CONFERENCE: MALTHUS, MENDEL, AND MONSANTO

KEITH AOKI*

Malthus, Mendel, and Monsanto: Intellectual Property and the Law and Politics of Global Food Supply: An Introduction

* Philip H. Knight Professor, University of Oregon School of Law. The author would like to thank Will Glasson, J.J. Haapala, Jessica McDonald, Charlotte Nisser, Charles Von Reis, and Michael Woo. Particular thanks to Kennedy Luvai for his editorial and research help on this Introduction.

INTRODUCTION

On April 9, 2004, the University of Oregon School of Law and the Wayne Morse Center for Law and Politics[1] presented a one-day symposium entitled, "Malthus, Mendel and Monsanto: Intellectual Property and the Law and Politics of Global Food Supply."[2] The symposium brought together academics, lawyers,

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[2] Speakers included (in alphabetical order: Professor Keith Aoki, University of Oregon School of Law; Dr. Susan Bragdon of the International Plant Genetic Resource Institute (IPGRI); Professor Stephen Brush, UC-Davis, Department of Human and Community Development; Professor Ignacio Chapela, Assistant Professor, UC-Berkeley, Department of Ecology; Professor Maggie Chon, Seattle University School of Law; Professor William Heffernan, University of Missouri, Columbia, Department of Rural Sociology; Professor Stephen Jones, winter wheat breeder at Washington State University and former chair of the National Wheat Crop Germplasm Committee; Ms. Kim Leval, Senior Policy Analyst in the Rural Policy Program of the Center for Rural Affairs and Executive Director, Consortium for Sustainable Agricultural Research; Professor Charles McManus, Green Professor of Law, Washington University School of Law; Professor Malla Pollack, Visiting Professor of Law, University of Oregon School of Law; Dr. Henry L. Shands, Director of the USDA's National Center for Genetic Resources Preservation; and Professor Madhavi Sunder, UC-Davis King School of Law.

scientists, farmers, and food activists to listen to three panels[3] and an evening keynote address by Canadian canola farmer Percy Schmeiser.[4]

The papers that follow this Introduction were presented at the conference; they critically assess how changes in intellectual property laws over the past two decades have affected the global food supply. These changes have been occurring on at least three interrelated fronts: (1) striking levels of concentration in the agricultural seed, fertilizer, transport, and retail sectors; (2) changes in how agricultural knowledge is produced and disseminated (as well as how access to seed germplasm is controlled); and (3) changes in both domestic U.S. and international treaties pertaining to intellectual property laws that are affecting, and are affected by, the prior phenomena.

I

MALTHUS, MENDEL, AND MONSANTO

The title of the conference arose from the present-day intersection of trends represented by the three Ms named in the title: Malthus, Mendel, and Monsanto. Thomas Malthus was a late eighteenth and early nineteenth century dystopian and dark economist who foresaw population outstripping food supply

[3] The panels were entitled: (1) The Global Food Supply: Concentraion, Erosion, Traditional Knowledge and Crisis (Brush, McManis, Heffernan, and Chapela); (2) The Production of Agricultural Knowledge and Access to Seed Germplasm (Bragdon, Haapala, Jones, and Shands); and (3) Intellectual Property and Beyond (Aoki, Chon, Leval, and Pollack). The lunch time keynote speaker was Professor Madhavi Sunder, who delivered a talk, "The Romance of the Public Domain," and the evening keynote, as mentioned in the text, was Canadian canola farmer Percy Schmeiser who delivered a talk entitled, "David and Goliath: Monsanto v. Schmeiser."

[4] Schmeiser v. Monsanto Co., 2004 S.C.C. 34 (In this case Monsanto alleged that Schmeiser, a farmer, had infringed its patent rights by planting, and later harvesting and selling, genetically modified canola seeds containing genes and cells protected by Monsanto's patent claims. Monsanto's patents covered only cells and genes that conferred herbicide resistance to the canola plants and not the plant themselves. Schmeiser challenged the validity of these patents. In a split decision, the Canadian Supreme Court held that whether patent protection for genes and cells extends to the whole plant was relevant only to an infringement rather than a validity analysis. Therefore, genes and cells may confer patent rights over the whole plant despite unpatentability of the whole plant. The other ruling concerned whether possession may constitute infringement. The majority stated that possession only raises a rebuttable presumption of use, one which Schmeiser failed to rebut in this case. However, Monsanto was not entitled to any monetary damages since Schmeiser did not profit from its invention.).

growth, thereby justifying cutting back on public support for the poor in his time.[5] From his time to ours, Malthus's name has been invoked for a variety of ends, many of them conservative and reactionary. Over the past few decades, Malthuisan analysis has been used by writers such as Paul Ehrlich and Garrett Hardin to argue against international food programs to fight hunger in the developing world.[6] At the very least, the specter of Malthusian population growth forms a disturbing backdrop to some of the claims of the life sciences industry that genetic engineering is necessary to avert a catastrophic food supply deficit.[7]

[5] Thomas Robert Malthus was born near Guildford, Surrey, England on February 13, 1766. Known almost exclusively for his influence on Charles Darwin, Malthus's interests were mainly centered on social conditions and political economy, with his work on population playing an integral part. Malthus's travels through Europe beginning in 1799 supplied much of the evidence he needed to develop his theory on population growth. Malthus's first major original work, initially published anonymously, was *An Essay on the Principle of Population, as It Affects the Future Improvement of Society, With Remarks on the Speculations of Mr. Godwin, M. Condorcet, and Other Writers* (London 1798). He later published *Principles of Political Economy Considered With a View to Their Practical Applications* (London, 1830). *The Travel Diaries of Thomas Robert Malthus* (Cambridge, 1966), edited by P. James, is a journal of his travels. He died near Bath, England on December 23, 1834. For more on Malthus's life, see AMERICAN COUNCIL OF LEARNED SOCIETIES, VOLUME IX, DICTIONARY OF SCIENTIFIC BIOGRAPHY 67-71.

[6] Ehrlich adopted a policy based on the concept of "triage" in military medicine first suggested by William and Paul Paddock. This concept classifies underdeveloped nations as: (1) those that will undergo a transition to self-sufficiency without food aid, (2) those that will achieve self-sufficiency only with food aid, and (3) those that are so far behind in the "population-food game" that there is little hope that food aid will result in later self-sufficiency. According to this policy, the finite assistance available should only be targeted towards the second group of nations, rather than those that can either survive without, or not be saved in spite of, such aid. *See* PAUL R. EHRLICH, THE POPULATION BOMB 146-47 (1968). For his part, Hardin contends that the markedly higher population growth in poor nations makes it unsustainable for rich nations to offer food aid in the long-term. Against this backdrop, he argues that food aid would only benefit select corporate entities in rich nations while serving as a disincentive for poor nations to implement policies that would foster food security. Because the population growth in poor countries may go unchecked, resulting in a limitless increase in the need for food aid, Hardin urges the denial of such aid. This denial, according to Hardin, would have the positive effect of checking the rapid population growth in poor nations, thus eventually stabilizing the proportion of poor to rich populations. *See* Garrett Hardin, *Life Boat Ethics, The Case Against Helping the Poor*, PSYCHOLOGY TODAY, Sept. 1974, at 38-43, 124-26.

[7] Nobel laureate economist, Amartya Sen sees the emphasis on food supply falling behind global population growth as misplaced owing to the scant evidence to support such a diagnosis. Sen contends that, in most areas of the world, the increase in food supply has been comparable to, or faster than, population growth. However, this increased supply has not eliminated starvation. In fact, some of the more severe famines have occurred with no significant reduction in food availability per person.

Gregor Mendel was an early to mid-nineteenth century Augustinian abbot who undertook and published the first work that uncovered the laws of heredity in pea plants.[8] When his work was published in the mid-nineteenth century, it was largely ignored, but was rediscovered by agronomists in the United States and Europe around the turn of the twentieth century.[9] The rediscovery of Mendel's work laid the groundwork for the development of hybrid crops in the second and third decades of the twentieth century, greatly speeding the industrialization of U.S. agriculture. This rediscovery also heralded a shift in the balance of agricultural seed research and development from the public to the private sector. Mendel's discovery of the laws of heredity, and subsequent technological discoveries that built on Mendel's

Therefore, Sen asserts that starvation is not simply a function of food supply but one that implicates distribution. The quest should thus be to improve the distribution of food across a community which necessarily involves scrutinizing the workings of the economic system. *See* AMARTYA SEN, POVERTY AND FAMINES: AN ESSAY ON ENTITLEMENT AND DEPRIVATION 7-8 (1981). The lack of food security has been described as "an extraordinarily complex social, economic, and political problem whose causes and solutions vary from country to country." While some nations, especially in Asia, have made great strides in increasing agricultural productivity to the extent that they are now net exporters of food, many in these nations still go hungry as a result not having the economic means to purchase or produce the food they need to subsist on. *See* Michael R. Taylor & Jerry Cayford, *American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change*, 17 HARV. J.L. & TECH. 321, 328 (2004).

[8] Johann Gregor Mendel was born in Heinzendorf, Austria [present-day Hynice, Czech Republic] on July 22, 1822. In elementary school, Mendel was taught natural science and encouraged to cultivate fruit trees. After becoming a monk in 1843, Mendel entered the Augustinian Monastery—a haven of learning and scientific endeavor. He later attended the University of Vienna. He then was placed as a substitute teacher at the Brünn Technical School, a position he held until 1868 when he gave up teaching. Mendel published thirteen papers, two on plant-damaging insects, nine on meteorology, and two on plant hybrids, his most important. The papers on plant hybrids were published in *Verhandlungen des Naturforschenden Vereins in Brünn* (1863 to 1871). Mendel lived until January 6, 1884. AMERICAN COUNCIL OF LEARNED SOCIETIES, Volume IX, DICTIONARY OF SCIENTIFIC BIOGRAPHY 277-83.

[9] In 1899 the Royal Horticultural Society organized the International Conference on Hybridisation and on Cross-Breeding of Varieties featuring prominent scientists, including H.J. Webber of the USDA's Plant Breeding Laboratory and Liberty Hyde Bailey of Cornell University. Some participants predicted that science was soon to make a significant impact on plant breeding. A year later, European botanists Hugo de Vries, Carl Correns, and Erich Tschermak independently published papers detailing rules of heredity that were later found to have been previously proposed by Gregor Mendel thirty-five years earlier. Across the Atlantic, a Washington State Experiment Station wheat breeder ensured the acceptance of these new theories in the United States when he came very close to an independent rediscovery of Mendelian inheritance in 1901. JACK KLOPPENBURG, FIRST THE SEED 68-69 (1986).

work, were crucial elements in the rise of the agricultural life sciences industry in the late twentieth century.

Monsanto was a St. Louis-based chemical company that came to be one of the dominant agricultural chemical suppliers as the so-called "Green Revolution" swept the globe in the 1970s.[10] The Green Revolution entailed a global economic dislocation of subsistence farmers as small, locally adopted agricultural practices were displaced with mass industrial farming techniques (and the attendant expensive, high-input fertilizers, pesticides, herbicides, and other chemical inputs designed to allow "one seed to feed the world.").[11] By the 1980s, however, the Green Revolution was beginning to be seen as having a disastrous effect on the preservation of plant genetic diversity worldwide as well as bringing about harmful levels of environmental degradation due in large part to fertilizer, pesticide, and herbicide runoff.[12]

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[10] Scientists working under the auspices of the Rockefeller and Ford foundations, which funded international agricultural research centers, were the main catalysts behind the Green Revolution. These two foundations had united, disparate, and privately funded centers into a coordinated network in the hope of side-stepping the bureaucracy of the U.N. system while, at the same time, exploiting the legitimacy that comes with the perception of being part of the U.N. system. CARY FOWLER, UNNATURAL SELECTION: TECHNOLOGY, POLITICS, AND PLANT EVOLUTION 182-83 (1994).

[11] The fear that the world would not be able to feed its ever-increasing population, especially in the developing world, was the concern that led to the Green Revolution. The Green Revolution inevitably caused the spread of modern agriculture worldwide. This new agriculture relied heavily on chemical inputs, machinery, technology, research and development networks, and state-supported investment. Elizabeth Bowles, *Andhra Pradesh, India, as a Case Study in Perspectives on GMO's*, 34 Cumb. L. Rev. 415, 415 (2004); *see also* CARY FOWLER & PAT MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 130-31 (1990) (stating that due to their reliance on chemical inputs and farm machinery the seeds developed as part of the Green Revolution opened up the world to agrichemical concerns). For a comprehensive discussion on the Green Revolution, see JACK DOYLE, ALTERED HARVEST: AGRICULTURE, GENETICS, AND THE FATE OF THE WORLD'S FOOD SUPPLY 255-81 (1985); PAT R. MOONEY, SEEDS OF THE EARTH 37-46 (1979).

[12] The success of the Green Revolution specifically in Punjab, India, as elsewhere, was predicated on the displacement of genetic diversity on two levels. First, mixtures of diverse crops like wheat, maize, millets, pulses, and oil seeds were replaced by monocultures of wheat and rice. Second, the wheat and rice introduced were reproduced from large-scale monocultures that were derived from a very narrow genetic base. *See* VANDANA SHIVA, THE VIOLENCE OF THE GREEN REVOLUTION 51 (1989). The well-recognized costs to the environment as a result of the Green Revolution's promotion of irrigation, fertilizers, pesticides, and herbicides include fertilizer and pesticide runoff into surface waters, and greater soil erosion. See Taylor & Cayford, *supra* note 7, at 328 n.19 (citing GORDON CONWAY, THE DOUBLY GREEN REVOLUTION: FOOD FOR ALL IN THE 21ST CENTURY (1999)). The increased use of pesticides specifically is significant. Of the estimated 2.5 million tonnes of **R**

In the wake of the U.S. Supreme Court's 1980 case, *Diamond v. Chakrabarty*,[13] a partial, if ultimately unsatisfactory, solution to the problems of high-input industrial agriculture began to be pursued by companies like Monsanto—genetic engineering. Because genetically engineered (GE) crops could be "designed" to produce their own pest and weed resistance or be adapted to grow in poor soil conditions of salinity or drought, genetic engineering researchers argued that GE crops presented a way out of the destructive cycles of high-chemical input agriculture.[14] By the mid-1990s, after discovering a delivery method to treat seeds (the "DNA Gun"),[15] Monsanto's GE cotton, corn, soybeans, and

pesticides applied annually worldwide, only 0.3% reach the intended target with the remainder going into the environment as runoff, or by seepage into groundwater, volatilization into the air, intake by plants and soil organisms, or retention in the soil. Paula Barrios, *The Rotterdam Convention on Hazardous Chemicals: A Meaningful Step Toward Environmental Protection?*, 16 GEO. INT'L ENVTL. L. REV. 679, 688 (2004).

[13] 447 U.S. 303 (1980).

[14] Opponents of the unchecked spread of genetically modified seeds see it differently. They point to Monsanto's "Roundup-Ready" crops. These are genetically modified crops designed to be resistant to the herbicide glyphosate so that all other unwanted vegetation is wiped out after spraying, leaving only the Roundup-Ready crop in place. However, when wind or bees transfer pollen from Roundup-Ready plants to wild plants, herbicide-resistant "super-weeds" may spring up. These superweeds may call for the use of more potent and thus highly toxic conventional herbicides. *See* Kristin Dawkins, *Unsafe in Any Seed, U.S. Obstructionism Defeats Adoption of an International Biosafety Agreement*, MULTINATIONAL MONITOR, March 1999, at 3, 13, *available at* http://multinationalmonitor.org/mm1999/mm9903.05.html (last visited Mar. 9, 2005); Ronnie Cummins, *Hazards of Genetically Engineered Foods and Crops: Why We Need a Global Moratorium*, *available at* http://www.inmotionmagazine. com/geff4.html (last visited Mar. 9, 2005). In a related vein, a report authored by consultant Charles Benbrook of the Northwest Science and Environment Policy Center in Sandpoint, Idaho, using data from the U.S. Department of Agriculture, contends that farmers are using more herbicide than ever before despite industry claims to the contrary. According to Benbrook, farmers applied 11.4 percent more herbicide on Roundup-Ready fields when compared with fields treated with conventional herbicides. Tina Hesman, *Report Says Monsanto's Roundup Could Become Victim of Its Success,* St. Louis Post-Dispatch, May 3, 2001, at C5.

[15] The "DNA Gun" is also referred to as the Gene Gun or Bioblaster. The technology at the heart of this innovation is Particle Gun Bombardment or Biolistic (*bio*logy + bal*listic*). This technology was developed by John Sanford, an electrical engineer at Cornell University, and permits the delivery of naked DNA into intact plant cells by accelerating dense DNA-coated microparticles by means of an explosion of sufficient velocity to penetrate the cell wall. The gun uses a .22 caliber cartridge as the means to deliver genetically coated particles into cultured cells. This process has been utilized to add genes to corn cells, which produced fertile plants and passed on the desired traits in new viable seeds. *See* P. Vain et al., *Foreign Gene Delivery into Monocotyledonous Species*, 13 BIOTECHNOLOGY ADVANCES 658

canola were positioned to take the U.S. and Canadian markets by storm.

However, while Monsanto's GE crops were able to quickly dominate the North American market, they ran into considerable trouble with public acceptance in the European Union (EU), especially in the United Kingdom and France (countries wary of the unknown hazards arising from the introduction of GE crops into the food chain and the environment).[16] In the late 1990s, Monsanto ran into a public relations nightmare when non-governmental organizations (NGOs) such as the Action Group on Erosion, Technology and Concentration and its predecessor, and the Rural Advancement Foundation International undertook an anti-Monsanto campaign that focused on Monsanto's licensing of what these NGOs called "Terminator" technology.[17] Terminator technology is a genetic engineering technique that renders crops sterile so that seed saving by farmers is futile.

The EU imposed a moratorium on the import of GE crops, which it began to lift in 2004.[18] Thus, at the beginning of the

(1995); Gregory Morris, *Gene Gun Targets Corn*, CHEMICAL WEEK, May 23, 1990, at 24.

[16] Owing to the mostly unfavorable coverage of these so-called "Frankenstein" foods in the European press, protests in Europe against their introduction consistently enjoyed front-page treatment whereas the American press dismissed protests here as insignificant. This European media coverage ranged from cautious questioning to outright panic. Moreover, the European consumers were supposedly less likely than their American counterparts to trust the judgment of authorities in the wake of a series of highly publicized food scares. *See* Julian Borger, *How the Mightly Fall*, THE GUARDIAN, Manchester (UK), Nov. 22, 1999, at 2. It is also noteworthy that European concerns extended beyond any unidentified hazards to human health. These concerns also encompassed economic and social considerations such as a decline in European market dominance and competitive advantage and a feared upsurge in dependence on the North American biotechnology industry. Young-Gyoo Shim, *Intellectual Property Protection of Biotechnology and Sustainable Development in International Law*, 29 N.C. J. INT'L L. & COM. REG. 157, 177 (2003).

[17] *See* Neil D. Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81, 106-09 (2001). The ETC website is located at http://www.etcgroup.org. Other NGOs include Greenpeace (online at http://www.greenpeace.org).

[18] For documents associated with this moratorium see Council Directive 2001/18/EC, 2001 O.J. (L 106) 1 (and its predecessor, Council Directive 90/220, 1990 O.J. (L 117) 15, as amended by Council Directive 94/15, 1994 O.J. (L 103) 20 and Council Directive 97/35/EC, 1997 O.J. (L 169) 72); and Council Regulation 258/97, 1997 O.J. (L 043) 1. In late October 2004, the European Union approved Monsanto's Roundup Ready corn NK603 and its processed products as food and food ingredients under the European Union's novel foods regulation, signaling the end of the five-year moratorium on new trait approvals. *See* Patricia Van Arnum, *Ag Biotech Gains Momentum*, CHEMICAL MARKET REPORTER, Nov. 8, 2004, at FR16. Three

twenty-first century, the trends exemplified by Malthus, Mendel, and Monsanto converge on the subject of plant genetic resources (PGR). These trends are increasingly articulated in the common language of intellectual property protection. First, this Introduction will briefly look at crop development and agriculture in a historical sense. Second, this Introduction will examine the emergence of a variety of different regimes for protecting PGR as intellectual property and how tensions and synergies between different national and legal regimes have been producing new and interesting legal treatments of PGR, such as the International Treaty for Plant Genetic Resources.[19] Third, this Introduction will discuss changes in the ways that access to PGR via international and national seed germplasm banks has been af-

months earlier, the E U had approved the importation of genetically modified corn for use as animal feed. *See* Elizabeth Becker, *Europe Approves Genetically Modified Corn as Animal Feed*, N.Y. TIMES, July 20, 2004, at C11. The Cartagena Protocol, an agreement that promotes trade in biotechnology products that are environmentally safe, offers some, albeit little, comfort to those still opposed to the unbridled entry of genetically altered foods and food products, in that it mandates that shipment of such products clearly identify that they may contain living modified organisms. *See* Howard Mann, *The Cartagena Protocol on Biosafety: An Analysis*, June 1, 2000, *available at* http://www.isdlaw. com/docs/ASEAN%20-Mann%20paper.doc (last visited Jan. 27, 2005) [hereinafter Cartagena Protocol Analysis]; Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 18(2)(a), 39 I.L.M. 1027, 1035 (2000). However, this labeling requirement is only required for transportation purposes and does not necessarily extend to subsequent consumer retailing. *See* Cartagena Protocol Analysis, at 9. Two months before the Protocol went into effect, a relatively obscure U.N. agency, the Codex Alimentarius Commission, with the backing of all 168 member states, produced the first set of international guidelines for assessing and managing health risks posed by GM foods. The most significant guideline called for safety assessments of all GM foods prior to their approval for commercial sale. Phil Bereano & Eliott Peacock, *Harmony or Havoc; Can the WTO, Biosafety Protocol and Codex Alimentarius Work Together?*, Sci. and Dev. Network, Jan. 2005, *available at* http://www.scidev.net/dossiers/index.cfm? fuseaction=policybrief &dossier=6&policy=54 (last visited Mar. 4, 2005). *See also* Codex Alimentarius, *available at* http://www.codexalimentarius.net/web/index_en.jsp (last visited Mar. 4, 2005).

[19] International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, *available at* ftp://ext-ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf (last visited Mar. 9, 2005) [hereinafter ITPGR]. This treaty is aimed at governing the international exchange of plant genetic resources. In November 2001, delegates from 116 countries voted to adopt the ITPGR, which was to enter into force only when at least 40 nations either ratified or acceded to it. *See* Kelly Day-Rubenstein & Paul Heisey, *Plant Genetic Resources*, AMBER WAVES, June 2003, at 22. The 40 nation threshold was surpassed when twelve European nations and the European Community ratified the treaty triggering a 90 day countdown that culminated in the treaty going into effect on June 29, 2004. *Biodiversity Treaty Signed,* SOUTHWEST FARM PRESS, Apr. 15, 2004, *available at* http://southwestfarmpress.com/mag/ farming_biodiversity _treaty_signed/index.html (last visited Mar. 9, 2005).

fected by the rise of intellectual property rights in PGR. Finally, this Introduction will briefly review the five papers presented at the conference.

II

WHAT IS AT STAKE?

Due to the convergence of a number of trends, plant genetic diversity is being lost as industrialized agriculture replaces traditional crop strains with increasingly uniform varieties.[20] In the mid-twentieth century, Rockefeller Foundation-backed institutions established "seed banks" in order to conserve rapidly disappearing genetic diversity.[21] As the means to breed resistance into crops is lost, there is a risk of increased dependence on chemical fertilizers, pesticides, and herbicides, which have the ironic effect of breeding resistance into weeds, insects, and diseases.[22]

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[20] Jack Kloppenburg notes that genetic diversity is an enemy of mechanization. For example, the genetic variability of open-pollinated corn posed grave problems to agricultural engineers whose task it was to mechanize the farming process. These plants not only bore different numbers of ears at different places on their stalks but also ripened at variable rates making mechanization of farming processes even more difficult. Thus, mechanization was one among many significant catalysts in the move towards genetic uniformity. *See* KLOPPENBURG, *supra* note 9, at 117.

[21] The Consultative Group on International Agricultural Research (CGIAR) was formed on the initiative of the Rockefeller Foundation and acts as the parent body of a network of international agricultural research centers. These centers which include the International Maize and Wheat Improvement Center (CIMMYT) in Mexico and the International Rice Research Institute (IRRI), among others, have served as "major collectors and storage sites for germplasm." *See* FOWLER & MOONEY, *supra* note 11, at 182-83. Most of these centers have local or regional responsibilities in collecting germplasm; only a small number have global responsibilities. The International Plant Genetic Resources Institute (IPGRI) is a center with the unique task of coordinating the activities of the other centers in addition to providing monetary support for some non-CGIAR conservation facilities. 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, 593-94 (2003). For more on gene banks, see generally DONALD L. PLUCKNETT ET AL., GENE BANKS AND THE WORLD'S FOOD SUPPLY (1987); Nat'l Research Council, Managing Global Genetic Resources (discussing the task that befalls the National Plant Germplasm System in the United States).

[22] Genetic uniformity has led to an unstable and unbalanced plant pathosystem which now risks relying exclusively on chemical inputs. Without these inputs, crops could either not be grown at all or would suffer unbearable reduction in yield and quality. RAOUL A. ROBINSON, RETURN TO RESISTANCE: BREEDING CROPS TO REDUCE PESTICIDE DEPENDENCE 71 (1996). The biotechnology industry played no small role in creating this predicament owing to its focus on creating herbicide-resistant and pesticide-tolerant crops that would survive when fields are sprayed with

Who should control this genetic diversity? The historical "baseline" is that different regions of the earth have dramatically different endowments of economically important plant species. Because of the Ice Age, and the geography of early human settlements and migrations, most cultivated and natural genetic diversity in plant species and varieties originated in equatorial regions and the southern hemisphere.[23] Indeed, beginning in the sixteenth century, one of the major features of colonialism was a contest among the imperial powers over extraction, transplantation, and exploitation of PGR.[24]

Until the late-nineteenth century, the conservation of genetic diversity was dependent on the mass selection of plant populations by farmers and botanists in state botanical gardens such as Kew Gardens in England.[25] "Ownership" of genetic resources could be framed in terms of national sovereignty despite instances in the nineteenth century when foreign powers defied

chemicals. Some fear that the widespread use of herbicide-resistant and pesticide-tolerant crops will lead to the evolution of resistance to these chemical inputs. For example, it may lead to the creation of "super-weeds," as briefly discussed *supra* note 14. The use of plants genetically engineered to contain genes for pesticides, like the Bt Toxin, "may encourage the selection of rare resistant genes in the pest population," thus rendering the pesticide ineffective in the long run. Elizabeth Duall, Note, *A Liability and Redress Regime for Genetically Modified Organisms Under the Cartagena Protocol*, 36 GEO. WASH. INT'L L. REV. 173, 187 (2004).

[23] While the northern hemisphere was severely impacted by the Ice Age, hunting and gathering flourished in the south. Agriculture first began in the warmer lands of the south, where a long history of interactions between human and plants played the key role in developing the extensive genetic diversity which is the foundation of modern agriculture. *See* FOWLER, *supra* note 10, at 4. **R**

[24] Unlike valuable mineral resources, *e.g.*, gold and silver, which can only be extracted once, plant germplasm came to be seen as a resource in which a single taking had the potential of providing a material base through which whole new sectors of production could be developed. This realization led imperial powers to shift focus from precious metals to germplasm. As a result, plant and seed transfers became important both in political and economic terms inspiring measures by the Dutch, English, and French to keep useful materials out of each others' hands. *See* KLOPPENBURG, *supra* note 9, at 154. **R**

[25] The earliest botanical gardens were those established with the mandate to study medicinal plants. The gardens in Florence, Leiden, Leipzig, Montpellier, Pisa, and Heidelberg were founded in the sixteenth century and were associated with medical faculties at universities. By the end of the eighteenth century, an estimated 1600 gardens existed in Europe alone. It was at this point that plant materials were evaluated for other possible uses including food and industrial use. The Royal Botanic Gardens at Kew on the outskirts of London was the world's leading botanic garden as of the nineteenth century owing to Britain's expansive economic and colonial powers. Kew played a pivotal role in developing and disseminating important economic plants. For more on botanic gardens in Europe, see FOWLER, *supra* note 10, at 6-14. **R**

sovereign edicts (as happened in Brazil when rubber trees were smuggled out contrary to the state's express wishes).[26] Currently, under the international system of seed/gene banks established in the 1960s and 1970s,[27] ownership of germplasm is vested in the country where the seed bank is located[28]—many of the largest seed banks are located in countries of the North, such as the United States.

Even before the advent of genetic engineering, ownership of genetic resources proved vexing. For example, should a plant breeder who develops a new variety of disease-resistant wheat be called the owner of that variety? If ownership and property rights in that particular plant variety vest in the plant breeder, what about the farmer or farming community that first identified and conserved the disease-resistant variety that the plant breeder relied on? What acknowledgement should we make, if any, to the generations of Neolithic ancestors who cultivated wild weeds, transforming them into domesticated crops?

III

CONTROVERSIES OVER CROP DEVELOPMENT AND AGRICULTURE

Human beings began cultivating plants approximately twelve thousand years ago as humans transitioned from hunter-gatherers to agriculturalists.[29] While this move to cultivation entailed a focus on a relatively small number of plant species, within those species genetic diversity thrived as crops traveled with people and were adapted through mass selection to new pests, diseases, soils, climates, and human cultures. This plant genetic diversity, developed over ten millennia, is crucial for the continued viability of major agricultural crops as farmers, plant breeders, and biologists draw upon this genetic diversity to adapt crop species to new pests, diseases, and other environmental changes.

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[26] LUCILLE H. BROCKAWAY, PLANT SCIENCE AND COLONIAL EXPANSION: THE BOTANICAL CHESS GAME 57-58 (Jack Kloppenburg ed., 1988) (In smuggling 70,000 rubber seeds out of Brazil in 1876, "Britain had no conceivable national security reason for invading Brazil's sovereignty by surrepticiously removing one of its natural resources; it had merely an economic incentive and, in the preautomotive era, not a very strong one at that.").

[27] *See* discussion of CGIAR system *supra* note 21.

[28] *See* discussion of the sovereignty principle in CBD *infra* Part IV.E.

[29] FOWLER & MOONEY, *supra* note 11, at 8.

The treatment of crop genetic diversity has changed drastically over the course of the past century. The 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. Until the late 1970s, these genetic resources were characterized as the "common heritage of humankind,"[30] with the result that farmers, plant breeders, and agricultural researchers had unrestricted and open access to genetic resources. 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 PGR with the goal of promoting crop improvement.[31]

Control over plant genetic diversity is no less controversial now than it was two hundred years ago when the colonial powers vied for control of plantation crops. Property institutions fundamentally shape a society; the legal constructs between individuals, objects, and the state are not always easy to justify, especially in the realm of intellectual property.[32] Should genetic resources be characterized as the "common heritage of humankind?" In this 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

[30] Plant genetic resources enjoy the unique distinction of being considered the "common heritage of mankind," or in other terms, humanity's collective "genetic estate." 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. 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. While the West has all along been reluctant to confer this "common heritage" status to resources that fall outside their boundaries, this reluctance to confer this status does not seem to have been extended to plant genetic resources. See KLOPPENBURG, *supra* note 9, at 152. For a comprehensive discussion on this concept of "common heritage," see ANTHONY J. STENSON & TIM S. GRAY, THE POLITICS OF GENETIC RESOURCE CONTROL 136-53 (1999). R

[31] Plant viruses claim up to four-fifths of the crops cultivated. 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. It has been further stated that crop improvement through biotechnology, among other means, leads to efficiency, productivity, and stability to an industry that is susceptible to pests, insects, and in most parts of the world, dependent on weather conditions. *See* Karen M. Graziano, *Biosafety Protocol: Recommendations to Ensure the Safety of the Environment*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 179, 183-84 (1995).

[32] Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 31 (1989), *available at* http://www.jstor.org/view/00483915/di984935/98p0163c/0 (last visited Mar. 9, 2005).

others. Should private individuals and firms be allowed to claim exclusive ownership in assorted aspects and elements of genetic resources? If we do allow such private claims to be made, how do we define, qualify, and tailor those newly minted rights? To what extent should national or supranational governments be involved in establishing frameworks and rules regarding PGR? Control and ownership are critical to the questions of how and whether those PGR will be conserved.

The papers presented at the conference examine the question of legal control over PGR in both public-private and national-supranational spheres. In the nineteenth and early twentieth centuries, the U.S. government was heavily involved in plant collecting and "plant improvement," and was also actively involved in freely spreading seed germplasm and information as widely as possible among U.S. farmers. Thus, the U.S. government laid the foundation for expanded commercial agriculture in the twentieth century.[33] 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 pest contexts.[34] During the early twenti-

[33] The United States may have been a latecomer in the colonial posturing for plant resources, but this does not mean that it did not participate. Early political leaders including Thomas Jefferson, George Washington, and Benjamin Franklin were enthusiastic importers of exotic plant material into the country. 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." 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. 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. By 1878, the United States Department of Agriculture, created sixteen years earlier, was spending a third of its budget on germplasm collection and distribution. This distribution entailed handing farmers enough seed to facilitate experimentation, but not enough to supply commercial farming needs. The U.S. government thus encouraged the individual farmer to be a selector, breeder, and multiplier of seed. *See* FOWLER, *supra* note 10, at 14-22. **R**

[34] In 1862, the Morrill Act, *infra* note 205, 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." 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." In 1890, a second Morrill Act provided funding to support seventeen land grant institutions created especially to serve African Americans in southern states. 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. *See* James Stuart, Comment, *The Academic-Industrial Complex: A Warning to Universities*, 75 U.

eth century, U.S. agriculture became increasingly rationalized and industrialized, a trend that continues to date. Specifically, during the early twentieth century, many farmers stopped saving seed and began producing for a commercial marketplace that favored crop uniformity and higher yields—marking the beginning of a shift toward purchased seed stock.

In particular, patent and para-patent laws applicable to plants emerged roughly during the first three decades of the twentieth century. These laws, however, are imperfect and incomplete in their tracking of technological plant breeding advances such as hybridization. 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 share 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[35] was followed and expanded by the Plant Variety Protection Act of 1970,[36] the 1980 Plant Variety Protection Act amendments,[37] and judicial decisions regarding the patent scope in terms of living organisms.[38] Against the backdrop of these legal developments, the Green Revolution occurred globally and the trend toward industrialized, mass commercial agriculture that is highly dependent on chemical inputs such as fertilizers, pesticides, and herbicides continued.[39] At the core of these developments is the attempt to create legal mechanisms for the economic control of plants, plant varieties, and ultimately, plant genes that express particular traits.

This same mid-twentieth century period also brought changes in the division of labor in the agricultural sector, both nationally and internationally. Land grant universities, which had encouraged and trained public plant breeders from the late nine-

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. At the time, it was apparent that a productive agricultural sector was contingent upon the development of improved crop varieties. Since private capital was lacking, it became evident that social capital was needed to accomplish this development. KLOPPENBURG, *supra* note 9, at 12. **R**

[35] 35 U.S.C. §§ 161-64 (2000).

[36] 7 U.S.C. §§ 2321-2582 (2000).

[37] Pub. L. 96-574, § 20, Dec. 22, 1980, 94 Stat. 3352.

[38] *See* discussion *infra* Part IV.A.2.a.

[39] Taylor & Cayford, *supra* note 12, at 328 n.19.

teenth century onward, had their mission redefined.[40] This redefinition involved characterizing their 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.[41] This displacement of public plant breeding from a central 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 improvement* that emphasized free exchange of seed germplasm, breeding techniques, and information. 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.[42]

By the late 1970s, North American and European agricultural activists and authors began voicing concerns that "the genetic base of the world's food supply was quickly disappearing and that restrictive legislation was making it possible for agribusiness

[40] 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 inefficiency, and inability or unwillingness to support critical research. 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* KLOPPENBURG, *supra* note 9, at 235. R

[41] 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. Second, research and the associated funding would be redirected to basic scientific research. Third, industry would have a greater opportunity in determining social division of labor in agricultural research. *See* KLOPPENBURG, *supra* note 9, 235-6. R

[42] *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.).

to gain control of this vital segment of the total food system."[43] These comments were the genesis of arguments arising from newly-emerging NGOs that were severely critical of the spread of industrialized agriculture in the so-called third world[44] with a particular focus on plant breeding and crop improvement.[45]

NGOs advanced their cause by employing several arguments. First, they argued that crop development policies and practices were effectively destroying the genetic base essential to plant breeding.[46] Because the Green Revolution drove the spread of new, high-yielding, uniform varieties (which were replacing traditional farmer landraces and their wild and weedy relatives), industrialized agriculture was accelerating the global erosion of plant genetic diversity. Second, the NGOs argued that there was a serious South-North appropriation of plant genetic diversity that went uncompensated because such resources were treated legally as the "common heritage of humankind."[47] Third, that throughout the last third of the twentieth century, the multinational chemical, pharmaceutical, and food processing corporations acquired control of smaller seed supply companies, thereby producing a striking economic concentration in the seed sector.[48] These corporations acquired smaller companies, gained control and access to unique seed and/or gene libraries, converted them into proprietary resources, and used the libraries to create new plant varieties suited to industrialized agriculture. In many instances, the proprietary resources were protected by plant breeders' rights or patents, meaning that these seeds could not be legally reproduced by farmers beyond the first sale.[49] The final set of claims centered on the concern that the rise of intellectual property rights in PGR for food and agriculture had slowed down or stopped the transfer of new crop development technol-

[43] Meeting in Canada under the aegis of the International Coalition for Development Action (ICDA), these authors and activists expressed concern about crop development and the world food supply in general and seed in particular. The book, Seeds of the Earth authored by R. Pat Mooney, resulted from this conference. The concerns vocalized in the conference and articulated in Seeds of the Earth were developed further by other authors. ROBIN PISTORIUS & JEROEN VAN WIJK, THE EXPLOITATION OF PLANT GENETIC INFORMATION: POLITICAL STRATEGIES IN CROP DEVELOPMENT 8 (1999).

[44] *See id*.

[45] *Id*. at 8-10.

[46] *Id*. at 9.

[47] *Id*.

[48] *Id*.

[49] *Id*. at 10.

ogy to farmers in the developing world. The technology contained in seeds and chemicals was protected by intellectual property rights that farmers risked infringing if they used such seeds and chemicals.[50] However, if they did not, they risked being driven out of their markets by farmers employing the technologies.[51] Additionally, such intellectual property rights were seen as creating a dependence on agrochemical companies and leading to a striking decline in traditional subsistence farming practices in the developing world, such as seed saving by farmers.[52]

The conference's purpose was not to critique genetic engineering per se, or to engage in a general neo-Luddite bashing of genetics or genomics. Indeed, one might consider the ten thousand year history of human selection, cultivation, and transformation of wild landraces into our current domesticated agricultural crops as a history of human intervention in and alteration of plant genomes—kimchi, bread, and beer being some of the earliest fruits of human biotechnical tampering with nature. However, the marked trends toward centralization and privatization of PGR gives rise to a critique of genetic engineering techniques that facilitate commodification of seed germplasm and concentration of control over such resources. The vision of "one seed that feeds the world" may lead to dystopian results.

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[50] While these new varieties were developed using genetic resources acquired from developing nations, these poorer nations are precluded from exploiting the new varieties without the consent of the respective developers. This situation has been seen by some as not only being unfair, but also a hindrance to agricultural development in these poorer countries. *Id*. at 10.

[51] This is just one of the criticisms leveled against the technology transfer provisions under TRIPS, discussion *infra* note 54, from the perspective of the developing world. *See also* Donald P. Harris, *TRIPS' Rebound: An Historical Analysis of How the TRIPS Agreement Can Ricochet Back Against the United States,* 25 NW. J. INT'L L. & BUS. 99, 108-09 (2004) (stating that while the long-term positive effects of TRIPS' technology transfer provisions are yet to come to fruition in addition to being questionable, the short-term negative effects are fully apparent).

[52] The extension of intellectual property rights to plant genetic resources threatens to eliminate farming as it has been practiced over the last ten millennia. For instance, patents protecting Terminator Technology—technology which renders seeds infertile—have led to the dependence on the ever expensive modified seed and chemical inputs from a handful of global biotechnology companies at the expense of farmers' ability to save and share the seed. As a consequence, family and indigenous farmers risk being driven off the land owing to the march toward "bioserfdom" whereby farmers have no choice but to license, or conceivably "lease," the crops they wish to cultivate from the conglomerates. *See generally* Cummins, *supra* note 14.

IV

OVERLAPPING INTERNATIONAL LEGAL REGIMES FOR PLANT GENETIC RESOURCES

To understand the complex contemporary state of intellectual property protection for PGR for food and agriculture, one needs to go back to the early 1980s and look at controversies over the exploitation of such resources. The papers presented at the Malthus, Mendel and Monsanto symposium also focus on how the controversies over intellectual property rights in PGR (both on the individual level of patent-like protection, and the national level of control of banked seed germplasm) have played out (and are playing out) on the international level. This Introduction analyzes and critiques developments such as the 1992 Biodiversity Conference and the resulting Convention on Biodiversity (CBD), the 2001 Cartegena Protocol,[53] the creation of the World Trade Organization, the ongoing implementation of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS),[54] and the 2001 Doha Round[55] and its subsequent collapse in Cancun in the summer of 2003.[56] Also considered is the

[53] 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 (1993).

[54] 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, 1867 U.N.T.S. 19, 33 I.L.M. 1143 (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 http://www.wto.org/english/docs_e/legal_e/ursum_e.htm#n Agreement (last visited Mar. 9, 2005). For a comprehensive analysis of the TRIPS agreement and its history see DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (2003). *See also* INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 11-47 (Jayashree Watal ed., 2001).

[55] 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. However, there were sticking points which were not ultimately resolved, mainly agricultural subsidies. 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." *The WTO Under Fire—The Doha Round*, THE ECONOMIST (U.S. Edition), Sept. 20, 2003, at 26. For documents relating to the Doha Round visit http://www.wto.org/english/ tratop_e/ dda_e/dda_e.htm (last visited Mar. 9, 2005).

[56] The Cancun negotiations were doomed from the start as countries seemed to disavow significant parts of the Doha Round. The E U, for example, denied it had

network of international agricultural research stations and seed conservation banks administered by the Rockefeller Foundation Consultative Group on International Agricultural Research (CGIAR)[57] and the role of the Food and Agriculture Organization of the United Nations (FAO).[58]

One cannot consider the past two decades of legal and technological development without taking account of the heavy influx of investment into biotechnology following the U.S. Supreme Court's *Diamond v. Chakrabarty*[59] 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.[60] This shift occurred contemporaneously with passage of the Bayh-Dole Act,[61] which mandated the patenting of inventions of all kinds produced at public research universities receiving federal fund-

agreed to get rid of export subsidies. Poorer countries for their part denied they assented to participating in talks on new rules. Agriculture was the biggest issue dividing negotiators. To ease the stalemate, the E U and the United States proposed a framework to free farm trade. This framework, however, was rejected by poor nations who felt it did not go far enough, export subsidies would remain in place for instance. *See The WTO Under Fire— The Doha Round*, *supra* note 55, at 26-27.

57 FOWLER, *supra* note 10, at 182-83. *See also* discussion *supra* note 21.

58 The FAO is a United Nations agency mandated to lead international efforts in the fight against hunger. 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. More information on the FAO and its activities is *available at* http://www.fao.org/UNFAO/about/index_en.html (last visited Mar. 9, 2005).

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

60 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 which break the DNA into fragments. The next step is to transfer the isolated gene to the target which could by 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?*, AMERICAN NURSERYMAN, Oct. 15, 2004, at 44.

61 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)). 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).

ing. The Bayh-Doyle Act triggered new policies mandating trade secrecy regarding any potentially patentable inventions (including possible patents in living organisms).

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

A. Changes in U.S. Intellectual Property Law, 1980-2004

1. Overview of Pre-1980 Protection for Plants

a. U.S. Patent Law in General

A positive, express grant in the U.S. Constitution facilitated the emergence of the U.S. patent regime.[62] The grant of a patent is tantamount to the grant of a statutory monopoly.[63] There are several rationales that support granting a patent monopoly to an inventor. The first, the "incentive theory," is the most widely accepted rationale.[64] This theory posits that the grant of exclusive rights creates an incentive for inventors to develop new products or processes.[65] The second rationale is that exclusive rights facili-

[62] 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* David R. Nicholson, *Agricultural Biotechnology and Genetically-Modified Foods: Will the Developing World Bite?*, 8 VA. J.L. & TECH. 7, 17 (2003).

[63] A patent is a privilege granted to an inventor as a reward for furthering "science and the useful arts" by creating an invention and disclosing it to the public. The patent privilege, however, does not grant the holder the exclusive right to use, make or sell his invention; it only prevents others from doing so without the patent holder's permission. *See* Susan E. Gustad, *Legal Ownership of Plant Genetic Resources—Fewer Options for Farmers*, 18 HAMLINE L. REV. 459, 461 (1995).

[64] Kenneth L. Port, *Foreward: Symposium on Intellectual Property Law Theory*, 68 CHI.-KENT L. REV. 585, 591 (1993).

[65] In granting this exclusive right, in effect, excluding others from appropriating the particular invention without the inventor's consent, the state enables inventors to not only recoup the associated developmental costs but also, more importantly, 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).

tate the dissemination of useful information.[66] Finally, there is the natural rights argument—an inventor ought to own title of the creations of the inventor's mind.[67]

Patents issued under 35 U.S.C. § 101 are referred to as utility patents on account of the requirement that a patentable invention under this section be useful.[68] Generally, patent law protects inventions that are novel,[69] nonobvious,[70] and useful.[71] The subject matter eligibility provisions under § 101 designate "four broad categories of patent-eligible subject matter: compositions, machines, articles of manufacture, and processes."[72] While patentable subject matter includes "any new and useful process, machine, manufacture or composition of matter or any new and useful improvement thereof,"[73] mathematical formulae, and natural laws, and products of nature are generally considered as unpatentable.[74]

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

[67] Port, *supra* note 64, at 591 (further noting that since 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").

[68] 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).

[69] The single source rule is utilized in order to determine whether an invention is novel. An invention is not novel if a single instance of prior art discloses each claimed element. 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. Port, *supra* note 64, at 592-93.

[70] Nonobviousness prevents patents from issuing when a person with ordinary skill would have found the invention to be "obvious" when it was made. *Id*. at 593.

[71] To be useful, "an invention need only be operable and capable of performing some function." *Id*. at 592.

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

[73] 35 U.S.C. § 101 (2000).

[74] Aoki, *supra* note 42, at 278.

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

Neither plants nor any other biological subject matter are included in the express language of § 101.[75] As a result of this omission, until 1980 the view proposed 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.[76] Moreover, the written description requirement specified in 35 U.S.C. § 112 was seen as an insurmountable hurdle that precluded the extension of utility patent protection to plants.[77]

b. The Plant Patent Act of 1930

In response to the barriers that made the recognition of plants as patentable subject matter infeasible, as early as the 1880s private plant breeders called for the establishment of a system for patenting plants.[78] What the plant breeders finally ended up with was the Townsend-Purnell Plant Patent Act of 1930 (PPA); the first of its kind anywhere in the world.[79] The congressional intent

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[75] *Id*.

[76] *See* Nicholas J. Seay, *Protecting the Seeds of Innovation: Patenting Plants*, 16 AIPLA Q.J. 418, 419 (1989) (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),] in 1899, which held that the fiber from the needle of an evergreen tree was an unpatentable product of nature.")

[77] 35 U.S.C. § 112 (2000). The statute specifically states that:

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

[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. "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." *See* Aoki, *supra* note 42, at 279. 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 68, 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. AgAG Supply v. Pionner Hi-Bred, 8 DRAKE J.

behind the Act, which extended patent-like protection to asexually propagated species,[80] was to provide agriculture with incentives and protections for developing new varieties and innovations similar to those employed in encouraging mechanical and scientific developments in other industries.[81]

To qualify for protection under the PPA, the plant breeder is required to show that the plant created has new and unique characteristics and that the plant can be reproduced through budding, grafting, or cutting techniques that result in a new plant variety with the exact same, unique characteristics.[82] The variety must be distinct,[83] new,[84] and nonobvious.[85] It is worth mentioning that the PPA contains an exemption from compliance with the "written requirement" of 35 U.S.C. § 112.[86] Accordingly, it is because the policy of the U.S. Patent and Trademark Office (PTO), with judicial backing, to accept the deposit of exact biological specimens at specified repositories as fulfillment of the § 112 requirement.[87] Protection under the PPA lasts for a period of twenty years and precludes other parties from making, selling, or

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 42, at 282 (citing J.E.M. AG Supply, Inc. v. Pionner 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.

[80] These species are those that are vegetatively produced from cuttings or grafts and not grown from seed. Peter J. Goss, *Guiding the Hand That Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1406 (1996). 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, Note, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 310 (1999).

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

[82] *Id*.

[83] To be distinct the variety must have characteristics that are clearly distinguishable from those of existing varieties. *See* Gustad, *supra* note 63, at 464.

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

[85] Nonobvious 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*.

[86] However, the exemption is not absolute since it permits noncompliance only "if the description is as complete as is reasonably possible." Seay, *supra* note 76, at 422 (referring to 35 U.S.C. § 162 (1982)).

[87] *Id*. This seed deposit alternative is significant. 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. *See* Crocker, *supra* note 79, at 257.

reproducing the patented variety.[88] 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.[89]

c. The Plant Variety Protection Act of 1970

In 1970, Congress enacted[90] a new form of statutory patent protection for plants styled as the Plant Variety Protection Act (PVPA).[91] Despite the perceived domestic demand for enlarged patent protection for plants, the PVPA was enacted in response to Western European nations forming the Paris Union, also known as the International Union for the Protection of New Varieties of Plants (UPOV).[92] The purpose of the PVPA is "to encourage the development of 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 inter-

[88] Seay, *supra* note 76, 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. Blair, *supra* note 80, at 311. Naturally, the PPA provided little or no incentive for researchers of such crops to create new varieties. Crocker, *supra* note 79, at 258. 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 62, at 18.

[89] Blair, *supra* note 80, at 311. By 1967 there was a patent law revision pending in Congress. The ASTA proposed broadening the reach of the PPA to cover useful "sexually" reproducing varieties by adding "or sexually" to all the relevant sections. 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. 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. Aoki, *supra* note 42, at 284.

[90] 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. Crocker, *supra* note 79, at 259. This statute is now codified as 7 U.S.C. § 2581.

[91] 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 76, at 424. The PVPA is administered by the Plant Variety Protection Office (PVPO) of the United States Department of Agriculture. Roberts, *supra* note 68, at 100.

[92] For more on UPOV see the discussion in Part IV.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.

est."[93] Thus, the PVPA provides patent-like protection to plant breeders whose plant varieties breed true-to-type for several generations.[94] To receive protection under the PVPA, the breeder must apply for a certificate of protection and show that the plant is (1) new and distinct, (2) novel, and (3) uniform and stable.[95] An application for a certificate is expected to generally provide a "description that is 'adequate or as complete as is reasonably possible.'"[96]

Anyone violating rights granted under the PVPA may be liable for infringement.[97] Procurement of a certificate affords the holder a legal right to exclude others from reproducing, selling, importing, or exporting the protected variety for a period of twenty years.[98] An important feature of the PVPA lies in the

[93] Blair, *supra* note 80, at 312.

[94] Crocker, *supra* note 79, at 259. Variety in the context of the PVPA refers to the taxonomic use of the term. 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.

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). 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 the PVPA more difficult to obtain than the PPA, the latter only requiring that the new variety be new and distinct. *See* Crocker, *supra* note 79, at 259.

[95] Nicholson, *supra* note 62, at 18. For definition of these terms, see 7 U.S.C. § 2402(1)-(4) (2002).

[96] Roberts, *supra* note 68, at 100. The 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. 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. AgAG 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).

[97] 7 U.S.C. § 2451.

[98] Nicholson, *supra* note 62, 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 76, at 424.

exemptions it contains. These exemptions include: (1) farmers' rights to save seeds,[99] and (2) researchers' rights to use protected plants for further development.[100]

Between 1970, when the PVPA was enacted, and 1985, the United States Department of Agriculture (USDA) issued over 2000 PVPA certificates.[101] While the PPA and the PVPA provided much sought after protection for plant breeders and the seed industry, a gaping hole still remained.[102] Advances in genetic engineering allowed scientists to accurately identify varieties that were previously indistinguishable to the naked eye.[103] 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.[104] Usually, once identified or analyzed for their genetic composition, seeds and plants may be utilized in a breeding program to create new varieties.[105]

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[99] 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. Presently, 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. Nicholson, *supra* note 62, at 20. 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 80, at 313.

[100] Nicholson, *supra* note 62, 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." This exemption was also narrowed by Congress by declaring that a variety which is "essentially derived" from a protected variety would be considered an infringement. 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. Crocker, *supra* note 79, at 261.

[101] Gustad, *supra* note 63, at 465. "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.*

[102] Blair, *supra* note 80, at 315.

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

[104] *Id*.

[105] Blair, *supra* note 80, at 315.

2. Post-1980 Developments

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

The seed industry felt that it needed a form of protection for inbred lines or hybrids created using two or more inbred lines—a protection aimed at preventing independent plant breeders or other seed companies from taking advantage of the plant breeder/innovator's research and development efforts.[106] Help came in the form of the U.S. Supreme Court decision in *Diamond v. Chakrabarty*,[107] which recognized the patentability of living inventions. The Court ruled that a bacterium invented by Chakrabarty that broke down crude oil was patentable subject matter because: (1) it was a product of human labor which contained characteristics "markedly different" from those found in nature, and (2) it showed potential for significant utility.[108]

In spite of the holding in *Chakrabarty*, whether complex living organisms, including sexually reproducing "man-made" plants, were patentable subject matter under the utility patent statute remained unclear.[109] The issue of the patentability of sexually reproducible plants was addressed in *ex parte Hibberd*.[110] In *Hibberd*, the PTO originally rejected a patent application for a maize plant containing high levels of amino acids by arguing that the enactment of the PVPA precluded the extension of standard utility patents for plant matter.[111] On review, the United States Board of Patent Appeals and Interferences rejected the examiner's assertion by noting that the statute did not expressly ex-

106 *Id*.

107 447 U.S. 303 (1980).

108 *Id*. at 310. 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 non-naturally 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).

109 Blair, *supra* note 80, at 316.

110 227 U.S.P.Q. 443 (1985).

111 *Id*. at 444.

clude any plant from being proper subject matter for a utility patent.[112]

The legitimacy of *Hibberd* was challenged in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*[113] The defendant, J.E.M., argued that, in light of the PPA and the PVPA, the PTO incorrectly extended the scope of utility patents because the extension was accomplished without congressional approval.[114] Justice Thomas, writing for the majority, upheld the validity of the Pioneer Hi-Bred patents and added that J.E.M.'s unauthorized resale of patented hybrid corn seeds infringed on those patents.[115] Justice Thomas seemed to say that since the PPA and the PVPA do not explicitly state that general utility patents cannot be issued for germplasm, the PTO was free to extend utility patent protection to asexually or sexually reproduced germplasm.

In Canada, the patentability of genetically engineered "higher" life forms was addressed in *Harvard College v. Canada (Commissioner of Patents)*,[116] a 2002 Canadian Supreme Court ruling. The case involved a patent application seeking to patent the "oncomouse."[117] In reaching its decision, the court first placed mammals in the "higher" life form category and then went on to rule that "higher" life forms would not fit into any of the patentable subject matter classes.[118] The court applied this reasoning

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[112] *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 1000 plant utility patents have been issued since the *Hibberd* decision in 1985. *Id*.

[113] 534 U.S. 124 (2001). In February 1998, Pioneer Hi-Bred International sued a small Iowa seed supply company for patent infringement claiming that the defendant infringed on 17 of Pioneer's patents by purchasing seed from authorized Pioneer Hi-Bred dealers and then reselling the seed.

[114] 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*.

[115] 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. As in *Chakrabarty,* [the court declines] to narrow the reach of § 101 where Congress has given us no indication that it intends this result." J.E.M. AG Supply, 534 U.S. at 145-46.

[116] [2002] S.C.R. 45.

[117] 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*.

[118] *Id*. 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,

and proscribed the patenting of plants by classifying such as "higher" life forms.[119] This proscription also applies to animal life that is "more complex than microbes but less complex than mammals."[120] With its holding, the Supreme Court of Canada seemed to reject the far-reaching holding its American peer reached in *Chakrabarty*.

Two years later, when deciding *Schmeiser v. Monsanto*,[121] the Supreme Court of Canada stated that "living" inventions are patentable as long as they are not expressed as a higher life form (i.e., plant genes and cells as opposed to the plant as a whole).[122] Therefore, in Canada, while a "higher" life form (e.g., a canola plant) is not eligible for patent protection, a claim to a modified plant gene or cell is.[123] Subsequent to *Schmeiser*, the Canadian Patent Office revised its position on the patentability of claims directed to plant or animal cells.[124]

In *Monsanto Co. v. McFarling*,[125] a 2004 decision of the U.S. Court of Appeals for the Federal Circuit, the court unanimously found that a farmer infringed a patent by saving and planting glyphosate-tolerant soybean seed.[126] In his defense, McFarling alleged violations of the PVPA and federal antitrust laws and invoked the patent misuse, patent exhaustion, and first sale doctrines.[127] However, unlike Schmeiser, McFarling did not challenge the validity of Monsanto's patents.[128] The court re-

because such a life form possesses qualities that transcend its mere genetic makeup. *Id*. at 45.

119 *Id*. 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).

120 Zahl, *supra* note 119, 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).

121 *See supra* note 5.

122 *Id.*

123 Zahl, *supra* note 119, at 558.

124 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. The Patent Office currently permits claims to cells as long as the description does not define "cells" to include plants, animals, or tissue. ABA Section on Intellectual Property Law Bulletin Jan. 2005, *available at* http://www.abanet. org/intelprop/bulletin/January_2005.doc (last visited Feb. 11, 2005) (on file with author).

125 363 F.3d 1336 (2004).

126 *Id*. at 1339-40.

127 *Id*. at 1340.

128 *Id*.

jected 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 cannot be patented.[129] Citing *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l Inc.*,[130] the court also 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."[131]

B. The 1983 International Undertaking on Plant Genetic Resources

The FAO became a flashpoint for debates between the countries of the North and the South regarding exploitation of PGR. Over the objections of the United States, the FAO adopted the International Undertaking on Plant Genetic Resources (IUPGR) in 1983 and also established an FAO Commission on Plant Genetic Resources (CPGR).[132] The IUPGR and the CPGR were spearheaded by a group of developing countries and were supported by an array of NGOs allied with the International Coalition for Development Action.[133]

The IUPGR was a nonbinding agreement that set out rules and standards for exchanging and conserving seeds and plant tissues. Importantly, the IUPGR took the position that PGR were

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

[130] *See supra* note 113.

[131] *McFarling*, 363 F.3d at 1344.

[132] 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).

[133] 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, *supra* note 10, at 187. **R**

to be considered the "common heritage of mankind."[134] Why would this be controversial given the fact that developed countries justified their access to and use of the genetic resources from developing countries of the South on just that basis? What made the IUPGR's "common heritage" principle so controversial was its extremely broad definition of PGR subject to the undertaking; commercial plant varieties protected by breeders' rights and plant patents were to be treated in the same way as traditional landraces and wild plants –- as "common heritage." Therefore, these commercial plant varieties would be freely accessible to farmers and breeders around the world.[135]

C. The Keystone Dialogues and "Farmers' Rights"

Countries such as the United States 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. The Keystone Dialogues first came to the consensus that plants protected by plant variety protection rights would not be considered freely accessible—a recognition of valid intellectual property rights in plant varieties.[136] Second, the parties agreed that common heritage or free accessibility to farmers' landraces and wild and weedy relatives did not mean access free of charge, i.e., that it might be possible to design an arrangement where plant breeders could be obligated to pay for plant tissue and seeds collected in a

[134] 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, U.N. Food & Agriculture Organization, 22d Sess., Annex, Res. 8/83, *available at* ftp://ext-ftp.fao.org/ag/cgrfa/Res/C8-83E.pdf (last visited Mar. 3, 2005) [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).

[135] It is no surprise that such an arrangement was unacceptable to industrial nations, especially those with established private seed industries. These nations viewed the undertaking was as a veiled attempt at undermining the principle of private property. They had good reason for concern since the undertaking literally sought to decommodify commercial plant varieties. KLOPPENBURG, *supra* note 11, at 174. *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.").

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

particular country's territory.[137] Finally, the parties adverted to a vague idea of farmers' rights.[138] 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.[139]

Farmers' rights was an idea that was proposed by a Canadian NGO, the Rural Advancement Foundation International (RAFI), in 1985 that was meant to embody concerns over genetic erosion and the North-South "gene drain."[140] As envisaged by RAFI, farmers' rights were a new type of collective intellectual property rights, meant to counter plant breeders' rights. Farmers' rights theoretically would allow farmers to receive compensation from an international genetic conservation fund to be administered by the FAO.[141]

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137 *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).

138 FOWLER, *supra* note 10, 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.'"). R

139 FAO Resolution (5/89): Farmers' rights are

> [R]ights 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*.

140 *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).

141 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).

Farmers' rights advocates focused on the following 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 decision-making processes related to acquiring, improving, and using PGR.[142]

In 1989, the FAO adopted a new interpretation of the 1983 IUPGR that declared 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.[143] 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 create UPOV, which was designed to create a legal basis for *plant breeders' rights* in privately-bred varieties of plants.[144] The UPOV protec-

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142 PATEL, *supra* note 137, at 96.

143 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).

144 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 on 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 43, at 79-85. The UPOV has been amended several times since 1961 when the original convention was finalized. These amendments include those of 1972, 1978, and 1991. Currently, different countries apply different versions of the UPOV convention as provided by the amendments. Steven M. Ruby, Note, *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, 19 (2004). For a list of the 58 member nations (as of November 2004) and the respective versions of UPOV the member nations currently apply, see *States Party to the International Convention for the Protection of New Varieties of Plants*, *available at* http:// www.upov.int/en/about/members/index.htm (last visited Jan. 20, 2004).

tions went farther than the PPA, which protected only asexually reproduced plants.[145] UPOV protected all varieties of plants, including sexually reproduced varieties, as long as they were (1) new,[146] (2) distinct,[147] (3) uniform,[148] and (4) stable.[149] The United States passed its own form of plant variety protection in 1970[150]—at the height of the Green Revolution.[151] 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 open access because they lacked the uniformity, and stability required for protection. 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.[152] The seed industry lobbied heavily to many governments

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[145] *See supra* Part IV.A.1.b.

[146] 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." 1991 UPOV Convention, ch. 3, art. 6(1).

[147] 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 . . . .

1991 UPOV Convention, ch. 3, art. 7.

[148] 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." 1991 UPOV Convention, ch. 3, art. 8.

[149] 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. 1991 UPOV Convention, ch. 3 art. 9.

[150] *See supra* Part IV.A.1.c.

[151] *See supra* Part III.

[152] The so-called "farmers' exemption" in the 1978 UPOV is implicit. The actual language of the 1978 UPOV art. 5(1) states that: "The effect of the right granted to the breeder is that his prior authorization shall be required for [(i)] the production for purposes of commercial marketing, [(ii)] the offering for sale, [and (iii)] 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., non-commercial) purposes.

to limit the 1978 UPOV farmers' exemption.[153] Then, in the 1991 UPOV, farmers' rights were curtailed as follows: (1) article 15(2) makes farmers' rights optional and allows each UPOV member nation to decide whether or not to extend such rights;[154] (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;[155] and (3) unlike the 1978 UPOV, which did not allow member nations to grant utility pat-

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153 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).

154 The farmer's exemption is contained in the 1991 UPOV Convention ch. 5, 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).

155 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 breeder's 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.

> 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.

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) (footnotes omitted).

ents for sexually reproduced varieties, article 35(2) of the 1991 UPOV seemed to do just the opposite.[156]

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 only possible if countries like the United States are content to allow 1978 levels of protection for protected varieties, which is doubtful.

E. Convention on Biological Diversity (1992)

The ongoing debate over PGR must be understood in the context of two multilateral agreements. The first is the CBD, which was adopted at the 1992 United Nations Conference on Environment and Development in Rio de Janeiro, Brazil.[157] The second is TRIPS, part of the General Agreement on Tariffs and Trade, which was finalized in 1992 in Marrakech, Morocco.[158]

The CBD was aimed at conserving biodiversity, but has direct implications on the issue of intellectual property rights in PGR. The CBD was a multilateral agreement resulting from a process

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[156] Article 35 of the 1991 UPOV states:

> (2) [*optionaloptionalOptional 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 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).

[157] 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 [hereinafter CBD].

[158] TRIPS, *supra* note 54.

that arose out of environmental concerns in the Organization for Economic Cooperation and Development member countries.[159] The CBD took the position that economic incentives are 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.[160] 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. 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; (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.[161]

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[159] For background on this convention, see 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.J. 415 (1997).

[160] 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. However, many activists favored a stronger legal framework to protect genetic diversity in the CBD, which they viewed as far from perfect, it nevertheless provided a framework on which to build. Ranee K. L. Panjabi, *Idealism and Self-Interest in International Environmental Law: The Rio Dilemma*, 23 CAL. W. INT'L L.J. 177, 191 (1992). 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. Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 260 (1998). 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. 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 that the same developments led to the destruction of biodiversity in the developing world. Catherine J. Tinker, *Introduction to Biological Diversity: Law, Institutions and Science*, 1 BUFF. J. INT'L L. 1, 21 (1994).

[161] On a related note, the United States refusal to ratify the CBD came as no surprise to many. The United States repeatedly voiced substantive objections in the areas of the CBD. First, the United States took issue with the CBD's requirement that developed countries fund environmentally conscious development in developing countries. The United States specifically was uncomfortable with what it perceived as the lack of definite restrictions on the amount of funds developed nations

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. 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 over plants, animals, and microorganisms within their national boundaries.[162] With PGR characterized as a species of sovereign national property,[163] the CBD posited that this sovereign property was a basis for informed consent (prior to extraction/exploitation) and benefit sharing.[164]

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could be forced to contribute to developing nations. Second, the CBD called for essentially open technology transfer including the transfer of biotechnology. 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. 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 disregarding patents and other intellectual property rights. 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. 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). While these arguments were articulated by the Bush Administration (1988-92), 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. However, the United States later became a signatory under the Clinton Administration. David B. Vogt, *Protecting Indigenous Knowledge in Latin America*, 3 OR. REV. INT'L L. 12, 19 n.57 (2001).

162 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 132, at 260. *Compare* IUPGR approach discussed *supra* note 134.

163 CBD, *supra* note 157, at art. 3 states that:

> 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.

31 I.L.M. 818, *824.

164 CBD art. 15(5) (requiring prior informed consent of the party 'owning' the natural resource); art. 8(j) (equitable sharing of benefits). Additionally, the CBD recognized the rights of subnational groups, such as indigenous and local communities to participate in "benefit sharing." 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)

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

In 1986, the initial focus of the Uruguay Round, and specifically TRIPS, was an attempt by industrialized nations to secure multilateral protection for new technologies, pharmaceuticals, and copyrighted media works against unauthorized imitation or duplication.[165] However, by 1990, intellectual property protection for biological organisms (including plants) had emerged as a major negotiating point, just as several newly patented biotech inventions began making their way to the market.[166] 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 GE plants, plant breeding, and crop development.[167]

165 *See supra* note 54; 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 . . . .").

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

167 Jack R. Kloppenburg & Daniel L. Kleinman, *Preface, Plant Genetic Resources: The Common Bowl*, *in* SEEDS AND SOVEREIGNTY: THE USE AND CONTROL OF PLANT GENETIC RESOURCES 1, 9 (Jack Kloppenburg 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.

Seed Industry Consolidation: Who Controls Whom?, RAFI Communique, July 30, 1998, *available at* http://www.etcgroup.org/article.asp?newsid=186 (last visited Jan. 28, 2005). Other observers note that U.S. regulatory changes served as a catalyst in the recent spate of mergers resulting in corporate realignment. However, this trend is not unique to the United States as there have been massive mergers within the chemical and "life sciences" and industries. For example, Novratis AG is one of the largest pharmaceutical companies and a global leader in crop protection chemicals. Novratis was the result of a $27 billion merger between two Swiss corporations, Ciba-Geigy SA and Sandoz Ltd. in 1996. The consummation of this merger had the effect of increasing the stakes in the biotechnology industry leading to a spate of mergers between large multinationals and smaller biotechnology companies. Strategic alliances between large multinationals and small biotechnology firms have also been popular arrangements. Stevan Pepa, *Research and Trade In Genetics: How Countries Should Structure for the Future*, 17 MED. & L. 437, 441 (1998).

Companies also aggressively acted to secure some form of global intellectual property protection for their biotech innovations.[168] 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.[169]

TRIPS was signed by 125 countries in 1994; it mandates that PGR be accorded either plant variety protection, patent, or effective protection under a *sui generis* system.[170] What this meant

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

> 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).

[169] TRIPS, *supra* note 54, at art. 27(2).

> 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. 33 I.L.M. 81, *94

Id. art. 27(2)-(3). *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).

[170] 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

was that many of the gains made by the developing world at the 1992 Earth Summit were weakened by TRIPS.[171]

It is useful to compare the different fora: the United Nations-sponsored IUPGR and 1992 Earth Summit (which produced the CBD), the intellectual property-forum UPOV, the CGIAR system (funded by the industrialized world), and the trade forum

> 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, plant variety protection is provided by several means. Utility patent protection is geared towards biotechnological inventions, plant patent protection targets new and distinct asexually reproducible plant varieties, and *sui generic* protection (plant variety protection) is aimed at sexually reproduced plant varieties. McManis, *supra* note 160, 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).

171 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. 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. *See* Shalini Bhutani & Ashish Kothari, *The Biodiversity Rights of Developing Nations: A Perspective From India*, 32 GOLDEN GATE U. L. REV. 587, 591 (2002). 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." 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. 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. 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. 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. 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, 53-54 (2000). *See generally* Evelyn Su, Comment, *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); 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).

General Agreement on Tariffs and Trade.[172] The 1989 and 1991 changes in the IUPGR (which ultimately became the 2004 International Treaty for Plant Genetic Resources) benefited the developing world, whereas the 1991 revisions to UPOV strengthened the position of private plant breeders.[173] The CBD represented some important gains for the developing world: (1) recognition of the national sovereignty principle[174] and (2) obliging corporations that use developing countries' seed germplasm to pay royalties and transfer technology to the host countries.[175] Additionally, under article 19 of the CBD, developing countries are given priority access to biotech products developed from their germplasm.[176] The CBD also links intellectual property

[172] Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=441463 (last visited March 9, 2005); Helfer, *supra* note 141.

[173] 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. It seeks to accomplish this exchange by creating a multilateral system to which member states and their nationals will be granted "facilitated access." Helfer, *supra* note 141, at 40. 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. In effect, UPOV sought to harmonize property rights associated with the creation or selective breeding of plant varieties. 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).

[174] TRIPS, *supra* note 157.

[175] 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. 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. 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 (1996). 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. Royalties or other remuneration paid to the state were envisioned as the results of such a bargaining process. These financial considerations are then in turn distributed to the community as proceeds arising from commonly-held traditional knowledge to the community. Shubha Ghosh, *Traditional Knowledge, Patents and the New Mercantilism (Part II)*, 85 J. PAT. & TRADEMARK OFF. SOC'Y 885, 921 (2003).

[176] *See* CBD, *supra* note 159, 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 bio-

rights to the distribution of benefits of biotechnology; stating 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."[177]

G. International Treaty on Plant Genetic Resources (2004)[178]

Although the FAO's 1983 IUPGR was non-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."[179] This fund was implemented in the 1990s, and as a result, the FAO decided to institute farmers' rights through a Global Plan of Action adopted at Leipzig in 1996.[180] However, the Global Plan of Action similarly lacked sufficient funding.[181]

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technologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

Id.

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

[178] ITPGR, *supra* note 19.

[179] Patel, *supra* note 137, at 97 (citing The Keystone Center, *supra* note 136). 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. 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. 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. To address this imbalance, the developing states proposed that the revised IUPGR vest farmers' rights in the international community as trustees. A vital component of this arrangement was the creation of an international fund to support conservation. However, FAO members failed to contribute in any meaningful way causing the fund to languish during the 1980s and 1990s. Helfer, *supra* note 141, at 36-37.

[180] *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. 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. Drawing on this report, delegates from 150 countries converged in Leipzig and agreed upon the Global Plan of Action (GPA).

[181] 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

In 1994, the FAO initiated an intergovernmental round of negotiations meant to revise the 1983 IUPGR in order to (1) make it legally binding, and (2) to harmonize its provisions with the 1992 CBD, which, as mentioned earlier, was at odds with the 1983 IUPGR's broad definition of common heritage (the CBD stressed the notion of PGR as sovereign property). In November 2001, 116 member nations (including the United States) signed a new agreement, the International Treaty on Plant Genetic Resources (ITPGR).[182]

The ITPGR reaffirms the commitment to farmers' rights as protecting traditional knowledge relevant to PGR, recognizing a right to equitable benefit sharing, and recognizing the right to participate in decision-making at national levels on matters related to conservation and use of PGR.[183] 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.[184] The ITPGR sought to achieve farmers' rights by exchanging information,[185] facilitating technology transfer and capacity building,[186] and sharing the ben-

> 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).

It is not surprising that the GPA seems to suffer the same fate as the revised IUPGR, discussed *infra* in note 172, when it comes to the reluctance of FAO to fund it. 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. Such language has led to the impression that national action is discretionary rather than mandatory. *See* 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, 592 (2003).

182 ITPGR, *supra* note 19.

183 Patel, *supra* note 137, at 97.

184 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).

185 ITPGR, *supra* note 19, art. 13.2(a).

186 ITPGR, *supra* note 19, 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. For a discussion on 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).

efits (monetary and non-monetary) of the commercialization of PGR.[187]

The ITPGR addresses intellectual property rights in PGR by proposing the creation of a multilateral system (MLS).[188] Under the MLS, a recipient of germplasm[189] received through the MLS (i.e., from 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."[190] 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 works to substantially undermine the farmers' rights provisions of the ITPGR.[191] The ITPGR does not recognize any rights in individual farmers/breeders who develop new plant varieties through systemic practices; however, institutional public and private plant breeders continue to enjoy protection.[192] Furthermore, while the ITPGR is more comprehensive in its treatment of farmers' rights, it does little to offer effective implementation or vindication of those rights.[193]

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187 ITPGR, *supra* note 19, art. 13.2(d). However, for an assessment on 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).

188 ITPGR, *supra* note 19, arts. 10, 13.

189 *See* ITPGR, *supra* note 19, at Annex I, List of Crops Covered Under the Multilateral System.

190 ITPGR, *supra* note 19, art. 12.3(d).

191 Patel, *supra* note 137, at 98.

192 *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. However, the ITPGR permitted plant breeders who utilized genetic materials from the CGIAR gene banks to obtain proprietary rights. 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.

193 While ITPGR article 9.2 recognizes the concept of farmers' rights with regards 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 decision-making. Although article 9.3 preserves the right

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THE "MALTHUS, MENDEL, AND MONSANTO" CONFERENCE

Papers from the "Malthus, Monsanto, and Mendel" conference examine three general themes: (1) the costs that proprietary rights in seeds impose on the global production of food, thus shaping industrial agriculture with effects down the distribution chain from the seed, to the crop, to transportation and manufacture, to the retail level; (2) the ways that production of agricultural knowledge in the twentieth century has shifted from public-sponsored research to a largely privatized model where "public" agricultural research is sponsored by and heavily beholden to private industry; (3) the expanding and changing role that intellectual property rights (whether patents or UPOV) play in the prior two areas. While all of the panelists are not represented by the following papers, the contributors to this symposium reflect these themes and offer valuable insights. I will briefly introduce the contributors.

A. Henry L. Shands, "Current Status of Access and Availability of Plant Genetic Resources"

Dr. Henry L. Shands is the director of the USDA's National Plant Germplasm System seed repository at Fort Collins, Colorado.[194] This is a national seed library that, as Dr. Shands describes, has operated under a norm of open access to material stored in its collection.

One important aspect of the national seed germplasm library has been the changing backdrop of international legal treatment of PGR. During Dr. Shands's tenure as director, he has seen the apparent demise of the problematic common heritage regime[195] that gave rise to the protests of activists such as Pat Mooney[196] in the 1980s and the rise of the current regime of the CBD and the

for farmers to save, use, exchange or sell farm-saved seed or propagating material, this right is subject to local legislation.

194 *See generally* NATIONAL RESEARCH COUNCIL, MANAGING GLOBAL GENETIC RESOURCES: THE U.S. NATIONAL PLANT GERMPLASM SYSTEM (1991).

195 Steven B. Brush, The Demise of "Common Heritage" and Protection for Traditional Agricultural Knowledge, *available at* http://law.wusn.edu/centeris/confpapers (last visited Mar. 9, 2003).

196 *See generally* PAT ROY MOONEY, SEEDS OF THE EARTH: A PUBLIC OR PRIVATE RESOURCE? (1979). For a brief biography of Pat Mooney see *Bio: Pat Mooney - About Staff - ETC Groups*, *available at* http://www.etcgroup.org/bio_mooney. asp (last visited Apr. 5, 2005).

ITPGR wherein PGR are considered sovereign national property.[197]

Dr. Shands's article describes how the National Gene Bank developed from the late nineteenth century and how it has strived to manage its valuable resources and administer them under an open access norm—a task that has grown increasingly difficult with the expansion of intellectual property rights in PGR over the past twenty years. The U.S. National Plant Germplasm System (NPGS) is the world's largest collection with more than 1500 genera and over 10,000 species. Dr. Shands notes that since the CBD[198] went into force, material received by the NPGS has declined due to uncertainty about how the CBD will work with the ITPGR[199] and other questions relating both to changing national intellectual property regimes as well as questions regarding equitable benefit sharing under the CBD.

Dr. Shands's short but informative piece raises the themes of how the spate of new treaties, such as the ITPGR and the CBD, interact with regard to either facilitating or restricting access to plant genetic materials.

B. Stephen S. Jones, "Progress Without Patents: Public Maintenance of Agricultural Knowledge"

Dr. Stephen Jones is a winter wheat breeder at Washington State University[200] in eastern Washington and represents an increasingly rare figure, a public plant breeder at a land grant university[201] that has not been co-opted by the infusion of massive private investment in public agricultural research over the past half century.

Dr. Jones has been working on breeding a variety of perennial winter wheat,[202] a holy grail of sorts for plant breeders who have been seeking to reverse the trend represented by "Terminator"

197 *See generally* JACK R. KLOPPENBURG, SEEDS AND SOVEREIGNTY (1988) for a wide range of views regarding the common heritage versus the sovereign property approach towards plant genetic resources.

198 *See* Henry L. Shands, *Current Status of Access and Availability of Plant Genetic Resources*, 19 J. ENVTL. L. & LITIG. 223 (2004).

199 The ITPGR came into force on June 30, 2004, when it gained the necessary ratifications in 40 countries that were signatories. *See* ftp://ext-ftp.fao.org/ ag/cgrfa/ it/ITPGRe.pdf (last visited Mar. 9, 2005).

200 *See* http://css.wsu.edu/Fac_Prof_Crops/Jones.htm (last visited Mar. 9, 2005).

201 *See* discussion *supra* note 34.

202 For more information on Dr. Jones's work on winter wheat, see http:// winterwheat.wsu.edu/index.html (last visited Mar. 9, 2005).

technology—genetically engineered seeds that only produce for one season and then are sterile.

Dr. Jones's research occurred against a fraught international backdrop. The EU was then in the process of lifting a moratorium it placed on the import of foods containing GE sequences[203]—the EU is the number one world market for American wheat. Not wishing to foreclose the European market, U.S. farmers have been hesitant to begin growing GE wheat. To the extent that Dr. Jones succeeds in breeding perennial winter wheat and it becomes widely adopted, the prospects of a market lock on GE wheat that only grows one season will be seriously diminished. During the summer of 2004, Monsanto announced that it was abandoning its attempt to introduce Roundup Ready GE wheat in the North American market.[204]

Dr. Jones's article warns against the co-optation of public agricultural research by global agrochemical money. The article also looks at the way that agricultural knowledge is produced and the role it plays in the way that food is produced.

Dr. Jones traces the major changes that U.S. agricultural research underwent in the 120 years from the passage of the Morril Act of 1862[205] (establishing the public research infrastructure of land grant universities) to the Bayh-Dole Act of 1980 (which encouraged public universities to patent and commercialize their inventions). Dr. Jones notes how public agricultural research programs began to increasingly partner with multinational agrochemical corporations. Finally, Dr. Jones argues that when thinking about the future of the global food supply, one must ask whether expansion of intellectual property rights is necessary to avert Malthusian famine or whether intellectual property rights in PGR are a misleading diversion that keeps us from examining serious distributive questions about the global food supply.

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[203] *See supra* note 18.

[204] Mike Toner, *Biotech Wheat Plan Halted; For Farmers and Food Firms, Move is 'Huge Victory,'* THE ATLANTA JOURNAL-CONSTITUTION, May 11, 2004, at 3A. For the Monsanto press release see Monsanto to Realign Research Portfolio, Development of Roundup Ready Wheat Deferred Decision Follows Portfolio Review, Consultation with Growers *available at* http://www.monsanto.com/ monsanto/layout/ media/04/05-10-04.asp (last visited Mar. 9, 2005).

[205] Morrill Act, ch. 130, 12 Stat. 504 (1862) (codified as amended at 7 U.S.C. § 304 (2000)) (last visited Mar. 9, 2005).

C. John E. Haapala, "Farmers' Rights" and "Patent Pools and Antitrust Concerns in Plant Biotechnology"

John E. Haapala, Jr. is an organic farmer who has worked with the Farmer Cooperative Genome Project[206] and Oregon Tilth's organic seed certification program.[207] His two articles squarely address the question of intellectual property rights in PGR.

1. "Farmers' Rights"

Haapala's first article addresses the drastic reversal in the meaning of farmers' rights that occurred between the early 1980s and the present, which entailed the loss of the traditional ability of farmers to select, save, use, and exchange seed stock grown in their own fields.[208] This sea change has occurred as intellectual property rights, whether plant variety protection certificates or utility patent protection in countries, such as the United States, have been dramatically expanded in administrative, legislative, and judicial fora. Haapala notes how even the very term "farmers' rights" has to a large extent been co-opted and used in treaties like the ITPGR.

Like Shands and Jones, Haapala references seed saving and exchange by farmers prior to and throughout recorded history, and notes that conservation of plant genetic diversity depends upon widespread use and development by farmers dependent on continuing access to these varieties. He further notes that while Luther Burbank argued for legal recognition of the innovative work that plant breeders engaged in, the PPA only extended legal protection to asexually propagated plants and not to sexually reproduced seed or plants, thus reserving to farmers the right to continue to use, save, and exchange seeds. He also notes that Congress, prior to 1970, had explicitly refrained from conferring intellectual property protection to sexually reproduced plants under the U.S. Patent Act. Finally, he observes that when Congress got around to conferring intellectual property rights on sexually propagated plants, it created a *sui generis* regime, the PVPA, which allowed farmers to save, use, exchange, and even sell sexually propagated seed.

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[206] For information on the Farmer Cooperative Genome Project, see http://www.fcgp.org/FCGPpages/foundmtg.html (last visited Mar. 9, 2005).

[207] For information on Oregon Tilth, see http://www.tilth.org/site/ABOUT.html (last visited Mar. 9, 2005).

[208] For a 1980s articulation of what farmers' rights meant, see *supra* note 139.

Haapala follows with a discussion of *ex parte Hibberd*, a case where the PTO's Board of Patent Appeals held that a maize plant with heightened levels of tryptophan was patentable under a general utility patent. He contends that the significance of the case was that it represented how an administrative agency decision could run counter to over sixty-five years of congressional policy on the scope of intellectual property rights in sexually propagated plants.

The concentration in the global agrochemical sector that has produced so-called "gene giants" such as Syngenta, DuPont, and Monsanto did not escape Haapala's notice. Haapala notes that the judicial expansion of utility patent rights to sexually propagated plants has shored up the economic underpinnings of these corporate giants, transforming farmers around the globe into bioserfs by hanging the guillotine of patent infringement liability over their heads.[209]

Haapala then points out how article 15 of the 1992 CBD[210] characterized PGR as a form of sovereign property[211] and iterated that national governments had the right to benefit via royalties for plant genetic materials that were derived from biomaterial within their sovereign boundaries. He notes that this meant that farmers' rights to save seed were suddenly transformed into intellectual property rights for all varieties held by a country, despite the lack of distinctness, uniformity, or stability.

As a remedy, Haapala suggests establishing an international registry where farmers, breeders, and curators could establish plant varieties as prior art and defeat any subsequent patent claims for lack of novelty. Haapala's take on farmers' rights serves to highlight ways that the emerging international regime for PGR has a remarkable blind spot—the needs and traditions of farmers and farming communities around the world.

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[209] *See* Monsanto v. Schmeiser, [2004] S.C.C. 34; Monsanto v. McFarling, 363 F.3d 1336 (2004).

[210] *See* discussion of the CBD *supra* Part IV.E.

[211] The position of the CBD that plant genetic resources were sovereign property was a drastic reversal of the position of the 1983 FAO International Undertaking on Plant Genetic Resources' characterization that plant genetic resources, whether unimproved landraces farmers' varieties or improved (and protected by intellectual property laws) varieties of the global North, were "the common heritage of mankind."

2. Patent Pools and Antitrust Concerns in Plant Biotechnology

In his second contribution to the symposium, Haapala describes the global rise of patents on genes and PGR. He then notes that with the rise of patented crops, agrochemical corporations holding the patents have required farmers to sign licensing agreements with forum selection clauses and rules and provisions preventing growers from saving, using, selling, and exchanging seeds.

Haapala observes that there may be antitrust problems that arise for a patent holder when they bring a patent infringement lawsuit and the defendant raises defenses such as false procurement of a patent, bad faith patent enforcement, monopoly power, and patent misuse.[212] In the area of plant biotechnology, Haapala discusses the "anticommons"[213] problem of patent thickets (when multiple patent holders control components of a product, driving the price higher than if a single firm controlled the relevant technology), reach-through claims (where upstream patent holders control technology used in the research process itself), and blocking patents (when improvement patents and pioneer technology cannot be exploited without infringing on one another). Additionally, Haapala mentions the antitrust concerns that may be triggered by grantback provisions (agreements to assign subsequent improvements in a technology to the licensor/grantor) and tying arrangements (conditioning the license of a patented technology on a "tied" license on an unpatented com-

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212 *See* Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172 (1965); Handguards, Inc. v. Ethicon, Inc., 601 F. 2d 986 (9th Cir. 1979); United States v. E.I. du Pont de Nemours & Co., 35 U.S. 377 (1956); Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359 (1999).

213 Michael Heller and Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998). *See generally* Michael Heller, *The Tragedy of the Anticommons*, 111 HARV. L. REV. 621 (1993). *But cf*. Chetan Gulati, *Tragedy of the Commons in Plant Genetic Resources: The Need for a New International Regime Centered Around an International Biotechnology Patent Office*, 4 YALE HUM. RTS. & DEV. L.J. 63 (2001). For further discussion on the concept of the "commons," see generally SUSAN J. BUCK, THE GLOBAL COMMONS (1998); JOHN A. BADEN & DOUGLAS S. NOONAN, MANAGING THE COMMONS (1998); ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION (1990). For a comprehensive treatment of the notion of the "public domain," see James Boyle, *Foreward: The Opposite of Property*, 66 LAW & CONTEMP. PROBS. 1 (2003); James Boyle, *The Public Domain: The Second Enclosure Movement and the Construction of the Public Domain*, 66 LAW & CONTEMP. PROBS. 33 (2003).

ponent/technology), which may be used to hold research projects hostage.[214]

In the vein of Stephen Jones, Haapala asks what the impact of the increasingly complex intellectual property environment is on public agricultural research. Haapala argues that industry concentration has negatively impacted agricultural research. In the face of this type of industry concentration, underwritten in part by patents (and potential patent infringement liability), Haapala asks what needs to be done.[215]

Haapala suggests establishing a patent pool for plant genetic information and plant patents. Haapala acknowledges the myriad difficulties with this idea, including: judicial hostility towards such pools, the ambivalent attitude towards such pools taken by the U.S. Department of Justice, and the transaction costs of bringing together diverse parties with different objectives. Yet another difficulty is the absence of a unitary international patent system. Nonetheless, Haapala sees a potentially important role for the government in facilitating such a patent pool involving PGR. He suggests exploring legislative establishment of a *sui generis* system applicable to PGR or even creating compulsory licenses.

An unanswered question is how the post-1992 CBD/ITPGR regime of sovereign property in PGR works on the international level with Haapala's proposed changes in U.S. law. If one takes the demise of the common heritage regime seriously, the complexity of implementing such changes in the intellectual property regimes of numerous nations may prove daunting indeed. Notwithstanding these questions, Haapala sketches out a number of interesting, if controversial, ideas on how our domestic legal system might avert a tragedy of the anticommons with respect to PGR and promote greater access and innovation with regard to such materials.

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214 *See* Transparent-Wrap Mach. Corp. v. Stokes & Smith Co., 329 U.S. 637 (1947); Eastman Kodak Co. v. Image Technical Services, Inc., 504 U.S. 455 (1992); Hensley Equip. Co. v. Esco Corp., 383 F.2d 252 (5th Cir. 1967); McCullough Tool Co. v. Well Surveys, Inc., 343 F.2d 381 (10th Cir. 1965).

215 The prolification of patents in biotechnology could be traced to the "patent first, ask questions later" approach that generally prevails in the United States. For more on this concept, see Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469 (2003).

D. Malla Pollack: "Originalism, **J.E.M.,** *and the Food Supply, or Will the Real Decision Maker Please Stand Up?"*

Professor Pollack's article focuses on the 2001 *J.E.M. v. Pioneer Hi-Bred* U.S. Supreme Court decision that held that sexually propagated plants are patentable subject matter if they otherwise meet the novelty, nonobviousness, and utility requirement of the U.S. Patent Act. Taking a critical stance, Professor Pollack points out that utility patents on many biotechnological inventions, including the patent at issue in *J.E.M. v. Pioneer Hi-Bred*, are suspect because the PTO has allowed deposit to substitute for the statutorily-mandated enabling written description required by the Patent Act in 35 U.S.C. § 112, paragraph 1 (section 112(1)). This is particularly curious because, during the 1980s, science began providing the appropriate language to accurately provide written descriptions of biotechnological inventions. Professor Pollack observes that the courts and the PTO have given a few large businesses the power to close down most independent research on basic food crops.

Professor Pollack lays her argument out methodically, first examining the parameters of Article I, Section 8, clause 8 of the U.S. Constitution (the Patent and Copyright clause).[216] Professor Pollack then examines the Patent Acts of 1790 and 1793, and reasons that if plants are patentable, they are either "manufactures" or "compositions of matter"—enacted terms going back respectively to the 1790 and 1793 Acts. Next, Professor Pollack assesses the PPA of 1930 and the PVPA of 1970, noting that neither statute required enabling descriptions for statutory protection, but also that neither statute gave the holder the exclusive rights a utility patent holder received. Indeed, the PVPA included an explicit farmer seed saving exemption as well as a research exemption.

After establishing the statutory context, Professor Pollack examines the *J.E.M.* court's understanding of the terms "manufacture" and "composition of matter" and finds that there was not a single patent on a seed, plant, plant part, or animal between 1790 and 1836. She then goes on to challenge the *J.E.M.* court's reli-

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216 *See* Malla Pollack, *What is Congress Supposed to Promote? Defining "Progress" in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754 (2001). *See generally*, EDWARD C. WALTERSHEID, TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1787-1836 (1998).

ance on the 1952 Patent Act's legislative history. Professor Pollack also criticizes the *J.E.M.* court's reliance on a 1999 amendment to the Patent Act, which allowed foreign plant variety protection documents to set priority for related patents. She is similarly dismayed by the *J.E.M.* court's reliance on congressional non-action in response to the PTO's recognition of full utility patents in the 1985 Board of Patent Appeals case, *ex parte Hibberd*.[217] Professor Pollack notes that congressional non-action is ambiguous at best and that, in the context of utility plant protection for sexually reproduced plants, it may be of no probative value, contrary to what the court suggests.

Beyond criticizing the *J.E.M.* case, Professor Pollack suggests that it was the PTO, and not Congress, that gutted section 112(1)'s stringent description requirement for biological material by approving use of specimen deposits as a replacement for section 112(1)'s required written description.

Pollack looks to Canadian patent jurisprudence for an alternative path that the United States Supreme Court could have followed. In the 2002 *Harvard College v. Canada* case, the Canadian Supreme Court declined to read "manufacture" and "composition of matter" broadly enough to allow a higher life form, such as an oncomouse, to be patented.[218] Professor Pollack suggests that the common sense represented by the *Harvard College* decision is preferable to the legal formalism run amok represented by the *J.E.M.* decision.

Professor Pollack makes a series of arguments, centered on the section 112(1) requirement of an enabling written description—a sufficiently clear, written description of the putative invention that would enable a person of ordinary skill in the relevant art to practice the invention. Indeed, the enabling written description is crucial to effectuating the purposes of the U.S. Patent Act, namely, that the public obtain practical use of the invention after the patent term expires. Professor Pollack notes that Congress has indeed relaxed this requirement for plant variety certificates, allowing that, in addition to a written description, PVPA applicants have to deposit "a viable sample of basic seed" in a public

[217] *See* discussion of *ex parte Hibberd infra* Part IV.A.2.a.

[218] Harvard College v. Canada, 2002 S.C.C. 76 ("The fact that inventions are unanticipated and unforeseeable does not mean that they are all patentable . . . . The objects of the [Canadian Patent] Act are the advancement of research and development and the encouragement of broad economic activity. This does not imply that to promote ingenuity is to render all inventions patentable.")

repository.[219] However, Professor Pollack points out that Congress has made no exceptions to the enabling written description requirement for utility patents, but the PTO has.[220]

Finally, Professor Pollack points out that the public availability difference between a written description and a deposit has now become even more important because of technological advances. Anyone with a computer can obtain full text patents, but deposits are not always available to the anonymous public before the patent has expired.

After usefully reviewing the patent files for possible patents vulnerable to a section 112(1) "lack of an enabling written disclosure" claim, Professor Pollack suggests that section 112(1) may provide fertile legal ground for opponents of utility patents on plants to create arguments that may force the hand of legislatures, courts, and even international entities.

CONCLUSION

The symposium brought together interested parties with the subject matter of panels organized into three groupings: (1) The Global Food Supply: Concentration, Erosion, Traditional Knowledge and Crisis; (2) The Production of Agricultural Knowledge and Access to Seed Germplasm, and (3) Intellectual Property and Beyond. Each of these three themes were addressed in depth by the panelists; the papers in this issue of the *Journal of Environmental Law and Litigation* address these themes in the ways discussed above.

This Introduction has laid out the emerging global backdrop of overlapping, and sometimes contradictory, treatment of PGR on both the national and international level. Dr. Shands addresses the stresses that shifting international agreements exert on the open access policies of the U.S. National Plant Germplasm System. Dr. Jones voices concern on the production of agricultural knowledge in public land grant universities as these institutions increasingly turn to private funding. Specifically, he addresses

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219 35 U.S.C. § 2422(4).

220 *See In re* Argoudellis, 434 F.2d 1390 (1970), 168 U.S.P.Q. (BNA) 99 (in a non-plant context, the CCPA reversed a PTO rejection of a claim for an antibiotic compound and a microbiological process for preparing the compound. The rejection involved the then-applicable PTO requirement of a deposit of the microorganism in a public repository. The applicant was late in making the deposit, but contended that the microorganism was available in a university. The PTO rejected the application as untimely and the CCPA reversed.)

how multinational agrochemical corporations have become extremely interested in the research agendas of individual researchers and plant breeding programs. Mr. Haapala's first article addresses the changes in the idea of farmers' rights over the past two decades and decries the strategy of the ITPGR's approach to create an annex of around sixty crops in international seed banks to which a modified common heritage treatment would apply—with all other plant genetic materials treated as sovereign national property. Mr. Haapala's other article paints a fairly dark picture of expansive patent rights held by an increasingly concentrated fistful of multinational agrochemical/lifescience corporations; but also gingerly explores the possibility of a chastened type of "patent pool." This patent pool may begin to create grounds for a chastened sort of open access to both plant genetic materials and other information that might serve the underlying purposes of patent law more effectively than the current situation. Finally, Professor Pollack presents both a trenchant critique of the Supreme Court's 2001 *J.E.M. v. Pioneer Hi-Bred* decision and a spirited and historically detailed argument about why utility patents on plants that were at issue in *J.E.M.* may be vulnerable to a § 112 written enablement attack.

Taken together, these articles suggest that the expanding scope of intellectual property laws and international treaties over the past twenty years have been wreaking fundamental changes in the way we think about agriculture. While it is important not to overstate the argument, at times it seems that the expansion of intellectual property has taken on a life of its own. The conference asked this still unanswered question about intellectual property law and global food policy: Are we in control of our institutions or are they in control of us?