Washington University Journal of Law & Policy

Volume 30 *Open Source and Proprietary Models of Innovation*

2009

The Interface of Open Source and Proprietary Agricultural Innovation: Facilitated Access and Benefit-Sharing Under the New FAO Treaty

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INTRODUCTION: PLANT INNOVATION AND PLANT GENETIC RESOURCES

The origin of plant innovation[1] traces back to primitive cropping and domestication of plants for food—to the very beginnings of agriculture. For millennia since then, farmers have selected naturally occurring variants that have shown higher yield or seemed better adapted for cultivation and have replanted seeds of those variants for the following season's cultivation. The resulting cultivars and landraces are important not only as sources of seeds for local farming but also as genetic resources for further plant innovation.[2]

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1. In this Article, the term "plant innovation" is used to mean all forms of invention and development relating to plants. Therefore, it includes the creation of new plant varieties, whether by genetic modification or more conventional plant-breeding techniques, and any new techniques or processes for creating same.

2. *See* JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 2 (2d ed. 2004) ("Over thousands of years the slow but steady accumulation of advantageous genes produced more productive cultivars."). A "cultivar" may be defined as "a cultivated variety of a domesticated crop plant (species or subspecies), which is clearly distinguishable from others by one or more characteristic and that, when reproduced, retains its distinguishing characteristics," whereas a "landrace" is "a farmer-developed variety of a crop plant that is evolved from a wild population, heterogeneous and adapted to local environmental conditions." Muriel S. B. Lightbourne, The FAO International Treaty on Plant Genetic Resources for Food and Agriculture: Towards Food Security, Conservation, Equity? 36

Historically, new cultivars and landraces largely have been treated as common property or the common heritage of humankind, and as such have been freely shared among farmers.[3] However, the era of free and unencumbered access to new plant varieties appears to be passing. Scientific plant breeding, which was triggered by the rediscovery of the Mendelian Laws of Heredity,[4] has drastically shifted the responsibility for plant innovation from farmers to public agricultural research organizations and, in recent years, to private plant-breeding companies. The advent of genetic engineering and agricultural biotechnology in particular have added important tools to the plant breeder's toolbox and are likely to accelerate the specialization and privatization of plant breeding.[5]

Plant materials themselves have been a fundamental resource for human survival throughout history. Most people in the world still "obtain a large share of their calories and nutrients from food [made]

(June 2007) (unpublished Ph.D. dissertation, Queen Mary, University of London) (on file with author). Lightbourne goes on to point out that "[t]he genetic variability of landraces is precisely what makes them interesting for plant breeders and farmers, especially those located in difficult environments; it is also what contributes to more stable yields from year to year than those of commercial varieties, although on a yearly basis, these yields are inferior to those of the commercial varieties." *Id.* For a scientific definition of "plant genetic resources" and the associated term, "plant germplasm," see *infra* notes 30 and 35.

3. *See* Keith Aoki, *Distributive and Syncretic Motives in Intellectual Property Law (with Special Reference to Coercion, Agency, and Development)*, 40 U.C. DAVIS L. REV. 717, 777–78 (2007) [hereinafter Aoki, *Distributive and Syncretic*] ("Prior to 1982, 'raw' seed germplasm was generally considered and legally regarded as the 'common heritage of mankind.' . . . As such, farmers, plant breeders, and agriculturalist scientists could freely access and use raw seed germplasm without qualification." (citation omitted)). For a more recent, book-length examination of the interface of plant innovation and plant genetic resources, see KEITH AOKI, SEED WARS: CONTROVERSIES AND CASES ON PLANT GENETIC RESOURCES AND INTELLECTUAL PROPERTY (2008) [hereinafter AOKI, SEED WARS].

4. The laws of plant inheritance were first discovered by the Austrian monk Gregor Mendel (1822–1884) and revealed that all characteristics are inherited through indivisible genes contributed by each parent to its offspring in sexually reproducing species. Mendel's work was largely ignored but was rediscovered by agronomists in Europe and the United States around the turn of the twentieth century. *See* Keith Aoki, *Malthus, Mendel, and Monsanto: Intellectual Property and the Law and Politics of Global Food Supply: An Introduction*, 19 J. ENV'TL L. & LITIG. 397, 401 (2004). *See generally* ROBERT OLBY, ORIGINS OF MENDELISM (2d ed. 1985). For an account of the rediscovery of Mendel's Laws of Heredity in the early 1900s, see *infra* note 40.

5. *See* KLOPPENBURG, JR., *supra* note 2, at 2–4 (describing that new genetic technologies poise us "on the edge of an era in which humanity *will* be 'making natural history' in a much more complete sense of the phrase").

from plants and plant parts."[6] Approximately half of the world's medicines are estimated to contain compounds of plant origin.[7] Recently, plant materials have been recognized as an important source of biofuels, which could provide an alternative to the world's reliance on limited fossil fuels.[8]

Although plant innovation is critical for a variety of industries, it is also vulnerable to unauthorized copying. Plant innovation is initially costly and time-consuming to produce but is relatively easy and inexpensive to reproduce. For that reason, the availability and scope of intellectual property protection for plant innovation has important implications for stimulating plant innovation by plant breeders.[9]

One of the most heated aspects of the international debate over extending intellectual property protection to the innovations of plant breeders concerns how to balance the intellectual property claims of plant breeders with countervailing claims to a fair and equitable sharing of benefits arising out of the utilization of preexisting plant genetic resources ("PGRs") contributed by farmers and others. In

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6. Wallace Huffman, *Economics of Intellectual Property Rights in Plant Materials* 2 (Iowa State Univ. Dep't of Econ. Working Paper Series, Working Paper No. 06016, 2006), *available at* http://www.econ.iastate.edu/research/webpapers/paper_12583_06016.pdf.

7. Bonwoo Koo & Brian D. Wright, *Dynamic Implications of Patenting for Crop Genetic Resources* 1 (Int'l Food Policy Research Inst., EPTP, Discussion Paper No. 51, 1999), *available at* http://www.ifpri.org/divs/eptd/dp/papers/eptdp51.pdf.

8. *See* Don Looper & Aaron Ball, *Feel the Heat: Biofuels Are a Hot Investment, But Don't Get Burned . . .*, 44 HOUSTON LAW. 22, 25–27 (2007) ("The . . . 97 ethanol plants [in the U.S.] are operating at capacity, and an additional 33 plants are under construction."); Judy Keen, *Midwest Farms Reap Benefits of Ethanol Boom*, USA TODAY, Oct. 2, 2006, at 10A ("U.S. plants can produce more than 5 billion gallons of ethanol per year, and that number will rise sharply as new facilities come on line.").

9. *See* Jorge Fernandez-Cornejo, *The Seed Industry in U.S. Agriculture: An Exploration of Data and Information on Crop Seed Markets, Regulation, Industry Structure, and Research and Development*, AGRIC. INFO. BULL. NO. 786 (U.S. Dep't of Agric., Washington, D.C.), Jan. 2004, at 51, *available at* http://www.ers.usda.gov/publications/aib786/aib786.pdf ("Estimates of the time involved in producing new varieties in a breeding program range from 10 to 15 years to produce a marketable product. . . . On an annual basis, a small breeding program was estimated to cost approximately $250,000 in the late 1980s, a sum adequate to cover the costs of a chief breeder, a staff of three or four, equipment, facilities and land. . . . Even where larger firms realize economies of scale and scope in producing multiple varieties, the estimated development costs of a new variety range between $2.0 million and $2.5 million for the same period. . . . Given the magnitude of these investments, it is unlikely that plant breeders would have made this type of R&D investment without property rights protection." (citations omitted)).

response to this often acrimonious North-South debate—in which Northern accusations of intellectual property "piracy" in the developing world are regularly met with counter-accusations of "biopiracy" on the part of innovators in the industrialized world—the International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA"), was promulgated by the Food and Agriculture Organization of the United Nations ("FAO") on November 2, 2001, and entered into force on June 29, 2004. The ITPGRFA represents the first binding international agreement attempting to address this issue by introducing a "Multilateral System" for facilitating access to and benefit-sharing arising out of the use of selected PGRs.[10]

The FAO Multilateral System is particularly noteworthy because it represents the first international attempt to combine an open source system of facilitated access to PGRs with a mandatory system of benefit-sharing, including mandatory sharing of monetary and other benefits arising out of commercialization of certain patent-protected plant innovation, thus implicitly recognizing a role for intellectual property protection and proprietary plant innovation in generating monetary benefits to maintain the open source system. This Article will critically examine how effectively the new ITPGRFA combines these open source and proprietary elements and will conclude by comparing this commendable, albeit imperfect, Multilateral System

10. International Treaty on Plant Genetic Resources for Food and Agriculture, *adopted* Nov. 3, 2001, S. Treaty Doc. No. 110-19, ftp://ftp.fao.org/ag/cgrfa/it/ITPGRe.pdf [hereinafter ITPGRFA], states in Article 1 that its objectives are "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity," which had been promulgated by the United Nations Environmental Programme and opened for signature at the U.N. Conference on Environment and Development (the Earth Summit) in Rio de Janeiro in 1992, and stated similar objectives with respect to biological diversity more generally. *See* Convention on Biological Diversity (with annexes), *opined for signature* June 5, 1992, 1760 U.N.T.S. 79 [hereinafter CBD]. However, as will be discussed in more detail, *infra* notes 59–64, 106–20, 139–40 and accompanying text, the FAO International Treaty and the CBD take two very different approaches to meeting their common objectives. Whereas the CBD explicitly recognizes the sovereign rights of its members to exploit their own genetic resources, and thus encourages bilateral agreements between industrialized and developing countries to facilitate access to genetic resources and an equitable sharing of benefits arising out of the utilization of these resources, the FAO International Treaty establishes a "Multilateral System" for facilitating access to and an equitable sharing of benefits arising out of the use of PGRs for food and agriculture.

with its potentially bipolar alternative—namely, the continuation of current controversies over the patentability of genetic materials and over reactive assertions of sovereignty over plant genetic resources.

I. OVERVIEW OF PLANT INNOVATION, PGRS, AND THE LEGAL PROTECTION OF SAME

A. Social and Economic Significance of Plant Innovation and PGRs

The historic transformation of agriculture in many developing countries from traditional farming to industrialized agriculture methods occurred in the 1950s and 1960s, in what is commonly called the Green Revolution,[11] and is frequently cited (notwithstanding some significant unintended adverse environmental consequences) as one of the more successful examples of utilizing PGRs to stimulate plant innovation in the agricultural field.[12] Unquestionably, the Green Revolution has led to significant increases in the world's food supply. "Total food production in developing countries more than doubled between 1960 and 1985, and food production more than kept pace with burgeoning population growth."[13] In one recent example, Brazil drastically enhanced its soybean production by introducing heat-tolerant varieties of soybean in its farmlands in 1997. As a result, Brazil is presently second in the

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11. The Green Revolution began with the development of a new set of high-yield varieties by the international crop-breeding institutions established in Mexico and the Philippines between the 1940s and 1960s with the support of the Rockefeller and Ford Foundations.

> These institutions produced new varieties of rice, wheat, and corn that were more responsive than traditional varieties to synthetic fertilizers and controlled irrigation. The new varieties were quickly adopted in many parts of the developing world, and resulted in dramatic increases in food production. By the 1990s, about 70% of the world's corn, over 50% of the wheat produced in Asia and Latin America, and almost 75% of the rice cultivated in Asia consisted of the new varieties.

Carmen G. Gonzalez, *Trade Liberalization, Food Security, and the Environment: The Neoliberal Threat to Sustainable Rural Development*, 14 TRANSNAT'L L. & CONTEMP. PROBS. 419, 440–41 (2004) (citations omitted); *see also* KLOPPENBURG, *supra* note 2, at 158–59.

12. *See* KLOPPENBURG, *supra* note 2, at 158–59. For a discussion of the unintended adverse environmental consequences of the Green Revolution, see *infra* notes 19–29 and accompanying text.

13. Gonzalez, *supra* note 11, at 441.

world's soybean production and is expected to surpass the United States soon.[14]

The pharmaceutical industry has also been cited as one of the major beneficiaries of PGRs. Human beings have a long history of relying strongly upon the materials of various plants to deal with illnesses. Many recently manufactured synthetic medicines drew their "chemical blueprints" from "natural plant materials before they were reproduced in the laboratory."[15]

Above all, PGRs have particular significance for global "food security"[16] because of their use as raw materials for improving productivity of crops. The Organization for Economic Co-operation and Development ("OECD") reports that "[w]orld agricultural production to 2010 is expected to grow at an average rate of around 1.8 percent a year, a slower pace than in preceding decades but fast enough to improve per capita food production as world population growth gradually loses momentum."[17] Of the many factors affecting the future food supply, farmers' access to improved crop varieties is among the most important.[18] Thus, for a sustainable world food supply, it is critical to conserve PGRs and to use them to develop new varieties.

Unfortunately, despite the highly recognized significance of PGRs, scientists worry that the number of PGRs in the world has declined, and some varieties are reportedly near extinction, or are

14. *See* Scott Wallace, *Last of the Amazon*, NAT'L GEOGRAPHIC, Jan. 2007, at 60.

15. David S. Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373, 376 (1998).

16. The definition of the term "food security" is somewhat controversial. While the World Food Summit held in 1996 defines food security as "physical and economic access by all people at all times to sufficient, safe and nutritious food to maintain a healthy and active life," there is a popular misconception that food insecurity is caused by food scarcity. Gonzalez, *supra* note 11, at 428 (citations omitted).

17. Reza Lahidji et al., *The Future of Food: An Overview of Trends and Key Issues*, *in* THE FUTURE OF FOOD: LONG-TERM PROSPECTS FOR THE AGRO-FOOD SECTOR 7, 7 (Org. for Econ. Co-operation and Dev. ed. 1998) [hereinafter THE FUTURE OF FOOD].

18. Per Pinstrup-Andersen & Rajul Pandya-Lorch, *Major Uncertainties and Risks Affecting Long-term Food Supply and Demand*, *in* THE FUTURE OF FOOD, *supra* note 17, at 53, 64. For examples of some of the unintended consequences of farmer access to improved plant varieties, however, see generally Glenn Davis Stone, *The Birth and Death of Traditional Knowledge: Paradoxical Effects of Biotechnology in India*, *in* BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE 207 (Charles R. McManis ed., 2007) [hereinafter BIODIVERSITY & THE LAW].

already extinct, due to the effects of increased population growth and industrial agriculture.[19] Rapid urbanization, industrialization, and pollution that accompany the continued increase in the world's population are detrimental to the conservation of PGRs.[20] Rapid increases in the human population compel more people to move from rural areas to the cities and also to encroach upon natural preserves. The amount of PGRs in the world is also said to be seriously shrinking due to a variety of pollutants, which exist due to the growth in industry, ranging from direct emission of carbon dioxide to the discharge of toxic substances into waterways and soil.[21]

Genetic erosion due to industrial agriculture is an additional concern.[22] Genetic uniformity resulting from mono-cropping over large areas in the world arguably accelerates genetic erosion, "displacing thousands of local varieties, often in those very communities where plant genetic diversity is greatest, as local farmers turn to the use of modern [elite] seeds."[23] Commentators worry that the introduction of hybridization has begun to degrade the genetic diversity in the farmlands of developed countries, and that the Green Revolution threatens to bring about genetic erosion in developing countries as well.[24]

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19. *See* June Starr & Kenneth C. Hardy, *Not by Seeds Alone: The Biodiversity Treaty and The Role for Native Agriculture*, 12 STAN. ENVTL. L.J. 85, 94 (1993). For a recent, detailed discussion of the genetic erosion hypothesis, including citation to commentators who argue that the hypothesis is "plausible but nowhere documented," see Lightbourne, *supra* note 2, at 94–100.

20. Starr & Hardy, *supra* note 19, at 94.

21. *Id*. at 95.

22. *Genetic Resources in Agriculture: The Key to Food Security*, FAO NEWSROOM, June 8, 2006, http://www.fao.org/newsroom/en/news/2006/1000316/index.html ("Throughout history, human beings have used some 10 000 [sic] plant species for food; today, our diet is based on just over 100 species, due to the introduction of a small number of modern and enormously uniform commercial varieties.").

23. Starr & Hardy, *supra* note 19, at 95–96 (citation omitted). *But compare* Lightbourne, *supra* note 2, at 98 (citing commentators who argue that "the genetic erosion hypothesis is 'plausible but nowhere documented.'"). At the same time, Lightbourne recounts several troubling examples of the near-extinction of potentially valuable landraces. *Id.* at 96–97 (rice), 284 (soy); *see also infra* note 28.

24. *See* KLOPPENBURG, *supra* note 2, at 6–7. Professor Kloppenburg describes the negative social and environmental impacts of Green Revolution as "the exacerbation of regional inequalities, generation of income inequalities at the farm level, increased scales of operation, specialization of production, displacement of labor, accelerating mechanization, depressed product prices, changing tenure patterns, rising land prices, expanding markets for commercial

The arguably increasing rate of plant species extinction ushers in the possibility of an "irreversible loss of genetic resources that may someday be of immense value to agriculture, biology, medicine, and industry," which means that "modern farming stands to lose the fundamental building blocks needed to produce the crops of tomorrow."[25] The World Watch Institute points out that "[p]robably the most immediate threat to human welfare posed by the loss of biological diversity arises from the shrinkage of the plant gene pools available to agricultural scientists and farmers."[26] To the extent that the PGRs pool shrinks, the search costs for new genes to be used for the development of novel plant varieties will increase. Eventually, the opportunity to breed higher-yield crops will decrease, and prices of agricultural products will increase.[27] Thus, continued efforts to conserve PGRs *in situ* and *ex situ* and to use them safely and efficiently are instrumental in securing human welfare against the extinction of PGRs.[28]

With the increased recognition of the economic significance of PGRs comes the increasingly complex struggle to strike a balance between the interests of developing countries, which house most raw genetic materials and seek remuneration for supplying them, and developed countries, which have most of the biotechnological know-how and are pressing for free access, open markets, and stronger intellectual property rights protection for plant innovation.[29]

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inputs, agrichemical dependence, genetic erosion, pest-vulnerable monocultures, and environmental deterioration." *Id.* at 6.

25. Starr & Hardy, *supra* note 19, at 86–87, 96.

26. *Id.* at 96 (quoting ERIK ECKHOLM, DISAPPEARING SPECIES: THE SOCIAL CHALLENGE 12 (Worldwatch Paper 22, 1978)).

27. *Id.* at 98.

28. Interestingly, the Norwegian government recently announced its plan to build the Svalbard International Seed Vault, a so-called "doomsday vault," inside a mountain on an Arctic island to save "all known varieties of the world's crops." It is aimed "to withstand global catastrophes like nuclear war or natural disasters that would destroy the planet's sources of food." *See 'Doomsday' Seed Bank to Be Built*, BBC NEWS (London), Jan. 12, 2006, http://news.bbc.co.uk/1/hi/sci/tech/4605398.stm. *But cf.* Jim Chen, *Across the Apocalypse on Horseback: Biodiversity Loss and the Law*, *in* BIODIVERSITY & THE LAW, *supra* note 18, at 42, 52 (noting that "[*i*]*n situ* preservation remains the only effective way to save biodiversity").

29. *See* Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 591–92 (1993); James O. Odek, *Bio-piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 143 (1994);

B. PGRs: Who Contributes Them, Who Develops Them, Who Owns Them?

Farmers' crops have contributed to the enrichment of the global store of PGRs[30] through the cumulated mass selection of plants ever since agriculture began. Humans began cultivating plants and exchanging seeds for food and agriculture in Neolithic times or earlier. While primeval farmers undertook their cultivation with a relatively small number of plant species, genetic diversity has flourished as crops developed through millennia of exchanges and resulting mass selection designed to meet changing environments and human preferences. These PGRs have been, and continue to be, central to the viability of major agricultural crops in the lives of human beings.[31]

Farmers have thus used artificial selection to intensively accelerate the ongoing process of natural selection. Farmers' cumulative efforts resulted in high levels of plant inter- and intra-specific genetic variability in particular and relatively confined geographic areas, known as "Vavilov centers of genetic diversity."[32]

Amy Nelson, Note, *Is There an International Solution to Intellectual Property Protection for Plants?*, 37 GEO. WASH. INT'L L. REV. 997, 1006–07 (2005).

30. Scientifically, the term "plant genetic resources" refers to the genetic information found in gene alleles of living plant cells. This genetic material is found in every living cell of every plant. PGRs have economic significance because of their actual and potential value to industry, medicine, agriculture, and energy development. Thus, PGRs encompass both identified and unidentified ranges of plant germplasm available in the global gene pool. *See* KLOPPENBURG, *supra* note 2, at 46; H. Garrison Wilkes, *Plant Genetic Resources over Ten Thousand Years: From a Handful of Seed to the Crop-Specific Mega-Genebanks*, *in* SEEDS AND SOVEREIGNTY: THE USE AND CONTROL OF PLANT GENETIC RESOURCES 67, 79 (Jack R. Kloppenburg, Jr., ed., 1988). The ITPGRFA also defines genetic material as "any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity." ITPGRFA, *supra* note 10, art. 2. In this Article, the term "plant genetic resources" will be used, as distinguished from the term "plant innovation," which is generally understood as the introduction of something new or useful, for example introducing new methods, techniques, or practices or new or altered products, into the previous plant genetic resources or plant innovations.

31. *See* CARY FOWLER & PAT MOONEY, SHATTERING: FOOD, POLITICS, AND THE LOSS OF GENETIC DIVERSITY 8 (1990).

32. "The existence of such areas was first identified in the 1920s by the Soviet botanist N. I. Vavilov." KLOPPENBURG, *supra* note 2, at 46. Through a series of botanical expeditions all over the world, he located a variety of areas where a bounty of wild relatives of cultivated crops was living. These areas are considered to be the centers of origin of particular crops where they were domesticated and initially evolved under cultivation. *See id.* at 46–49.

Although the concept of Vavilov centers is sometimes challenged by new data, there is a considerable consensus among crop scientists that cradle areas of crop domestication are identifiable and reasonably well known.

> While genetic resources [may be] found in all farming systems, they are particularly valuable and abundant in Vavilov Centers . . . . because of their on-going processes of crop evolution, such as gene flow between wild relatives and cultivated types and decentralized selection by farmers.[33]

Farmers and consumers in other parts of the world have also enjoyed the benefits of PGRs derived from Vavilov centers.[34] The diffusion of plant germplasm[35] beyond these Vavilov centers was accomplished through the exchange of seeds among farmers, forming one of the dominant patterns of crop evolution. The incessant quest for new crops and crop varieties to overcome the obstacles to crop production has propelled the diffusion of PGRs throughout the world. As each country recognized the remarkable economical importance of PGRs, pubic sectors such as governments, national gardens and public research institutes have also augmented each nation's role in exploring and collecting new crop resources.

In 1493, Christopher Columbus inaugurated what came to be called the "Columbian Exchange" in the diffusion of PGRs from the New World to European countries, bringing maize, beans, potatoes,

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33. Stephen B. Brush, *Protecting Traditional Agricultural Knowledge*, 17 WASH. U. J.L. & POL'Y 59, 61 (2005) (arguing that "conservation and protection of traditional knowledge associated with" Vavilov centers is critical to keep global plant genetic resources).

34. For example, maize and cassava cultivated in Africa and Asia have their origin in MesoAmerica and the Amazon Basin, respectively, and farmers in North America grow rice originating in Asia and sorghum originating in Africa. *Id.* at 61.

35. "Plant germplasm" encompasses the sum total of the heritable basis of a species or variety of plants. This term is generally used by plant breeders and geneticists to describe the genetic stocks within a species of plants collectively. *See* JOHN MILTON POEHLMAN, BREEDING FIELD CROPS 4–5 (3d ed. 1987). In this Article, the term "plant germplasm" is used interchangeably with "plant genetic resources." To a large extent, they mean the same thing. The German biologist August Weismann (1834–1914) first used the term "germplasm" in order to "describe a component of germ cells that he proposed were responsible for heredity, roughly equatable to our modern understanding of DNA." Wikipedia, Germplasm, http://en.wikipedia.org/wiki/Germ_plasm (last visited Jan. 17, 2009).

squash, sweet potatoes, cassava, and peanut seeds back to Europe.[36] Beginning in the sixteenth century, the rapid expansion of European colonialism significantly boosted the amount, rapidity, formalization and institutionalization of crop diffusion.[37] Many plant explorers conducted expeditions to collect economically important plants from the New World. Although the plant collection and exchange that occurred during these expeditions appears to have been viewed as a "normal part of diplomatic and economic intercourse among nations," such missions subsequently have been pilloried for their "colonial or imperial intentions,"[38] as the Columbian Exchange resulted in plantation economies in the colonies, while simultaneously contributing to the feeding of the swelling population in Europe.[39]

As a result of the discovery of the basic principles of inheritance in plant genetics in the early twentieth century, public plant breeding programs brought about of the direct introduction of exotic plant germplasm. This newly fledged plant genetic science, based upon re-discovery of Mendelism,[40] fundamentally changed PGRs "from a

36. Professor Alfred Crosby describes this event as "the Columbian Exchange," emphasizing the two-way nature of transfers of germplasm, including transfers from Europe to the Americas of crops such as wheat, rye, and oats. *See* ALFRED W. CROSBY, THE COLUMBIAN EXCHANGE: BIOLOGICAL AND CULTURAL CONSEQUENCES OF 1492, at 67 (30th Anniversary ed. 2003).

37. *Id.* at 65–67.

38. *See* Brush, *supra* note 33, at 63.

39. *See* Keith Aoki, *Weeds, Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 262 (2003). Professor Jack Kloppenburg points out that "plant germplasm is a resource that reproduces itself, and a single 'taking' of germplasm could provide the material base upon which whole new sectors of production could be elaborated," and explains that "new crops from the Americas certainly played an important role in feeding a European population that nearly doubled between 1750 and 1850 as the Industrial Revolution swept people off the land and into Marx's 'dark, satanic mills.'" KLOPPENBURG, *supra* note 2, at 154, 156.

40. "Mendelism" refers to the laws of plant inheritance first discovered by Gregor Mendel, who conducted extensive plant hybridity experiments. Through his experiments with some twenty-eight thousand pea plants between 1856 and 1863, he concluded that all characteristics are inherited through indivisible genes contributed by each parent to its offspring in sexually reproducing species. Mendel's result was largely neglected during his lifetime, but, after the work was rediscovered in 1900 by three European scientists, Hugo de Vries, Carl Correns, and Erich von Tschermak, the importance of his studies was recognized as a major breakthrough. Aoki, *supra* note 4, at 401 n.9 (citing KLOPPENBURG, *supra* note 2, at 68–69). Mendel's discoveries later became known as Mendel's Laws of Heredity, Mendelism or Mendelian inheritance. *See generally supra* note 4 and accompanying text.

possible source of new production to a probable source."[41] Due to the significant increase of private sector agricultural research investment over the last thirty years or so, major private companies currently are taking the lead in plant breeding. However, because the public and private sectors have coexisted from the beginning of modern scientific plant breeding, the important role of the public sector in plant breeding will likely continue, especially in the following areas: education and training of plant breeders, plant breeding methodology development, and plant germplasm preservation and development.[42]

The rediscovery of the Mendelism, which changed plant breeding "from a practical 'art' into a 'science,'" significantly stimulated the emerging private seed business.[43] The subsequent development of hybrid seed further prompted rapid growth in the nascent seed business, affording a technical solution to the "problem" posed by the self-reproducibility of the seed, as second- and third-generation hybrid progeny produce drastically lower yields, thus enabling private seed breeders to protect their inbred lines as trade secrets.[44]

The advent of plant biotechnology in the 1980s led to an increase in the market share of major plant-breeding companies and the involvement of large chemical companies in the seed industry, spurred by confirmation of the patentability of living organisms.[45]

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41. Brush, *supra* note 33, at 63–64 ("Vavilov was one of the first crop scientists to recognize and promote this idea."); *see also* KLOPPENBURG, *supra* note 2, at 12 (noting that "[p]lant breeding began to move from a craft foundation to a truly scientific basis with the rediscovery of Mendel's work in 1900").

42. *See generally* Paul W. Heisey et al., *Public Sector Plant Breeding in a Privatizing World*, AGRIC. INFO. BULL. NO. 722 (U.S. Dep't of Agric., Washington D.C.), Aug. 2001, *available at* http://www.ers.usda.gov/publications/aib772/aib772.pdf; Gurdev S. Khush, *Biotechnology: Public-Private Partnerships and Intellectual Property Rights in the Context of Developing Countries*, *in* BIODIVERSITY & THE LAW, *supra* note 18, at 179.

43. Aoki, *supra* note 39, at 268.

44. *See* KLOPPENBURG, *supra* note 2, at 11, 91–94, 130 ("Hybridization has proved to be an eminently effective technological solution to the biological barrier that historically had prevented more than a minimum of private investment in crop improvement."); Debra L. Blair, *Intellectual Property Protection and Its Impact on the U.S. Seed Industry*, 4 DRAKE J. AGRIC. L. 297, 304–05 (1999) ("In 1926, Henry Wallace set up the Hi-Bred Corn Co. (now Pioneer Hi-Bred International, Inc.) in Des Moines, Iowa, and marketed the first hybrid seed corn." (quoting CURTIS NORSKOG, HYBRID SEED CORN ENTERPRISES: A BRIEF HISTORY 69 (Maracom Corp. 1995))).

45. *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (holding that the patent laws enacted by Congress were broad enough to allow a man-made microorganism to be patented); U.N. CONFERENCE ON TRADE AND DEV., TRACKING THE TREND TOWARDS MARKET

Large chemical companies such as Monsanto and Dupont became major producers in the seed industry by "either purchasing seed companies or building alliances with seed companies in an effort to better market their chemical and biotechnology products."[46] Consequently, through these technological and institutional changes over the past century, private companies now play a larger role in the development of new plant innovation than the public sector, at least in the developed world.[47]

From the late nineteenth century until the late twentieth century, PGRs generally were considered part of the public domain. Under this public domain, or "common heritage of mankind," concept, PGRs were available for the use of all, as a kind of global genetic commons, and were not thought to be subject to the sovereignty of any country.[48] Researchers could collect and use samples of genetic material without restrictions.[49] However, as intellectual property protection was extended to an ever-widening array of genetic

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CONCENTRATION: THE CASE OF THE AGRICULTURAL INPUT INDUSTRY 7 (2006), *available at* http://www.unctad.org/en/docs/ditccom200516_en.pdf ("Many [large chemical companies] branched out into seeds because of declining margins in the agrichemical market, and the increasing profit potentials of the seed market."); Blair, *supra* note 44, at 323–26.

46. Blair, *supra* note 44, at 323 ("For example, Monsanto purchased Holden Foundations Seeds for just over $1 billion, the remaining sixty percent share of DeKalb that it did not already own it purchased for $2.3 billion, and now Monsanto has joined with Cargill in 'a marketing and research joint venture worth perhaps $200 million over five years.' Monsanto now owns DeKalb Genetics, Holden's Foundation Seeds, Asgrow, and Delta & Pine Land Co. (bought for $1.9 billion in 1998). In addition, Monsanto had approximately a fifty-five percent equity investment with Calgene, then went on to purchase the rest in April 1997. Monsanto also purchased the 'crop biotech assets of W.R. Grace & Co.'s Agracetus unit' in April 1996." (footnotes omitted)).

47. *See* Fernandez-Cornejo, *supra* note 9, at 42 (explaining that, from 1960 to 1996, private companies' expenditure in agricultural R&D increased by 224%, while the public sector's increased by 97%, and annual R&D expenditure of private companies has exceeded the public sector's every year since 1982); Gregory D. Graff et al., *The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology*, 21 NATURE BIOTECH. 989, 994 (2003) (noting that internationally, while the private sector has generated 74% of the intellectual property in agricultural biotechnology, the public sector accounts for just 24%).

48. *See* AOKI, SEED WARS, *supra* note 3, at 99–103. (distinguishing the public domain, or global commons, from the concept of a "limited commons"); Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT'L L. 641, 644–45 (2004).

49. Safrin, *supra* note 48, at 645. However, because the public domain concept did not necessarily grant researchers "the right to trespass on private or state property to obtain genetic samples," researchers did have to obtain "any consent normally required before entering such property." *Id.*

materials, the traditional paradigm that PGRs formed part of the public domain gave way to an enclosure of such resources as property.[50] Presently, intellectual property rights in a number of countries extend to new plants and to isolated and purified plant genes.[51]

Many scholars have argued that the proliferation of overlapping patents could create patent "thickets" that block the broad dissemination of new discoveries and stifle further technological advancement.[52] Michael Heller and Rebecca Eisenberg, for example, assert that transaction costs for downstream innovation are increased as a result of a "tragedy of anti-commons," which emerges when "multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use."[53] Thus far, however, this concern does not appear to be fully supported by empirical evidence.[54] In contrast, the recent biotechnology upsurge in the United States supports the proposition that "privatization of research tools is essential for the continued success of the biotechnology industry and stimulates rather than stifles commercialization of useful products."[55] Likewise, various empirical

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50. *See id.* at 645–46; Odek, *supra* note 29, at 149.

51. For example, in the United States, the creator of a new plant variety can seek intellectual property rights under utility patent, plant patent and plant variety legislation. *See* Safrin, *supra* note 48, at 641 ("By mid-2000, the U.S. Patent and Trademark Office . . . had issued over six thousand patents on full-length genes isolated from living organisms and were considering over twenty thousand gene-related patent applications.").

52. *See* Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting*, *in* INNOVATION POLICY AND THE ECONOMY 119 (Adam B. Jaffe et al. eds., 2001); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285, 286–89 (Wesley M. Cohen & Stephen A. Merrill eds., 2003); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698–99 (1998).

53. Heller & Eisenberg, *supra* note 52, at 698.

54. *See* F. Scott Kieff, *Property Rights and Property Rules for Commercializing Inventions*, 85 MINN. L. REV. 697, 719 (2001) (questioning whether such an anticommons problem actually exists); *see also* Charles R. McManis & Sucheol Noh, *The Impact of the Bayh-Dole Act on Genetic Research and Development: Evaluating the Arguments and Empirical Evidence to Date* (Wash. Univ. Sch. of Law, Working Paper, 2007), *available at* http://law.wustl.edu/crie/index.asp?ID=5906 (last visited Mar. 31, 2009) (summarizing recent empirical studies casting doubt that an anticommons problem exists).

55. *See also* Heather Hamme Ramirez, *Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons" in Biotechnology Research and Development*, 53 EMORY L.J. 359, 372 (2004); Kieff, *supra* note 54, at 727 (stressing that

studies on plant biotechnology support such a proposition. For example, Pray and Naseem suggest in the their case study of rice genomics and plant transformation technologies that the benefits to farmers of patents on platform technologies such as transformation methods have outweighed the costs of the few possible holdups, by stimulating research on these technologies, which have led to major increases in efficiency.[56] Koo and Wright also find that "the high dynamic incentive associated with the privatization of genetic innovations can increase dynamic social welfare if it dominates the discounted effect of subsequent permanent slowdown in innovation [due to private breeders' efforts to maximize their profits]."[57] Thus, as in other biological fields, it appears that the strong incentives of intellectual property protection for plant biotechnology are essential to facilitate the further development of plant innovation.

C. International Legal Norms Concerning Plant Innovation and PGR Protection

As with intellectual property rules generally, the movement towards creating international rules relating to the protection of plant innovation and PGRs is a relatively recent phenomenon, despite the long history of plant innovation dating back to primitive agricultural ages.[58] Initially, efforts toward the establishment of international standards on plant innovation and PGRs were motivated by research facilitation and conservation.[59] The former motivation was prompted

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commercialization incentives are strongly needed in the biotechnology industry to offset the extremely high costs of commercializing biotech products).

56. Carl E. Pray & Anwar Naseem, *Intellectual Property Rights on Research Tools: Incentives or Barriers to Innovation? Case Studies of Rice Genomics and Plant Transformation Technologies*, 8 AGBIOFORUM 108, 115–16 (2005).

57. Koo & Wright, *supra* note 7, at 29. The authors add that, although "providers of the original genetic resources are naturally anxious to claim part of the windfall from the privatization of the chain of innovation initiated by those resources[,] . . . if they achieve their compensation by taxing current innovators, the dynamic social benefits of privatization are reduced, even though the longer innovation rate might be unaffected." *Id.* The authors also note that it is "likely that alternative means of compensation could be found that are more efficient." *Id.*

58. Carrie P. Smith, *Patenting Life: The Potential and the Pitfalls of Using the WTO to Globalize Intellectual Property Rights*, 26 N.C. J. INT'L L. & COM. REG. 143, 143 (2000); C.S. Srinivasan, *The International Trends in Plant Variety Protection*, 2 eJADE 182, 182 (2005).

59. Tilford, *supra* note 15, at 388.

by "the desire to house the building materials (the genes) in international 'genetic warehouses' accessible to all, rather than have them haphazardly stored in various jurisdictions throughout the globe . . . to facilitate the development of newer and better crops for the entire world."[60] The FAO was animated by this motivation. In association with the World Bank and the U.N. Development Program, the FAO established in 1971 the Consultative Group on International Agricultural Research ("CGIAR"), which was to be the "primary caretaker of the international germplasm collections."[61] In 2001, after long negotiations over the conservation, sustainable use, and benefit-sharing with respect to PGRs for food and agriculture, adopted the ITPGRFA.

The latter motivation reflected an international recognition of the need to preserve and sustainably use plant genetic diversity, which was being lost due to global industrialization, and to ensure an equitable sharing of benefits arising out of the use of this diversity.[62] This motivation eventually prompted adoption of the Convention on Biological Diversity ("CBD") in 1992[63] and adoption of the associated Cartagena Protocol on Biosafety in 2000.[64]

In addition to the aforementioned international agreements designed to facilitate plant research and conservation, increasing global trade in plant germplasm stimulated the emergence of international norms regarding the protection of plant innovation as intellectual property.[65] These norms are found in the Paris Convention for the Protection of Industrial Property ("Paris Convention"),[66] the International Convention for the Protection of New Varieties of Plants ("UPOV"),[67] and the Agreement on Trade-

60. *Id*.

61. *Id.* at 389.

62. *Id*. at 388–89.

63. *Supra* note 10.

64. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, *adopted* Jan. 29, 2000, http://www.biodiv.org/biosafety/protocol.asp [hereinafter Biosafety Protocol].

65. *See* Srinivasan, *supra* note 58, at 183.

66. Paris Convention for the Protection of Industrial Property art. 1(2), *last revised* July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305, *available at* http://www.wipo.int/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf [hereinafter Paris Convention].

67. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 109 (as amended in 1978 & 1991), *available at* http://www.upov.org/en/publications/conventions/1991/pdf/act1991.pdf [hereinafter 1991 UPOV Act]. The

Related Aspects of Intellectual Property Rights ("TRIPS Agreement").[68] The main objective of the Paris Convention was to establish the principle of national treatment and an international "right of priority."[69] Under the "national treatment" principle, each country is required to provide foreign nationals treatment no less favorable than it grants to its own nationals with respect to industrial property.[70] The international "right of priority" established by the Paris Convention specifies that any person who has duly filed an application for industrial property in any member country shall be entitled to use that filing date as an international priority date for any further applications filed in other countries within a given grace period.[71]

While the Paris Convention, as the oldest existing intellectual property treaty, provided the first elementary and minimum standards for the international protection of "industrial property," no provision of the Convention dealt specifically with plant innovation.[72] Nevertheless, the Paris Convention did suggest the possibility of

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acronym represents the French-language title of the treaty and its governing organization (Union Internationale pour la Protection des Obtentions Vegetales).

68. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Annex 1C, 1869 U.N.T.S 299, *available at* http://www.wto.org/english/docs_e/legal_e/27-trips.pdf [hereinafter TRIPS Agreement]; *see* Srinivasan, *supra* note 58, at 183. *See generally* R. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, 26 J. MARSHALL L. REV. 457 (1993) (evaluating the historical evolution toward international intellectual property protection).

69. *See* Moy, *supra* note 68, at 478–79 (explaining that "the negotiations [of the Paris Convention] began primarily at the insistence of industrial interests").

70. Paris Convention, *supra* note 66, art. 2(1) ("Nationals of any country of the Union shall, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals; all without prejudice to the rights specially provided for by this Convention.").

71. *Id.* art. 4A(1) ("Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed."). The right of priority rule extends for twelve months for patent and utility models and six months for industrial designs and trademarks. *Id.* art. 4C(1). During this time, any individual who has filed in one member country can file in any other without fear of appropriation of their industrial property.

72. *Id.* art. 1(3). Although the Paris Convention established the principle of national treatment, an international right of priority, and certain minimum standards for protection against unfair competition, the Convention suffers from the lack of a meaningful dispute settlement mechanism and the failure to specify minimum standards for industrial property rights. *See* Smith, *supra* note 58, at 149.

intellectual property protection for plant innovation by prohibiting technology discrimination.[73] Article 1(3) of the Paris Convention provides:

> Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to *agricultural* and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour.[74]

The UPOV was adopted on December 2, 1961, as a *sui generis* intellectual property rights system to protect the rights of plant breeders,[75] and was the culmination of efforts to provide intellectual property protection for agricultural products, including plant varieties.[76] European countries initially led this movement.[77] Several European countries met in Paris in 1957, and again in 1961, to create a system recognizing and protecting the legal rights of plant breeders. Through these two negotiating conferences, UPOV was eventually adopted as an intergovernmental agreement among European countries for the protection of plant variety rights. Subsequent to the

73. *See, e.g.*, Paris Convention, *supra* note 66, art. 1(3); Charles R. McManis, *Taking TRIPS on the Information Superhighway: International Intellectual Property Protection and Emerging Computer Technology*, 41 VILL. L. REV. 207, 248 (1996) ("[The language of the Paris Convention art. 1(3)], which is clearly designed to eliminate all but specifically enumerated subject-matter exclusions from the field of patent law, may eventually enable the United States to convince a dispute panel that software inventions cannot be excluded from patent protection solely on the ground that software is not patentable subject-matter." (footnotes omitted)).

74. Paris Convention, *supra* note 66, art. 1(3) (emphasis added).

75. *See* Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 123 (1996) ("The difficulties of obtaining patent protection for the cultivation of plants under existing legislation, and the recognition of the extraordinary importance of plant cultivation for the agricultural sector and the food industry . . . . led eventually to the adoption of the [UPOV].").

76. *Id.* at 121–22.

77. *See id.* at 121; J. Benjamin Bai, Note, *Protecting Plant Varieties Under TRIPS and NAFTA: Should Utility Patents Be Available for Plants?*, 32 TEX. INT'L L.J. 139, 143 (1997) ("In 1956, the French Government invited the governments of Western Europe to send representatives to a diplomatic conference on the protection of new plant varieties. After four years of preparatory work, an international convention was finalized and signed by the member states. The UPOV Convention was the result of this conference." (footnotes omitted)).

adoption of UPOV in 1961, it was amended in 1978 to allow non-European countries to join.[78]

UPOV, an offspring of the Paris Convention, is an international agreement "to introduce uniformity in plant variety protection laws while allowing for variations in national plant patent legislation."[79] Like the Paris Convention, UPOV requires member countries to provide "national treatment" and an international "right of priority."[80] Under UPOV, plant breeders can obtain a breeder's right for their plant variety if it is new (novel),[81] is clearly distinguishable by one or more important characteristics (distinct),[82] is homogeneous in its sexual reproduction or vegetative propagation (uniform),[83] and is stable in its essential characteristics (stable).[84]

Plant breeders can prevent others, for a limited time, from producing or propagating materials of their protected variety without their authorization.[85] Although UPOV provides substantial protection

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78. For a detailed discussion of the history of UPOV, see UPOV, THE FIRST TWENTY-FIVE YEARS OF THE INTERNATIONAL CONVENTION FOR THE PROTECTION OF NEW VARIETIES OF PLANT (1987). *See also* Hamilton, *supra* note 29, at 605–07.

79. Tilford, *supra* note 15, at 406.

80. *Id*.

81. 1991 UPOV Act, *supra* note 67, art. 6, reads as follows:

> The variety shall be deemed to be new if, at the date of filing of the application for a breeder's right, propagating or harvested 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
>
> (i) in the territory of the Contracting Party in which the application has been filed earlier than one year before that date and
>
> (ii) in a territory other than that of the Contracting Party in which the application has been filed earlier than four years or, in the case of trees or of vines, earlier than six years before the said date.

82. *Id.* art. 7 ("The variety shall be deemed to be 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.").

83. *Id.* art. 8 ("The variety shall be deemed to be 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.").

84. *Id.* art. 9 ("The variety shall be deemed to be stable if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle.").

85. *Id.* art. 14(1)(a):

> Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder: (i) production or

for plant varieties, the scope of its protection prior to 1991 was significantly limited because it implicitly allowed both a farmer's privilege, permitting farmers to reuse or sell the seed from the crops they grew in subsequent seasons without paying additional royalties, and a breeder's exemption, permitting other breeders to use freely the protected varieties for research purposes and to commercialize the products of that research.[86] However, the 1991 UPOV Act restricted the (optional) farmer's privilege to on-farm replanting, barring farmers from selling or exchanging seeds with other farmers for propagating purposes,[87] and extended the breeder's right to include (and thus limited the privilege of other breeders with respect to) "essentially derived" varieties.[88] The 1991 UPOV Act also removed

> reproduction (multiplication), (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing, (vii) stocking for any of the purposes mentioned in (i) to (vi), above.

86. *See* Aoki, *supra* note 4, at 431–32; Smith, *supra* note 58, at 151.

87. 1991 UPOV Act, *supra* note 67, art. 15(2), states

> (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 breeder's 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).

See also Barry Greengrass, *The 1991 Act of the UPOV Convention*, 12 EUR. INTELL. PROP. REV. 466, 469–70 (1991).

88. 1991 UPOV Act, *supra* note 67, art. 14(5), states:

> 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.

See Aoki, *supra* note 4, at 432 n.155 ("While the UPOV protects plant breeder's [sic] 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 [sic] private parties in the midst of contractual negotiations."). As article 14(5)(b) makes clear, however, an essentially derived variety must be "predominantly derived" from the protected variety. Article 14(5)(c) provides various examples of how essentially derived varieties can be obtained—e.g., selection of mutants, somoclonal or individual variants, backcrossing or (interestingly) transformations by genetic engineering. The phrase "essentially derived" itself suggests that the scope of protection to be provided under UPOV is considerably narrower than the scope of protection that copyright law provides for "derivative works," as only those varieties that are "essentially" (i.e., predominantly) derived from the protected variety are to be protected under UPOV 1991. *See, e.g.*, 17 U.S.C. § 106(2) (2000).

the prohibition against double protection of varieties by allowing member countries to grant patents for asexually reproduced varieties.[89] Consequently, the 1991 UPOV Act materially strengthened breeder's rights, even though it did not extend the same level of protection afforded by patents. The UPOV currently has fifty-four member countries, forty-three of which are parties to the 1991 UPOV Act.[90] However, because, like the Paris Convention UPOV does not have any enforcement mechanism, its implementation depends entirely on the national legislation of each member country.[91]

The TRIPS Agreement was concluded on December 15, 1993, as part of the Uruguay Round of Multilateral Trade Negotiations establishing the World Trade Organization ("WTO"), and was based on a recognition of the dual need to "promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[92] It provides "universally acknowledged international minimum standards for intellectual property protection" including protection of copyright and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs of integrated circuits, and undisclosed but commercially valuable information.[93] The TRIPS Agreement is further distinguished from its predecessors, the Berne and Paris Conventions, in that it provides comprehensive minimum enforcement standards and contains effective international dispute resolution procedures for intellectual property disputes, in addition to

89. 1991 UPOV Act, *supra* note 67, art. 35(2)(a), states:

> (2) [*Possible 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.

90. Int'l Union for the Protection of New Varieties of Plants, Members of the International Union for the Protection of New Varieties of Plants, http://www.upov.int/en/about/members/pdf/pub423.pdf (last visited Apr. 1, 2009).

91. *See* Andres A. Gallo & Jay P. Kesan, *Property Rights Legislation in Agricultural Biotechnology: United States and Argentina*, 7 MINN. J.L. SCI. & TECH. 565, 574 (2006).

92. TRIPS Agreement, *supra* note 68, at pmbl., para. 1.

93. McManis, *supra* note 73, at 214; *see* TRIPS Agreement, *supra* note 68, art. 1.2.

incorporating into TRIPS the minimum substantive standards of the Berne and Paris Conventions.[94]

Initially, the intellectual property rights negotiations in the Uruguay Round were "an attempt by industrialized nations to secure multilateral protection for new technologies, pharmaceuticals, and copyrighted media works against unauthorized imitation or duplication."[95] However, around 1990, reflecting aggressive global marketing and the business of several major biochemical companies newly armed with powerful patents, the matter of intellectual property protection for biological materials, including plants, had become a major issue in the TRIPS negotiations.[96] Demands of developed countries for more expansive intellectual property protection of biological materials were accordingly 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."[97] Thus, Article 27 of the TRIPS Agreement reflects the compromise results of confrontations on intellectual property protection of biological materials between developing countries and developed countries.[98]

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94. *See* McManis, *supra* note 73, at 214–16; Doris Estelle Long, *The Impact of Foreign Investment on Indigenous Culture: An Intellectual Property Perspective*, 23 N.C. J. INT'L L. & COM. REG. 229, 250 n.53 (1998) ("Although scholars debate the desirability and efficacy of the protection regime established under TRIPS, there is no doubt that the intention was to establish stricter standards for protection. Hence, some of the vagaries of the Paris and Berne Conventions, such as the definition of a patented invention or a trademark, have been clarified in TRIPS.").

95. Aoki, *supra* note 4, at 436.

96. *Id.* at 436–37 ("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. Companies also aggressively acted to secure some form of global intellectual property protection for their biotech innovations." (footnote omitted)).

97. *Id.* at 437.

98. *See* Charles R. McManis, *Patenting Genetic Products and Processes: A TRIPS Perspective*, *in* PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 79, 81–82 (F. Scott Kieff ed., 2003) (describing the negotiations of the TRIPS as a "bare-knuckled 'North-South' confrontation"). McManis also points out that, with respect to the negotiations of Article 27, there were some fundamental confrontations among developed countries. *Id.* at 82 ("[T]he debate increasingly became a 'North-North' debate, exposing some fundamental differences among the intellectual property regimes of industrialized countries that would have to be reconciled if any agreed-upon international minimum standards were to be achieved. The

In order to reconcile the conflicts between developing and developed countries, as well as conflicts among various developed countries, Article 27.1 of the TRIPS Agreement provides a broad minimum standard for the subject matter of patent protection, defining patentable subject matter as any new invention that involves an inventive step and has a potential industrial application.[99] Article 27.1 further states that, subject to the transitional provisions contained in Articles 65.4, 70.8, and 27.3, "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[100]

However, exclusions from patentability are somewhat left to the mercy of each member country, as Articles 27.2 and 27.3 recognize a number possible exceptions. Under Article 27.2, a member country may exclude certain subject matter from patentability in order to "protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."[101] However, member countries may exclude an invention from patentability only if the commercial exploitation of the invention is not permitted in the member country and such a prohibition is actually shown to be necessary in order to protect the interests outlined in Article 27.2. Additionally, Article 27.3(a) also allows a member country to exclude "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."[102]

Finally, with respect to subject matter exclusion of plants, Article 27.3(b) squarely states:

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specific provisions of Article 27 of TRIPS are as much a product of this 'North-North' debate as they are of the larger confrontation between the North and South." (footnote omitted)).

99. TRIPS Agreement, *supra* note 68, art. 27.1, the first sentence of which states that "[s]ubject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."

100. *Id*.

101. *Id.* art. 27.2.

102. *Id.* art. 27.3(a).

> Members may also exclude from patentability . . . plants and animals other than micro organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. 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 subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.[103]

It is important to note that, although Article 27.3(b) allows the patentability exclusion for plants and animals other than microorganisms, it obliges member countries to provide either patent or effective *sui generis* protection, or any combination of the two, to protect plant varieties. Notably, this delicate balance contained in Article 27.3(b) essentially echoes a European approach to the protection of plant innovation, while the final sentence of Article 27.3(b), requiring as a "built-in" agenda item that the Article 27.3(b) exception be reviewed in 1999, obviously reflects the desire of the United States to extend broad patent protect to biotechnological inventions generally.[104] Apparently, under Article 27.3(b), all member countries must provide some intellectual property protection for plant innovations either by patent, or by an "effective sui generis system," or by a combination of the two methods. While the TRIPS Agreement does not expressly define what constitutes an "effective sui generis system," it was arguably intended to refer to the UPOV as the model *sui generis* system.[105]

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103. *Id.* art. 27.3(b).

104. *See* John Linarelli, *Trade-Related Aspects of Intellectual Property Rights and Biotechnology: European Aspects*, 6 SING. J. INT'L & COMP. L. 406, 412–13 (2002); McManis, *supra* note 98, at 86; *see also supra* note 98 and accompanying text. Interestingly, as the recent international political circumstances changed, while developed countries now turn into the defensive concerning the "built-in" review of Article 27.3(b), calling for a merely implementation review of member countries, developing countries increasingly claim to revise the text to meet the needs of the developing worlds. McManis, *supra* note 98, at 93–94.

105. *See* Bai, *supra* note 77, at 140 (suggesting that the UPOV is a suitable system of protection on the international level); Bosselmann, *supra* note 75, at 125 ("[T]he nations of Europe adopted *sui generis* plant-variety protection schemes under UPOV rather than patent-based protection schemes."); Susan K. Sell, *What Role for Humanitarian Intellectual Property? The Globalization of Intellectual Property Rights*, 6 MINN. J.L. SCI. & TECH. 191, 203 (2004)

In response to the efforts on the part of the industrialized world to expand intellectual property rights over plants and their genetic components, many developing countries sought to assert sovereign rights over PGRs, in the belief that these PGRs might be valuable.[106] Most developing countries resist the notion that "biodiversity should [flow freely to industrial countries] while the flow of biological products from the industrial countries is patented, expensive, and considered the private property of the firms that produce them."[107] Consequently, the CBD responded to this concern of developing countries by proclaiming the sovereignty of nations over PGRs.[108] In international debates over plant genetic resources, developing countries assert that they have sovereign rights over raw genetic material, and are entitled to extensive national control over such material, including the right to demand compensation or "benefit-sharing."[109]

This sharp conflict between developing and developed countries over the ownership and control of PGRs is not likely to be resolved in the near future.[110] However, it is politically difficult for governments in the developed world, who vigorously promote the strengthening of intellectual property rights in plant innovation, to altogether deny the

("[T]here really is no consensus on what a sui generis system needs to include. Additionally, the negotiations leading to the adoption of Article 27 provide little guidance because they provide no record on the meaning of *sui generis*. American plant breeders have been pushing the UPOV as the model *sui generis* system. American support of UPOV may be due in part to how generous UPOV is to the corporate plant breeder." (footnotes omitted)).

106. *See* Safrin, *supra* note 48, at 646.

107. *Id.* at 647 (quoting Statement of President Ali Hassan Mwinyi of Tanzania, UN Doc. A/CONF. 151/26/Rev. 1, at 36 (1993)).

108. *Id.*

109. *See* Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 927 (1996); Safrin, *supra* note 48, at 648–49. Professor Safrin points out the problems related to the sovereign right over genetic material: "(1) it is creating an anticommons in raw genetic material; (2) it threatens the autonomy and liberty of individuals and indigenous communities; and (3) it is based on a flawed approach in international law that has led to unenforceable regimes destined to increase tensions between nations and threatens to lead to a major TRIPS dispute." *Id*. at 668.

110. *See* Chika B. Onwuekwe, *The Commons Concept and Intellectual Property Rights Regime: Whither Plant Genetic Resources and Traditional Knowledge?*, 2 PIERCE L. REV. 65, 88 (2004).

rights of developing country governments to control plant genetic materials that are housed within their territory.[111]

With respect to the ongoing international debate over the ownership and utilization of PGRs, it is thus necessary to understand generally the basic requirements of the CBD, which was adopted at the 1992 United Nations Conference on Environment and Development in Rio de Janeiro, Brazil.[112] The objectives of the CBD are:

> the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.[113]

As will become clearer in the third and final Part of this Article, contrary to the ITPGRFA, the CBD takes a national-sovereignty approach to PGRs, supporting the view that the countries of origin of biological resources exercise sovereignty over plants, animals, and microorganisms within their national boundaries, rather than the "global commons" approach of the ITPGRFA with respect to selected PGRs.[114]

With respect to intellectual property protection of PGRs, the CBD's recognition of intellectual property rights represents a compromise between developing and developed countries, as it encourages developed countries to support transfers of technology to developing countries as a quid pro quo for access to developing countries' genetic resources.[115] CBD Article 16.3 requires each

111. *See id.* at 76–77; Safrin, *supra* note 48, at 662–63. For an economic justification, see Koo & Wright, *supra* note 7.

112. *See supra* note 64 and accompanying text.

113. CBD, *supra* note 10, art. 1.

114. *See* Aoki, *supra* note 4, at 435.

115. Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 28 (2004) ("In negotiations leading to the CBD's adoption in 1992, biodiversity-rich but biotechnology-poor developing countries sought financial benefits and technology transfers as incentives to conserve rather than exploit the genetic resources within their borders. Biodiversity-poor but

contracting party to "take legislative, administrative or policy measures" to ensure transfers of technology to developing countries, which provide genetic resources, "including technology protected by patents and other intellectual property rights."[116] Article 16.5 recognizes that intellectual property rights should be supportive of, and not run counter to, the objectives of the CBD.[117] Although these provisions could conceivably be interpreted by developing countries as authorizing limitations on intellectual property protection for PGRs,[118] Article 16.2 of the CBD specifies that access to technology on concessional and preferential terms will occur only "where mutually agreed,"[119] and explicitly requires that any transfers of technology "be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."[120]

An associated source of international rules for PGRs and biodiversity is the Cartagena Protocol on Biosafety,[121] which was adopted by the contracting parties to the CBD on January 29, 2000, "to address safety issues involved in the transboundary movement of living modified organisms ('LMOs') resulting from modern

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biotechnology-rich industrialized states, by contrast, sought to minimize benefits and transfers while maximizing access to those resources.").

116. CBD, *supra* note 10, art. 16.3.

117. *Id.* art. 16.5.

118. *See* Linarelli, *supra* note 104, at 425. It was this possibility that caused the United States to hesitate in joining the CBD. However, as McManis points out, The United States' concern is arguably unfounded, as the negotiating history of Article 16.5 makes it clear that this provision amounts to little more than an agreement to disagree over whether patents and other intellectual property rights would have a beneficial or adverse impact on achieving the objectives of the CBD. Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 269 (1998) ("[T]his provision amounts to little more than an agreement to disagree for the time being over the precise nature of the interface between international intellectual property and environmental protection."). However, based upon CBD Article 16.5, some developing countries are currently advocating an amendment of the TRIPS Agreement that would require a patent applicant to disclose origin of biological material and to give evidence of prior informed consent. Kuei-jung Ni, *The Incorporation of the CBD Mandate on Access and Benefit-Sharing into TRIPS Regime: An Appraisal of the Appeal of Developing Countries with Rich Genetic Resources*, 1 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 433, 446 (2006).

119. CBD, *supra* note 10, art. 16.2

120. *Id*.

121. *Supra* note 64.

biotechnology."[122] Although the Biosafety Protocol recognizes that "trade and environmental agreements should be mutually supportive,"[123] it may implicate international trade issues, as the importation of LMOs into some countries could be refused on the basis of speculative and uncertain adverse impacts on the environment and health.[124] At the moment, "neither treaty law nor international trade case law clearly determines whether such trade restrictions under the Biosafety Protocol violate WTO principles."[125] Indeed, "the interplay between the Biosafety Protocol and WTO is just one of many similar international debates between trade interests and environmental concerns."[126]

D. Plant Innovation Protection in Developing Countries

The evidence about the socio-economic impact of intellectual property protection on plant innovation in developing countries is mixed. Early reports asserted that there was little or no evidence concerning the direct benefits of introducing intellectual property protection systems for plant innovation into developing countries.[127] Based on that belief, many developing countries argued that stronger intellectual property protection would create an obstacle to economic development by blocking technology transfers from developed countries.[128]

Other studies, however, suggest that while intellectual property protection for plant innovation might initially impact the economies of most developing countries in a negative way, in the long run it should stimulate wider economic development and social welfare in developing countries. For instance, William Lesser's study on the

122. *See* Gretchen L. Gaston & Randall S. Abate, *The Biosafety Protocol and the World Trade Organization: Can the Two Coexist?*, 12 PACE INT'L L. REV. 107, 108 (2000).

123. Biosafety Protocol, *supra* note 64, at pmbl., para. 9.

124. Gaston & Abate, *supra* note 122, at 108–09.

125. *Id.* at 109.

126. *Id.*

127. *See, e.g.*, Dwijen Rangnekar, *Access to Genetic Resources, Gene-based Inventions and Agriculture* 14 (Comm'n on Intell. Prop. Rights, Study Paper No. 3a, 2001).

128. *See* Jean Raymond Homere, *Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries*, 27 COLUM. J.L. & ARTS 277, 285 (2004).

effects of intellectual property rights on foreign direct investment and imports into developing countries in the post-TRIPS era shows that "both imports and FDI are positively and significantly associated with the [intellectual property rights] strength index."[129] An earlier study by Robert Evenson, employing an international model for policy analysis of agricultural commodities, similarly concluded that "[t]he expansion of [intellectual property rights] to plants (and animals) should, if properly managed, actually lead to welfare improvements for food consumers."[130] A study by Kesan and Gallo suggests that "a change in legislation providing for plant variety protection for seed protection and an increase in enforcement efforts in the early 1990s produced an increase in the number of new corn varieties registered in Argentina."[131] Professor Carl Pray et al. likewise concluded, after conducting case studies of intellectual property rights' impact in South Africa, China, Argentina and Brazil, that "if policymakers in developing countries strengthen intellectual

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129. W. Lesser, *The Effects of Intellectual Property Rights on Foreign Direct Investment and Imports into Developing Countries in the Post TRIPs Era*, 5 IP STRATEGY TODAY 1, 2 (2002) ("A one point rise in the IPR score (about 10%) is associated with a $1.5 billion increase in FDI (50% of the median amount) and an $8.9 billion increase in imports (40% of the median).").

130. R. E. Evenson, *Intellectual Property Rights, Access to Plant Germplasm, and Crop Production Scenarios in 2020*, 39 CROP SCI. 1630, 1635 (1999). Professor Evenson evaluates global equilibriums in real prices by using the International Model for Policy Analysis of Agricultural Commodities developed by the International Food Policy Research Institute, which covers seventeen commodities and thirty-five countries and regions. *Id.* at 1632. Evenson explores two policy scenarios, the first involving an expansion of intellectual property rights in developed countries, but not in developing countries, the second involving a temporary block in the international exchange of genetic resources. *Id.* at 1635. He concludes that the first policy scenario will have "deleterious effects on the welfare of consumers in developing countries and relatively minor effects on consumers in developed countries." *Id.* The second policy scenario will have even "more serious welfare implications than the first because many of the poorest developing countries are dependent on international exchange of plant genetic resources." *Id.* However, Evenson also notes that a shift "to a regime with strong [intellectual property rights] protection could . . . have serious implications for developing countries," for while developed countries have the experience and institutions to enable this transition, developing countries generally do not. *Id.* On the other hand, Evenson concludes that "[n]either scenario need obtain if policy makers understand the importance of maintaining systems of genetic resource exchange." *Id.*

131. Jay P. Kesan & Andres A. Gallo, *Property Rights and Incentives to Invest in Seed Varieties: Governmental Regulations in Argentina*, 8 AGBIOFORUM 118, 124 (2005). This contrasts with the effects on "soybean varieties, which need stricter property protection than currently available in Argentina, did not experience a strong increase in the number of new varieties." *Id.*

property rights and allow the use of plant biotechnology, small farmers and consumers could increase their incomes."[132]

Despite some promising evidence that stronger intellectual property protection for plant innovation, if properly organized and administered, could increase economic growth and encourage technological development, many developing countries have been hesitant to adopt a full-fledged intellectual property system because of their limited ability to establish and manage such a system.[133] With respect to intellectual property protection for plant innovation, while the TRIPS Agreement mandates that developing countries provide some form of effective protection for plant varieties, it also gives them flexibility in designing the optimal protection system to meet their own particular needs and circumstances. The TRIPS Agreement expressly recognizes that member countries may, "in formulating or amending their laws and regulations, adopt measures necessary . . . to promote the public interest in sectors of vital importance to their socio-economic and technological development."[134] In addition, as we have seen, Article 27.3(b) of the TRIPS Agreement gives members broad discretion in fashioning a domestic system of plant variety protection.

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132. CARL E. PRAY ET AL., THE IMPORTANCE OF INTELLECTUAL PROPERTY RIGHTS IN THE INTERNATIONAL SPREAD OF PRIVATE SECTOR AGRICULTURAL BIOTECHNOLOGY 2, 9–16, 22–23 (2001). For other studies addressing the potential impact of strengthened intellectual property rights on developing countries, see Stanley P. Kowalski & R. David Kryder, *Golden Rice: A Case Study in Intellectual Property Management and International Capacity Building*, 13 RISK 47, 67 (2002) ("[O]ver the longer term, increased international harmonization of [intellectual property] laws and management might serve to ameliorate many . . . risks, and hence facilitate the sustained transfer of Golden Rice as well as future advances in agri-biotech."); Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 472 (2001). ("[T]he short-run impacts of TRIPS will be to redistribute income between countries, with most gains accruing to the United States and other technology developers. Moreover, intellectual property protection will generate additional market power that could harm information users. Over the longer term, however, there are channels through which technical change and growth in the technology importing countries could be improved.); Robert M. Sherwood, *The TRIPS Agreement: Implications for Developing Countries*, 37 IDEA 491, 544 (1997) ("Once adequately financed public administration and politically supported high-performance judicial remedies are in place, it can be expected that developing countries will experience the solid economic benefits which flow from robust protection for intellectual property.").

133. *See* Kowalski & Kryder, *supra* note 132, at 65; Nelson, *supra* note 29, at 1009.

134. TRIPS Agreement, *supra* note 68, art. 8.1. Article 8, however, contains a proviso that these measures must be "consistent with the provisions of this Agreement." *Id.*

Given the foregoing flexibilities in TRIPS, many developing nations have attempted to craft domestic laws that reflect their own perceived needs. For example, in 2001, India adopted the Protection of Plant Variety and Farmers' Rights Act, adopting a *sui generis* system for plant innovation protection that recognizes the contribution of both commercial plant breeders and farmers, although India has thus far not joined UPOV.[135] India's *sui generis* law contains provisions recognizing a broad farmer's privilege and benefit-sharing for local communities, as well as requiring applicants to provide information about the origin of the genetic material used. It is questionable whether the Act will constitute an "effective" *sui generis* system under the TRIPS Agreement, as it overtly favors the interests of farmers over plant breeder's rights.[136]

China also enacted Regulations on the Protection of New Varieties of Plants (Council Regulations) in 1997 in order to satisfy its obligation under the TRIPS Agreement, immediately after joining the WTO, and ratified the UPOV 1978 Act in 1999.[137] Nonetheless, the protection of plant varieties under the Council Regulations is limited to certain designated plant varieties, and the term of protection for most plant varieties is only fifteen years. Thus, the

135. *See* Nelson, *supra* note 29, at 1010–11; Brush, *supra* note 33, at 93–95.

136. *See* Nelson, *supra* note 29, at 1011; Brush, *supra* note 33, at 94–95. Besides the enactment of the Protection of Plant Varieties and Farmers' Rights Act, India amended its Patent Act three times, most recently in January 2005, in order to fulfill its obligations under the TRIPS Agreement; yet it is still not certain that the Act is TRIPS-compliant, as the Act still precludes the patentability of plants and methods of agriculture or horticulture. Nelson, *supra*, at 1010.

137. Nelson, *supra* note 29, at 1011–12. China's accession to the UPOV 1978 Act appears to derive from an unwillingness to comply with the more demanding obligations of the UPOV 1991 Act. *See* Lester Ross & Libin Zhang, *Agricultural Development and Intellectual Property Protection for Plant Varieties: China Joins the UPOV*, 17 UCLA PAC. BASIN L.J. 226, 240 (1999). However, it is unclear how China was eligible for the accession to the UPOV 1978 Act rather than the UPOV 1991, as Article 37 of the UPOV 1991 does not allow a deposit of instrument of accession to the Act of 1978, either after the entry into force of the 1991 UPOV Act or after December 31, 1995, for developing countries. *See* UPOV, *supra* note 67, art. 37; Press Release, China Accedes to UPOV (Mar. 23, 1999), http://www.upov.int/en/news/pressroom/36.htm. However, China did not receive special treatment, as many developing countries were apparently allowed to adhere to the 1978 UPOV between 1995 and 1999. *See* Int'l Union for the Protection of New Varieties of Plants, *supra* note 90.

protection of plant varieties in China appears to be weaker than in the United States or Europe.[138]

II. THE INTERFACE OF OPEN SOURCE AND PROPRIETARY PROTECTION IN THE ITPGRFA

A. An Overview of the ITPGRFA

The ITPGRFA was adopted by the FAO conference on November 3, 2001, stating its objectives to be "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security."[139] Notwithstanding the reference to the CBD, however, it bears emphasizing that the ITPGRFA represents a marked departure from the approach of the CBD. Whereas the CBD represents an assertion of national sovereign ownership of biological diversity generally, and thus apparently envisages a series of bilateral negotiations over access to such diversity and benefit-sharing, the ITPGRFA represents a waiver of those sovereign rights with respect to the sixty-four food and feed crops that are included in the ITPGRFA's "Multilateral System," which creates a form of "limited common property" in crops that "account for the bulk of human nutrition."[140]

As we have seen, the expansion of intellectual property protection standards in the plant biotechnology field ultimately engendered disputes between developing countries and developed countries over ownership rules for PGRs.[141] In the early 1980s, developing countries that had initially regarded PGRs as "common heritage" began to press international institutes such as the FAO "to staunch the flow of PGRs from centers of biodiversity in the developing world to plant

138. Nelson, *supra* note 29, at 1012–13.

139. ITPGRFA, *supra* note 10, art. 1.

140. *See* Laurence R. Helfer, *Using Intellectual Property Rights to Preserve the Global Genetic Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 217, 219–20 (Keith E. Maskus & Jerome H. Reichman eds., 2005).

141. *Id.* at 217.

breeding industries in industrialized nations."[142] They also raised compensation claims against commercial plant breeders who used their PGRs as raw material for developing new plant innovations.[143]

These arguments were made in response to the FAO's 1983 adoption of a non-binding declaration known as the International Undertaking on Plant Genetic Resources ("Undertaking"), which stated that all PGRs are part of the "heritage of mankind and consequently should be available without restriction" for scientific research, plant breeding, and conservation.[144] By the early 1990s, although developing countries had successfully incorporated their most critical priorities—recognition of farmers' rights, national sovereignty, and a prohibition on intellectual property rights for germplasm held in international seed banks—in a revision of the Undertaking, they still felt the need "to create legally binding rules to address these issues more conclusively" because "those rules were reflected only in soft law declarations that were normatively underdeveloped or contested by many industrialized states."[145]

Through extended and difficult negotiations over seven years, the ITPGRFA was eventually adopted in November 2001.[146] This treaty creates a Multilateral System, a form of "limited common property," which is designed to facilitate access by member countries and their nationals to germplasm of sixty-four staple crops held in government and international seed banks for research, breeding, and crop development purposes.[147] Under this system, private parties who

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142. *Id.*

143. *Id.* at 217–18.

144. International Undertaking on Plant Genetic Resources art. 1, Nov. 23, 1983, ftp://ftp.fao.org/ag/cgrfa/iu/iutextE.pdf; *see also* Helfer, *supra* note 140, at 218.

145. Helfer, *supra* note 115, at 35–39, 39 (describing the adoption of the ITPGRFA as a result of forum-shifting by developing countries, led by Mexico and aided NGOs). In response to developed countries' claim that the Undertaking created a conflict with the UPOV, which protected breeders' rights, the Undertaking was also revised to include a statement that the UPOV's protection of breeders' rights was "not incompatible" with the common heritage principle. *Id.* at 36.

146. *See* Ronan Kennedy, *International Conflicts over Plant Genetic Resources: Future Developments?*, 20 TUL. ENVTL. L.J. 1, 26 (2006).

147. *Id.* at 27 ("This creation is, to a certain extent, a reversal of the process of propertization that brought the CBD into being, caused perhaps by the prohibitive cost of segregating seeds and tracing samples to those working on core crops for the poor, and therefore, the most important PGRs were essentially placed back in the public domain."); Helfer, *supra* note 115, at 40; ITPGRFA, *supra* note 10, art. 10.2 ("In the exercise of their

develop commercial products using genetic materials from the Multilateral System must accept a Material Transfer Agreement ("MTA"), the terms of which were adopted by the Governing Body of the ITPGRFA in 2006, and then obligatorily pay "an equitable share of the benefits" to a fund to be used to promote conservation and sustainable use of germplasm when the product has restrictions on its availability to others for further research and breeding, and they are encouraged to pay voluntarily when the product is available without restriction for such purposes.[148]

A further critical restriction on recipients of germplasm from the Multilateral System is the provision in article 12.3(d) that "[r]ecipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System."[149] The wording of this

sovereign rights, the Contracting Parties agree to establish a multilateral system, which is efficient, effective, and transparent, both to facilitate access to plant genetic resources . . . , and to share . . . the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis.").

148. *See* Helfer, *supra* note 140, at 220 n.15; *see also* ITPGRFA, *supra* note 10, art. 13.2(d)(ii). Article 13.2(d)(ii) states:

> The Contracting Parties agree that the standard Material Transfer Agreement referred to in Article 12.4 shall include a requirement that a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay to the mechanism referred to in Article 19.3f, an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.
>
> The Governing Body shall, at its first meeting, determine the level, form and manner of the payment, in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialize such products; it may also decide on the need to exempt from such payments small farmers in developing countries and in countries with economies in transition. The Governing Body may, from time to time, review the levels of payment with a view to achieving fair and equitable sharing of benefits, and it may also assess, within a period of five years from the entry into force of this Treaty, whether the mandatory payment requirement in the MTA shall apply also in cases where such commercialized products are available without restriction to others for further research and breeding.

149. ITPGRFA, *supra* note 10, art. 12.3(d). Article 12.3(d) is a compromise between developing countries and developed countries over "whether to bar patenting of isolated and

provision was the most controversial part of the negotiations over the ITPGRFA, as developing countries insisted on a prohibition against intellectual property or other rights, not only for PGRs as such, but also for "their genetic parts and components," while developed countries insisted that the ban merely limit assertion of intellectual property rights in PGRs "in the form received" from the Multilateral System.[150]

In addition, although the ITPGRFA reaffirms a commitment to farmers' rights, recognizing the contributions that local farming and indigenous communities have made, and will continue to make, to the conservation and development of PGRs,[151] this provision is described as "merely a symbolic expression of gratitude," without offering any effective implementation tool for those rights at the international level.[152] The practical implementation of farmers' rights—defined in the treaty as including the right to participate in decision-making and benefit-sharing, as well as the right to protect traditional knowledge—explicitly remains within the sole discretion of national governments.[153] Thus, although the ITPGRFA offers a more

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purified genes extracted from seeds placed in the common seed pool." Helfer, *supra* note 140, at 220–21.

150. *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, 620–21 (2003). For a more detailed discussion of this issue, see *infra* notes 222–27.

151. *See* Aoki, *supra* note 4, at 441; Rose, *supra* note 150, at 622–24; *see also* ITPGRFA, *supra* note 10, art. 9.1.

> The Contracting Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.

Id.

152. Rose, *supra* note 150, at 622, 622–24 (analyzing the negotiation history over farmers' right between the South and the North).

153. *See* ITPGRFA, *supra* note 10, art. 9.2. Article 9.2 states:

> The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to plant genetic resources for food and agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights including:

comprehensive definition of farmers' rights than the earlier Undertaking, it does nothing to advance the argument of proponents that farmers' rights should be recognized as a property right.[154]

At the same time, however, the ITPGRFA does represent an unprecedented international effort to combine an open source system of facilitated access to PGRs with a mandatory system of benefit-sharing, including mandatory sharing of monetary and other benefits arising out of commercialization of certain patent-protected plant innovation. To get a sense of whether a kind of "Bio-Linux"[155] can in fact be created under the auspices of the ITPGRFA, it will be useful to compare the characteristics of the Multilateral System under the ITPGRFA with open source approaches in other intellectual property fields.

B. The Free & Open Source Software Movement(s)

Free or open source software ("F/OSS") refers to computer software, the source code of which is made available to the public under a free or open source copyright license that permits members of the public "to use, change, and improve the software, and to

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> (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture:
>
> (b) The right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
>
> (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

Id. Article 9.3 states: "Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." *Id*. art. 9.3.

154. *See* Rose, *supra* note 150, at 625.

155. Professor Aoki uses the term "Bio-Linux" as a symbolic term representing an open source licensing scheme in the biotechnological field and asserts that an open source licensing scheme such as the General Public License for open source software should be introduced in order to safeguard the public PGRs from privatization. *See* Aoki, *Distributive and Syncretic*, *supra* note 3, at 798–99. "BioLinux" is "a term used in a variety of projects involved in making access to bioinformatics software on a Linux platform easier using one or more of [a variety of] methods." Wikipedia, BioLinux, http://en.wikipedia.org/wiki/BioLinux (last visited Apr. 20, 2009). For recent, book-length examinations of this topic, see AOKI, SEED WARS, *supra* note 3; JANET HOPE, BIOBAZAAR: THE OPEN SOURCE REVOLUTION AND BIOTECHNOLOGY (2008).

redistribute it in modified or unmodified form."[156] A computer program is typically comprised of both "source code" and "object code." A programmer first writes a series of commands in a "human readable" programming language, known as source code, and then uses a software tool such as a compiler to transform this "source code" into a machine-readable language expressed in a binary format, the so-called "object code" version of the program.[157] In most cases, commercial software is sold without disclosing the source code, which is withheld as a carefully guarded trade secret, and the license accompanying the product merely provides a limited right to use the product, and little or no right to make or distribute derivative works, thus preventing users from modifying the software, and also preventing competitors from engaging in reverse-engineering.[158] In contrast, open source software is distributed without such restrictions; both the object code version and the source code version of a program are provided under a free or open source license.[159]

In recent years, the F/OSS movement has moved beyond the realm of the hobbyist and scientific communities, in which software developers shared their source code so that anyone could "freely view and modify the program."[160] The rise of the Internet facilitated widespread proliferation of open source projects by reducing the transaction costs of collaboration around the globe.[161] In 1985, Richard Stallman institutionalized the F/OSS movement by establishing the Free Software Foundation ("FSF") to encourage software development based on free modification and free distribution of source code.[162] The FSF sets forth the Free Software Definition, which determines whether a license is a free software

156. *See* Wikipedia, Open-source Software, http://en.wikipedia.org/wiki/Open_source_software (last visited Apr. 20, 2009).

157. *See* RON WHITE, HOW COMPUTERS WORK 87–88, 92–93 (8th ed. 2006).

158. *See* Joseph Eng, Jr., *From Software to Life Sciences: The Spreading of the Open Source Production to New Technological Areas*, 24 TEMP. J. SCI. TECH. & ENVTL. L. 419, 422 (2005).

159. *Id*.

160. Robert W. Gomulkiewicz, *How Copyleft Uses License Rights to Succeed in the Open Source Software Revolution and the Implications for Article 2B*, 36 HOUS. L. REV. 179, 182–85 (1999).

161. *Id.* at 183.

162. *Id.*

license. The Free Software Definition is largely comprised of four freedoms: "[t]he freedom to run the program, for any purpose"; "[t]he freedom to study how the program works, and adapt it to your needs"; "[t]he freedom to redistribute copies so you can help your neighbor"; and "[t]he freedom to improve the program, and release your improvements (and modified versions in general) to the public, so that the whole community benefits."[163]

The term "open source" was first suggested and adopted in 1998 by the Open Source Initiative ("OSI"), which was founded by Bruce Perens and Eric S. Raymond to release the source code of their popular Web browser, Netscape, as open source software.[164] The OSI also adopted the Open Source Definition as a means of determining whether programs qualify as open source software. The Open Source Definition requires free redistribution, availability of the source code, permission to make derivative works, integrity of the author's source code, no restrictions on accompanying software, neutrality with respect to technology, and forbids discrimination against persons, groups, or fields of endeavor.[165] The Open Source Definition was also designed to make the principles of F/OSS more compatible with proprietary software. Contrary to the Free Software Definition, the Open Source Software Definition permits the licensee to combine the free source code with proprietary software.[166] As a result, the Open Source Definition is considered to be more compatible with commercial interests than the Free Software Definition, as it generally allows the interface of open source software and proprietary software.

The F/OSS movement operates in conformity with, and is dependent upon, the existing intellectual property rights regime. Notably, most participants in the F/OSS movement use "copyright

163. Free Software Foundation, The Free Software Definition, http://www.gnu.org/philosophy/free-sw.html (last visited Apr. 20, 2009). However, these four freedoms are subject to an important constraint. *See infra* notes 170–71 and accompanying text.

164. Open Source Initiative, History of the OSI, http://www.opensource.org/history (last visited Apr. 20, 2009).

165. Open Source Initiative, The Open Source Definition (Annotated), http://www.opensource.org/docs/definition.php (last visited Apr. 20, 2009).

166. *See* José J. González de Alaiza Cardona, *Open Source, Free Software, and Contractual Issues*, 15 TEX. INTELL. PROP. L.J. 157, 182–84 (2007).

ownership and contracts to enforce social norms of sharing and openness."[167] Unlike proprietary software, in which copyright is used "to exclude," however, copyright in F/OSS is used to confer a right "to distribute."[168] Open source software is distributed under a license ensuring that source code will remain freely available to the public for further modification and redistribution. Over the past decade, a variety of open source licenses have been proposed. These licenses can be broadly classified into two types: the viral (or "free") software license and the non-viral (or "open source") license.[169]

The GNU General Public License ("GPL"), which was developed by the FSF, is the most famous example of the viral license. Under the GPL, both the original source code and that of any derivative works based on same must be released to the public even when the software has been modified and redistributed by subsequent programmers; downstream licensees cannot make derivative software proprietary.[170] Therefore, under the "viral" aspect of the GPL, if a company uses software operating under the GPL with a proprietary product that it has developed, the company must distribute the source code of the entire product without charge to the public.[171]

On the other hand, the non-viral license allows the licensee "to modify the source code without requiring [him] to redistribute the modified software under the same licensing terms."[172] The Berkeley Software Distribution License ("BSD License") is one of the most popular non-viral licenses.[173] The BSD License is considered to be the least restrictive of the open source licenses. Contrary to the GPL, BSD allows the licensee to combine the source code with proprietary

167. JULIE E. COHEN ET AL., COPYRIGHT IN A GLOBAL INFORMATION ECONOMY 199 (2d ed. 2006).

168. *See* STEVEN WEBER, THE SUCCESS OF OPEN SOURCE 1 (2004).

169. *See* Adam Kubelka & Matthew Fawcett, *No Free Beer—Practice Tips for Open Source Licensing*, 22 SANTA CLARA COMPUTER & HIGH TECH. L.J. 797, 812, 812 n.52 (2006).

170. *See* FREE SOFTWARE FOUNDATION, GNU GENERAL PUBLIC LICENSE (2007), http://www.fsf.org/licensing/licenses/gpl.html.

171. *See id.* ("You must license the entire work, as a whole, under this License to anyone who comes into possession of a copy. this License will therefore apply . . . to the whole work, and all its parts, regardless of how they are packaged.").

172. Jyh-An Lee, Note, *New Perspectives on Public Goods Production: Policy Implications of Open Source Software*, 9 VAND. J. ENT. & TECH. L. 45, 52 (2006).

173. *See* Kubelka & Fawcett, *supra* note 169, at 812–13.

software because its derivatives can be released under a proprietary license.[174]

Compared to commercial proprietary software, F/OSS has some distinct advantages. First, open source software offers the human-readable source code as well as the machine-readable object code, thus opening the program to the critical scrutiny of users, whereas proprietary software is generally sold only in its object code form. Second, an open source license gives a licensee broad rights, "granting the licensee the ability to freely copy, distribute and modify the software," whereas a proprietary license normally restricts a licensee's ability to use the software for such purposes.[175] Third, "open source software is usually licensed free of charge, whereas proprietary software is almost always licensed for a license fee."[176] Due to these benefits, the open source software movement has gained widespread acceptance as a viable collaborative innovation and distribution model, and has recently begun to compete successfully with proprietary software in a number of commercial areas. A 2003 report of the United Nations Conference on Trade and Development presented evidence that the F/OSS process produces better software, and thus offers a viable mode of software production, particularly in developing countries.[177] The Linux operating system, Apache web server, and Firefox Internet browser are all well-known examples of successes in the open source software movement.[178]

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174. *See* Natasha T. Horne, *Open Source Software Licensing: Using Copyright Law to Encourage Free Use*, 17 GA. ST. U. L. REV. 863, 879–80 (2001).

175. Peter Brown, *Legal Issues in the Open Source Community*, PATS., CPYRTS., TMS. & LIT. PROP. COURSE HANDBOOK SERIES (Practicing Law Inst., New York, N.Y.), Mar. 2004, at 309, 317.

176. *Id.*

177. *United Nations Conference on Trade and Development, 2003, E-Commerce and Development Report 2003*, at 95–96, U.N. Doc. UNCTAD/SIDTE/ECB/2003/1. For discussions of the growing acceptance of open-source innovation and its successful competition with proprietary innovation in many commercial areas, see generally David W. Opderbeck, *The Penguin's Genome, or Coase and Open Source Biotechnology*, 18 HARV. J.L. & TECH. 167 (2004); Eng, Jr., *supra* note 158.

178. *See* Eng, Jr., *supra* note 158, at 419–20.

> [I]n the web server market, the open source program known as "Apache" has captured approximately 70% of the web server market share as of January 2005, and continues to gain market share at the expense of all other competitors, including those that produce proprietary software. In the operating system market, the open source software known as "Linux" has made spectacular gains in market share over a short

C. Open Source Innovation in Biotechnology

The success of the open source software movement has engendered growing interest in the use of open source licensing to distribute creative works and scientific research results in other technological fields.[179] This has been particularly true in the field of biotechnology.

Tim Hubbard of the British Sanger Institute first attempted to implement an open source scheme in biotechnology in an effort to foster the exchange of research information and the transfer of technology among human genome researchers.[180] However, Hubbard's attempt failed to produce meaningful fruit because the Sanger Institute ultimately released all of its human genome research materials into the public domain.[181] Indeed, the Human Genome Project ("HGP")[182] freely released all of its data on the Internet under a traditional public domain model, allowing the public to use the data without any restriction.[183] Critics complained that "this public domain model would permit commercial users to diminish the utility and accessibility of the HGP's public domain data by making proprietary their improvements to that data,"[184] and that criticism influenced subsequent efforts to create open biotechnology projects.[185]

> time. As of June 2001, Linux was running on approximately 30% of the machines connected to the web, up from a mere 0.1% as of May 1999. Furthermore, the open source internet browser known as Firefox, though currently possessing less than 10% of the browser market, appears to be rapidly eroding the market dominance of Microsoft's Internet Explorer.

Id. (footnotes omitted).

179. *See* Andrés Guadamuz González, *Open Science: Open Source Licenses in Scientific Research*, 7 N.C. J.L. & TECH. 321, 321 (2006); *see also* AOKI, SEED WARS, *supra* note 3, at 109–22; HOPE, *supra* note 155.

180. *See* González, *supra* note 179, at 336.

181. *See id.*

182. The Human Genome Project (HGP) is the worldwide project to identify and sequence the human genome, led by the International Human Genome Sequencing Consortium and private companies such as Celera Genomics. *See generally* Robert Mullan Cook-Deegan, *Origins of the Human Genome Project*, 5 RISK 97 (1994).

183. Donna M. Gitter, *Resolving the Open Source Paradox in Biotechnology: A Proposal for a Revised Open Source Policy for Publicly Funded Genomic Databases*, 43 HOUS. L. REV. 1475, 1478 (2007).

184. *Id*.

185. *Id.* at 1478–79.

For example, the International HapMap Project was launched in October 2002 as a consortium among scientists in Japan, the United Kingdom, Canada, China, Nigeria, and the United States to "develop a haplotype map of the human genome, . . . which will describe the common patterns of human DNA sequence variation."[186] The haplotype map "is expected to be a key resource for researchers to use to find genes affecting health, disease, and responses to drugs and environmental factors."[187] With respect to the data generated, individual genotype data was initially made available under a temporary policy of minimal restraints, whereby users had to "agree to not reduce others' access to the data, and to share the data only with others who have made the same agreement," in order to ensure that Project data remained in the public domain.[188] Once the data became dense enough to define regions of strong association, all of the data was to be released into the public domain without restrictions.[189] In December 2004, the license was dropped and the HapMap Project released its full project results into the public domain, so that any researcher could use the information.[190]

A more overtly open source approach to biotechnology was undertaken in 2005 by the Center for the Application of Molecular

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186. *See* International HapMap Project, About the International HapMap Project, http://www.hapmap.org/abouthapmap.html (last visited Apr. 20, 2000).

187. *Id*.

188. *Id.*; *see also* Gitter, *supra* note 183, at 1482–83.

> In order to make certain that the HapMap data would remain accessible to all users, the HapMap Project explained at the outset that it "had to adopt a Data Release Policy where some data are released quickly without restriction and some data are released with restrictions for a limited period of time." Thus, the HapMap Project implemented "a free, non-exclusive, non-royalty-bearing licensing agreement to obtain access to certain types of data the project had collected on individuals' DNA sequences, specifically the genotypes."

Id. (citations omitted). Noting a significant shortcoming of the open source approach used by the HapMap Project, namely that it is inadequate to prevent the dangers of parasitic patenting, Professor Gitter proposes an alternative open source framework, which relies on the doctrine of trade secrecy, for future publicly funded genomic databases. *Id.* at 1519–20.

189. *See* International HapMap Project, *supra* note 186.

190. *The* Int'l HapMap Consortium, *A Haplotype Map of the Human Genome*, 437 NATURE 1299, 1317 (2005); *see also* Gitter, *supra* note 183, at 1485 ("Indeed, on December 10, 2004, the International HapMap Consortium announced that it would end its licensing policy, with the result that all the consortium's data would from that time forth be available to the public without restriction.").

Biology to International Agriculture ("CAMBIA").[191] In 2005, CAMBIA developed three different strains of bacteria that could be substituted for the traditional method of introducing genetic material into plants, and decided to use this technology as a starting point to generate a protected commons for researchers in the life sciences, which became known as Biological Innovation for Open Source ("BIOS").[192] CAMBIA gives free access to its discoveries, but subject to a GPL-style license analogous to that used in the F/OSS movement, requiring anyone using the technology to contribute improvements to the core toolkit of others who have agreed to the same terms.[193] The BIOS license requires licensees who want to use the BIOS technologies to give other participants in the BIOS initiative "a worldwide, non-exclusive, royalty-free, fully paid-up license" to any improvements they might make, even though they are permitted to patent and license such improvements.[194] It is as yet unclear, however, whether this BIOS license will be compatible with existing intellectual property systems, and whether it will be adequate to prevent the dangers of parasitic patenting by commercial users.[195]

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191. CAMBIA is "an independent, international non-profit institute" in Australia that aims to develop new technologies, tools and paradigms to foster collaboration and life-sciences enabled innovation, in order to enable disadvantaged communities and developing countries to meet their own challenges in food security, health, and natural resource management. Center for the Application of Molecular Biology to International Agriculture, CAMBIA Homepage, http://www.cambia.org/daisy/cambia/home.html (last visited Jan. 16, 2009).

192. Eng, Jr., *supra* note 158, at 429–30.

193. *See id.* at 430–31; Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271, 303–04 (2007).

194. Nolan-Stevaux, *supra* note 193, at 304–06.

195. *See* Robin Feldman, *The Open Source Biotechnology Movement: Is It Patent Misuse?*, 6 MINN. J.L. SCI. & TECH. 117, 167 (2004) (noting that "[t]he restrictions necessary to maintain the open source nature of such projects may implicate the doctrine of patent misuse in that they appear to use the power of the patent grant to affect inventions beyond the teachings of the original patent," but concluding that under a proper analysis of whether the patent holder's "behavior impermissibly extends the scope of the patent grant," either because the effects of the behavior are inconsistent with patent policy or because the effects run afoul of the antitrust rule of reason, open source biotechnology projects should not constitute patent misuse); *see also* González, *supra* note 179, at 356–57, 357 ("The potential incompatibility between patents and open source licenses is difficult to resolve."); Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1072 (2005) ("BIOS, like the HGP and HapMap Projects, is betting that certain research tools are shareable, even in wealthy markets and under current IP regimes, because the tools' research value is greatest if they are freely accessible.").

Additional examples of groups that take an open source approach in biotechnology include the Universities Allied for Essential Medicines ("UAEM") and the Tropical Disease Initiative ("TDI").[196] The UAEM is a nationwide, student-run organization in the United States that exists for the purpose of encouraging universities to reserve rights to improve access to essential medicines in the developing world.[197] It seeks to use the rights owned by universities to create a "self-binding commons," analogous to the open source movement, by granting a non-exclusive license to third parties to provide the approved drug to developing or least developed countries.[198] Stephen Maurer, Arti Rai, and Andrej Sali have recently proposed the creation of the TDI as an open source production model in which scientists could work together on early-stage development of drugs to fight tropical diseases.[199] Scientists would be required to post their research results on an online database when they identify new drug candidates, and this will serve to coordinate research for the development of new drugs.[200]

Notwithstanding these attempts to adopt an open source approach to biotechnology, because this movement is still in its infancy, it is unclear whether the open source principles developed in the software arena will successfully migrate to the field of biotechnology. Some commentators argue that biotechnology is not a good candidate for the open source model of innovation for a variety of reasons. For example, David Opderdeck reaches such a conclusion through his

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The enforceability of open-source licenses received an important boost in the United States with the decision of the Court of Appeals in Jacobsen v. Katzer, 535 F.3d 1373, 1382–1383 (Fed. Cir. 2008), which held that the terms of an open source artistic license are enforceable copyright conditions, and that the licensor would thus be entitled to pursue preliminary injunctive relief under the Copyright Act of 1976.

196. In addition to these examples, bioinformatics might be one area of open source biotechnology. Bioinformatics, the application of information technology to solve biological problems, began to use open source software as a favored tool. "Nevertheless, the relative success of bioinformatics has more to do with the success of open source software than with the application of open biotechnology." González, *supra* note 179, at 337.

197. *See* Nolan-Stevaux, *supra* note 193, at 296.

198. *Id.* at 296–97.

199. *See* Stephen M. Maurer et al., *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, *in* BIOTECHNOLOGY: ESSAYS FROM ITS HEARTLAND 33, 33–36 (Lynn Yarris ed., 2004), *available at* http://www.bayeconfor.org/pdf/BioTechReport.pdf.

200. *Id.* at 33.

analysis of various characteristics of biotechnology, based upon a theory of Yochai Benkler, who posits three layers of communication in open source software development—namely, "the 'physical' layer across which information travels, the 'code' layer that makes the physical layer run, and the 'content' layer of information."[201] First of all, says Opderdeck, the physical layers in biotechnology are fundamentally different than those of computer software because "the hardware layer typically is organic and the interaction between the hardware and code layers often is highly specialized and complex."[202] The biological code layers, which are composed of genetic codes, are also more complex than computer code, as they "cannot be created by simply typing on a keyboard."[203] Finally, the content layer, which is a particular function (e.g., an enzyme) performed by the specific genetic code, "is not highly granular" because the synthesis of the enzyme would require more specialized equipment, techniques and materials.[204] In addition, with regard to the social-psychological rewards that will attract collaborators, Opderbeck asserts that biotechnology research calls for stronger compensation (e.g., intellectual property protection) than the peer-reviewed reputations applied to software development, since, while computer software can be developed in a garage with a handful of cheap, readily available tools, biotechnology development demands a significant amount of expensive equipment and materials.[205]

Similarly, Joseph Eng, Jr., contends that "the inability [of biotechnology researchers] to externalize [the cost of scarce resources] will be enough to prevent contributions from even the most motivated would-be contributor," while a computer programmer can usually absorb the cost of open source software development himself because the cost is relatively minimal.[206] By contrast, most biotechnology researchers will have to externalize at least some of

201. *See* Opderbeck, *supra* note 177, at 181–85 (quoting Yochai Benkler, *From Consumers to Users: Shifting the Deeper Structures of Regulation Toward Sustainable Commons and User Access*, 52 FED. COMM. L.J. 561, 562–63 (2000)).

202. *Id.* at 183.

203. *Id.*

204. *Id.* at 185.

205. *Id.* at 195–96.

206. Eng, Jr., *supra* note 158, at 434.

their costs because biotechnology research requires more expensive resources, such as reagents, equipment, and laboratory space.[207] He further stresses that the open source approach is more difficult to apply to the biotechnological field because open source contributions in biotechnology are patent-protected, rather than copyright-protected.[208] Unlike copyright protection, which seems generally compatible with the open source approach, patent protection appears to be problematic because small inventors who would be major contributors to open source development often fail to obtain patent protection for their inventions due to the high cost and knowledge barriers associated with obtaining patent protection, and would thus be faced with two undesirable choices: disclosing inventions without any intellectual property protection or disclosing them subject to individually negotiated contracts.[209] Eng recommends forming a confidential "protected commons" of the sort envisioned in the CAMBIA BIOS initiative, but Eng nevertheless concludes that such an open source model would be far less "open" than the open source software movement.[210]

D. ITPGRFA as an Open Source System of Plant Innovation

With this overview of the open source software movement and its application to the field of biotechnology in mind, this Article now turns to an analysis of whether the facilitated access and benefit-sharing mechanism under the ITPGRFA will successfully function as an open source innovation system.

The ITPGRFA, which was adopted at the FAO conference on November 3, 2001, entered into force on June 29, 2004, creating a Multilateral System for facilitated access and benefit-sharing with

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207. *Id.*

208. *Id.* at 435.

209. *Id.* at 436–37; *see also* Feldman, *supra* note 195, at 124.

210. Eng, Jr., *supra* note 158, at 438–39; *see also* Sara Boettiger & Dan L. Burk, *Open Source Patenting*, 1 J. INT'L BIOTECH. L. 221, 231 (2004) (concluding that, while open source patenting presents a promising and intriguing approach to resolving the tension between the communality of science and the economic incentive of patent law, the correspondence between the licensing of open source software and that of open source biotechnology is not perfect, as the differing nature of patent and copyright shifts the analysis in a variety of ways, some stark and some subtle).

respect to selected PGRs for food and agricultural purposes, while simultaneously recognizing the sovereign rights of each country over its own PGRs.[211] Under this Multilateral System, facilitated access must be provided pursuant to a Standard Material Transfer Agreement ("SMTA"), which was adopted by the Governing Body of the ITPGRFA, and a recipient who develops commercial products using genetic materials from the System must accept the SMTA and pay "an equitable share of the benefits" to an FAO trust account.[212] Under the mandate of the ITPGRFA, the Governing Body adopted the SMTA in the first session, which was held in June 2006, detailing the rights and obligations of both providers and recipients of plant genetic materials accessed from the Multilateral System, including the rate and modalities for benefit-sharing.[213]

Notwithstanding several controversial and potentially ambiguous provisions, the Multilateral System clearly appears to envision an open source approach to plant innovation. Like the open source software movement, the Multilateral System seeks to promote facilitated access to genetic materials held under the System. Facilitated access means that access is to be provided expeditiously, free of charge or at a minimal cost, to legal and natural persons under the jurisdiction of any member state, on the condition that the material, accessed under the Multilateral System and conserved by the member, continue to be made available to the System by recipients of those materials.[214] Pursuant to these provisions, the genetic resources held under the System would be used as an open resource to facilitate plant innovation and to promote both benefit-sharing and conservation of genetic resources.[215]

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211. ITPGRFA, *supra* note 10, art. 10.

212. *Id.* arts. 12.4, 13.2(d)(ii), 19.3(f). The ITPGRFA also encourages those who are not obliged to voluntarily share their benefit from the Multilateral System. The benefit sharing is voluntary for the commercialization of a product that incorporates plant genetic material accessed from the Multilateral System when the product is "available without restriction to others for further research and breeding." *Id.* art. 13.2(d)(ii).

213. *See* FOOD AND AGRICULTURE ORGANIZATION OF THE U.N. REPORT OF THE GOVERNING BODY OF THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE app. G (2006), *available at* ftp://ftp.fao.org/ag/cgrfa/gb1/gb1repe.pdf [hereinafter SMTA].

214. ITPGRFA, *supra* note 10, art. 12.3(b), (g).

215. *See* Helfer, *supra* note 140, at 220.

A number of potential ambiguities lurking in the language of the ITPGRFA could undermine its actual operation. For example, according to Article 11.2, only those PGRs listed in Annex I that are "under the management and control of the Contracting Parties *and in the public domain*" fall within the Multilateral System.[216] This provision suggests that the prohibition in Article 12.3(d) against claiming any intellectual property or other rights that limit facilitated access to PGRs, "or their genetic parts or components, in the form received from the Multilateral System" is largely surplusage, as the PGRs themselves would not, in any event, be entitled to intellectual property protection because they are by definition in the public domain.[217] Indeed, Article 12.3(d) seems primarily designed to prohibit intellectual property rights in the genetic parts or components of these PGRs, at least in the form that these genetic parts and components are "received" from the Multilateral System.

This interpretation of Article 12.3(d) serves to highlight three further potential ambiguities in Article 12. First, Article 12.3(d) does not preclude the assertion of intellectual property rights as such, but merely prohibits recipients from claiming intellectual property rights or other legal rights that "limit facilitated access" to PGRs. Facilitated access, in turn, is defined in Article 12.3(a) as access "solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed uses."[218] This definition implies that any intellectual property rights that are limited by a sufficiently broad "experimental use" privilege would not be prohibited under Article 12.3(d). For example, although the UPOV Convention is arguably unclear as to what it means by an "essentially derived" variety falling within the scope of the registered plant breeder's right, the UPOV nevertheless clearly creates a broad breeder's privilege to use protected plant varieties to produce new and distinct varieties that are not "essentially derived," free of any obligation to pay royalties. Thus, UPOV-compliant plant variety protection would arguably not "limit"

216. ITPGRFA, *supra* note 10, art. 11.2 (emphasis added).
217. *Id*. art. 12.3(d).
218. *Id*. art. 12.3(a).

facilitated access to PGRs and would thus not give rise to any obligation to share benefits arising out of the commercialization of plant varieties derived from the Multilateral System. In other words, Article 12.3(d) seems primarily aimed at barring patent protection—or at least patent protection that is not subject to an experimental use privilege that is at least as broad as the UPOV breeders' privilege—on any genetic parts or components of PGRs, at least in the form "received" from the Multilateral System.

A second potential ambiguity in the language of Article 12 arises with respect to which plant innovations that are derived from PGRs accessed from the Multilateral System must be obligatorily incorporated into the System and which plant innovations will escape the Multilateral System but give rise to an obligation to share benefits arising out of the commercialization of a plant variety derived from the Multilateral System. Neither the ITPGRFA nor the SMTA provide a clear answer to this question.[219] However, Article 12.3(g) of the ITPGRFA and Article 6.3 of the SMTA seem to require recipients of genetic material from the Multilateral System to make

219. The meaning of the term "in the form received" was one of the most contentious issues during the negotiations of the ITPGRFA. Although the resulting compromise between developing countries and developed countries was expected to be further interpreted by the Governing Body, the SMTA adopted by the Governing Body simply replicates the corresponding wordings in the ITPGRFA without further clarification. *See* Kennedy, *supra* note 146, at 28. According to Kennedy,

> While all participating countries agreed that it should not be possible to patent genetic materials in the form received under the [Multilateral System], disagreement existed among them as to whether and when DNA sequences could be patented. There are two genetic material categories to consider: "parts and components" (patenting of raw DNA sequences simply extracted from PGRs) and "derivatives" (where extracted DNA is combined with other DNA to create a new PGR). The first category is probably excluded by the language of the [ITPGRFA], although some developed countries interpret it as allowing some patents, even though this interpretation would seem to run counter to the spirit of the treaty. The position with the second is more vague, with the European Union taking the position that if parts and components are the subject of innovation, they can be the subject of [intellectual property rights].

Id. (footnotes omitted); *cf.* ITPGRFA, *supra* note 10, art. 12.3(d) ("Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant generic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System."); SMTA, *supra* note 213, art. 6.2 ("The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System.").

the material available to the System only when the recipients conserve the actual material supplied.[220] This, in turn, suggests that virtually any plant innovation based on materials derived from the Multilateral System could escape the System if the source materials themselves are not conserved but may (or may not) be subject to Article 13.2(d)'s obligation to share monetary benefits,[221] depending on whether any intellectual property rights are claimed in the plant innovation and whether those intellectual property rights "limit" facilitated access. In short, the Multilateral System appears to be more analogous to the Open Source Definition than to the Free Software Definition governing software development, in that the ITPGRFA does not contain a "viral" clause to ensure that any product derived from open source data will be available under the same license terms.[222]

A third and more fundamental (albeit apparently intended) ambiguity lurking in the language of Article 12.3(d) arises from the fact that it prohibits the assertion of intellectual property rights that limit facilitated access to either the PGRs "or their genetic parts or components," at least "in the form received" from the System.[223] There is, of course, considerable disagreement between developing and developed countries as to the precise meaning of the two phrases, "their genetic parts or components," and "in the form received." Developing countries argue that the two phrases would bar any patents on isolated genetic parts or components derived from the Multilateral System, while developed countries adhere to their interpretive statement on the official record that nothing in the ITPGRFA conflicts with national and international intellectual property rights regimes.[224] No clarifying details were added by the

220. ITPGRFA, *supra* note 10, art. 12.3(g) ("Plant genetic resources for food and agriculture accessed under the Multilateral System and conserved shall continue to be made available to the Multilateral System by the recipients of those plant genetic resources for food and agriculture, under the terms of this Treaty."); SMTA, *supra* note 213, art. 6.3 ("In the case that the Recipient conserves the Material supplied, the Recipient shall make the Material . . . available to the Multilateral System using the Standard Material Transfer Agreement.").

221. *See* ITPGRFA, *supra* note 10, art. 13.2(d).

222. *See supra* notes 169–74 and accompanying text.

223. ITPGRFA, *supra* note 10, art. 12.3(d).

224. *See* Helfer, *supra* note 140, at 221.

Governing Body that drafted the SMTA.[225] Reflecting the view of developed countries, however, Article 12.3(f) specifies that "[a]ccess to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws."[226] Given that the insertion of the phrase "in the form received" was insisted upon mainly by developed countries, "in light of their position that [Article 12.3(d)] should not prevent [PGRs], or their genetic parts or components, from being the subject of intellectual property rights, provided that the criteria relating to such rights are met,"[227] the phrase "in the form received" will probably be interpreted to allow patent claims if a product that incorporates PGRs accessed from the Multilateral System is the result of "significant, inventive manipulation."[228] After all, contrary interpretation would seriously undermine the other distinctive feature of the ITPGRFA—namely the obligation to share monetary benefits arising out of the commercialization of certain products derived from PGRs obtained through the Multilateral System.

It is this feature, in turn, that most significantly distinguishes the Multilateral System from the standard Open Source Definition of software development. Under Article 13.2(d)(ii) of the ITPGRFA,

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225. SMTA, *supra* note 213, art. 6.2; *see supra* note 219.

226. ITPGRFA, *supra* note 10, art. 12.3(f); *see* Helfer, *supra* note 115, at 40–41 ("To avoid the possibility that this language might be read to conflict with TRIPs or domestic patent statutes, Australia, Canada, Japan, and the United States appended interpretive statements after the final round of negotiations indicating . . . that nothing in the ITPGR[FA] is inconsistent with national or international intellectual property laws.").

227. *Intellectual Property and Development: Overview of Developments in Multilateral, Plurilateral, and Bilateral Fora*, S. CENTRE AND CENTER FOR INT'L & ENVTL. L. INTELL. PROP. Q. UPDATE (S. Centre & Ctr. for Int'l & Envtl. Intellectual Prop. Law), 3d Quarter, 2004, at 5–6 [hereinafter *Intellectual Property and Development*].

228. *See* Brush, *supra* note 33, at 83. However, it must be noted that the interpretation of the phrase "in the form received" in Article 12.3(d) squarely reflects ongoing disagreement between developing countries and developed countries about patentability criteria of life forms in the review of Article 27.3(b), and the controversial invention versus discovery debate in the ongoing negotiations in the World Intellectual Property Organization for a Substantive Patent Law Treaty. It is difficult to say whether and to what extent the phrase "in the form received" limits patent rights in genetic materials accessed from the Multilateral System without resolution of these issues. *Intellectual Property and Development*, *supra* note 227, at 6. *See* GERALD MOORE & WITOLD TYMOWSKI, EXPLANATORY GUIDE TO THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE 93 (2005), *available at* http://data.iucn.org/dbtw-wpd/edocs/EPLP-057.pdf; Rose, *supra* note 150, at 621.

recipients of genetic material accessed from the System are obliged to share financial benefits arising from the commercialization of such genetic material if the commercialized product is covered by intellectual property rights restricting the free access for further research and breeding.[229] The concept of facilitated access and benefit-sharing under the Multilateral System is based upon the premise that each country has sovereign rights over its PGRs.[230] Thus, unlike the open source software movement under the Open Source Definition, the Multilateral System recognizes a kind of sovereign proprietary right in PGRs held under the System and levies a monetary fee for having benefited commercially from having accessed these genetic resources. In this respect, the Multilateral System is more accurately viewed as a hybrid approach to agricultural innovation, combining open source and proprietary elements.[231]

In order to accomplish benefit-sharing under the Multilateral System, it is critical to establish who must share benefits growing out of commercial uses of the communal genetic materials under the System. As the controversy over the phrase "in the form received" reveals, however, neither the ITPGRFA nor the SMTA make clear who will be obliged to share benefits arising from commercial uses. Article 13.2(d)(ii) of the ITPGRFA merely requires a recipient who commercializes a product that incorporates a plant genetic material accessed from the Multilateral System to pay an equitable share of

229. ITPGRFA, *supra* note 10, art. 13.2.(d)(ii). Some commentators argue that "[t]his requirement may violate TRIPs by placing an obligation on holders of [intellectual property rights] in PGRs over and above what is required of other patent holders, which is not permitted under article 27.1 of TRIPs." Kennedy, *supra* note 146, at 31 (citing Helfer, *supra* note 115, at 41).

230. *See* ITPGRFA, *supra* note 10, pmbl. para. 14 ("Recognizing that, in the exercise of their sovereign rights over their [PGRs], states may mutually benefit from the creation of an effective multilateral system for facilitated access to a negotiated selection of these resources and for the fair and equitable sharing of the benefits arising from their use." (emphasis removed)).

231. In this regard, some commentators describe the Multilateral System as a form of "limited common property." *See, e.g.*, Helfer, *supra* note 140, at 219 ("The multilateral system is a form of 'limited common property' composed of 64 food and feed crops"); Kennedy, *supra* note 147, at 27 ("This treaty creates 'a special collective property right for a limited number of staple food and feed crops'; it is a type of limited common property right within these defined PGRs." (footnote omitted)).

the benefits arising from the commercialization of that product into the FAO trust account, unless "such a product is available *without restriction* to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment."[232] The SMTA states that "a Product is considered to be available without restriction to others for further research and breeding when it is available for research and breeding without any legal or contractual obligations, or technological restrictions, that would preclude using it in the manner specified in the Treaty."[233]

As we have seen, the UPOV-based plant variety protection ("PVP") system contains a broad research exemption that allows other breeders to use and reproduce protected varieties for plant breeding or other bona fide research, without any obligation to pay royalties on resulting new varieties, so long as they are not "essentially derived" from a protected variety.[234] Consequently, a product protected under the PVP system would arguably meet the requirement of being "available without restriction" under the Multilateral System.[235] Thus, if a commercialized product based on genetic resources derived from the Multilateral System is protected by a UPOV-compliant PVP system, a recipient of those resources is not obliged, but only encouraged, to share any of the monetary benefits arising out of commercial use of those genetic resources.

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232. ITPGRFA, *supra* note 10, art. 13.2(d)(ii) (emphasis added). In addition, this provision specifies that, in case the commercialized product is available without restriction to others for further research and breeding, the recipient who commercializes the product is encouraged to make such payment. *Id.*

233. SMTA, *supra* note 213, art. 2.

234. *See* 7 U.S.C. § 2544 (2006); UPOV, *supra* note 67, art. 5; *see also supra* note 88 (discussing the lack of a clear definition of what constitutes an "essentially derived" variety under the UPOV Agreement).

235. Berne Declaration, a Swiss non-governmental organization that aims to promote more equitable, sustainable and democratic North-South relations, agrees with this assertion. *See* FRANCOIS MEIENBERG, ACCESS AND BENEFIT-SHARING UNDER THE FAO SEED TREATY 4 (2006), *available at* http://www.evb.ch/cm_data/ABS_under_the_ITPGR_engl_2_2_2.pdf (asserting that "[i]t was quite clear during the negotiations for the Treaty that 'without restriction for further research and breeding' means that a product is available for further breeding by . . . PVP laws, which allow the breeder the right to sell new varieties developed from this product without restriction"). *But see Intellectual Property and Development*, *supra* note 227, at 6–7 (arguing that "[i]t is not clear . . . that these exceptions are sufficient to prevent these intellectual property rights from being classified as 'rights that limit the facilitated access' to [PGRs]").

Instances in which plant products derived from PGRs obtained from the Multilateral system are covered by patents, on the other hand, are likely to trigger an obligation to share monetary benefits.[236] This is so, even though the patent laws in many jurisdictions, including most developing countries and even some developed countries, such as the United Kingdom, Germany and Japan,[237] contain broad research exemptions, for even the broadest of these research exemptions are narrower than the breeders' exemption specified in the UPOV Convention. Certainly, the benefit-sharing obligation would be triggered where a patent on a product derived from the Multilateral System is subject only to a narrow or qualified research exemption, as in the United States.[238]

To summarize, the Multilateral System under the ITPGRFA adopts a hybrid open source and propriety approach to plant innovation, seeking to maintain the openness of genetic materials held under its System for the conservation and sustainable use of PGRs for food and agriculture, while obliging a recipient who commercializes a patented product that incorporates plant genetic

236. *See* H. David Cooper, *The International Treaty on Plant Genetic Resources for Food and Agriculture*, 11 REV. EUROPEAN COMMUNITY & INT'L ENVTL. L. 1, 9 (2002) ("[O]n the basis of the negotiating history of this provision . . . it is understood that such mandatory monetary benefit sharing would be invoked when commercialized products are protected by patents.").

237. See Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 969–70 (2004) ("Most of the world's leading patent systems, including both civil and common law jurisdictions, have codified in their patent codes a general experimental use exemption from patent infringement liability. . . . Developing country patent regimes have followed the approach of the industrialized nations' patent systems." (footnotes omitted)). However, even broad experimental use exceptions to patent protection generally do not include the privilege to commercially develop a derivative product free of any obligation to pay royalties, as under UPOV, which would arguably be required to avoid the obligation to share monetary benefits.

238. *See* MEIENBERG, *supra* note 235, at 4; Rose, *supra* note 150, at 620 ("The payment exception for [PGRs], 'available without restriction,' is purported to ensure mandatory payment by holders of plant patents but not by holders of plant breeders' rights."); *see also* Mueller, *supra* note 237, at 927 ("[T]he notion of a well-defined [experimental use] exemption from liability for certain uses of innovation protected by patents never received wide application or statutory codification [in the United States] as it did with respect to copyrighted works."). Even in jurisdictions in which a patent does not contain a research exemption, it is unclear "whether a patent holder in such jurisdictions could renounce those [rights to exclude a research exemption] and thus escape the mandatory benefit-sharing provision." MOORE & TYMOWSKI, *supra* note 228, at 111.

material accessed from the System to pay an equitable share of the benefits arising from the commercialization of that product into the FAO trust. Thus, to determine whether the Multilateral System will work efficiently, it is important to ascertain whether the FAO trust account will accumulate enough money to accomplish its initial purpose of promoting benefit-sharing.

Under the SMTA, a recipient, its affiliates, contractors, licensees and lessees are required to pay 1.1% of the sales of the product, with an additional 30% subtraction, into the trust account established by the Governing Body, when a patented product containing plant genetic material accessed from the System is commercialized.[239] Unfortunately, under the current SMTA, the Multilateral System is unlikely to generate significant benefits, at least in the short term,[240] and perhaps in the long term as well. This is so for a number of reasons: First, as a practical matter, there is a significant waiting period between initial access to genetic resources and eventual commercialization.[241] Second, "identifying the contribution of a specific resource within the complex pedigree of an improved crop variety poses a major obstacle" in determining who, and how much, will share in the commercialized benefits.[242] A third significant unresolved issue is the extent to which the benefit-sharing obligation under the Multilateral System will be "transferred through a chain of varieties."[243] Neither the ITPGRFA nor the SMTA clearly indicates whether this obligation would continue through successive varieties,

239. SMTA, *supra* note 213, art. 6.7, annex 2.

240. *See* Rose, *supra* note 150, at 622 ("[T]he PGR Treaty can be considered as having inherited the weaknesses of both its parent instruments in relation to benefit-sharing. . . . [The treatment of] monetary benefits [under the Multilateral System] remains inchoate."); Cooper, *supra* note 236, at 11 ("[D]uring a considerable period of time following the entry into force of the Treaty, mandatory payments triggered by commercial use may turn out to be a small part of the total benefit-sharing package.").

241. Brush, *supra* note 33, at 83.

242. *Id.*; Cooper, *supra* note 236, at 11 ("There will clearly be a lag between transfer of [PGRs] and the realization of benefit sharing due to the time needed for research, development and commercialization."); *see also* Rose, *supra* note 150, at 608 (stating that the Multilateral System "foresaw many difficulties in evaluating the benefits to be shared").

243. *See* INT'L PLANT GENETIC RES. INST., ACCESS TO PLANT GENETIC RESOURCES AND THE EQUITABLE SHARING OF BENEFITS: A CONTRIBUTION TO THE DEBATE ON SYSTEMS FOR THE EXCHANGE OF GERMPLASM 83 (1996), *available at* http://www.bioversityinternational.org/fileadmin/bioversity/publications/pdfs/467.pdf.

even if the actual proportion of the original germplasm constituting the new varieties produced inevitably decreases.[244]

It should also be noted that, although the System covers most crops that are vital to world food security,[245] benefit-sharing under the Multilateral System does not yet cover many crops, including both *ex situ* private collections of crops listed in the ITPGRFA and such non-listed crops as soybeans, groundnuts, sugar cane, wild relatives of cassava, tomatoes, and industrial crops including tea, coffee, oil-palm and rubber.[246] Moreover, even those crops that are within the Multilateral System and that can be used for profitable applications other than as food or feed, for example pharmaceutical or industrial products, "remain outside the scope of the benefit-sharing [obligations] of the Multilateral System."[247] Finally, and most importantly, a Swiss NGO, called the Berne Declaration, estimates that the amount of money that would annually be put into the FAO trust account will probably not even cover the administrative budget for the Multilateral System.[248] Moreover, as Professor Aoki notes, the benefit-sharing provisions of the Multilateral System arguably pay "mere lip service to the idea of farmers' rights," even if the amount of money accruing from the Multilateral System somehow turns out to be significant.[249] Although the ITPGRFA states that benefits arising from the Multilateral System "should flow primarily, directly and

244. *Id.*; *cf.* ITPGRFA, *supra* note 10, art. 13; SMTA, *supra* note 213, arts. 2, 6, annex 2.

245. *See* ITPGRFA, *supra* note 10, art. 11, annex 1.

246. *See* Rose, *supra* note 150, at 616, 622. ITPGRFA contains a built-in review agenda that mandates the Governing Body to assess the progress on the Multilateral System within two years of the entry into force of the Treaty, and following the review, to decide whether or not access shall continue to be facilitated to those natural and legal persons who were initially encouraged to include their PGRs in the Multilateral System. *See* ITPGRFA, *supra* note 10, art. 11.4.

247. *See* Rose, *supra* note 150, at 622.

248. See MEIENBERG, *supra* note 235, at 5, for an illustration of this financial problem:

> A rough and optimistic calculation may illustrate this point: ten years from now the global seed market (in US-dollars) will be worth some 30 billion dollars. Ten percent or 3 billion dollars worth of seed will have been bred with genetic resources from the multilateral system, of which, again, only 10% ($ 300 million) are protected by a patent and thus subject to benefit sharing at 0.77%. The resulting 2.31 million dollars per year do not even cover the treaty administrative budget.

Id.

249. Aoki, *Distributive and Syncretic*, *supra* note 3, at 796.

indirectly, to farmers in all countries, especially in developing countries,"[250] under the current SMTA, at least, farmers are unlikely to receive direct financial benefits and the benefits to farmers will thus accrue only indirectly, "through 'trickle down' information exchange, technology transfer, and capacity-building via the scientific community."[251]

Consequently, although the Multilateral System under the ITPGRFA is a commendable effort to avoid the high transaction costs associated with market-based bilateral contracts,[252] it is unclear whether it will in fact succeed in combining open source and proprietary approaches to plant innovation. As Opderbeck and Eng argue with respect to open source biotechnology, it may likewise be the case that agricultural innovation is not a particularly good candidate for an open source approach, due to the greater complexity of biological innovation and the inevitable reliance on patent, rather than copyright, protection. It does bear noting that the Multilateral System is distinguishable from conventional biotechnology innovation in one important respect, as the cost of obtaining patent protection will be borne by the commercial user, rather than the contributor, of PGRs. More importantly, the success of the Multilateral System will ultimately hinge on the benefit-sharing scheme, which is unlikely to generate significant monetary benefits, at least in the short term, and perhaps in the long term as well, as the benefit-sharing obligation is limited to those who restrict the access to their commercialized product through patents that can be shown to have been derived in some way from PGRs obtained from the Multilateral System. Enforcement of this obligation will itself impose considerable transaction costs on developing country governments if it is to be effective.[253]

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250. ITPGRFA, *supra* note 10, art. 13.3.

251. Aoki, *Distributive and Syncretic*, *supra* note 3, at 796–97.

252. *Id.* at 797.

253. To reduce these transaction costs, a number of proposals have been made to impose an international obligation on members of the World Trade Organization and/or the Paris Convention, that patent applicants disclose the origin of any genetic resources or associated traditional knowledge on which the patented invention is based and produce evidence of prior informed consent of the sources of the genetic resources or associated traditional knowledge. While imposing such an obligation as a condition for *obtaining* a patent would arguably be inconsistent with the TRIPS Agreement (at least as it currently stands), and more importantly

Nevertheless, the ITPGRFA is a commendable, if imperfect, attempt to moderate a potentially corrosive international phenomenon that one commentator has called "hyperownership in a time of biotechnological promise."[254] As we have seen, the fundamental issue is "who should own or control access to the subcellular genetic sequences that direct the structure and characteristics of all living things."[255] Developed countries are seeking to privatize plant and other genetic resources through imposition of the minimum patent standards contained in the TRIPS Agreement. In response, developing countries, which house most of the world's wild or raw genetic resources, are increasingly asserting sovereign ownership over these raw genetic resources.[256] "This interactive spiral of increased enclosure, or 'hyperownership,'" could potentially result in the "suboptimal utilization, conservation, and improvement of vital genetic materials."[257] In any event, the phenomenon reflects current

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would impose its own crushing administrative burden on patent examiners in both developing and developed countries, imposing such a disclosure of origin and prior informed consent requirement as a condition for *enforcing* an otherwise valid patent would arguably reduce the transaction costs entailed in enforcing the benefit-sharing provisions of the ITGRFA. *See generally* Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000); Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent*, 17 WASH. U. J.L. & POL'Y 111 (2005).

254. *See* Safrin, *supra* note 48, at 641. *See generally* Sabrina Safrin, *Chain Reaction: How Property Begets Property*, 82 NOTRE DAME L. REV. 1917 (2007) [hereinafter Safrin, *Chain Reaction*].

255. Safrin, *supra* note 48, at 641.

256. *Id.* at 642.

257. *Id.* It should be noted, however, that, as with concerns over "genetic erosion," *see supra* note 19 and accompanying text, and the potential for a "tragedy of the anticommons" and "patent thickets" in biotechnology research, *see supra* notes 52–57 and accompanying text, Safrin is ultimately making an empirical claim here. Although Safrin cites abundant anecdotal evidence of the international phenomenon of hyperownership and offers a fascinating theoretical explanation for it, *see generally* Safrin, *Chain Reaction*, *supra* note 254, her conclusion that this spiral could potentially result in the suboptimal utilization, conservation, and improvement of important plant genetic resources is based at least in part on the debatable assumption that the expansion of patent rights in the genetic area "is, or at a minimum, risks creating an anticommons in genetic material that deters innovation." *See id.* at 1961. She also offers anecdotal evidence that the "second wave of property rights [demanded by the developing world in response to the expansion of intellectual property rights] appears to have little to do with any efficient economic calculus." *Id.* at 1957. In the absence of persuasive empirical evidence to support the first part of her hypothesis, Safrin does not succeed in

international tensions between the developing and developed worlds, as the expansion of intellectual and other property rights take on an "internally generative dynamic," in which the demand for property rights by some engenders the demand for related property rights by others,[258] even if "the second wave of property rights appears to have little to do with any efficient economic calculus."[259] Before altogether abandoning the FAO's Multilateral System, it at least behooves the international community to make a sober assessment of the alternative. At the moment, at least, that alternative can only be described as profoundly bipolar, preoccupied as it is with continuing controversies over the patentability of genetic materials and reactive assertions of sovereignty over raw PGRs.

CONCLUSION

The rise of intellectual property rights for plant innovation, the commercialization of seeds, the increasing use of genetic resources in crop breeding, and the declining availability of crop genetic resources have engendered increasing doubt about the wisdom of adhering to the concept of "common heritage" in developing countries. Many developing countries have contended that free access to their PGRs by developed countries in the name of "common heritage" is tantamount to exploitation. Asserting that a host of their PGRs have been appropriated without permission, they denounce these unauthorized and uncompensated appropriations as "bio-piracy," and insist on international recognition of their sovereign ownership of any and all genetic resources found within their national borders.

With the rise of such claims by developing countries, there is an increasing need for international rules that guarantee access to genetic resources and ensure an equitable sharing of benefits arising from that access. In an effort to respond to this need, the ITPGRFA, a new multinational agreement in the biotechnology field, has

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establishing her initial conclusion that "[t]hese twin systems of hyperownership interact in a corrosive fashion," *see* Safrin, *supra* note 48, at 685, but only that even economically justified property claims run the risk of generating economically unjustified second-wave hyperownership claims.

258. *See* Safrin, *Chain Reaction*, *supra* note 254, at 1921.

259. *Id.* at 1957.

established a Multilateral System for facilitated access and benefit-sharing with respect to selected PGRs. As with other open source biotechnology projects, such as the International HapMap Project, CAMBIA/BIOS, UAEM, and TDI, the prospects for the Multilateral System are uncertain. Whereas those private biotechnology projects attempt to make open source use of patents, however, the monetary benefit-sharing feature of the Multilateral System will ultimately depend on proprietary patenting of genetic products, about which the ITPGRFA itself seems ambivalent. As a result, it is not at all clear that the benefit-sharing scheme under the Multilateral System will in fact provide direct and substantial financial benefits to farmers in developing countries. On the other hand, it is likewise unclear that a bilateral approach to promoting plant innovation and the conservation of PGRs, with its attendant controversies over private patenting of genetic material and reactive assertions of sovereignty over raw PGRs, is preferable to the FAO's Multilateral System.