wild cousins. Evolutionary theory suggests that, far from becoming superorganisms that supplant wild biodiversity, GM organisms and the genetic material they carry will tend to disappear quickly after entering natural ecosystems.

78. *See, e.g.*, Michael Specter, *The President and the Scientists*, THE NEW YORKER, Mar. 13, 2006, *available at* http://www.newyorker.com/archive/2006/03/13/060313on_onlineonly01?currentPage=1 (noting the United States may be an exception to this observation because it has recently taken policy positions on such issues as global climate change, air pollution, and biomedical research in the face of overwhelming scientific evidence).

79. THE NAT'L ACADS., SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS 180 (2004).

were insufficient data to make an assessment), clones, their progeny, and their products, pose no additional threat to human health than do non-clones:

> Extensive evaluation of the available data has not identified any food consumption risks or subtle hazards in healthy clones of cattle, swine, or goats . . . . [Edible] products from healthy clones that meet existing requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals . . . . Edible products derived from the progeny of clones pose no additional food consumption risk(s) relative to corresponding products from other animals based on underlying biological assumptions, evidence from model systems, and consistent empirical observations.[80]

The government of the United Kingdom has also considered the safety of GMOs, and, after reviewing more than 600 published scientific studies of GMOs, concluded both that:

> [on] balance . . . the risks to human health are very low for GM crops currently on the market[81] . . . [and] . . . detailed] field experiments on several GM crops . . . in a range of environments have demonstrated that they are very unlikely to invade our countryside or become problematic plants . . . [n]or are they likely to be toxic to wildlife or to perturb soil structure in such a way that the functioning of soil communities is substantially affected.[82]

The British Royal Society, an independent organization of prominent scholars similar to the U.S. National Academies of Science, supported the Science Review's conclusions, and noted that the popular media, in publishing sensational accounts of GMOs' risks, "have been ignoring the scientific evidence."[83] Furthermore, a report by the Nuffield Council on Bioethics summarized the scientific evidence on GM food and human health as follows: "A number of authoritative reviews have concluded that there are no proven health damages arising from the consumption of GM crop products on the market as yet."[84] Paul F. Lurgquin, a prominent professor of plant genetics, summarized in his book, *High Tech Harvest*:

> The projected threats of plant biotechnology against humanity have not come to pass. There is no scientific evidence that engineered corn, soybean, or canola have had a detrimental impact on humans and the environment. Americans and Canadians are not suffering short-term or medium-term effects from the consumption of these transgenic foods.[85]

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80. U.S. FOOD AND DRUG ADMINISTRATION, ANIMAL CLONING: A DRAFT RISK ASSESSMENT, Dec. 28, 2006, at 309, *available at* http://www.fda.gov/cvm/Documents/Cloning_Risk_Assessment.pdf.

81. THE GM SCIENCE REVIEW PANEL, GM SCIENCE REVIEW – FIRST REPORT 23 (July 2003), *available at* http://www.gmsciencedebate.org.uk/report/pdf/gmsci-report1-full.pdf.

82. *Id.* at 24.

83. Shaoni Bhattacharya, *supra* note 71.

84. NUFFIELD COUNCIL ON BIOETHICS, *supra* note 51.

85. PAUL F. LURQUIN, HIGH TECH HARVEST—UNDERSTANDING GENETICALLY MODIFIED

In short, the biological scientific community appears to be approaching broad consensus that the scientific evidence does not indicate significant unique threats posed by GMOs or GM foods to either human health or environmental safety. Such a consensus would strongly undermine both human health and environmental safety as policy rationales for restrictively regulating GMOs and GM food.

D. The Precautionary Principle

The precautionary principle has been formulated in numerous ways. Principle 15 of the Rio Declaration on Environment and Development states that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[86] By comparison, Annex III of the CPB states that "lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk."[87] The precautionary principle holds obvious relevance for analyzing potential threats not only to environmental safety, but to human health as well. It is commonly invoked to justify strict regulation, or outright rejection, of GMOs and GM foods.[88] Unsurprisingly, it is also interpreted and implemented differently from country to country.

Rather than operate as a straightforward decisional mechanism, the precautionary principle tends to operate by shifting the burden of proof away from taking an action whose consequences are uncertain and potentially detrimental and toward the precautionary *status quo*. It tends to offer a perspective on how to balance identifiable and predictable risks, but does not provide easy answers about whether or not to pursue any particular course of action (or inaction).

In approaching legal regulation of GMOs and GM food, different jurisdictions have applied the precautionary principle in different manners, often in justification of particular regulatory regimes. Canada and the United States have tended to regulate with a relatively light touch, allowing research, field testing, and marketing of GMOs in the absence of clear scientific evidence suggesting adverse risks.[89] Europe has tended to reverse this burden of proof, requiring clear and affirmative scientific evidence of safety prior to

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FOOD PLANTS 162 (2002).

86. REPORT OF THE UNITED NATIONS CONFERENCE ON ENVIRONMENT AND DEVELOPMENT (UNCED), June 3-14, 1992, *Rio Declaration on Environment and Development*, Principle 15, U.N. Doc A/CONF.151/26 (Vol. I) (Aug. 12, 1992) [hereinafter *Rio Declaration*].

87. Convention on Biological Diversity, *supra* note 34.

88. *E.g.*, COMMISSION ON THE EUROPEAN COMMUNITIES, COMMUNICATION FROM THE COMMISSION ON THE PRECAUTIONARY PRINCIPLE (2000).

89. *See, e.g.*, Daniel Bodansky, *Scientific Uncertainty and the Precautionary Principle*, 33 ENV'T 4 (Sept. 1991) (This approach is consistent with that suggested by some critics of an overcautious application of the precautionary principle).

regulatory approval.[90] For example, Canada and the United States tend to regulate the health safety of GM food based upon the scientifically reasonable assumption that it is substantially equivalent to non-GM food, whereas Europe tends to assume that GM food is substantially different from non-GM food.[91]

In these two approaches, the regulatory outcome often depends upon where the burden of scientific proof is initially allocated. Because the United States and Canada tend to require scientific evidence indicating lack of safety—and such scientific evidence has proven rare—GMOs and GM food have generally been approved there for field-testing and commercial use. By requiring proof of safety, a form of scientific evidence logically equivalent to proof of a negative, Europe has ensured that GMOs and GM food are often denied regulatory approval.

The precautionary principle employed by Europe to regulate GMOs and GM food is vulnerable to several growing threats. The precautionary principle is not absolute; rather, it relies on the weight of scientific data. GMOs and GM food have now been subject to many hundreds of rigorous scientific studies. The overwhelming weight of the scientific data indicates little evidence that GMOs and GM food pose unique risks to human health or environmental safety. The European precautionary principle risks being overprecautionary.[92] As its decision to accept the findings of the WTO panel on restricting GMOs and GM food indicates,[93] Europe appears to have accepted that its regulatory approach can no longer be sustained by scientific evidence.[94]

III. MONOPOLY CONTROL OVER AGRICULTURE

A. The Phony War of GMO Regulation

On September 1, 1939, Germany launched an invasion of Poland. Immediately thereafter, the United Kingdom and its former colonies declared war on Germany. The Second World War had begun. However, very little in the way of actual war-making took place between the fall of Poland, on October 6, 1939, and the commencement of major military engagements after Germany's invasion of Denmark and Norway on April 9, 1940. This period of military sideshows has been named the "Phony War". Human health and environmental safety as rationales for legally regulating GMOs and GM food may also come to be seen as a "Phony War". Europe and many developing

90. *See The Numerology of Idiocy*, 19 NATURE BIOTECH. 319 (2002).

91. John Hodgson, *Ten Years of Biotech Gaffes*, 24 NATURE BIOTECH. 270, 271 (2006).

92. *See, e.g.*, Bodansky, *supra* note 88, at 4 (stating that some scholars have warned against the overcautious application of the precautionary principle).

93. World Trade Organization, Dispute Settlement: DS291, European Communities—Measures Affecting the Approval and Marketing of Biotech Products, http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm (last visited Apr. 19, 2007) [hereinafter "Dispute Settlement: DS291"].

94. *See generally* Council Directive 98/44, 1998 J.O. (L 213) 13 (EC).

countries, the United Nations, many NGOs, and millions of citizens worldwide have long been skeptical of the safety of GMOs ("Superweeds") and GM food ("Frankenfood"). In response, many jurisdictions have imposed strict regulations. In Europe, such regulations resulted in a "*de facto* moratorium" on GMOs and GM food.[95] Desperately poor countries, such as Zambia, have even refused free donations of GM food in the face of widespread starvation among their own citizens.[96] Meanwhile, scientists have achieved a near-consensus that existing scientific evidence indicates neither threats to human health nor environmental safety uniquely posed by GMOs and GM food.

There is growing evidence that the real war over GMOs and GM food may be beginning. Rather than the Phony War over human health and environmental safety, the real war may be fought over monopoly control of agriculture.[97] Concerns over monopoly control of GMOs and GM food are being expressed with increasing frequency and forcefulness. As Jerry Crawford, of the influential environmental NGO, Resources for the Future, has publicly stated:

> [The extent to which transgenic organisms differ from traditionally bred organisms] is not what underlies the controversy . . . . What underlies the controversy is whether crop germplasm is public domain or is privately owned through patents on plants and animals. If scientists really want to address the root of opposition to transgenic food, they first need to acknowledge what that underlying root is: monopoly control of the world's food supply . . . . In the GMO controversy, the solutions may be difficult, but the key distinction is not. It really is up or down, black or white, as definite as whether a patent office says 'yes' or 'no'.[98]

Similarly, concerns about GMO patents, as well as related "terminator technology," were also voiced by a group of more than 300 scientists in a letter to the Fifth Conference of the Parties (COP) to the CBD:

> We call for the immediate suspension of the release of [terminator] crops and products, both commercially and in open field trials, for at least five years, for patents on living processes, organisms, seeds, cell lines and genes to be revoked and banned, and for a comprehensive public enquiry into the future of agriculture and food security for all . . . .[99]

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95. Dispute Settlement: DS291, *supra* note 90.

96. Martin Plaut, *Zambia 'Furious' Over GM Food*, BBC NEWS: WORLD EDITION, Nov. 6, 2002, *available at* http://news.bbc.co.uk/2/hi/africa/2371675.stm (last visited Apr. 20, 2007).

97. *See e.g.*, Vernon W. Ruttan, *Controversy about Agricultural Technology: Lessons from the Green Revolution*, 6(1) INT'L J. OF BIOTECH. 43 (2004). Fears about monopoly or oligopoly ownership over new food technologies date back at least to the Green Revolution, when many developing countries opposed the adoption of Green Revolution food technologies on the grounds that a small group of large, multinational agricultural companies might come to control the means of agricultural production.

98. Jerry Cayford, *GMO Opposition Not Based on a Mistake*, 21 NATURE BIOTECH. 493 (2003).

99. Wandera Ojanji, *Suspend GM Crops for Five Years—Scientists*, THE EAST AFRICAN,

Recognition of the real war over GMOs and GM food has important implications for their legal regulation.

Concerns raised by patent protection and monopoly ownership of GMOs and GM foods are nearly the obverse of those concerning human health and environmental safety, the first two faces of GMO regulation. In fact, anxieties over patent monopolies imply that GMOs and GM food are valuable and possess significant benefits for society. After all, unless patent monopolies on GM foods threaten access to potentially superior food options, consumers could avoid the problems of monopoly simply by choosing to purchase non-GM, or even organic, food. Since patents do often act as the gatekeepers to access to new varieties of GM food, intellectual property control over this new source of food represents a third face of regulation of GMOs.

B. "Terminator" Technology

The example of "terminator" technology illustrates growing concerns about monopoly control over food supplies. In many developing countries, protection for, and enforcement of, intellectual property rights remain lax. Consequently, agricultural crop companies tend to avoid introducing advanced proprietary crop breeds in such countries for fear of rampant infringement without hope of remedy. "Terminator technology" represents one solution to this problem. Sometimes characterized as Genetic Use Restriction Technology (GURT), terminator technology involves the genetic engineering of a "suicide gene" into an organism.[100] Such a "terminator gene" renders the organism sterile, thus preventing it from reproducing once it has yielded its agricultural product.[101] Although some opposition to terminator technology has rested on fears that GM crops might break the bonds of domesticity and invade surrounding ecosystems, thus spreading terminator genes, this particular worry is likely misplaced, since any tendency towards self-destruction is self-eliminating.

In the 1990s, the USDA and the Delta and Pine Land Company (currently pending merger with the Monsanto Company) actively pursued the development of terminator technology for use in agricultural crop plants.[102] These efforts led to the issuance of several U.S. patents claiming aspects of terminator technology.[103] Issuance of the first of these U.S. patents sparked much controversy around the world. Terminator technology was criticized as a threat to global agricultural security.[104] Numerous environmental NGOs

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May 29, 2000, *available at* http://www.nationaudio.com/News/EastAfrican/29052000/Regional/Regional6.html.

100. NUFFIELD COUNCIL, *supra* note 51.

101. *See id.*

102. *See generally* JASON SUTTON, 'TERMINATOR' TECHNOLOGY (2004), *available at* http://cls.casa.colostate.edu/TransgenicCrops/terminator.html.

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

104. *See generally*, Ricarda A. Steinbrecher & Pat Roy Mooney, *Terminator Technology:*

condemned the technology as a threat to agricultural food security.[105] For example, India announced a ban on imports of terminator seeds.[106] Maurice Strong, former head of the United Nations Conference on the Environment and Development (UNCED), spoke out strongly against use of terminator technology: "If the owners of technology, such as big companies, used [biotechnology] to victimize people through methods such as promotion of 'terminator genes,' the state should intervene and not leave the task to the market mechanism."[107] Even the USDA, erstwhile developers of terminator technology, was instructed by the Clinton administration to discourage further research into terminator technology.[108] In 1999, Monsanto Company, an agricultural biotechnology corporation that had announced its intention to acquire the Delta Pine and Land Company, publicly pledged not to use terminator technology in its products in the absence of clear evidence indicating the safety of such use.[109]

At the fifth COP meetings in 2000, Parties to the CBD voted to institute a moratorium on field trials of GURT crops in the absence of clear scientific evidence of safety.[110] At the eighth COP meetings in 2006, the Parties voted to extend the moratorium, despite pressure from Australia, Canada, and New Zealand to allow some field trials.[111] To date, it appears that terminator technology has not been adopted anywhere in the world.

The opposition to terminator genes brings into high relief worries about monopoly control of new GM foods. The weak logical and scientific

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the Threat to World Food Security, 28 THE ECOLOGIST 276(4) (1998).

105. Nigel Hawkes, *War on Killer Seed*, TIMES, Nov. 4, 1998.

106. Rob Edwards, *US Officials Fear a Backlash Over 'Terminator Technology,'* NEW SCIENTIST 2121, 2121, Oct. 10, 1998.

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

108. Edwards, *supra* note 106, at 2121.

109. *Terminator Gene Halt a 'Major U-Turn'*, BBC NEWS, Oct. 5, 1999, *available at* http://news.bbc.co.uk/2/hi/science/nature/465222.stm. Note that Monsanto did not, in fact, acquire Delta Pine and Land Company; however, acquisition of Delta Pine and Land Company by Monsanto was pending as of February 2007.

110. THE CONFERENCE OF THE PARTIES, CONVENTION ON BIOLOGICAL DIVERSITY, DECISION V/5 AGRICULTURAL BIOLOGICAL DIVERSITY: REVIEW OF PHASE I OF THE PROGRAMME OF WORK AND ADOPTION OF A MULTI-YEAR WORK PROGRAMME 5 (2000).

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

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

foundation of worries that self-eliminating terminator genes might introgress into natural populations suggests the existence of an alternative justification for opposition to terminator technology. A more logical explanation is fear of monopoly control over new and useful GM crops, enforced by terminator technology.

Companies employing terminator technology would be able to control the use and unauthorized perpetuation of their GM crops. Consequently, farmers choosing to grow GM crops would have no option but to purchase seeds from supply companies each growing season because saving seeds from a terminator crop would be futile. Thus, by employing terminator technology, companies that developed GM crops could achieve monopoly control over those crops akin to the monopoly control offered by patents on GM crops. In fact, terminator technology, which was developed at least in part in response to rampant infringement of patented GM crops in developing countries, may offer better monopoly control than do patents. Terminator technology offered the prospect of reliable built-in control instead of the uncertainties of obtaining and enforcing patent rights in countries with weak legal systems.

The controversy that greeted the prospect of terminator technology demonstrated that at least some anxieties over GMOs center around monopoly control. Though often invoked rhetorically in opposition to GMOs, concerns over human health and environmental safety may be waning in the face of waxing fears over monopoly control, whether in the form of patent protection or technological control, such as that promised by terminator technology.

V. INTELLECTUAL PROPERTY AS REGULATION OF GMOS

A. Intellectual Property Covering GM Plants and Animals

Despite their differences with respect to regulating GMOs and GM food on the basis of human health and environmental safety, the United States and Europe do share a permissive policy regarding the availability of patent protection for GM plants and animals. By contrast, Canada does not allow patents on GM animals or plants. Consequently, despite similar approaches to the legal regulation of GMOs with respect to human health and environmental safety at both the domestic and international levels, Canada and the United States differ greatly in availability of patent protection for GMOs. In light of the growing emphasis on monopoly ownership of GMOs as a focus of opposition, differences in availability of patent rights covering GMOs in Canada and the United States may increase in salience. The approach to GMO patents taken by Canada may also indicate an alternative strategy that Europe might adopt to regulate GMOs and GM food as it shifts its regulatory emphasis away from human health and environmental safety.

B. Availability of Patent Protection for GMOs

The European Union (and its individual member countries), the United States, and Canada are all members of the WTO.[112] As members of the WTO, they must all comply with TRIPS. TRIPS Article 27, entitled "Patentable Subject Matter", sets forth the areas of technology for which patent protection must be available in WTO member countries.[113] Specifically, Article 27(1) stipulates that, subject to several enumerated exceptions, "patents shall be available for any inventions, whether products or processes, in all fields of technology [and that] patents shall be available and patent rights enjoyable without discrimination as to . . . the field of technology".[114] However, Article 27(2) and (3) carve out significant exceptions to patentable subject matter. Article 27(2) allows member countries to:

> [E]xclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[115]

Moreover, Article 27(3) specifically allows member countries to exempt from patentability "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes," though it goes on to mandate that member countries "shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."[116]

Both the United States and Europe have taken an "Article 27(1)" approach, allowing patents on plants and animals, including those that have been genetically modified. In 1980, the U.S. Supreme Court considered the patentability of a "human-made, genetically engineered bacterium . . . capable of breaking down multiple compounds of crude oil" in *Diamond v. Chakrabarty*.[117] In a famous pronouncement, the U.S. Supreme Court defined the realm of the patentable as "anything under the sun that is made by man," including living organisms.[118] Later cases have confirmed the patentability of plants[119], animals[120], and even mammals.[121] The U.S. Supreme Court

112. World Trade Organization, Understanding the WTO: The Organization, Members and Observers (2007), http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

113. World Trade Organization, Agreement on Trade-Related Aspects of Intellectual Property Rights at Article 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Uruguay Round Agreement, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm.

114. *Id.* at Article 27(1).

115. *Id.* at Article 27(2).

116. *Id.* at Article 27(3).

117. Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

118. *Id.* at 309.

119. *Ex parte* Hibberd, 227 U.S.P.Q. 443, 444 (Bd. Pat. App. & Int'f 1987); J.E.M. AG

reaffirmed the patentability of living organisms in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*[122]

Living organisms, including both GM plants and animals, are also patentable subject matter in Europe. The European Patent Office (EPO) has even granted a patent on a non-human mammal: the "Harvard Mouse".[123] Though patentability of the Harvard Mouse was vigorously challenged under Article 53(a) of the European Patent Convention ("EPC")[124] on grounds that patents on living organisms threaten *ordre public* and morality, the EPO disagreed, and granted the patent.[125]

Canada has applied legal standards of patentable subject matter in a distinctly different manner from both the United States and Europe. Where multicellular living organisms, like plants and animals, are patentable subject matter in the United States and Europe, they are not in Canada. In 2002, the Canadian Supreme Court decided *Harvard College v. Canada (Commissioner of Patents)*, a case centering on whether the Harvard Mouse, a transgenic mammal, constituted statutory subject matter for patenting.[126] The Canadian Supreme Court held that "[a] higher life form is not patentable because it is not a 'manufacture' or 'composition of matter' within the meaning of 'invention' in s. 2 of the *Patent Act*."[127] This decision was supported by the barest of majorities—five of nine Canadian Supreme Court justices—and the dissents made clear that four justices considered the decision not to allow patents on multicellular genetically modified organisms a significant jurisprudential mistake.[128]

C. Canada's GMO Patentability Transition

Canada has cleaved more closely to an "Article 27(3)" approach, prohibiting the patentability of GM plants and animals, most notably in the 2002 Canadian Supreme Court case *Harvard College v. Canada (Commissioner of Patents)*.[129]

The Canadian Biotechnology Advisory Board (CBAB) has recognized the significance of the patentability issue to Canada's international interests:

Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 145 (2001).

120. *Ex parte* Allen, 2 U.S.P.Q.2d 1425, 1427 (Bd. Pat. App. & Int'f 1987).

121. Transgenic Non-Human Mammal, U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988).

122. *J.E.M.*, 534 U.S. at 145.

123. Method for producing transgenic animals, European Patent No. EP0169672 (published Jan. 29. 1986). Note that this is the European equivalent of U.S. Patent No. 4,736,866, *supra* note 123.

124. EPC Article 53(a) is similar to TRIPS Article 27(2).

125. Harvard/Onco-mouse, 1992 O.J. E.P.O. at 593 (Examining Division).

126. Harvard College v. Canada, [2002] 4 S.C.R. 45, 47.

127. *Id.*

128. *Id.*

129. *Id.*

> Article 27.3(b) of The World Trade Organization (WTO) Agreement on the Trade-Related Aspects of Intellectual Property (TRIPs) allows member countries to exclude plants and animals from patentability. When the mandated review of this section takes place, some countries (mostly developing nations) can be expected to support maintaining or expanding this section, while other countries (most notably the United States) will likely want to either narrow or eliminate this exception. Canada will be better able to contribute to this debate by developing a domestic position on this matter prior to the commencement of these negotiations.[130]

Furthermore, the CBAB was not neutral in which "domestic position" it advised Canada to adopt, recommending that Canada change its policy to recognize GM plants and animals as patentable subject matter.[131]

A significant step in the direction CBAB advised took place two years after *Harvard College v. Canada.* In 2004, the Canadian Supreme Court issued its decision in *Monsanto Canada Inc. v. Schmeiser*, a dispute over whether a farmer was liable for infringement by growing and selling canola containing genes and cells covered by Monsanto's patent claims.[132] Although the court was careful to point out that patentability of the canola plant itself was not at issue, its decision may have opened the door to *de facto* patenting of plants and animals.[133] It did this by upholding the validity of patent claims covering modified genes inserted into canola.[134] If a gene within a GM crop plant can be the subject of a valid patent claim, then unauthorized use of the plant containing that gene can constitute infringement; this has the same effect as if the plant itself were claimed in a patent. Thus, it appears that Canada's domestic legal approach to GM organisms and products is converging with that of the United States as the CBAB recommended it should. The result may be to bring Canada and the United States into convergence in both their

130. CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE, PATENTING OF HIGHER LIFE FORMS AND RELATED ISSUES: REPORT TO THE GOVERNMENT OF CANADA BIOTECHNOLOGY MINISTERIAL COORDINATING COMMITTEE (2002), *available at* http://www.cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00213e.html (last visited Apr. 20, 2007).

131. *Id.*

132. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 902 (2004).

133. Confidential Personal Communication to the author (September 2004). In fact, an attorney very closely associated with the case interprets *Monsanto Canada Inc. v. Schmeiser* as overturning *Harvard College v. Canada.* One potential explanation for Canada's reluctance to allow patents on GM organisms may be cultural. Canada's legal system derives from both civil law (Québec and New Brunswick) and common law (all provinces and territories other than Québec) traditions. Common law countries, such as the United States, the United Kingdom, and Australia, have tended to adopt a more permissive approach to the patentability of animals and plants. Civil law countries, by contrast, have shown more resistance to such patents, often on grounds that it violates public morality or the *ordre public.* Consistent with this pattern, all Supreme Court Justices from Québec opposed patentability of higher life forms in *Harvard College v. Canada*, whereas the majority from common law provinces supported patentability. Two years later, after an outcry from Canada's biotechnology industry and CBAB's recommendations for change, this pattern had shifted, with a majority of civil law Justices upholding the patent in *Monsanto Canada Inc. v. Schmeiser.*

134. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 902 (2004).

international and domestic legal approach to the regulation of GM organisms and products.

Several factors may be offered as possible contributors to convergence. First, if Canada and the United States indeed share a common epistemic community of biotechnology scientists with expertise in biotechnology, to the extent Canada relies upon this community to inform its legal regulation of GMOs, that community will tend to provide the same advice to Canada as it does to the United States, whether the issue is human health, environmental safety, or availability of patent rights.

The apparent use of a similar precautionary principle by Canada and the United States, at least with respect to GMOs, may not be very surprising. After all, these two countries share a pool of scientists with expertise in biotechnology that possesses characteristics of a common epistemic community[135]—a common epistemic community that may share a common understanding of, and approach to, the precautionary principle as it relates to GMOs. Evidence for this proposition includes the observation that biotechnology scientists in the two countries tend to receive their education and training at the same pool of universities and scientific institutes, belong to the same professional and scientific societies, attend the same scientific conferences, read and publish in the same peer-reviewed journals, apply for financial support to many of the same funding sources, and share the same pool of graduate students and postdoctoral fellows. It is not unreasonable to predict that the same epistemic community of scientists will tend to advise governments to adopt similar approaches to the regulation of GMOs with respect to both human health and environmental safety, as Canada and the United States have done.

Scrutiny of the CBAB provides specific evidence of a common epistemic community. The Canadian federal government relies upon an appointed body of experts—the CBAB—to provide it with expert advice regarding the regulation of biotechnology. The CBAB is composed primarily of biological

135. Peter M. Haas, *Introduction: Epistemic Communities and International Policy Coordination*, 46 INT'L ORG. 3 (1992).

> An epistemic community is a network of professionals [usually natural scientists] with recognized expertise and competence in a particular domain and an authoritative claim to policy-relevant knowledge within that domain or issue-area. Although an epistemic community may consist of professionals from a variety of disciplines and backgrounds, they have (1) a shared set of normative and principled beliefs, which provide a value-based rationale for the social action of community members; (2) shared causal beliefs, which are derived from their analysis of practices leading or contributing to a central set of problems in their domain and which then serve as the basis for elucidating the multiple linkages between possible policy actions and desired outcomes; (3) shared notions of validity—that is, intersubjective, internally defined criteria for weighing and validating knowledge in the domain of their expertise; and (4) a common policy enterprise—that is, a set of common practices associated with a set of problems to which their professional competence is directed, presumably out of the conviction that human welfare will be enhanced as a consequence.

scientists with expertise in biotechnology. Among their activities is the production of advisory reports relating to regulation of GMOs. CBAB's website points visitors not only to reports authored by CBAB itself, but also to reports authored by the U.S. National Academy of Sciences, CBAB's counterparts who advise the United States federal government.[136]

An additional reason for Canada's transition toward *de facto* patentability of GM plants and animals may be that by denying patentability to GM plants and animals, Canada risks subjecting itself to international shaming by appearing hypocritical in the international arena, where it is currently litigating to open up markets for its own GM products, and attempting to negotiate amendments to international agreements such as the Patent Law Treaty and the TRIPS agreement that would be favorable to such products. Finally, unless it offers patent protection for GM plants and animals, Canada risks being perceived as a location unfriendly to biotechnology companies and research that can relocate with ease to the United States.

Domestic policy considerations can motivate states to promote similar policy positions at the international level.[137] An inverse relationship has also been suggested, wherein international law and institutions influence states to alter their domestic laws.[138] The legal regulation of GMOs in Canada may offer a combination of both phenomena: a country's existing domestic law influences what international legal positions the country can reasonably promote, and the same domestic law is under pressure to change to conform with legal positions the country would prefer to promote at the international level. In any case, in the near future it is likely that there will be even broader congruence in the legal approaches that Canada and the United States take to the regulation of GMOs at both the domestic and international levels.

D. Monopoly Control of Agriculture by Patents on GMOs

Legal regulation of GMOs and GM food by the United States has been relatively light in terms of human health, environmental safety, and patent monopoly control. By contrast, Europe has allowed patents on GM agricultural plants and animals, while imposing relatively strict legal regulation in the realms of both human health and environmental safety despite minimal scientific justification. Canada has taken yet a third path. While its legal regulation of the human health and environmental safety risks of GMOs approaches that of the United States in lightness of touch, Canada does not allow patents covering GM plants or animals *per se*.

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136. Canadian Biotechnology Advisory Committee, Archived Features (2006), http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00547e.html (last visited Apr. 20, 2007).

137. ELIZABETH R. DESOMBRE, DOMESTIC SOURCES OF INTERNATIONAL ENVIRONMENTAL POLICY: INDUSTRY, ENVIRONMENTALISTS, AND U.S. POWER 2 (2000).

138. Marc A. Levy, *European Acid Rain: The Power of Tote-Board Diplomacy in* PETER M. HAAS ET AL., INSTITUTIONS FOR THE EARTH: SOURCES OF EFFECTIVE INTERNATIONAL ENVIRONMENTAL PROTECTION 132 (1993).

Because of its approach to GMO patenting, Canada is best placed to limit monopoly control of agricultural products, including human food. Patent protection for GM plants and animals has long been available in the United States and Europe. Despite the fact that public anxiety over GMOs is higher in Europe than in North America, Europe appears to have backed the wrong regulatory horse, since the science underpinning its human health and environmental safety concerns has yet to materialize. However, if monopoly control over agricultural goods is indeed a greater concern than either human health or environmental safety, it might not be surprising if Europe soon began to try to cut off, or make more difficult, access to patents on GMOs. Though Canada has been alone among these three jurisdictions in having in place a legal means to prevent patent monopoly control of GM agricultural goods, its Supreme Court appears to have weakened this means in *Schmeiser v. Monsanto*.[139]

VI. CONCLUSION

In the past, opposition to GMOs and GM crops has tended to focus on alleged dangers to human health and environmental safety. The United States, Canada, and Europe have all established regulatory frameworks whose stated aims are to ensure that GMOs and GM crops do not harm the health of their citizens or threaten the well-being of their environments. However, these jurisdictions have set up regulatory hurdles of significantly different heights. North American neighbors, the United States and Canada, have tended to regulate GMOs and GM crops with a relatively light touch that tends to ease approval for field-testing and commercial marketing. By contrast, Europe has applied much stricter regulatory standards, with the result that few GM crops have been field-tested or GM foods allowed onto the market there.

A large and growing body of scientific studies into the human health and environmental safety of GMOs and GM crops has failed to find significant justification for the extreme precautionary approach adopted by Europe. Furthermore, a WTO panel decision forcefully critical of the European regulatory regime for GMOs and GM crops was recently accepted by Europe, and may herald the adoption of a new regulatory regime more accepting of GMOs and GM crops.

As prospects fade that scientific evidence will demonstrate that GMOs and GM crops pose unique threats to human health and environmental safety, a third locus of anxieties has been growing in significance: patent monopolies over new and useful GM crops. Concerns about monopoly control of GM crops are the obverse of concerns about human health and environmental safety. Where the latter rationales counsel against the easy and widespread adoption of GM crops, the former rationale would operate to ensure such easy and widespread adoption. Both the United States and Europe offer patent

139. Monsanto Canada Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 902 (2004).

protection for GM plants and animals, making regulation against patent monopolies in GM crops difficult. However, Canada does not allow the patenting of GM plants and animals, thus avoiding patent monopolies in GM crops *per se*. Ironically, just as Europe might look to Canada for a new method of regulating GMOs and GM crops, Canada may be undergoing a transition toward allowing such inventions to be patented.

Of the three loci of regulation of GMOs and GM crops, the patent system maintains the most integrity. The scientific justifications for strictly limiting GMOs and GM crops due to concerns over human health and environmental safety have yet to materialize to any significant degree. In fact, there is so little scientific evidence of unique risks of GMOs and GM crops that even invocation of a conservative precautionary principle may be unjustified. Regardless of how regulation of GMOs and GM crops changes in Canada and Europe in the future, it is likely that concerns over monopoly control will grow in significance as a rationale for regulation, while the rationales of human health and environmental safety will continue to fade in the absence of a reversal of the current trend of scientific evidence.