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## Intellectual Property Reform for Genetically Modified Crops: A Legal Imperative

Carlos Scott Lopez

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# INTELLECTUAL PROPERTY REFORM FOR GENETICALLY MODIFIED CROPS: A LEGAL IMPERATIVE

*Carlos Scott López\**

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\*\* The pronoun “his” is also used to refer to individuals who are male and unidentified individuals who may be male or female. If contextually appropriate, the phrase “his or her” is used.

*Everything that can be invented has been invented.*

*Charles H. Duell, Director of the U.S.  
Patent Office 1899 (recommending that the Patent Office be abolished)*

*The patent landscape is a minefield.*

*- Tom Abage, San Francisco Chronicle  
January 12, 2000<sup>1</sup>*

*[T]he . . . patent system may . . . be described as dislocated and being  
“out of sync” with the vibrant and explosive advances in science and  
technology.*

*- Kojo Yelapaala, Professor of Law University  
of the Pacific, 2000<sup>2</sup>*

*Designed more than a hundred years ago to meet the . . . needs of a  
[simpler] economy . . . our system of intellectual property rights are an  
undifferentiated one-size-fits-all system.*

*- Lester C. Thurow, Dean Emeritus MIT Sloan  
School of Management, 1999<sup>3</sup>*

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1. Tom Abage, *Words and Germs Bait Biotech's Hooks*, SAN FRANCISCO CHRONICLE, Jan. 12, 2000, at D1, cited in Cliff D. Weston, *Chilling of the Corn: Agricultural Biotechnology in the Face of U.S. Patent Law and the Cartagena Protocol*, 4 J. SMALL & EMERGING BUS. L. 377, 408 n.229 (2000).

2. Kojo Yelapaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 32 MCGEORGE L. REV. 111, 187 (2000).

3. Lester C. Thurow, *Poaching Patents*, 19 CAL. LAW., Nov. 1999, at 23, cited in Yelapaala, *supra* note 2, at 188 n.298. See generally Lester C. Thurow, *Globalization: The Product of a Knowledge Based Economy*, ANNALS AM. ACAD. POL. & SOC. SCI., July 2000, at 19.

## I. INTRODUCTION AND RECENT CURRENT EVENTS

During the last decade, Genetically Modified Crops (GMCs) and the scientific techniques that inspire them have become commonplace. So, too, have the controversies. While GMCs are being grown, sold, and consumed at unprecedented levels — and genetic cloning techniques have become ubiquitous in scientific research — critics contend that the economic, social, political, and ecological risks of GMCs are too great; therefore, GMCs should be more vigorously controlled. On the other hand, the inertia behind the development and potential benefits of GMCs are enormous. In fact, the main problem with GMCs is not the risks they impose, but the ways by which they are inconsistently and inadequately managed. More specifically, the intellectual property (IP) rights associated with GMCs are often muddled, inconsistent, or unclear, leading the interests of key inter-regional, inter-state, and international constituencies to be either ignored, misunderstood, or unprotected. Ultimately, IP rights enable the producers of GMCs to wield an inordinate amount of economic and political power in dictating the use of GMCs; however, their actions have gone largely unchecked because of the nature of the IP rights granted. If the IP rights of GMCs are not managed more effectively — addressing the unique scientific origins of GMCs and the roles of their creators — critics' worst fears could come to fruition.

This article highlights the need for a new legal framework for managing GMC IP interests and suggests five guiding principles for creating such a framework. In doing so, the article explores the specific case of Australia, which is currently overhauling its IP system, and analyzes the case of *Monsanto Canada v. Schmeiser*, decided by the Canadian Federal Court in 2002.<sup>4</sup> Australia's current challenges are an example of both an inadequate IP system and a failed attempt to reform and adequately address key problems posed by GMCs. Furthermore, the case of *Monsanto Canada* illustrates a decision which serves as a significantly damaging precedent for the IP law it both creates and inspires. Ultimately, an effective IP regime must be international in scope. Indeed, individual countries not only must take initiatives to meet their own needs, but also must address the inadequacies of the world's current administrative and legal IP systems. Countries must recognize IP rights for GMCs and simultaneously account for the economic, social, ecological, political,

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4. *Monsanto Canada, Inc., v. Schmeiser*, [2002] F.C. 309.

and international interests that GMCs raise. This task is not simple, but is an essential prerequisite for a sustainable, ethically viable system that accommodates GMCs and the scientific technology they inspire.

## II. THE GENETICALLY MODIFIED CROP (GMC) DEBATE

### A. Context & Background

In many ways, GMCs are nothing new. The romanticization of sowing seeds and growing plants has existed for literally thousands of years of recorded history.<sup>5</sup> Furthermore, humans have “genetically modified plants and animals through domestication and controlled breeding for some ten thousand years with little controversy.”<sup>6</sup> In the early 1970s, scientists developed and refined new biotechnological techniques which enabled them to transfer genes from one species into other species.<sup>7</sup> The seeds of controversy then were sown.

During the 1980s, developments proceeded rapidly. In 1986, the United States was home to the first patent “covering a genetically engineered variety of corn with increased nutritional value.”<sup>8</sup> This was followed in 1987 with the successful transplant of a “gene from a bacterial cell into tomato plants, making the plants resistant to caterpillars.”<sup>9</sup> In 1989, Australia was the first nation in the world to approve the sale of a genetically modified organism; Bio-Care Technology, a company specializing in microbial-based inoculants for use in agriculture and horticulture,<sup>10</sup> introduced the world’s first commercial pesticide, Nogall<sup>TM</sup>, which is essentially a genetically

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5. See Paul Healy, *Buzz on bee-u-tiful plants*, THE MERCURY (Hobart, Austl.), Nov. 23, 2002, at 44 (observing how farming over the ages has been associated with romantic ideals).

6. Sabrina Safrin, *Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements*, 96 AM. J. INT’L L. 606 (2002). See generally JARED DIAMOND, *GUNS, GERMS, AND STEEL: THE FATES OF HUMAN SOCIETIES* (1997) (providing extraordinary insights into the ecological and biological impetuses which enabled civilizations to develop—and collide—as they did).

7. Safrin, *supra* note 6, at 606.

8. Theresa Ambrose, *The Story So Far*, THE AGE, June 16, 1999, at 8.

9. *Id.*

10. See Bio-Care Technology Pty. Ltd. website, available at <http://www.bio-care.com.au/> (last visited Apr. 29, 2004).

manipulated bacterium with a long shelf-life.<sup>11</sup> Based on the species *Agrobacterium radiobacter* (strain K1026), Nogall™ effectively helped stem the tide “of crown gall disease in stone fruit (peaches, cherries, apricots, plums, and nectarines), nut trees (e.g., almonds, walnuts, and pecans), caneberries (boysenberries [and] raspberries), clematis, hops, kiwifruit, persimmon, [and] roses.”<sup>12</sup> Five years later, in 1994, Calgene employed anti-sense RNA technology<sup>13</sup> to produce the first plant product, the Flavr Savr™ Tomato, to reach dining hall tables; it was

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11. Additional products produced by Bio-Care Technology include the following:

(a) Twist Fungus Inoculum (containing *Dilospora alopecuri* for the biological control of annual ryegrass toxicity in pastures in Southern Australia), available at <http://www.agrobiologicals.com/products/P1642.htm> (last visited Apr. 18, 2004);

(b) Nitrogerm and Nobulaid (inoculents for creating nodulation and nitrogen fixation in pasture and grain legumes such as lucernes (e.g., alfalfa), clovers, lotus, lablab, vetches, guar, peas, soybeans, cowpeas, mung beans, lupins, chickpeas, faba beans, and lentils), available at <http://www.agrobiologicals.com/products/P1643.htm> (last visited Apr. 18, 2004);

(c) BioCane Granules (containing *Metarhizium anisopliae*, strain FI-1045, for the biological control of the beetle white grub, *Dermolepida albohirtum*, in sugarcane in North Queensland), available at <http://www.agrobiologicals.com/products/P1641.htm> (last visited Apr. 18, 2004); and

(d) BioGreen Granules (containing *Metarhizium anisopliae*, strain F001, for the biological control of the pasture beetle scarab, *Adoryphorus couloni*, in turf and pastures in southeastern Australia), available at <http://www.agrobiologicals.com/products/P1640.htm> (last visited Apr. 18, 2004); see also [http://www.ats.business.gov.au/ats-members/nogall-control\\_of\\_crown\\_gal.htm](http://www.ats.business.gov.au/ats-members/nogall-control_of_crown_gal.htm) (last visited Apr. 26, 2004) (providing an overview of Nogall).

12. Agrobiologicals website, available at <http://www.agrobiologicals.com/products/P247.htm> (last visited Apr. 18, 2004).

13. In prokaryotes, antisense RNA is known to down-regulate expression of specific genes. This type of regulatory control has not been observed in higher eukaryotes, but in frog oocytes and *Drosophila* embryos, antisense RNA can cause decreased expression of target genes. In the tomato, the enzyme polygalacturonase (PG), encoded by the PG gene, is expressed during ripening. PG activity causes depolymerization of the pectin fraction of the cell wall, which results in softening of ripe tomatoes. Theoretically, the introduction of an antisense PG gene was the expected result in an mRNA that would suppress the expression of the endogenous PG enzyme, which is what was ultimately achieved in the Flavr Savr™ tomato. See C. J. S. Smith et al., *Antisense RNA inhibition of polygalacturonase gene expression in transgenic tomatoes*, 334 NATURE 724 (1988), cited by University of Toronto, *The Genetics of the Flavr Savr* website, available at <http://dragon.zoo.utoronto.ca/~jlm-gmf/T0101A/Enzyme.html> (last visited Apr. 18, 2004).

also the first genetically modified food (GMF) sold in the United States.<sup>14</sup> One year later, Monsanto's NewLeaf® potato<sup>15</sup> was the first commercial crop with built-in insect repellent; it included a gene from the bacterium *Bacillus thuringiensis*, or BT, engineered to protect it primarily from the Colorado Beetle and other insect larvae in the *lepidoptera* class (e.g., butterflies and moths).<sup>16</sup>

The late 1990s brought more technological developments and the first significant sets of scares and controversies. Given this article's later discussion of Australia as illustrative of a jurisdiction in need of a new IP regime, it is worth focusing on particular developments there. Just months after Australia's approved release of patented Ingard™ cotton<sup>17</sup> (containing a genetic defense to caterpillar attack and the first, and only, genetically modified crop grown in Australia), it was discovered that five of twenty major brands of cheddar cheeses had used genetic engineering to produce the cheeses, though this fact was not noted on their labels.<sup>18</sup> Consumers reacted by boycotting the cheeses and, just four months later, the Australian government halted the sale of *all* GMFs after an Adelaide-based company, BresaGen, called for the destruction of cattle which had eaten feed with a modified growth gene producing leaner meat.<sup>19</sup> On February 3, 1997, the Australian government instituted labeling requirements requiring any products with more than five percent of modified agreements to

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14. See U.S. Dept. of Agriculture, *NBIAP News Report: Two Views of the Flavr Savr*, available at [http://www.accessexcellence.org/AB/BA/Two\\_Views\\_of\\_Flavr\\_Savr.html](http://www.accessexcellence.org/AB/BA/Two_Views_of_Flavr_Savr.html) (last visited Apr. 29, 2004).

15. Varieties of potatoes are currently widely sold on the market by Monsanto (designated by a series of codes, including BT-6, SPBT02-05, RBMT21-129, RBMT21-350, and RBMT22-82). See <http://www.mhlw.go.jp/english/topics/qa/dna/> (last visited Apr. 12, 2004) (detailing information about current strains being assessed by Japan's Ministry of Health, Labor and Welfare for use in Japan).

16. See W.D. Gelernter & J. T. Trumble, *Factors in the Success and Failure of Microbial Insecticides in Vegetable Crops*, 4 INTEGRATED PEST MANAGEMENT REVIEWS 301 (1999), abstract available at <http://www.kluweronline.com/article.asp?PIPS=254056&PDF=1> (last visited Apr. 17, 2004); see also <http://www2.kenyon.edu/Projects/Agri/ghei01.html> (last visited Apr. 14, 2004).

17. The active constituent in this strain of cotton is a subspecies of *Bacillus thuringiensis*. The *kurstaki* delta endotoxin is produced by the CryIA(c) gene and its controlling sequences. See Gelernter & Trumble, *supra* note 16, *passim*. See generally <http://www.monsanto.com.au/images/cotton/labels/ingard.pdf> (last visited Apr. 18, 2004) (displaying the label affixed to bags of the insecticide).

18. Ambrose, *supra* note 8, at 8.

19. *Id.*

obtain approval — on a case-by-case basis — for public consumption.<sup>20</sup> Less than two weeks later, on February 14, 1997, Australia prohibited BT-genetically modified Maize, followed by Luxembourg on March 17, 1997, and the EU required labeling of all products with genetically modified foodstuffs in early April.<sup>21</sup> Only three weeks later, the United Kingdom's Prince Charles called a complete halt to genetic manipulations of food, warning that scientists were straying into "realms that belong to God, and to God alone."<sup>22</sup> On June 7, 1998, Swiss voters overwhelmingly supported a referendum banning all genetic alterations and patenting of animals.<sup>23</sup>

Despite these controversies, genetic crops have continued to multiply and a wide range of varieties now exist. Most GMCs comprise four crops: soya, corn, cotton, and canola;<sup>24</sup> and, as Professor Marsha A. Echols notes, they take one of three forms: (a) basic agricultural or bulk products (e.g., the long-life Flav'r Savr<sup>TM</sup> Tomato, insect-resistant maize, and Roundup Ready<sup>TM</sup> Soybeans); (b) processed products with genetically engineered ingredients (e.g., tomato puree from long-life tomatoes); and (c) genetically engineered foods (e.g., chymosin, a vegetarian milk coagulant for cheese).<sup>25</sup> A wide variety of products currently being developed include "salt-tolerant and drought-tolerant crops; coloured cotton; plants that make plastic starters; and plants in which drugs and vaccines are produced."<sup>26</sup>

Internationally, "the OECD has estimated that more than 1,100 field trials were conducted with transgenic plants between 1986 and 1992."<sup>27</sup> Furthermore, Monsanto currently owns ninety percent of the world's

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20. *Id.*

21. See Europe Information Service, *Genetic Engineering: Labeling Proposals for GMOs will still 'leave consumers in the dark,'* EUROPEAN REPORT, April 5, 1997; see also <http://www.american.edu/TED/SOYBEAN.HTM> (last visited Apr. 16, 2004) (quoting a *Reuters* report entitled *European Commission Announces New Labeling Laws* dated Apr. 7, 1997).

22. See sources cited *supra* note 21.

23. See sources cited *supra* note 21.

24. Adrienne Clarke, *Australia Needs to Protect its GM Technology: Ownership the Key*, WEEKLY TIMES, Oct. 9, 2002, at 15.

25. Marsha A. Echols, *Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws*, 4 COLUM. J. EUR. L. 525, 536 nn.51, 53-54 (1998).

26. Adrienne Clarke, *Enormous Environmental Benefits in GM Crops*, CANBERRA TIMES, October 10, 2002, at A18.

27. Stevan M. Pepa, *International Trade and Emerging Genetic Regulatory Regimes*, 29 LAW & POL'Y INT'L BUS. 415, 423-24 (1998).



GMCs, charges “technology fees” for its services,<sup>28</sup> and is leading the way in research and development efforts. India, among others, has fought back with a very loose IP system as a means of encouraging innovation and allowing its citizens to make use of the technologies without needing to pay key royalties. The United States Trade Representative Office, however, used access to U.S. markets as a lever to induce other countries to follow its lead in protecting IP issues.<sup>29</sup> In so doing, it has suggested that arguments over the efficacy of GMCs will most likely be addressed in the halls of legislatures enacting IP regulation, and *not* laboratories or public rallies.

### B. Positive & Negative Implications of GMCs

The potential benefits of GMCs are arguably enormous and pundits often raise these in response to arguments considering GMCs a threat to the environment, public health, and the “naturalness” of scientific endeavors.<sup>30</sup> Their arguments fall into seven main categories, addressing issues related to (a) production, (b) economics, (c) health, (d) the environment, (e) development, (f) risk, and (g) politics. Each of these is considered in turn.

The most salient argument for GMCs is that higher quality foodstuffs can be produced in greater quantities, more than meeting market demand.<sup>31</sup> The main implication of this observation is decreased hunger, as more food can be produced while protecting biodiversity. This stems from the fact that land can be used more efficiently, with currently untouched land protected for future generations.<sup>32</sup> Providing enough food for the world’s population has been deemed the “biggest problem facing the world” this upcoming

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28. See Victoria Laurie, *Seeds of Revolution*, AUSTRALIAN MAGAZINE, Sept. 28, 2002, at 16; see also Exhibit 14, contained in the Appendix (highlighting Monsanto’s business interests, spanning a host of areas).

29. Pepa, *supra* note 27, at 430.

30. See *Enormous Environmental Benefits in GM Crops*, *supra* note 26.

31. See George E.C. York, *Global Foods, Local Tastes and Biotechnology: The New Legal Architecture of International Agricultural Trade*, 7 COLUM. J. EUR. L. 423, 429 (2001).

32. See Henrique Freire de Oliveira Souza, *Genetically Modified Plants: A Need for International Regulation*, 6 ANN. SURV. INT’L & COMP. L. 129, 174 (2000).

millennium,<sup>33</sup> a comment echoed by followers of David Ricardo in the early 1800s and those who laud increased crop yields, reduced dependence on fertilizers, and reduced labor capital in the face of large population increases.<sup>34</sup>

The second and third sets of arguments favoring GMCs address the economic and health benefits provided by GMCs. Economically, for example, Roundup Ready™ Soybeans are reported to save farmers hundreds of millions of dollars annually<sup>35</sup> in increased yields and reduced waste, thus promoting sustainable farming.<sup>36</sup> Furthermore, GMCs can be designed with enhanced nutritional profiles, readily applicable for developing pharmaceuticals.<sup>37</sup> Mortality rates can be lowered as food production is expanded, simultaneously increasing the nutritional value of available food.<sup>38</sup> An example is the Golden Rice developed by the Swiss scientist Ingo Potrykus to help address Vitamin A deficiencies leading to 250,000 cases of childhood blindness in Asia and “millions of deaths worldwide each year.”<sup>39</sup>

The fourth and fifth sets of reasons for promoting GMCs address their environmental and developmental benefits. The former stems directly from the fact that crops can be designed which are resistant to pests, “drought and frost, able to grow in high alkaline and high metal soils, able to grow more quickly, and produce higher yields”<sup>40</sup> by ripening more slowly. Because they often require fewer natural resources to grow, they also — as noted above — are less taxing on the environment. This particularly benefits both (a) developing countries (amassing the majority of GMCs’ “developmental” benefits), and (b)

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33. Valkerie Mangnall, *Enough Food the World's Biggest Problem, Expert Say[s]/[sic]*, AAP NEWSFEED, July 20, 1999. See DAVID RICARDO, *PRINCIPLES OF POLITICAL ECONOMY AND TAXATION passim* (Empiricus 2002) (1804).

34. See RICARDO, *supra* note 33, *passim*.

35. JANET E. CARPENTER, NATIONAL CENTER FOR FOOD & AGRICULTURAL POLICY, CASE STUDIES IN BENEFITS AND RISKS OF AGRICULTURAL BIOTECHNOLOGY: ROUNDUP READY SOYBEANS AND BT FIELD CORN 1, *cited in* York, *supra* note 31, at 429.

36. Press Release, U.S. State Department, *U.S. Officials Press Biotechnology to Fight Hunger* (June 11, 2002), available at WESTLAW research ref. no. 25989286.

37. See York, *supra* note 31, at 430.

38. Julie Teel, *Rapporteur's Summary of the Deliberative Forum: Have NGOs Distorted or Illuminated the Benefits and Hazards of Genetically Modified Organisms?*, 13 COLO. J. INT'L ENVTL. L. & POL'Y 137, 146 (2002).

39. *Id.* at 147.

40. *Id.* at 146.

research scientists ("developing" new scientific ideas and experimental processes).

All these benefits are enhanced by a sixth set of arguments holding that GMCs carry very low risks. Two years ago, 3,200 scientists signed an on-line declaration drafted by AgBio World entitled "Scientists in Support of Agricultural Biotechnology," among them Nobel Laureates Norman Borlaug, James Watson, Paul Berg, Peter Doherty, Paul Boyer, and the 1998 National Medal of Science Recipient, Bruce Ames.<sup>41</sup> This fact does not independently guarantee that GMCs are safe, particularly in light of the fact the declaration is decidedly partisan, though it does suggest that individuals with noted scientific achievement have voiced their feelings that the use of GMCs does not portend disaster.

Finally, there are the socio-political benefits. One cannot understate the degree to which public health issues have come to be a major geopolitical force. The case for fighting AIDS is the most striking example, as evidenced by U.S. Secretary of State Colin Powell's calling for strong HIV/AIDS prevention measures in developing countries as a key element of National Security.<sup>42</sup> The role of developing GMCs in the interests of facilitating exchanges of views among various groups, particularly non-governmental organizations (NGOs), is also helpful. NGOs not only can provide information about GMCs, but encourage public participation in their creation and oversight; oversee the creation of new laws; influence corporate behavior (ideally positively); and oversee compliance with the law.<sup>43</sup>

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41. See AgBioWorld.org, *Petition, Scientists in Support of Agricultural Biotechnology*, available at <http://www.agbioworld.org/declaration/petition/petition.php> (last visited Apr. 19, 2004); list of Nobel Laureate signatories available at <http://www.agbioworld.org/declaration/nobelwinners.html> (last visited Apr. 19, 2004).

42. See Human Rights Campaign, *HRC Encouraged by Colin Powell's Comments on MTV Supporting Strong HIV/AIDS Prevention Measures*, available at [http://www.hrc.org/Content/ContentGroups/News\\_Releases/2002/HRC\\_Encouraged\\_by\\_Colin](http://www.hrc.org/Content/ContentGroups/News_Releases/2002/HRC_Encouraged_by_Colin) (last visited Feb 22, 2004).

43. See Teel, *supra* note 38, at 148-156. But consider the fact that NGOs also can be seen as distorting the debate by (a) not representing the public, (b) overestimating health and environmental risks, and (c) responding inconsistently to regulatory concerns. *Id.*

The risks of GMCs often appear to significantly outweigh these benefits. In fact, GMCs have come to be seen as more “periah[s] than messiah[s]”<sup>44</sup> as the unintended risks they *do* impose are amplified, since the world population is expected to grow from 5.8 billion today to 8.4 billion by 2025, and this growth will require a doubling of current food production.<sup>45</sup> While gene alternations may thus make such growth possible,<sup>46</sup> they are also harbingers of disaster. There are four main problem areas cited vis-à-vis GMCs, with the central theme that “when discrepancies between scientific consensus and government policy result in unwanted consequences, the blame is often placed,” for better or for worse, “directly on GM crop technology itself.”<sup>47</sup>

The first set of concerns stem from the inevitable fact that GMCs cannot be managed. Indeed, once they are “released” into the environment, the consequences of their uncontrolled reproduction in the face of decreased biodiversity cannot be predicted. This can take many forms, the first of which are the crops’ unknown side effects. Nitrogen fixing in high yielding crops is one example,<sup>48</sup> as are the migration of trans-genes into non-target organisms via inbreeding, assorted mating, and outcrossing — namely, the processes by which domesticated plants hybridize with wild relatives, thereby producing new varieties.<sup>49</sup> The main concern is that while “outcrossing is a common occurrence in conventional agronomy, outcrossing in transgenic plants may occur at significantly higher rates.”<sup>50</sup> The *New*

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44. Editorial Staff, *Food Fight*, BUSINESS REVIEW WEEKLY, June 9, 2000, at 98.

45. Editorial staff, *World's Double Trouble*, WEEKLY TIMES, Oct. 21, 1998, at 3.

46. *Id.*

47. Honor Hsin, *Bittersweet Harvest: The Debate Over Genetically Modified Crops*, 24 HARV. INT’L REV. 38 (2002).

48. Mae-Wan Ho, *Perils and Promises of Genetically Modified Foods*, Prepared on behalf of Greenpeace International, November, 1996, at 1, available at <http://archive.greenpeace.org/geneng/reports/food/food002.htm> (last visited Apr. 18, 2004), cited in York, *supra* note 31, at 432 n.54.

49. ANTHONY J. F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS (7<sup>th</sup> ed.) 726 *passim* (2000) [hereinafter “GENETIC ANALYSIS”]. This is a particular concern in countries with significantly large amounts of transgenic crops. See Exhibit 6, contained in the Appendix (summarizing the leading countries with transgenic crops today).

50. Holly Saigo, Note, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12 GEO. INT’L ENVTL. L. REV. 779, 787 (2000), cited in George Van Cleve, *Regulating Environmental and Safety Hazards of Agricultural Biotechnology for a Sustainable World*, 9 WASH. U. J. L. & POL’Y 245, 258 n.40 (2002). For a more detailed discussion, see Joy Bergelson et al., *Promiscuity in Transgenic Plants*, 395 NATURE 25 n.40 (2002) (reporting the results of a field

*York Times* reported on October 2, 2001, for example, that Maize growing in fifteen different locations in Mexico contained genetically engineered genes without the growers' knowledge.<sup>51</sup> This mirrored the StarLink® scare of 2000, when foodstuffs containing StarLink® corn, genetically modified to produce a bacterial protein Cry9c creating *Bacillus thuringiensis* (Bt) insect resistance,<sup>52</sup> were discovered on supermarket shelves. This resulted in a nationwide recall of 300 kinds of corn-based foods.<sup>53</sup> The concerns that Cry9c was an allergen stemmed from a range of clear scientific facts, including that it (a) "was relatively resistant to acid treatment;" (b) "was relatively resistant to breakdown by digestive enzymes;" (c) in the "general molecular weight range for an allergen (i.e., 10-70 kd);" (d) had a "native protein which was probably a glycoprotein;" (e) induced an "immunologic response in Brown Norway rats;" and (f) could "be found intact in the bloodstream after oral feeding in the rat model."<sup>54</sup> For these purposes, StarLink® was originally only approved for "animal feed due to concerns it might cause allergic reactions in humans."<sup>55</sup> The EPA later

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experiment in which *Arabidopsis thaliana* mutants for the *Csr1-1* allele of acetolactate synthase—conferring resistance to the herbicide chlorsulphuron—were compared with transgenic plants; "a survey of approximately 100,000 seeds showed that the per-plant outcrossing rate was 0.30% for mutant fathers and 5.98% for transgenic fathers, indicating that transgenic *A. thaliana* were roughly twenty times more likely to outcross than ordinary mutants."). The authors note that they did not know the underlying genetic mechanism, though highlight that "genetic engineering can substantially increase the probability of transgene escape, even in a species considered to be almost completely selfing." This is significant cause for concern since it suggests transgenes can escape even in the most elemental circumstances (i.e., a completely selfing species).

51. Carol K. Yoon, *Genetic Modification Taints Corn in Mexico*, N.Y. TIMES, Oct. 2, 2001, at F7, cited in Van Cleve, *supra* note 50, at 288 n.153.

52. See *infra* Exhibit 10, listing the key properties and methods used to produce StarLink® corn.

53. See Teel, *supra* note 38, at 141 n.14 (citing Andrew Pollack, *1999 Survey on Gene-Altered Corn Disclosed Some Improper Uses*, N.Y. TIMES, Sept. 4, 2001, at C2; Marc Kaufman, *Biotech Corn Fuels a Recall: Unapproved Variety Used in Taco Shells*, WASH. POST, Sept. 23, 2000, at A1.).

54. Institute of Food Technologies, *Questions about Starlink®*, available at <http://aggiehorticulture.tamu.edu/extension/newsletters/foodproc/feb01/art3feb.html> (last visited Apr. 10, 2004).

55. Randy Fabi, *Japan Finds StarLink Corn in US Cargo*, Reuters, Dec. 27, 2001, reproduced at the Organic Consumers Association Website, available at [http://www.organicconsumers.org/ge/010403\\_starlink\\_corn.cfm](http://www.organicconsumers.org/ge/010403_starlink_corn.cfm) (last modified Apr. 18, 2004).

noted that wet-milling corn could remove virtually all of the StarLink® protein from products made for human food<sup>56</sup> and that StarLink® corn would in any event be essentially eliminated from the corn grain supply by 2002.<sup>57</sup> The short-term problem was ultimately solved, though the far broader problem of unpredictability remained.

These fears of unpredictability — and ultimately unmanageability — are mirrored in the second major set of concerns about GMCs addressing broader environmental issues, particularly with regard to the unintended effects of GMOs (often linked with GMCs) on humans. Indeed, having general side effects is one concern, though the “unintended consequences in the ecosystems in which” the GMOs reside is another matter.<sup>58</sup> The worry is that the negative effects of GMCs will transcend their unintended consequences on humans and damage the broader ecosystem within which they coexist.

When it comes to the specific effects of GMCs on humans, there are several worries. The first relates to the way in which lives will be significantly affected if allergic responses are either initiated or exacerbated by ingestion of GMCs. Soybeans, for example, are low in the amino acids methionine<sup>59</sup> and cysteine,<sup>60</sup> so people whose diets are bean-based face a nutritional deficiency.<sup>61</sup> Researchers responded by transferring a gene from Brazil nuts which codes for large amounts of these acids. While seen as a great opportunity, these researchers were ultimately disappointed by the fact that the protein was *also* an

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56. See U.S. ENVIRONMENTAL PROTECTION AGENCY, WHITE PAPER ON THE POSSIBLE PRESENCE OF CRY9C PROTEIN IN PROCESSED HUMAN FOODS MADE FROM FOOD FRACTIONS PRODUCED THROUGH THE WET MILLING OF CORN (2002), available at <http://www.epa.gov/scipoly/sap/2001/july/wetmilling.pdf> (last visited Apr. 18, 2004); see also Exhibits 11-12, contained in the Appendix (illustrating the benefits of wet-milling)

57. See sources cited *supra* note 56.

58. York, *supra* note 31, at 433.

59. The linear structural formula for methionine is  $\text{CH}_3\text{-S-(CH}_2\text{)}_2\text{-CH(NH}_2\text{)-COOH}$ .

60. The linear structural formula for cysteine is  $\text{HS-CH}_2\text{-CH(NH}_2\text{)-COOH}$ .

61. ALLEN MCHUGHEN, PANDORA'S PICNIC BASKET: THE POTENTIAL AND HAZARDS OF GENETICALLY MODIFIED FOODS 120 (2000), cited in Kurt Buechle, *The Great, Global Promise of Genetically Modified Organisms: Overcoming Fear, Misconceptions, and the Cartagena Protocol on Biosafety*, 9 IND. J. GLOBAL LEGAL STUD. 283, 293 n.77 (2001). Consider also the case for new GMCs providing antibiotic resistance (given the fact that plants which receive a gene of interest also contain antibiotic resistant gene and there is concern this gene can be transferred to humans).

allergen.<sup>62</sup> A second example is the case of antibiotics, whereby plants with genes of interest containing antibiotic resistant genes (for the purpose of assays) might transfer this resistance to humans and reduce the efficacy of antibiotics for treating humans. This is feared to stimulate the evolution of resistant plants and insects from overusing genetically modified seeds.<sup>63</sup>

The third set of concerns stem from the legal and socio-economic consequences of GMCs and integrate the concepts of property ownership and economic power. First, there is the fundamental concern that GMCs are goods which are inherently 'public' in nature, but are now being patented by individuals and corporations. In this regard, the biggest problem with GMCs is not the GMCs themselves, but the "corporate attempts to dominate world markets by owning the technology."<sup>64</sup> The existence of patents and IP protections thus impose costs on society because the patentees are "able to charge monopoly prices" for their patented products or for "products made with [a] . . . patented process."<sup>65</sup> This may allow patentees to "recoup" their initial research investments,<sup>66</sup> but puts consumers at a decided disadvantage, particularly in developing countries.<sup>67</sup> The fact that companies can "sit" on their patents, effectively *failing* to exploit them and denying others the opportunity to do so, may cause the most concern in a society which can yield powerful insights from the technology.<sup>68</sup> Also, IP rights to genes create a series of economic incentives compelling manufacturers to produce GMCs for the market very quickly regardless of the risks. Newly patented genes, it is argued, should not be patentable<sup>69</sup> for any reason.

The fourth and final area addresses the more opaque issue of culture and the ways in which GMCs can deleteriously affect and change

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62. *Id.*

63. Sara M. Dunn, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 155 (1998).

64. Editors, *Who Owns Wins*, TASMANIAN COUNTRY (Austl.), Sept. 27, 2002, at 1.

65. STAINFORTH RICKETSON, *THE LAW OF INTELLECTUAL PROPERTY* ¶ 46.32, at 871 (1984).

66. See *infra* Exhibit 5, illustrating the huge investment costs associated with GMCs—and their increased use—in the world today.

67. York, *supra* note 31, at 429.

68. *Id.*

69. Mark Thornton, *Seeds of Destruction*, COURIER MAIL (Austl.), Jun. 23, 2001, at 31.

cultures. Some cuisines, for example, may be predicated on “naturalness,”<sup>70</sup> while in other cultures food represents a “symbol of belonging, [and] code of social or cultural recognition.”<sup>71</sup> This serves to explain why “international commerce in foods and ingredients has existed throughout human history, [though] local traditions and attitudes about diet persist.”<sup>72</sup> It has often been these factors which enable NGOs and the arguably “motley assemblage of environmental activists, farmers, scientists, and consumer groups” to publicize successfully their points against GMCs and “disrupt the powerful and pervasive multinational industry of agricultural biotechnology.”<sup>73</sup> Public opinion is molded by many forces, but particularly by NGOs. Often, this molding results in emotive responses to ensuing problems, divorced from scientific realities.<sup>74</sup>

In these regards, the seemingly chaotic responses to GMCs make more sense. Europe’s digging up thousands of hectares of crops inadvertently planted with GM seeds,<sup>75</sup> as well as an array of extensive U.S. federal guidelines allowing regulators to “question and/or halt

70. See Echols, *supra* note 25, at 525.

71. Sophie Bessis, *Foreword to MILLE ET UNE BOUCHES: CUISINES ET IDENTITÉS CULTURELLES* [A Thousand and One Mouths: Cuisine and Cultural Identity] 12 (Sophie Bessis ed., 1995) *quoted in* Echols, *supra* note 25, at 525, and *cited in* York, *supra* note 31, at 423 n.1.

72. Echols, *supra* note 25, at 525.

73. Teel, *supra* note 38, at 137.

74. See Thomas R. DeGregori, *NGOs, Transgenic Food, Globalization, and Conservation*, 13 *COLO. J. INT’L ENVTL. L. & POL’Y* 115, 115-16 (2002). DeGregori writes,

The organizations advance their agenda through emotional pleas, fear tactics, and propaganda, supported by little sound scientific or factual data . . . embark[ing] on neo-colonialism in a form of ecological colonialism . . . by seek[ing] control over the habitat or wildlife resources in developing countries . . . attacking modernization and industrialization. . . . While NGOs frequently decry the evils of ‘globalization’ . . . the organizations are no less global in their agendas.

*Id.* at 116.

75. See *Food Fight*, *supra* note 44, at 98. Noting that 30,000 hectares of land was reported to have been planted with Canadian canola seed by seed giant Advanta, into which a small volume of genetically modified canola or rapeseed had been mixed. It had accounted for less than 1% of the seeds, but the National Farmers Union and Scottish Agricultural Minister advised farmers to dig them up because they were unsaleable [sic] in Europe.

*Id.*



development of a biotech plant variety”<sup>76</sup> if one of a large array of authorizations does not yield a clean “bill of health,”<sup>77</sup> all result from GMC-based fears.

### *C. Recent Scientific & Political Developments*

There have been four main sets of responses to these concerns in the hopes of realizing the benefits of GMCs: (a) labeling standards; (b) strong, mandatory regulations; (c) international agreements; and (d)

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76. AMERICAN CROP PROTECTION ASSOCIATION, PLANT BIOTECHNOLOGY REGULATION: SCIENCE BASED AND CONSUMER ACCESSIBLE FROM FLOW TO PLATE 1 (2002), *cited in* York, *supra* note 31, at 439 n.99.

77. These authorizations include:

- (1) Biosafety Committee Review: Following NIH guidelines, an advisory group evaluates the plant for potential health and environmental risks;
- (2) Greenhouse Approval: USDA determines the adequacy of research facilities for biotechnology development;
- (3) Field Trial Authorization: GM crop developers must receive USDA approval for field trials and submit summary reports;
- (4) Seed Transport Authorization: USDA oversees the shipment of GM seeds from facilities to the field trial sites;
- (5) Commercialization Permission: APHIS experts must review all field trial studies before a GM crop can be grown, tested or used for traditional plant breeding without further USDA action;
- (6) Experimental Use Permit Approval: EPA must grant an experimental use permit (EUP) for test of 10 acres or more;
- (7) Food Tolerance or Exemption: EPA examines the product characterization, toxicology, allergenicity, non-target organisms, environmental impact and pest resistance to establish limits on the amount of pest-control proteins in GM foods;
- (8) Product Registration: EPA reviews all relevant environmental and toxicological studies before deciding to register a GM product;
- (9) Review Process: FDA’s review procedure is in the process of moving from a voluntary, albeit universally used, consultation mechanism to a mandatory four-month-prior-to-release notification mechanism requiring a showing by the introducing party of substantial equivalence; and
- (10) Post-Commercialization Review: All three regulators have the authority to demand the immediate removal from the marketplace of any product in the case of new and valid data indicating a question of safety for consumers or the environment.

*Id.* at 2-4, *cited in* York, *supra* note 31, at 439 n.100.

recommended, largely unsupervised guidelines.<sup>78</sup> Unfortunately, none of these can adequately suffice, largely stemming from the fact that they each try to address a part of the issue without considering the problem in its entirety. When one considers the Food and Agriculture Organization's key guiding principles iterated in the late 1990s, one can better envisage the enormity of the task. These included

- (a) the sustainable use of plant genetic resources is essential for increasing agricultural productivity, and this fact can contribute not only to food security but also to natural development, allowing both the alleviation of poverty and starvation;
- (b) modern agriculture is the most important cause of loss of genetic diversity, and the loss of diversity increases the possibility of crop losses; and
- (c) much needs to be done, and done locally . . . [and] in the long term the preparation of a Report on the State of Agricultural Diversity [globally] should be considered.<sup>79</sup>

With these in mind, the first and most common governmental response has been labeling regimes which stipulate that if a food contains GMCs, this fact should be noted and the market can decide if genetic modifications should be rewarded. Consumers will be able to decide if the benefits outweigh the costs. An example of a labeling scheme includes a proposal of the FDA for GM producers to label their products with certain information if the absence of the information may

- (1) pose special health or environmental risks (e.g. [allergens, toxins and] . . . protein products used in very low calorie diets);
- (2) mislead the consumer in light of other statements made on the label (e.g. requirement for quantitative nutrient information when certain nutrient content claims are made about a product);
- or
- (3) [lead consumers to] . . . assume that a food, because it is similar to another food, has nutritional, organoleptic, or

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78. This list (assembled by this author) parallels several others, such as that proposed by Echols, *supra* note 25, *passim*, listing five key responses, namely: (a) labeling, (b) treatment, (c) testing and certification, (d) destruction, and (e) bans.

79. Souza, *supra* note 32, at 147 (citing FOOD AND AGRICULTURE ORGANIZATION (FAO), REPORT ON THE STATE OF THE WORLD'S PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE-PREPARED FOR THE INTERNATIONAL TECHNICAL CONFERENCE ON PLANT GENETIC RESOURCES 6, 8, 13, 15 (1996)) [*hereinafter* FAO].

functional characteristics of the food it resembles when in fact it does not (e.g. reduced fat margarine not suitable for frying).<sup>80</sup>

These guidelines have parallels in other jurisdictions, though are often inconsistent, leading to the fact that labeling standards vary from place to place and there is no consistent labeling protocol.<sup>81</sup> Probably the most controversial step in these regards was that taken by an E.U. Directive in October 1999 requiring the "mandatory labeling of novel food products containing more than one percent engineered DNA or protein content (and insinuated associated food safety risks based on the 'precautionary principle'),"<sup>82</sup> discussed in greater detail below.

A second major set of responses has been to legislate, and to legislate rigorously. In 1996, for example, the EU rejected the use of genetically modified Maize corn seed, arguing that the convention on Biological Diversity was too weak and it had to take matters into its own hands.<sup>83</sup> This was largely in response to companies producing products which were not just resistant to pests, but were sterile.<sup>84</sup> "Terminator genes," as they were called, had been originally developed by the USDA at a comparatively marginal cost of just under \$250,000 in cooperation with Delta and Pin Land Company, the largest producer of cotton seeds in the United States with a seventy-three percent market share.<sup>85</sup>

A third major route for managing GMCs has involved relying on international agreements. Article XX(b) of the General Agreement on Tariffs and Trade (GATT) allows governments to enact trade

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80. Press Release, U.S. Food and Drug Administration, Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, Draft Guidance 2 (January, 2001) *cited in* York, *supra* note 31, at 441 n.109.

81. Matthew Franken, *Fear of Frankenfoods: A Better Labeling Standard for Genetically Modified Foods*, 1 MINN. INTELL. PROP. REV. 153 (2000).

82. Briefing Paper for the June 13, 2000 meeting of the ACIEP, Advisory Committee on International Economic Policy (ACIEP), U.S. Department of State 24, *cited by* York, *supra* note 31, 453 n.178; *see also infra* Exhibit 15, highlighting how most countries about to join the E.U. do not want GM products distributed within their borders.

83. Land and Resource Management Division of the University of Colorado, *Biotechnology and Biodiversity*, COLO. J. INT'L ENVTL. L. & POL'Y 47 (1996).

84. Forum Proceedings, *A Greener Shade of Crimson: Law & the Environment Alumni Forum*, 24 HARV. ENVTL. L. REV. 317, 324 (2000).

85. Nathan A. Busch, *Jack and the Beanstalk: Property Rights in Genetically Modified Plants*, 3 MINN. INTELL. PROP. REV. 1, 121 nn.470-472 (2002).

barriers “necessary to protect human, animal, or plant life or health.”<sup>86</sup> More specifically, the International Biosafety Protocol approved in 2000 by representatives of 130 countries regulates the international trade of genetically modified organisms (GMOs).<sup>87</sup> The trade regulations in the Biosafety Protocol mirrors principles first contained in the Convention on Biological Diversity passed in 1992,<sup>88</sup> as well as the United Nations Convention on Biodiversity. The latter describes biodiversity as having an “intrinsic value” beyond its “ecological, genetic, social, economic, scientific, education [sic], cultural, recreation, and aesthetic values.”<sup>89</sup> These principles have thus informed the EU’s approach to observing the rights of its member states to GMC protection by allowing any country to bar GMCs on the basis of any reasonable fears which the country might have relating to such crops. This EU approach has come to be known as the “precautionary principle,” referenced above.<sup>90</sup> Though its import lies in provisions which allow it to be used with the force of law,<sup>91</sup> the precautionary principle is arguably on weak ground because of (a) regional differences in sentiments toward GM foods, (b) myths and poor reporting, (c) anti-biotech activism, and (d) a lack of a clear way to disseminate knowledge, understanding, and acceptance of new technological developments.<sup>92</sup>

The fourth and final approach has been recommending guidelines for GMC producers to follow, but which governments would not

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86. York, *supra* note 31, at 456.

87. See Transgenic Crops Resource Guide, *available at* <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/> (last visited Apr. 18, 2004).

88. Convention on Biological Diversity, *available at* <http://www.biodiv.org> (last visited Apr. 18, 2004).

89. United Nations Conference on Environment and Development, preamble, June 5, 1992, S. Treaty Doc. No. 20 (1993), *reprinted in* 31 I.L.M. 818, 922, *cited in* Judy J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT’L L. J. 1160, 1185, (1993).

90. See <http://www.biotech-info.net/precautionary.html> (last visited Apr. 14, 2004) (providing an overview of the precautionary principle, its history, and its current applications in political, social, and environmental arenas).

91. See Communication from the Commission on the Precautionary Principle, Commission of the European Communities 2 (February 2, 2000), *cited in* York, *supra* note 31, at 444 n.125.

92. Buechle, *supra* note 61, at 300-305 (utilizing these four items as subheaders within his article to discuss the problems with the precautionary principle).

directly oversee. The U.S.-E.U. Biotechnology Consultative Forum,<sup>93</sup> for example, recommended:

- (1) mandatory pre-market testing for all GMCs,
- (2) the refinement of the substantial equivalence concept,
- (3) the development and implementation of GMO tracing technology,
- (4) the fulfillment of a reasonable certainty of safety threshold prior to the use of risk-benefit analysis,
- (5) a risk assessment regime whereby regulators should act proactively on the side of safety,
- (6) the creation of a content-based mandatory labeling requirements for products derived from GMOs, and
- (7) the implementation of the Cartagena Protocol on Biosafety.<sup>94</sup>

The idea is that NGOs would, as referenced above, act as enforcers and help ensure that the market manages itself independent of external regulation.

For the most part, these efforts have born little fruit. Not only have many laws gone unrecognized — or been simply ignored — but the power of GMC producers has flummoxed even their greatest critics as IP rights have essentially dictated what is made, by whom, and when. Current rules in the United States, for example, state that farmers must leave twenty percent of their crops outside the corn belt to conventional corn, though only seventy-one percent of farmers follow the rule despite the fact ninety percent claim to know or follow it.<sup>95</sup> Current contracts for food production, as well, are often bogged down with extraordinary details, making it practically impossible for every item to be addressed, particularly with regards to export concerns.<sup>96</sup>

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93. See U.S.-E.U. Biotechnology Consultative Forum, *Final Report* (December 2000), available at <http://www.usembassy.it/pdf/other/biotech.pdf> (last visited Apr. 12, 2004). See also U.S. Department of State: Office of the Spokesman, *U.S. and E.U. Establish Biotechnology Consultative Forum*, U.S. Mission to the European Union (June 7, 2000), available at <http://www.useu.be/ISSUES/biot0607.html> (last visited April 18, 2004).

94. Fact Sheet: Report of the U.S.-E.U. Biotechnology Consultative Forum, U.S. Department of State 2 (December 19, 2000), cited in York, *supra* note 31, at 464 n.231.

95. Marc Lappe, *Biotechnology and Agriculture*, 10 MSU-DCL J. INT'L L. 39, 43-44 (2001).

96. See Illinois Law & Agribusiness Association, *Agricultural Production and Marketing Contracts*, IL&A IL-CLE 6-1 (2001).

There is also the fact that the Biosafety Protocol “does *not* apply to the inanimate products of living modified organisms such as corn cereal or soybean oil that might be *made* from genetically modified corn or soybeans,”<sup>97</sup> rendering key parts of the Protocol largely moot.<sup>98</sup> Monsanto, the largest producer of GMCs, even once refused to submit to a labeling regime,<sup>99</sup> leading U.S. Trade Representative Robert Zoellick to use his “first major interview to accuse . . . companies of putting at risk the whole intellectual property rights system.”<sup>100</sup> Indeed, it would appear that Mary Lynne Kupchella’s argument that “[w]ith proper regulation, biotechnology can save biodiversity and solve numerous other environmental concerns”<sup>101</sup> is not as simple as she makes it seem. There are serious concerns over the decreasing access to new discoveries as the line between fundamental research and applied research has gotten thinner.<sup>102</sup>

In essence, the core of the problem is improperly managed and mediated IP systems. Adrienne Clarke, Professor at the University of Melbourne, has noted explicitly that “intellectual ownership, not health concerns, is the real danger associated with GM foods,”<sup>103</sup> and the main risk is of companies’ patent rights overcoming farmers’

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97. Safrin, *supra* note 6, at 608 (emphasis added).

98. See Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000), *available at* <http://www.biodiv.org> (last visited Apr. 27, 2004) [hereinafter “Protocol”]. Key sections of the Protocol address (a) requirements for commodities (i.e., requiring parties to create a Biosafety Clearinghouse with information about products); (b) “Precaution” ideas (*see* discussion in the text); (c) Documentation (i.e., shipping different types of LMOs, identifying identities and relevant traits of LMOs); and (d) trade with nonparties (i.e., one needs to be party to the Convention on Biological Diversity before joining the Protocol).

99. The editors of the Australian Financial Review, commenting on this development, wrote that “by refusing to submit to a labeling regime, Monsanto had effectively cut its own throat.” Editorial staff, *The Growing GM and Drug Disaster*, AUSTRALIAN FINANCIAL REVIEW, Mar. 22, 2001, at 41 [hereinafter “*Growing Disaster*”].

100. *Id.*

101. Mary Lynne Kupchella, *Agricultural Biotechnology: Why it Can Save the Environment and Developing Nations, But May Never Get a Chance*, 25 WM. & MARY ENVTL. L. & POL’Y REV. 721 (2001).

102. See Kenneth W. Dam, *Intellectual Property in an Age of Software and Biotechnology*, in CHICAGO LECTURES IN LAW AND ECONOMICS 113, 114-116 (Eric A. Posner ed., 2000), *cited in* Yelapaala, *supra* note 2, at 212 n.374.

103. Clarke, *supra* note 24.

rights.<sup>104</sup> Indeed, there are benefits to GMCs, such as crops grown to produce proteins instead of traditional fruit or fiber.<sup>105</sup> But the outcry over Monsanto's "terminator seed," which could be seen as an unprecedented self-enforcing patent, seemed to give too much control to one single entity over both the farmers and the environment it was seeking to influence and control.<sup>106</sup> There is no doubt that the "gene genie," freed from its bottle, has continued "promising to grant wishes to everyone"<sup>107</sup> while letting alarmist responses go unabated<sup>108</sup> and increasing calls to "go organic."<sup>109</sup> The press has posited the argument that the future leading countries of the world will be those that let people come to "patent their ideas and take a cut every time someone else uses them."<sup>110</sup> This, however, remains to be seen.

#### D. Case Study: Australia

Australia is an excellent case study for assessing alternative IP regimes which could better address these concerns. International and domestic critics alike have cited Australia's need to "get its house in order" with regard to IP issues. United States government officials, in fact, have specifically "renew[ed] [their] complaints of sloppy Australian protection of intellectual property rights,"<sup>111</sup> and public

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104. See Laurie, *supra* note 28.

105. See Paul Parkinson, *Future Farms*, COURIER MAIL, Jul. 16, 2002, at H02 (noting the discovery at the Queensland Institute of Technology of INPACT (In-Plant Activation)—in which one of a plant's protein-producing genes is replaced with a gene "trained" to create the desired proteins instead.)

106. See Karen Charman, *Genetically Engineered Food: Promises & Perils*, MOTHER EARTH NEWS, Oct./Nov. 2002, at 74, 76 (writing how terminator seeds continue "to spark outrage throughout the world").

107. Editorial Staff, *Harnessing the Gene Genie*, PERSONAL INVESTOR, Sept. 1, 2000, at 40 [hereinafter "*Gene Genie*"].

108. Consider, as a case in point, the alarmist responses to Australian Natural Foods (ANF) labeling its soymilk as "free from genetically modified soybeans and soy protein isolate." James Button, *Guess Who's Coming to Dinner?*, THE AGE, Jan. 3, 1998, at 1.

109. Monica Jackson, *Go Organic, Suzuki Says*, WEEKLY TIMES, Mar. 1, 2000, at 26.

110. Simon Collins, *Smart Shall Inherit the Earth*, NEW ZEALAND HERALD, Feb. 20, 2003, available at <http://www.nzherald.co.nz/storydisplay.cfm?thesection=news&thesubsection=&storyID=3147263&reportID=812597> (last visited Apr. 16, 2004).

111. Editorial staff, *US Slams Australian Bans*, AUSTRALIAN FINANCIAL

interest critics have called for “corporate ownership of intellectual property rights” in Australia to be “watched.”<sup>112</sup> Critics of Australia’s government note that Australia’s problem is a need for an IP regime where IP “can be protected, developed and traded *from* Australia” because too often the country has “sold the rights to publicly funded research at a very early stage to get paltry returns.”<sup>113</sup> Economists would likely cite the need for a system which accounts for Australia’s comparatively small economy (mirroring its small population).<sup>114</sup> Australia is unique in having (a) a small population with high average incomes; (b) large agricultural and mining sectors which are highly competitive and export oriented; (c) a developed manufacturing sector highly protected and highly concentrated; (d) a large service sector employing seventy percent of labor force; (e) foreign investment as a major influence on economic development; (f) major sectors with oligopolistic industry structures; and (g) status as a heavy net importer of technology (shared by all less developed countries).<sup>115</sup> These points lead to a set of interests which should be arguably integrated into an IP system for GMCs.

The Constitution of the Commonwealth of Australia charges the Parliament with overseeing “[c]opyrights, patents of inventions and designs, and trademarks.”<sup>116</sup> Arguments have thus been levied that the High Court needs to transcend its current approaches to interpreting this law — which have been quite literal<sup>117</sup> — and instead pursue a broader approach characterized by a more purposive rationale of the Constitution’s provisions (i.e., focusing on the framers’ intents).<sup>118</sup> This would allow for more creative solutions vis-à-vis novel regulations and

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REVIEW, Apr. 2, 2002, at 8.

112. Paul McIntyre, *Food for Thought in Cause of the Foot and Mouth Crisis*, THE AUSTRALIAN, Mar. 22, 2001, at M8.

113. Clarke, *supra* note 24 (emphasis added).

114. For more information, see the CIA WORLD FACTBOOK ON AUSTRALIA, available at <http://www.cia.gov/cia/publications/factbook/geos/as.html> (last visited Apr. 17, 2004).

115. RICKETSON, *supra* note 65, at 871; see also *infra* Exhibit 1, illustrating that Australia is also the least densely populated country on earth.

116. AUSTL. CONST., § 51 (xviii).

117. See Atty. General for N. S. W. v. Brewery Employés Union of N. S. W. [Union Label Case] (1908) 6 CLR 469, 521, 533-535, cited in Geraldine Chin, *Technological Change and the Australian Constitution*, 24 MELB. U. L. REV. 609, 626 n.126 (2000).

118. See, e.g., The King v. Brislan, *Ex parte* Williams (1935) 54 CLR 262, 282-3, cited by Chin, *supra* note 117, at 626 n.127.



approaches to managing IP for GMCs. To date, the main set of provisions which have governed IP interests is contained in the Patents Amendment Act 1979 (Cth). One of the main problems cited soon after the legislation passed, however, was the fact that it applied the same sets of standards to all types of patents and, in particular, petty versus regular patents (i.e., requiring an “inventive step” approach, the importance of which will be discussed in greater detail below).<sup>119</sup> These were later amended with the Patents Act 1990 (Cth).<sup>120</sup>

Most recently, Australia sought to accommodate the unique needs of GMCs by creating an “Innovative Patent System” in 1997 to encourage “individuals and small to medium sized businesses to realize their good ideas.”<sup>121</sup> This stemmed from a review by the Advisory Council on Intellectual Property (ACIP), with the legislation ultimately watering down the “standard of inventiveness”<sup>122</sup> so that protection would be “withheld if the claimed invention varie[d] from previously publicly available articles, products or processes ‘only in ways which make no substantial contribution to the effect of the product or working of the article or process.’”<sup>123</sup> The idea was that the approval of new, novel IP patent applications needed to be streamlined and this was the most effective way to do so.

Subsequent events proved this approach largely unworkable for IP and biotechnology inventions. In May 1999, the Australian government formed a new agency, Biotechnology Australia, to address biotechnology and GMFs along with an Interim Office of the Gene Technology Regulator to administer a voluntary labeling code until

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119. See Patents Amendment (Innovations Patents) Act, 1979, ¶ 6 (Austl.), available at [http://www.austlii.edu.au/au/legis/cth/consol\\_act/papa2000400/](http://www.austlii.edu.au/au/legis/cth/consol_act/papa2000400/) (last visited Apr. 10, 2004).

120. For a comprehensive discussion of the Patent Act 1990 (Cth), see JILL McKEOUGH, *INTELLECTUAL PROPERTY: COMMENTARY AND MATERIALS* (4th ed. 1992). See generally JILL McKEOUGH & ANDREW STEWART, *INTELLECTUAL PROPERTY IN AUSTRALIA* (2nd ed. 1994); COLIN GOLVAN, *AN INTRODUCTION TO INTELLECUTAL PROPERTY LAW* (1992).

121. Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT’L L. J. 151, 171 n.111 (1999). See generally CHRISTOPHER ARUP, *INNOVATION, POLICY, AND LAW: AUSTRALIA AND THE INTERNATIONAL HIGH TECHNOLOGY ECONOMY* (1993) (discussing the need for innovation for patenting genetic discoveries).

122. See Roland Liesegang, *German Utility Models after the 1990 Reform Act*, 20 AIPLA Q.J. 1, 4-5 (1992), cited in Janis, *supra* note 121, at 158 n.43.

123. See [http://www.ipaustralia.gov.au/patents/what\\_innovation\\_review.shtml](http://www.ipaustralia.gov.au/patents/what_innovation_review.shtml) (last visited Apr. 12, 2004), at recommendation no. 2, cited in Janis, *supra* note 121, at 173 n.122.

more formal legislation could be passed by Parliament.<sup>124</sup> Just three months later in August, the Australia and New Zealand Food Safety Council decided in principle on mandatory labeling of GM food, though the cost was estimated at more than \$A 2 billion (U.S. \$1.5 billion)<sup>125</sup> in only the first year, compelling the council to rethink its options.<sup>126</sup> In March 2000, a revised report dramatically reduced the estimated labeling costs to \$A 315 million. The report was followed by a 1,000 hectare-trial of GM cotton in Western Australia; after illegal GM canola was found dumped in a bin in South Australia in April 2000, however, the West Australian government froze *all* commercial releases of GM crops for two years.<sup>127</sup>

These events precipitated the Australian Patents Amendment Bill 2001 (Cth),<sup>128</sup> which sought to make it easier for individuals to patent GM products, though it did not take any steps to address directly the risks. Indeed, the Bill widened the scope of IP publications which qualified for meeting the “novelty, inventive step, and innovative step”<sup>129</sup> requirement for patent protection (i.e., they could be from anywhere in the world instead of just in Australia) — but not much else. This arguably harmonized Australia’s legislation with other patent regimes, though on its face it was somewhat superficial. It did little to address issues stemming from the 1997 amendments which created a “second tier” patent scheme, which by all accounts was not working as was hoped. Mark Janis, who wrote extensively about such schemes in a recent article in the *Harvard International Law Journal* noted many problems with such “second tier” schemes, including the observations that (a) lower application fees bear little relation to ultimate costs, due to attorney’s fees which can comprise fifty percent

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124. *Food Fight*, *supra* note 44.

125. See <http://www.x-rates.com/calculator.html> (last visited Apr. 17, 2004) (providing swift currency calculations on the web and noting an exchange rate of A \$1.31 to US \$1).

126. *Id.*

127. *Id.*

128. “Cth” refers to Commonwealth (i.e., federal) legislation passed by the Australian Parliament, as opposed to state and territory legislation passed by one of Australia’s seven states or the Northern Territory [these include – proceeding clockwise from the northeast – Queensland (Qld), New South Wales (NSW), the Australian Capital Territory (ACT), Victoria (Vic), Tasmania (Tas), South Australia (SA), West Australia (WA), and the Northern Territory (NT)].

129. See Patents Amendment Bill, 2001 (Austl.); see also Carolyn Harris, *Patents Amendment Bill*, WATERMARK JOURNAL, March, 2002, available at <http://www.watermark.com.au/> (last visited Apr.13, 2004).

of acquisition costs and later enforcement actions; (b) speed is largely a misnomer since enforcement actions require judicial review; (c) the standard for "nontraditional subject matter"<sup>130</sup> is also a misnomer given its semblance to the standards for regular patents; and (d) little, if any, GMC technology comes from smaller, "indigenous" enterprises, rendering the system largely moot.<sup>131</sup> With secret trials of GMCs reported in the Australian outback<sup>132</sup> and the risks of GM pollen integrating with wild-type strains,<sup>133</sup> IP issues spanned a much broader scope than the issues addressed by the most recent bill.

Australia's attempts to revamp its IP system thus failed to address key issues. Nothing in its amendments addressed the argument that strong IP protection was "necessary to offset the enormous cost of research" in IP areas,<sup>134</sup> though the technologies were of such a nature that they seemed like public goods. David Dumaresq, Head of the Australian National University's Faculty of Science, stated, "Australians will be giving away intellectual property rights over the basic building blocks of life if genetic modification is allowed to continue . . . making the mistake scientists of the 19<sup>th</sup> century did not make."<sup>135</sup> On the other hand, at issue were "basic biological processes" which often appear to *defy* private ownership. Kim Woods draws a parallel between GMCs and basic oxidation processes: it would be madness to require scientists to pay royalties on basic chemical processes, she argues, just as it would make little sense to require royalties to be paid on genetic manipulative processes.<sup>136</sup> A prime example of this is the pPlex technology developed by RhoBio, a joint-venture between Rhone-Poulenc Agro and Biogemma, in cooperation with CSIRO, Australia's National Research Organization.<sup>137</sup> pPlex is essentially a set of "DNA switches for turning genes on and off, enabling the expression of genes giving plants new trait[s] such as

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130. Janis, *supra* note 121, at 190-193.

131. Janis, *supra* note 121, at 184-185.

132. See Laurie, *supra* note 28.

133. Mary A. Rieger et al., *Pollen Mediated Movement of Herbicide Resistance Between Commercial Canola Fields*, 296 SCIENCE 2386-2388 (2002); see also Exhibits 2-3, contained in the Appendix (highlighting results of the study).

134. Weston, *supra* note 1, at 380.

135. Kim Woods, 'Debate is Needed' on Genetics, WEEKLY TIMES, Mar. 15, 2000, at 12.

136. *Id.*

137. Editorial Staff, *RhoBio Signs a Plant Biotechnology Research Agreement with CSIRO in Australia*, PR NEWswire, Sept. 28, 1999.

herbicide tolerance or resistance to insects or disease.”<sup>138</sup> In many ways, however, this is neither unique nor novel because this is a *fundamental* process which is present in all genes and applied by humans who first developed crops thousands of years ago around the Tigris and Euphrates rivers.<sup>139</sup> A stronger argument can be made for patenting the research work by teams from Belgium and Australia to “identify and patent sequences of genes from three strains of banana streak virus.”<sup>140</sup> Because the teams focused on identifying three gene promoter sequences from the virus which *acted* to switch on 154 new genes so the plants exhibited a set of desired characteristics,<sup>141</sup> their ‘discovery’ could be seen as more “novel.” In Australia, it is not clear which of these ostensible inventions would be protected. Furthermore, a proposed Gene Technology Act does little but create “GM-free zones” within states to address the fear that Australia would lose key overseas markets if GMCs got into the supply chain.<sup>142</sup>

### III. THE ROLE OF INTELLECTUAL PROPERTY (IP)

#### A. Power Dynamics, Floating Seeds, and Localizing Fault

As noted above, IP issues are arguably the biggest stumbling block — and source of potential benefits — of GMCs. IP rights and guidelines ultimately determine the amount of money a technology owner can make by allowing the owner to set margins and establish license fees based on market forces. An IP owner can also influence where production will occur and dictate the terms of trade. Australia, in these regards, has been cited as *not* being “particularly clever at devising structures in which intellectual property can be protected, developed and traded” *from* Australia because it has too often “sold off rights to publicly funded research at a very early stage for paltry returns.”<sup>143</sup> There are issues addressing international trade, which in

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138. *Id.*

139. See generally DIAMOND, *supra* note 6.

140. Simon Grose, *Banana-Gene Therapy Patent Signals Boost in Production*, THE CANBERRA TIMES, Jan. 5, 1999, at A3.

141. *Id.* The plants included corn, sorghum, canola, millet, grasses, bananas, sugarcane, trees, ferns, and plant tissue under pressure.

142. See Laurie, *supra* note 28.

143. Clarke, *supra* note 24.

Australia's case are poignant given its small size, and feeling that in order to "maintain its edge" in world agriculture, it needs to "identify genes" important for these purposes.<sup>144</sup> Finally, there are issues of where IP rights and responsibilities begin and end; in the case of GMCs and floating pollen particles, these issues address who should be held responsible if nature incorporates GMCs into its fold and these GMCs are unknowingly used by others. A series of additional issues further deserve mention in these regards, including (a) the current nature of GMC research and IP owners; (b) the wide array of individuals affected by GMCs; (c) the subtleties of defining IP rights for GMCs; (d) the problems of concentrated market power; and (e) more general policy concerns. They all help "set the stage" and give one a sense of the broad range of issues surrounding IP rights and GMCs today. Each of these is considered in turn.

First, it is important to recognize that most biotechnology companies are small and have tight resources and, thus, little power.<sup>145</sup> The current IP regime, with or without second tier patenting systems, is thus deleterious because of the likely risk of litigation over issues which are neither clear nor clear-cut. The prohibitive costs of enforcing patent rights has become a major problem, with second tier patent systems proving inadequate because of their promises of shorter term protection and less rigorous protection standards.<sup>146</sup> Indeed, a second tier patent system cannot solve access problems that may vary dramatically from place to place (making harmonization across borders incredibly difficult, if not impossible) and fails to consider enforcement costs.<sup>147</sup> There is also no doubt that patenting is essential for researchers in the modern era. A clear example is the "blue gene" in carnations, which Florigene was able to patent and trademark just three months before its rival resulting in the famous Moondust carnation™ en route to developing the elusive blue rose.<sup>148</sup> If one does not patent quickly, then one's discovery could be claimed by others.<sup>149</sup>

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144. See Liz Dennis, *Biological Revolution*, HOME HISS OBSERVER, Jan. 10, 2002, at 9.

145. Weston, *supra* note 1, at 380 (noting that "[in] 1998, there were 1,283 domestic biotech firms, roughly two-thirds of which employed fewer than 135 persons").

146. See Janis, *supra* note 121, at 152.

147. *Id.* at 154.

148. MATP, *Patent or Perish, Science Doyen Says – Thinking Melbourne*, THE AUSTRALIAN, Nov. 3, 1998, at 6.

149. An example of this in the case of Trademarks is the image of bell which had been associated with the collection of companies known as the "Bell system"

Second, the individuals affected by GMCs now extend well beyond the individuals who expressly purchased rights or consciously assumed risks associated with the GMCs, and this poses significantly challenging legal and philosophical issues with regards to who should have responsibility for GMCs' unintended consequences. A study of canola pollen drift in Science on sixty trial fields across South Australia concluded that unwanted gene transfer only occurred in 0.07 percent of cases — supporting the conclusion that “non-GM crops” were not “in any danger.”<sup>150</sup> On the other hand, as discussed below, seeds *have* been found to float and farmers have been held responsible. Monsanto went to efforts to ensure that it retained property rights for seeds used by those who purchased them, though it has taken actions indicating it should have rights to ‘floating seeds,’ too.<sup>151</sup> This underscores the imperative of improving regulatory processes to “ensure a proper weighing of the full social benefits and costs of agricultural biotechnology” and to “clarify liability rules governing the use of agricultural biotechnology.”<sup>152</sup> There is also the fact that patents have been used to gauge farmers. A case in point is the gene protecting cotton from insect attack, which was licensed at \$110 per hectare to U.S. growers and \$245 to Australian growers because of Australia’s marginalized position as an exporter.<sup>153</sup> In this light, it is imperative that farmers be clearly accounted for as “integral part[s] of agricultural biotechnology,” especially when property rights are interpreted.<sup>154</sup>

A third main area addresses the way IP statutes and patents are construed. Does the word “growing,” for example, mean “making” or “using”?<sup>155</sup> If the former, then a host of GMC IP rights flow to the producers of the seeds and, possibly, the genes, though users can be insulated from potential IP infringement; contrarily, if the latter,

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operating local and long distance telephone services for AT&T before it was divided. The image, it turned out, had not been copyrighted, so an industrious employee did so and subsequently demanded millions of dollars in royalty payments for the image which was ubiquitously prominent throughout the United States. Interview with Leonard Macaluso, former engineer for AT&T Bell Labs, in Clifton, NJ (Mar. 12, 2003).

150. Rieger, *supra* note 133, cited by Laurie, *supra* note 28.

151. See generally Van Cleve, *supra* note 50.

152. *Id.* at 246.

153. MATP, *Genes Threaten Bigger Harvest*, THE AUSTRALIAN, Nov. 9, 1998, at 5.

154. Busch, *supra* note 85, at 4.

155. See Busch, *supra* note 85, at 134.

individuals unknowingly incorporating IP technology in their own efforts (as farmers or organic cross-breeders) can be held liable for using the technology without permission. There are also different “schools” of thought vis-à-vis assessing patent infringements. The “American school” focuses only on a final product and testing if it is equivalent to other patented products, while the “European school,” in contrast, looks at the process taken to achieve a final result, which absolves all those achieving an already patented result of liability if the process they follow substantially *differs* from that taken by the original patent holders.<sup>156</sup>

As mentioned above, a fourth concern is the ability of large companies, like Monsanto, to corner the market with their technology. Monsanto’s response to being barred from using its Terminator Seed technology after its patent for glyphosate expired in September 2002 was to institute Technology Use Agreements (TUAs). These prevented farmers from giving unused seeds to others or saving seeds for the next season. They also, however, went beyond the use of the seeds and included provisions which required growers to only use Monsanto products on Monsanto GMCs. Monsanto also reserved its right to enter freely onto farmers’ properties and inspect growers’ fields for “seed pirating” whenever it wished.<sup>157</sup> One can legitimately argue that Monsanto was within its rights in securing these guarantees given its patents. On the other hand, the scope and extent were unprecedented and were an omen for many farmers of future legal demands and requisites. In this respect, the “biggest concern” about GMCs is the “corporate attempts to dominate world markets by owning the technology.”<sup>158</sup>

The fifth area is one of more general social policy, particularly internationally, with regard to GMCs. Many companies may want to head to countries with ostensibly strong IP protection, such as Singapore,<sup>159</sup> but what does this mean if the country’s market is obviously limited? A key area of policy evolution relates to developing rules that govern biological inventions internationally, fully addressing their “presumed risks to human health and the

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156. See York, *supra* note 31, at 434-435.

157. Nicole C. Nachtigal, *A Modern David and Goliath Farmer v. Monsanto: Advising a Grower on the Monsanto Technology Agreement*, 6 GREAT PLAINS NAT. RESOURCES J. 50, 59 (2001).

158. Australian Associated Press General News, *GM Danger Greatest in Control of the Technology* (Sept. 25, 2002).

159. See Chang Ai-Lien, *Pulse Quickens for the Life Sciences Here*, STRAITS TIMES, Nov. 1, 2002.

environment” worldwide.<sup>160</sup> Tools for risk management exist, such as the aforementioned “precautionary principle,” though this provides little protection because it can be applied intermittently and inconsistently. The concern with coordinating policy addressing living organisms and GMCs among disparate nations has remained. Calestous Juma and Victor Konde, for example, make the telling observation that “historically, living organisms have fallen outside the scope of protection by most intellectual property systems; now, the question is whether it falls outside the public interest.”<sup>161</sup>

These points culminate in the proposition that it is imperative for countries like Australia — instead of focusing energies on secondary patent protection regimes — to “direct[] energies towards the reform of regular patent law, and towards the exploration of alternative avenues for protecting incremental innovation.”<sup>162</sup> The key question is how this can best be done.

### B. Patentability Issues

The locus of IP protection is patent law, which is the main area needing revision to accommodate GMCs and their related technologies. Basic patent protection law is essentially quite simple: one gets a limited term of protected “exclusivity” to a new invention (the benefit) by making the discovery completely available and accessible to the public (the cost). Individuals cannot directly benefit from the invention because of the exclusive rights granted to the patent holder. It is hoped that understanding the patent and what it creates, however, can and will stimulate further research, discoveries, and inventions. In the United States, the first country to introduce a formal patent regime, patent laws stem directly from the Constitution. Article 1 explicitly states that one of Congress’ goals is to “promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their respective . . . Discoveries.”<sup>163</sup>

In essence, patentable items must be novel and useful and “non-obvious”;<sup>164</sup> in Australia, similar to many other developing nations, these concepts are captured in the statutorily specified needs for

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160. Calestous Juma & Victor Konde, *Industrial Applications for Biotechnology: Opportunities for Developing Countries*, 44 ENVIRONMENT 2235 (2002).

161. *Id.*

162. Janis, *supra* note 121, at 219.

163. U.S. CONST. art. 1, § 8, cl. 8.

164. See 35 U.S.C. §§ 102-103 (2000).



“novelty,”<sup>165</sup> an “inventive step,”<sup>166</sup> and an “innovative step.”<sup>167</sup> Novelty is required as a barrier from preventing technology from being patented which is already in the public domain; utility, at least in the United States, ensures that the government only gets involved if the public is expected to derive benefits; and non-obviousness (or inventiveness) is necessary to prevent granting rights to individuals for taking actions which would be apparent to one skilled in the relevant field.<sup>168</sup> These rights vest when the object takes physical form<sup>169</sup> and are largely rooted in the old-fashioned ideas of inventors making new objects in backyard barns, such as the prodigious John Yates.<sup>170</sup>

The theoretical underpinnings of patent law stem from many sources. Foremost are fundamental principles of property which, generally speaking, recognize human “dominion over a thing reinforced by the power of exclusion.”<sup>171</sup> Foremost in bringing such “dominion” to fruition is the idea of “first occupancy”— namely, the fact that he who stakes the first claim on something takes the thing. This concept was the basis of the European settlement of Australia, which viewed the land as *terra nullius* (literally: land belonging to nobody),<sup>172</sup> albeit this concept was debunked by the High Court’s recognition of Native Title in the famous *Mabo* case.<sup>173</sup> The second major underpinning of dominion is Locke’s concept of “labor-

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165. See Patents Act, 1990, § 7(1) (Austl.).

166. *Id.* at § 7(2).

167. *Id.* at § 7(4)-(6). See generally GOLVAN, *supra* note 120.

168. See generally LI WESTERLUND, BIOTECH PATENTS: EQUIVALENCE AND EXCLUSIONS UNDER EUROPEAN AND U.S. PATENT LAW (2002); Toshiko Takenaka, Comparative Study of Patent Claim Interpretation in the United States, Federal Republic of Germany, and Japan (1992) (unpublished Ph.D. Thesis, University of Washington) (on file with the author).

169. See Busch, *supra* note 85, at 52.

170. Yates is best known for inventing the speed-loader bag technology which put loaves of bread into plastic bags, though is also known for an array of other inventions. Yates is known to have said that “inventing is a hard slog. Paranoia is essential.” Editorial Staff, *Ideas People*, NEWCASTLE HERALD, Oct. 10, 1998, at 48; see also Editorial Staff, *Inventor Who Touches Us All*, NEWCASTLE HERALD, Sept. 30, 1998, at 39.

171. See Yelapaala, *supra* note 2, at 124.

172. See Carlos Scott López, *Reformulating Native Title in Mabo’s Wake: Aboriginal Sovereignty and Reconciliation in Post-Centenary Australia*, 11 TULSA J. COMP. & INT’L LAW 21, 22 (2003).

173. See *Mabo v. Queensland* [No 1] (1989) 166 CLR 186; *Mabo v. Queensland* [No. 2] (1992) 175 CLR 1.

insertion”— namely, that “a person is entitled to the fruit of his labor,”<sup>174</sup> but not all products of one’s labor constitute property (e.g., one’s child) and not all property is the product of one’s labor (e.g., one’s internal organs).<sup>175</sup> The patent, then, is an attempt to elucidate one’s “dominion” over certain ideas in a quid pro quo statutory bargain whereby the patentee gets a monopoly while giving the public knowledge it would not have otherwise obtained.<sup>176</sup> Patents are thus a “law of secrecy supported by the law of contract” capturing elements of both branches of law.<sup>177</sup> As such, one must ask whether this exclusion makes sense for GMCs and, if not, how it should be changed. Independent of the philosophical arguments that nothing which is “naturally occurring” and is a “public good” should be owned, there is the fact that GMCs and genetic alterations also often lack specificity and inherent uniqueness. Copying genes is not like copying computer disks: it is a quasi-binary system, with the replication process (through RNA) neither necessarily exact nor secure. Variation and mutation is the essence of genetic development and genetic analysis; thus, even the best “inventions” can be changed by nature itself.<sup>178</sup>

The locus of this problem stems from the fact that property is of three types and it is not clear which type GMCs are or should be. The first type, on which IP patent regimes are currently based, assume that GMCs are *private* property having (a) identifiable owners with (b) all or most of a core bundle of rights. The second type, in contrast, applies to *commons* property in which no individual holds a right to exclude others so multiple individuals can enjoy the privilege of using the property; this is most often applied to natural resources such as air and light. The third type, to which GMC technologies might belong, is *anticommons* property in which *multiple* users have the right to exclude others from a resource over which they *disagree who should have access*; this then *ensures that nobody has the effective privilege* of using or accessing the resource. The law recognizes, in the case of private property, the use of easements to ensure individuals’ rights to certain property; with anticommons property, however, easements are impossible because of the de facto inalienable private property rights which contribute to the anticommons. In the case of GMCs, which

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174. See Yelapaala, *supra* note 2, at 160.

175. See *id.* at 133-4.

176. See *Monsanto Canada, Inc., v. Schmeiser*, [2002] FCA 309, at ¶ 30.

177. See Yelapaala, *supra* note 2.

178. Essentially, mutations are induced in GMCs to create the desired results. See Exhibit 4, contained in the Appendix, listing the methods used to induce mutations in developing a range of major GMCs.

often rely on technologies and “upstream” research requiring sets of pieces to be assembled — all owned by different individuals — “concurrent fragment”<sup>179</sup> anticommons property results (i.e., a series of protected pieces which either cannot be assembled without cross-licensing agreements or, in the case of Monsanto, are owned entirely by Monsanto which controls all access rights). The pre-clinical discovery phase of drugs illustrates this well, with the segments of (a) gene sequencing, (b) gene hunting, (c) gene functioning, (d) drug target identification, and (e) validation all needed to make a successful drug; none can be overlooked or avoided.<sup>180</sup> Similarly, genetic information resists control because it exists within every living being and “will continue” to do so “regardless of the institutions created to deal with the legal repercussions of its manipulation.”<sup>181</sup> GMCs thus appear to be quintessential commons property, with anticommons repercussions.

For these reasons, GMCs and other genetic inventions “initially struggled to overcome the utility barrier to patentability,”<sup>182</sup> with lower standards drawing opposition because of their tendency to recognize IP rights to property whose functions were unknown. Cases in point are gene sequences, for which individuals could theoretically gain patents even when *others* discovered what the sequences actually did.<sup>183</sup> In these regards, problems emerged about the written description requirement and ensuring that descriptions were full and complete. One of the first seminal cases addressing this matter was *Regents of the University of California (“UC”) v. Eli Lilly*,<sup>184</sup> in which UC sought to prove infringement of a patent<sup>185</sup> which it had obtained for identifying DNA sequences comprising vertebrate insulin-encoding regions and bacterial expression vectors containing the sequences. Eli Lilly had used a bacterial system to produce a type of human insulin after attaching a length of bacterial protein; the bacterial protein portion was then subjected to a cleavage step from which active human insulin

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179. Janis, *supra* note 121, at 202.

180. See *Gene Genie*, *supra* note 107.

181. Alexis Gorton, *Edible Equivalents: An Increase in Patent Protection for Genetically Modified Organisms*, 9 WASH. U. J. L. & POL’Y 321, 326 (2002).

182. See *Weston*, *supra* note 1, at 388.

183. See *id.*

184. *Regents of the University of California (“UC”) v. Eli Lilly*, 119 F.3d 1559 (Fed. Cir. 1997).

185. Patent no. 4,652,525 was at issue in the case. See *Regents*, 119 F.3d at 1569.

emerged.<sup>186</sup> The UC patent was ultimately deemed invalid because it failed to describe its invention adequately in writing.<sup>187</sup>

Another major challenge posed by GMCs and genetic inventions is the genetic code's degeneracy, and the fact the code can change dramatically over time.<sup>188</sup> Given the fact that each amino acid can be described by a range of different codons,<sup>189</sup> the question arises as to how specific one can or should be required to be in patenting a sequence. The effect of a small modification of an amino acid in a protein (e.g., by the substitution of one amino acid for another) can have either minimal or dramatic effects.<sup>190</sup> Whether or not a substitution alters the backbone of a given protein, destabilizes the hydrophobic core, results in significant steric clashes, or destabilizes key hydrogen bonds all contribute to determining if the change is significant. Despite the advancement of science, it is still impossible to predict a protein's exact structure simply given its amino acid sequence. However, key patterns and trends have been identified.<sup>191</sup> This has led academicians such as Kojo Yelapaala to propose that there are three levels of patentability for modern genetic innovations.<sup>192</sup> The first are those discoveries which have been simply outlawed because they offend moral sensibilities, independent of specificity; human cloning and creating new stem cell lines fall in this area. Second are items which are subjected to more serious scrutiny, such as gene-therapy, organ cloning, and developing new seed, plant, and animal varieties, largely hinging on whether scientists are creating anything

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186. Weston, *supra* note 1, at 391.

187. *Regents*, 119 F.3d at 1569, *cited in* Weston, *supra* note 1, at 391 n.116.

188. See generally GENETIC ANALYSIS, *supra* note 49; JEREMY M. BERG, JOHN L. TYMOCZKO & LUBERT STRYER, BIOCHEMISTRY (5<sup>th</sup> ed. 2002); WILLIAM K. PURVES ET AL., LIFE: THE SCIENCE OF BIOLOGY (6<sup>th</sup> ed. 2001).

189. See *infra* Exhibit 8, summarizing the codon sequences coding amino acids.

190. See *infra* Exhibit 7, for examples of some dramatic effects.

191. See generally David Baker & Wendell Lim, *Folding and Binding: From Folding towards Function*, 12 CURRENT OPINION IN STRUCTURAL BIOLOGY 11-13 (2002); BERNARD GLICK & JACK PASTERNAK, MOLECULAR BIOTECHNOLOGY (1998); Wendell Lim & Robert Sauer, *Alternative Packing Arrangements in the Hydrophobic Core of Lambda Repressor*, 339 NATURE 31 (1989); Wendell Lim & Robert Sauer, *The role of Internal Packing Interactions in Determining the Structure and Stability of a Protein*, 219 J. MOLECULAR BIOLOGY 359-376 (1991); Jay Ponder & Frederic Richards, *Tertiary Templates for Proteins: Use of Packing Criteria in the Enumeration of Allowed Sequences for Different Structural Classes*, 193 J. MOLECULAR BIOLOGY 775-791 (1987); Frederic Richards, *The Protein Folding Problem*, SCI. AM., Jan. 1991, at 54-63.

192. See Yelapaala, *supra* note 2.

new or instead just doing *what nature has already taught humans how to do* (albeit more indirectly in the past). Finally, there are those items which appear to pose no threat to the “natural order” of things and should be simply specified as much as possible; identifying a means of mass producing a theoretical, naturally growing herb used by a group of indigenous people to address a simple malady would most likely fall into this category.<sup>193</sup>

Responses to these issues have taken many forms. The United States passed the first patent law protecting breeds of asexually reproducing plants in 1930,<sup>194</sup> though not until 1970 did it protect sexually reproducing plants.<sup>195</sup> Utility patents for other living organisms were only recognized in the seminal U.S. Supreme Court case *Diamond v. Chakrabarty*,<sup>196</sup> upheld in *J.E.M. Ag. Supply, Inc. v. Pioneer H0Bred Intern, Inc.*<sup>197</sup> In *Diamond*, Chief Justice Burger, writing for a divided 5-4 court, held that the language of section 101 of the Patent Act was broad enough to cover the patents of genetically engineered bacterium and microorganisms.<sup>198</sup> Justice Brennan, writing for the four dissenters, however, noted that despite the broad language of the Patent Act, Congress anticipated the need to address special biological inventions separately, as evidenced by the separate Plant Patent Act and Variety Protection Acts.<sup>199</sup> He further held that these acts “strongly evidence a congressional limitation that excludes bacteria from patentability.”<sup>200</sup> Four special criteria for protecting plant products are noted in 7 U.S.C. § 2402,<sup>201</sup> buttressing Brennan’s

193. See Yelapaala, *supra* note 2. See also *infra* Exhibit 13, illustrating figuratively a way of thinking about items which should and could be patented.

194. See Plant Patent Act 1930, 35 U.S.C. § 163 (2002).

195. See Plant Variety Protection Act 1970, 7 U.S.C. § 2321 (2002), *cited in* Kim, *supra* note 89, at 1160 n.115

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

197. *J.E.M. Ag. Supply, Inc. v. Pioneer H0Bred Intern, Inc.*, 535 U.S. 1013 (2001).

198. *Diamond*, 447 U.S. at 305.

199. *Id.* at 319; see also Klaus Bosselmann, *Focus: Plants and Politics: The International Legal Regime Concerning Biotechnology and Diversity*, 7 COLO. J. INT’L ENVTL. L. & POL’Y 111 (1996).

200. *Diamond*, 447 U.S. at 319.

201. 7 U.S.C.A. § 2402 states:

§ 2402. Right to plant variety protection; plant varieties protectable

(a) In general

The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety,

claims. Five years later, the Board of Patent Appeals faced the question of whether *seeds* were patentable as living organisms like bacteria and microbes under *Diamond*. In *Ex parte Hibberd*,<sup>202</sup> the United States Board of Patent Appeals and Inferences (BPAI) held that plant matter can be patented following the rationales in *Diamond* because § 101 included, according to the Supreme Court in *Diamond*, “everything under the sun made by man”<sup>203</sup> and that the plant matter thus met the “statutory requirements for a utility patent.”<sup>204</sup>

Silence was the rule in the U.S. until 1999, when a Delaware court debunked the value of scientific processes in *Monsanto Co. v. Mycogen Plant Science, Inc.*<sup>205</sup> In *Mycogen*, the Court held that two U.S. patents held by the Mycogen Corporation covering *Bacillus thuringiensis* (Bt) gene technology used to make insect-resistant plants were *invalid* because of the processes used to make the plants (which were genetically identical to two species already patented by Monsanto).<sup>206</sup> The Court focused its analysis on the production process of a modified chimeric gene (MCG) which could be made in two ways. The first, known as “site-directed mutagenesis,” was originally used by

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or the successor in interest of the breeder, shall be entitled to plant variety protection for the variety, subject to the conditions and requirements of this chapter, if the variety is—

(1) new, in the sense that, on the date of filing of the application for plant variety protection, propagating or harvested material of the variety has not been sold or otherwise disposed of to other persons, by or with the consent of the breeder, or the successor in interest of the breeder, for purposes of exploitation of the variety....

(2) distinct, in the sense that the variety is clearly distinguishable from any other variety the existence of which is publicly known or a matter of common knowledge at the time of the filing of the application;

(3) uniform, in the sense that any variations are describable, predictable, and commercially acceptable; and

(4) stable, in the sense that the variety, when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety with a reasonable degree of reliability commensurate with that of varieties of the same category in which the same breeding method is employed.

202. *Ex Parte Hibberd*, 227 U.S.P.Q. 443 (Bd. Pat. App. & Infer. 1985).

203. *Diamond*, 447 U.S. at 309.

204. Nachtigal, *supra* note 157, at 56 n.51 (referencing *Ex parte Hibberd*, 227 U.S.P.Q. 443, 447 (Bd. Pat. App. & Infer. 1985)).

205. *Monsanto Co. V. Mycogen Plant Science, Inc.*, 61 F. Supp. 2d 133, 143 (D. Del. 1999).

206. *Id.*

Monsanto. This process involved designing a gene by substituting one or more nucleotides at predetermined sites in a natural gene.<sup>207</sup> The second, termed “chemical synthesis” and developed by Mycogen, involved creating synthetic DNA by chemically linking nucleotides in the proper sequence to produce the desired DNA sequence and then incorporating the synthetic DNA into the native gene to alter the sequence of that native gene.<sup>208</sup> The defendant, Mycogen, argued that a MCG included only those genes made by site-directed mutagenesis — which it did *not* perform — while Monsanto argued that a MCG could be made by either method and its patent for the gene in question essentially covered *all* means used to make it.<sup>209</sup> The Court ultimately ruled in Monsanto’s favor, establishing a precedent that Mycogen’s chemical synthesis method, while novel, broke Monsanto’s patent and Monsanto deserved compensation.<sup>210</sup> Notably, this result comported with common law standards that “inventive steps” were inconsequential to an invention (i.e., the process leading to a result) and only the “novelty” mattered (i.e., the result itself). This dramatically increased Monsanto’s power, and had important implications for biotechnology IP rights.

Globally, these issues have found parallels in key international agreements, though few countries have faced judicial controversies similar to those in the U.S. by virtue of the amount of IP in the U.S. The Convention for the Protection of New Varieties of Plants (UPOV) in 1961,<sup>211</sup> for example, dealt with breeders’ rights instead of patents, holding that IP protection for new plant varieties would only be upheld if the new varieties were (a) distinguishable based on one or more key characteristics, (b) sufficiently homogenous in their sexual reproduction or asexual propagation, and (c) stable in their essential characteristics.<sup>212</sup> The General Agreement on Tariffs and Trade

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207. See generally Michael P. Weiner et al., *Site-Directed Mutagenesis Using PCR*, in *MOLECULAR BIOLOGY: CURRENT INNOVATIONS AND FUTURE TRENDS* (A.M. Griffin and H.G. Griffin eds., 1995).

208. *Monsanto*, 61 F. Supp.2d at 143.

209. See *id.* at 144.

210. *Id.* at 150.

211. International Convention for the Protection of New Varieties of Plants of Dec. 2, 1961 [UPOV], as revised Nov. 10, 1972, Oct. 23, 1978, and Mar. 19, 1991 available at <http://www.austlii.edu.au/au/other/dfat/treaties/2000/6.html> (last visited Apr. 14, 2004).

212. See Kim, *supra* note 89, at 1160-61 n.120. UPOV also had a “saved seed exemption” allowing farmers explicitly to save seed for future growing seasons or sell “saved seed” to other growers. Nachtigal, *supra* note 157, at 54 n.38. Congress

(GATT) took up this mantle in the annexed Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) by ensuring that IP patent protection was available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.<sup>213</sup> Most notably, however, TRIPS also included a notable *exception* to patentability where any inventions could be excluded in the interests of protecting “human, animal, or plant life or health or . . . avoid[ing] serious prejudice to the environment.”<sup>214</sup> In this light, critics have found TRIPS disquieting<sup>215</sup> as it has opened up potential floodgates of disagreements over what things should and should not be patentable. In the Uruguay round, arguments over the scope of patent protections (i.e., developing countries had and wanted shorter IP patent protection times) and ways to accommodate piracy and the local use of foreign trademarks went unresolved.<sup>216</sup>

The status of IP patent claims thus vary enormously in different jurisdictions, though there are two particularly challenging trends which deserve mention. First, it is now clear that one can overturn a patent by arguing that patent holders have failed to pursue rigorous experimentation to confirm *all* possible mutative arrangements of a genetically modified product. At issue here are the claims of patent holders which “circumscrib[e] the technology protected by the patent.”<sup>217</sup> An excellent case study from the United States illustrating this principle is *Amgen, Inc. v. Hoechst Marion Roussel Inc.*,<sup>218</sup> which addressed the IP rights of the recombinant form of erythropoietin. In *Amgen*, Hoechst and Transkaryotic Therapies (TKT) defended their

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eliminated this in 1994 and the Supreme Court limited a “saved seed” exemption which remained in *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995) (holding that a “grower is prohibited from selling seed to other farmers in excess of the amount needed to grow on his own farm”), *cited in* Nachtigal, *supra* note 157, at 55 n.42.

213. Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, *Legal Instruments-Results of the Uruguay Round*, vol. 1, 33 I.L.M. 1125 (1994), Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights, 33 I.L.M. 1197 (entered into force Jan. 1, 1995) [hereinafter “TRIPS”].

214. TRIPS, *supra* note 213, at 1208 art. 27(2).

215. See Pepa, *supra* note 27, at 417.

216. See *id.*

217. Weston, *supra* note 1, at 393 n.133, *citing* 35 U.S.C. § 112 (1994).

218. *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 3 F. Supp. 2d 104 (D. Mass. 1998).



production of the protein in human cells because these cells produced a fully human protein in which carbohydrate groups were attached in the cells.<sup>219</sup> This contrasted with Amgen's process, which used hamsters in which, as expected, hamster-specific carbohydrate groups were attached. The Court held that Hoechst and TKT's action fell within a "limited clinical trials exemption from patent infringement"<sup>220</sup> and paved the way for more opaqueness in guaranteeing inventors the IP rights to their discoveries. How to strike a balance between ensuring that patents are broad enough to ensure benefits — yet not too narrow so they are open to litigation and struck down — is the ultimate balancing test which needs to be made.

A second major challenge is meeting the standards of "the doctrine of equivalents" (TDOE) referenced earlier. In essence, TDOE is a legal means to protect patent holders from "small changes" in their inventions when these are used by others. TDOE thus holds that "infringement exists when all elements of [an] invention are substantially equivalent to the elements of the accused device such that one skilled in the art would know of their interchangeability."<sup>221</sup> The "same-function-way-result (SFWR) test," first enumerated by the Supreme Court of the United States in *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*,<sup>222</sup> captures the essence of TDOE. In *Graver*, the Court held that "[t]o prohibit [only literal infringement] would place the inventor at the mercy of verbalism."<sup>223</sup> At issue in the case was Graver's patented welding flux composition containing alkaline earth metal silicates calcium and *magnesium*, which appeared strikingly similar to Linde's flux composition containing calcium and *manganese*.<sup>224</sup> Graver Tank prevailed, with Justice Jackson noting on behalf of the Court that "to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing."<sup>225</sup> The advent of GMCs calls TDOE into question given the fact that GMCs exhibit variations which, *ceteris paribus*, would fail the SFWR test.

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219. See *id.* at 105.

220. *Id.* at 104.

221. Gorton, *supra* note 181, at 336. Invocation of TDOE typically results in both a permanent injunction preventing the patent infringer from continuing his activity and extensive damages to put the patent holder back "in the position she would have been in had the infringement never taken place." *Id.* at 338.

222. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605 (1950).

223. *Id.* at 607, cited in Weston, *supra* note 1, at 397 n.155.

224. *Graver Tank*, 339 U.S. at 610-11.

225. *Id.* at 607, cited in Weston, *supra* note 1, at 398.

Studies of Monsanto's Roundup Ready™ Soybeans, for example, indicated that they exhibited a significant reduction in two out of three major phytoestrogens found in soybeans of equivalent species without Monsanto's genetic modifications<sup>226</sup> and, impliedly, potentially other soybean varieties with other genetic modifications. This suggests that Monsanto's patent could easily be invalidated, though time will tell. Indeed, one approach would assess any new technologies element-by-element, looking to see if any steps were taken which suggested infringement; another would look at the whole, attempting to assess the overall import of the ostensibly new invention. The U.S. Supreme Court upheld the former approach in *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*,<sup>227</sup> though it could distinguish future cases.

Applying IP doctrines to GMCs and biotechnology is rife with challenges. DNA sequences lack discrete elements, save for the nucleotides which comprise them. If one is analyzing a GMC, therefore, then it is virtually impossible for a patent to identify *all* the possible genetic sequences which could cause a plant to act in a certain way or fulfill certain expectations. The number of possible nucleotide changes could be massive — since other sequences could obtain the same result — not to mention deleted sequences. Also, the degree to which one could patent *knock-outs* poses a special challenge because one would be seeking to patent something which does *not* exist; this is particularly problematic when one considers the fact that DNA can be knocked out naturally (and regularly) in mitotic events. Furthermore, there is the fact that huge amounts of DNA are conserved between species, raising the question of whether a corporation can *reserve* its right to conserved genetic information across different species — including humans — over the entire planet. Clearly, these questions have no easy answers; they do underscore, however, why the clarion call for reforming IP rights is ubiquitous and seemingly unending. Christian Dambrini writes that “globalization of economies cannot be effective without a strong, affordable, enforceable intellectual property rights system to protect its results,”<sup>228</sup> echoing Joseph Villela's assertions how important it is “that all countries set high standards of intellectual property protection and enforcement in their national laws

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226. Lappe, *supra* note 95, at 39.

227. *Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 516 U.S. 1145 (1996).

228. Christian Dambrini, *Globalization of Research and Development: A Business Viewpoint in Facilitating International Technology Cooperation Proceedings of the Seoul Conference DSTI/STP/TIP (97) 14/FINAL*, Mar. 28, 1999, at 27, available at [www.oecd.org](http://www.oecd.org) (last visited Apr. 15, 2004) [hereinafter “Viewpoint”], cited in Souza, *supra* note 32, at 133 n.16.

and effectively support and enforce the standards once the improved laws are in place.”<sup>229</sup> This is one of many next steps.

### C. Lessons from Monsanto Canada

Probably the most seminal case to date addressing a host of these problems is *Monsanto Canada, Inc., v. Schmeiser*,<sup>230</sup> decided last year in the Canadian Federal Court. While the case is not international precedent, its legal analysis is likely to be used by other courts in other jurisdictions to set precedents in the area of GMC IP property rights. Unlike other areas of the common law which are often domestically insulated, IP legal issues have transcended international borders. This makes sense given the extent to which IP-related activities, particularly vis-à-vis GMCs, cross borders. *Monsanto Canada* thus provides a troubling precedent.

Some background to *Monsanto Canada* is needed to understand the import of its holding. For over ten years, Monsanto had become a leading producer of herbicides, largely a result of its Roundup Ready<sup>TM</sup> herbicide technology.<sup>231</sup> Soon before its patent expired, however, Monsanto began marketing a Roundup Ready<sup>TM</sup> seed which was more enduring, longer lasting, and naturally resistant to bugs. It also, most notably, contained a gene making plants resistant to Roundup Ready<sup>TM</sup> herbicide.<sup>232</sup> By cross-selling the seeds to its Roundup Ready<sup>TM</sup> customers in advance of the expiry of its herbicide patent, Monsanto ensured that individuals making Roundup herbicide off its *old* patent would fail to gain any customers to whom it had sold its new Roundup Ready<sup>TM</sup> seed. In a very short time, Monsanto was able to sell huge numbers of Roundup Ready<sup>TM</sup> seeds, making them arguably ubiquitous across swaths of Canada.

At issue in *Monsanto Canada* was whether Percy Schmeiser, a local farmer, had infringed Monsanto's patent for Roundup Ready<sup>TM</sup> seeds by planting a crop of glyphosate resistant canola having a gene which was the subject of Monsanto's patent. Schmeiser argued that he had

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229. Joseph Villela, *Intellectual Property Protection: A Business Viewpoint in Facilitating International Technology Co-Operation Proceedings of the Seoul Conference*, DSTI/STP/TIP (97) 14/FINAL, Mar. 29, 1999, at 83, cited in Souza, *supra* note 32, at 134, n.17.

230. *Monsanto Canada, Inc., v. Schmeiser*, [2002] F.C. 309.

231. See <http://www.monsanto.ca/products/roundupready/index.shtml> (last visited Apr. 13, 2004).

232. See Carpenter, *supra* note 35.

no intent and no idea that some of his crops had the gene. In fact, only trace amounts of plants with the gene of interest had even been identified. Monsanto's patent, specifically, was for a "genetic insert which, when introduced into the DNA of canola cells by a transformation vector, produces a variety of canola with a high level of resistance to glyphosate."<sup>233</sup> In essence, this involved a cloning vector

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233. *Monsanto Canada, Inc., v. Schmeiser*, [2002] FCA 309, at ¶ 8. Specifically, the patent identified the gene of interest as:

1. A chimeric plant gene which comprises
  - (a) a promoter sequence which functions in plant cells;
  - (b) a coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5— enolpyruvylshikimate-3-phosphate synthase (EPSPS) fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and
  - (c) a 3' non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotides to the 3' end of the RNA;

the promoter being heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.
2. A chimeric gene of Claim 1 in which the promoter sequence is a plant virus promoter sequence.
- ....
5. A chimeric gene of Claim 1 in which the coding sequence encodes a mutant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS).
6. A chimeric gene of Claim 1 in which the EPSPS coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.
7. A chimeric gene of Claim 1 in which the chloroplast transit peptide is from a plant EPSPS gene ....
- ....
22. A glyphosate-resistant plant cell comprising a chimeric plant gene of Claim 1.
- ....
23. A glyphosate-resistant plant cell of Claim 22 in which the promoter sequence is a plant virus promoter sequence.
- ....
26. A glyphosate-resistant plant cell of Claim 22 in which the coding sequence encodes a mutant 5-enolpyruvylshikimate-3-phosphate synthase.
27. A glyphosate-resistant plant cell of Claim 22 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

comprising a gene which encoded the 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) polypeptide. When expressed in a plant cells, EPSPS allows chloroplast transit peptides to transport it (or an enzymatically active portion thereof) from the cytoplasm of the plant cell into a chloroplast. This process ultimately “confers a substantial degree of glyphosate resistance upon the plant cell and plants regenerated therefrom.”<sup>234</sup> Because the Glyphosate inhibited an enzyme required to produce a particular amino acid essential for the growth and survival of a broad range of plants, plants sprayed with a glyphosate based herbicide, such as Roundup Ready™ herbicide, would not survive. A canola plant grown from seed containing the modified gene, however, would be composed of cells with the modified gene and would survive if sprayed with a glyphosate-based herbicide.

Monsanto won the case, though the court’s reasons pose significant concern. First, the court held that the property rights granted by the patent were so clear that — independent of whether Schmeiser did not intend to use the seed or *even if the seed had naturally mutated* — Monsanto’s rights to the gene had been recognized by law. Second, there was evidence that Schmeiser had saved some seeds which were plant resistant and had thus been duplicitous with regard to the seed. Third, the court found that reasonable efforts had been taken to avoid the spread of seeds from other neighbors, but it was not incumbent on Monsanto to do more than was reasonably necessary to prevent the inadvertent spread of its seeds by individuals who purchased them.

The implications of the court’s analysis were significant. First and foremost, it suggested that individuals could be held liable for innocently growing or helping reproduce GMCs. Second, these GMCs — even if resulting from natural, random mutations — would still be covered by the IP rights of whoever patented them. Even the unconscious production<sup>235</sup> of GMCs with patented genes would be

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28. A glyphosate-resistant plant cell of Claim 22 in which the chloroplast transit peptide is from a plant EPSPS gene.

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45. A glyphosate-resistant oil seed rape cell of Claim 22.

*Monsanto Canada*, at ¶ 38.

234. See *Monsanto Canada*, at ¶ 42. Monsanto, notably, had been hurting financially, with its stock tumbling because it could not “deliver” on many promises; it was just under threat to ensure that its new technologies worked and worked well. Rachel Melcer, *Monsanto Wants to Sow a Genetically Modified Future*, ST. LOUIS POST-DISPATCH, Feb. 23, 2003, at E1.

235. See JAMES LAHORE, INTELLECTUAL PROPERTY LAW IN AUSTRALIA ¶ 110, at 7 (1977).

tortious activity demanding a cause of action for damages. One of the reasons why these conclusions are so onerous is their import: because GMCs are patented inventions which can *reproduce, produce progeny, and travel* without human intervention, they are essentially inescapable. Furthermore, GMCs are also, theoretically, reproducible unknowingly through the process of random genetic mutations. GMCs run the risk of completely redefining a host of legal concepts, such as inventiveness, individual autonomy, and tortious interference. Based on *Monsanto Canada*, Monsanto gained an unprecedented set of legally enforceable rights based on its patent. These include cause to enter on to private property and even confiscate that property without the owners' consent, based purely on a genetic sequence which could occur naturally.

#### D. International Concerns

Little has been done to address these concerns, and little is likely to be done. The WTO's TRIPS agreement, mentioned above, may have "globalized" traditional IP concepts, though has done nothing to assess the complexities of GMCs vis-à-vis individuals *qua* companies, companies *qua* countries, and different legal IP regimes in different countries.<sup>236</sup> Similarly, the Cartagena Protocol on Biosafety — devoted to regulations affecting GMCs — does not impose a consistent labeling scheme for GMCs, though it does require labels for shipments of all food products, even if they have been shown to prove no risk whatsoever.<sup>237</sup> Biotechnological developments have appeared to become simply "technical extension[s] of traditional agricultural selective breeding practices,"<sup>238</sup> which are both time-tested and "largely harmless or self-correcting."<sup>239</sup> Depending on the degree to which other countries agree with this approach, GMCs run the risk of being given increasingly disparate treatment to the chagrin of those seeking greater controls. Floating seeds have no borders.

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236. See Fredrick Musungu, *The TRIPS Agreement, the Patents Controversy and the Right to Health: Placing the International and National Debates in Context*, unpublished manuscript, Abstract at 1 (2002) (on file with the author).

237. See Michael P. Healy, *Information Based Regulation and International Trade in Genetically Modified Agricultural Products: An Evaluation of the Cartagena Protocol on Biosafety*, 9 WASH. U. J. L. & POL'Y 205, 205-206 (2002).

238. Van Cleve, *supra* note 50, at 248.

239. *Id.* at 249.

There is, however, some hope in the international arena. The Cartagena Protocol,<sup>240</sup> while imperfect, empowers countries to refuse to import GMCs under the precautionary principle (i.e., the country can ban the import even if there is a lack of scientific certainty that something is dangerous). The Protocol also elevates environmental considerations to an unprecedented level, lauded by many environmentalists. The 1961 Union for the Protection of New Varieties (UPOV) similarly has increased its membership and helped ensure steps be taken to protect indigenous plants and foods.<sup>241</sup> Depending on the degree to which GMCs are found to threaten indigenous varieties, this agreement could be used in limiting GMCs posing quantifiable risks.

Still, these initiatives only begin to address the broader set of issues which remain, including (a) "equitable concerns regarding the patenting of genetically modified products;"<sup>242</sup> (b) the level of transparency for exports of genetically modified products; (c) import bans on genetically modified products; (d) liability for damage of genetically modified products; (e) liability for extraterritorial damage of genetically modified products; and (f) "long-term decline in global biological diversity."<sup>243</sup> The Biosafety Protocol negotiations broke down in 1999 over issues surrounding whether producers of GMCs had to obtain explicit permission from importing countries to proceed with their exports; tentative arrangements were subsequently negotiated, though the issue has not vanished.<sup>244</sup>

Hopeful international solutions must be built on a commitment to address these issues, as embraced in the principles underpinning the WTO. The WTO, despite its critics' fears, can work to achieve agreements which have met the needs of rich and poor countries alike. Its schemes have ostensibly been supported by the principles of (a) non-discrimination, as encapsulated under the Most Favored Nation (MFN) status, (b) national recognition, and (c) consistent elimination of quotas and non-tariff barriers.<sup>245</sup> The clear need for international regulation of GMCs and the IP regimes which support them may thus

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240. Cartagena Protocol on Biosafety to the Convention of Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000), *cited in* Healy, *supra* note 196, at n.2, at <http://www.bba.de/gentech/cartagena.pdf> (last visited Apr. 18, 2004).

241. See Nachtigal, *supra* note 157, at 53-54 n.23.

242. See Sean D. Murphy, *Biotchnology and International Law*, 42 HARV. INT'L L. J. 47, 61 (2001).

243. *Id.*

244. See Kupchella, *supra* note 101, at 744 nn.193-195.

245. See Souza, *supra* note 32, at 167.

be redressed given increasing safety concerns and the interest in ensuring stability in international trade.<sup>246</sup>

Indeed, it is possible to allay the fears associated with the international community's addressing of GMC IP issues. Although trade representatives have stressed how "it would be a tragedy and health setback if the promotion of the flexibilities within the TRIP accord degraded into an assault"<sup>247</sup> on IP, this need not be so. Effective protection of IP is "critical for developing nations" because of their need to "find and develop" ways to deal with the public health challenges faced by their respective societies.<sup>248</sup> This opens the door to considering "utility-based"<sup>249</sup> standards for IP protection, as opposed to novelty or originality standards, in the interests of meeting these needs. Such standards could account for the risks associated with GMCs and mete out IP rights accordingly.

#### *E. Hopeful Resolutions: Five Guiding Principles*

It is impossible to design an optimal IP system accommodating GMCs in a vacuum. However, the previous discussion of *Monsanto Canada* and international developments suggest a set of five key guiding principles. By embracing these principles, actors such as NGOs, government representatives, and private citizens could begin developing new IP systems accommodating GMCs.

**Principle 1: IP protection of GMCs must include multiple sets of rights.** The first guiding principle is that IP protection for GMCs needs to acknowledge the rights of more than just the developers and manufacturers of the GMCs. To date, all IP systems focus simply on the developers and ensuring that "patent protection" grants them a monopoly to (a) refine the technology, (b) exclude others from making profits, and (c) make profits for themselves. In light of the *Monsanto Canada* case, however, this fails to address the interests of honest but

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246. *Id.* at 171.

247. *President Bush's Trade Agenda for 2002: Hearing Before the House Comm. on Ways & Means*, 107<sup>th</sup> Cong. 23 (2002) (statement of Robert B. Zoellick, U.S. Trade Representative).

248. *Id.*

249. See the UK Utility Designs Act, 1843, (protecting "form" and not "function or principle") 6 & 7 Vict. ch. 65, cited in Janis, *supra* note 121, at 156 n.25. It is worth highlighting that the Utility Designs Act embedded a "functional equivalent" ethos which arguably resulted in effective design protection.



unfortunate farmers who also have the right to (a) engage in the legitimate practice of farming, (b) maintain autonomous businesses, (c) use and dispose of their property as they see fit, and (d) prevent transgene contamination. Finally, the public shares the right to (a) a stable and safe food supply and (b) minimal impact level on the commonly shared environment for producing food. These rights impose obvious liabilities on the other parties; and these liabilities cannot, and should not, be left to miscellaneous statutes and courts to construe when the need arises.

**Principle 2: New standards for IP protection of GMCs are needed.**

Current IP systems protecting GMCs apply standards which fail to address the complexities of GMCs. First, one could eliminate patent protection for GMCs entirely, so there would be no patents to infringe.<sup>250</sup> This, however, fails to provide protection or any incentives to develop and improve GMCs. Second, one could simply lower the amount of time during which patents are in force.<sup>251</sup> This, however, fails to address the more fundamental issues of the way in which patents are issued. Third, one could eliminate TDOE so there are no excessively broad patent constructions to manage.<sup>252</sup> This, however, simply eliminates the one main semblance of flexibility in the IP system which can accommodate the unique needs of GMCs. Instead of employing these current standards, a broader set of guidelines needs to be developed which can accommodate an analysis of the unique characteristics of GMCs in order to facilitate comparisons between inventions within various biotechnological subgroups. Gorton proposes that a "pyramid test" be introduced — retaining TDOE though in a more flexible, yet rigorous manner — to *begin* imbuing a greater spirit of flexibility into the current system.<sup>253</sup> In time, this could be used to help the system evolve even more dramatically.

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250. See Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1374 (1998), cited in Gorton, *supra* note 181, at 343 n.108.

251. See Laura E. Ewens, Note, *Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285 (2000), cited in Gorton, *supra* note 181, at 343-344 nn.113-114.

252. Lawrence S. Graham, Note, *Equitable Equivalents: Biotechnology and the Doctrine of Equivalents after Warner Jenkins Co. v. Hilton Davis Chemical Co.*, 6 J. L. & POL'Y 741, 770 (1998), cited by Gorton, *supra* note 181, at 344 n.120; see also Weston, *supra* note 1.

253. See *infra* Exhibit 9, outlining the "pyramid" approach to applying TDOC. Essentially, in comparing two organisms with a given characteristic (such as a genetically modified gene), the processes in which a DNA fragments or genes were

**Principle 3: New processes for ensuring IP protection GMCs need to be developed.** The current system of IP protection for GMCs relies simply on patents which are reviewed by courts of general jurisdiction; however, something else is needed given their complexities. For these purposes, one can envisage a new system in which (a) judges with scientific backgrounds are appointed; (b) new notice requirements are established for public comment; (c) negotiated, contract-based settlements are increasingly accommodated — and encouraged — between conflicting parties to avoid expensive, drawn-out, extensive litigation; and (d) uniform application standards crossing state and international boundaries are applied.<sup>254</sup> In this system, new processes would accommodate the new standards, and the new standards would be supported by these new processes. Only in this way can the risk of the anti-commons, discussed above, be avoided, in turn preventing “every grain of sand” from systematic ownership. In many ways, this principle counterbalances the first principle: it is important to recognize parties’ broader sets of rights, though these rights are also limited. Private property exists, mistakes are made, and developing nations have special needs.<sup>255</sup> Ideas integrating public clearinghouses on GMCs, public-private partnerships reviewing GMCs, and pre-market consultations are all possible.

**Principle 4: Recognize concertedly that GMCs have a *qualitatively different impact on society* than previous inventions.** It is essential to recognize in developing any new system of IP protection for GMCs that GMCs have an impact on society which differs dramatically from other inventions — predominantly because GMCs are living organisms. The impracticalities of labeling are illustrated by the fact that once seed is released into the environment, humans cannot

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created are isolated. They are then identified and compared. Second, their genetic codes are examined, and it is determined how any given modifications were inserted into the given organisms. Third, the mechanism by which transcription occurred and a protein was encoded by the DNA is reviewed. And finally, the protein’s effects on the function of the relevant organisms — as well as products generated by the genetically modified organisms — are reviewed. “If each level of the accused organism matches the patented invention, either literally or as an equivalent, then the accused party is guilty of infringement.” Gorton, *supra* note 181, at 349.

254. Definitions, for example, could be agreed upon — ideally transnationally. The term “transgenic plant,” for example, is vague and *might* include *all* plants on the planet because one could argue that any gene of interest which can be demonstrated to have been altered is, by definition, transgenic.

255. See Souza, *supra* note 32, at 138 n.35, quoting FAO, *supra* note 79.

control the course of events. Similarly, the process by which GMCs are developed differs enormously from inventions of the past. Gone are the days of individual inventors in their living rooms. Large corporations and teams of researchers are now the norm.<sup>256</sup> These “individuals” have different interests and deeper pockets than their predecessors. The latter is important in adjusting tort liability to require more stringent standards.<sup>257</sup>

**Principle 5: IP regimes for GMCs must have different theoretical underpinnings than typical IP systems.** On the broadest level, the theoretical underpinnings of IP regimes for GMCs differ from other types of property. Kojo Yelapaala, in his telling discussion on the evolution of IP rights, references a range of property types recognized in Roman law. Several of these could be applied in developing new IP regimes for GMCs. Roman law distinguished between (a) things susceptible to private ownership, though not presently owned (*res in nostro patrimonio*) and (b) things not susceptible to private ownership, so not owned (*res extra nostrum patrimonium*). This latter category included (i) things owned by everybody, or common goods (*res communes*), (ii) sacred property (*res sacrae*), (iii) religious property (*res religiosae*), and (iv) religious antiquities (*res sanctae*). Thus, there were things susceptible to private ownership, though not owned, such as things governed by “divine law” (*res nullius*), and there were things assigned to new categories altogether.<sup>258</sup> The time may now be ripe for creating a new set of property, *res physciae* (or “scientific biochemical things”), to which would be associated new sets of legal rights and responsibilities.

The above five principles are not representative of a given philosophy, though they address a range of interests which cross many philosophical lines. Indeed, they are utilitarian in the degree to which they seek to ensure that biotechnological developments are managed in ways which maximize the greatest good for the greatest number.<sup>259</sup>

256. From 1985 to 1995, corporations owned between seventy-three and seventy-six percent of patents; this increased to seventy-nine percent in 1998 (depending on how one defines “corporation,” which could include universities). National Science Foundation, *Industry Technology, and the Global Marketplace*, Chapter 7, available at <http://www.nsf.gov/sbe/srs/seind00/access/c7/c7s3.htm> (last visited Apr. 24, 2004).

257. See Van Cleve, *supra* note 50, at 306. See generally GUIDO CALABRESI, *THE COST OF ACCIDENTS* (1970).

258. Yelapaala, *supra* note 2, at 132.

259. See generally JEREMY BENTHAM, *AN INTRODUCTION TO THE PRINCIPLES OF MORALS AND LEGISLATION* (Clarendon Press, 1879) (1789).

They are also Kantian in the degree to which they posit certain categorical imperatives (i.e., that GMCs are unique “inventions” which deserve special treatment).<sup>260</sup> Third, they are libertarian, in the degree to which they suggest that individuals should be allowed to research, investigate, and develop new technologies as much as possible, albeit under the watchful eye of affected parties.<sup>261</sup> Finally, they abide by principles akin to economic rationalism, in that they view GMCs as a form of property and as “instrument[s] for achieving . . . concrete societal objectives,” with efficiency (defined broadly) as an implicit object and purpose of IP rights.<sup>262</sup> Lines *need* to be drawn, and lines *can* be drawn, as illustrated by the global rejection of the “Terminator Seed” technology developed by Monsanto<sup>263</sup> and increasing attempts to bound IP claims.<sup>264</sup>

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260. See generally IMMANUEL KANT, *GROUNDWORK FOR THE METAPHYSICS OF MORALS* (Allen W. Wood ed., trans., Yale University Press, 2002) (1785).

261. See generally JOHN LOCKE, *POLITICAL ESSAYS* (Mark Goldie ed., Cambridge University Press, 1997) (1690).

262. See *id.* at 180-81. There is a problem with using the word “efficiency” since biochemical patents are often linked to processes and these processes can often be hard to imitate in scope (in other words, one cannot obtain ownership over *literally* all the processes which lead from A to B in a given genetic manipulation since these processes incorporate countless biological, chemical, and physical steps on the cellular, atomic, and subatomic levels).

263. Yelpaala, *supra* note 2, at 208. The “Terminator Seed” technology was resoundingly rejected because of the public policy implications of the technology and illustrate the degree to which IP rights for GMCs already transcend traditional IP boundaries. Indeed, critics felt that an invention that “has as its motive, explicit or implicit, the destruction of a source of human ingenuity, the spread of knowledge, and the ability to tinker with ideas in nature should not be patentable.” *Id.* There was also the pointlessness of IP protection given the fact that the invention allowed its holder to create a natural ‘absolute monopoly’ not in need of any protection from humans.

264. Consider, for example, the increasingly common arguments that elements of an IP claim for GMCs should

extend no further than . . . the composition of a genome constituting a transgene, inserted by genetic manipulation techniques, which is *expressed*. The legal estate created by the granting of the claim is therefore to either an (a) expressed transgene, inserted into the plant genome by genetic manipulation techniques or (b) at most, to the composition of the plant genome with the expressed transgene inserted by genetic engineering techniques. The exclusive interest of the patentee is then the right of the patentee to exclude others from (1) making, (2) using, (3) selling, or (4) offering to sell a genome constituting an expressed transgene, inserted by genetic engineering techniques.

## IV. CONCLUSION

Ensuring that the benefits of GMCs are best harnessed — and pitfalls avoided — will require a significant dose of will and creativity. It will imply significantly altering the ways in which IP rights for GMCs are distributed and managed, and it will transcend national borderlines. It will require significant investment, as well as political capital. And it will require imagination and inspiration, particularly in different forms of private-public partnerships if the public's fears increasingly associated with GMCs<sup>265</sup> are to be allayed.

Despite these seemingly highfalutin goals, resolution is possible, if not inevitable. This article proposes, as a start, five guiding principles which stem from the current GMC debate, particularly applicable to countries faced with (a) developing new IP systems, such as Australia, and (b) wresting with management of current IP systems, such as Canada. There is no reason to believe that novel solutions cannot be unearthed which also allow legislatures and international bodies to transcend their current approaches to the ways in which IP laws are made and adjudicated. GMCs are unique; and the legal protection afforded them must — and ultimately will — reflect this.

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Busch, *supra* note 85, at 102 (emphasis and alphanumeric notations added).

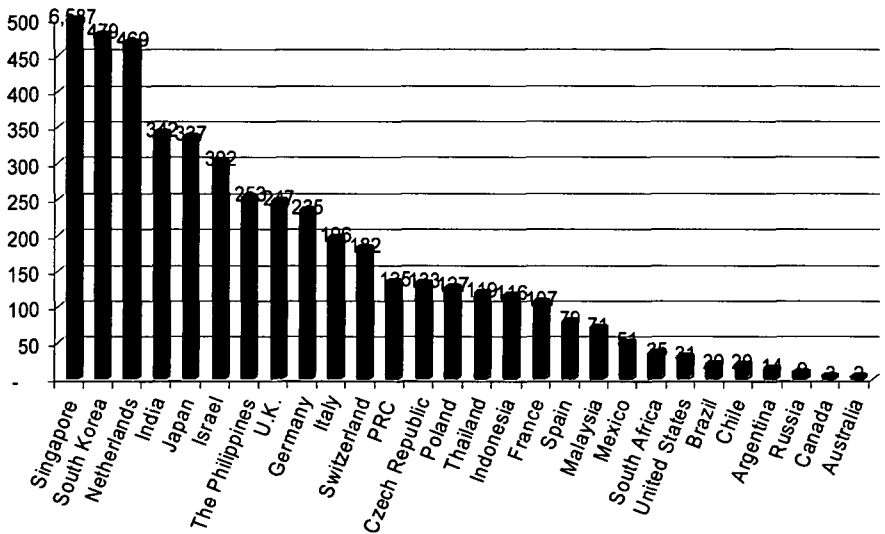
265. See *infra* Exhibit 15, *supra* note 82.

## APPENDIX OF EXHIBITS

- Exhibit 1. Chart: No. of persons per square km for selected countries, 2000.
- Exhibit 2. Graph: Percentage of ALS herbicide-resistant individuals in seed from nonresident varieties vis-à-vis distance from source fields.
- Exhibit 3. Graph: Percentage of ALS herbicide-resistant individuals in sink fields, by seed varieties.
- Exhibit 4. List: Key crops, cultivar names, and major methods used to induce mutations.
- Exhibit 5. Miscellaneous charts depicting pharmaceutical and biotechnological R&D spending and areas of transgenic crops world-wide (sorted by types of crops and countries), various sets of years during late 1990s.
- Exhibit 6. List: Transgenic crop production, by country, 2000.
- Exhibit 7. Photographs of corn and soybean varieties with genetic modifications.
- Exhibit 8. Chart: Amino acids coded by different combinations of nucleotides.
- Exhibit 9. Graphic representation of the 'pyramid' approach applied to GMCs.
- Exhibit 10. Data on StarLink™ corn and the Cry9c gene.
- Exhibit 11. Data on wet-milling corn.
- Exhibit 12. Tables containing data illustrating that wet-milling corn is one way to reduce the amount of Cry9c protein in the corn.
- Exhibit 13. Graphic illustrating ways of classifying possibly patentable items.
- Exhibit 14. Graphic representation of areas in which Monsanto has developed business interests.
- Exhibit 15. Chart: EU Eurobarometer survey of countries due to join the EU in 2004 re: attitudes towards GM food.

Exhibit 1

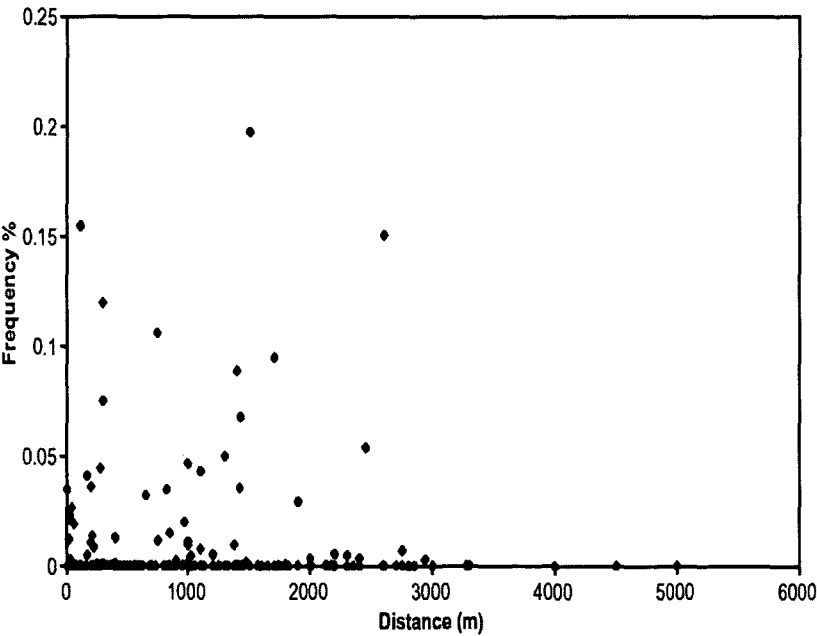
**AUSTRALIA IS THE LEAST DENSELY POPULATED COUNTRY ON EARTH\***  
**No. of persons per square km, 2000**



\* Australia's Bureau of Statistics reported Australia's population at 19,815,822 as of 10:21am (NSW EST) on March 2003, making it still the least densely populated country on earth; for up-to-the-second statistics and the population clock, see <http://www.abs.gov.au/Ausstats>. Source: World Bank; *The Economist*; South Australia Geological Society; Australian Bureau of Statistics; South Australia Museum; research conducted by C. Scott López

Exhibit 2

**MOST POLLEN TRAVELS A COMPARATIVELY SHORT DISTANCE FROM ITS SITE OF ORIGIN**  
**Percentage of ALS herbicide-resistant individuals in seed from nonresistant varieties *vis-à-vis* distance from source fields\***



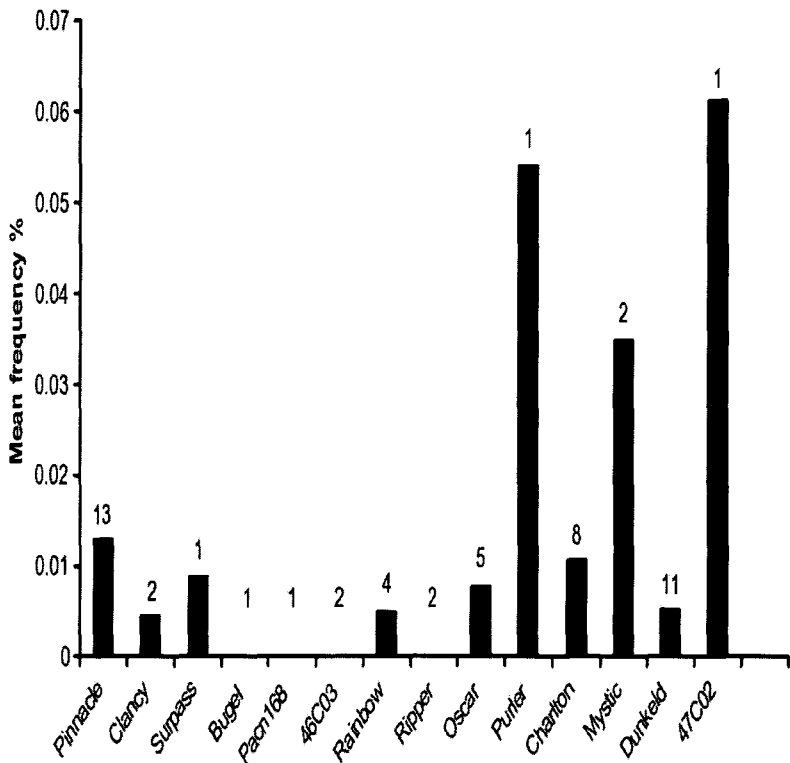
\* Three individual samples were collected per field, with 190 individual collection locations. Source: Mary A. Rieger et al., *Pollen Mediated Movement of Herbicide Resistance Between Commercial Canola Fields*, 296 SCI. 2386. 2387 (2002).



Exhibit 3

**DIFFERENT VARIETIES OF SEEDS TEND TO SPREAD OUT MORE WIDELY THAN OTHERS**

Percentage of ALS herbicide-resistant individuals in sink fields, by seed varieties; number of fields screened are indicated *above* each bar



Source: Mary A. Rieger et al., *Pollen Mediated Movement of Herbicide Resistance Between Commercial Canola Fields*, 296 Sci. 2386, 2387 (2002); selected by C. Scott López.

## Exhibit 4

**VARIOUS METHODS HAVE BEEN USED TO INDUCE  
MUTATIONS IN KEY CROPS**

**Key crops, cultivar names, and major methods used to induce mutations**

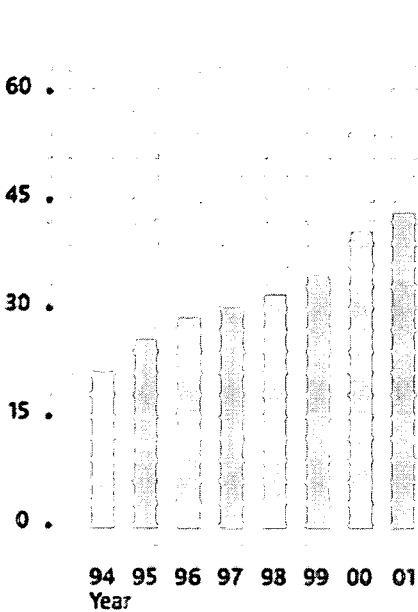
Crop	Cultivar Name	Method Used to Induce Mutation
rice	Calrose 76	gamma rays
wheat	Above	sodium azide
	Lewis	thermal neutrons
oats	Alamo-X	X-rays
grapefruit	Rio Red	thermal neutrons
	Star Ruby	thermal neutrons
burmuda grass	Tifeagle	gamma rays
	Tifgreen II	gamma rays
	Tift 94	gamma rays
	Tifway II	gamma rays
lettuce	Ice Cube	ethyl methanesulphonate
	Mini-Green	ethyl methanesulphonate
common bean	Seafarer	X-rays
	Seaway	X-rays
lilac	Prairie Petite	thermal neutrons
St. Augustine grass	TXSA 8202	gamma rays
	TXSA 8212	gamma rays

Source: *Transgenic Crops Resource Guide*, available at <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/history.html>; research by C. Scott López.

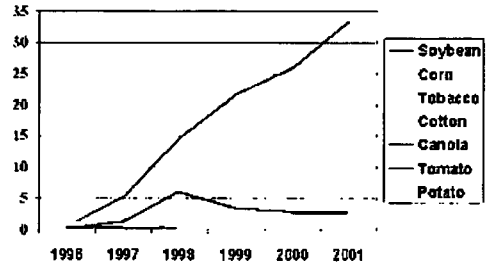
## Exhibit 5

# INCREASED R&D INVESTMENTS HAVE MIRRORED THE GROWTH IN TRANSGENIC CROPS – PARTICULARLY FOR SOYBEANS

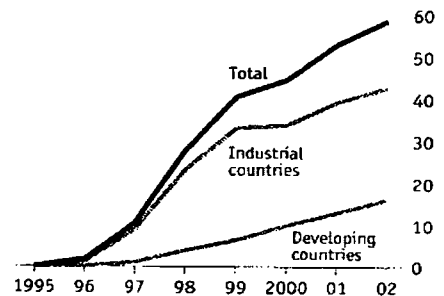
**Pharma & biotechnology  
R&D spending, 1994-2001**  
Pounds Sterling, billions



**Area of transgenic crops world-wide, 1996-2001**  
Millions of hectares, sorted by type of crop



**Area of transgenic crops world-wide, 1995-2002**  
Millions of hectares, sorted by industrial and developing countries



Source: SCRIP Reports, *Transgenic R&D Compendium*, available at <http://www.amersham.co.uk/investors/AR01/rep27.html>; *Transgenic Crops Resource Guide*, available at <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/current.html>; Survey of Technology Insert, *THE ECONOMIST*, Mar. 29, 2003, at 16 following 50; research and selections by C. Scott López.

## Exhibit 6

**THE UNITED STATES CURRENTLY LEADS THE WORLD IN  
TRANSGENIC CROP PRODUCTION**  
**Transgenic Crop Production, by country, 2000**

Country	Area planted in 2000 (millions of acres)	Crops grown
USA	74.8	soybean, corn, cotton, canola
Argentina	24.7	soybean, corn, cotton
Canada	7.4	soybean, corn, canola
China	1.2	cotton
South Africa	0.5	corn, cotton
Australia	0.4	cotton
Mexico	minor	cotton
Bulgaria	minor	corn
Romania	minor	soybean, potato
Spain	minor	corn
Germany	minor	corn
France	minor	corn
Uruguay	minor	soybean

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Source: *Transgenic Crops Resource Guide*, available at  
<http://www.colostate.edu/programs/lifesciences/TransgenicCrops/current.html>;  
 research by C. Scott López.

## Exhibit 7

**THE GENETIC MODIFICATIONS CAN—UNSURPRISINGLY—HAVE  
DRAMATIC EFFECTS**

**Photographs of corn and soybean varieties with genetic modifications  
(genetically modified species on left; wild-type on right)**

**Corn****Soybeans**

Source: *Transgenic Crops Resource Guide*, available at <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/current.html>; research by C. Scott López.



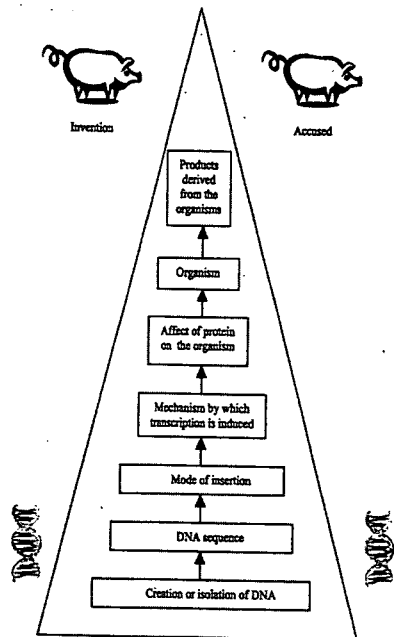
## Exhibit 9

**ONE METHOD OF ADDRESSING PROBLEMS WITH THE DOCTRINE OF EQUIVALENTS IS BY USING A "PYRAMID" APPROACH TO ASSESS POSSIBLE PATENT INFRINGEMENTS**

**Graphic representation of the 'pyramid' approach applied to genetically modified crops**

**Key ideas:**

- (1) The Doctrine of Equivalents *will be applied* by searching for insubstantial changes at *each* level of creation required to develop a GMO.
- (2) At each level there are *less* possible ways to achieve the desired result; thus, the range of equivalents will depend on how much latitude exists to allow competitors to design around the patent.



Source: Alexis Gorton, *Edible Equivalents: An Increase in Patent Protection for Genetically Modified Organisms*, 9 WASH. U. J. L. & POL'Y 321, 352 (2002); research by C. Scott López.

## Exhibit 10

## StarLink™ CORN, CONTAINING THE GENE Cry9c, WAS AT THE CENTRE OF A MAJOR PUBLIC RELATIONS FIASCO

Host Organism / Variety	<i>Zea mays</i> L. (Maize) StarLink™
Trait	Resistance to European corn borer ( <i>Ostrinia nubilalis</i> ); phosphinothricin (PPT) herbicide tolerance, specifically glufosinate ammonium.
Trait Introduction Method	Microparticle bombardment of plant cells or tissue
Proposed Use	Production of meal and silage for livestock feed, and products for industrial applications. This material will not be grown outside of the normal production area for maize.
Company Information	Aventis CropScience



### Summary of Introduced Genetic Elements

Code Name	Type	Promoter, other	Terminator	Copies	Form
<i>bar</i>	phosphinothricin N-acetyltransferase ( <i>S. hygroscopicus</i> )	HT	CaMV 35S	<i>A. tumefaciens</i> nopaline synthase ( <i>nos</i> ) 3'-polyadenylation signal	>=4
<i>cry9c</i>	<i>cry9c</i> delta-endotoxin ( <i>Bacillus thuringiensis</i> subsp. <i>Tolworthi</i> )	IR	CaMV 35S ; leader sequence of the <i>cab22L</i> gene of <i>Petunia hybrida</i> (chloroplast transit peptide)	CaMV 35S poly (A) signal	>=1 Truncated N-C-terminal
<i>bla</i>	beta lactamase	SM	bacterial promoter		Not expressed in plant tissues

### Modification Method

CBH-351 maize was produced by biolistic transformation of the backcrossed hybrid maize line (PA91 x H99) x H99 with two pUC19 based plasmids, PRSVA9909 and pDE110. Both plasmids contained the modified *cry9C* gene and the *bar* gene, respectively, engineered for enhanced expression in plants. The *cry9C* and *bar* genes were fused to noncoding regulatory sequences that enabled them to be expressed at high levels, constitutively throughout most of the plant. Specifically, the expression of the modified *cry9C* gene was regulated by the promoter and terminator sequences from the 35S transcript of CaMV, along with the leader sequence of the *cab22L* gene from *petunia*. The expression of the *bar* gene was also directed by the 35S CaMV promoter along with the 3' untranslated region from the nopaline synthase (*nos*) gene from *A. tumefaciens* which is involved in transcription termination and polyadenylation. Although most of these regulatory regions were derived from plant pathogens, the regulatory sequences cannot cause plant disease by themselves or with the genes that they are designed to regulate. Additional genetic elements present on the transforming plasmids included the ampicillin resistance gene beta-lactamase (*bla*) and the origin of replication (*ori*) both from the enteric bacterium, *Escherichia coli*. Both were introduced into CBH-351 maize, however these elements are nonfunctional in plants. The *bla* gene was present on the plasmids only as a selectable marker to detect transformed *E. coli* host bacteria.

### Characteristics of *Zea mays* L. (Maize)

Center of Origin	Reproduction	Toxins	Allergenicity
Mesoamerican region, now Mexico and Central America	Cross-pollination via wind-borne pollen is limited, pollen viability is about 30 minutes. Hybridization reported with teosinte species and rarely with members of the genus <i>Tripsacum</i> .	No endogenous pollen toxins or significant levels of antinutritional factors.	Although some reported cases of maize allergy, protein (s) responsible have not been identified.

### Donor Organism Characteristics

Latin Name	Gene Pathogenicity
<i>Streptomyces hygroscopicus</i>	<i>bar</i> <i>S. hygroscopicus</i> is ubiquitous in the soil and there have been no reports of adverse effects on humans, animals, or plants.
<i>Bacillus thuringiensis</i> subsp. <i>tolworthi</i>	<i>cry9c</i> While target insects are susceptible to oral doses of <i>Bt</i> proteins, no evidence of acute toxicity in laboratory mammals, birds, or non-target beneficial insects has been reported. The <i>Cry9C</i> protein is resistant to heat and proteolytic degradation and may have allergenic potential

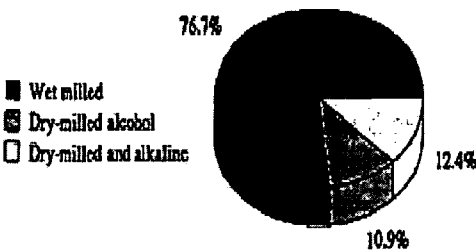
Source: Essential Biosafety website, available at <http://www.essentialbiosafety.info/dbase.php?action=ShowProd&data=CBH351&frma=LONG>; research by C. Scott López.



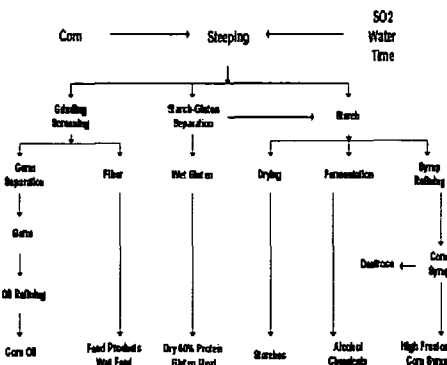
Exhibit 11

WET-MILLING CORN IS THE MOST POPULAR MEANS OF PROCESSING CORN WORLDWIDE

Type of corn used worldwide, by milling process  
Percent



Wet milling process



Protein content & uses of wet milled corn

Fraction	Approximate Percent Protein Content <sup>1</sup>	Uses
Steep Liquor (condensed)	45-48% Protein	Animal Feed
Corn Germ	20%	Animal Feed
Bran/Gluten Feed	18-22% Protein	Animal Feed <sup>2</sup>
Gluten Meal	≥ 60% Protein	Animal Feed <sup>2</sup>
Starch	0.3-0.35% Protein (high amylose corn - up to 1%) <sup>3</sup>	unmodified corn starch, specialty corn starch, corn syrups, and dextrose
Syrup	Not Detectable <sup>4</sup> (made from corn starch)	pure dextrose, corn syrup, and high fructose corn syrup
Alcohol	Not Detectable <sup>4</sup> (made from corn starch)	ethanol
Corn Oil	Not Detectable	cooking or salad oil

<sup>1</sup> Source: Blanchard, 1992; Kyd Brenner, 2000  
<sup>2</sup> Most corn gluten is used for animal feed. Some is treated to extract corn zein and some is subjected to acid hydrolysis to produce hydrolyzed vegetable protein as described in Section III. B.  
<sup>3</sup> Cry9C protein has not been engineered into high amylose and waxy corn varieties  
<sup>4</sup> Further processing of corn starch removes remaining protein

Source: U.S. Environmental Protection Agency, *White Paper on the Possible Presence of Cry9c Protein in Processed Human Foods Made from Food Fractions Produced Through the Wet Milling of Corn* (Washington, DC, EPA, 2002), available at <http://www.epa.gov/scipoly/sap/2001/july/wetmilling.pdf>; research by C. Scott López.

## Exhibit 12

**WET MILLING CORN IS ONE WAY TO REDUCE THE AMOUNT OF Cry9c PROTEIN—THEREBY ELIMINATING FEARS OF ALLERGIC REACTIONS FROM HUMAN CONSUMPTION**

**Estimated upper bound exposure to Cry9c protein for various population groups assuming food containing corn starch was made from grain containing 1.2% StarLink™ corn**

Percentiles in percent; other figures in micrograms

Group	Potential Daily Exposure of Cry9C Protein from Corn Starch		
	Upper Bound Exposure for 1999 (1.2%)		
Percentile:	95	99	99.5
US Population	0.00387 ug	0.01103 ug	0.01567 ug
Infants	0.00135 ug	0.00213 ug	0.00232 ug
Children 1 to 6 yrs	0.00116 ug	0.00290 ug	0.00387 ug
Children 7 to 12 yrs	0.00174 ug	0.00484 ug	0.00639 ug

**Estimated upper bound exposure to Cry9c protein for various population groups assuming food containing corn starch was made from grain tested by GIPSA guidelines and containing 0.125% or less StarLink™ corn**

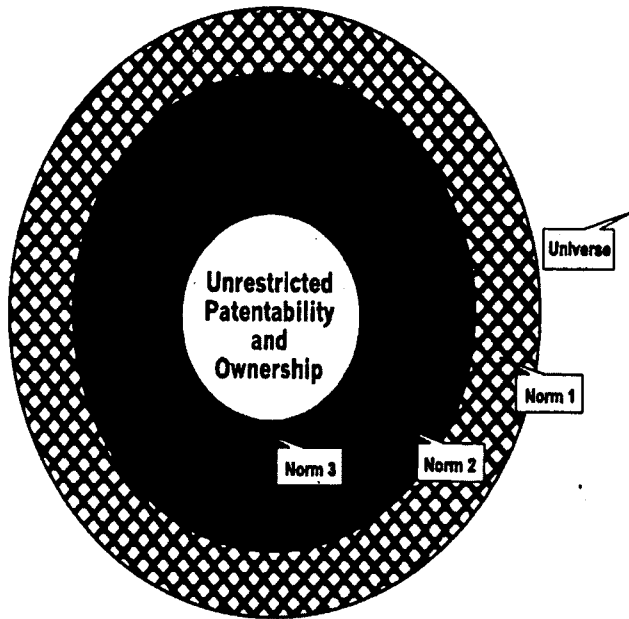
Percentiles in percent; other figures in micrograms

Group	Potential Daily Exposure of Cry9C Protein from Corn Starch		
	Upper Bound Exposure (0.125%)		
Percentile:	95	99	99.5
US Population	0.0003249 ug	0.0009261 ug	0.0013161 ug
Infants	0.0001137 ug	0.0001785 ug	0.000195 ug
Children 1 to 6 yrs	0.0000975 ug	0.0002436 ug	0.0003249 ug
Children 7 to 12 yrs	0.0001461 ug	0.0004062 ug	0.0005361 ug

Source: U.S. Environmental Protection Agency, *White Paper on the Possible Presence of Cry9c Protein in Processed Human Foods Made from Food Fractions Produced Through the Wet Milling of Corn*, at tbls. 5-6 (Washington, DC, EPA, 2002), available at <http://www.epa.gov/scipoly/sap/2001/july/wetmilling.pdf>; research by C. Scott López.

Exhibit 13

**POSSIBLY PATENTABLE ITEMS CAN BE CLASSIFIED IN ONE OF 3 KEY WAYS**



**Universe:** Universe of Ideas in biotechnology.

**Norm 1:** That which cannot be owned is not patentable.

**Norm 2:** That which can be owned may nevertheless not be patentable.

(a) Specific exclusion.

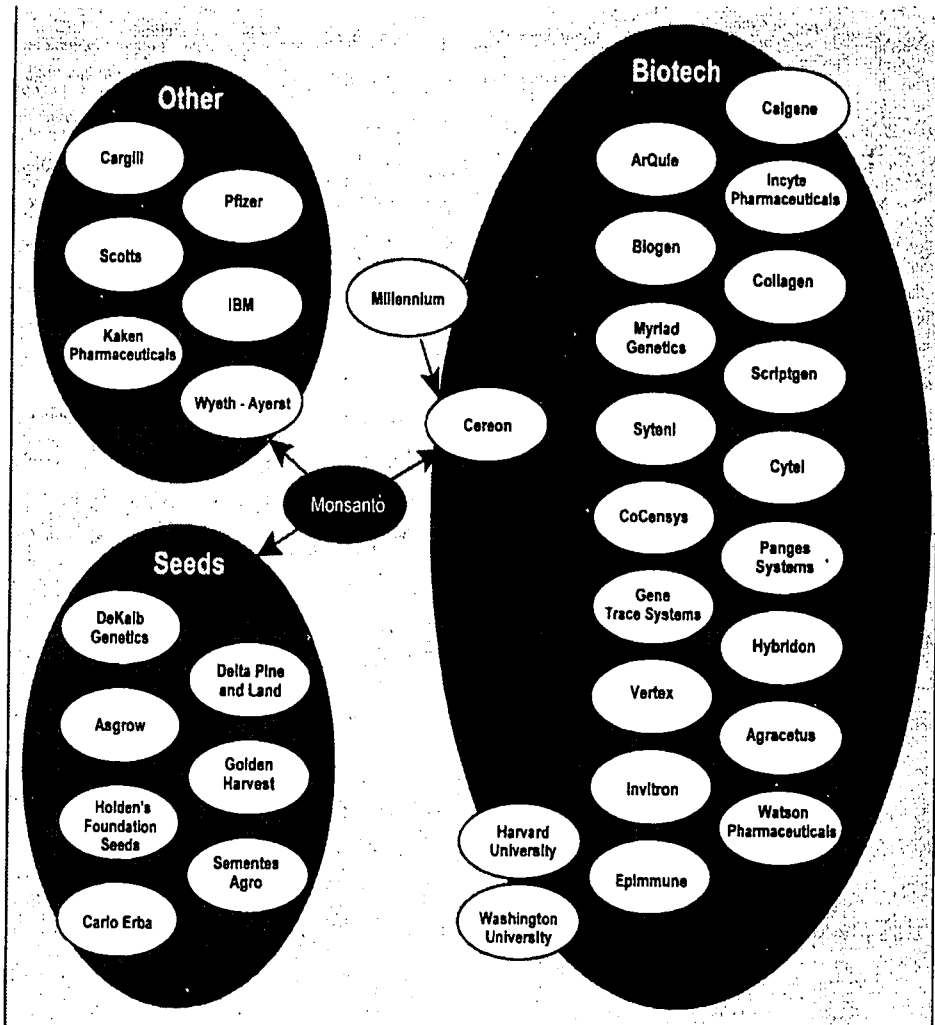
(b) Exclusion through patentability criteria.

**Norm 3:** That which is patentable may nevertheless not be patented on public policy grounds.

Source: Kojo Yelapaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 31 MCGEORGE L. REV. 111, 194 (2000); research by C. Scott López.

Exhibit 14

**MONSANTO HAD EXPANDED ITS BIOLOGICAL RESEARCH INTERESTS IN MANY AREAS BY THE MID-90s**



Source: Kojo Yelapaala, *Owning the Secret of Life: Biotechnology and Property Rights Revisited*, 31 MCGEORGE L. REV. 111, 168 (2000); research by C. Scott López.

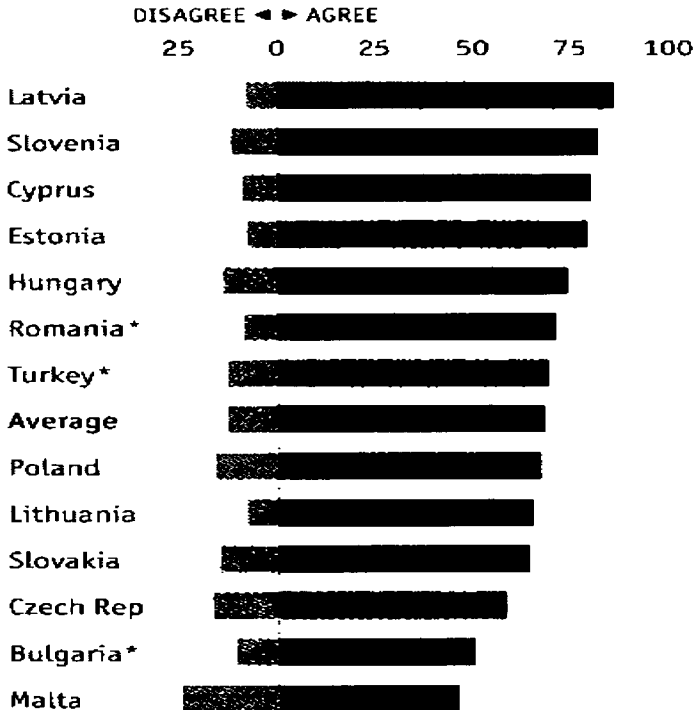
Exhibit 15

**MOST COUNTRIES SOON JOINING THE EU DO NOT WANT GM PRODUCTS DISTRIBUTED**

**EC Eurobarometer Survey of countries due to join the EU in 2004 re: attitudes towards GM food**

*"I do not want this type of food."*

EU candidate countries, %, November 2002



Source: Survey, *Genetically Modified Food*, ECONOMIST, Apr. 5, 2003, at 98; research by C. Scott López.