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Seeds of Dispute: Intellectual-Property Rights and Agricultural Biodiversity

Keith Aoki

ARTICLE

SEEDS OF DISPUTE: INTELLECTUAL-PROPERTY RIGHTS AND AGRICULTURAL BIODIVERSITY

KEITH AOKI*

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* Professor, University of California at Davis King Hall School of Law. Thanks to my research assistants Rebecca Barlow Yalcinkaya Amanda E. Sherwood, and Patrick Richey.

I. INTRODUCTION

This Article is about the interrelationship between expanding intellectual-property rights and the conservation of biodiversity. While these rights are not strictly correlated with conservation, the types of markets and companies producing commercial seeds and other agricultural inputs tend to promote monocultures that erode biodiversity in both the developed and developing world. Furthermore, this Article argues that the rise of genetically engineered crops in the last two decades further exacerbates both intellectual-property claims of companies owning patented seed and biodiversity, as metaphorical monoculture becomes realized with genetically engineered crops in fields where all the plants have the same genetic structure.

This Article begins with a brief overview of crop genetic diversity up to the late nineteenth century and examines the importance of controlling plant genetic diversity since the age of colonialism.

The Article then moves on to look at how mass-scale industrialized agriculture occurred in the United States in the early twentieth century as private companies began to produce seeds and other high-chemical crop inputs like fertilizer, pesticides, and herbicides. During this period, commercial agriculture underwent a fundamental change from a model in which farmers bred and adapted crops to local soil and growing conditions to a model where "one seed feeds the world," and local conditions were modified to suit a particular seed using chemical supplements. This was the so-called "Green Revolution," which, in the middle twentieth century, gave rise to high-yield industrial agriculture; environmental degradation and dramatic loss of plant genetic diversity followed.

By the 1970s, an international network of seed libraries was established by the Rockefeller Foundation, the United Nations' Food and Agriculture Organization, and the United States to conserve the swiftly vanishing store of plant genetic diversity. The parties characterized such resources as the "common heritage of [hu]mankind" and allowed open access to plant breeders around the world.

This Article also traces the growth of intellectual-property protection during the twentieth century, beginning with the Plant Patent Act of 1930, which granted protection to asexually propagated plants such as clones, the Plant Variety Act of 1970, which granted protection for sexually reproduced crop plants, and the landmark 1980 U.S.

Supreme Court case, *Diamond v. Chakrabarty*, which held that living organisms with a requisite degree of creative human agency may be granted utility-patent protection.

This Article additionally traces developments at the international level regarding intellectual-property protection for agricultural crop plants, culminating in the 2001 International Treaty for Plant Genetic Resources (ITPGR), which characterized plant genetic resources as a form of "sovereign property" and established a list of staple crops available from the international seed banks as a "limited commons." Of course, the ITPGR co-exists with multilateral trade treaties such as the 1995 Trade Related Aspects of Intellectual Property (TRIPS), the World Trade Organization (WTO), and multilateral agreements aimed at conservation such as the 1992 Convention on Biodiversity (CBD).

Against this increasingly complicated backdrop of national and international agreements, major technological advances were occurring in the area of agricultural biotechnology such as genetic engineering. This Article looks at how, by the 1990s, all of these developments were beginning to intersect. By the end of the twentieth century, genetically engineered (GE) crops such as soybeans, cotton, canola, and corn were beginning to dominate certain agricultural niches in countries like the United States and Canada. This Article considers how the fragmented regulatory framework for genetically modified crops reinforces the increasingly broad intellectual-property rights in such crops, which in turn brings about further erosion of biodiversity.

Finally, the Article examines a 2004 Canadian Supreme Court case, *Monsanto Canada Inc. v. Schmeiser*, in which the themes outlined above played decisive roles.

II. CROP DIVERSITY UP TO THE NINETEENTH CENTURY

Humans began cultivating plants ten to twelve thousand years ago during the transition from hunting and gathering to agriculture.[1] While this move to cultivation entailed a focus on a relatively small number of plant species, within those species genetic "diversity flourished as plants traveled with people and encountered and were adapted to new climates, solids, insects and diseases, and human cultures."[2] Farmers, plant

[1] CARY FOWLER & PAT MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 8 (1990) [hereinafter FOWLER & MOONEY, SHATTERING]; CARY FOWLER, UNNATURAL SELECTION: TECHNOLOGY, POLITICS AND PLANT EVOLUTION xiii (1994) [hereinafter FOWLER, UNNATURAL SELECTION].

[2] FOWLER, UNNATURAL SELECTION, *supra* note 1, at xiii.

breeders, and biologists draw upon plant genetic diversity that was developed over ten millennia to adapt crop species to new pests, diseases, and other environmental changes; this diversity is crucial to the continued viability of major agricultural crops.[3]

Our treatment of crop genetic diversity has changed drastically over the course of the past century. Major food crops of the world have genetic components that may be traced to many local varieties developed by small subsistence farmers and farming communities around the globe.[4] Until the late 1970s, these plant genetic resources (PGRs) were characterized as the "common heritage of [hu]mankind"[5] to which farmers, plant breeders, and agricultural researchers had unrestricted and open access.[6] Many of the procedures and norms of twentieth-century agricultural research and breeding institutions were designed to facilitate open access to—and the exchange of—PGRs to improve crops.[7]

III. THE IMPORTANCE OF CONTROL OVER PLANT GENETIC RESOURCES

Control over plant genetic diversity is as controversial now as it was two hundred years ago when the major colonial powers vied for control of plantation crops.[8] "Property institutions fundamentally shape a society"; the way that the law constructs relationships between

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[3] *Id.*

[4] *See* STEPHEN B. BRUSH, FARMERS' BOUNTY: LOCATING CROP DIVERSITY IN THE CONTEMPORARY WORLD (2004).

[5] Plant genetic resources enjoy the unique distinction of being considered the "common heritage of mankind," or in other terms, humanity's collective "genetic estate." JACK KLOPPENBURG, FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 152 (UNIV. OF WIS. PRESS 2004) (1988). As a result, plant genetic resources have been available as a free good with the only costs associated with their acquisition being the expenses inherent in the collection of the same. *Id.* In contrast, resources such as coal, oil, and valuable minerals do not share this distinction; even water may be commodified, as wrangling over the "Law of the Sea" shows. *Id.* While the West has all along been reluctant to confer this "common heritage" status to resources that fall outside the West, this reluctance to confer this status does not seem to have been extended to plant genetic resources. *Id.* For a comprehensive discussion of this concept of "common heritage," see ANTHONY J. STENSON & TIM S. GRAY, THE POLITICS OF GENETIC RESOURCE CONTROL 136-53 (1999).

[6] KLOPPENBURG, *supra* note 5, at 152.

[7] Plant viruses claim up to four fifths of cultivated crops. Karen M. Graziano, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 179, 183 (1995). With increasing global population calling for increased agricultural output, it has been argued that making crops disease-resistant and immune is vital for future generations. *Id.* at 183-84. It has been further stated that crop improvement through biotechnology, among other means, leads to efficiency, productivity, and stability in an industry that is susceptible to pests, insects, and (in most parts of the world) climatic variability. *Id.*

[8] LUCILLE H. BROCKWAY, PLANT SCIENCE AND COLONIAL EXPANSION: THE BOTANICAL CHESS GAME 49-65 (Jack R. Kloppenburg, Jr., ed. 1988).

individuals, objects, and the state is not always easy to justify, especially in the realm of intellectual property.[9] Should genetic resources be characterized as the "common heritage of [hu]mankind," or should such resources be treated as freely appropriable and therefore susceptible to private ownership via intellectual-property laws?

In the intellectual-property context, "common heritage" is a misnomer because it implies common ownership, but resources characterized as such are available for entrepreneurs to use as the "raw materials" for intellectual property, which is anything but held in common with others. There are several important questions. An important normative question is whether private individuals and firms should be allowed to claim exclusive ownership in assorted aspects and elements of PGRs. If we allow such private claims to be made, how do we define, qualify, and tailor those newly minted, privately owned rights? To what extent should national governments, supranational bodies, and non-governmental organizations and their actions be involved in establishing frameworks and rules regarding PGRs? Control and ownership are critical to the questions of how and whether those PGRs will be conserved.

Control over PGRs via intellectual-property rights have been expanding in scope for the past eighty years in both public-private and national-supranational spheres.[10] In the nineteenth and early twentieth centuries, the U.S. government was heavily involved in plant collecting and "plant improvement."[11] The federal and state governments during this period were also actively involved in freely distributing such collected seed germplasm and information as widely as possible among U.S. farmers.[12] The U.S. government thus laid the foundation for expanded commercial agriculture in the twentieth century.[13]

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[9] Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 31 (1989), *available at* https://courses.washington.edu/techdev/readings/hettinger_justifying.pdf.

[10] *See* KLOPPENBURG, *supra* note 5, at 157-61 (discussing development and expansion of intellectual-property concepts with respect to PRGs).

[11] FOWLER, UNNATURAL SELECTION; *supra* note 1, at 15-21.

[12] *Id.* at 17.

[13] "[T]he United States may have been a latecomer in the botanical chess game of the colonial era, but this is not to say that the country did not participate." *Id.* at 14. Early political leaders including Thomas Jefferson, George Washington, and Benjamin Franklin were enthusiastic importers of exotic plant material into the country. *Id.* Jefferson is often quoted as noting that "[t]he greatest service which can be rendered to any country is to add a useful plant to its culture." *Id.* Most of the original seed stocks in the United States were either brought into the country by immigrant families or imported by the U.S. government. *Id.* at 15. Later, in the early part of the nineteenth century, the U.S. government played an active role in obtaining crop diversity and facilitating its testing and adaptation as a means of commercially expanding agriculture. *Id.* By 1878, the U.S.

In the United States, from the 1860s onward, land-grant universities played a major role in disseminating agricultural information and germplasm by breeding plants tailored to local soil, climate, and pests.[14] For example the Morrill Act,[15] passed in 1862, established a system of public land-grant agricultural universities.[16] Additionally that same year, the U.S. Department of Agriculture (USDA) was established.[17] In the second half of the nineteenth century, the U.S. government played a major role in promoting, sustaining, and expanding domestic agriculture. As mentioned before, the 1862 Morrill Act created an extensive system of agricultural land-grant universities.[18] Additionally, the USDA promoted and worked with State Agricultural Experimental Stations (SASEs).[19] These SASEs worked with farmers and plant breeders from land-grant universities to improve and adapt crop varieties to local soil and climate conditions.[20]

Drawing on extensive governmental seed collection, the USDA embarked on an ambitious program of mailing seeds to U.S. farmers, subsidized by the free franking privileges of members of Congress.[21] By

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Department of Agriculture, created sixteen years earlier, was spending a third of its budget on germplasm collection and distribution. *Id.* at 15-16. This distribution entailed handing farmers enough seed to facilitate experimentation, but not enough to supply commercial farming needs. *Id.* at 17. The U.S. government thus encouraged the individual farmer to be a selector, breeder, and multiplier of seed. *Id.* at 17.

[14] In 1862, the Morrill Act, *see* 7 U.S.C.A. § 301 et seq. (Westlaw 2009), led to the creation of public land-grant universities on the premise that states should create centers of education that teach "agriculture and the mechanic arts." *Id.* Federal funds were disbursed to the various states based on the number of each state's congressional representatives, providing each state with an endowment to form at least one university; hence, the term "land grant university." *Id.* In 1890, a second Morrill Act provided funding to support seventeen land-grant institutions created especially to serve African Americans in southern states. *Id.* As of 1994, when the Equity in Educational Land Grant Status created twenty-nine Native American colleges in the western and plains states, the total number of land-grant universities had peaked in excess of 100. James Stuart, Comment, *The Academic-Industrial Complex: A Warning to Universities*, 75 U. COLO. L. REV. 1011, 1023-24 (2004). These state-supported land-grant universities were part of the government's undertaking in the task of plant improvement. KLOPPENBURG, *supra* note 5, at 12. At the time, it was apparent that a productive agricultural sector was contingent upon the development of improved crop varieties. *Id.* Since private capital was lacking, it became evident that government funding was needed to accomplish this development. *Id.*

[15] 7 U.S.C.A. § 301 et seq. (1862) (Westlaw 2009).

[16] KLOPPENBURG, *supra* note 5, at 58.

[17] *Id.*

[18] *Id.*

[19] *Id.*; *see also* JIM HIGHTOWER, HARD TOMATOES, HARD TIMES: THE HIGHTOWER REPORT 8 (1978); DAVID B. DANBOM, THE RESISTED REVOLUTION: URBAN AMERICA AND THE INDUSTRIALIZATION OF AGRICULTURE 1900-1930 17 (1979).

[20] KLOPPENBURG, *supra* note 5, at 58.

[21] *Id.* at 63.

the turn of the twentieth century, millions of seed packages were mailed by the USDA to U.S. farmers.[22]

At the end of the nineteenth century, crop genetic diversity was a resource that was taken for granted by all concerned. This was because crop genetic diversity was not susceptible to commodification. While Gregor Mendel had been uncovering the laws of heredity in the middle nineteenth century, his work had not achieved recognition at the time, so plant breeding remained much more of an art than a science.[23]

Second, because of the ability of farmers who purchased seed to save and re-grow seeds, the private seed business encountered obstacles to large-scale capitalist operations—so long as the initially purchased commodity could be freely reproduced and improved without repurchase, investment would be deterred.

Third, substantial public-sector subsidy and support for farming and related activities also deterred private investment in seed selling.

Taken together, these three factors created considerable crop genetic diversity in the early twentieth century arising from decentralized adaptation of crops to different soil and climate conditions in different regions of the country.

However, this began changing in the early twentieth century, when the SASEs began working on hybrid corn, and private firms such as Pioneer Hi-Bred began moving into the market for high-yielding hybrid corn.[24] By the end of the 1920s, private firms were treating the parent lines used to produce hybrid corn as proprietary trade secrets.[25] The USDA discontinued its program of free seed distribution to farmers in the 1920s.[26] Additionally, the SASEs and land-grant universities found themselves displaced by private firms in their plant improvement and distribution efforts and were increasingly channeled into "basic" rather

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[22] *Id.* at 63-64. The top annual volume of seed distributed by the USDA was 22,195,381 packages in 1897, with each package containing packets of different varieties. *Id.* at 64.

[23] *Id.* at 69, 77; *see also* ERNST MAYR, THE GROWTH OF BIOLOGICAL THOUGHT: DIVERSITY, EVOLUTION, AND INHERITANCE (1985); CHARLES E. ROSENBERG, NO OTHER GODS: ON SCIENCE AND AMERICAN SOCIAL THOUGHT (1977); EDWARD M. EAST, THE RELATION OF CERTAIN BIOLOGICAL PRINCIPLES TO PLANT BREEDING (1907); FOWLER, UNNATURAL SELECTION, *supra* note 1, at 46, 48 ("Mendel's theories were seemingly neither accepted nor understood when they were public in 1866. . . . [T]he importance of his work was not realized until it was 'rediscovered' by . . . several scientists . . . in 1900.").

[24] *See* FOWLER, UNNATURAL SELECTION, *supra* note 1, at 52 (stating that Pioneer Hi-Bred, founded in 1926, among other companies and agricultural colleges, was instrumental in the proliferation of hybrid corn; for instance, hybrid corn numbers jumped from 4% of corn acreage in 1933 to 90% in 1945).

[25] *See id.* at 52-61.

[26] *Id.* at 63.

than "applied" research. Moving forward, SASEs and land-grant universities were seen as sources of input for private agricultural industry, rather than as competitors. From the 1930s onward, U.S. agriculture has become increasingly rationalized and industrialized. During this period, many farmers stopped saving seed and began producing crops for an increasingly large commercial marketplace that favored crop uniformity and higher yield—shifting toward purchased seed stock.

IV. THE "GREEN REVOLUTION" AND GENETIC EROSION

A. CHANGES IN THE DIVISION OF LABOR IN THE AGRICULTURAL SECTOR: PUBLIC AND PRIVATE AGRICULTURAL RESEARCH AND DEVELOPMENT

The middle twentieth century brought significant changes in the division of labor in the agricultural sector, both nationally and internationally. In the United States, these changes were reflected in the changing mission of public land-grant universities, which had encouraged and trained public plant breeders from the late nineteenth century onward.[27] As mentioned earlier, this involved re-characterizing their core role as one of basic scientific agricultural research, as opposed to being in the business of producing public plant breeds that were in competition with breeds and hybrids produced by increasingly powerful private-sector companies such as Pioneer Hi-Bred, Garst Seeds, and Cargill.[28] This displacement of public plant breeding from the central position it occupied in the late nineteenth and early twentieth centuries to a marginal position not only cleared the way for the privatization of seed production, but also meant the displacement of the model of *plant*

[27] The public agricultural research system had been the target of critics who questioned the quality of its work. The land-grant universities along with the USDA were accused of "parochialism, bureaucratic inefficiencies, and inability or unwillingness to support basic research of critical importance." KLOPPENBURG, *supra* note 5, at 235. A report issued jointly by the Rockefeller Foundation and the White House Office of Science and Technology Policy, which came to be known as the Winrock Report, warned that unless the current situation was improved, the nation would not be in a position to harness the benefits of newly emerging advances in biotechnology. *See id.*

[28] The Winrock Report provided a template for reforming public agricultural research along lines more amenable to the needs of capital. This reform would be accomplished in three ways. First, the highly decentralized system that existed previously would be streamlined; part of this streamlining process involved creating a competitive grant system by which institutions outside the land-grant system could access funds administered by the USDA. *Id.* Second, research and the associated funding would be redirected to basic scientific research. *Id.* Third, industry would have a greater opportunity in determining social division of labor in agricultural research. *Id.*

improvement that had emphasized free exchange of seed germplasm, breeding techniques, and information.[29] These plant-improvement practices had the effect of maintaining and enlarging plant genetic diversity. Public plant breeds were replaced with hybrids developed from closed proprietary lines—heralding a move towards asserting legally protected rights in new plant varieties and away from enlarging plant genetic diversity.[30]

The environmental effects of this shift from public plant breeding and open exchange of plant materials, techniques, and information to a private proprietary market model in the early twentieth century had significant repercussions that did not become fully evident for decades.

B. THE RISE OF INTELLECTUAL PROPERTY IN PLANT GENETIC RESOURCES IN THE TWENTIETH AND TWENTY-FIRST CENTURIES

Patent and para-patent laws applicable to plants began emerging during the first three decades of the twentieth century, crystallizing in the U.S. Plant Patent Act of 1930.[31] These laws were imperfect and incomplete in their tracking of technological plant breeding advances such as hybridization. For example, the Plant Patent Act of 1930 provided limited intellectual-property protection to *asexually* reproduced plants, i.e., plants reproduced through grafting or cloning, such as many fruit trees.[32] Hybrid corn is a sexually reproduced crop and fell outside the ambit of the Plant Patent Act,[33] although private hybrid corn firms utilized state-based trade-secrets law to protect the parent lines used to produce hybrid corn.[34] This meant that farmers growing hybrid crops

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[29] *See, e.g.*, MICHAEL R. TAYLOR & JERRY CAYFORD, AMERICAN PATENT POLICY BIOTECHNOLOGY AND AFRICAN AGRICULTURE: THE CASE FOR POLICY CHANGE 8 (2003) ("For most of history, innovation in seed technology has been a freely shared or public good . . . . With the advent of biotechnology and the availability of plant patents, the balance between the public and private sectors . . . has shifted.").

[30] *See generally* Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 278-80 (2003) ("The nineteenth and early twentieth centuries provided ample genetic diversity for both public and private plant breeders to introduce new traits into the cultivated varieties. However, this process has now become a booming market through which proprietary varieties are introduced with the accompanying genetic uniformity.").

[31] *See* 35 U.S.C.A. § 161 et seq. (1930) (Westlaw 2009).

[32] 35 U.S.C.A. § 161 (Westlaw 2009) ("Whoever invents or discovers and asexually reproduces any distinct and new variety of plant . . . may obtain a patent therefor . . . .").

[33] *See* 35 U.S.C.A. § 161 (Westlaw 2009) (extending patent protection to asexually reproduced plants).

[34] *See, e.g.*, Peter J. Goss, *Guiding the Hand That Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1417 (1996) (noting that companies producing hybrid corn, most notably Pioneer Hi-Bred, used "Confidentiality"

needed to return season after season if they wanted to continue growing hi-yield hybrid varieties.[35] Firms selling hybrid seed could effectively prevent farmers who bought their seed from reproducing further generations of the hybrid corn using "hybrid vigor" seeds in which the higher yield would last for only one crop season.[36]

These laws did not arise because of new technologies, but in large part because of political pressure from nursery companies trying to protect their market shares in asexually reproduced (cloned) trees produced through cuttings and grafting, and because of deep structural changes in markets for agricultural produce.

The 1930 Plant Patent Act[37] was followed and expanded four decades later by the Plant Variety Protection Act of 1970[38] and the 1980 Plant Variety Protection Act amendments,[39] as well as significant judicial decisions expanding the scope of patent to cover living organisms.[40]

Against the backdrop of these legal developments, the "Green Revolution"[41] occurred globally, and the trend toward industrialized, mass commercial agriculture that is highly dependent on chemical inputs such as fertilizers, pesticides, and herbicides continued.[42] At the core of these developments was the attempt to create legal mechanisms for the economic control of plants, plant varieties, and ultimately, plant genes that express particular traits.

One cannot consider the past two decades of legal and technological

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provisions in their seed purchase agreements, stating that "[o]ne or more of the parental lines used in this hybrid are the exclusive property of Pioneer Hi-Bred . . . . Buyer agrees that purchase of this bag of seed does not give any rights to use any such parental line seed which may be found herein . . . . This language puts the purchaser on notice that Pioneer's hybrid parent lines are trade secrets.").

[35] *Id.* at 1418.

[36] *Id.*

[37] 35 U.S.C.A. §§ 161-164 (Westlaw 2009).

[38] 7 U.S.C.A. §§ 2321-2582 (Westlaw 2009).

[39] Pub. L. No. 96-574, § 20, 94 Stat. 3352 (1980).

[40] *See, e.g.,* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[41] The so-called "Green Revolution" involved the widespread dissemination of hi-yielding crop varieties that were heavily dependent on herbicides, pesticides, fertilizers and other chemical inputs. *See* BRUSH, *supra* note 4, at 202-03. The core idea of the "Green Revolution" was the idea of creating one seed to feed the world (using heavy chemical inputs), which was in marked contradistinction to the traditional approach to agriculture that sought to adapt seeds to local climate and soil conditions. *Id.* By the 1970s, institutions such as the Rockefeller Foundation that had promoted high-input industrial agriculture in the developing world recognized that the "Green Revolution" had resulted in alarming erosion of agricultural genetic diversity, spurring the formation of the Consultative Group for Agricultural Research (CGIAR), the International Board for Plant Genetic Resources (IBPGR), and the related international network of genetic seed libraries to preserve and make available to plant breeders plant genetic diversity that such libraries contained. *Id.*

[42] TAYLOR & CAYFORD, *supra* note 29, at 328 n.19.

development in PGRs without also taking account of the heavy influx of investment into biotechnology following the U.S. Supreme Court's *Diamond v. Chakrabarty*[43] decision in 1980 and the subsequent rise of recombinant DNA technology. This new technology allowed corporate plant breeders to manipulate genetic sequences of plants on the finely tuned molecular level and acquire an exclusive (though temporally limited) monopoly in those sequences that expressed particular plant traits.[44]

The passage of the Bayh-Dole Act[45] transformed the nascent U.S. biotechnology industry as well, speeding the licensing of public university research via technology transfer.[46] The Bayh-Dole Act mandated the patenting of all inventions produced at public research universities receiving federal funding.[47] The Bayh-Doyle Act triggered new requirements for mandating trade secrecy regarding any potentially patentable inventions—including U.S. utility patents in living organisms.

On the international front, there have been several key developments with regard to plant genetic resources and intellectual property. Controversies over intellectual-property rights in PGRs have played out (and are playing out) on the international level.[48] This Article

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[43] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[44] New genetic information can now be incorporated into an organism's pre-existing DNA through a number of recombinant DNA techniques. One technique is gene splicing, whereby scientists first isolate the gene responsible for the trait they would like to transfer to the target organism. This isolation is accomplished using restrictive enzymes -- chemicals that break the DNA into fragments. The next step is to transfer the isolated gene to the target, which can be done by use of a weakened bacterium to infect the target organism; if all goes as planned, the bacterium transfers the new DNA into the chromosomes of the host. Cynthia C. Urbano, *Gene Splicing: How Does It Work and What Can It Do?*, AM. NURSERYMAN, Oct. 15, 2004, at 44.

[45] Bayh-Dole University and Small Business Patent Procedures Act, Pub. L. No. 96-517, § 6(a), 1980 U.S.C.C.A.N. 3015, 3018-29 (1980) (codified at 35 U.S.C. § 200-212 (2000)); *see also* Bd. of Trs. of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 487 F. Supp. 2d 1099 (N.D. Cal. 2007).

[46] Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261, 262 (2006); Sara Boettiger & Alan B. Bennett, *Bayh-Dole: If We Knew Then What We Know Now*, 24 NATURE BIOTECHNOLOGY 320 (2006), *available at* www.nature.com/nbt/journal/v24/n3/abs/nbt0306-320.html.

[47] Sara Boettiger & Alan Bennett, *The Bayh-Dole Act: Implications for Developing Countries*, 46 IDEA 261, 262 (2006). For a discussion on the impact of the Bayh-Dole Act on university-based research in the scientific realm, see Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289 (2003).

[48] *See* BRUSH, FARMERS BOUNTY, *supra* note 4; KLOPPENBURG, *supra* note 5, at 152; *see also* ANTHONY J. STENSON & TIM S. GRANT, THE POLITICS OF GENETIC RESOURCE CONTROL (1999); ROBIN PISTORIUS & JEROEN VAN WIJK, THE EXPLOITATION OF PLANT GENETIC INFORMATION: POLITICAL STRATEGIES IN CROP DEVELOPMENT (1999); RIGHTS TO PLANT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE: BASIC ISSUES AND PERSPECTIVES (Susan Biber-Klemm & Thomas Cottier eds., 2006).

analyzes and critiques developments such as the 1992 Rio Conference and the resulting Convention on Biodiversity (CBD),[49] the 2001 Cartagena Protocol,[50] the creation of the World Trade Organization (WTO),[51] the ongoing implementation of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS),[52] and the 2001 Doha Round[53] of the WTO and its subsequent collapse in Cancun in the summer of 2003.[54] Also considered are the network of international

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[49] United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 1730 U.N.T.S. 79, 31 I.L.M. 818, *available at* www.eoearth.org/article/Convention_on_Biological_Diversity [hereinafter CBD]. For a study on the achievements, limitations, and implications of the United Nations Convention on Biological Diversity, see MICHAEL GRUBB ET AL., THE EARTH SUMMIT AGREEMENTS: A GUIDE AND ASSESSMENT 75-82 (Brookings Inst. Press 1993); *see also* Amanda Hubbard, Comment, *The Convention on Biological Diversity's Fifth Anniversary: A General Overview of the Convention—Where Has It Been and Where Is It Going?*, 10 TUL. ENVTL. L. REV. 415 (1997); Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L. Q. 255 (1998).

[50] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 39 I.L.M. 1027 (2000).

[51] "The Uruguay Round of multilateral trade negotiations held under the framework of the General Agreement on Tariffs and Trade ('GATT') was concluded on December 15, 1993. The agreement embodying the results of those negotiations, the Agreement Establishing the World Trade Organization was adopted on April 15, 1994, in Marrakech." INTRODUCTION TO INTELLECTUAL PROPERTY 475 (World Intellectual Property Organization ed., 1997). *See also* Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 33 I.L.M. 1140 (1994).

[52] Marrakech Agreement Establishing the World Trade Organization, Apr. 15, 1994, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade, 33 I.L.M. 81, 84 [hereinafter TRIPS]; *see also* "The Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations," 33 I.L.M. 1, 9 (1994). This agreement was signed by ministers in Marrakech, Morocco, on April 15, 1994, and was meant to clarify the results of the negotiations since the Round was launched in Punta del Este, Uruguay, in September 1986. A summary of the Final Act of the Uruguay Round is available online at the WTO website at www.wto.org/english/docs_e/legal_e/ursum_e.htm#nAgreement (last visited Sept. 28, 2009). For a comprehensive analysis of the TRIPS agreement and its history see DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (2003); *see also* JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 11-47 (2001).

[53] In November 2001, the WTO meeting in Doha, Qatar, set in motion discussion meant to further liberalize global trade, this time bearing in mind the needs of poorer nations. *The WTO Under Fire—The Doha Round*, THE ECONOMIST (U.S. Edition), Sept. 20, 2003, at 26. However, there were sticking points that were not ultimately resolved, mainly agricultural subsidies. *Id.* The Doha Round was meant to "reduce trade-distorting farm support, slash tariffs on farm goods and eliminate agricultural-export subsidies in areas poor countries cared about, such as textiles." *Id.* For documents relating to the Doha Round, visit www.wto.org/english/tratop_e/dda_e/dda_e.htm (last visited Mar. 9, 2005).

[54] The Cancun negotiations were doomed from the start, as countries seemed to disavow significant parts of the Doha Round. *See The WTO Under Fire—The Doha Round*, *supra* note 53, at 26-27. The European Union, for example, denied it had agreed to get rid of export subsidies. *Id.* Poorer countries, for their part, denied they assented to participating in talks on new rules. *Id.* Agriculture was the biggest issue dividing negotiators. *Id.* To ease the stalemate, the European Union and the United States proposed a framework to free farm trade. *Id.* This framework, however,

agricultural research stations and seed-conservation banks administered by the Rockefeller Foundation Consultative Group on International Agricultural Research (CGIAR)[55] and the role of the United Nations Food and Agriculture Organization (FAO).[56]

This section briefly introduces the legal protections available to plant breeders prior to and following the landmark 1980 *Chakrabarty* decision. It then examines developments in U.S. intellectual-property law vis-à-vis plants from 1980 onward as a backdrop to a discussion of the emergence of concurrent international and transnational legal regimes regarding PGRs.

i. A Very Brief Overview of Pre-1980 Intellectual-Property Protection for Plants

a. U.S. Patent Law

This Article most definitely does not argue that a goal of the U.S. patent system has been the conservation of plant genetic biodiversity. However, to discuss questions of preservation of biodiversity arising during the twentieth century, understanding the trajectory of patent protection, particularly with regard to patents in living organisms, is important. This section briefly summarizes several important points about patents in the United States, and because the United States has been instrumental in shaping international trade regimes such as TRIPS, a basic understanding of U.S. patent law is relevant.

An express grant of power to Congress in the U.S. Constitution to "promote the Progress of Science and useful Arts" underwrote the U.S. patent regime from 1790 onward.[57] A patent may be thought of as a

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was rejected by poor nations that felt it did not go far enough: for instance, export subsidies would remain in place under the proposed framework. *Id.*

[55] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 182-83.

[56] The FAO is a United Nations agency mandated to lead international efforts in the fight against hunger. Food and Agric. Org. of the U.N., About FAO, www.fao.org/UNFAO/about/index_en.html (last visited Sept. 17, 2009). It is meant to be a neutral forum where all member nations meet as equals to debate policy and negotiate agreements in addition to aiding developing countries in their transition towards modern agriculture, forestry, and fisheries practices. *Id.* More information on the FAO and its activities is available at www.fao.org/UNFAO/about/index_en.html.

[57] U.S. CONST. art. I, § 8, cl. 8 (granting Congress the broad power to legislate in order to "promote the Progress of Science useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."). In exercising this authority, Congress enacted the first Patent Act (now codified as 35 U.S.C. § 101), which President George Washington signed into law on April 10, 1790. *See generally* Edward C. Walterscheid, *The Use and Abuse of History: The Supreme Court's Interpretation of Thomas Jefferson's Influence on Patent Law*, 39 IDEA 195 (1999); *see also* BRUCE BUGBEE, THE GENESIS OF AMERICAN PATENT

temporally and geographically limited grant of a monopoly by the government to a particular inventor who receives the exclusive right to "make, use or sell" the patented invention.[58] There are several rationales supporting granting a patent to an inventor. The first, the "incentive theory"[59] posits that the grant of exclusive rights creates incentives for inventors to develop new products or processes and bring them to market.[60] A second rationale is that the grant of exclusive rights facilitates the widespread dissemination of socially useful information.[61] Finally, there are traces of a Lockean "natural rights" argument—inventors ought to, as a normative matter, hold title to their own creations.[62]

Patents issued under the U.S. Patent Act, which is codified at 35 U.S.C. § 101 *et seq.*, are referred to as "utility" patents on account of the requirement that a patentable invention under the Act be useful.[63] U.S. patent law protects inventions that fall within the category of patentable

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AND COPYRIGHT LAW (1967); David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J.L. & TECH. 7, 17 (2003).

[58] The current U.S. patent term is twenty years from application. *See* Mark A. Lemley, *An Empirical Study of the Twenty Year Patent Term*, 22 AIPLA Q. J. 369, 370 (1994). Prior to the adoption of the current term in 1995, the U.S. term was seventeen years from the issue of the patent. *Id.* Also note that the exclusive right conferred by the patent enables a patent owner to sue anyone who "makes, uses, or sells" the patented invention within the United States for the term of the patent. *Id.*

[59] Kenneth L. Port, *Foreword: Symposium on Intellectual Property Law Theory*, 68 CHI.-KENT L. REV. 585, 591 (1993); *but cf.* Edmund Kitch, *The Nature and Function of the Patent System*, 30 J. L. & ECON. 265 (1977) (advancing the "prospect" theory of patent protection: patents are entitlements to innovate within particular fields).

[60] In granting this exclusive right, in effect excluding others from appropriating the particular invention without the inventor's consent, the state enables inventors not only to recoup the associated developmental costs, but also, and more importantly, to financially benefit from their inventions, with the ultimate goal being the progress of the sciences. *See* David G. Scalise & David Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exceptions for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 86-87 (1995).

[61] Without adequate legal protections, "inventors would be likely to shroud their new ideas in secrecy while attempting to realize commercial value." *Id.* at 87. Such secrecy would lead to an inefficient and duplicative research process. *Id.* Current patent statutes seek to reverse this tendency by mandating the full disclosure of the patented products or processes. *Id.* Disclosed information becomes freely available to the public, thus permitting the development of derivative inventions once patent holders are compensated. *Id.*

[62] Adam Mossoff, *Rethinking the Development of Patents: An Intellectual History, 1550-1800*, 52 HASTINGS L. J. 1255, 1257 (2001); Port, *supra* note 59, at 591 (noting further that because a statute cannot grant or deny rights in one's own intellectual creations, "an inventor has title in and to these inventions regardless of any statutory monopoly").

[63] Michael T. Roberts, *National Aglaw Center Research Article,* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*: Its Meaning and Significance for the Agricultural Community*, 28 S. ILL. U. L.J. 91, 97 (2003).

subject matter,[64] and that are novel,[65] nonobvious,[66] and useful.[67] Additionally, the U.S. Patent Act requires that the invention be disclosed and described in a written description in such a way as to enable others to make and use the invention following the expiration of the patent term.[68] There are "four broad categories of patent-eligible subject matter: compositions [of matter], machines, articles of manufacture, and processes."[69] While patentable subject matter includes "any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof,"[70] mathematical formulae,[71]

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[64] 35 U.S.C. § 101 broadly states that the categories of patentable subject matter may include "any . . . process, machine, manufacture, or . . . improvement thereof . . . ." 35 U.S.C.A. § 101 (Westlaw 2009); *see also* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that a living, human-made organism was patentable subject matter under 35 U.S.C. § 101).

[65] *See* 35 U.S.C.A. § 102 (Westlaw 2009) (stating the requirement that there be no identical prior inventions that were made before or sold more than a year before a patent application was filed, or otherwise disqualified by pre-existing prior art). The single source rule is utilized in order to determine whether an invention is novel. Port, *supra* note 59, at 592-93. An invention is not novel if a single instance of prior art discloses each claimed element. *Id.* For example, if an article described the elements of a machine prior to the patent application, the application would be held invalid since the article was already anticipated. *Id.*; *see also* Rosaire v. National Lead Co., 218 F. 2d 72 (5th Cir. 1955).

[66] *See* 35 U.S.C.A. § 103 (Westlaw 2009). This is probably the most important requirement for a patent. The "nonobviousness" inquiry analyzes the technical accomplishment or inventive step represented by a particular invention—in essence, whether the invention is a big-enough technical step beyond prior art known in a particular field. *See* Graham v. John Deere, 383 U.S. 1, 35-37 (1966). Nonobviousness prevents patents from issuing when a person with ordinary skill would have found the invention to be "obvious" when it was made. *Id.*; *see also* KSR Int'l v. Teleflex, Inc., 550 U.S. 398 (1007).

[67] *See* 35 U.S.C.A. § 101 (Westlaw 2009) ("Whoever invents . . . any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent therefor . . . ."). To be useful, an invention need only be operable and capable of performing some function. *See* Brenner v. Manson, 383 U.S. 519 (1966).

[68] 35 U.S.C. § 112 requires that a patentee give a sufficiently good description of their patented invention so that "one of ordinary skill in the art" would be able to make and use the invention – a combination of disclosure and enablement, so that when the patent expires, the invention may be freely practiced. *See* 35 U.S.C.A. § 112 (Westlaw 2009); *see also* The Incandescent Lamp Patent, 159 U.S. 465 (1895).

[69] Mark D. Janis, *Sustainable Agriculture, Patent Rights, and Plant Innovation*, 9 IND. J. GLOBAL LEGAL STUD. 91, 94 (2001).

[70] 35 U.S.C.A. § 101 (Westlaw 2009).

[71] Initially, the question whether software could be patented was framed as whether an invention consisting of a mathematical algorithm was patentable subject matter. In *Gottschalk v. Benson*, Justice William O. Douglas equated "numerical conversion software" at issue in the case with laws of nature and naturally occurring products. Gottschalk v. Benson, 409 U.S. 63 (1972). However, a subsequent case opened the door for patent protection for software-related inventions. *See* Diamond v. Diehr, 450 U.S. 175 (1981); *see also* State Street Bank & Trust v. Signature Financial Servs., 149 F.3d 1368 (Fed. Cir. 1998); Donald Chisum, *The Future of Software Protection: The Patentability of Algorithms*, 47 U. PITT. L. REV. 959 (1986). *But cf.* Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other*

natural laws,[72] and products of nature are generally considered unpatentable.[73]

With this basic background, we can now move on to examining how the scope of patent and patent-like protection for plants is similar to and different from the scope of protection accorded traditional utility patents.

b. Rationale for the Exclusion of Plants as Patentable Subject Matter Under 35 U.S.C. § 101

Plants and other biological subject matter are not included in the express description of patentable matters in 35 U.S.C. § 101.[74] Until the *Chakrabarty* decision in 1980, the view taken by the Commissioner of Patents was that plants did *not* fall under the purview of the protections afforded under § 101 since they were "products of nature" and not inventions.[75] Moreover, in the pre-*Chakrabarty* era, the written-description requirement specified in 35 U.S.C. § 112 was seen as imposing an insurmountable hurdle that precluded the extension of utility-patent protection to plants.[76] Additionally, the fact that Congress

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Computer Program-Related Inventions, 39 EMORY L. J. 1025 (1990); *see also* Symposium "Article of Manufacture" Patent Claims for Computer Instruction, 17 J. MARSHALL J. COMPUTER & INFO. L. 5 et seq. (1998); John R. Thomas, *The Patenting of the Liberal Professions*, 40 B.C. L. REV. 1139 (1999); Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L. J. 577 (1999).

[72] O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853). (denying Samuel Morse a claim on the use of "electromagnetism, however developed, for making or printing intelligible characters, signs or letters, at any distances."). *But cf.* The Telephone Cases, 126 U.S. 1 (1887) (upholding a patent issued to Alexander Graham Bell for his telephone).

[73] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (holding that a species of root-nodule nitrogen-fixing bacteria was an unpatentable "product of nature"); *cf.* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that a "human-made, genetically engineered bacterium capable of breaking down components of crude oil" was patentable subject matter and was a not a pre-existing product of nature.); Parke-Davis & Co. v. H. K. Mulford Co., 189 F. 95 (C.C.S.D.N.Y. 1911) (holding that a refined purified form of adrenaline was patentable).

[74] 35 U.S.C.A. § 101 (Westlaw 2009) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."); *see also* Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 427-29 (1989).

[75] *See* Seay, *supra* note 74, at 419 (stating that "[t]his proposition was cited as the holding by the Commissioner of Patents in *Ex parte Latimer*, 1889 Comm'n Dec. 123 (1899), . . . which held that the fiber from the needle of an evergreen tree was an unpatentable product of nature."); *see also* *Ex parte* Latimer, 1889 Commn. Dec. 123 (1889) (holding that fiber from the needle of an evergreen tree was an unpatentable product of nature).

[76] 35 U.S.C.A. § 112 (Westlaw 2009). 35 U.S.C. § 112 specifically states that

> [t]he specification shall contain a written description of the invention, and of the manner and

had extended patent-like protection to asexually reproduced plants in 1930 and protection to sexually reproduced plants in 1970 allowed arguments that *both* asexually reproduced and sexually reproduced plants were excluded from § 101 utility-patent protection.

c. The Plant Patent Act of 1930[77]

As early as the 1880s private plant breeders called for the establishment of a system for patenting plants.[78] After decades of seeking intellectual-property protection for sexually reproduced plants, private plant breeding firms eventually ended up with the Townsend-Purnell Plant Patent Act of 1930 (PPA), the first legislation of its type anywhere in the world.[79] The word "plant" in the PPA is used in its lay sense rather than a strict scientific sense; therefore, under the PPA, bacteria are not eligible.[80] The congressional intent behind the Act, which extended patent-like protection to asexually propagated species,[81] was to provide nursery firms with incentives and protections for developing new

process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention. *Id.*

[77] 35 U.S.C.A. § 161 (Westlaw 2009).

[78] A bill supported by the American Breeders Association was introduced in Congress, supposedly to accomplish the goal of patenting plants; it never made it past the committee stage and was eventually abandoned. *See* Aoki, *supra* note 30, at 279. "Breeders argued that plants were akin to machines and as such, innovations in the way that plants 'worked' should be protected in the same way that innovations in machinery were protected through patent law." *Id.* Along the same lines, Thomas Edison, a proponent of plant patents, testified before Congress that "nothing that Congress could do to help farming would be of greater value and permanence than to give the plant breeder the same status as the mechanical and chemical inventors now have through the law." *See* Roberts, *supra* note 63, at 98.

[79] Anne E. Crocker, *Will Plants Finally Grow into Full Patent Protection on an International Level? A Look at the History of U.S. and International Patent Law Regarding Patent Protection for Plants and the Likely Changes After the U.S. Supreme Court's Decision* in J.E.M. Ag Supply v. Pioneer Hi-Bred, 8 DRAKE J. AGRIC. L. 251, 257 (2003). Initially, the PPA was included in the section governing utility patents but in a redrafting of the U.S. Patent Act of 1952, the Act was moved to a separate section now codified as 35 U.S.C. § 161. *See* Aoki, *supra* note 30, at 282 (citing *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, noting that there has been considerable ambiguity as to what Congress intended by this move). Like utility patents, plant patents are administered by the PTO, which is part of the United States Department of Commerce. *Id.* at 287-88.

[80] In re Arzberger, 112 F. 2d 834 (C.C.P.A. 1940).

[81] These species are those that are vegetatively produced from cuttings or grafts and not grown from seed. Goss, *supra* note 34, at 1406. The rationale for the restriction to asexually propagated plants was the belief that plant varieties could not be reproduced reliably by seed. Debra L. Blair, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 310 (1999).

varieties and innovations similar to those used to encourage mechanical and scientific developments in other industries.[82]

To qualify for protection under the PPA, the plant breeder must show that the plant for which protection is sought possesses new and unique characteristics and that the plant may be reproduced through budding, grafting, or cutting techniques that result in a new plant variety with the exact same, unique characteristics.[83] The variety must be distinct,[84] new,[85] and non-obvious.[86] Notably, the PPA contains an exemption from compliance with the written-description requirement of 35 U.S.C. § 112.[87] Accordingly, the U.S. Patent and Trademark Office (PTO) accepts the deposit of biological specimens at specified repositories as fulfilling the § 112 requirement.[88]

Protection under the PPA gives the plant-patent holder the exclusive right to reproduce the patented plant by asexual means.[89] A plant-patent application may include only a single claim applicable to the plant for which protection is sought.[90] However, the courts are split as to whether a plant patent covers the independent derivation of a plant possessing the same varietal characteristics of a protected plant or whether patent protection applies only to plant material that is actually

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[82] Crocker, *supra* note 79, at 257.

[83] *Id.*

[84] To be distinct the variety must have characteristics that are clearly distinguishable from those of existing varieties. *See* Yoder Bros, Inc., v. California-Florida Plant Corp., 537 F.2d 1347, 1377-78 (5th Cir. 1976). The PPA substituted the requirement of distinctness for the requirement of utility. Distinctness may be measured by the characteristics that make a particular plant distinct from others, but do not have to make a plant superior. *Id.*

[85] "New" in this context means that the variety has not previously existed. *Id.*

[86] "Non-obvious" means that the variety is sufficiently different from previous varieties so as not to be obvious at the time of invention to someone having ordinary skill in the art. *Id.* at 1378-79.

[87] 35 U.S.C.A. § 162 (Westlaw 2009). However, the exemption is not absolute since it permits noncompliance only "if the description is as complete as is reasonably possible." *Id.*; *see* Seay, *supra* note 74, at 422 (referring to 35 U.S.C. § 162 (1982)).

[88] *Id.* at 422. This seed deposit alternative is significant. *See* Crocker, *supra* note 79, at 257-58. The development of traditional plant varieties were difficult to record on paper with sufficient detail to satisfy the "written requirement," yet the same developments could be readily seen with the naked eye. *Id.*

[89] Seay, *supra* note 74, at 422. The PPA has significant limitations; the most important one is that most agricultural crop plants are reproduced sexually and multiplied by seed, thus falling outside the purview of the PPA. Crocker, *supra* note 79, at 258. Naturally, the PPA provided little or no incentive for researchers of such crops to create new varieties. *Id.* Also, the PPA "provides patent protection for only a plant in its entirety and does not permit separate claims for parts of the plant." Nicholson, *supra* note 57, at 18.

[90] 35 U.S.C.A. § 162 (Westlaw 2009); *see also* MPEP § 1605, as noted in Seay, *supra* note 74, at 422.

derived from a patented plant.[91] Additionally, plant-patent protection has drawbacks: certain parts of the plants may not be protected in the way they would be under a utility patent.[92] Also, the PPA does not bar the sexual propagation of a protected plant or any plant material arising from sexual reproduction of the plant.[93]

Seeking to obtain similar protection for sexually reproduced plants, the American Seed Trade Association unsuccessfully lobbied in support of a bill to amend the PPA.[94] However, changes in the seed market proceeded apace over the next four decades, and by 1970, Congress was willing to extend a form of intellectual-property protection to certain sexually reproduced plant varieties, responding in part to the move in the early 1960s by a group of European countries extending protection to plant breeders that "created" new plant varieties.[95]

d. The Plant Variety Protection Act of 1970

In late 1970, Congress enacted[96] a new form of statutory patent protection for plants styled as the Plant Variety Protection Act (PVPA).[97] Despite the perceived domestic demand for enlarged patent protection for sexually reproduced plants, the PVPA was enacted partially in

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[91] *Compare* Cole Nursery Co. v. Youdath Perennial Gardens, Inc., 17 F. Supp. 159 (N.D. Ohio 1936), *with* Pan-American Plant Co. v. Matsui, 433 F. Supp. 693 (N.D. Cal. 1977).

[92] Seay, *supra* note 74, at 434.

[93] *Id.*

[94] Blair, *supra* note 81, at 310. By 1967 there was a patent law revision pending in Congress. Aoki, *supra* note 30, at 284. The ASTA proposed broadening the reach of the PPA to cover useful "sexually" reproducing varieties by adding "or sexually" to all the relevant sections. *Id.* However, the USDA, agronomists, farmers, and public plant breeders all opposed the move and effectively halted it in its tracks. In spite, and as a result, of this setback, it became apparent that some type of protection for sexually reproducible varieties was inevitable. *Id.* Between 1967 and 1969, the foundation of new statutory provisions was laid during negotiations between the ASTA, the USDA, public plant breeders, and members of Congress. *Id.*

[95] Blair, *supra* note 81, at 307.

[96] As constitutional authority in enacting this statute, Congress invoked both clause 3 (the "commerce clause") and clause 8 (the "patent clause") of Article 1, Section 8. *See* Crocker, *supra* note 79, at 256-59. This statute is now codified as 7 U.S.C. § 2581; *see also* Robert Evenson, *Intellectual Property Rights and Agribusiness Research and Development: Implications for the Public Agricultural Research System*, 65 AM. J. AGRIC. ECON. 967 (1983) (analyzing the degree to which the PVPA helped the U.S. seed industry). *But see* Julian M. Alston & Raymond J. Venner, *The Effects of the U.S. Plant Variety Protection Act on Wheat Genetic Improvement*, 31 RES. POL'Y 527 (2002) (noting that the PVPA may have had little effect on commercial wheat yields).

[97] Crocker, *supra* note 79, at 259. However, "[t]he PVPA itself never refers to the protection afforded or its character as a 'patent'"; rather, the plant variety is issued a "Certificate of Plant Variety Protection." Seay, *supra* note 74, at 424. The PVPA is administered by the Plant Variety Protection Office ("PVPO") of the United States Department of Agriculture. Roberts, *supra* note 63, at 100.

response to Western European nations' formation of the Paris Union in 1960, also known as the International Union for the Protection of New Varieties of Plants (UPOV).[98] The purpose of the PVPA was "to encourage the development of novel varieties of sexually reproduced plants and to make them available to the public, providing protection available to those who breed, develop, or discover them, and thereby promoting progress in agriculture in the public interest."[99] The PVPA provides patent-like protection to plant breeders whose plant varieties breed true-to-type through successive generations.[100] However, successful applicants receive not a patent, but a "Certificate of Plant Variety Protection" (sometimes called a PVP Certificate").[101]

To receive a PVP Certificate, a breeder must show that the plant is (1) distinct, (2) novel, (3) uniform, and (4) stable.[102] "Distinctness" is the most important requirement, and the PVPA provides that distinctness may be based on "one or more identifiable morphological, physiological or other characteristics."[103] Parallel with the problems regarding the § 112 written-description requirement for a utility patent, the PVPA requires that an application for a certificate is expected to generally provide a "description that is 'adequate or as complete as is reasonably possible.'"[104]

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[98] For more on UPOV, see the discussion in this Article, section IV.B.ii.d. While the United States did not join UPOV until 1981, Congress enacted the PVPA eleven years earlier so as to be consistent with UPOV and in the process facilitate patent protection for plant breeders working at both a domestic and an international level. Crocker, *supra* note 79, at 259.

[99] Blair, *supra* note 81, at 312.

[100] Crocker, *supra* note 79, at 259. Variety in the context of the PVPA refers to the taxonomic use of the term. Elisa Rives, *Mother Nature and the Courts: Are Sexually Reproducing Plants and Their Progeny Patentable Under the Utility Patent Act of 1952?*, 32 CUMB. L. REV. 187, 200-01 (2001-2002). This use means that a variety is a

> plant grouping within a single botanical taxon of the lowest rank . . . defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one characteristic and considered as a unit with regard to the sustainability of the plant grouping for being propagated unchanged. *Id.* at 201.

Protection under the PVPA will be denied unless the variety generates the same novel and distinct characteristics when reproduced over multiple generations. The only variations acceptable are those that are "predictable and commercially acceptable, and have reasonable stability." *Id.* This requirement makes protection under the PVPA more difficult to obtain than under the PPA, the latter requiring only that the new variety be new and distinct. *See* Crocker, *supra* note 79, at 259.

[101] Seay, *supra* note 74, at 424.

[102] Nicholson, *supra* note 57, at 19. For definition of these terms, *see* 7 U.S.C.A. § 2402(a) (Westlaw 2009).

[103] 7 U.S.C.A. § 2401(b)(5) (Westlaw 2009); *see also* In re Bergy, 596 F. 2d 952 (C.C.P.A. 1976).

[104] 7 U.S.C.A. § 2422(2) (Westlaw 2009); *see* Roberts, *supra* note 63, at 100-01. The

A PVP Certificate confers on its owner the right to exclude others from "selling the variety, or offering it for sale, or reproducing it, or importing it, or exporting it, or using it in producing . . . a hybrid or different variety therefrom."[105] Receiving a PVP Certificate gives the holder a legal right to exclude others from reproducing, selling, importing, or exporting the protected variety for a period of twenty years.[106] An important feature of the PVPA lies in its exemptions, which include (1) farmers' rights to save seeds,[107] and (2) researchers' rights to use protected plants for further development.[108]

Between 1970, when the PVPA was enacted, and 1985, the USDA issued over 2000 PVPA certificates, with the majority going for

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application need not provide a level of detail necessary to enable other parties to recreate the new variety as mandated by § 112; however, an applicant may satisfy § 112 by furnishing a precise description (by use of a procedural device and deposit of a sample) in a way that permits others to reproduce the variety without unnecessary experimentation. *Id.* However, "neither the [PVPA] statute nor the applicable regulation mandates that such material be accessible to the general public during the term of the PVP certificate." Timothy P. Daniels, *Keep the License Agreements Coming: The Effect of* J.E.M. Ag Supply, Incorporated v. Pioneer Hi-Bred International, Incorporated *on Universities' Use of Intellectual Property Laws to Protect Their Plant Genetic Research*, 2003 B.Y.U. EDUC. & L.J. 771, 776 (2003).

[105] 7 U.S.C.A. § 2483(a) (Westlaw 2009).

[106] Nicholson, *supra* note 57, at 19. Infringement also entails "sexually multiplying the novel variety, using the novel variety in producing (as distinguished from developing) a hybrid or different variety, using seed which has been prohibited from propagation, or distributing the protected variety to another without proper notice." Seay, *supra* note 74, at 424-25.

[107] The depiction by the seed industry of the farmers' right to save seed as a disincentive to investment aimed at developing new varieties prompted Congress to amend the PVPA so as to restrict but not entirely eliminate this exception. Nicholson, *supra* note 57, at 19-20. Currently, a farmer may sell seeds of a protected variety but only that amount of seed that could have been saved for the farmer's own replanting purposes. *Id.*; Delta & Pine Land Co. v. Peoples Gin Co., 694 F.2d 1012 (5th Cir. 1983) (holding that Congress intended the PVPA's exemptions to be read narrowly). The Supreme Court in *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995), interpreted the PVPA as permitting the sale of seed saved for purposes of replanting on the farmer's own acreage with the farmer's primary farming occupation being such that the sale of crops for reasons other than reproductive purposes constitutes the preponderance of the farmer's business in the protected seed. Blair, *supra* note 81, at 313.

[108] Nicholson, *supra* note 57, at 19. The second exemption, the research exemption, allows others to use protected varieties as "stepping stones to develop new varieties and advance agricultural biotechnology through research." Crocker, *supra* note 79, at 261. This exemption was also narrowed by Congress by declaring that a variety that is "essentially derived" from a protected variety would be considered an infringement. *Id.* A side effect of this restriction has been the reduction of the amount of research conducted using protected varieties, based on researchers' fears of violating the PVPA, a recipe for inviting costly litigation. *Id.* Note that the 1970 PVPA exemptions bear significant differences from utility patents, which have no such exemptions, and the PVPA's exemptions have been construed narrowly. *See* Asgrow Seed v. Winterboer, 513 U.S. 179, 185-86 (1995); *see also* J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 136-38 (2001) (holding that availability of PVPA protection did not foreclose the possibility that an "inventor" (plant breeder) might also seek and receive a utility patent for a plant variety meeting the utility-patent standards.).

food crops as opposed to other horticulture.[109] While the PPA and the PVPA provided protection for plant breeders and the seed industry, it was unclear in the 1970s and early 1980s to what extent genetic alterations within a plant's genome would be legally protected. What was the scope of intellectual-property protection available for a plant's genotype vs. its phenotype (the type of protection accorded under the PPA and the PVPA)?[110] Advances in genetic engineering allowed scientists to accurately identify varieties that were previously indistinguishable to the naked eye.[111] Genetic engineering techniques also permitted the identification of plant varieties based upon a seed's genetic composition, making it possible to satisfy the written-description provision of § 101.[112] Usually, once identified or analyzed for their genetic composition, seeds and plants may be utilized in a breeding program to create new varieties.[113]

ii. Post-1980 Developments

a. Extension of 35 U.S.C. § 101 Utility-Patent Protection to Plants

Following the passage of the 1930 PPA, the hybrid corn industry utilized trade-secrets law to protect their hybrid corn crosses.[114] Keeping the parent lines secret meant that farmers buying high-yielding hybrid corn would have to return annually to the seed company, because offspring of hybrid corn lack the high yields.[115] Trade-secrets law notwithstanding, the seed industry felt that it needed a federal type of intellectual-property protection aimed at preventing independent plant breeders or other seed companies from taking advantage of the plant breeder/innovator's research and development efforts.[116]

In 1980, the U.S. Supreme Court issued its landmark *Diamond v. Chakrabarty* decision,[117] recognizing the patentability of living

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[109] Susan E. Gustad, *Legal Ownership of Plant Genetic Resources--Fewer Options for Farmers*, 18 HAMLINE L. REV. 459, 461 (1995). "One of the main attractions the PVPA holds for plant breeders is that the breeders themselves can complete the applications for certificates of protection without the services of a patent attorney," thus making it both cost-effective and user-friendly. *Id.*

[110] Blair, *supra* note 81, at 315.

[111] Crocker, *supra* note 79, at 262.

[112] *Id.*

[113] Blair, *supra* note 81, at 315.

[114] *See, e.g.*, Goss, *supra* note 34, at 1417.

[115] *Id.* at 1418.

[116] Blair, *supra* note 81, at 315.

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

organisms.[118] In *Chakrabarty*, the Court ruled that a bacterium invented by a scientist working for General Electric that broke down crude oil was patentable subject matter because (1) it was a product of creative human agency containing characteristics "markedly different" from those found in nature, and (2) it possessed potential for significant utility.[119]

In spite of the holding in *Chakrabarty*, whether living organisms more complex than a bacterium, such as sexually reproduced plants selectively bred by plant breeders, were patentable subject matter under the general U.S. patent statute remained unclear.[120] However, five years after the *Chakrabarty* decision, the issue of the patentability of sexually reproducible plants was addressed in *Ex parte Hibberd*.[121] In *Hibberd*, a PTO examiner had rejected a patent application for a maize plant containing high levels of the amino acid tryptophan, on the grounds that the enactment of the PVPA in 1970 precluded granting of general utility patents for plant matter.[122] On review of the patent examiner's rejection of the maize patent application, the U.S. Board of Patent Appeals and Interferences rejected the examiner's assertions, noting that the patent statute did not expressly *exclude* any plant from being proper subject matter for a utility patent.[123]

The legitimacy of the 1985 administrative adjudication by the U.S. Board of Patent Appeals and Interferences in *Hibberd* was challenged in the 2001 U.S. Supreme Court case of *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*[124] The defendant, J.E.M.,

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[118] *Id.* at 310.

[119] *Id.* In so ruling, the Court rejected the patent examiner's rationale that these microorganisms were "products of nature" and thus not protected under the statute. *See id.* at 306. The Court noted that patents are available for "a nonnaturally occurring manufacture or composition of matter -- a product of human ingenuity 'having a distinctive name, character [and] use.'" *Id.* at 309-10. This decision was groundbreaking since prior to 1980, the PTO and the federal courts were reluctant to allow the extension of utility patents to living matter. Lara E. Ewens, *Seed Wars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285, 293 (2000).

[120] Blair, *supra* note 81, at 316.

[121] 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences 1985).

[122] *Id.* at 444.

[123] *Id.* at 444-45. Although *Hibberd* "heightened the stakes for inventors and breeders of transgenically modified plants by stating that such products were eligible for utility patent protection, the question of whether plants and seeds would ever actually receive patent protection as proper subject matter under [the utility patent provisions] was not answered . . . ." Crocker, *supra* note 79, at 267. Nevertheless, over one thousand plant utility patents have been issued since the *Hibberd* decision in 1985. *Id.*

[124] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124, 136-38 (2001). In February 1998, Pioneer Hi-Bred International sued a small Iowa seed supply company for patent infringement, claiming that the defendant infringed on seventeen of Pioneer's patents by purchasing seed from authorized Pioneer Hi-Bred dealers and then reselling the seed. *Id.*

argued that in light of the PPA and the PVPA, the Board of Patent Appeals and Interferences in 1985 incorrectly extended the scope of utility patents because the extension was accomplished without congressional approval.[125] Justice Thomas, writing for the majority of the Court, upheld the validity of the Pioneer Hi-Bred patents at issue in the case, adding that J.E.M.'s unauthorized resale of patented hybrid corn seeds infringed Pioneer Hi-Bred's patents.[126] Justice Thomas declared that since the PPA and the PVPA did not explicitly state that general utility patents *cannot* be issued for germplasm, the PTO was therefore free to extend utility-patent protection to asexually and sexually reproduced germplasm.[127]

Following the 2001 *J.E.M.* decision in the United States, it was unclear what path Canada would take with regard to the general patentability of living organisms as well as the related issue of allowing utility-patent protection in plant varieties. The patentability of genetically engineered "higher" life forms was addressed in *Harvard College v. Canada (Commissioner of Patents)*,[128] a 2002 Canadian Supreme Court ruling. The case involved an application to patent the infamous Harvard "oncomouse."[129] In reaching its decision, the court first placed mammals in the category of "higher" life forms and then went on to rule that "higher" life forms would not fit into any of the patentable classes of subject matter under the Canadian patent statute.[130] The court applied this reasoning and proscribed the patenting of plants by classifying them as "higher" life forms as well.[131] The Canadian Supreme Court also applied this bar on patenting to animal life that is "more complex than microbes

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[125] Farm Advantage claimed that by explicitly providing for asexually reproduced plants in the PPA and for sexually reproduced varieties in the PVPA, Congress intended to preclude utility-patent prosecution under 35 U.S.C. § 101. *Id.*

[126] Justice Thomas noted that the Court "hold[s] that newly developed plant breeds fall within the terms of § 101, and that neither the PPA nor the PVPA limits the scope of § 101's coverage. *J.E.M. Ag Supply*, 534 U.S. 124, at 145-46. As in *Chakrabarty,* [the court declines] to narrow the reach of § 101 where Congress has given us no indication that it intends this result." *Id.*

[127] *Id.*

[128] Harvard College v. Canada, [2002] 4 S.C.R. 45 (Can.).

[129] The oncomouse is a mouse that is genetically engineered to be predisposed to certain cancers and was hailed to be a valuable research tool. *Id.* at ¶ 1.

[130] *Harvard College*, [2002] 4 S.C.R. 45, at ¶ 47. A "higher life form" cannot be described as an art, process, machine, manufacture, or composition of matter, the categories of patentable subject matter, because such a life form possesses qualities that transcend its mere genetic makeup. *Id.* at ¶ 120.

[131] *Id.* at ¶ 47. However, it has been noted that the qualities the court described defining higher life forms could hardly apply to plants especially in terms of displaying emotion or even responding to stimuli in a complex and unpredictable manner. *See* Adrian Zahl, *Patenting of "Higher Life Forms" in Canada*, 23 BIOTECHNOLOGY L. REP. 556, 557 (2004).

but less complex than mammals."[132] With this decision, the Canadian Supreme Court seemed to reject the far-reaching holding that its U.S. counterpart reached in *Chakrabarty* that living organisms that did not occur in nature were patentable.

However, two years later, in *Monsanto Canada Inc. v. Schmeiser*,[133] the Supreme Court of Canada stated that "living" inventions were patentable as long as they were not expressed *as* a higher life form (i.e., plant genes and cells as opposed to the plant as a whole).[134] Therefore, in Canada, while a "higher" life form (e.g., a canola plant as was in issue in *Schmeiser*) would not be eligible for patent protection, a claim to a modified plant gene or cell within such a plant would be.[135] Subsequent to *Schmeiser*, the Canadian Patent Office revised its position on the patentability of claims directed to plant or animal cells.[136]

Back in the United States in 2004, in *Monsanto Co. v. McFarling*,[137] the U.S. Court of Appeals for the Federal Circuit unanimously found that a farmer infringed a Monsanto patent by saving and planting glyphosate-tolerant soybean seed.[138] In his defense, McFarling alleged violations of the PVPA and federal antitrust laws and invoked the patent-misuse, patent-exhaustion, and first-sale doctrines.[139] However, unlike Schmeiser, McFarling did not challenge the underlying validity of Monsanto's patents.[140] The court rejected McFarling's patent-misuse argument, which claimed that by prohibiting seed-saving Monsanto had extended its patent on gene technology to include the germplasm—a product that could not be patented.[141] Citing *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*,[142] the court also

[132] Zahl, *supra* note 131, at 557 (noting that the court appreciated the difficulty in drawing a line between higher and lower life forms and made a conscious decision not to do so).

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

[134] *Id.*; *see also* Zahl, *supra* note 131, at 558-59.

[135] Zahl, *supra* note 131, at 558.

[136] Before this decision came down, the Canadian Patent Office required claims to plant or animal cells to be restricted to isolated cells, cell lines, or cells in culture. Cynthia Tape et al., Schmeiser v. Monsanto *and its Effects on Patent Prosecution,* 9 INTELL. PROP. L. 5 (2005) (Amer. Bar Ass'n Section on Intellectual Prop.), *available at* www.abanet.org/intelprop/bulletin/january_2005.shtml. The Patent Office currently permits claims to cells as long as the description does not define "cells" to include plants, animals, or tissue. *Id.*

[137] Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004).

[138] *Id.* at 1339-40.

[139] *Id.* at 1340.

[140] *Id.*

[141] *Id.* at 1341-43.

[142] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

declined McFarling's invitation to reconsider an earlier ruling that the PVPA "does not demonstrate a congressional intent to preempt or invalidate all prohibitions on seed saving contained in utility-patent licenses."[143]

b. The 1983 International Undertaking on Plant Genetic Resources

In the early 1980s, as utility-patent protection was being extended to living organisms by U.S. patent law, the United Nations Food and Agriculture Organization (FAO) became a controversial forum for a contentious debate between the countries of the North and the South regarding exploitation of PGRs.[144] The FAO adopted the International Undertaking on Plant Genetic Resources (IUPGR) in 1983 and also established an FAO Commission on Plant Genetic Resources (CPGR).[145] The IUPGR and the CPGR were spearheaded by a group of developing countries and were supported by an array of non-governmental organizations (NGOs) allied with the International Coalition for Development Action.[146]

Although the IUPGR was a *nonbinding* agreement that set out rules and standards for exchanging and conserving seeds and plant tissues, it proved to be controversial. This was because the IUPGR took the position that PGRs should be treated as resources that were the "common heritage of mankind."[147] This was a political and ideological

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[143] McFarling, 363 F.3d at 1344.

[144] For instance, FAO Assistant Director-General Obaidullah Khana labeled U.S.-backed plant-patent attempts "biopiracy." Scott Holwick, *Developing Nations and the Agreement on Trade-Related Aspects of Intellectual Property Rights*, 1999 COLO. J. INT'L ENVTL. L. & POL'Y 49, 61 (2000).

[145] U.N.F.A.O. Res. 8/83, U.N.F.A.O., 22d Session, Nov. 5-23, 1983. "At the 1981 FAO biennial conference, a resolution was adopted, against the vehement opposition of developed countries (especially the United States, United Kingdom and Australia) and the seed industry, calling for the drafting of a legal convention. In 1983, the over-ambitious demand for a convention was replaced by a call for a non-binding undertaking, and for the creation of a new FAO Commission on Plant Genetic Resources (CPGR) where governments could meet for discussion and monitor what became known as the International Undertaking on Plant Genetic Resources." Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 265 (2001).

[146] NGOs such as the International Coalition for Development Action were more knowledgeable on the outstanding issues than were most of the delegates from the developing world. Thus, the delegates viewed these NGOs as resources that they could consult for analysis and information. Also, the NGOs played the important role of bridging the gap between Latin American delegates and their counterparts from Africa and Asia. *See* FOWLER, UNNATURAL SELECTION, *supra* note 1, at 187.

[147] The principle of "common heritage" is embodied in the "International Undertaking on Plant Genetic Resources" of the Food and Agriculture Organization of the United Nations. INTERNATIONAL UNDERTAKING ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE,

point, made by the developing countries of the Third World, that what was good for the goose, was good for the gander. By asserting the "common heritage" principle the IUPGR used an extremely broad definition of PGRs: commercial plant varieties protected by breeders' rights and plant patents from the industrial countries of the global North were to be treated in the same way as traditional landraces[148] and wild plants—as "common heritage." Accordingly, under the IUPGR, these commercial plant varieties would be freely accessible to farmers and breeders around the world.[149]

Lawrence Helfer observes that

> [a]lthough the Undertaking was merely a nonbinding statement of principles, it was opposed by the United States and some European governments who argued that the document conflicted with a multilateral document [the UPOV]. . .[and] also with their national patent laws, which grant intellectual property rights in isolated and purified genes.[150]

A second reason why the IUPGR was so controversial may be found in its failure to abide by the traditional distinction between "raw" and "worked" plant germplasm. Prior to the 1980s, "raw" germplasm was not commodified, but "worked" germplasm was commodifiable.[151]

U.N. FOOD & AGRIC. ORG., 22D SESS., ANNEX, RES. 8/83, *available at* ftp://ftp.fao.org/ag/cgrfa/iu/iutextE.pdf [hereinafter IUPGR] ("Recognizing that (a) *plant genetic resources* are a *heritage of mankind* to be preserved, and *to be freely available for use, for the benefit of present and future generations*.") (emphasis in original).

[148] A landrace "is the result of selective breeding whereby only the seeds of plants with the most desirable characteristics are replanted, generation after generation, until a new 'breed' emerges, distinguishable from other breeds and typically characteristic of a particular geographic region." Nicholson, *supra* note 57, at n. 36.

[149] It is no surprise that such an arrangement was unacceptable to industrial nations, especially those with established private seed industries. KLOPPENBURG, *supra* note 5, at 174. These nations viewed the undertaking as a veiled attempt at undermining the principle of private property. *Id.* They had good reason for concern, since the undertaking literally sought to decommodify commercial plant varieties. *Id.*; *see also* Jim Chen, *Webs of Life: Conservation as a Species of Information Policy*, 89 IOWA L. REV. 495, 583 (2004) ("[In adopting the undertaking, the] Food and Agriculture Organization of the United Nations (FAO) provides one example of an approach repudiating private property.").

[150] Laurence R. Helfer, *Using Intellectual Property Rights to Preserve the Global Genetic Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROP. REGIME 218-219 (Keith E. Maskus & Jerome H. Reichman eds., 2005); *see also* DAN LESKIEN & MICHAEL FLINTER, INTELLECTUAL PROPERTY RIGHTS AND PLANT GENETIC RESOURCES: OPTIONS FOR A SUI GENERIS SYSTEM, ISSUES IN GENETIC RESOURCES, 6 INTERNATIONAL PLANT GENETIC RESOURCES INSTITUTE 8 (1997).

[151] The terms "commodified" and "commodifiable" here designate a partial product of

Yet what is the source of this asymmetric distinction between "raw" and "worked," and how coherent is it? Consider this observation by Cary Fowler:

> Third World farmers have been found to employ taxonomic systems, encourage introgression, use selection, make efforts to see that varieties are adapted, multiply seeds, field test, record data, and even name their varieties. In short, they do what many northern plant breeders do, except they do not apply for patents. . . . If the actions of Third World farmers can so closely resemble the steps taken in more formal plant breeding programs, and if the product of their labors is valuable, then the argument can be made that the genetic diversity of the Third World cannot be considered a "raw material."[152]

In terms of an international division of labor, the developing world has generally been defined by the export of "raw" materials.[153] Northern industrialized nations have historically and systemically acquired "raw" germplasm, generally without compensation, from "gene-rich" regions of the equatorial Southern Hemisphere for nearly four centuries and "worked" it to produce staple crops (and, more recently, plants and seeds) that are protected by intellectual-property laws.[154] One explanation as to why "worked" germplasm has been increasingly commodified may be that "none of the world's twenty most important food crops is indigenous to North America or Australia . . . [and] it is clearly the West Central Asiatic and Latin American regions where germplasm resources have historically made the largest genetic contribution to feeding the world."[155]

Although it is tempting to picture a gene-poor Northern Hemisphere siphoning the genetic wealth of a gene-rich Southern Hemisphere, neither the North nor the South is "genetically" independent. Rather, there is a deep and politically contentious genetic interdependence between the two hemispheres, and it is instructive to examine global germplasm flows. Many international institutions largely rely on existing germplasm banks for samples.[156] The banks are located primarily in the

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intellectual-property laws.

[152] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 193.

[153] *Id.*

[154] *Id.*

[155] KLOPPENBURG, *supra* note 5, at 181.

[156] Note that "mining" genetic resources does not directly cause the depletion of the genetic resource. The samples taken for a gene bank are *de minimis* in terms of physical quantity or size of the species. In other resources, such as coal or oil, the value of the resource is related directly to the amount extracted.

industrialized countries of North America and Europe.[157] Because most funds from the IBPGR have gone to germplasm collections in the industrialized North, these countries are now rich in gene-banked germplasm, and they possess "more stored germplasm accessions than do those nations that are regions of natural diversity for the crop."[158] Indeed, Professor Stephen Brush writes that

> of the 6,159,248 accessions inventoried among all gene banks in 1996, slightly more than half (3,447,469) were held by gene banks in Europe, North America, Japan and international agricultural research centers of. . .[the] CGIAR, and that a large portion of the total diversity of the world's major crops has been captured and stored in gene banks of major industrial countries and agricultural research centers.[159]

As a result, the United States, which has been characterized as "gene-poor" but which developed extensive seed collections under the "common heritage" regime, is a net *exporter* of seed germplasm to supposedly "gene-rich" countries.[160]

Conversely, the least-developed countries (LDCs) are net *importers* of seed germplasm, left dependent on access to seed banks in the industrial nations, even though they may have been the sources of the very seeds now collected in seed banks. As a result of their germplasm dependence, Professor Brush notes that

> a slowdown in crop germplasm exchange is likely to hurt poor countries . . . more than wealthy industrial countries without indigenous crop resources [because] industrial countries have established effective crop collections that are used not only by their national breeding programs but by programs elsewhere. . . .[T]he poorest countries are net borrowers from other countries, including the United States.[161]

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[157] KLOPPENBURG, *supra* note 5, at 162 ("By 1970 it was apparent that such predictions were correct and that a corollary to the adoption of the new Green Revolution cultivars was the displacement and disappearance of the land races that provided breeders with the genetic variability on which their advances were founded."); FOWLER, UNNATURAL SELECTION, *supra* note 1, at 243 ("During the green revolution, not only was an infrastructure of agricultural colleges and extension services built, but also a new market for seeds was created. This process destroyed much of the old system of seed-saving and farmer-breeding.").

[158] BRUSH, *supra* note 4, at 166.

[159] *Id.* at 237-38.

[160] *Id.* at 237.

[161] *Id.* at 236.

The different roles that germplasm flow has played in the Northern and Southern Hemispheres further complicate whether (and, if so, in what sense) germplasm can be called a "raw" material at all. The trend in both the laws and agricultural technology in the developed countries has been to define germplasm as private intellectual property. The contradiction between characterizing "raw" germplasm as "common heritage" and "worked" germplasm as intellectual property complicates the task of creating a coherent system for addressing germplasm flows.

One partial explanation for uncompensated taking of germplasm from the countries of the Southern Hemisphere is the pervasive idea that "the major food plants of the world are not owned by any one people and are quite literally a part of our human heritage."[162] This idea has allowed those germplasm collectors to attempt to justify and rationalize both the historical and contemporary practices—as well as institutional structures—of uncompensated appropriation.[163] Such difficulties and controversies are also important indicators as to why subsequent multilateral agreements have steered away from the "raw"/"worked" distinction.

c. The Keystone Dialogues and "Farmers' Rights"

The United States and the countries of Europe flatly refused to participate in the IUPGR, resulting in a stalemate until 1989, when the developing and developed countries were able to reach preliminary agreement on three principles related to PGR.[164] Participants in the so-called Keystone Dialogues first came to the consensus that plants protected by plant variety protection rights would not be considered freely accessible—a recognition of then-valid intellectual-property rights in plant varieties.[165] Second, the parties agreed that application of the "common heritage" principle, or free accessibility, to farmers' landraces and wild and weedy relatives did not mean access *free* of charge, i.e.,

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[162] H. Garrison Wilkes, *The World's Crop Germplasm – An Endangered Resource*, 33 BULL. ATOM. SCI. 8 (1977).

[163] United Nations Food and Agricultural Organization, PROPOSAL FOR THE ESTABLISHMENT OF AN INTERNATIONAL GENEBANK AND THE PREPARATION OF A DRAFT INTERNATIONAL CONVENTIONAL FOR PLANT GENETIC RESOURCES (conference resolution), Document D 83/LIM/2 September (1983); Norman Myers, A WEALTH OF WILD SPECIES at 24 (1983); Dominic Fuccillo, Linda Sears & Paul Stapleton, BIODIVERSITY IN TRUST: CONSERVATION AND USE OF PLANT GENETIC RESOURCES IN CGIAR CENTRES (1997); KLOPPENBURG, *supra* note 5, at 152-90.

[164] THE KEYSTONE CTR., FINAL CONSENSUS REPORT OF THE KEYSTONE INTERNATIONAL DIALOGUE SERIES ON PLANT GENETIC RESOURCES: MADRAS PLENARY SESSION (1990).

[165] *Id.*

that it might be possible to design a legal regime where plant breeders might be obligated to pay for plant tissue and seeds collected in a particular country's territory.[166] Finally, the parties adverted to a vague idea of farmers' rights.[167] At that time, these rights were undefined, but the FAO referred to some sort of recognition for the thousands of years of farmers' efforts spent in domesticating current agricultural staple crops and varieties.[168]

The farmers' rights idea was proposed in 1985 by a Canadian NGO, the Rural Advancement Foundation International (RAFI); it was meant to embody concerns over genetic erosion and the North-South "gene drain."[169] As envisaged by RAFI, farmers' rights were a new type of collective intellectual-property rights, meant to counter plant breeders' rights.[170] Farmers' rights theoretically would allow farmers to receive compensation from an international genetic conservation fund to be administered by the FAO.[171]

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[166] *See* Kirit K. Patel, *Farmers' Rights over Plant Genetic Resources in the South: Challenges and Opportunities, in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY 97 (F.H. Erbisch & K.M. Maredia eds., 2d ed. 2004).

[167] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 199 ("[I]mportant ground was broken in two areas—in defining the notion of genetic resources as 'common heritage' and in the emerging concept of 'farmers' rights.'").

[168] FAO Resolution (5/89): Farmers' rights are

> rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the international community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.

Carol B. Thompson, *International Law of the Sea/Seed: Public Domain Versus Private Commodity*, 44 NAT. RESOURCES J. 841, 866 n.94 (2004). While the FAO formulated the concept of farmers' rights, these rights were not defined in a legal sense because the term was considered political. *Id.*

[169] *See* Susan K. Sell, *Post-TRIPS Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193, 216 n.50 (2002).

[170] Goss, *supra* note 34, at 1422 (RAFI argues that "strengthening plant breeders' rights will accelerate genetic erosion.").

[171] Larry Helfer defines farmers' rights as

> a loosely defined concept that seeks to acknowledge the contributions that traditional farmers have made to the preservation and improvement of [plant genetic resources]. Unlike other natural resources such as coal and oil, [plant genetic resources] are maintained and managed by humans, who cultivate the wild plant varieties that serve as raw materials for future innovations by plant breeders. But whereas breeders obtain proprietary rights in new varieties to compensate them for the time and expense of innovation, no system of remuneration rewards farmers. Farmers' rights thus act as a counterweight to plant breeders' rights, compensating the upstream input providers who make downstream innovations possible. Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 37 (2004).

Advocates focused on four issues: (1) the right to grow, improve, and market local varieties and their products; (2) the right to access improved plant varieties and use farm-saved seeds of commercial varieties for planting and exchange; (3) the right to be compensated for the use of local varieties in the development of new commercial products by outsiders; and (4) the right to participate in decisionmaking processes related to acquiring, improving, and using PGR.[172]

In 1989, the FAO adopted a new interpretation of the 1983 IUPGR, declaring that plant breeders' rights were compatible with common heritage and also recognized the principle of farmers' rights, i.e., that most of the world's valuable germplasm came from the developing world and was the result of thousands of years of selection by farmers, and that some form of compensation should be paid for use of that germplasm.[173] However, neither the international fund nor farmers' rights crystallized in the period following 1989, in large part because contributing to the fund was voluntary.

d. The International Union for the Protection of New Varieties of Plants: 1960, 1978, and 1991

In 1960, a group of European nations met to form the International Union for the Protection of New Varieties of Plants (UPOV), which was designed to create a legal basis for *plant breeders' rights* in privately bred varieties of plants.[174] The UPOV protections went further than the PPA in the United States, which protected only asexually reproduced plants.[175] UPOV protected all varieties of plants, including

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[172] Patel, *supra* note 166, at 96.

[173] Annie Patricia Kameri-Mbote & Philippe Cullet, *The Management of Genetic Resources: Developments in the 1997 Sessions of the Commission on Genetic Resources for Food and Agriculture*, 1997 COLO. J. INT'L ENVTL. L. & POL'Y 78, 83-84 (1997).

[174] UPOV is the French acronym for Union Internationale pour la Protection des Obtentions Végétales. International Union for the Protection of New Varieties of Plants, Dec. 16, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89. For a discussion of the first plant breeders' protection systems in Europe, the conflicts between industry and plant breeders, the adoption of UPOV, and the introduction of plant breeders' rights in the United States, see PISTORIUS & VAN WIJK, *supra* note 48, at 79-85. The UPOV has been amended several times since 1961 when the original convention was finalized. Steven M. Ruby, *The UPOV System of Protection: How to Bridge the Gap Between 1961 and 1991 in Regard to Breeders' Rights*, 2 OKLA. J.L. & TECH 19 (2004). These amendments include those of 1972, 1978, and 1991. *Id.* Currently, different countries apply different versions of the UPOV convention as provided by the amendments. *Id.* For a list of the 58 member nations (as of May 2009) and the respective versions of UPOV the member nations currently apply see MEMBERS OF THE INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS, www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf (last visited Sept. 20, 2009).

[175] 35 U.S.C.A. § 161 (Westlaw 2009).

sexually reproduced varieties, as long as they were (1) new,[176] (2) distinct,[177] (3) uniform,[178] and (4) stable.[179] The United States passed its own form of plant variety protection in 1970[180]—at the height of the Green Revolution.[181] These pieces of legislation were indications that plant breeding in North America and Europe was becoming increasingly dominated by private plant breeders.

Under the 1978 UPOV, local varieties grown by farmers were considered openly accessible because they lacked the uniformity and stability required for protection.[182] The 1978 UPOV, however, did have a "farmers' exemption," which allowed any farmer who purchased seeds of a protected variety to save seeds from those crops for subsequent replanting without paying additional royalties.[183] The seed industry lobbied heavily with many governments to limit the 1978 UPOV

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[176] A variety is deemed new if "at the date of filing of the application for a breeder's right, propagating or harvesting material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder, for purposes of exploitation of the variety." UPOV Convention, ch. 3, art. 6(1).

[177] Under the UPOV Convention

> [a] variety is distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. . . . [T]he filing of an application for the granting of a breeder's right or for the entering of another variety in an official register of varieties, in any country, shall be deemed to render that other variety a matter of common knowledge from the date of the application, provided that the application leads to the granting of a breeder's right or to the entering of the said variety in the official register of varieties . . . . UPOV Convention, ch. 3, art. 7.

[178] A variety is uniform if "subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics." UPOV Convention, ch. 3, art. 8.

[179] To be stable, a variety's relevant characteristics must remain unchanged after repeated propagation or in case of a cycle of propagation, at the end of that cycle. UPOV Convention, ch. 3 art. 9.

[180] 7 U.S.C.A. §§ 2321-2582 (Westlaw 2009).

[181] *Id.*

[182] For a discussion of uniformity requirements, see Ruby, *supra* note 174.

[183] The so-called "farmers' exemption" in the 1978 UPOV is implicit. The actual language of the 1978 UPOV art. 5(1) states

> The effect of the right granted to the breeder is that his prior authorization shall be required for:
>
> - the production for purposes of commercial marketing
> - the offering for sale
> - marketing
>
> of the reproductive or vegetative propagating material as such, of the variety.

Thus the 1978 UPOV, in limiting the rights of plant breeders to only prevent the commercial exploitation of their varieties, indirectly extended to farmers the right to save seed for their own personal (i.e., noncommercial) purposes.

farmers' exemption.[184] Finally, in the 1991 version of the UPOV, farmers' rights were curtailed as follows: (1) article 15.2 makes farmers' rights optional and allows each UPOV member nation to decide whether to extend such rights;[185] (2) plant breeders' exemptions are narrowed in articles 14 and 15.1—"essentially derived" varieties cannot be marketed without permission from the original plant breeders;[186] and (3) unlike the 1978 UPOV, which did not allow member nations to grant utility patents for sexually reproduced varieties, article 35(2) of the 1991 UPOV allowed the granting of such patents.[187]

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[184] The global seed and biotechnology industries still continue to pressure developing countries to adopt the 1991 version of UPOV with its stronger monopoly rights and watered-down farmers' exemption. Nadine Barron & Ed Couzens, *Intellectual Property Rights and Plant Variety Protection in South Africa: An International Perspective*, 16 J. ENVTL. L. 19, 36 (2004).

[185] The farmers' exemption is contained in the 1991 UPOV Convention art. 15, which reads as follows:

> (2) [*Optional exception*] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeders' right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

[186] Ch. 4, art. 14 reads as follows:

> (5) [essentially derived and certain other varieties] (a) The provisions of paragraphs (1) to (4) shall also apply in relation to (i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety, (ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and (iii) varieties whose production requires the repeated use of the protected variety.

While the UPOV protects plant [breeders'] rights over "essentially derived" varieties, the convention itself fails to define what "essentially derived" may entail. It therefore leaves this interpretation to domestic legislation, judicial interpretation, or to private parties in the midst of contractual negotiations. Mark Hanning, *An Examination of the Possibility to Secure Intellectual Property Rights for Plant Genetic Resources Developed by Indigenous People of NAFTA States: Domestic Legislation Under the International Convention for Protection of New Plant Varieties*, 13 ARIZ. J. INT'L & COMP. L. 175, 241-42 (1996). Hanning continues,

> The convention itself defines essentially derived varieties as "predominantly derived . . . while retaining the expression of essential characteristics," "clearly distinguishable," or "conforming to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes in the variety." These definitions rely on an understanding of the phrases "essential characteristics" and "clearly distinguishable." As discussed . . . because these phrases are left to UPOV signatory states, various meanings may evolve. *Id.* (footnotes omitted).

[187] Article 35 of the 1991 UPOV states

> (2) [*Optional exception*] (a) Notwithstanding the provisions of Article 3(1), any State which, at the time of becoming party to this Convention, is a party to the Act of 1978 and which, as far as varieties reproduced asexually are concerned, provides for protection by an industrial

The effect of TRIPS on the ability of developing countries to enter into UPOV remains to be seen. Arguably, developing countries may accede to the 1978 version of UPOV (which allows farmer seed saving) and stay out of the 1991 agreement; however, this is possible only if countries like the United States are content to allow 1978 levels of protection for protected varieties, which is doubtful.[188]

e. Convention on Biological Diversity (1992)

The ongoing debate over PGRs as embodied in agreements such as the different versions of the UPOV must be understood in the context of two important multilateral agreements. The first is the Convention on Biological Diversity (CBD), which was adopted at the 1992 United Nations Conference on Environment and Development (Rio Conference) in Rio de Janeiro, Brazil.[189] The second is TRIPS, part of the General Agreement on Tariffs and Trade, which was finalized in 1992 in Marrakech, Morocco.[190]

The CBD aimed at conserving biodiversity, but it has strong implications for the issue of intellectual-property rights in PGR.[191] The CBD was a multilateral agreement resulting from a process addressing

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property title other than a breeder's right shall have the right to continue to do so without applying this Convention to those varieties.

One commentator noted that the 1991 Act aided plant breeders in that it removed

the prohibition against double protection of varieties, found in Article 2, which had prevented UPOV members from offering both breeders' rights protection and patents for plant varieties. The United States had previously been exempted from the ban on double protection, but its removal creates the opportunity for the rapid expansion of both forms of protection in other countries, especially some in Europe. Under the present European Patent Convention, a specific prohibition for patenting was created for 'plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.' While the provision appears to prevent all patenting of plants, it has been interpreted as applying only to varieties per se. As a result, the European Patent Office now examines and grants utility patents on plants when the claims are not directed at a variety. Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 606-07 (1993) (footnotes omitted).

[188] *See* TRIPS, *supra* note 52, at 94. Article 27(3)(b) requires that "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or any combination thereof." *See also* JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 135-65 (2001) (discussing the array of possible intellectual-property regimes applicable to plants that are permissible under the WTO).

[189] CBD, *supra* note 49.

[190] TRIPS, *supra* note 52.

[191] *See generally* Hubbard, *supra* note 49.

growing environmental concerns in the Organization for Economic Cooperation and Development member countries.[192] The CBD took the position that economic incentives were necessary in order for developing countries to conserve their biodiversity rather than seek quick gains through activities, such as deforestation, that result in the destruction of biodiversity.[193] While the CBD did *not* focus on PGR for food and agriculture, it addressed general concerns relating to the conservation of all plants and other organisms in the global ecology.[194] Many of the same divides and controversies that surfaced in the FAO debates over the IUPGR also surfaced in the CBD negotiations. Some of these concerns were (1) the North-South divide over distribution of the benefits of biological organisms and conservation of biodiversity, (2) the propriety of granting intellectual-property rights over living organisms, and (3) technology-transfer questions regarding access to technologies necessary to utilize the benefits of such biological organisms.[195]

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[192] For background on this convention, see *Id.*

[193] Under the terms of the CBD, in which developing countries, rich in biodiversity, agreed to conserve their biodiversity in return for financial aid and royalties from companies that exploit the same, there was an incentive for developing nations to safeguard these resources and in the process protect against short-term ventures whose consequences are likely to include rapid deforestation and subsequent species destruction. Ranee K. L. Panjabi, *Idealism and Self-Interest in International Environmental Law: The Rio Dilemma*, 23 CAL. W. INT'L L.J. 177, 190-91 (1992). However, many activists favored a stronger legal framework to protect genetic diversity in the CBD, which they viewed as far from perfect; nevertheless, it provided a framework on which to build. *Id.* The CBD obligates developing biodiversity-rich countries to conserve, sustainably use, and guarantee access to genetic resources, in return for a fair and equitable sharing of benefits arising out of the utilization of these resources. McManis, *supra* note 49, at 260. The creation of a system of financial aid and royalty payments was instituted based on the realization that most developing nations would be unable to pay for the measures called for in the CBD without adequate compensation. Catherine J. Tinker, *Introduction to Biological Diversity: Law, Institutions and Science*, 1 BUFF. J. INT'L L. 1, 21 (1994). An element of historical justice has also been proposed with the premise that while the developed world industrialized and subsequently ensured higher standards of living for its citizenry. The same developments led to the destruction of biodiversity in the developing world. *Id.*

[194] Hubbard, *supra* note 49, at 421.

[195] *See generally* Hubbard, *supra* note 49. On a related note, the United States' refusal to ratify the CBD came as no surprise to many. George Van Cleve, *Regulating Environmental and Safety Hazards of Agricultural Biotechnology for a Sustainable World*, 9 WASH. U. J.L. & POL'Y 245, 252 n.16 (2002). The United States repeatedly voiced substantive objections in the areas of the CBD. *Id.* First, the United States took issue with the CBD's requirement that developed countries fund environmentally conscious development in developing countries. *Id.* The United States specifically was uncomfortable with what it perceived as the lack of definite restrictions on the amount of funds developed nations could be forced to contribute to developing nations. *Id.* Second, the CBD called for essentially open technology transfer including the transfer of biotechnology. *Id.* This aspect of the CBD was seen as endangering intellectual-property rights since the treaty mandated transfer of not only publicly owned but also privately owned technology. *Id.* This reading, it was argued, was apparent when the technology transfer provisions of the CBD were analyzed in context with other provisions serving as a backdrop which led to the conclusion that the treaty was

The CBD differed in one key respect from the IUPGR in that the CBD acknowledged that many nations had already granted intellectual-property protection of biotechnological inventions.[196] Additionally, and contrary to the IUPGR, the CBD did not take a "common heritage" approach to biological resources but applied the notion that *countries of origin* of biological resources exercised sovereignty/ownership over plants, animals, and microorganisms within their national boundaries.[197] With PGR characterized as a form of sovereign national property,[198] the CBD posited that this sovereign property required informed consent prior to extraction/exploitation as well as equitable benefit-sharing arising from exploitation of those bio-resources.[199]

f. Agreement on Trade-Related Aspects of Intellectual Property (1994)

In 1986, the initial focus of the Uruguay Round,[200] and specifically

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disregarding patents and other intellectual-property rights. *Id.* Finally, that the CBD called for regulatory measures that applied only to biotechnology as opposed to other environmentally harmful and diversity-depleting activities was unacceptable for the United States. *Id.* While these arguments were articulated by the Bush Administration (1989-93), these same concerns were repeatedly expressed by large and influential U.S. corporations that the ratification of the CBD would be adverse to American interests. David B. Vogt, *Protecting Indigenous Knowledge in Latin America*, 3 OR. REV. INT'L L. 12, 19 n.57 (2001). However, the United States later became a signatory under the Clinton Administration. *Id.*

[196] For instance, the FAO, through the CBD, sought to integrate already-existing seed banks into an international network. Gregory Rose, *International Law of Sustainable Agriculture in the 21st Century: The International Treaty on Plant Genetic Resources for Food and Agriculture*, 15 GEO. INT'L ENVTL. L. REV. 583, 594 (2003).

[197] The CBD treats genetic resources as "tradable commodities subject to national sovereignty rights" and whose transfer from the developing to the developed world was envisioned to entail a transfer of technology among other benefits. Dutfield, *supra* note 145, at 260. *Cf.* IUPGR approach, discussed *supra* note 147.

[198] CBD, *supra* note 49, at art. 3, states

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

[199] CBD, *supra* note 49, at art. 15.5 (requiring prior informed consent of the party 'owning' the natural resource); Article 8(j) (equitable sharing of benefits); *Id.* at art. 8(j). Additionally the CBD recognized the rights of subnational groups, such as indigenous and local communities to participate in "benefit sharing." *Id.* For more on traditional resource knowledge and resources, and indigenous heritage *see* DARRELL A. POSEY & GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY (2000); INDIGENOUS HERITAGE AND INTELLECTUAL PROPERTY (Silke von Lewinski ed. 2004).

[200] The Uruguay Round of the General Agreement on Trade and Tariffs (GATT) was a seven

TRIPS, was an attempt by industrialized nations to secure multilateral intellectual-property protection for new technologies, pharmaceuticals, and copyrighted media works against unauthorized imitation or duplication.[201] However, by 1990, intellectual-property protection for living organisms (including plants) had emerged as a major negotiating point, just as several newly patented biotech inventions began making their way to the market.[202] Additionally, the phenomenal spate of mergers and acquisitions in the chemical and pharmaceutical economic sectors that began in the 1970s continued, with these companies swiftly moving into the areas of genetically engineered plants, plant breeding, and crop development.[203] These firms also acted aggressively to secure some form

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and a half year long round of multilateral negotiation that began in 1986 in Punta del Este, Uruguay. World Trade Organization, Understanding the WTO: Basics, The Uruguay Round, www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm (last visited Sept 30, 2009). The Uruguay Round was signed by 123 countries in April 1994 in Marrakech, Morocco and culminated in the creating GATT's successor organization the World Trade Organization. *Id.* The Uruguay Round included heated discussion of new trade area, such as trade in services and intellectual property and reformed trade in the agricultural and textile sectors, as well as providing for arbitration to settle trade disputes between member nations. *Id.* On December 8, 2004 President Clinton signed the Uruguay Round Agreements Act, which made several substantive changes in U.S. law. *See Id.*

[201] Andrew T. Guzman, *International Antitrust and the WTO: The Lesson from Intellectual Property*, 43 VA. J. INT'L L. 933, 950 (2003) ("[T]he agreement seeks to prevent developing countries from allowing what in developed countries would be viewed as violations of intellectual property rights . . . .").

[202] In fact, there were differences among the various states as to how to deal with intellectual property with respect to genetically engineered products. *See* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 67-68 (2001). These discussions formed part of the negotiations that led to the 1994 Uruguay Round agreements on trade. *Id.* Interestingly, however, the language that emerged from these negotiations failed to address the treatment of genetically engineered products, inevitably leaving many questions unanswered. *Id.*

[203] Jack R. Kloppenburg & Daniel L. Kleinman, *Plant Genetic Resources: The Common Bowl*, *in* SEEDS AND SOVEREIGNTY: DEBATE OVER THE USE AND CONTROL OF PLANT GENETIC RESOURCES 1, 9 (Jack Kloppenburg Jr. ed. 1988). More recently, according to the NGO RAFI (now known as ETC),

> [t]he first half of 1998 witnessed a dramatic consolidation of power over plant genetics worldwide, punctuating a trend that began over three decades ago. The global seed trade is now dominated by life industry giants whose vast economic power and control over plant germplasm has effectively marginalized the role of public sector plant breeding and research.

RAFI COMMUNIQUE, SEED INDUSTRY CONSOLIDATION: WHO CONTROLS WHOM? 1 (July/Aug. 1998), *available at* www.etcgroup.org/en/materials/publications.html?pub_id=404. Other observers note that U.S. regulatory changes served as a catalyst in the recent spate of mergers resulting in corporate realignment. Stevan Pepa, *Research and Trade In Genetics: How Countries Should Structure for the Future*, 17 MED. & L. 437, 441 (1998). However, this trend is not unique to the United States as there have been massive mergers within the chemical and "life sciences" and industries. *Id.* For example, Novartis AG is one of the largest pharmaceutical companies and a global leader in crop protection chemicals. *Id.* Novartis was the result of a $27 billion merger between two Swiss corporations, Ciba-Geigy SA and Sandoz Ltd. in 1996. *Id.* The consummation of this merger had the effect of increasing the stakes in the biotechnology industry leading to a spate of mergers of global intellectual-property protection for their biotech innovations.[204]

While the dominant framework of intellectual property at this time was domestic protection within a particular nation's borders, the negotiations that eventually produced TRIPS were creating a supplementary framework that required "minimum standards" of intellectual-property protection from WTO member nations.[205] However, these claims for more-expansive intellectual-property protection were met with opposition from some developing countries opposed to strengthening international patent law; these countries advocated for the exclusion from patent of plant or animal varieties if required on particular public-interest grounds.[206]

TRIPS was signed by 125 countries in 1994; it requires that member nations accord PGRs plant-variety protection, patent, or effective protection under an effective sui generis system that is neither

between large multinationals and smaller biotechnology companies. *Id.* Strategic alliances between large multinationals and small biotechnology firms have also been popular arrangements. *Id.*

[204] *See generally* Debora Halbert, *Intellectual Property in the Year 2025*, 49 J. COPYRIGHT SOC'Y U.S.A. 225, 242 (2001):

> Intellectual property law is the key component of the globalized world, allowing for corporations to enforce their property rights internationally. The ability of corporations to enforce their intellectual property rights was codified into international law. TRIPS, the international trade agreement which had helped globalize intellectual property regimes, was the product of a lobbying effort by twelve American multinational corporations. By successfully equating intellectual property rights with trade these companies ensured they would remain firmly entrenched as players in the global future. *Id.* (footnote omitted).

[205] TAYLOR & CAYFORD, *supra* note 29, at 42-43.

[206] TRIPS, *supra* note 52, at 94 (art. 27(2) excludable if threat to public order, etc.) ("WTO members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."). *Id.* art. 27(3)(b). *See* Susan H. Bragdon and D.R. Downes, Recent Policy Trends and Developments Related to the Conservation, Use and Development of Genetic Resources: Issues in Genetic Resources, IPGRI Paper No. 7, International Plant Genetic Research Institute, IPGRI (Rome 1998); TRIPS Article 27 (2)-(3) (ordre public morality clause)

> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law. 3. Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the MTO. TRIPS, *supra* note 52, at art. 27(2)-(3).

patent protection nor premised on plant breeders' rights.[207] This meant that many of the gains made by the developing world at the 1992 Rio Biodiversity Summit were undermined by TRIPS.[208]

Consider the different fora and their differing treatment of plant genetic resources: the UN FAO-sponsored 1983 IUPGR and 1992 Rio Biodivdersity Summit (which produced the CBD), the intellectual-property forum UPOV, the CGIAR system (funded by the industrialized world), and WTO.[209] The 1989 and 1991 changes in the IUPGR (which

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[207] While the UPOV regime, on which the European plant variety protection (PVP) measures are based, seems to many to be an effective sui generis system, it does fall short.

> To meet the TRIPS standard, all species would have to be eligible for protection, and the rights guaranteed under law in one nation would have to extend not just to other members of UPOV, but to all countries under the World Trade Organization. The general UPOV approach, nevertheless, is certainly what parties to the TRIPS agreement had in mind for an acceptable *sui generis* alternative to patents. However, UPOV does not provide for protection of traditional farmer-varieties of crops, and thus cannot substantially help meet the goals of the Convention on Biological Diversity to ensure the conservation, sustainable utilization and fair and equitable sharing of benefits arising from the use of biological diversity.

Cary Fowler, *By Policy or Law? The Challenge of Determining the Status and Future of Agro-Biodiversity*, 3 J. TECH. L. & POL'Y 1, 36-37 (1997). In the United States, there are several avenues of intellectual-property protection available for plant varieties. Utility-patent protection is geared toward biotechnological inventions, plant-patent protection targets new and distinct asexually reproducible plant varieties, and sui generis protection (plant variety protection) is aimed at sexually reproduced plant varieties. McManis, *supra* note 49, at 276. The Supreme Court has previously ruled that both measures, i.e., utility patents and plant variety protection measures, do coexist. For a discussion on the options for sui generis protection, *see* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 78-80 (2000).

[208] TRIPS had been construed as providing not only for international recognition, but also for the enforceability of private patents for microorganisms and even life itself. *See* Shalini Bhutani & Ashish Kothari, *The Biodiversity Rights of Developing Nations: A Perspective From India*, 32 GOLDEN GATE U. L. REV. 587, 591 (2002). It should therefore come as no surprise that it has been railed at as legitimizing the piracy of indigenous biodiversity-related knowledge of local communities of developing nations. *Id.* One view of the split between rich and poor nations has been characterized as "arrogant, cash-rich, resource-poor northern nations attempting to solidify their economic position at the expense of naive, cash-poor, resource-rich southern nations." Holwick, *supra* note 144, at 53. This rift was supposedly mended with the signing of the CBD, but the United States' refusal to join in the final agreement caused concern in the South. *Id.* India, acting on behalf of the developing nations, squared off against the developed nations at a WTO meeting to plan the final agenda for the next meeting to be held in Seattle. *Id.* The two sides were unable to reach a consensus on any of the outstanding issues, including the reconciliation of the TRIPS agreement with the CBD. *Id.* As a result, many of the developing nations traveled to the WTO meeting in Seattle ready to disavow their previous TRIPS commitments and in the process force a renegotiation of the entire TRIPS agreement. *Id.* at 53-54. For more, see generally Evelyn Su, *The Winners and the Losers: The Agreement on Trade-Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries*, 23 HOUS. J. INT'L L. 169 (2000) (providing analysis of the TRIPS Agreement and its implications for developed and developing nations), and Ruth L. Gana, *Prospects for Developing Countries Under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735 (1996) (analyzing the relationship between the TRIPS Agreement and developing nations).

[209] Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, 58

ultimately became the 2004 International Treaty for Plant Genetic Resources [ITPGR]) benefited the developing world, whereas the 1991 revisions to UPOV strengthened the position of private plant breeders.[210] The CBD represented some important gains for the developing world: (1) recognition of the national sovereignty principle[211] and (2) obligating corporations that use developing countries' seed germplasm to share the economic benefits arising from exploitation of those resources as well as to transfer technology to the host countries.[212] Additionally, under article 19 of the CBD, developing countries are given priority access to biotech products developed from germplasm originating within their borders.[213] The CBD also linked intellectual-property rights to the distribution of benefits of biotechnology. The CBD stated that intellectual-property rights should not run counter to the objectives of the CBD, one of which is "the fair and equitable sharing of the benefits of genetic resources."[214]

INT'L ORG. 277 (2004), *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=441463; Helfer, *supra* note 171.

[210] The ITPGR goes beyond recognizing farmers' rights; one of its main aims is to facilitate the exchange of seeds and other plant materials for research, breeding, and crop development purposes. Helfer, *supra* note 171, at 40. It seeks to accomplish this exchange by creating a multilateral system to which member states and their nationals will be granted "facilitated access." *Id.* In contrast, the UPOV aims at protecting breeders' rights and creates an obligation for the respective signatory states to enact legislation to further that goal. Eric B. Bluemel, *Substance Without Process: Analyzing TRIPS Participatory Guarantees in Light of Protected Indigenous Rights*, 86 J. PAT. & TRADEMARK OFF. SOC'Y 671, 695-96 (2004). In effect, UPOV sought to harmonize property rights associated with the creation or selective breeding of plant varieties. *Id.*

[211] *See supra* note 198.

[212] The CBD language is framed in terms of an "equitable sharing" of the benefits resulting from the exploitation of traditional knowledge between developed and developing nations. Wesley A. Cann, Jr., *On the Relationship Between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Global Constitutionalism*, 25 U. PA. J. INT'L ECON. L. 755, 925 (2004). The convention further promotes broader participation in scientific research, the exchange of information amongst the various member signatory states, the facilitation of both public- and private-sector technology transfer, and the equitable sharing of the results of the scientific research and the benefits of genetic-resource commercialization. *Id.* Therefore, the CBD then creates a legal basis for the developed signatory states to bargain with the developing signatories should they require access to traditional knowledge for commercial development. Shubha Ghosh, *Traditional Knowledge, Patents and the New Mercantilism (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 885, 921 (2003). Royalties or other remuneration paid to the state were envisioned as the results of such a bargaining process. *Id.* These financial considerations are then in turn distributed to the community as proceeds arising from commonly held traditional knowledge. *Id.*

[213] *See* CBD, *supra* note 49, at art. 19(2).

> Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms. *Id.*

[214] *Id.* at art. 1.

g. International Treaty on Plant Genetic Resources (2004)[215]

Although the FAO's 1983 IUPGR was not binding, farmers' rights were recognized in an FAO resolution in 1989 that proposed "establishing a mandatory international fund to support conservation and utilization of [PGR] through various [programs] particularly, but not exclusively, in the Third World."[216] This fund was implemented in the 1990s, and as a result, the FAO decided to operationalize a version of farmers' rights through a Global Plan of Action adopted at Leipzig in 1996.[217] However, the Global Plan of Action lacked an efficient funding mechanism.[218]

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[215] International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf [hereinafter ITPGR].

[216] Patel, *supra* note 166, at 97 (citing The Keystone Center *supra* note 164). It is worth noting that as applied to plant genetic resources, the IUPGR was viewed as conflicting with the UPOV, which favored plant breeders' rights, when it came to cultivated plant varieties. Helfer, *supra* note 171, at 36-37. However, proponent states lobbied successfully for a revision of the IUPGR, stating that plant breeders' rights were "not incompatible" with the principles underlying the IUPGR. *Id.* This reconciliation had the effect of permitting unrestricted access to unimproved plant genetic resources without the benefit of compensation to the states, communities, or institutions that maintained them. *Id.* To address this imbalance, the developing states proposed that the revised IUPGR vest farmers' rights in the international community as trustees. *Id.* A vital component of this arrangement was the creation of an international fund to support conservation. *Id.* However, FAO members failed to contribute in any meaningful way, causing the fund to languish during the 1980s and 1990s. *Id.*

[217] *See* David S. Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373, 426-27 (1998). Creation of an international fund in support of farmers' rights was a controversial proposition at the FAO-sponsored Fourth Technical Conference on Plant Genetic Resources held in Leipzig, Germany, in June 1996. *Id.* Prior to the conference, 154 governments submitted country reports to FAO. These reports, assessing the status of plant genetic resource conservation within their respective jurisdictions, served as the basis for the FAO Report on the State of the World's Plant Genetic Resources. *Id.* Drawing on this report, delegates from 150 countries converged in Leipzig and agreed upon the Global Plan of Action (GPA). *Id.*

[218] ITPGR Article 14 expressly acknowledges the Global Plan of Action:

> Recognizing that the rolling Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture is important to this Treaty, Contracting Parties *should promote* its effective implementation, including through national actions and, *as appropriate*, international cooperation to provide a coherent framework, inter alia, for capacity-building, technology transfer and exchange of information, taking into account the provisions of Article 13. (emphasis added).
> ITPGR, *supra* note 215, at art. 14.

That the GPA seems to suffer the same fate as the revised IUPGR discussed *supra* in note 216 when it comes to the reluctance of FAO to fund it is not surprising. The language in article 14 is framed in soft terms, including "should promote" when referring to effective implementation and "as appropriate" when talking about international cooperation. *See* Rose, *supra* note 196, at 592. Such language has led to the impression that national action is discretionary rather than mandatory. *Id.*

Given the changes in emphasis and interpretation since the Keystone Dialogues, in 1994 the FAO initiated an intergovernmental round of negotiations meant to revise the 1983 IUPGR in order to make it a legally binding multilateral treaty, and to harmonize its provisions with the 1992 CBD, which is at odds with the 1983 IUPGR's broad definition of "common heritage" (the CBD stressed the notion of PGR as sovereign property).[219] In November 2001, 116 member nations (including the United States) signed a new multilateral agreement, the International Treaty for Plant Genetic Resources (ITPGR).[220]

The ITPGR reaffirmed a commitment to farmers' rights as protecting traditional knowledge relevant to PGRs, recognized a right to equitable benefit sharing, and also recognized the right of farmers to participate in decisionmaking at national levels on matters related to conservation and use of PGR.[221] However, the ITPGR allowed the most important issue with regard to farmers' rights—the right to use, exchange, and sell farm-saved seeds of traditional as well as improved varieties—to remain within the sole discretion of national governments.[222] The ITPGR sought to advance farmers' rights by information exchange,[223] facilitating technology transfer and capacity building,[224] and sharing the benefits (monetary and non-monetary) of the commercialization of PGRs.[225]

The ITPGR addresses intellectual-property rights in PGRs by proposing the creation of a multilateral system (MLS).[226] Under the MLS, a recipient of germplasm[227] received through the MLS (i.e., from

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[219] Rose, *supra* note 196, at 596.

[220] ITPGR *supra* note 215; Rose, *supra* note 196, at 613.

[221] Patel, *supra* note 166, at 97.

[222] ITPGR article 9.3 states that "[n]othing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange or sell farm-saved seed/propagating material, *subject to national law* and as appropriate." (emphasis added). ITPGR, *supra* note 215, at art 9.3.

[223] ITPGR, *supra* note 215, at art. 13.2(a).

[224] ITPGR, *supra* note 215, at art. 13.2(b)-(c). Compare with TRIPS article 66, which mandates developed countries to provide incentives for businesses to promote and encourage technology transfer to poorer nations. TRIPS, *supra* note 52, at 108. For a discussion of technology transfer after the TRIPS agreement, *see* Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279, 287-91 (2004).

[225] ITPGR, *supra* note 215, at art. 13.2(d). However, for an assessment of the adverse impact of the diffusion of commodified plant genetic resources on the peasant sectors of less developed countries, *see* Stephen B. Brush, *Genetically Modified Organisms in Peasant Farming: Social Impact and Equity*, 9 IND. J. GLOBAL LEGAL STUD. 135 (2001).

[226] ITPGR, *supra* note 215, at arts. 10, 13.

[227] *See* ITPGR, *supra* note 215, at Annex I, List of Crops Covered Under the Multilateral System.

one of the international seed banks) "shall not claim any intellectual property or other rights" that limit access to PGR "in the form received from the Multilateral System."[228] This means that seed germplasm in the original form received from a seedbank cannot be protected by intellectual-property rights; however, any individual genes, advanced lines, cells, particular DNA sequences, and compounds derived from such germplasm may be protected. The "in the form received" language is in tension with and works to undermine the farmers'-rights provisions of the ITPGR.[229] The ITPGR does *not* recognize any rights in individual farmers/breeders who develop new plant varieties through systemic practices. In comparison, however, institutional public and private plant breeders continue to enjoy protection under patent or plant-variety protection regimes.[230] Furthermore, while the ITPGR is more comprehensive in its treatment of farmers' rights, it does little to effectively implement or vindicate those rights.[231]

V. RAPID TECHNOLOGICAL DEVELOPMENTS: PLANT BREEDING, MOLECULAR BIOLOGY, GENETIC ENGINEERING, AND GENETIC EROSION AND VULNERABILITY

During the 1970s advances in molecular biology made possible the genetic engineering of crops and other living organisms.[232] The question was whether genetic engineering was part of the problem or part of the solution.

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[228] ITPGR, *supra* note 215, at art. 12.3(d).

[229] Patel, *supra* note 166, at 98.

[230] *See, e.g.*, Thomas Cottier & Marion Panizzon, *Legal Perspectives on Traditional Knowledge: The Case for Intellectual Property Protection*, 7 J. INT'L ECON. L. 371, 377-78 (2004). ITPGR article 12.3 is opposed to the extension of intellectual-property rights to traditional knowledge and on plant genetic resources used for food or agriculture. *Id.* However, the ITPGR permitted plant breeders who utilized genetic materials from the CGIAR gene banks to obtain proprietary rights. *Id.* Article 12.3(f) and (g) does not preclude private plant breeders or public institutions from claiming intellectual-property rights on modifications of plant genetic materials; once protection is extended, only the patent holder can release control over it. *Id.*

[231] While the ITPGR recognizes the concept of farmers' rights with regard to plant genetic resources for food and agriculture, it places the primary responsibility of its realization on national governments. The ITPGR only calls for each signatory nation to enact legislation to protect farmers' rights in the areas of (1) protection of traditional knowledge; (2) the right to equitable participation; and (3) the right to participate in decisionmaking. ITPGR art. 9.2, *supra* note 215. Although article 9.3 preserves the right of farmers to save, use, exchange or sell farm-saved seed or propagating material, this right is subject to local legislation. *Id.* at art. 9.3.

[232] *See* John Charles Kunich, *Mother Frankenstein, Doctor Nature, and the Environmental Law of Genetic Engineering*, 74 S. CAL. L. REV. 807, at 809-810 (2001), for a brief history of the scientific developments that made genetic engineering possible.

Genetic engineering in the context of commercial crops necessarily entails decreased genetic diversity. Because it is essential that GE crops have a uniform genetic structure, genetic engineering encourages monoculture.[233] As GE crops come to dominate particular market sectors, the ability to substitute non-GE crops diminishes and genetic diversity decreases.[234] The uniformity of genetically modified seeds makes them less resistant and vulnerable to diseases, weeds, and pests.[235] Because plants bred from similar varieties are all vulnerable to the same pests and diseases, a single instance of disease or infestation of a pest can spread rapidly, practically unchecked, amongst the entire crop.[236] By contrast, traditional genetically diverse landraces developed their own localized, natural defenses against disease.[237]

The genetic diversity present in farmers' landraces is an insurance policy for cultivated crops.[238] While one variety of a cultivated crop might be vulnerable to a particular pest or disease, farmers' seed-saving and the availability of genetic diversity in wild and weedy relatives in landraces protects commercially cultivated varieties from a wipeout.[239] Thus, genetic diversity within a particular variety prevents widespread epidemics from destroying an entire harvest.[240]

When commercial plant breeders began selecting plants for certain characteristics (such as yield or a particular type of taste) until they arrived at a uniform "pure line" that reproduced uniformly,[241] they inadvertently and unintentionally opened a Pandora's box leading to widespread crop monoculture and increased vulnerability to pests and diseases.

Two historical events illustrate the importance of crop genetic diversity: the Irish potato famine during the 1840s and the Southern Corn Leaf Blight during the 1970s.[242] Though many at the time blamed

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233 Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlap: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 WM. & MARY L. REV. 2167, 2197 (2004).

234 *Id.* at 2176.

235 FOWLER & MOONEY, SHATTERING, *supra* note 1, at 47 ("As use of the pre line and hybrid varieties increased, so did pest and disease problems.").

236 *Id.* at 47.

237 *Id.* at 50.

238 *Id.*

239 *Id.* at 46-47 ("In a field of landraces a pest might gobble up one plant but find the next one different enough to be distasteful. In a field of modern varieties, if the first tasted good, they were all going to taste good.").

240 *Id.*

241 *Id.* at 46.

242 Holly Saigo, *Agricultural Biotechnology and the Negotiation of the Biosafety Protocol*, 12

weather for the Irish potato famine, a potato fungus called *Phytophthora infestans* actually caused this disaster.[243] Since all of the potatoes in Ireland descended from one crop line from the Andes, they had no natural resistance to the disease, and it spread rapidly amongst the potato fields.[244] Eventually a potato variety that was resistant to *Phytophthora infestans* was discovered amongst the thousands of distinct potato varieties found in the Andes and in Mexico.[245]

The Southern Corn Leaf Blight in the United States during the early 1970s exhibited a similarly disturbing pattern.[246] A human-created change to corn plants, designed to make a high-yield hybrid corn variety, created a vulnerability to the fungus *Helminthosporium maydis.*[247] One billion bushels of corn were lost to the blight during 1970-1971.[248] Official reports described the blight as caused by "a quirk in the technology that had redesigned the corn plants of America until, in one sense, they had become as alike as identical twins. Whatever made one plant susceptible made them all susceptible."[249]

In their natural environment, plants and their pests co-evolve as they continuously adapt to each other.[250] This means that "[l]andraces, because they have survived so long among pests and diseases in the centers of diversity, offer a wealth of potential resistance."[251] Breeders turn to these landraces when they cannot find resistance to a particular disease or pest among the varieties they have cultivated.[252] Wild species and weedy relatives of cultivated crops may offer the only genetic source of resistance to the most rare and serious diseases.[253] Genetic erosion, or the loss of genetic diversity, eliminates the only defense against disease that farmers and plant breeders may have.[254]

The value of genetic diversity extends beyond being a stopgap

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GEO. INT'L ENVTL. L. REV. 779, 795-796 (2000).

[243] FOWLER & MOONEY, SHATTERING, *supra* note 1, at 45; Saigo, *supra* note 242, at 795.

[244] FOWLER & MOONEY, SHATTERING, *supra* note 1, at 43.

[245] *Id.* at 45.

[246] Saigo, *supra* note 242, at 796.

[247] Jack Doyle, ALTERED HARVEST: AGRICULTURE, GENETICS, AND THE FATE OF THE WORLD'S FOOD SUPPLY (1985).

[248] Saigo, *supra* note 242, at 796.

[249] DOYLE, *supra* note 247, at 14.

[250] FOWLER & MOONEY, SHATTERING *supra* note 1, at 50.

[251] *Id.*

[252] *Id.*

[253] *Id.* at 50-51 (asserting that these so-named "wild relatives" "have now been used in the breeding program of virtually every cultivated crop.").

[254] *Id.* at 51.

against diseases and pests. Without variation, some crops may cease evolving effectively and may eventually become extinct.[255] Modern, genetically engineered crops may "be incapable of changing, of evolving, of adapting to new conditions, or stronger pests."[256] In other words, there would be no viable commercial agriculture if not for genetically diverse farmer landraces.

Crop genetic diversity is crucial to the world's food supply. Decreased crop genetic diversity means more than just the loss of specific genes. It may also bring about the extinction of entire varieties, as Cary Fowler, executive director of the Global Crop Diversity Trust, explains:

> The genetic diversity being lost today is the foundation of future plant breeding, of future plant evolution. If enough diversity is lost, the ability of crops to adapt and evolve will have been destroyed. We will not have to wait for the last wheat plant to shrivel up and die before wheat can be considered extinct. It will become extinct when it loses the ability to evolve, and when neither its genetic defenses nor our chemicals are able to protect it. And this day might come quietly even as millions of acres of wheat blanket the earth.[257]

Production and distribution of uniform varieties and hybrids are not the only causes of genetic erosion.

The expansion of intellectual-property laws to encompass plants, plant varieties, and the genetic sequences they contain cannot be said to be a primary cause of genetic erosions. However, the commodification of plant genetic resources has had a significant effect on the strategies taken by multinational agrochemical corporations as they bring their intellectual-property-protected products to market and strive to expand their markets in the countries of the developing world. And whether those products are hybrid seed or genetically engineered seed, backed up as they are by the technical and marketing infrastructure of those corporations, is it surprising that those seeds and supporting technologies conquer any markets that they enter?

Habitat destruction and the abandonment of traditional varieties also contribute to the extinction of old varieties: "Dams, occasional famines that cause people to eat up their seeds, church parking lots, and oil

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[255] RAOUL A. ROBINSON, RETURN TO RESISTANCE: BREEDING CROPS TO REDUCE PESTICIDE DEPENDENCE 217 (1995), *available at* www.idrc.ca/en/ev-9339-201-1-DO_TOPIC.html.

[256] FOWLER & MOONEY, SHATTERING, *supra* note 1, at 53.

[257] *Id.* at 89.

drilling that affect certain trees, all constitute a certain degree of danger to genetic resources."[258] Genetic erosion threatens to cause the degradation of the ability of agriculture to meet global food demand.[259] Thousands of unknown and unidentified varieties in remote regions of the globe are lost each year.[260] While there are no simple solutions to this problem, since the 1970s there have been systematic efforts to collect plant genetic resources in *ex situ* seed banks for future use.[261]

The treatment of seed germplasm in the United States can be understood as breaking down into four periods. During the Colonial era, plants were considered to be a rudimentary form of national property, and numerous officials (including Thomas Jefferson) encouraged the wide collection of diverse germplasm from expeditions abroad.[262] In the nineteenth century, U.S. federal and state governments heavily subsidized seed cultivation and distribution via land-grant universities and State Agricultural Experiment Stations, as well as direct seed distributions by mail by the USDA.[263] During the period from the turn of the twentieth century leading up to the 1930s, the private seed industry moved into the production, marketing, and distribution of seeds and created and exploited the market for hybrids.[264] The fourth period was from the end of World War II to the present and has been characterized by seed-industry concentrations via mergers (particularly from 1980 on)[265] and the market penetration of and spread of chemical-intensive high-input industrial agriculture.[266] It is important to note the crucial role that federal- and state-sponsored agricultural research played in the

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[258] *Id.* at 78.

[259] *Id.* at 78-79 ("But the single greatest threat to our agricultural heritage comes not from agriculture itself, from the precludement of traditional seeds and farming practices by modern, increased crop varieties. . . . And with the advent of biotechnology and its promise of even higher yields . . . the threat to traditional varieties would seem to be even more severe and more immediate. Which crops are most threatened? Primarily the crops where active breeding programs are producing new varieties. And, of course, these are the crops most important to human survival.").

[260] *11,000 Species Said To Face Extinction, with Pace Quickening*, N.Y. TIMES, July 5, 2009, *available at* www.nytimes.com/2000/09/29/science/29EXTI.html.

[261] John Seabrook, *Sowing for Apocalypse: The Quest for a Global Seed Bank*, NEW YORKER, Aug. 27, 2007, *available at* www.newyorker.com/reporting/2007/08/27/070827fa_fact_seabrook; *see also* BRUSH, *supra* note 4.

[262] KLOPPENBURG, *supra* note 5, at 52.

[263] *Id.* at 61-64.

[264] *Id.* at 91-92.

[265] For instance, in 1980 72% of the seed market for corn was controlled by eight companies, with the remaining market divided among 200 smaller companies. *Id.* at 110.

[266] "The volume of agrichemicals applied to corn (or any other crop, for that matter) before 1945 was negligible." *Id.* at 118. In contrast, between 1950 and 1980, nitrogen use on corn crops alone jumped by a factor of seventeen. *Id.*

development of hybridization, as well as the way that public institutions were pushed to the margins by those interests that sought to commodify hybrids during the fourth period.[267]

The success of hybrids was an important factor in the rise of industrial agriculture, with characteristic high chemical inputs in the form of pesticides, herbicides, and fertilizers.[268] By seeking to adapt monocultured seeds to new localities, industrial agriculture and the so-called "Green Revolution" reversed the traditional ideas of seed cultivation vis-à-vis adaptation of plants to local conditions, a process that drew upon and contributed to broad genetic diversity.

Against the backdrop of rapid and massive investment in commodifying germplasm from a technical perspective, there was a parallel, but uncoordinated, trend in legislation and cases towards conferring and protecting innovative efforts to develop and market new plant varieties, underwritten by expanding intellectual-property rights in plants.

VI. GENETIC EROSION AND CONSERVATION: ESTABLISHMENT OF NATIONAL AND INTERNATIONAL SEED BANKS

In the 1950s, the U.S. Congress created and funded a National Seed Storage Laboratory (NSSL)[269] as a network of gene banks to house the U.S. government's global germplasm collection.[270] This indicated a growing awareness of the importance of conserving plant genetic resources in the face of genetic erosion brought about by the "Green Revolution."

Genetic erosion was an unintended consequence of the mid-twentieth-century move towards industrial agriculture characterized by the heavy use of chemical inputs such as pesticides, herbicides, and

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[267] *Id.* at 105.

[268] *Id.* at 119.

[269] *Id.* at 172 (quoting a 1977 Agricultural Research Service letter to the chairman of the IBPGC to the effect that deposits made at the NSSL pursuant to IBPGR became the property of the U.S. government); *see also* FOWLER, UNNATURAL SELECTION, *supra* note 1, at 242 ("[T]he U.S. Department of Agriculture established the [NSSL] in 1958. . . . [The NSSL] sought to collect and store genetic diversity for future use in plant breeding [and] . . . operated much the way botanical gardens had in previous centuries.").

[270] KLOPPENBURG, *supra* note 5, at 159 ("[By the 1950s, t]he need for effective storage facilities for acquired plant genetic materials became acute. Improved understanding of seed physiology and advances in seed preservation technology made long-term storage feasible. In 1956, Congress appropriated funds for the construction of a National Seed Storage Laboratory (NSSL) at Fort Collins, Colorado. The NSSL was completed in 1958 and is the flagship of the network of gene banks that now serves as the repository for the fruits of global germplasm collection.").

fertilizers. One consequence of this reliance on high-input agriculture was to create "super"-resistant strains of weeds and pests.[271] If the herbicides and pesticides killed off the weaker pests and weeds, those that survived passed their resistance to subsequent generations and so on. This triggered a vicious cycle where weeds and pests would need to be dosed with stronger and stronger herbicides and pesticides, further degrading environmental conditions where such industrial agriculture was used.[272]

By the 1970s, the Rockefeller Foundation collaborated with the U.S. government to create agricultural programs and International Agricultural Research Centers to "improve" crops in different regions of the world,[273] which included collecting and cataloging germplasm samples with the express goal of preserving *ex situ* the rapidly disappearing store of crop genetic diversity.[274] The Rockefeller and Ford Foundations, along with the United States and the World Bank, created the Consultative Group on International Agricultural Research (CGIAR) to coordinate the global network of International Agricultural Research Centers (IARCs).[275]

Ironically, it was the Rockefeller Foundation and the United States that had promoted a unilinear model of agricultural high-yielding crop development in the post-war era that put crop genetic diversity in jeopardy in the first place. The FAO organized two conferences, in 1961 and 1967.[276] Those present for the FAO conferences decided to undertake a coordinated global germplasm collection and conservation program.[277] These pieces of legislation and public-private collaborations

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[271] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 46-47.

[272] INT'L FOOD POLICY RESEARCH INST., GREEN REVOLUTION: CURSE OR BLESSING? (2002), *available at* www.ifpri.org/sites/default/files/publications/ib11.pdf.

[273] KLOPPENBURG, *supra* note 5, at 159 ("'[T]he early initiatives sponsored by the Rockefeller Foundation and the U.S. government spawned a whole series of secondary agricultural programs that encompassed an increasingly broad number of crops, countries and funding agencies. These programs spread to other countries during the 1960s.").

[274] *Id.* at 160-61 ("[T]he IARCS perform a dual role in the processing of plant germplasm. They necessarily collect and evaluate indigenous land races and primitive cultivars that are the raw material from [High-Yielding varieties] are bred. And because their "imported" agricultures are based on the very species that the IARCS are mandated to improve (i.e., corn, wheat, potato), such collection and evaluation are of direct value to the developed nations . . . [and] are also vehicles for the efficient extraction of plant genetic resources from the Third World and their transfer to the gene banks of Europe, North America and Japan.").

[275] *Id.*

[276] *Id.* at 163.

[277] *Id.* at 161 ("At these [FAO] meetings, in 1961 and 1967, there developed a consensus that a coordinated global program of collection and conservation was necessary to ensure that the essential raw materials of plant improvement would not be lost to humanity."); *see also* Otto H.

indicated that private breeders increasingly dominated plant breeding in North America and Europe and were eager to introduce their varieties into Latin America and Asia.

The IARCs provided a framework for the transformation of agriculture in the developing world. The IARCs introduced new varieties that were double-edged. They were higher-yielding, but they were also high-input because of the necessity of high use of fertilizers, herbicides, and water. Cary Fowler writes that these new varieties

> spread over Latin America and Asia with astonishing speed. In the process ancient centers of crop genetic diversity nearly disappeared. . . .In the twinkling of the evolutionary eye, the effects of thousands of years of crop evolution were wiped out. . . .Over 100 million acres of new uniform rices and wheats were soon being grown where tens of thousands of farmer varieties had once been found.[278]

Thus, farmer varieties were being avidly collected and stored *ex situ* in places like the NSSL, while at the same time a legal regime was being constructed that would treat uniform varieties bred for industrial agriculture as intellectual property.

VII. THE CGIAR SYSTEM: FREE FLOW OF GENETIC RESOURCES AND NORM OF RECIPROCITY

As mentioned previously, a collaboration between the Rockefeller Foundation, the United States, and the U.N.'s Food and Agriculture Organization created the Consultative Group on International Agricultural Resources (CGIAR), which is the parent institution of an international network of agricultural research centers (IARCs).[279] For example, the International Maize and Wheat Center in Mexico focuses on collection, storage and breeding of barley, maize, wheat, and triticale.[280] The International Rice Research Center focuses its work on varieties of rice.[281]

Frankel, *Genetic Resources: The Founding Years*, 7 DIVERSITY 26 (Fall 1985); Otto H. Frankel, *Genetic Resources: The Founding Years – Part Two: The Movement's Constituent Assembly*, 8 DIVERSITY 30 (Winter 1986); Otto H. Frankel, *Genetic Resources: The Founding Years – Part Three: The Long Road to the International Board*, 9 DIVERSITY 30 (1986).

[278] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 241-42.

[279] CGIAR Research: Genebanks and Plant Genetic Resources, www.cgiar.org/impact/genebanksdatabases.html (last visited Sept. 20, 2009). The CGIAR centers "together maintain over 650,000 samples of crops, forages and agro-forestry genetic resources in the public domain." *Id.*

[280] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 183.

[281] *Id.*

The CGIAR is governed by a board representing donors of funds such as the Rockefeller and Ford Foundations.[282] These foundations created and funded the CGIAR in part to try and unite privately or nationally funded gene banks into an international network.[283] The CGIAR is headquartered in Washington, D.C.[284]

In 1974, the CGIAR formed the International Board for Plant Genetic Resources (IBPGR), whose scientific experts would serve as a spur to plant genetic resource conservation activities.[285] While the rhetoric surrounding the founding of the IBPGR was shot through with talk of "neutrality" and "expertise," Cary Fowler notes that proponents of the Green Revolution and others with a unilinear view of international development were on the IBPGR.[286] Fowler notes that Richard Demuth, "a Washington lawyer for the State Department, who long had ties with

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[282] *Id.*

[283] *Id.*

[284] *Id.* at 182.

[285] *Id.*

[286] *Id.* at 183. The term "development" and terms such as "developed" and "developing" used to designate different countries are drawn from a larger debate about the United Nations and the Bretton Woods Initiatives that were created following World War II. *See* RICHARD PEET with ELAINE HARDWICK, THEORIES OF DEVELOPMENT (1999). Bretton Woods established the International Monetary Fund and the World Bank, and, in the 1990s, the World Trade Organization. *Id.* Margaret Chon writes that

> [a]ccording to the (neo)liberal world view, the development system basically works, with some minor adjustments needed as problems arise. To remedy politically unacceptable differences among the developing and developed countries, policymakers need just add a little more 'equality' and stir. Mistakes are minor and the overall direction is positive. One underlying assumption is that the short term costs of free trade will result in long term gains by pushing countries into greater economic growth. Economic growth is the sine qua non of development. . . .(Neo)liberalism is characterized by certain policy recommendations, including, among other things, trade liberalization, foreign direct investment and property rights. Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2861-2862 (2006).

Andy Crump defines "developing countries" as countries that

> include states which are variously labeled as . . . underdeveloped countries, low income countries, Majority world, the South or the Third World. These nations have low levels of technology, basic living standards and little in the way of an industrial base . . . . Their economies are mainly agricultural . . . . Per capita incomes are below $5000 and often less than $1500. Around 70% of the world's population lives in developing countries. Andy Crump, THE A TO Z OF WORLD DEVELOPMENT 78-79 (Wayne Elwood ed. 1999).

Crump goes on to describe "developed countries" as

> Northern, industrialized nations, sometimes also referred to as the 'First World' . . . . [This category] almost always includes the 35 market-oriented countries of the Organization for Economic Co-operation (OECD) . . . . Generally, nations having a per capita income of over $10,000 are included in this group. *Id.*; *see also* Chon, *supra* note 286, at 2826.

the Agency for International Development . . . retired . . . and became the first to chair this 'purely' technical and scientific body."[287]

The IBRGR has an unusual relationship with the United Nations Food and Agriculture Organization (FAO).[288] While the IBPGR has its headquarters at the FAO's Rome offices and the FAO pays the IBPGR's staff salaries, the IBPGR has autonomy in setting its own programmatic agenda.[289] Cary Fowler noted that during this period the IBPGR had a "distinctly northern flavor," and pointed out that in the late 1980s, "[o]nly 15 percent of the [germplasm] samples collected [were] designated for storage in Third World collections. . . [and] [f]ully 85 percent [have] been stored in industrialized countries and IARC seed banks."[290]

The IBPGR had the power to designate officially which crops were endangered as well as the order in which germplasm from such crops would be collected and preserved.[291]

The legal treatment of these stored PGRs was somewhat ambiguous prior to the 1990s but, as discussed later, became clearer later in that decade. At the least, prior to the 1980s, PGRs would have been treated as belonging to the "common heritage of [hu]mankind" and thus would have been subject to a principle of "open access" with a norm of reciprocity. Stephen Brush writes:

> Common heritage was the *ex ante* governance of biological resources until the last quarter of the twentieth century. . . . Common heritage refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest. Common heritage is similar to common property regimes that anthropologists and other social scientists have described for nonmarket economies. Neither common heritage nor common property implies a lack of rules (*res nullius*) . . . . Rather they imply community management (*res communes*) that involves regulated access to common resources and reciprocity among users.[292]

As mentioned earlier, during the mid-1980s, the legal characterization of PGRs underwent significant transformation. This shift may be seen in the way that the 1992 Convention on Biological Diversity

[287] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 183.

[288] *Id.* at 184 ("The structure was what IBPGR itself called an 'historical anomaly.'").

[289] *Id.*

[290] *Id.*

[291] *Id.*

[292] BRUSH, *supra* note 4, at 221-22.

(CBD)[293] recharacterized PGRs as being the "sovereign national property" of the country in which they are located.

This was a significant change, particularly when the IBPGR "has been particularly generous to the United States when it has come to designating sites for global and regional storage responsibility [for germplasm]. . . . Of the top 15 crops, the United States ranks among the top four germplasm holders in the world."[294]

With the CGIAR system, there were marked critiques of the IBPGR channeling PGRs to U.S. gene banks in the early 1980s.[295] The United States also placed conditions to the IBPGR under which the United States would accept germplasm storage responsibilities, one of which was that accepted germplasm would "become the property of the U.S. government."[296]

"Common heritage" treatment of PGRs and "open access" came under critical pressure during this decade. Anti-colonialist critics of "common heritage" argued that it was a vestige of colonialism that facilitated a unilateral flow of genetic resources out of the poor nations of the global south.[297] Others argued for abandoning the "common heritage" principle because it led to a "Tragedy of the Commons" result—because the resources were treated as "open access," it left them open to premature degradation.[298]

It was against this increasingly contentious backdrop that delegates from developing countries met at the 1981 FAO Conference to express their growing discontent with the IBPGR's tilt toward the United States and other countries of the global North with what they saw as a

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[293] Convention on Biological Diversity, 5 June 1992, UNEP/Bio.Div./N7-INC5/4, 31 I.L.M. 818 (1993) (Opened for signature, May 1992, and entered into force, Dec. 1993); *see also* Convention on Biological Diversity, List of Parties, www.biodiv.org/world/parties.asp (last visited Sept. 20, 2009).

[294] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 185; *see also* FOWLER & MOONEY, SHATTERING *supra* note 1, at 190-91.

[295] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 185 (describing a letter from the Institute for Tropical Agriculture's David Wood to the IBPGR criticizing the way that there seemed to be an untoward relation between the financial donations to IBPGR and the number of collections designated to that country by the IBPGR).

[296] *Id.* at 186 (citing a letter from T.W. Edminste to Richard Demuth, Chairman of the IBPGR, Jan 19, 1997).

[297] BRUSH, *supra* note 4, at 231.

[298] *Id.* at 230 (describing the argument that "[a]s long as biological resources were common heritage goods, nations richly endowed with genetic diversity had no incentive to conserve them. Indeed the lack of ownership was seen as incentive to overexploit biological resources."); *see also* Roger A. Sedjo, *Property Rights and the Protection of Plant Genetic Resources*, *in* SEEDS AND SOVEREIGNTY: DEBATE OVER THE USE AND CONTROL OF PLANT GENETIC RESOURCES 293 (Jack R. Kloppenburg Jr. ed. 1988).

generally unilateral and northward flow of PGRs.

Concerns over the erosion of genetic diversity in major crops as well as disquiet at the way industrialized nations were quickly moving to adopt intellectual-property systems, such as the UPOV or the U.S. PVPA, protecting plant varieties and providing patent protection for plant gene sequences, coalesced during this period.

These critiques and concerns finally crystallized at the March 1983 meeting of the FAO's Committee on Agriculture, where delegates from the countries of the global south openly challenged the status quo, calling for changes in IBPGR policy and a restructuring of the CGIAR system.[299]

One of the major challenges was to the basic assumption underlying both the PVPA and the UPOV – the distinction between "raw" and "worked" germplasm. This distinction provided a rationale for protecting germplasm that had been "worked" by plant breeders, and denying it to germplasm that was merely "raw." "Raw" germplasm could be further distinguished as highly variable and when "found" (generally by someone in the developed world) would be transformed from a "primitive" landrace into an elite "stable" cultivar and protectable as intellectual property.

Needless to say, this debate was politically fraught. Countries such as the United States were unwilling to give an inch when a country like Mexico insisted that the "common heritage" principle should apply to both "raw" and "worked" germplasm, to elite cultivars as well as "primitive" landraces and farmers' varieties.[300]

VIII. GENETIC EROSION AND VULNERABILITY: ARE GENETICALLY ENGINEERED PLANTS A PART OF THE PROBLEM OR PART OF THE SOLUTION?

A. THE DIRECTIONS IN WHICH GENES FLOW

The problems of genetic erosion due to monoculture agriculture in the developing world and genetic vulnerability due to uncompensated appropriation in the developed world present a curious symmetry and further support for the notion that the two hemispheres are genetically interdependent. As the global seed industry expands, genetic erosion increases. The global regions that produced the genetic diversity that

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[299] FOWLER, UNNATURAL SELECTION, *supra* note 1, at 188-89.
[300] *Id.* at 185.

enabled plant breeders (both public and private) to introduce traits into cultivated varieties have also become growing markets for the introduction of proprietary plant varieties, agricultural systems, and high-chemical-input products. Unfortunately, uniform genetically engineered and other proprietary varieties are extremely vulnerable to new pests, diseases, and blights.[301]

Genetic diversity acts as a kind of "insurance policy" against problems such as the corn blight that devastated U.S. crops in the Midwest during the 1970s. That blight, which attacked a characteristic present in 90% of American corn varieties, cost American farmers 15% of that year's harvest.[302] A subsequent National Academy of Sciences study found that American crops were "impressively uniform genetically and impressively vulnerable."[303] Though agronomists and policymakers tried addressing the genetic vulnerability of industrial agriculture from the late 1950s through the 1970s, the consensus on genetic vulnerability as a serious global problem attenuated over time. This may be due in part to a sanguine sense of genetic security that rests on the national and international system of *ex situ* gene banks such as the NSSL and the CGIAR system. However, these gene banks are underfunded and cannot replace a global system for *in situ* preservation and related traditional agricultural knowledge and know-how.[304]

Ultimately, the emerging global germplasm system has produced genetic vulnerability and genetic erosion—processes and products that further link the developed and developing world. Elite commercial varieties that provide the basis of modern industrial agriculture show a high degree of genetic uniformity because they have undergone rigorous selection in breeding. Their narrow genetic makeup renders them systemically vulnerable to diseases and pest infestations in a way that heterogeneous landraces are not. As genetic erosion drains the gene pool for entire species, it becomes more difficult to find characteristics to combat disease or pest epidemics that challenge the genetically vulnerable commercial cultivars.[305]

Under the legal regime in place prior to the 1990s, once "primitive" or "raw" plant germplasm was construed legally as the "common heritage of mankind," it could be removed from genetically rich regions

[301] FOWLER & MOONEY, SHATTERING, *supra* note 1, at 47.

[302] KLOPPENBURG, *supra* note 5, at 163; *see also* FOWLER, UNNATURAL SELECTION, *supra* note 1, at 111; DOYLE, *supra* note 247, at 1-8.

[303] KLOPPENBURG, supra note 5, at 163.

[304] BRUSH, *supra* note 4, at 200-01.

[305] KLOPPENBURG, supra note 5, at 162.

for as little as it cost to gather a few samples. These "free" genetic resources then flowed into Northern gene banks and laboratories of agrichemical giants, where their genetic diversity was "worked" to improve and safeguard proprietary, patented varieties. Then, these "stabilized" varieties were sold at a premium in the emerging agricultural markets of the very countries and regions where the genetic resources originated, pushing formerly genetically diverse countries toward industrial agriculture and monoculture. Ironically, the last reserve of genetic diversity may reside in the developed world's gene banks, where genetic diversity has finally been priced.

The final irony here is that "common heritage" treatment for PGRs was vilified and abandoned as (1) an artifact of colonialism, or (2) as giving rise to a "Tragedy of the Commons" scenario, *precisely* at the time when developing countries were becoming net *importers* from gene banks located in countries like the U.S.

B. Regulation of Genetically Engineered Crops

i. A Very Brief History of Genetically Engineered Crops

Against the backdrop of expanding intellectual-property protection for plants in the context of multilateral treaties such as TRIPS or the characterization of plant genetic resources as "sovereign national property" under the CBD, what are we to make of the rapid advances in the area of GE plants, created in the wake of the 1980 *Chakrabarty* decisions holding living organisms patentable subject matter? Undoubtedly, *Chakrabarty* spurred investment in the plant biotechnology sector, holding out the promise of a patent in particular plant innovations that met the standards of patent law.

Despite the nod toward "farmers' rights" in the 2001 ITPGR, how does the market introduction of genetically engineered crops such as corn, soybeans, cotton, and canola in North America affect plant genetic diversity? After all, part of the point of "farmers' rights" was to recognize and reward the role that farmers play and have played in preserving plant genetic diversity over the centuries. Put another way, the question is, how are genetically engineered plants that are underwritten by intellectual-property laws affected by other national or international public health and safety regulations?

We have seen how the CBD, whose overarching goal was to create market incentives for nations to conserve biodiversity within their borders, is consonant with the application of intellectual-property laws within those borders. Is there a similar consonance with environmental laws, food and drug laws, and agricultural laws? How do GE plants interact with these multiple layers of domestic and international régimes with differing underlying goals and diverse iterations?

Clearly, on many levels, GE plants present challenges to national and international regulatory systems that were created before such "products" entered the global market. The fact that the technologies that produce such plants may be patented or patentable, as is the fact that sequences within plants may be patented, further complicates the regulatory matrix.

Looked at one way, GE plants are a mere continuation of trends begun in the early twentieth century that gave rise to mass-scale industrial agriculture. Hybridization, mechanization, and high-chemical-input fertilizers, herbicides, and pesticides have driven up agricultural yields but with environmental costs, including erosion, water degradation, and marked decreases in plant genetic diversity. Genetically engineered plants may be seen as the epitome of industrial agriculture – patented, designed to grow only one season, high yielding, with one or more characteristics such as drought or salinity tolerance. This Article will briefly survey the history of GE plant varieties before moving on to critically examine the regulatory regimes to which such organisms are currently subject.

Arguably, genetic modification of crops has been going on for at least ten thousand years, since humans shifted from a nomadic hunter-gatherer mode to cultivating crops via selective plant breeding.[306] By the mid-nineteenth century, Augustinian monk Gregor Mendel (1822-1884) began unlocking the laws of plant heredity.[307] When Mendel's work was first published it was ignored, but the rediscovery of his work in the early twentieth century was crucial to the development of plant hybrids possessing higher yields.[308]

One drawback of hybridization is that it is extremely labor-intensive.[309] By the 1980s, genetic engineering allowed scientists to locate and move the particular genetic sequences responsible for particular traits in a plant variety, or even to move traits from one species

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[306] Kunich, *supra* note 232, at 808.

[307] Encyclopedia Britannica Online, Gregor Mendel, www.britannica.com/EBchecked/topic/374739/Gregor-Mendel (last visited Sept. 20, 2009).

[308] NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 22-23 (2000).

[309] NAT'L RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS: THE SCOPE AND ADEQUACY OF REGULATION 37-43 (2002) [hereinafter NRC REPORT 2002] (discussing traditional methods for crop improvement).

and insert those characteristics into another species.[310] This transgenic manipulation of living organisms at a cellular level is referred to as recombinant DNA (rDNA) genetic engineering.[311] rDNA genetic engineering provides plant breeders with important "advantages" over sexual reproduction. For example, genes from different species may be introduced into particular varieties.[312] Additionally, new plant varieties are able to be produced much faster than through the traditional generation process of cross breeding.[313] Finally, because a particular trait that is being introduced can be identified as located within a particular genetic sequence, variability in offspring is reduced, or to put it another way, predictability of offspring is enhanced.[314]

By the end of the first decade of the twenty-first century, GE food is ubiquitous in the United States.[315] Since 1994, when the first GE crop—the patented Flavr Savr tomato—was introduced,[316] GE crops have penetrated the commercial food marketplace.[317] These genetically engineered crops have been altered for heightened pest resistance, herbicide tolerance, and virus, bacteria and fungus resistance.[318]

By 2004, 45% of the corn, 85% of the soybeans, and over half of the canola and papaya grown in the United States were genetically engineered.[319] The first generation of GE crops was designed for specific traits such as pest resistance or herbicide tolerance. Second-generation crops are being engineered to produce pharmaceuticals, vaccines, and

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[310] MARGARET MELLON, BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING, 20 (1988). Rebecca M. Bratspies, *Consuming (F)ears of Corn: Public Health and Biopharming*, 30 AM. J. L. & MED. 371, 379 (2004) [hereinafter Bratspies, *Consuming (F)ears of Corn*]; Rebecca M. Bratspies, *The Illusions of Care: Regulation Uncertainty and Genetically Modified Food Crops*, 10 N.Y.U. ENVTL. L. J. 297 (2002).

[311] Mandel, *supra* note 233, at 2167.

[312] NRC REPORT 2002, *supra* note 309, at 43.

[313] *Id.* at 37-43 (discussing traditional labor intensive methods for crop improvement).

[314] *Id.* at 47.

[315] Thomas O. McGarity, *Seeds of Distrust: Federal Regulation of Genetically Modified Foods*, 35 U. MICH. J. L. REFORM 403, 404 (2002) (noting ease with which GE foods reached the marketplace).

[316] Mandel, *supra* note 233, at 2176.

[317] *Id.*

[318] *Id.* at 2177 (citing Information Systems for Biotechnology, Charts for Field Test Release in the U.S., www.isb.vt.edu/CFDOCS/biocharts1.cfm (last visited Sept. 20, 2009).

[319] PEW INITIATIVE ON FOOD & BIOTECHNOLOGY, FACTSHEET: GENETICALLY MODIFIED CROPS IN THE UNITED STATES 2 (Aug. 2004), *available at* www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Fact_Sheets/Food_and_Biotechnology/PIFB_Genetically_Modified_Crops_Factsheet0804.pdf (indicating that the United States, Argentina, Canada, Brazil, China, and South Africa produce 99% of all genetically modified crops.).

industrial compounds for use in paper and detergents.[320]

ii. Risks and Benefits of Genetically Engineered Crops

a. Potential Benefits

Promoters of genetically engineered crops contend that such crops will have higher yields and produce greater amounts of food.[321] In a Malthusian vein, a growing population puts greater pressures on global food supply that may be met only by high-yielding GE crops. Law Professor Gregory Mandel points out that approximately $14 billion of crops in the United States are lost to pests.[322] Genetically engineered herbicide-tolerant crops can further reduce production costs.[323] Similarly, resistance to disease and drought can raise crop yields and reduce costs.[324]

Theoretically, reduction in the costs of production and higher yields should decrease the cost of food.[325] Lakshman Guruswamy estimates that agricultural production will need to double over the next fifty years to keep pace with projected population growth.[326]

Are genetically engineered foods more nutritious and better tasting? There is the example of "golden rice" – rice that was genetically engineered to raise its vitamin A content.[327] However, the intersection with intellectual property in this context is vexing – if indeed "golden rice" is more nutritious, the fact that it took clearance of over seventy patents and other intellectual-property rights to create "golden rice" indicates that negotiating and clearing the thicket of overlapping intellectual property rights may increase the costs of agricultural innovation and chill, delay, or deter such innovation altogether.[328]

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[320] Mandel *supra* note 233, at 2178 (citing Andrew Pollack, *New Ventures Aim To Put Farms in Vanguard of Drug Production*, N.Y. TIMES, May 14, 2000, at A1.); *see also* Bratspies, *Consuming (F)ears of Corn*, *supra* note 310.

[321] Julie Teel, *Regulating Genetically Modified Products and Processes: An Overview of Approaches*, 8 N.Y.U. ENVTL. L.J. 649, 650 (2000).

[322] Mandel, *supra* note 233, at 2180.

[323] *Id.* at 2181.

[324] Lakshman D. Guruswamy, *Sustainable Agriculture: Do GMOs Imperil Biosafety?*, 9 IND. J. GLOBAL LEGAL STUD. 461, 472-73 (2002).

[325] McGarity, *supra* note 315, at 409.

[326] Guruswamy, *supra* note 324, at 466.

[327] Golden Rice, Fact Sheets, Clinical Significance of Vitamin A Deficiency, www.goldenrice.org/Content3-Why/why4_facts.html (last visited Sept. 20, 2009).

[328] Christopher Marquis, *Monsanto Plans to Offer Rights to its Altered Rice Technology*, N.Y. TIMES, Aug. 4, 2000, *available at* www.nytimes.com/2000/08/04/world/monsanto-plans-to-offer-

Roughly half of the land in the United States is under agricultural and livestock production.[329] Arguably, to the extent that genetically engineered crops produce "natural" pesticides (such as Bacillus thuringeisis, or Bt), the result would be less chemical pesticide spraying and less residue.[330] Bt is naturally occurring and is toxic to particular insects.[331] If a GE crop produces its own Bt, it produces it continuously and alleviates the need to spray Bt.[332] Gregory Mandel says that in 2001, there was a forty-six-million-ton reduction in the amount of sprayed Bt due to GE crops that produced their own Bt.[333] In the context of herbicides, genetically engineered crops require much less pre-emergent herbicide,[334] with herbicide application focused on post-emergent plants, meaning less herbicide will be worked into the soil, with concomitant lessening of erosion and water loss.[335] Arguably, there is less habitat loss because genetically engineered crops produce higher yields.[336]

Genetically engineered crops that are only now coming on line or will be coming on line include crops that remove toxics from soils, and crops that will manufacture vaccines and other pharmaceuticals as well as assorted industrial compounds whose manufacture currently requires hydrocarbons such as oils and plastics.[337]

b. Potential Risks and Costs

There are risks associated with the introduction of genetically modified crops into the food chain. At the core of the debates over genetically modified crops is a disagreement over a presumption. On one hand are advocates of the "precautionary principle."[338] When a new

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rights-to-its-altered-rice-technology.html. For a much less sanguine view of genetically engineered food, *compare StarLink Corn: How It Reached the Food Supply*, ASSOCIATED PRESS, Dec. 4, 2000, *available at* http://archive.showmenews.com/2000/dec/20001204busi011.asp; *see also* Rebecca M. Bratspies, *Myths of Voluntary Compliance: Lessons From the StarLink Corn Fiasco*, 27 WM. & MARY ENVT'L L. & POL'Y REV. 593 (2003).

[329] Mandel, *supra* note 233, at 2185; *see also* NRC REPORT 2002, *supra* note 309, at 37.

[330] Mandel, *supra* note 233, at 2183-84.

[331] *Id.* at 2185.

[332] McGarity, *supra* note 315, at 411 (noting that traditional applications of Bt lose their efficacy within a few days after application, but in an engineered crop that creates its own Bt, the efficacy of this technique lasts throughout the life of the crop).

[333] Mandel, *supra* note 233, at 2185.

[334] Guruswamy, *supra* note 324, at 470.

[335] Mandel, *supra* note 233, at 2185.

[336] *Id.* at 2185-86.

[337] *Id.* at 2187.

[338] *See* The Precautionary Principle Project, www.pprinciple.net/ (last visited Sept. 20, 2009); *see also* Rebecca M. Bratspies, *Some Thoughts on the American Approach to Regulating Genetically*

technology becomes available, advocates of the precautionary principle argue that precautions should be taken in adopting such a technology, i.e., that lengthy testing and evaluation are needed to ensure that genetically engineered crops do not pose unacceptable risks for humans and animals who consume them.[339] Such foods are presumed unsafe until they can be proven safe.

On the other hand are those who argue for the principle of "substantial equivalence": to the extent that the chemicals found in non-genetically engineered foods are present in genetically engineered foods, the genetically engineered foods should be presumed to be "substantially equivalent" to non-genetically engineered crops.[340] Under this view, such crops are presumed safe, and hence not subject to additional testing or other precautions, unless something goes wrong.

To date, the "precautionary" principle has been embodied by the European Union's "go slow" treatment of genetically modified crops.[341] Conversely, the United States has adopted the "substantial equivalence" position toward the introduction of genetically modified crops into the food chain.[342]

Some of the risks associated with genetically engineered crops are associated with allergenicity of such crops.[343] Especially given that GE food ordinarily is not labeled as such,[344] there is a possibility for common

Modified Organisms, 16 KAN. J. L. & PUB. POL'Y 393 (2007) [hereinafter Bratspies, *Some Thoughts*].

[339] *See* Teel, *supra* note 321, at 652-62 (illustrating precautionary-principle approach versus substantial-equivalence approach to GE food).

[340] McGarity, *supra* note 315, at 404 (noting that the federal agencies primarily responsible for regulating GE foods, the FDA and the EPA, have relied on the "substantial equivalence" standard when weighing risks of GE foods).

[341] Nicholson, *supra* note 57, at 29.

[342] McGarity, *supra* note 315, at 404 (noting that the federal agencies primarily responsible for regulating GE foods, the FDA and the EPA, have relied on the "substantial equivalence" standard when weighing risks of GE foods); *see also* Vern R. Walker, *Some Dangers of Taking Precautions Without Adopting the Precautionary Principle: A Critique of Food Safety Regulation in the United States*, 31 ENVTL L. REP. 10040 (2001); John S. Applegate, *The Prometheus Principle: Using the Precautionary Principle to Harmonize the Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEG. STUDS. 207 (2001); Bratspies, *Some Thoughts*, *supra* note 338, at 407-13.

[343] Food & Drug Administration Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22987 (May 29, 1992). [hereinafter FDA Statement of Policy]. For instance, there were multiple claims of severe allergic reactions related to the StarLink® GE corn incident, in which millions of bushels of StarLink® GE corn were intermingled with traditional corn. *See 44 Claim Illness Was Caused by Biotech Corn in Food*, WASH. POST, Nov. 29, 2000; Marc Kaufman, *Biotech Corn Is Test Case for Industry, Engineered Food's Future Hinges on Allergy Study*, WASH. POST, Mar. 19, 2001, *available at* www.biotech-info.net/future_hinges.html.

[344] For a brief discussion of the lack of labeling of GE foods and the public's support for labeling, *see* Nicholson, *supra* note 57, at 31-33.

allergens to be transferred into other organisms, where they can be consumed without knowledge or warning of the allergen.[345] The approach that is used to analyze risks matters quite a lot in determining whether such crops should be allowed to enter the human and animal food chain. In particular, genetically engineered crops may contain different levels of naturally occurring toxins than non-genetically engineered crops, or may possess different mixtures of nutrients that may have effects on human immune systems.[346]

Indirect risks from GE crops may arise from the method used by scientists to tell if gene transfer has been successful, which is to attach antibiotic-resistant gene sequences to the genes that they insert.[347] Scientists then use antibiotics to see if the plant exhibits antibiotic resistance; if so, the gene insertion has been successful.[348] One side effect of this may be that antibiotic resistance may be transferred up the food chain.[349] There may also be unintended genetic consequences arising from synergistic effects when gene sequences from different species are combined in one organism.[350]

If genetically engineered material moves into the environment, organisms may be affected other than those particular pests or weeds targeted.[351] Because genetically engineered crops will continuously produce a particular herbicide or pesticide, it will be present during the entire growing season, not only during periods of sprayed applications.[352] This increases the likelihood that particular weeds and pests will develop enhanced resistance to such pesticides or herbicides.[353] If pests and weeds develop this resistance, it makes the particular pesticide or herbicide useless.[354]

Methods of dispersal of genetically engineered material may occur through dispersal of genetically engineered seeds or via the wind carrying genetically engineered pollen.[355] In particular, the phenomenon of "superweeds" – weeds that can tolerate herbicides because of crossbreeding via airborne pollen with herbicide-tolerant crops—has

345 Mandel, *supra* note 233, at 2191.

346 *Id.* at 2190, 2192.

347 FDA Statement of Policy, *supra* note 343, at 22987.

348 *Id.*

349 Mandel, *supra* note 233, at 2192.

350 *Id.* at 2194.

351 *Id.*

352 *Id.* at 2197.

353 *Id.*

354 *Id.* at 2198.

355 *Id.* at 2194.

been documented.[356] A related risk is the spread of genetically engineered crops into natural habitats, threatening either extinction or disruption of indigenous ecosytems.[357] Gregory Mandel has written about the problem caused in western Canada by invasive weeds that have crossed with Monsanto's genetically engineered canola crops.[358]

A more general threat to biodiversity occurs as genetically engineered crops become adopted widely, which means increased genetic uniformity and greater vulnerability to a wipeout by pests or disease.[359] To the extent that there is market competition between genetically engineered seeds and non-genetically engineered seeds, there is a rough substitutability that gives farmers, such as Percy Schmeiser, discussed in the next section, a choice regarding what crops they choose to plant.[360] To the extent that genetically engineered crops triumph in the market, that rough substitutability disappears and farmers have no choice but to plant genetically engineered crops.

Widespread adoption of genetically engineered crops as has occurred in Canada and the United States raises questions about protection of food supply and containment of deleterious effects of such crops. The next generation of genetically engineered crops that will produce pharmaceuticals and industrial products raises the question of what will happen if genes from these crops are introduced into the food supply.[361]

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[356] Kunich, *supra* note 232, at 818; *see also* NRC REPORT 2002, *supra* note 309, at 67.

[357] Mandel, *supra* note 233, at 2196.

[358] *Id.*

[359] *Id.* at 2197.

[360] There is also the problem of "genetic drift" in which GE seeds inadvertently spread to, and contaminate, non-GE crops. *See* Hilary Preston, *Drift of Patented Genetically Engineered Crops: Rethinking Liability Theories*, 81 TEX. L. REV. 1153 (2003).

[361] Mandel, *supra* note 233, at 2199; *see also* In re StarLink Corn Products Liab. Litig., 212 F. Supp. 2d 828 (N.D. Ill . 2001), in which the EPA had approved Aventis CropScience's registration for genetically engineered corn as animal feed as well as for ethanol production. Gregory N. Mandel, *Building Confidence Through Teamwork on Regulatory Proposals: The Genetically Modified Product Model*, 44 JURIMETRICS J. 41, 50-54. Aventis requested approval for use in food for humans and the EPA was unable to determine if StarLink® was safe for human consumption. *Id.* Because StarLink® wasn't approved for use in human food, the EPA required certain special procedures for StarLink® such as segregation from other corn and buffer zones around StarLink® corn fields. *Id.* However, in September 2000, StarLink® was discovered in a wide variety of U.S. consumer foods. *Id.* Aventis agreed to buy back the entire year's crop of genetically engineered corn at an estimated cost of $1 billion. *Id.* Finally, Aventis cancelled its EPA registration for StarLink®. Consumers claimed of bad reactions from eating products containing StarLink® arising from sensitivity to the transgenic Cry9C protein in StarLink®. *Id.* In the *In re StarLink Corn Products Liability Litigation*, Aventis settled with assorted parties for over $100 million. *Id.*; Mandel, *supra* note 233, at 2203-07; Andrew Pollack, *Kraft Recalls Taco Shells That Contain Bioengineered Corn*, N.Y. TIMES, Sept. 23, 2000, at C1; EPA, White Paper on the Possible Presence of CRY9C Protein in Processed Human

This Article now moves on to consider problems caused by the fragmentation of regulatory authority over genetically engineered crops in the United States.

iii. *Regulatory Fragmentation of Federal Administrative Agencies Regarding Genetically Engineered Crops*

Despite the publication of a document in 1986 entitled, "Coordinated Framework for Regulation of Biotechnology," from the Office of Science and Technology Policy,[362] the federal government's response to the risks and questions posed by genetically engineered crops has been anything *but* coordinated.[363]

Three federal agencies share jurisdiction over genetically modified crops: (1) the Food and Drug Administration (FDA),[364] (2) the Environmental Protection Agency (EPA),[365] and (3) the USDA.[366] The FDA addresses food-safety issues regarding genetically engineered crops as well as drug safety issues from genetically engineered crops used to

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Foods Made From Food Fractions Produced Through the Wet Milling of Corn (Mar. 7, 2001), *available at* www.epa.gov/oppbppd1/biopesticides/pips/wetmill18.pdf; James Cox, *StarLink Fiasco Wreaks Havoc in the Heartland: Developer Wants EPA To Approve Seed for Food Supply*, USA TODAY, Oct. 27, 2000, at 1B; Andrew Pollack, *European Company Will Buy Entire Crop of Corn in Recall*, N.Y. TIMES, Sept. 30, 2000, at C14; Andrew Pollack, *Aventis Gives Up License to Sell Bioengineered Corn*, N.Y. TIMES, Oct. 13, 2000, at C5; Allison Beers, *Food, Biotech Firms Settle StarLink Consumer Lawsuit*, FOOD CHEM. NEWS, Mar. 11, 2002.

[362] White House Office of Science and Technology Policy, Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986).

[363] *See* Mandel, *supra* note 233, at 2171 (discussing gaps and lack of coordination in federal regulations regarding genetically-engineered food); *see also* Bratspies, *Some Thoughts*, *supra* note 338, at 407-13.

[364] The FDA has authority to regulate "adulterated food," and inserted genes are considered an adulterant unless they are "generally recognized as safe" (GRAS), which means that they are the same or substantially similar. Note that there are no labeling requirements. *See* Mandel, *supra* note 233, at 2220.

[365] The EPA has authority to regulate pesticides under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) because the genetic alterations that allow plants to produce pesticide fall under FIFRA. *Id.* at 2223. However FIFRA requires only that covered pesticides be registered with the EPA prior to commercialization. *Id.* In 1988, the EPA exempted plants and microorganisms from FIFRA, but it still has jurisdiction to regulate genetic material inserted into genetically engineered plants. *Id.* Also, if there is pesticide residue left on food crops, the EPA requires that "tolerance" levels must be calculated. *Id.*

[366] The USDA regulates genetically engineered crops to ensure safety in movement and importation of such foods as well as regulating field tests of genetically engineered crops through the Animal and Plant Health Inspection Services (APHIS). *Id.* at 2228. While APHIS is supposed to ensure that genetically engineered crops are grown and handled in ways that prevent their release into the environment, notification to APHIS prior to release satisfies APHIS requirements in terms of field tests. *Id.*

manufacture pharmaceuticals.[367] The EPA is supposed to monitor health and environmental effects of pesticide-protected genetically engineered crops.[368] The USDA is supposed to monitor the effects of genetically engineered crops on other plants and animals in agricultural environments.[369] The 1986 Office of Science and Technology Policy report urges these agencies to adopt consistent definitions and to use scientific review of comparable rigor in regulating genetically engineered crops.[370] Furthermore, these agencies assume that there is no evidence of unique hazards in the use of transgenic processes; that the risks associated with the introduction of rDNA-engineered organisms are the same as those associated with the introduction of non-genetically engineered organisms; and that assessment of risks of a genetically engineered organism should be based on the nature of the organism and the environment it will be introduced into, and not the method of producing such an organism.[371] Taken together, these assumptions mean that to these federal agencies, genetically modified crops are not significantly different from non-genetically engineered crops;[372] rather, they are substantially equivalent (the opposite position from the "precautionary" principle).

Gregory Mandel criticizes this highly fragmented regulatory scheme and catalogs the followings gaps and flaws in the schema.[373] The EPA has no role in approving the field-testing of genetically engineered crops other than those that are pesticide-protected, and therefore the EPA will have no regulatory role in the second generation of genetically engineered pharmaceutical and industrial compound crops.[374] The Animal and Plant Health Inspection Services (APHIS) has been criticized by the National Research Council for conducting inadequate environmental assessments of genetically engineered crops and often relying on existing scientific literature rather than conducting its own tests and experimental data.[375] The FDA and APHIS do not evaluate the environmental impact of pharmaceutical crops. There are no requirements that a company notify the FDA prior to the introduction of

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367 *Id.* at 2216.

368 *Id.* at 2172.

369 *Id.* at 2216-17.

370 *Id.* at 2216 (citing the Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986)).

371 *Id.* at 2217.

372 *Id.*

373 *See generally id.*

374 *Id.* at 2231.

375 *Id.* at 2232.

a new genetically engineered crop.[376] Once APHIS grants permission to field-test a genetically engineered crop, APHIS has no further authority to monitor the plant or its progeny.[377] APHIS regulations do not extend to the release of wind-borne genetically engineered plant pollen.[378]

If the question of intellectual-property protection on both national and international levels is added to the fragmented regulatory regimes pertaining to genetically engineered crops, the issue becomes yet more complicated. On the one hand is the standoff between Europe and the United States over "substantial equivalence" or the "precautionary" principle to guide regulation of such crops. In the United States, a fragmented regulatory approach—based on the presumption that genetically engineered crops are "substantially equivalent" to non-genetically engineered crops—gives short shrift to anxieties and concerns of environmentalists that such crops may bear unacceptably high and unpredictable risks to public health. Moreover, in North America, the presumption in favor of agrochemical companies seeking to commercialize such crops is reinforced by the granting of patents in plants, plant varieties, and genetic sequences within such plants, and has effects on biodiversity because intellectually-property protection depends on the uniformity and stability of such traits, giving rise to agricultural monocultures. In the following section, this Article examines the *Schmeiser* case as a lens to view the complex and intersecting issues that arise in this area.

C. MONSANTO CANADA INC. V. SCHMEISER (2004)

Monsanto Canada Inc. v. Schmeiser[379] established a troubling precedent, one that continues the North American legal trends commodifying seeds, plants, and the genetic structures they contain, thereby favoring the interests of large agribusiness at farmers' expense. In a five-to-four decision, the Supreme Court of Canada upheld a lower-court ruling[380] that Percy Schmeiser, a third-generation Saskatchewan farmer who has farmed canola for more than 55 years,[381] had infringed

[376] *Id.* at 2234.

[377] *Id.*

[378] *Id.* at 2230-42.

[379] Monsanto Can., Inc. v. Schmeiser, [2004] 1 S.C.R. 902 (Can.) (McLachlin, C.J., with Major, Binnie, Deschamps and Fish, JJ., concurring; Arbour, J., writing for Iacobucci, Bastarache, and LeBel, JJ., dissented in part.).

[380] *Id.* at ¶ 7.

[381] Monsanto vs Schmeiser, Profile of Percy & Louise Schmeiser, http://percyschmeiser.com/profile.htm (last visited Sept. 18, 2009).

Monsanto's Canadian utility patent[382] on its genetically modified Roundup Ready® canola seed.[383] Interpreting the Canadian Patent Act,[384] the court concluded that the owner of genetically modified seed possesses the exclusive right to that seed and the genetic sequences it contains.[385] The court also upheld the strict-liability standard for patent infringement, focusing not on Schmeiser's intent, but rather on his actions.[386] Although Monsanto seeds, possibly borne by the wind,[387] invaded Schmeiser's fields and outcrossed with his crops, thereby ruining his own non-genetically engineered custom-bred canola plants and seeds,[388] Schmeiser's unlicensed use, storing, and re-planting of Monsanto's genetically modified canola seed[389] in pursuit of his own commercial interests infringed on Monsanto's rights in its patented seed.[390] The court limited the scope of Monsanto's utility patent to the cells and genes conferring herbicide resistance in canola plants,[391] thereby drawing what may seem an arbitrary line between cells and genes on one hand (as patentable "technology"), and plants on the other hand (as unpatentable subject matter because they were higher life forms).[392] The court also limited the scope of Schmeiser's liability and

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[382] Canadian Patent No. 1313830 (issued Feb. 23, 1993), *available at* http://brevets-patents.ic.gc.ca/opic-cipo/cpd/eng/patent/1313830/summary.html.

[383] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶¶ 1, 7.

[384] Patent Act, R.S.C. 1985, c. P-4, § 44.

[385] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 25.

[386] *Id.* at ¶¶ 49-50; *see also* Stephanie M. Bernhardt, *High Plains Drifting: Wind-Blown Seeds and the Intellectual Property Implications of the GMO Revolution*, 4 NW. J. TECH. & INTELL. PROP. 1 (Fall 2005) (discussing *Schmeiser* decision and its implications).

[387] Bernhardt, *supra* note 386, at 14 ("Wind is a major contributor to the unwanted spread of GM ["genetically modified"] seeds. Bentgrass seed, another GM seed produced by Monsanto, can travel up to thirteen miles by wind alone. Canola seeds are not nearly as mobile, but because they are small, round, and smooth they also travel easily in the wind. Some estimates show that 800 meters of buffer are required to isolate canola from cross-contamination.").

[388] Monsanto vs Schmeiser, Profile of Percy & Louise Schmeiser, *supra* note 381. ("[F]or 55 years, Percy had saved and used his own seed, developing his own variety that was tolerant to local farming conditions. It has been destroyed by Monsanto's Roundup Ready canola being released uncontrolled into the environment. Percy is now unable to use his seed again, and views that as one of the hardest things to happen and accept as a farmer. His lifetime of work is gone and has been taken away.").

[389] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶¶ 62-63.

[390] *Id.* at ¶ 1.

[391] *Id.* at ¶¶ 72, 77.

[392] For instance, *cf.* Monsanto Can., Inc. v. Schmeiser, [2001] F.C.J. 436; *Cf.* President & Fellows of Harvard Coll. v. Canada (Commissioner of Patents) [2000] 4 F.C. 528 (F.C.A.) (reversing an earlier denial of a utility-patent application in the OncoMouse®, a transgenic mammal genetically engineered for predisposition to certain cancers), *reversed,* [2002] 4 S.C.R. 45 (Can.).
The reasoning of the Canadian Supreme Court's dissent in *Schmeiser* follows the majority opinion from the Federal Court of Appeals in *Harvard College*. There, the court concluded that though a

denied Monsanto's claim to damages, court costs, and technology fees, on grounds that Schmeiser "sold the Roundup Ready Canola [he] grew in 1998 for feed, and thus obtained no premium for the fact that it was Roundup Ready Canola. [His] profits were precisely what they would have been had [he] planted and harvested ordinary canola."[393]

Genetically engineered crops have become widespread in North America[394] because of advances in plant genetics and molecular biology, augmented by legal developments that make such innovations protectable as intellectual property. Since the early 1980s, biotechnology and agrochemical companies have made massive capital investments in the genetically engineered crops with eyes toward recouping their investment in a potentially limitless market for genetically engineered crops. Monsanto, which is among the world's largest biotechnology companies, exercises a high degree of control over the global genetically engineered crop industry.[395] Two of Monsanto's most important products

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company can patent products and processes, they cannot patent higher forms of life such as a whole plant itself. *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 138. That is, "the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant tissues, at which point the claim would be for every cell in the plant," which would extend the patent too far. *Id.* The patent can only be for the founder plant and not necessarily its offspring. *Id.* at ¶ 161. Please see the discussion, *infra* at note 460, of the *Harvard College* case, in which the Canadian Supreme Court held that higher life forms (in that case an oncomouse) were higher life forms and therefore not patentable subject matter under the Canadian patent statute. *See* Harvard College v. Canada, [2002] 4 S.C.R. 45, at ¶¶ 73-74, 86 (Can.).

[393] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶¶ 104-05.

[394] Bernhardt, *supra* note 386, at 14 ("With 600,000 acres of Roundup Ready® canola planted in the U.S. and over 4,000,000 acres planted in Canada, GMO farming is becoming a common practice."); Teel, *supra* note 321, at 649 ("Around sixty percent of packaged foods in supermarkets contain genetically modified organisms.").

[395] Bernhardt, *supra* note 386, at 7; Monsanto Co., Evaluation: Canola, www.biotechknowledge.com/biotech/bbasics.nsf/biotech01_canola.html (last visited Sept. 18, 2009); *see* ETC Group, RAFI COMMUNIQUE, BIOSERFDOM, TECHNOLOGY, AND THE EROSION OF FARMERS' RIGHTS IN THE INDUSTRIALIZED WORLD 2-5 (Mar/Apr. 1997), *available at* www.etcgroup.org/en/materials/publications.html?pub_id=450. By 2000, Monsanto's genetically engineered seed comprised 94% of the global area sown with genetically modified seed, with Roundup Ready® seed planted on approximately 41.6 million hectares (103 million acres) globally. ETC Group, RAFI COMMUNIQUE, MONSANTO VS. PERCY SCHMEISER: NO CORPORATE LIABILITY FOR UNSAFE SEX AND BIOSERFDOM (Apr. 2, 2001), *available at* www.etcgroup.org/en/materials/publications.html?pub_id=272. Roundup Ready® canola was introduced in Canada in 1996, and by 2003, Roundup Ready® crops represented 48% of western Canada's canola-planted area. RENE C. VAN ACKER, ET AL., GM – NON-GM CROPS COEXISTENCE IN WESTERN CANADA: CAN IT WORK? 190, *available at* http://umanitoba.ca/afs/agronomists_conf/2003/pdf/vanacker_GM_nonGM_crops.pdf. As of 2005, more than 600,000 acres of Roundup Ready® canola had been planted in the United States and more than 4,000,000 acres had been planted in Canada. Bernhardt, *supra* note 387, at 14. Other genetically engineered canola technology systems are Liberty Link (resistant to glufosinate ammonium), Navigator/Compas (resistant to bromoxynil), and SMART canolas (resistant to certain ALS inhibitors). E. Ann Clark, The Implications of the Schmeiser

are Roundup® and Roundup Ready®. This tandem makes up what the company markets as a full agricultural technology system.[396] Monsanto sells Roundup Ready® Corn 2, Roundup Ready® Soybeans, and Roundup Ready® Canola,[397] all of which are meant to be used in conjunction with Roundup,® Monsanto's patented broad-spectrum, non-selective herbicide.[398] The major active ingredient of Roundup® is glysophate, an enzyme inhibitor that alters plant metabolism and prevents root development.[399] Around the same time that it introduced Roundup®, Monsanto acquired general utility patents in Canada and the United States for Roundup Ready® (glysophate-resistant) seeds. Farmers who purchase and use Roundup® and Roundup Ready® seed can spray an entire field for weeds without worrying about harming the glysophate-resistant crops, thereby eliminating weeds more easily and cutting associated costs.[400]

Monsanto has gone to great lengths to protect its legal interests in its patented genetically engineered crops.[401] Roundup Ready® seeds are accompanied by extensive and complicated contractual licensing provisions that make farmers who use the seed licensees for an annual fee.[402] These contracts grant Monsanto personnel permission to monitor and test farmers' crops to make sure that the terms of agreement are

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Decision, http://percyschmeiser.com/crime.htm (last visited Sept. 21, 2009).

[396] David Barboza, *A Weed Killer Is a Block To Build on*, N.Y. TIMES, Aug. 2, 2001, *available at* www.nytimes.com/2001/08/02/business/02CHEM.html ("Monsanto has maintained and even souped up Roundup's status by forging what analysts say was a brilliant strategy of dropping its price years ahead of patent expiration and tying its use to the early growth of genetically modified crops – crops made to work in tandem with the herbicide.").

[397] Monsanto US Ag Products, All Products, www.monsanto.com/monsanto/ag_products/input_traits/products.asp (last visited July 30, 2009).

[398] Monsanto, History of Monsanto's Glyphosate Herbicides (2005), *available at* www.monsanto.com/monsanto/content/products/productivity/roundup/back_history.pdf.

[399] History of Monsanto's Glyphosate Herbicides, www.monsanto.com/monsanto/content/products/productivity/roundup/back_history.pdf (last visited Aug. 20, 2009).

[400] Monsanto Can., Inc. v. Schmeiser, [2004] 1 S.C.R. 902, at ¶ 5 (Can.). As mentioned in the prior section, one of the unforeseen side effects of growing glyphosate-resistant canola is that it outcrosses with wild and weedy relatives that acquire herbicide resistance; the progeny of this outcrossing are "superweeds" possessing glyphosate resistance. This requires that more and stronger doses of chemical herbicides be sprayed, defeating the goal of reducing chemical herbicide use that spurred these crops in the first place.

[401] *See, e.g.*, Blair, *supra* note, 81, at 326-29 (discussing Monsanto's enforcement mechanisms, which include investigating farmers' fields and suing fellow biotechnology companies for patent infringement); Bernhardt, *supra* note 386, at 23 ("Monsanto has filed 100 seed piracy cases in the United States and so far has recovered over $15 million.").

[402] The licensing agreement specifies that users must purchase new seed from Monsanto every year, and they are not permitted to save and replant any of the Roundup Ready® seeds in subsequent seasons — in other words, there are no "brown bag" exemptions for farmers. Aoki, *supra* note 30, at 255.

being followed.[403] Monsanto has robustly patrolled its contractual and intellectual-property rights, making numerous investigations and reaching out-of-court settlements with farmers to collect licensing fees, all the while steadily increasing its market share.[404]

Yet Monsanto knows that efforts to control the distribution and use of Roundup Ready® canola seed literally fly in the face of nature. Like conventional plants, genetically modified plants produce pollen that bears the plant's genetic material. Reproductive isolation of germplasm, whether pre- or post-harvest, is difficult if not impossible.[405] In contrast to plants like corn and wheat, which have been domesticated by more than thousands of generations of breeding, canola is a relatively "primitive" crop that retains many of its wild characteristics. Because canola pods mature unevenly, canola farmers must place the crop in "wind rows" to allow green seed to dry prior to mechanical combining. Similar to their conventional counterparts, genetically engineered canola seed can spread accidentally over significant distances due to wind, insects and wild animals, harvesting and hauling equipment (e.g., combines and trucks), or commingling while in storage.[406] While incidents of cross-contamination via accidental seed dispersal are thought to be relatively isolated, seed dormancy and accidental cross-pollination present more significant and costly problems.[407] Once genetically engineered canola pollen and seed are released into the environment, plant reproduction—and any reproductive consequences—are beyond human control.[408] Because self-fertilizing crops like canola can outcross in a variety of ways[409] or remain dormant for as long as a decade,[410] even

[403] *Id.*

[404] *Id.*

[405] *Id.* at 297.

[406] Bernhardt, *supra* note 386, at 7; E. Ann Clark, The Implications of the Schmeiser Decision, http://percyschmeiser.com/crime.htm (last visited Sept. 21, 2009); Drew L. Kershen, *Of Straying Crops and Patent Rights*, 43 WASHBURN L. J. 575, 579 n.66 (2004). Canola is an oilseed that works well in rotation with crops like wheat, oats, and barley. *Id.* Canola seeds are round, smooth, and very small. *Id.* Because of their shape and the necessity of windrowing, windblown canola seeds can travel easily to adjacent fields. *Id.* Some estimates show that at least 800 meters of buffer are required to isolate canola from windblown cross-contamination. Canola seed can also be dispersed by hauling equipment (e.g., blowing off the top or falling over the edges of an uncovered truck). *Id.* However, some studies indicate that the frequency and amount of gene flow through seeds between adjacent fields is less than 1%. *Id.*

[407] Bernhardt, *supra* note 386, at 7.

[408] Carlos Scott Lopez, *Intellectual Property Reform for Genetically Modified Crops: A Legal Imperative*, 20 J. CONTEMP. HEALTH L. & POL'Y 367, 377 (2004) (once genetically modified seeds are released into the environment, "the consequences of their uncontrolled reproduction . . . cannot be predicted.").

[409] Phil Thomas, *Outcrossing Between Canola Varieties* (Mar. 24, 2000), *available at*

the most diligent farmer's efforts to remove unwanted genetically modified plants may be insufficient. Furthermore, it is impossible to distinguish conventional canola from the Roundup Ready® variety without the aid of either scientific testing or inspection, or the application of Roundup® to reveal whether crops are glysophate-resistant.[411] Thus, even for those canola farmers who do not wish to use Monsanto's patented seeds and who would prefer not to have Monsanto's patented technology contaminate their fields (such as Percy Schmeiser), it is highly likely that (1) genetically modified seeds or pollen may infiltrate the farmer's crops; (2) some genetically modified seeds will remain dormant; and (3) some of these seeds will eventually germinate, releasing their pollen into the environment and crossing with wild and weedy relatives, thus causing other unintended consequences.[412]

To complicate matters for farmers, Monsanto has successfully shifted to non-licensees many costs (not to mention the burden of farmers' resultant lost profits) of policing patent-infringement prevention, even when infringement occurs accidentally and against farmers' wishes. Monsanto's utility-patent rights and licensing agreements put those who are accidental users due to natural forces in the position of being vulnerable to lawsuits for patent infringement.[413] Its corporate policy is to remove cross-contaminated and other unlicensed plants upon farmers' request.[414] This places the burden on farmers to identify infringing canola plants and to initiate the removal request. However, removal efforts might well result in the uncompensated destruction of a farmer's non-infringing plants.[415] Furthermore, in order to be effective such removal processes require the destruction of *all* canola plants on a farmer's land. Even so, the realities of seed dormancy and pollen dispersal mean that even *total* crop destruction cannot ensure against accidental patent infringement in the future. Only total

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www.mindfully.org/GE/Outcrossing-Canola-Alberta.htm. While canola is a self-fertilizing species, canola outcrosses in the range of 20–30%. *Id.* Alberta Agriculture estimates that even at a low outcrossing rate of .2 percent, a crop yielding twenty-five bushels per acre would deposit 10,000 outcrossed seeds per acre in one season. *Id.* The outcrossing rates increase with every season, factoring in the lengthy dormancy period of canola seed. *Id.* Under the no-till conditions favored in prairie areas such as Saskatchewan, canola can remain dormant for as long as ten years. *See also* Bernhardt, *supra* note 386, at 14-16 (discussing how GE seeds can spread via wind or pollen).

[410] Bernhardt, *supra* note 386, at 16.

[411] Monsanto Can., Inc. v. Schmeiser, [2004] 1 S.C.R. 902, at ¶ 13 (Can.); Bernhardt, *supra* note 386, at 2.

[412] Lopez, *supra* note 408, at 377-78; Bernhardt, *supra* note 386, at 7.

[413] Bernhardt, *supra* note 386, at 24; Aoki, *supra* note 30, at 292-93.

[414] Clark, *supra* note 406.

[415] Aoki, *supra* note 30, at 297; Preston, *supra* note 360, at 1159-60.

replacement of soil—an extremely costly proposition—could insure non-infringement, and then for only as long as the soil remains free from contamination by Monsanto's wind-borne patented genetically engineered materials.[416]

In order to protect its patented invention from unlicensed use, Monsanto also monitors the crops of farmers who have *not* bought Roundup Ready® seeds. This is what happened to Percy Schmeiser, whose custom strain of canola seed was developed through selective breeding over many years from a conventional variety (called Argentine canola).[417] Schmeiser's canola variety was invaded and damaged by Monsanto's genetically engineered canola. Based on an anonymous tip, Monsanto dispatched investigators to survey and sample canola plants on Schmeiser's property.[418] Monsanto also contacted Humboldt Flour Mill, where Schmeiser had his canola seed milled, which provided Monsanto with glysophate-resistant samples in Schmeiser's seeds.[419] Upon confirming the presence of canola plants bearing their patented genetic material, Monsanto sued Schmeiser for infringement of their utility patent, as well as injunctive relief, delivery of all infringing seeds and crops in his possession, plaintiff's costs, actual damages, and exemplary (or punitive) damages.[420]

Schmeiser first discovered the presence of Roundup Ready® canola plants on his property in 1997.[421] Although Schmeiser did not adopt Monsanto's canola seed technology system, wind-blown pollen from neighboring farms using Roundup Ready® canola outcrossed with his plants.[422] Schmeiser discovered the presence of Monsanto's genetically

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[416] Preston, *supra* note 360, at 1171-72 (discussing the burdensome and costly affirmative duties the *Schmeiser* decision places on farmers to keep Monsanto's seeds off their land so as to avoid liability).

[417] Monsanto Can., Inc. v. Schmeiser, [2001] F.C.J. 436, at ¶¶ 7, 29-30. Schmeiser practiced "brown bagging" for many years, which allowed him to develop a custom crop from seeds he had selected based on his choice of desirable genetic characteristics. *Id.*

[418] *Schmeiser*, [2001] F.C.J. 436, at ¶¶ 37-58.

[419] *Id.* at ¶ 46.

[420] *Id.* at ¶ 9; Monsanto Can., Inc. v. Schmeiser, [2004] 1 S.C.R. 902, at ¶¶ 98-105 (Can.) (damages overturned). The Federal Court of Appeals had affirmed the trial court's decision on the matter of Monsanto's receipt of injunctive relief and money damages. *Id.* The trial court had ordered Schmeiser to deliver all of the Roundup Ready® canola seeds or plants held in his possession. *Schmeiser*, [2001] F.C.J. 436, at ¶ 128. It had also required Schmeiser to make restitution of $105,000 CDN and awarded Monsanto $15,450 CDN in actual damages (for Schmeiser's patent infringement at the rate of $15 CDN per acre containing Monsanto genetics, plus lost licensing fees) and $25,000 CDN in exemplary (or punitive) damages. *Id.*

[421] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 61.

[422] By 2000 approximately 20,000 farmers had planted Roundup Ready canola, comprising some 4.5 to 5 million acres, and producing nearly 40% of Canadian grown canola—including five of

engineered seed when he sprayed Roundup® to kill weeds around the power poles and ditches next to the public road that ran by one of his fields.[423] When Schmeiser noticed that some of the canola plants that had been sprayed did not die, he then tested a larger area by spraying Roundup® on approximately four acres of the same field.[424] He discovered that 60% of the canola plants he sprayed survived numerous sprayings.[425] This meant that those particular plants were glyphosate-resistant and that Monsanto's patented genetically engineered material had invaded his crops.[426] However, Schmeiser took no action to contact Monsanto, did not remove the glyosphate-resistant plants himself, and did not become one of Monsanto's licensed users.[427] Instead, he instructed a farmhand to harvest the test field and store its seed separate from the rest of the harvest.[428] Schmeiser used seed from the glysophate-resistant canola plants to plant approximately 1000 acres of canola in 1998, selling that harvest for feed.[429]

At trial, and later on appeal, Schmeiser advanced several unsuccessful alternative defenses to Monsanto's allegations of patent infringement, attempting to turn the tables on the corporate gene giant. First, he argued that the Monsanto seeds were on his fields without his intent or invitation.[430] However, at trial Judge Andrew McKay pointed out "the source of the Roundup resistant canola . . . is really not significant for the resolution of the issue of infringement."[431] The trial court found that the presence of the patented gene in Schmeiser's fields could not be attributed solely to accidental causes; between 95-98% of the 1000-plus acres involved were contaminated.[432] Although the fact that the presence of Monsanto's product in his crops damaged Schmeiser's custom variety of canola seeds (which he had developed through years of careful "brown bagging"[433] efforts), thereby harming his

Schmeiser's neighboring farmers. *Schmeiser*, [2001] F.C.J. 436, at ¶¶ 17, 33. Schmeiser's fields were located near a major hauling road and in the direction of the area's prevailing winds. *Id.* at ¶ 117.

[423] *Schmeiser*, [2001] F.C.J. 436, at ¶ 38.

[424] *Id.* at ¶ 61.

[425] *Id.* at ¶¶ 38-39.

[426] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 63.

[427] *Schmeiser*, [2001] F.C.J. 436, at ¶ 40.

[428] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 62.

[429] *Id.* at ¶¶ 63, 68.

[430] *Schmeiser*, [2001] F.C.J. 436, at ¶ 12; Bernhardt, *supra* note 386, at 5-6.

[431] *Schmeiser*, [2001] F.C.J. 436, at ¶ 119.

[432] *Id.* at ¶¶ 107, 118.

[433] Brown-bagging refers to a farming practice in which commercial seeds, bearing mostly homozygous genes, are saved so as to yield seeds that will grow an essentially identical plant. Blair,

overall farming enterprise, supported Schmeiser's claim that he never intended to cultivate the patented plants, he could not rebut the presumption of intent to cultivate—and therefore infringe Monsanto's patent—because he continued saving and re-planting seeds after receiving notice from Monsanto that his actions infringed on its patent.[434]

Second, Schmeiser argued that the outcrossed germplasm belonged to him. Schmeiser based his claim upon an analogy he drew between the Roundup Ready® gene and a "stray bull" as the latter is dealt with under admixture law.[435] Schmeiser contended that he was entitled to ownership of *any* seed on his land, including seed from volunteer plants that resulted from Roundup Ready® germplasm invading his land and outcrossing with his crops.[436] However, the trial court disagreed with Schmeiser and distinguished plant germplasm subject matter from that of admixture law, on the grounds that Monsanto's utility patent extended only to the gene's use, not to plants.[437]

Third, Schmeiser argued that the patent was invalid for improper subject matter on grounds that the seed was neither caused nor controlled by human intervention.[438] The trial court rejected Schmeiser's argument and upheld Monsanto's patent rights in the particular herbicide-resistant genetic material, but the court limited Monsanto's claim specifically to genetically modified seeds and sequences and held that Monsanto's utility patent did not extend to the entire plant.[439]

Fourth, Schmeiser argued that he did not use the patented gene sequence because he did not use Roundup® on his fields.[440] This argument was based on the tandem status of Roundup® and Roundup Ready® as a total agricultural technology system.[441] Schmeiser contended that, within the terms of the licensing agreement, in order to have used the Monsanto system on the 1000-plus acres involved in this case, Schmeiser would have had to spray the 1000-plus acres with Roundup®, which he did not.[442] Anticipating that he did not have the

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supra note 81, at 311.

434 *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 63.

435 *Schmeiser*, [2001] F.C.J. 436, at ¶ 91; Bernhardt, *supra* note 386, at 3. Under "stray bull" case law, any reproductive offspring that result from a rancher's bull wandering onto another rancher's land belong to the latter. *Id.*

436 *Schmeiser*, [2001] F.C.J. 436, at ¶ 92.

437 *Id.* at ¶ 93.

438 *Id.* at ¶ 78.

439 *Id.* at ¶¶ 436, 82.

440 *Id.* at ¶¶ 436, 121.

441 *Id.* at ¶ 122.

442 *Id.* at ¶ 121.

right to use the patented genetic sequence, Schmeiser also argued that he had not benefited from the Roundup Ready® gene sequences because, although he had used Roundup® to spray around telephone poles on his property, and he had planted some of his acreage with outcrossed seed to determine the extent of genetic contamination caused by the wind-blown pollen, he sold that particular crop for grain (rather than as seed) and never used (and therefore did not benefit from) Roundup® to protect his canola crop.[443]

On appeal, Schmeiser again unsuccessfully tried turning the tables on Monsanto by arguing that Monsanto had failed to control the spread of its product, thereby contaminating and genetically polluting his crop via an "unconfined release."[444] Therefore, Schmeiser argued, Monsanto should either lose its monopoly or be liable for damages.[445] Here, Monsanto's patented, genetically engineered seed was, at least to Schmeiser, a nuisance and an invasive pollutant.[446] Monsanto countered that, through its infringement notification and removal policies, it had taken reasonable efforts to avoid spreading patented genetically engineered material to neighboring farms.[447] The court of appeals agreed that Monsanto was not required to do more than was reasonably necessary to prevent the inadvertent spread of its seeds by the individuals who legally purchased them.[448]

In arguments before the Supreme Court of Canada, Schmeiser revived some of these arguments but presented them with new twists. He once again raised lack-of-use and lack-of-intent defenses, arguing that the gene's presence in his fields was uninvited and that he did not seek to cultivate the outcrossed plants.[449] Since he lacked intent and had derived no advantage from the uninvited, unwanted contaminant, Schmeiser argued that he did not infringe upon Monsanto's patent.[450] The court rejected this argument on grounds that a patent prohibits all unauthorized making, selling, or use of an invention, not just those unauthorized uses

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[443] *Id.*

[444] *Id.* at ¶ 12.

[445] *Id.* at ¶¶ 12, 13.

[446] *Id.* at ¶ 13. *See also* Preston, *supra* note 360, at 1165-66 (discussing how farmers might use common-law theories such as nuisance and trespass for protection from liability arising from situations such as Schmeiser's).

[447] *Schmeiser*, [2001] F.C.J. 436, at ¶ 96.

[448] *Schmeiser*, [2003] 2 F.C. 165, at ¶¶ 59-60. The Supreme Court of Canada did not revisit this issue.

[449] Monsanto Can., Inc. v. Schmeiser, [2004] 1 S.C.R. 902, at ¶¶ 49-56, 86 (Can.).

[450] *Id.* at ¶ 81.

for intended purposes and by intended processes.[451] The majority looked to whether Schmeiser's activity had "deprive[d] the inventor, in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by law."[452]

Under the Canadian Patent Act, the definition of "use" includes use of not only patented products, but also patented processes and the output from such products or processes.[453] Furthermore, the court held that the intent of an unlicensed user and whether that unlicensed "use" results in actual benefit to the unlicensed user are irrelevant to the issue of patent infringement.[454] Schmeiser had infringed Monsanto's patent simply because Monsanto's patented genetic sequences were present in the canola crops growing on his land.[455] This standard for patent infringement applies regardless of whether infringement is accidental or intentional and regardless of how patented material finds its way into an unlicensed user's possession.[456] The mere opportunity to benefit is all that matters.[457]

Ultimately, the court concluded that Schmeiser had not "made" the patented invention within the meaning of the Canadian Patent Act.[458] To support its reasoning, the majority of the court analogized Schmeiser's outcrossed plants containing Monsanto's patented gene to a building made of Lego® blocks.[459] From the standpoint of Canadian patent law, a user's intervening contribution is irrelevant to the matter of who is entitled to the patent and all of its business advantages—those rest with the patent owner.[460] Contrary to Schmeiser's assertion that a farmer's "brown bag" rights under the Canadian version of the Plant Variety

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[451] *Id.* at ¶¶ 81-84; Bernhardt, *supra* note 386, at 4.

[452] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 35.

[453] *Id.* at ¶¶ 41-43.

[454] *Id.* at ¶ 57.

[455] *Id.* at ¶¶ 68, 80, 82, 87.

[456] *Id.* at ¶ 49.

[457] *Id.* at ¶ 57.

[458] *Id.* at ¶ 63.

[459] *Id.* at ¶ 42 ("[I]f an infringing use were alleged in building a structure with patented Lego blocks, it would be no bar to a finding of infringement that only the blocks were patented and not the entire structure.").

[460] *Id.* at 81-85. *But cf.* Harvard College v. Canada, [2002] 4 S.C.R. 45, at ¶¶ 73-74, 86 (Can.). The *Schmeiser* majority's reliance on the Lego® metaphor is contentious in that it equates lifeforms (seeds and cells) with mechanical devices (building blocks). This is precisely the distinction that the *Harvard College* decision attempted to maintain and sought to leave in the hands of the Canadian Parliament to work out through legislation. *Id.* It also parses the "higher life form" criteria of *Harvard College* and draws an arguably arbitrary line between seeds and cells on one side and whole plants on the other as patentable or unpatentable subject matter. *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 21.

Protection Act supersede Monsanto's rights under its utility patent, the Canadian Supreme Court held that a farmer's rights to save and replant seed are no greater than an ordinary property owner's right to use her or his own property subject to ordinarily applicable limits and restrictions to prevent infringement. The patent holder's rights in the patented "invention" foreclose the possibility of a farmer's rights to save and replant seeds where doing so infringes upon patent rights.[461]

However, the Canadian Supreme Court's holding in *Schmeiser* is ambivalent. Ultimately, the majority overturned Monsanto's award of damages and costs, on the grounds that while the matters of Schmeiser's use, intent, and actual benefit were irrelevant to the issue of patent infringement, they were directly relevant to the question of Monsanto's damages.[462] Schmeiser did not benefit from the presence of the patented genetic sequence because he did not use Roundup® on the 1000-plus acres of canola crops involved.[463] Therefore, he made no more profit in the sale of these crops than he would have received if he grew non-genetically engineered canola.[464] The holding that Monsanto was not entitled to receive money damages (and therefore was not entitled to reimbursement for its litigation costs) surely allowed Percy Schmeiser to avoid economic ruin.[465]

Because the Canadian Supreme Court denied Monsanto's claim for damages, Schmeiser avoided having to reimburse Monsanto for several hundred thousand dollars in litigation costs.[466] Although Schmeiser's profits were less than $20,000 CDN,[467] Schmeiser sustained economic

[461] *See Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 85 (suggesting that "brown-bag" practices deprive Monsanto of "the full enjoyment of their monopoly").

[462] *Id.* at ¶¶ 100, 104, 105.

[463] *Id.* at ¶ 103.

[464] *Id.*

[465] *See* Bernhardt, *supra* note 386, at 27 ("The costs of litigation make fighting an issue of infringement unfeasible for most farmers. Schmeiser spent $400,000 (Canadian) on his battle with Monsanto. On Schmeiser's website, he claims to have received hundreds of phone calls from farmers in similar situations. These farmers have received threatening letters to pay up or go to court. The Centre for Food Safety believes that hundreds of farmers have been coerced into paying technology fees to avoid costly litigation. With Monsanto's budget of $10 million and a staff of 75 investigators, it is easy to see that farmers are sorely lacking the legal resources to combat Monsanto.").

[466] Monsanto Can., Inc. v. Schmeiser, [2001] F.C.J. 436, at ¶ 104, for trial court's award of damages. *See id.* at ¶ 142 (plaintiffs entitled to pre-judgment interest on damages).

[467] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶¶ 98, 103. The trial judge found that Schmeiser's profits from growing the Roundup Ready crop were $19,832. *Id.* at ¶ 98. However, the appellate court rejected this finding, stating that "[t]he difficulty with the trial judge's award is that it does not identify any causal connection between the profits the appellants were found to have earned through growing Roundup Ready Canola and the invention. On the facts found, the appellants made no

losses arising from his lengthy legal defense (which cost approximately $400,000 CDN, most of which he covered through fundraising efforts) and his lost right to use his own strain of canola that he had developed over many decades because he could not prove his canola seed was free from the Roundup Ready® gene.[468] As a result, Schmeiser's own strain of canola no longer exists and he has had to purchase seed anew, thus adding another economic burden arising from this situation.[469]

However, the *Schmeiser* holding ultimately increases and solidifies the legal protections that agrochemical and biotechnology companies enjoy in Canada and the United States and places Canadian farmers in a difficult position.[470] Farmers may have to pay royalties on genetically engineered materials found on their land and in their crops, even if they did not buy the seed or seek to benefit from it. The possibility of farmers' rights for crop or "brown bag" exemptions in such cases has been largely foreclosed in Canada and the United States. The strict-liability standard for patent infringement forces those who discover plants containing patented genes in their fields into a choice between signing a licensing agreement, facing a possible patent-infringement suit, or making a costly out-of-court settlement.[471] Most farmers lack the necessary resources to mount a successful legal defense against an adversary with the resources that Monsanto and other multinational agro-business companies are able to bring to bear.[472] Meanwhile, a patent owner is under no obligation to control or prevent accidental dispersal of or reproduction by its patented genetically engineered material, despite the fact that the presence of the

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profits *as a result of the invention*." *Id.* at ¶ 103.

[468] Monsanto vs Schmeiser, Profile of Percy & Louise Schmeiser, *supra* note 381.

[469] *Id.*

[470] For discussion of likely consequences of *Schmeiser* in the United States, see Bernhardt, *supra* note 386, at 7-11.

[471] Bernhardt, *supra* note 386, at 24-26.

[472] *Schmeiser*, [2004] 1 S.C.R. 902, at ¶ 933; Bernhardt, *supra* note 386, at 9-11; Paul Elias, *Saving Seed is Latest Tech Piracy*, WIRED, Jan. 14, 2005, *available at* www.wired.com/news/technology/0,1282,66282,00.html; Stephen Leahy, *Monsanto's "Seed Police" Watching Farmers* (available at LEXIS, IPS-Inter Press Service, Jan. 14, 2005). Monsanto's patent compliance and investigation includes a staff of 75 investigators alone and has an annual operating budget of $10 million. *Id.* Unlicensed users receive threatening letters to sign a licensing agreement and pay technology fees or face the prospect of defending themselves in court. *Id.* While it is unlikely that Monsanto would go after every farmer whose crops or land contain traces of its patented germplasm, as of 2005 Monsanto had filed 100 seed piracy cases in the United States, recovering more than $15 million US and winning in every case decided thus far. *Id.* In addition to these economic disparities of power and their direct translation into disparities of legal or dispute resolution power, Monsanto's patented technology use agreements include silencing provisions. *Id.* Because of these provisions, it is difficult to say with certainty how many of the approximately 500 investigations Monsanto conducts each year ultimately result in licensing agreements. *Id.*

genetic material transmitted via wind-borne pollen may force some farmers into the position of unlicensed and infringing users. Farmers may also face additional economic hardships such as the loss of the custom-designed seed that they have cultivated over time, the loss of organic certifications (if contamination via genetic modification appears in the plant or seed),[473] and replacement costs for purchasing new seed and new soil. Under this patent-maximalist view, farmers who do not want to use a patented genetically engineered agricultural technology system should either switch to another line of business or sell their farms to those who will use those systems.

IX. CONCLUSION

This Article has looked at the rise of intellectual property in agricultural crops during the twentieth century as well as the alarming erosion of plant genetic diversity during the same period. This Article does not argue that intellectual-property rights in plants directly cause erosion of genetic diversity. However, there is an indirect connection: as private companies move into the seed and agricultural sector, they avail themselves of different types of intellectual-property protection to secure their investment. With hybrids in the early twentieth century, the identity of parent lines used to create hybrids were kept as trade secrets. In 1930, Congress granted protection to nurserymen who produced their plants through asexual means, such as grafts and cloning. In 1970, Congress enacted the Plant Variety Protection Act, granting protection to sexually reproduced plant varieties, and in 1980, the U.S. Supreme Court held that a living organism could be the subject of a utility patent, if there was the requisite creative human agency present in the creation of such an organism. The point is that the presence of intellectual-property protection encourages certain types of activity and investments that, while not antagonistic to biodiversity, may give rise to patterns that erode biodiversity. One of the distinctions that was challenged was the distinction between "raw" and "worked" seeds. "Worked" seeds could be protected by intellectual-property laws, whereas "raw" (wild and weedy relatives of cultivated crops and farmer landraces) were not protectable by intellectual-property laws but were seen as "raw" materials to be turned into intellectual property.

This Article also noted the drastic shift in the legal treatment of plant genetic resources from the early 1980s to 2001. In 1983, a proposal

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[473] Preston, *supra* note 360, at 1161.

was floated to treat all plant germplasm as open access, or as the "common heritage of [hu]mankind" including patented and otherwise protected (under PVPA certificates) cultivars of the industrial countries of the North. Within a decade, this treatment had been abandoned and an approach that treated plant genetic resources as "sovereign national property" was adopted, first in the CBD and then in the 2001 ITPGR. There is a tension between genetic conservation regimes, such as the CBD, and trade regimes, such as TRIPS. However, both manage to reconcile intellectual-property protection for crops in one way or another.

Another point made by this Article is that the emerging intellectual-property regimes governing plant genetic resources overlap with the conservation regimes promoted by the international network of seed banks in the early 1970s in response to the dramatic erosion of plant genetic resources brought about by the high-chemical-input, water-intensive, high-yielding crops of the "Green Revolution." Until the 1990s, these international seed banks applied "common heritage" to the seed germplasm they stored, a stance that was in tension with national and international treatment of plant genetic resources as intellectual property.

Finally, this Article observed the rise of genetically engineered crops from the 1980s onward and the fragmentation of regulatory authority between different federal agencies in a way that gave rise to gaps in coverage and short shrift to concerns over the risks and dangers that the release of genetically engineered crops into the food supply could cause. However, this regulatory fragmentation also worked to harden the kinds of intellectual-property claims that companies such as Monsanto could bring against farmers such as Percy Schmeiser.

Without national and international coordination on global conservation of crop biodiversity, the scope of intellectual-property rights in agricultural crops and their genetic components, and the effects of genetically engineered crops on public health, environment, and biodiversity, these seeds of dispute may be a hard row to hoe indeed.