By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

THE APPLICATION OF TRIPS TO GMOS:

INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS AND BIOTECHNOLOGY

DEBRA M. STRAUSS*

TABLE OF CONTENTS

INTRODUCTION

Through genetic engineering, the DNA of one organism is inserted into the

* Assistant Professor of Business Law, Charles F. Dolan School of Business, Fairfield University; B.A., Cornell University; J.D., Yale Law School. Professor Strauss, a former Food and Drug Law Institute Scholar, currently teaches the legal environment of business, international law, and law and ethics.

Electronic copy available at: http://ssrn.com/abstract=1523514

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

genes of an unrelated species, generating the desired trait in every cell of the target organism and producing genetically modified food.[1] In the case of a genetically modified plant, the desired trait is typically a resistance to sprayed pesticides or a toxicity towards predatory insects.[2] In the process, scientists created a technology that has morphed into a creature of economics, of the privatization of the natural world, and of international trade.[3] It is not surprising, then, that the next frontier in the battle over genetically modified organisms (GMOs) manifests itself in the context of intellectual property rights. Ironically, the issues raised are no longer merely matters of science and the answers no longer hinge on scientific knowledge, which has proven inadequate.[4] Instead, policy makers should use a broader perspective to examine the critical implications for the international community and reshape this application of intellectual property in line with the long-term public interest.

First, it is important to acknowledge that global business stands behind biotechnology. Worldwide, the adoption of genetically modified crops has surged exponentially since its inception, with the area of farmland increasing by sixty times in its first decade from 1996 to 2006.[5] In 2006, the global area of biotech crops continued to grow at a double-digit rate of 13%, or 12 million hectares (30 million acres), reaching 102 million hectares (252 million acres), 54% of which

---

[1] *See* Debra M. Strauss, *The International Regulation of Genetically Modified Organisms: Importing Caution into the U.S. Food Supply*, 61 FOOD & DRUG L.J. 167, 167 (2006) (discussing the health and environmental risks of genetically modified food) (citing NATIONAL RESEARCH COUNCIL, REPORT IN BRIEF, SAFETY OF GENETICALLY ENGINEERED FOODS: APPROACHES TO ASSESSING UNINTENDED HEALTH EFFECTS (July 2004), http://www.nap.edu/html/ge_foods/ge-foods-reportbrief.pdf) [hereinafter Strauss, *Importing Caution*].

[2] World Health Organization, 20 Questions on Genetically Modified (GM) Foods, http://www.who.int/foodsafety/publications/biotech/20questions/en/index.html (last visited Aug. 2, 2008).

[3] For more on issues of international trade involving genetically modified foods, see Debra M. Strauss, *Feast or Famine: The Impact of the WTO Decision Favoring the U.S. Biotechnology Industry in the EU Ban of Genetically Modified Foods*, 45 AM. BUS. L.J. 775 (2008) [hereinafter Strauss, *Impact of the WTO*].

[4] The World Trade Organization has rejected attempts by certain member states of the European Communities to ban genetically modified food under the safeguard measures exception to the The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) because of their failure to do a scientific risk assessment. The European Community (EC) states had argued that there was substantial scientific uncertainty as to the risks of bioengineered products and that the insufficiency of scientific evidence made it impossible to conduct risk assessments. *See* WTO, Reports of the Panel, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291, WT/DS292 and WT/DS293 (Sept. 29, 2006) at ¶¶ 8.9, 8.10, at 1069 [hereinafter "EC-Biotech"]. Article 5.7 of the SPS Agreement provides an exception to the risk assessment requirement:

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members.

WTO, Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (last visited Aug. 3, 2008); *see also* Strauss, *Impact of the WTO*, *supra* note 3, at 836–38 (discussing this decision and its implications in detail).

[5] *See* Clive James, *Global Status of Commercialized Biotech/GM Crops: 2006*, ISAAA BRIEFS NO. 35; *see also* Clive James, *Global Status of Commercialized Transgenic Crops: 2005*, ISAAA BRIEFS NO. 34, *available at* http://www.isaaa.org/Resources/publications/briefs/34/download/isaaa-brief-34-2005.pdf.

Electronic copy available at: http://ssrn.com/abstract=1523514

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

proliferated in the United States.[6] In the United States in 2007, 91% of all soybeans, 87% of cotton, and 73% of corn consisted of genetically modified strains, genetically engineered mainly to control weeds and insects.[7] As a result, most of the food products on U.S. grocery shelves now contain GMOs.[8]

The global biotech market currently produces $5.5 billion per year.[9] Monsanto, the biggest proponent of genetically modified crops, has touted record profits and reaps 60% of its revenue from biotech seeds.[10] These biotechnology companies have pressed the U.S. government to shape the law in favor of their property rights in this technology. Despite its foundation of natural plant material, the United States not only allows but vigorously encourages patenting the genetic modifications to these plants.[11] As a result, the number of agricultural biotechnology patents in the United States has risen dramatically. In plant technology, a total of 2,976 patents had been awarded as of 2000, 68% of which occurred in the most recent four-year period.[12] Similarly, 66% of the 4,129 total patents for genetic transformations were awarded between 1996 and 2000.[13] Out of all U.S. agricultural biotechnology patents awarded, most have been awarded to U.S. firms (4,331), followed by non-U.S. firms (3,051) and U.S. nonprofits (2,344). The U.S. government also owns a significant number of patents (421), mostly in joint ventures with private industry.[14]

As such patents have proliferated, ownership of these patents has become concentrated in a small number of companies, a trend which has been heightened by mergers in the industry.[15] One survey revealed that 71% of all agribiotechology patents are owned by the top five companies in the field: Pharmacia (now owned by Pfizer, Inc.) (21%, 287 patents), DuPont (20%, 279 patents), Syngenta (13%, 173 patents), Dow (11%, 157 patents), and Aventis (6%, 77 patents).[16] Most

---

[6] *Id.*

[7] USDA Economic Research Service, Adoption of Genetically Engineered Crops in the U.S., http://www.ers.usda.gov/data/BiotechCrops (last visited Aug. 2, 2008) (reporting figures for 2005 of 87% of soybeans, 79% of cotton, and 52% of corn).

[8] The Grocery Manufacturers of America (GMA) estimates that 75% of all processed foods in the United States contain a genetically modified ingredient, including almost every product with a corn or soy ingredient and some containing canola or cottonseed oil. The Associated Press, *Americans Clueless About Gene-Altered Foods*, Mar. 23, 2005, http://www.msnbc.msn.com/id/7277844/ (statement of Stephanie Childs, GMA).

[9] Strauss, *Impact of the WTO*, *supra* note 3, at 820.

[10] Brian Hindo, *Monsanto: Winning the Ground War*, BUS. WK., Dec. 6, 2007, *available at* http://www.businessweek.com/magazine/content/07_51/b4063034300400.htm?chan=magazine+channel_top+stories.

[11] The first genetically modified crop, a tomato, was sold in the market in 1994. *See* BELINDA MARTINEAU, FIRST FRUIT: THE CREATION OF THE FLAVR SAVR TOMATO AND THE BIRTH OF GENETICALLY ENGINEERED FOODS 269 (2001). For a discussion of U.S. patent law as applied to biotechnology, see *infra* notes 23–54 and accompanying text.

[12] Andres A. Gallo & Jay P. Kesan, *Property Rights Legislation in Agricultural Biotechnology: United States and Argentina*, 7 MINN. J.L. SCI. & TECH. 565, 580 (2006).

[13] *Id.*

[14] *Id.*

[15] *Id.* at 581. Since the early 1990s, Monsanto has purchased Holden's Foundation Seed for $1.2 billion, along with Asgrow, Agracetus, and Global Calgene, and obtained a forty percent hold on the seed company Dekelo. *See* Haley Stein, *Intellectual Property and Genetically Modified Seeds: The United States, Trade, and the Developing World*, 3 NW. J. TECH. & INTELL. PROP. 160, 164 (2005).

[16] Tzu-Ming Pan, *Current Status and Detection of Genetically Modified Organism*, 10 J. FOOD & DRUG ANALYSIS 229, 230 (2002) (citing ETC Group, Globalization Inc. Communique #71 (2001));

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

significantly, more than 90% of the genetically modified seeds in the world today are sold either by Monsanto or by licensees of Monsanto genes.[17]

At the international level, biotechnology companies have fought vigorously for recognition and enforcement of the rights to their seeds in the international community. Their efforts, and the pressure exerted internationally by the U.S. government on their behalf, resulted in the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),[18] a treaty that is generally recognized as the most robust embodiment of intellectual property rights. After analyzing the TRIPS Agreement in the context of the other treaties and national laws that preceded it, this Article will assess whether the biotech industry has succeeded in this effort and some of the potential negative social and economic impacts. This Article will compare the treatment of GMOs in the United States, as well as the treatment of GMOs by laws of other nations, to the application of TRIPS. It will then contrast TRIPS with other international laws that concern GMOs and have embraced the precautionary principle in restricting this technology. A few key questions will linger throughout the course of this journey. Are actions such as the U.N. ban on Terminator technology (GURTs)[19] inconsistent with TRIPS, or does such technology violate international principles? Moreover, does the application of TRIPS to GMOs contradict the U.N. Convention on Biological Diversity's affirmation of respect for the value of life?[20] Has there been any effort by the World Trade Organization (WTO) or the World Health Organization (WHO), through their study of food policy and safety, to reconcile these competing goals? What alternatives might be explored that would be a more appropriate use of intellectual property and which international organizations should oversee this regime?

Particular emphasis will be given to the broader issues of intellectual property rights as applied to developing countries that rely upon small farmers. Research has suggested that GMOs have failed to alleviate world hunger because in today's socioeconomic context, a quick "technofix" and emphasis on monocultures is insufficient.[21] Indeed, the use of GMOs may actually hamper efforts towards

---

see also Debra M. Strauss, *Genetically Modified Organisms in Food: A Model of Labeling and Monitoring With Positive Implications for International Trade*, 40 INT'L LAW. 95, 96 (2006) [hereinafter Strauss, *A Model of Labeling*].

[17] Hindo, *supra* note 10; *see also* JEREMY RIFKIN, HARNESSING THE GENE AND REMAKING THE WORLD: THE BIOTECH CENTURY 68 (1998) (describing the seed industry as a global $15 billion industry).

[18] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/27-TRIPS.pdf [hereinafter TRIPS Agreement].

[19] U.N. Convention for Biological Diversity (CBD), Agricultural Biodiversity Genetic Use Restriction Technologies (GURTs), http://www.biodiv.org/programmes/areas/agro/GURTs.aspx; *see* Ban Terminator, The Issues, http://www.banterminator.org/The-Issues/Introduction (last visited Aug. 5, 2008).

[20] U.N. Convention on Biological Diversity (CBD), June 5, 1992, 31 I.L.M. 818, *available at* http://www.cbd.int/convention/convention.shtml. The CBD was adopted in Rio de Janeiro in 1992 and has been ratified by 191 Parties. *See* IISD Linkages, A Brief Introduction to the Convention on Biological Diversity, http://www.iisd.ca/biodiv/cbdintro.html (last updated Feb. 18, 2000). The United States signed the CBD, but did not ratify it.

[21] *See* Debra M. Strauss, *Defying Nature: The Ethical Implications of Genetically Modified Plants*, 3 J. FOOD L. & POL'Y 1, 8–9 (2007) (discussing the failed promise of this technology and

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

food sustainability and biodiversity.[22] Accordingly, this justification for the recognition and enforcement of intellectual property rights may be misplaced and, in the long run, exacerbate world hunger.

In approaching the intellectual property rights of GMOs within the framework of the international regulatory scheme, one must determine whether the current system actually undermines the broader goals of the international community. Part I of this Article explores the intellectual property rights available in the United States for genetic material and plants, discussing well-established statutory patent law and how courts have applied it. Part II examines comparable European and national laws overseas, as well as the international impact of significant cases. Part III presents potential negative impacts and policy considerations that underlie the continuing controversy over the granting of intellectual property rights for living organisms, including issues of social ethics, the commodification of life, monopoly control, biodiversity, innovation, and the value of traditional knowledge. Given these concerns, Part IV analyzes the TRIPS Agreement in the context of the other international efforts and treaties embraced by members of the international community, with special attention to the options and strategies available to developing countries after TRIPS. Part V concludes that, overall, these treaties do not support the United States' approach to intellectual property for biotechnology. In light of critical issues of control and scarcity of resources, which cause particular disparities for farmers in developing countries, the patenting of GMOs in their current manner may prove to be ill advised. Ultimately, this application of intellectual property may undermine the public interest in the security of a global food supply. Therefore, efforts should focus on transforming intellectual property rights with a model and process that will openly utilize international trade to promote constructive innovation for the public benefit.

I. U.S. PATENT LAW AND GENETICALLY MODIFIED PLANTS

U.S. patent law grants strong, unequivocal protection for genetically modified plants. In the United States, the patenting of biotechnology has been encouraged by statutes and reinforced by the courts. The U.S. Constitution empowers Congress to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[23] In pursuit of this goal, the U.S. Patent Act of 1952 establishes the broad protection of "utility patents," giving the patent holder exclusive rights of use for a period of twenty years if the invention meets the requirements of novelty, nonobviousness, disclosure, patentable subject matter, and utility.[24] In defining patentable subject matter, § 101 authorizes the award of utility patents for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[25] There were early hints that

---

presenting an ethical framework in support of labeling and monitoring) [hereinafter Strauss, *Ethical Implications*].

[22] *Id.*

[23] U.S. CONST. art. I, § 8, cl. 8.

[24] U.S. Patent Act of 1952, 35 U.S.C. §§ 101–103 (2000).

[25] *Id.* § 101.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

the courts supported an expansive interpretation of this definition.[26] Then, in the landmark case *Diamond v. Chakrabarty*, the U.S. Supreme Court held that a live, genetically-engineered micro-organism came within the scope of patentable subject matter under § 101.[27] At issue was a "human-made, genetically engineered bacterium . . . capable of breaking down multiple components of crude oil" for which the U.S. Patent and Trademark Office (USPTO) had denied a patent on the grounds that § 101 did not allow patenting of living things.[28] Using sweeping language, the Court stated that "Congress intended statutory subject matter to include anything under the sun that is made by man."[29] Commentators have recognized the landmark nature of the *Chakrabarty* decision, which "extends protection to nearly anything that is not naturally occurring and can meet the other requirements of patentability."[30] The decision made clear that "the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability, as long as the invention is the result of human intervention."[31]

In *Ex parte Hibberd*, the Board of Patent Appeals and Interferences construed this language to mean that plants are a patentable life form, reversing the USPTO's denial of a patent application for a corn plant.[32] Thus, more complex living organisms—in this case a new plant variety with an extremely high level of amino acids—could qualify for a utility patent.[33] The applicant made over 260 separate claims for a single item that included DNA sequences and genes. After *Hibberd*, the PTO awarded over 1800 broad utility patents for germplasm.[34] The patentability of plants and seeds was confirmed in *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, which emphasized that "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."[35] Accordingly, the Supreme Court upheld the

---

[26] *See* Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156, 164 (4th Cir. 1958) (upholding patent of Vitamin B12 on the grounds that there is nothing in the language of the Patent Act of 1952 which precludes the issuance of a patent upon a "product of nature" when it is a new and useful composition of matter); *In re* Schechter, 205 F.2d 185 (C.C.P.A. 1953) (patent for synthesizing pyrethrin-like insecticides). *But see* CTS Corp. v. Electro Materials Corp. of Am., 469 F. Supp. 801, 818–22 (S.D.N.Y. 1979) (dismissing patent infringement claim for electrical resistance compositions due to the standard required to establish advancement over prior art).

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

[28] *Id.* at 305, 306. Under the "product of nature" doctrine, "a cell or other substance occurring in nature is not patentable unless it is given a substantially new form, quality, or property not present in the original." SCIENCE INFORMATION RESOURCE CENTER, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 50 (1988 ed.). Accordingly, the USPTO had historically denied patents for higher life forms such as mammals, fish, and insects as not patentable subject matter, until the Supreme Court in *Chakrabarty* widened its scope. *Id.*

[29] Chakrabarty, 447 U.S. at 303.

[30] Zachary Lerner, *Rethinking What Agriculture Could Use: A Proposed Heightened Utility Standard for Genetically Modified Food Patents*, 55 U. KAN. L. REV. 991, 1007 (2007).

[31] SCIENCE INFORMATION RESOURCE CENTER, *supra* note 28, at 49; *see also* Daniel J. Kevles, *Diamond v. Chakrabarty and Beyond: The Political Economy of Patenting Life*, *in* PRIVATE SCIENCE: BIOTECHNOLOGY AND THE RISE OF THE MOLECULAR SCIENCES, at 65 (Arnold Thackray ed., 1998).

[32] *Ex parte Hibberd*, 227 U.S.P.Q. 443, 443–44 (Bd. of Pat. App. & Interferences 1985).

[33] *Id.* at 444–45; *see also* Peter J. Goss, *Guiding the Hand that Feeds: Toward Socially Optimal Appropriability in Agricultural Biotechnology Innovation*, 84 CAL. L. REV. 1395, 1405 (1996).

[34] Stein, *supra* note 15, at 166 (citing Keith Aoki, *With Seeds & Deeds: Recent Skirmishes in the Seed Wars*, 11 CARDOZO J. INT'L & COMP. L. 247, 288 (2003)).

[35] *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001) (quoting *Chakrabarty*, 447 U.S. at 313).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

patentability of hybrid corn seed and newly developed plant breeds.[36] Subsequent decisions affirmed the patentability of animals, even mammals.[37]

Additional protection is provided by the U.S. Plant Patent Act of 1930,[38] which until 1970 served as the only source of intellectual property rights for inventions that contained living matter.[39] The Plant Patent Act provides that: "Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore . . . ."[40] By its terms, protection for plant breeders is limited to asexually reproducing plants that reproduce by means other than seeds, such as by the rooting of cuttings, budding, or grafting. Tubers (e.g., the Irish potato and the Jerusalem artichoke) and wild uncultivated plants are excluded from eligibility for these patents. Since many of the plant varieties used in commercial agriculture are sexually reproduced, the Plant Patent Act provides only limited protection for commercial plant breeders.[41]

In 1970, Congress enacted the Plant Variety Protection Act of 1970, which includes twenty-year protection for the breeder of "any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria)" that is new, distinct, uniform, and stable.[42] With its expanded coverage, the Plant Variety Protection Act provides a broad definition of the method of production: "An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, transformation by genetic engineering, or other method."[43] The Plant Variety Protection Act also established a Plant Variety Protection Office to issue these "certificates of plant variety protection."[44]

Unlike the Plant Protection Act, which offers intellectual property protection only to asexually reproducing plants and their offspring, the Plant Variety Protection Act extends protection to sexually reproducing plants and their seeds.[45] Though it expands protection, the Plant Variety Protection Act contains

---

[36] *Id.* at 127.

[37] *Ex parte Allen*, 2 U.S.P.Q.2d 1425, 1427 (Bd. of Pat. App. & Interferences 1987) (considering induction of polyploidy as a way to increase growth in cultured Pacific oysters to be patentable subject matter but rejecting patent claim on the grounds of obviousness due to existing patent for similar technique for Atlantic oysters), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988); Transgenic Non-Human Mammal, U.S. Patent No. 4,736,866 col.9 l.35 (filed June 22, 1984) (issued Apr. 12, 1988) ("a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal . . . .").

[38] U.S. Plant Patent Act of 1930, 35 U.S.C. § 161 (2003).

[39] Lara E. Ewens, Note, *Seedwars: Biotechnology, Intellectual Property, and the Quest for High Yield Seeds*, 23 B.C. INT'L & COMP. L. REV. 285, 292 (2000).

[40] 35 U.S.C. § 161.

[41] Tim Van Pelt, *Is Changing Patent Infringement Liability the Appropriate Mechanism for Allocating the Cost of Pollen Drift?*, 31 IOWA J. CORP. L. 567, 576 (2006); *see also* Roger A. McEowen, *Legal Issues Related to the Use and Ownership of Genetically Modified Organisms*, 43 WASHBURN L.J. 611, 629 (2004) (exploring the history of the Plant Patent Act).

[42] Plant Variety Protection Act, 7 U.S.C. § 2402 (2000).

[43] *Id.* § 2401(a)(3)(B).

[44] *Id.* §§ 2321, 2481.

[45] *See* Van Pelt, *supra* note 41, at 576, (comparing scope of protection under Plant Variety Protection Act and Plant Patent Act) (citing McEowen, *supra* note 41, at 630 & n 110).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

two critical exceptions. One allows breeders to use protected seed to create new varieties (the "research exception"); the other allows farmers to save seed from crops grown with the protected variety and replant them without compensating the breeder (the "saved-seed exemption").[46] Both of these exceptions, however, have been narrowed by Congress and the courts. In 1994, Congress passed amendments to the Plant Variety Protection Act to limit potential abuse and removed the sale provision from the saved-seed exemption, so that farmers can now sell seed only for food or feed, not for planting.[47] The courts have also limited these reciprocal rights. In *Asgrow Seed v. Winterboer*, the U.S. Supreme Court in effect narrowed the seed-saving exemption to farmers who saved seeds to plant their own crop.[48] An Iowa couple had saved the second generation of the Plant Variety Protection Act patented seeds originally bought from Asgrow Seed Company and sold them to a third party, claiming protection under the exemption; through the courts, the large seed company successfully stopped this practice.[49] This case, and others like it, eroded the farmer's common law right to save seeds in the United States, though that tradition persists in developing countries.

Currently most biotechnology applications are pursued under utility patents rather than plant patents,[50] further undermining the statutory exemptions put in place to protect the tradition of the small farmer and the innovative efforts of independent plant breeders. Aside from the plant itself, utility patents protect plant genes, including the use of the genetic material of multiple plants and the coverage of multiple uses and traits.[51] Moreover, because the Plant Variety Protection Act contains saved-seed and research exemptions, albeit narrowed, plant breeders seek the utility patent system for its wider scope of protection.[52]

Treatment by the courts and U.S. Patent Office, as well as a strong enforcement mechanism, has resulted in a proliferation of biotechnology patents. Under this regime and the explosion of patents that followed, there is statistical evidence of "a rush to patent new varieties," "an increase in private sector

---

[46] Plant Variety Protection Act, 7 U.S.C. § 2543 (2000); *see J.E.M. Ag. Supply, Inc.*, 534 U.S. at 140 (comparing Plant Variety Protection Act to utility patent protection).

[47] Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103–349, 108 Stat. 3138 (codified as amended at 7 U.S.C. § 2543 (1994)) (amending the Plant Variety Protection Act to make it consistent with the more robust International Convention for the Protection of New Varieties of Plants including restricting farmers' right of use); *see* Ewens, *supra* note 39, at n. 58; Goss, *supra* note 33, at 1409–11; McEowen, *supra* note 41, at 631–33.

[48] *Asgrow Seed v. Winterboer*, 513 U.S. 179 (1995).

[49] *Id.* at 192–193; *see also Delta & Pine Land Co. v. Peoples Gin Co.*, 694 F.2d 1012 (5th Cir. 1983) (ruling that farmers who save seed must do so on their own and not through other organizations such as farm cooperatives).

[50] Ewens, *supra* note 39, at 293. *But see* Goss, *supra* note 33, at 1414 (noting that the Plant Variety Protection Act is often still an attractive option because plant patents are not available for sexually reproducing plants and utility patents are often very expensive and difficult to obtain).

[51] Goss, *supra* note 33, at 1414 (citing Frederic H. Erbisch & Carlos Velazquez, *Introduction to Intellectual Properties*, *in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY 3, 9 (F.H. Erbisch & K.M. Maredia eds., 1998)).

[52] *See* Van Pelt, *supra* note 41, at 575–6. The Supreme Court has attributed this difference to the fact that, unlike utility patents, the Plant Variety Protection Act does not have requirements such as nonobviousness: "because of the heightened requirements for obtaining a patent, 'utility patent holders receive greater rights of exclusion than holders of a PVP certificate. Most notably, there are no exemptions for research or saving seed under a utility patent.'" *Id.* at 577 (quoting *J.E.M. Ag. Supply, Inc.*, 534 U.S. at 143) (holding that neither the Plant Patent Act nor the Plant Variety Protection Act can limit the scope of a utility patent).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

participation in seed production," and "an increase in the number of utility patents devoted to biotechnology patents for new varieties."[53] Purportedly, these developments "helped to foster research and development efforts in biotechnology and the creation and adoption of genetically modified seeds."[54] Moreover, the United States has made significant strides in its efforts to propagate this view of international property of genetically engineered living matter—with seeds as a licensed commodity—overseas.

II. EUROPEAN AND NATIONAL TREATMENT OVERSEAS

Despite the sharp differences between the European Community's and the United States' regulatory treatment of genetically modified foods in matters of human health and environmental safety,[55] both have rigorous and well-enforced systems in the intellectual property arena.[56] Like the United States, Europe permits patent protection of genetically modified animals and plants.[57] The European Patent Office has even granted a patent on a non-human mammal, the "Harvard Mouse,"[58] despite an argument that patents on living organisms violate Article 53(a) of the European Patent Convention, which precludes patentability for "inventions the commercial exploitation of which would be contrary to 'ordre public' or morality."[59] Even more than the interests of international trade,[60] intellectual property rights provide a common link between the European Union and the United States. This mutual recognition may serve as starting point to address the important policy issues that will shape the direction of food and genetic resources in the international community.

One of the most infamous cases of patent infringement that had an enormous impact on the international community was *Monsanto Canada, Inc. v.*

---

[53] Gallo & Kesan, *supra* note 12, at 579; for statistics on patent awards, see *supra* notes 14–16 and accompanying text.

[54] Gallo & Kesan, *supra* note 12, at 579.

[55] *See* Strauss, *Importing Caution*, *supra* note 1 (analyzing the U.S. and E.U. regulatory treatment of GMOs and proposing that the United States adopt a more cautious model of labeling and monitoring).

[56] Andrew W. Torrance, *Intellectual Property as the Third Dimension of GMO Regulation*, 16 KAN. J. L. & PUB. POL'Y 257, 265 (2007).

[57] *Id.*

[58] Method for producing transgenic animals, European Patent No. EP0169672 (published Jan. 29, 1986); Harvard/Onco-mouse, 1992 O.J. E.P.O. 588, 593 (Examining Division) (this is the European equivalent of U.S. Patent No. 4,736,866, *supra* note 35); *see* Torrance, *supra* note 56, at 280; *see also* Jerzy Koopman, *The Patentability of Transgenic Animals in the United States of America and the European Union: A Proposal for Harmonization*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 103 (2002) (comparing the patentability of animals in the European Union and the United States).

[59] Convention on the Grant of European Patents, art. 53(a), Oct. 5, 1973, as amended by the Act revising the European Patent Convention, Nov. 29, 2000 (EPC 2000), *available at* http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar53.html. European Patent Convention Article 53(a) is similar to TRIPS Article 27(2), discussed *infra* notes 133 and 172 and accompanying text. *See* Torrance, *supra* note 56, at n. 124; *see generally* IAN MUIR, ET AL., EUROPEAN PATENT LAW: LAW AND PROCEDURE UNDER THE EPC AND THE PCT 122–124 (Oxford University Press, 1999).

[60] *See* Strauss, *Impact of the WTO*, *supra* note 3, at 779 (characterizing the E.C.-Biotech dispute as a disruption in trade between the United States and the European Union caused by their different regulatory approaches toward GMOs, which are in turn a reflection of the differing views and levels of concern about genetically modified food in the face of scientific uncertainty).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

Schmeiser.[61] The Supreme Court of Canada ruled that Percy Schmeiser, a farmer in Saskatchewan, infringed a Monsanto patent under the Canadian Patent Act although he never deliberately purchased or used genetically modified seeds.[62] The patented product was a canola seed genetically engineered to be resistant to Roundup Ready® herbicide (glyphosate), so that the crops survive field-spraying with Roundup Ready® targeting the weeds. Schmeiser claimed, and it was generally accepted, that the genetically modified seed had blown accidentally into his fields and mixed with his crop.[63] A visual inspection alone would not have detected the genetic modification; the genetically modified variety could only be distinguished from the non-genetically modified plant through a chemical test or microscopic inspection. Schmeiser apparently realized the presence of the genetically modified crop after some of his canola survived repeated sprayings of the herbicide, but he took no action to notify Monsanto or remove the plants. There was some evidence presented that he subsequently replanted the patented seed along with his own the following year,[64] but the contamination with the patented seeds also destroyed Schmeiser's years of work to develop his own strain of canola. None of this was determinative, however: the court held that the mere presence of the patented crop in his field without licensing from or payment to Monsanto constituted infringement of the patent.[65] Rejecting Schmeiser's contention that the gene and cell were unpatentable because they could be replicated without human intervention, the court determined the patent was presumptively valid.[66] Moreover, it determined that protection of a patented gene or cell extends to its presence in a whole plant, even while the plant itself, as a higher life form, cannot be patented.[67] On appeal, the Supreme Court of Canada affirmed the finding of infringement but overturned the award of damages for Monsanto (upwards of $150,000 Canadian by the trial court) because Schmeiser did not use the herbicide on his crops and thus did not benefit from the Roundup Ready® gene.[68] It is significant, however, that patent infringement occurred even without intent or use of the gene.[69]

The *Schmeiser* case was only the beginning and had ramifications well beyond Canada. In the United States, Monsanto has filed one hundred seed piracy cases and, thus far, has succeeded every time; the courts have already awarded

---

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

[62] Patent Act, R.S.C., ch. P-4, 44 (1985) (Can.).

[63] The fields of several nearby neighbors grew the Monsanto patented crop, having purchased the seed and signed licensing agreements with Monsanto. Even Monsanto's lead investigator admitted a lack of any evidence that Schmeiser illegally obtained the patented gene. *See generally* Stephanie M Bernhardt, *High Plains Drifting: Wind-Blown Seeds and the Intellectual Property Implications of the GMO Revolution*, 4 NW. J. TECH. & INTELL. PROP. 2, 2–6 (2005) (discussing background of the case and facts about windblown seeds).

[64] Van Pelt, *supra* note 41, at 569–70.

[65] *Schmeiser*, 1 S.C.R. at 911, 930.

[66] *Id.* at 939, para. 14; 943, para. 24.

[67] *Id.* at 940, para. 17.

[68] *See* Bernhardt, *supra* note 63, at 3 (discussing seed patent infringement cases and proposing the stray animal defense for suits against small farmers due to pollen drift); *see also* Van Pelt, *supra* note 41, at 569–571.

[69] Note that the United States takes a similar approach, finding infringement where the use of the patented material took place without the authorization of the owner, regardless of knowledge or intent of the infringer. "Intent to utilize a patented invention is not an element of any form of infringement." Bernhardt, *supra* note 63, at 8.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

Monsanto over fifteen million dollars.[70] Faced with the prospect of being sued by the seed giant, many small farmers feel threatened and harassed.[71] As a result, many farmers in Canada and the United States will sign Monsanto's technology license with its silencing provisions rather than face the possibility of the high cost of litigation.[72] In fact, many farmers have been forced out of business by Monsanto's lawsuits due to the enormous legal costs and court injunctions that permanently prohibit the farmers from selling Monsanto's products.[73]

The disparity in resources and lopsided incentives that stifle economic sustainability render the application of patent laws to this "passive use" of genetically modified seeds inappropriate and against the interests of society.[74] This is true particularly in the case of pollen drift, where the farmers did not intend to use the genetically modified seed and could arguably sue for contamination and economic loss, especially if the farm was organic.[75] If the companies creating GMOs truly do not want the spread of their organisms, they seem to be in the best position in terms of knowledge and control to stop it. Shifting legal liability onto these companies would provide the economic incentive for them to take adequate measures to prevent such pollen drift in the future.[76] Many proposals for modifications to the current system of intellectual property rights as applied to biotechnology have been suggested.[77] Ultimately, however, these adjustments may

---

[70] *Id.* at 9; *see also* A REPORT BY THE CENTER FOR FOOD SAFETY, MONSANTO VS. U.S. FARMERS 5 (2005).

[71] *See Agricultural Giant Battles Small Farmers*, CBS NEWS, Apr. 26, 2008, http://www.cbsnews.com/stories/2008/04/26/eveningnews/main4048288.shtml (reporting cases where Monsanto sent investigators onto small farms to sample seeds without permission, employed questionable tactics to interfere with customers, demanded voluminous records, and threatened to sue individual small farmers).

[72] Bernhardt, *supra* note 63, at 10, 11. Percy Schmeiser reportedly spent $400,000 (Canadian) on his failed battle with Monsanto, an unwieldy sum for most farmers; in contrast, Monsanto has a budget of $10 million and a staff of seventy-five investigators. *Id.*

[73] A REPORT BY THE CENTER FOR FOOD SAFETY, *supra* note 70, at 21 (2005), *cited in* Peter Straub, *Farmers in the IP Wrench—How Patents on Gene-modified Crops Violate the Right to Food in Developing Countries*, 29 HASTINGS INT'L & COMP. L. REV. 187, 191 (2006).

[74] *Id.*

[75] Perhaps the same inequity of resources is the only reason more farmers have not pursued their legal rights in this manner. *See generally* DAVID R. MOELLER, GMO LIABILITY THREATS FOR FARMERS: LEGAL ISSUES SURROUNDING THE PLANTING OF GENETICALLY MODIFIED CROPS (Farmers' Legal Action Group, Inc. 2001); *see also* Margaret R. Grossman, *Biotechnology, Property Rights and the Environment*, 50 AM. J. COMP. L. 215, 247 (2002) (discussing common-law tort actions as a remedy to the general public and to property owners who have suffered economic losses from Cross-pollution and commingling, "especially when growers plant GM crops not approved for all uses and by important trading partners"); Strauss, *Importing Caution*, *supra* note 1, at 192 (citing Tana N. Vollendorf, Comment, *Genetically Modified Organisms: Someone is in the Kitchen with DNA—Who is Responsible When Someone Gets Burned?*, 21 MISS. C.L. REV. 43 (2001)) (raising general liability issues); A. Bryan Endres, *"GMO:" Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damages in the United States and the European Union*, 22 LOY. L.A. INT'L & COMP. L. REV. 453 (2000).

[76] *Cf.* Van Pelt, *supra* note 41, at 577–78 (arguing that since the pollen drift generates costs for the farmers who want to avoid passive infringement or who want to preserve genetic purity in their crops, the patent holder should be forced to internalize the costs related to the spread of its own patented genes).

[77] *See, e.g.*, Baruch Brody, *Intellectual Property and Biotechnology: The U.S. Internal Experience—Part II*, 16 KENNEDY INST. OF ETHICS J. 105 (2006) (proposing modifications in intellectual property rights as applied to biotechnology, including alternate disclosure requirements, exemptions for research tools, and improved access to clinical advances); Ewens, *supra* note 39 (proposing a reduction in the length of time patents extend protection to plant varieties); Lerner, *supra*

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

not go far enough to address the fundamental issues and incentives. A closer examination of the detrimental implications raises compelling reasons to reconsider this patent regime in the area of biotechnology.

III. POTENTIAL NEGATIVE IMPACTS

Unlike in other areas of inventive work product, the application of intellectual property protection for plant and genetic material can lead to significant negative consequences. The logical gap between patent infringement and liability illustrated by the pollen-drift cases suggests we ought to reconsider whether this system works for or against our long-term goals of maintaining the integrity of the ecosystem and enhancing food security, which can be better achieved by encouraging containment. Intellectual property rights and the patentability of life raise ethical and legal issues regarding patents on living organisms as well as questions about the soundness, as a matter of public policy, of granting such property rights.

Perhaps there are flaws in the legal treatment of GMOs as a property interest suitable for protection by treaties, the courts, and other international bodies. When viewed from the perspective of global resources and the developing world, the problem becomes more acute, raising concerns of equity, biodiversity, and the adverse economic and cultural effects of reverse biopiracy. Accordingly, this Part will explore, in turn, compelling issues of social ethics and commodification of life; monopoly control over biodiversity; encouraging innovation or acting as an impediment; and developing countries with the value of traditional knowledge.

A. Pirated and Sterile Seeds

The patenting of genetic material is fundamentally problematic as it involves issues of social ethics and cultural norms, such as respect for nature and the value of life.[78] The increasing removal of genetic material and plant resources from the natural world through privatization of plant genetic research and control of biotech crops exacerbates the disparity between public and private access to these resources.[79] As an added dimension, the germplasm of developing countries has

note 30 (arguing for an increased utility standard); and Van Pelt, *supra* note 41 (exploring possible counterclaims that could be raised in cases of pollen drift and recommending restrictions be imposed by regulatory agencies).

[78] *See* Strauss, *Ethical Implications*, *supra* note 21, at 21–23; Gautam Naik, *Switzerland's Green Power Revolution: Ethicists Ponder Plants' Rights*, WALL ST. J., Oct. 10, 2008, at A1 (under a new constitutional amendment in Switzerland, scientists seeking government permission to do a field trial of genetically modified crops must address ethical questions on the flora's dignity); Keith Douglass Warner, *Are Life Patents Ethical? Conflict Between Catholic Social Teaching and Agricultural Biotechnology's Patent Regime*, 14 J. AGRIC. & ENVTL. ETHICS 301, 316 (2001), *available at* http://www2.ucsc.edu/cgirs/research/environment/afsrg/publications/Warner_2001.pdf (stating that "[t]he privatization of germplasm formerly considered the common heritage of humankind is incompatible with notions of the common good and economic justice"). *See generally* DONALD BRUCE & ANN BRUCE, ENGINEERING GENESIS: THE ETHICS OF GENETIC ENGINEERING IN NON-HUMAN SPECIES (1998); MARTIN TEITEL & HOPE SHAND, THE OWNERSHIP OF LIFE: WHEN PATENTS AND VALUES CLASH (1997).

[79] Ewens, *supra* note 39, at 306.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

generally been thought of by these countries as "a free good, part of the cultural commons and the common heritage of humankind."[80]

Biotechnology companies have strived to wield control over seeds and their "new" variations as company property.[81] Large businesses such as Monsanto require farmers who purchase their genetically modified seeds to sign contracts that prohibit their reuse of the seed so that they must repurchase additional seed each year. However, these contracts prove particularly difficult to enforce in developing countries.[82] Monsanto has aggressively pursued farmers who follow the traditional farming practice of saving and replanting seeds, accusing them of "pirating" its patented varieties.[83] As seen in the case of Percy Schmeiser, under the patent law rubric companies have even sued farmers for unintentional seed drift into their fields, a scenario that could more appropriately be viewed as contamination and warrant a countersuit by the farmer.[84] There have been notable exceptions to this, as in the case of LibertyLink® Rice, where U.S. rice farmers, representing the industry as a whole, sued the manufacturer for their economic loss due to contamination of the national rice crop.[85] Generally, however, the strategy of the biotech companies prevails despite its lack of logic or appropriateness in terms of public policy.

In addition to these legal actions, biotech companies recently developed a direct intellectual property enforcement mechanism referred to as "Terminator" technology.[86] The plants effectively self-destruct at the end of their cycle, requiring farmers to purchase new seeds every year and overriding nature's germination of future generations.[87] From an ethical perspective, Terminator seeds represent the

---

[80] *Id*. at 289.

[81] *See* Strauss, *Ethical Implications*, *supra* note 21, at 23.

[82] *See* Stein, *supra* note 15, at 168; Aoki, *supra* note 34, at 255.

[83] Brian Tokar, *Resisting Biotechnology and the Commodification of Life*, 18 SYNTHESIS/REGENERATION, Winter 1999, *available at* http://www.greens.org/s-r/18/18-01.html; *see also* Miguel A. Altieri & Peter Rosset, *Ten Reasons Why Biotechnology Will Not Ensure Food Security, Protect the Environment and Reduce Poverty in the Developing World*, 2 AGBIOFORUM 155, 156 (1999), *available at* http://www.agbioforum.org/v2n34/v2n34a03-altieri.htm (arguing that "[b]y controlling germplasm from seed to sale, and by forcing farmers to pay inflated prices for seed-chemical packages, companies are determined to extract the most profit from their investment").

[84] See the discussion of the *Schmeiser* case, *supra* notes 61–69 and accompanying text.

[85] LibertyLink® Rice (LL 601), a genetically modified rice from the United States that was in an experimental trial phase and not approved for human consumption, was found on supermarket shelves in the EU. As a result, Japan and the EU placed strict limits on U.S. rice imports and U.S. rice prices dropped dramatically. A class-action lawsuit was subsequently filed by rice farmers in Arkansas, Missouri, Mississippi, Louisiana, Texas, and California against Bayer CropScience, alleging its genetically modified rice contaminated the crop and caused severe economic loss. *See* Alexander, Hawes & Audet, LLP, Bayer GM Rice (Genetically Modified Liberty Link Rice) Lawsuit Investigation,

http://www.alexanderlaw.com/bayer-crop-science/index.html?source=GOOGLE&campaign=RICE&gclid=CMW6v_vEnIgCFRt7UAodl34RTw; Physorg.com, *GM Rice from U.S. found in EU* (Sept. 13, 2006), http://www.physorg.com/news77388811.html (Genetically modified rice from the United States has been found in the European Union, in violation of a ban on import, growth and sale of such crops.). This new approach by the farmers—a class action so widespread that it represents the industry as a whole—if successful, may be the beginning of a turning tide, as was seen in the tobacco litigation.

[86] This technology was developed in a joint venture between the U.S. Department of Agriculture (USDA) and the Delta and Pine Land Company, which has since been purchased by Monsanto. U.S. Patent No. 5,977,441 (filed Nov. 2, 1999); U.S. Patent No. 5,925,808 (filed July 20, 1999); U.S. Patent No. 5,723, 765 (filed Mar. 3, 1998). *See generally* Tokar, *supra* note 83.

[87] *Id. See* Strauss, *Ethical Implications*, *supra* note 21, at 23; *see also* Sina Muscati, *Terminator*

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

height of commodification. Biotechnology companies—in a joint development effort with the U.S. Department of Agriculture (USDA)—have taken away the essential function of life to reproduce. As one critic has observed, "[f]rom a marketing perspective, the technology is brilliant. From a social perspective, it's pathological. This is a question of who controls the seeds of life."[88] Sterile seeds pose particular problems for small farmers in developing countries, who rely upon the tradition of saving seeds to replant for the next year. Moreover, if spread through common cross-pollination, these seeds could have a catastrophic impact on the global food supply.[89] Recognizing these dangers, the United Nations through the United Nations' Convention on Biological Diversity (CBD) in 2000 implemented a de facto moratorium on sterile seed technologies under the term "Genetic Use Restriction Technologies" (GURTs).[90] Despite pressure from Canada, Australia and New Zealand, along with the U.S. government and the biotechnology industry, the CBD has nevertheless maintained the international de facto moratorium on Terminator technology.[91] However, this technology continues to advance with the support of other countries that persist in the issuance of patents.[92] Sterile seed technology thus represents the logical extreme in the utilization of intellectual property for genetic modifications, reflecting broader issues of ownership and the appropriateness of patenting life forms.

Technology: Protection of Patents or a Threat to the Patent System?, 45 IDEA 477, 483 (2005) (analyzing intellectual property aspects of Terminator technology and potential restrictions under the current patent system).

[88] Ewens, *supra* note 39, at 307, citing Jeffrey Kluger et al., *The Suicide Seeds Terminator genes could mean big biotech buck—but big trouble too, as a grass-roots protest breaks out on the Net,* TIME, Feb. 1, 1999.

[89] *Id.*; *see also* Strauss, *Ethical Implications*, *supra* note 21, at 31–32; Samantha M. Ohlgart, Note, *The Terminator Gene: Intellectual Property Rights v. The Farmers' Common Law Right to Save Seed*, 7 DRAKE J. AGRIC. L. 473 (2002) (discussing legal and ethical issues raised by Terminator technology, including the opposition of developing countries). *But see* Jeremy P. Oczek, Note, *In the Aftermath of the 'Terminator' Technology Controversy: Intellectual Property Protections for Genetically Engineered Seeds and the Right to Save and Replant Seeds*, 41 B.C. L. REV. 627 (2000) (arguing that use of the terminator technology in genetically engineered seeds would be an effective way to enforce existing intellectual property protections and that public property doctrines would fail to recognize a common law right to save and replant seed).

[90] Ban Terminator, The Campaign, http://www.banterminator.org/The-Campaign (last visited Aug. 5, 2008). *See* CBD, Agricultural Biodiversity Genetic Use Restriction Technologies (GURTs), http://www.biodiv.org/programmes/areas/agro/gurts.aspx (last visited Aug. 5, 2008); *see also* Naik, *supra* note 78, at A9 (concluding that sterile technology would be banned in Switzerland under a new constitutional amendment because a panel interpreting the law argued that the dignity of the plants could be safeguarded "as long as their independence, i.e., reproductive ability and adaptive ability, are ensured.").

[91] Press Release, Ban Terminator, UN Upholds Moratorium on Terminator Seed Technology, Worldwide Movement of Farmers, Indigenous Peoples and Civil Society Organizations Calls for Ban, Mar. 31, 2006, http://www.banterminator.org/News-Updates/News-Updates/UN-Upholds-Moratorium-on-Terminator-Seed-Technology (last visited Aug. 5, 2008).

[92] Ban Terminator, Delta & Pine Land, developer of Terminator seeds, extends global reach, May 22, 2006, http://www.banterminator.org/News-Updates/News-Updates/Delta-Pine-Land-developer-of-Terminator-seeds-extends-global-reach (last visited Aug. 5, 2008). Monsanto has indicated that is has not ruled out future development of this technology. Monsanto, Is Monsanto Going to Develop or Sell "Terminator" Seeds?,
http://monsanto.mediaroom.com/index.php?s=59&item=136?s=59&item=136 (last visited Aug. 9, 2008).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

B. Creation of Monocultures

At the core of this issue is the fact that a small number of corporations are taking legal and physical control over the world's food supply, decreasing biodiversity while working within systems of ownership at the genetic level.[93] Some commentators consider the underlying problem with Terminator technology, as well as all GMO patents, to be a fear of monopoly control over agriculture.[94] Intellectual property control is critical for the food supply and serves as a way of regulating GMOs, "[s]ince patents do often act as the gatekeepers to access to new varieties of GM food."[95] The agrochemical industry increasingly dictates the decisions that farmers make each year about that season's crops through the systematic patenting of seed varieties and the restricting of plant and pesticide usage under contract.[96] Large monoculture genetically modified crops become dominant, diminishing the small traditional farms as well as the diversity of other plants; this decrease in biodiversity threatens the long-term stability of the planet and security of the global food supply.[97] Moreover, the self-destruct mechanism embedded in each plant with the Terminator has reached the pinnacle of corporate domination over these natural resources and, from this perspective, may offer better monopoly control than patents.[98] The issues of patents on living organisms, ag-biotech monopolies, and the creation of monocultures also raise serious questions about the soundness of genetically engineering the world's food supply.[99] These companies threaten to squeeze out the voices of small farmers and consumers in the debate about genetically engineered food to protect their financial interests in the technology.[100] Relying on a handful of self-interested corporations to make important and far-reaching decisions about agriculture and food cannot possibly result in equitable policies. The current system of awarding intellectual property rights for these genetic modifications necessitates this result.

C. Constricting Markets, Innovation, and Scientific Resources

One general argument in favor of patent protection is the need for

---

[93] Most of these genetically modified crops are owned by "a small number of transnational corporations who have come to dominate seed markets by buying up seed companies and smaller competing biotechnology companies." Today the ten leading seed companies dominate 30% of the world seed market; and shape the development of domestic and international intellectual property regimes. Straub, *supra* note 73, at 189–90.

[94] *See, e.g.*, Torrance, *supra* note 56, at 275–278.

[95] *Id.* at 276.

[96] *See* Tokar, *supra* note 83.

[97] *See* NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION (2000); Declan Butler & Tony Reichhardt, *Long-Term Effect of GM Crops Serves Up Food for Thought*, NATURE, Apr. 22, 1999, at 651–56; John E. Beringer, *Releasing Genetically Modified Organisms: Will Any Harm Outweigh Any Advantage?*, 37 J. APPLIED ECOLOGY 207 (2000); Anthony J. Conner et al., *The Release of Genetically Modified Crops Into the Environment*, 33 PLANT J. 19 (2003); Stephen Tromans, *Promise, Peril, Precaution: The Environmental Regulation of Genetically Modified Organisms*, 9 IND. J. GLOBAL LEGAL STUD. 187 (2001).

[98] *See* Torrance, *supra* note 56, at 278; Strauss, *Ethical Implications*, *supra* note 21, at 31.

[99] *See* Strauss, *Importing Caution*, *supra* note 1, at 169.

[100] *See* Straub, *supra* note 73, at 190.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

innovation and the recognition that without the promise of exclusivity, no biotechnology company would have the financial incentive to commit to research and development.[101] Although this argument applies well to drug development, gene-based pharmaceutical products present a different public interest than do plant patents, for which the benefits for society have not been established.[102] Moreover, there is evidence that allowing such monopolies by patents on genes hampers scientific progress and is therefore not in the public interest.[103]

Patents can have a negative effect on society. "[T]he more costly and restricted the access to information protected by patents, the more inefficient the market."[104] In the area of biotechnology, patents run counter to the ideal of public discourse and free access to information by removing from the public domain information that is needed to build upon to create future inventions. Overprotection of high-yield seeds could critically restrict farmers' ability to plant the most desirable crops and the capacity of farmers and seed companies to develop future generations of seeds. "The result would be the underutilization of genetic resources that have been in the cultural commons for over 10,000 years."[105] The impact on the global food supply could be catastrophic.

A further dilemma involves conflicts of interest from the issuing of patents to universities.[106] Starting in 1980, coinciding with the beginning of biotechnology patenting, patents became available for universities and other nonprofit institutions on federally funded inventions, with the federal agency retaining a nonexclusive worldwide license.[107] The Patent and Trademark Amendment Act requires universities to share royalties with the inventor and to use their share for research,

---

[101] *See, e.g.*, William A. Haseltine, *The Case for Gene Patents*, 59 MIT TECH. REV. (2000), http://www.mit-technology-review.com/BizTech/wtr_12164,311,p1.html?PM=GO (arguing that patents for gene-based pharmaceutical products are necessary for drug development). *But see* Michael Crichton, *Patenting Life*, N.Y. TIMES, Feb. 13, 2007, *available at* http://www.nytimes.com/2007/02/13/opinion/13crichton.html (arguing that gene patents are being used to halt research, prevent medical testing, keep vital information from patients and doctors, slow the pace of medical advance on deadly diseases, and raise costs exponentially). *See generally* Konstantinos Giannakas, *Infringement of Intellectual Property Rights: Causes and Consequences*, 84 AM. J. OF AGRIC. ECON. 482 (2002) (analyzing economic causes of intellectual property rights infringement and its consequences for the pricing and adoption of new technology).

[102] *See* Strauss, *Ethical Implications*, *supra* note 21 (discussing the failed promise of the technology and the violation of ethical principles embodied by GM plants).

[103] *See* WORLD HEALTH ORGANIZATION (WHO), MODERN FOOD BIOTECHNOLOGY, HUMAN HEALTH AND DEVELOPMENT: AN EVIDENCE-BASED STUDY 55 (2005) [hereinafter WHO Study], *available at* http://www.who.int/foodsafety/publications/biotech/biotech_en.pdf; Antonio Regalato, *The Great Gene Grab*, 59 MIT TECH. REV. (2000), http://www.technologyreview.com/read_article.aspx?id=12184&ch=biotech (arguing that the frenzy of gene patenting will not drive innovation but will stifle medical advances).

[104] Ewens, *supra* note 39, at 291; *see also* JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY xii (1996).

[105] Id. at 292; *see also* Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection*, 6 IND. J. GLOBAL LEGAL STUD. 11, 20, 21 at 35 (1998).

[106] *See* Strauss, *Ethical Implications*, *supra* note 21, at 32–33.

[107] 35 U.S.C.A. §§ 200–211 (1980); 37 C.F.R. § 401 (1989); 45 C.F.R. § 650 (1992). *See* SCIENCE INFORMATION RESOURCE CENTER, *supra* note 28, at 50. During the first five years, from 1980–1984, patent applications by universities and hospitals for inventions containing human genetic material increased more than 300 percent as compared with the prior five-year period, amounting to 33 percent of their total patent applications. *Id.*

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

development, and education.[108] With a direct financial stake in the outcome of their research, this practice may discourage inquiry into the risks of the technology, and potentially divert research from sustainability and environmentally friendly alternatives.[109] Some critics raise concerns that these intellectual property practices actually impede the development of more beneficial genetically engineered crops, such as those that might offer drought resistance or enhanced nutrition for the malnourished. In July 2003, a coalition of public sector research institutions established the Public-Sector Intellectual Property Resource for Agriculture (PIPRA), funded by the Rockefeller and McKnight Foundations.[110] PIPRA contends that "the benefits of much publicly funded research come to private industry through university technology transfer programs, limiting universities' flexibility to conduct research."[111] The fear is that biotechnology patents will not be applied to enhancements that could help the impoverished but offer only minimal commercial value.[112]

D. Discouraging Developing Countries

Many experts have noted the inequities of the current system of intellectual property protection as applied to developing countries in the area of biotechnology. Imposing a Western view of intellectual property that fails to protect traditional knowledge creates a one-way flow of genetic resources from the South (*i.e.*, developing countries abundant in germplasm) to the North (*i.e.*, industrialized nations advanced in biotechnology).[113] The genetically modified organisms and plants are then patented and removed from the public domain, while their use back in the developing country from which they originated, without permission and payment, is labeled "biopiracy."[114] Yet the genetic material upon which the patent

---

[108] *Id.*

[109] *See* Strauss, *Ethical Implications*, *supra* note 21, at 32–33; *see also* William B. Lacy, *Commercialization of University Research Brings Benefits, Raises Issues and Concerns*, 54 CAL. AGRIC. 72 (2000) (discussing concerns that collaborations between the University of California and industry may narrowly redirect research agendas, disrupt long-term research and create conflicts of interest).

[110] Richard C. Atkinson et al., *Public Sector Collaboration for Agricultural IP Management*, 301 SCI. 174 (2003); Public Sector Intellectual Property Resource for Agriculture (PIPRA), http://www.pipra.org/ (last visited Aug. 8, 2008).

[111] Diane E. Hoffman & Lawrence Sung, Symposium Report: *Future Public Policy and Ethical Issues Facing the Agricultural and Microbial Genomics Sectors of the Biotechnology Industry*, 24 BIOTECHNOLOGY L. REP. 10, 15 (2005).

[112] *Id.*

[113] *See* Ewens, *supra* note 39, at 289. *See generally* Neil D. Hamilton, *Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge: Forced Feeding: New Legal Issues in the Biotechnology Policy Debate*, 17 WASH. U. J.L. & POL'Y 37, 52–53 (2005).

[114] "Pharmaceutical, seed and agrochemical industries . . . coined the term 'biopiracy' to denote the extraction and utilization of traditional knowledge, associated biological and genetic resources, and the acquisition of intellectual property rights on inventions derived from such knowledge or resources without providing for benefit-sharing with the individuals or community that provided the knowledge or resources." Daniel J. Gervais, *The Internationalization of Intellectual Property: New Challenges from the Very Old and the Very New*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 929, 961(2002) (exploring the history of the internationalization of intellectual property and the need to provide protection of traditional knowledge in developing countries); *see also* J.M. Spectar, *Patent Necessity: Intellectual Property Dilemmas in the Biotech Domain & Treatment Equity for Developing Countries*, 24 HOUS. J. INT'L L. 227, 230–42 (2002) (contending that the North/South conflict over the nature,

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

is based comes from farmers in those countries who have enhanced plant species and genetic diversity over generations without private ownership rights in the common heritage to which they have contributed.[115]

Small and peasant farmers are ill-suited to genetically modified crops, which are "the antithesis of sustainable and self-reliant food production."[116] The aggressive promoting of intellectual property rights by biotechnology companies and their governments challenges traditional seed saving and sharing.[117] Under the intellectual property system being forced upon them, farmers become dependent on seed companies and need to change their farming practices, cultivating "cash crops" to sell for export to afford to buy more seed; the shift and limitation in crops, together with the elimination of farmers unable to pay licensing fees or defend lawsuits, further jeopardizes food production in these countries.[118] In response to the global nature of this technology, an international roundtable raised the issue of legal harmonization in the framework of intellectual property and public health and safety regulations, as well as in the context of natural resource and expertise disparities.[119] These experts also concluded that the laws should advance scientific research that helps developing countries with new technologies.[120]

These complex issues underlie the continuing controversy over granting intellectual property rights for living organisms, particularly ones that have been genetically engineered by biotechnology companies. With these considerations in mind, this Article next analyzes the major international treaties in this area—the TRIPS Agreement and its progeny—and how they impact and shape the direction of trade policy, socioeconomic development, and ultimately, the world food supply.

IV. THE TREATMENT OF GMOS BY TRIPS AND OTHER TREATIES

Securing intellectual property protection for its agricultural industry was a major goal of the United States during the TRIPS negotiation.[121] The United States has forged ahead in the expansion of these intellectual property rights as a

purpose, and extent of intellectual property rights, as seen with the patentability of plant genetic resources and their pharmaceutical products, presents a barrier to achieving treatment equity for developing countries).

[115] Their traditional agricultural innovation is not eligible for patent protection under the current intellectual property regime because it fails to meet the "innovation," "novelty," and "inventiveness" requirements. *See* Ewens, *supra* note 39, at 298; *see also* World Intellectual Property Organization (WIPO), *Intellectual Property Needs and Expectations of Traditional Knowledge Holders*, WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge 21–22 (1998–1999), *available at* http://www.wipo.int/tk/en/tk/ffm/report/index.html (Apr. 2001).

[116] Straub, *supra* note 73, at 197.

[117] Stein, *supra* note 15, at 161; *see also* Emmanuel Opoku Awuku, *Biotechnology, Intellectual Property Rights & the Rights of Farmers in Developing Countries*, 8 J. WORLD INTELL. PROP. 75 (2005) (arguing that traditional knowledge held by indigenous and local communities is not recognized or adequately protected by IPR systems and that an effective sui generis system for protecting plant varieties is needed).

[118] Straub, *supra* note 73, at 198.

[119] *See* Hoffman & Sung, *supra* note 111, at 27.

[120] *Id.* at 23–24. The participants observed that the cost-benefit analysis for each type of technology is very different. For example, a GM product like Golden Rice to address vitamin A deficiency would be considered more cost effective than Roundup Ready® soybeans, which are not positioned as the solution to world hunger.

[121] Straub, *supra* note 73, at 187.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

cornerstone of its trade policy.[122] Prior to TRIPS, the Paris Convention of 1883 provided the international framework for intellectual property, but it did not dictate a uniform standard of intellectual property protection. It required "national treatment," a principle of non-discrimination between the goods of home and foreign applications, but left each country free to set its own intellectual property system.[123] The Patent Cooperation Treaty supplemented the Paris Convention in 1970 and established a centralized utility patent application process.[124] However, with the TRIPS Agreement, the influence of international trade reached a new height in the formulation of intellectual property rights.[125]

When the TRIPS Agreement went into effect on January 1, 1995, it raised the global protection of intellectual property rights and principally patented technology to an "unprecedented level."[126] Linking intellectual property rights to trade, the WTO made compliance with TRIPS—including its intellectual property regime—mandatory for member countries.[127] The stated purpose of TRIPS is to "reduce distortions and impediments to international trade . . . taking into account the need to promote effective and adequate protection of intellectual property rights."[128] However, conflicts emerged between its Western big business interests couched in international trade and the preexisting economic and cultural values of developing countries.[129] For many countries, the internationalization of U.S. intellectual property policies has clashed with their national interests and infrastructures, disrupting the balance between individual and societal interests.[130] Critics have observed that, using the "ideological banner" of free trade, TRIPS has achieved "through the potential threat of economic ostracism, what could not be accomplished through negotiations independent of the international economic

---

[122] Stein, *supra* note 15, at 169.

[123] Paris Convention for the Protection of Industrial Property (Paris Convention), Mar. 20, 1883, as revised at Stockholm on July 14, 1967, 21 U.S.T. 1630, 828 U.N.T.S. 305, *available at* http://www.wipo.int/treaties/en/ip/paris/index.html. *See* RICHARD SCHAFFER ET AL., INTERNATIONAL BUSINESS LAW AND ITS ENVIRONMENT 561 (7th ed. 2009).

[124] Patent Cooperation Treaty (PCT), June 19, 1970, 28 U.S.T. 7645 (signed in Washington on June 19, 1970, amended on September 28, 1979 and modified on February 3, 1984). Although the PCT streamlined the process of filing a patent application, it did not create an international patent; applications must still be submitted to individual patent offices for each country or region in which patent protection is sought. *See* Gervais, *supra* note 114, at 948–49 & n.110.

[125] *See* Gervais, *supra* note 114, at 930.

[126] Stein, *supra* note 15, at 169. *See* Susan K. Sell, *Industry Strategies for Intellectual Property and Trade: The Quest for TRIPS, and Post-TRIPS Strategies*, 10 CARDOZO J. INT'L & COMP. L. 79 (2002).

[127] *See* Spectar, *supra* note 114, at 235–36.

[128] *Id.* at 236; TRIPS Agreement, *supra* note 18, at 320.

[129] For example, the pharmaceutical industries, backed by the United States and Europe, have disputed South Africa's asserted right to allow cheap imports of patented AIDS medicine and Brazil's endorsement of compulsory licensing of AIDS medicine in those countries. These conflicts involve socioeconomic rights such as the right to "the enjoyment of the highest attainable standard of physical and mental health," including "the prevention, treatment and control of epidemic, endemic, occupational and other diseases," and the right to food under the International Covenant on Economic, Social and Cultural Rights (CESCR), art. 2(1), art. 12(1) and (2)(c), Dec. 16, 1966, 6 I.LM. 360, 361, *available at* www.unhchr.ch/html/menu3/b/a_cescr.htm. Straub, *supra* note 73, at 188–89.

[130] Stein, *supra* note 15, at 169–70, citing Srividhya Ravavan, *Can't We All Get Along? The Case for a Workable Patent Model*, 35 ARIZ. ST. L.J.. 117, 125–26 (2003); *see also* VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 56 (1996) (arguing that the current intellectual property rights system establishes a reverse piracy with resources taken from Third World countries for patents in American agricultural and pharmaceutical products).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

framework."[131]

The patent provisions of TRIPS set forth as patentable subject matter "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."[132] However, TRIPS makes provisions for a couple of significant exceptions. Under Article 27(2):

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.[133]

In addition, Article 27(3)(b) allows members to 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.[134]

Thus, for plant varieties, as long as there is some level and form of protection—even one unique to the individual country—there is no requirement of international standardization, or that the protection be comparable to the patents granted under TRIPS. Those patents confer on the owner exclusive rights to prevent third parties from using, selling, or importing that product or process, and to assign, transfer, or make licensing contracts, for a period of twenty years.[135] The United States, however, concerned that resort to this provision could weaken intellectual property rights of their biotech products, pressured developing countries into entering additional treaties, referred to as "TRIPS-plus" bilateral agreements.[136] These "TRIPS-plus" agreements contain more stringent intellectual property standards, obligate developing countries to implement TRIPS more quickly than the specified transition periods, or require adherence to other multilateral intellectual property agreements.[137]

By its terms, TRIPS protection would extend to the altered genetic material of GMOs at the cellular level, but not necessarily to the genetically modified plant

---

[131] Aoki, *supra* note 105, at 20–21; Michelle McGrath, *The Patent Provisions in TRIPS: Protecting Reasonable Remuneration for Services Rendered - or the Latest Development in Western Colonialism?*, 18 EUR. INTELL. PROP. REV. 398, 399 (1996); Spectar, *supra* note 114, at 241.

[132] TRIPS Agreement, *supra* note 18, art. 27(1).

[133] *Id.* art. 27(2) (emphasis in original).

[134] *Id.* art. 27(3)(b).

[135] *Id.* art. 28, 33.

[136] *See* Peter Drahos, *BITs and BIPs*, 4 J. WORLD INTELL. PROP. L. 791, 792–807 (2001) (discussing "TRIPS-plus" bilateral agreements by the United States and EC with individual developing country governments); Genetic Resources Action International (GRAIN), "*TRIPS-plus" Through the Back Door: How Bilateral Treaties Impose Much Stronger Rules for IPRs on Life than the WTO*, *available at* http://www.grain.org/docs/trips-plus-en.pdf (July 2001).

[137] Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 24, n.10 (2004).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

itself as long as an alternate patent or other system is offered. As a practical matter, however, the protection of the part equals protection of the whole, as Percy Schmeiser could attest.[138] Most significant is the TRIPS' central recognition that living things may be patented; there is no general exclusion for micro-organisms, and even developers of plant varieties (but not animals) must receive some sort of intellectual property protection for their "inventions." This recognition is considered by some critics to have breached the ideals of many nations. In order to comply with TRIPS pursuant to WTO membership regulations, countries that have not allowed the patenting of plants and agricultural products previously (e.g., India) will need to do so on some level even if this diverges from their national policies.[139] Arguably a country could try to resist granting biotechnology patents through Article 27(2) on the grounds of strong public interest or to protect human health and the environment,[140] although a similar argument was unsuccessful in the Harvard mouse case decided under the European Patent Convention.[141] Even so, several of these countries have begun to demonstrate their resistance to TRIPS, particularly its characterization of life as patentable, and to counter perceived coercion from more powerful nations.[142]

In the volatile area of genetic engineering and biodiversity, the TRIPS Agreement has sparked developing countries to fashion alternate and parallel treaties that are more in line with their national interests and cultural beliefs.[143] By

---

[138] "If a gene within a GM crop plant can be the subject of a valid patent claim, then authorized use of the plant containing that gene can constitute infringement; this has the same effect as if the plant itself were claimed in a patent." Torrance, *supra* note 56, at 281 (analyzing Canadian law in the context of the Schmeiser case).

[139] *See* Ewens, *supra* note 39, at 302, citing David Tilford, *Saving the Blueprints: The International Legal Regime for Plant Resources*, 30 CASE W. RES. J. INT'L L. 373, 408–09 (1998). In India, the negative reaction took a dramatic form in October 1993 as half a million farmers protested the patenting of agricultural products, arguing "for collective, not individual control over seeds and plants." *See* Charles McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L. Q. 255, 257, 267 (1998).

[140] *See, e.g.*, Ruth L. Gana, *Prospects for Developing Countries under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 753 (1996); McManis, *supra* note 139, at 266.

[141] *See supra* notes 58–59 and accompanying text. However, perhaps the interests would weigh differently than was the case for a laboratory mouse used for important cancer research, if sufficient risk of harm could be demonstrated versus the questionable benefits of genetically modified plants. *See* Strauss, *Ethical Implications*, *supra* note 21, at 7–19.

[142] For example, Brazil and Thailand refused to recognize pharmaceutical patents but relinquished under pressure by the United States. Spectar, *supra* note 114, at 240. *See, e.g.*, Thammasat Resolution, Dec. 5, 1997, *available at* http://web.greens.org/s-r/16/16-13.html (organizational representatives from 19 countries—including Thailand, Brazil, Costa Rica, Ethiopia, Ecuador, Columbia, Indonesia, Philippines, India, South Africa, Zambia—opposing the privatization of biodiversity, life forms, and traditional knowledge by TRIPS with nonbinding resolution); *see also* Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 65 (2001) (discussing the belief of some developing states that life forms "were considered special and different and not reducible to property rights that might be possessed by some and denied to others"); Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy 5–6 (2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm (criticizing "the patenting of life forms on ethical grounds" because "private ownership of substances created by nature is wrong, and inimical to cultural values in different parts of the world").

[143] *See* Helfer, *supra* note 137, at 27; U.N. Development Programme, Making Global Trade Work for People 221, 222 (2003), *available at* http://www.networkideas.org/doc/mar2003/UNDP_Trade.pdf (criticizing the relevance of TRIPS for the developing world and encouraging developing countries to "modif[y]. . . the way the agreement is interpreted and implemented" and to "begin dialogues to replace TRIPS . . . with alternate intellectual property paradigms").

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

comparing TRIPS to other international treaties and exploring the formation of alternative approaches to intellectual property, one can envision a more harmonious role for intellectual property rights in the international arena.

A. Convention on Biological Diversity

With its absolute recognition that genetic material and micro-organisms are appropriate subject matter for patenting, TRIPS appears inconsistent with other international treaties. For example, the United Nations' Convention on Biological Diversity (CBD)—the international cornerstone for environmental interests—recognizes the implicit value of nature itself.[144] The CBD by its terms embraces life, "the conservation of biological diversity," and "the sustainable use of its components."[145] Thus, the CBD recognizes that "biological diversity is about more than plants, animals and micro-organisms and their ecosystems—it is about people and our need for food security, medicines, fresh air and water, shelter, and a clean and healthy environment in which to live."[146] In describing the CBD, a WHO report observes: "The summary of these objectives shows that all the main arguments usually discussed in a risk-benefit evaluation of food biotechnology interfere with each other, thus requiring a high level of ethical consideration."[147] This directly contrasts TRIPS' perspective of the biotechnology industry: that genetic material and life forms are commodities to be manipulated, and the fruits of this labor become objects of property whose ownership must be exclusive and remunerative.[148]

Intellectual property interests did come into play during the CBD's foundation. This treaty, with its emphasis on the environment and biological diversity, became a compromise between the interests of the industrial, biotechnology-skilled North and the developing, genetic resource-storehouse South, with the North seeking access to these resources and the South wanting technology transfers and a share in the benefits of the resulting biotech products.[149] However, the resulting treatment sharply slanted these issues in the direction of the developing world. Accordingly, the CBD explicitly values the "sovereign rights" of nations in their natural resources, and directs that research results and "benefits arising from the commercial and other utilization of genetic resources" be shared in a "fair and equitable way" and "upon mutually agreed terms" with the contracting nation providing these resources.[150] Article 16 likewise provides that the technology for exploiting plant resources be made available to developing countries, where necessary, on fair "mutually agreed terms," with the proviso that

---

[144] CBD, *supra* note 19. *See* FOOD AGRICULTURE ORGANIZATION (FAO), ETHICAL ISSUES IN FOOD AND AGRICULTURE (2001), *available at* http://www.fao.org/DOCREP/003/X9601E/X9601E00.HTM; *see also* WHO Study, *supra* note 103, at 56.

[145] CBD, *supra* note 20, art. 1.

[146] CBD, *About the CBD*, *available at* http://www.biodiv.org/convention/default.shtml (last visited Aug. 6, 2008).

[147] WHO Study, *supra* note 103, at 56.

[148] *See* Strauss, *Ethical Implications*, *supra* note 21, at 21.

[149] Helfer, *supra* note 137, at 15–16.

[150] CBD, *supra* note 19, arts. 3, 15(7).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

"[i]n the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."[151] Although this language supports the application of intellectual property rights, a further provision in Article 16 counters that such rights are subjugated to the objectives of the CBD:

> The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.[152]

The latter passage suggests that a system of intellectual property rights must be revised if it contradicts the CBD objectives: conservation of biological diversity, sustainable use of biological components, and the fair and equitable sharing of the benefits from the use of genetic resources.[153]

Developing countries may have reason to evoke this provision with regard to TRIPS, since its kind of intellectual property protection arguably can be implemented in a manner that undermines the CBD's objectives.[154] For instance, TRIPS neither requires sharing the benefits of biotech products with the countries that supply the genetic resources, nor gives recognition for the traditional knowledge of original communities as a form to be patented.[155] Moreover, TRIPS does not mandate disclosure of the origin of genetic resources for applicants to exercise their intellectual property rights.[156] As a consequence, developing countries have been attempting to harmonize intellectual property rights with the biodiversity framework through CBD bodies. The Conference of the Parties, an implementing body of CBD member states, has been working in the intellectual property area to ensure protection for "traditional knowledge of indigenous communities" and to urge applicant disclosure of "the country of origin of the genetic resources or traditional knowledge which form the basis of their applications."[157] Some of these initiatives will be discussed below.[158]

Article 19 of the CBD sets forth additional instructions for the handling of biotechnology and distribution of its benefits, stating that "priority access" to the "results and benefits arising from biotechnologies based upon genetic resources"

---

[151] *Id.* art. 16(2).

[152] *Id.* art. 16(5).

[153] *Id.* art. 3. *See* Tilford, *supra* note 139, at 419; Ewens, *supra* note 39, at 300.

[154] *See* Helfer, *supra* note 137, at 30.

[155] *See, e.g.*, Graham Dutfield, *TRIPS-Related Aspects of Traditional Knowledge*, 33 CASE W. RES. J. INT'L L. 233, 240–41 (2001); David R. Downes, *How Intellectual Property Could Be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253, 258–78 (2000); Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge: Towards More Specific Rights and Obligations in World Trade Law*, 1 J. INT'L ECON. L. 555, 567 (1998).

[156] *See* Helfer, *supra* note 137, at 29–30; *see also* Nuño 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, 372–75 (2000).

[157] Helfer, *supra* note 137, at 29–51.

[158] *See infra* notes 176–80, 185–87, 190–99 and accompanying text.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

must be given especially to developing countries on "mutually agreed terms."[159] The financial support for this agreement must come from the biotech applicant as a condition of obtaining access to the resources, taking "full account of the specific needs and special situation of least developed countries."[160] Under Article 19(4), the party must provide "any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced."[161]

The United States objected to Articles 16 and 19, contending that they undermined the prevailing system of intellectual property rights.[162] U.S. biotechnology firms viewed Article 16(4) as mandating compulsory licensing and feared that the CBD might not require full payment for the technology transfer.[163] Although the majority of the world has ratified the CBD, the United States refused to do so.[164] In this context, one can see that promoting the TRIPS Agreement under the guise of international trade was the next logical step for the United States, since it took a divergent approach as to the ownership and exclusivity of intellectual property rights.

B. Cartegena Protocol on Biosafety

Similarly, the Cartegena Protocol on Biosafety, the only international regulatory instrument expressly established to protect biological diversity from the risks of biotechnology, seeks to regulate the safe transfer, handling, and use of "living modified organisms" (LMOs) in order to limit any negative impact on biodiversity.[165] Although the preamble acknowledges "modern biotechnology has great potential for human wellbeing if developed and used with adequate safety measures for the environment and human health," the Protocol focuses on the

---

[159] CBD, *supra* note 19, art. 19(2).

[160] *Id.* art. 20(4), (5).

[161] *Id.* art. 19(4).

[162] *See* Spectar, *supra* note 114, at 249, citing Klaus Bosselmann, *Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity*, 7 COLO. J. INT'L ENVTL. L. & POL'Y 111, 139–40 (1996).

[163] Ewens, *supra* note 39, at 300; *see* Tilford *supra* note 139, at 419 ("The South wants the technology and the North wants the South to have it. But while the South sees itself as [a] potential partner, the North looks south and sees only paying customers.").

[164] For a list of 191 countries who have ratified the CBD, see The Convention on Biological Diversity, List of Parties, http://www.cbd.int/convention/parties/list.shtml (last visited Aug. 6, 2008); *see also* Richard J. Blaustein, *The United States Needs to Join the Rest of the World in Ratifying the Convention on Biological Diversity*, LEGAL TIMES, Nov. 7, 2005.

[165] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 1, *available at* http://www.cbd.int/biosafety [hereinafter Biosafety Protocol]. The Biosafety Protocol was put forth in January 2000 and went into effect on September 11, 2003, the ninetieth day after receiving the fifty instruments of ratification by States or regional economic integration organizations that are Parties to the U.N. Convention on Biological Diversity (CBD). As of August 2008, 147 Parties had ratified the Protocol, but not the United States. Its stated objective is: "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements." *Id.*

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

potential adverse effects of LMOs[166] on the environment and seeks to avoid harm to biodiversity, not to facilitate transfer of technology to developing countries.[167] The Biosafety Protocol adopts a precautionary approach, in keeping with the language of the Rio Declaration on Environment and Development, that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[168] This precautionary approach has, in turn, become the lens for the international regulatory system concerning GMOs, in other words, banning their introduction into the food supply when the risks to human health and the environment cannot be adequately dispelled.[169] In addition, the precautionary principle is embodied in a number of multilateral environmental agreements.[170]

In contrast, TRIPS contains not a single reference to biodiversity, with its stated mission "to reduce distortions and impediments to international trade."[171] While it makes reference to permitting member states to avoid patentability in order "to protect human, animal or plant life or health or to avoid serious prejudice to the environment," it remains to be seen how the WTO will evaluate the adequacy of that justification in its implementation of TRIPS.[172] Not surprisingly, as a predominantly U.S. vehicle, the TRIPS Agreement also makes no mention of the precautionary principle, which has been rejected by the United States in its laissez-faire regulatory approach to genetically modified foods.[173] TRIPS is, after all, a trade agreement, and its enforcer (the WTO) is an organization whose primary

---

[166] Under the Biosafety Protocol, a living modified organism (LMO) is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology" and living organism means "any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids." Biosafety Protocol art. 3(g)–(h). Note that this definition does not encompass all forms of GMOs but only those that are capable of transferring or replicating genetic material. *See* Strauss, *Importing Caution*, *supra* note 1, at 178 (discussing this difference, together with the exclusion of consideration for human health, and concluding that, "the Protocol alone . . . is not sufficient for the international regulation of GM foods").

[167] Biosafety Protocol, *supra* note 165, preamble. *See* Jack A. Bobo, *The Role of International Agreements in Achieving Food Security: How Many Lawyers Does It Take to Feed a Village?*, 40 VAND. J. TRANSNAT'L L. 937, 943 (2007); *see also* Strauss, *Importing Caution*, *supra* note 1, at 177–78 (analyzing the Biosafety Protocol from the regulatory perspective); WHO STUDY, *supra* note 103, at 19.

[168] U.N. Conference on Environment and Development, June 3–14, 1992, Rio Declaration on Environment and Development, at 6, U.N. Doc. A/CONF.151/26/Rev. 1 (Jan. 1, 1993). *See* Comisión Nacional de Recursos Fitogenéticos, Frequently Asked Questions About the Cartagena Protocol on Biosafety, http://www.conarefi.ucr.ac.cr/Bioseguridad1.htm (last visited Aug. 6, 2008).

[169] *See, e.g.*, Council Directive 2001/18/EC, 2001 O.J. (L106); Biotechnology Industry Organization, European Union Moratorium, http://www.bio.org/foodag/background/eumoratorium.asp (last visited Aug. 7, 2008). The Codex Alimentarius Commission—an international standard setting body for food safety jointly administered by two United Nations agencies, the FAO and the WHO—adopted principles that set a uniform standard for assessing food safety for foods derived from modern biotechnology, including an evaluation of both direct effects from the inserted gene and unintended effects that may arise as a consequence of insertion of the new gene. Food and Agriculture Organization of the United Nations/World Health Organization [FAO/WHO] Food Standards: Codex Alimentarius Commission, Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, CAC/GL 44-2003 (2003), *available at* http://www.codexalimentarius.net/download/standards/10007/CXG_044e.pdf. *See* Strauss, *Importing Caution*, *supra* note 1, at 176–81.

[170] Bobo, *supra* note 167, at 943–45.

[171] TRIPS Agreement, *supra* note 18, at 320.

[172] *Id.* art. 27(2).

[173] *See* Strauss, *A Model of Labeling*, *supra* note 16, at 97–103.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

focus is to remove the barriers to international trade. As a result, the WTO has not been successful in considering scientific matters such as risks to human health and the environment and has repeatedly failed to acknowledge the importance of the precautionary principle and environmental treaties.[174] In the enforcement of biological intellectual property rights, as in earlier disputes over GMOs, the WTO will be asked "to make decisions on very complex issues that involve deep domestic social and environmental foundations," a task it has proven to be ill-equipped to handle.[175]

C. Post-TRIPS Strategies and Treaties by Developing Countries

Developing countries can take the opportunity to develop their own sui generis system of intellectual property protection in order to comply with TRIPS under the exception in Article 27. Under this exception, states can exclude plants from patentability, and TRIPS does not dictate the scope and extent of the sui generis protection. Such a system may give greater weight to human rights and the concerns of farmers relative to plant breeders' rights.[176] One alternative mechanism is the International Union for the Protection of New Varieties of Plants (UPOV), a multilateral agreement of industrialized states that does provide uniform provisions on the extent of plant breeders' rights.[177] However, its latest revision limits researchers' exemptions and the farmers' rights to save seeds, and prohibits the sale of seed.[178] Since it offers few benefits for developing countries, most have not

---

[174] *See, e.g.*, EC-Biotech, *supra* note 4; Strauss, *Impact of the WTO*, *supra* note 3, at 815–17. In the EC-Biotech dispute, the WTO refused to embrace the precautionary principle, which is a key principle in environmental governance widely recognized to allow countries to take action to protect the environment when there is scientific uncertainty. "The fact that the Panel did not view the Biosafety Protocol—the only comprehensive international agreement on genetic engineering—as relevant is a 'bad sign' as the WTO is currently negotiating the relationship between trade rules and global environmental agreements." Strauss, *Impact of the WTO*, *supra* note 3, at 822; *see also* SABRINA SHAW & RISA SCHWARTZ, TRADING PRECAUTION: THE PRECAUTIONARY PRINCIPLE AND THE WTO (UNU-IAS Report 2005); Sabrina Safrin, *Treaties in Collision? The Biosafety Protocol and the World Trade Organization Agreements*, 96 AM. J. INT'L L. 606, 619 (2002); 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, 118 (2000).

[175] Strauss, *Impact of the WTO*, *supra* note 3, at 824. Ultimately "we may be left with critical decisions about the food supply being made not by the scientists and policymakers but by isolated panels of individuals concerned primarily with the economics of international trade." *Id.* at 826; *see also* Laylah Zurek, *The European Communities Biotech Dispute: How the WTO Fails to Consider Cultural Factors in the Genetically Modified Food Debate*, 42 TEX. INT'L L.J. 345, 362, 368 (2007) (arguing that the WTO opinion fails to recognize "other values have weight alongside free trade" and advocating international labeling as an alternative to "solve the trade issues—without having to resolve the debate over safety.").

[176] *See* Straub, *supra* note 73, at 206–07.

[177] International Union for the Protection of New Varieties of Plants (UPOV), http://www.upov.org/en/about/members/pdf/pub423.pdf (last visited Aug. 7, 2008).

[178] The UPOV rules offer less stringent property rights protection than the U.S. regulatory system but too strict for local farmers in some countries; as a result, not all of the member nations have implemented the UPOV proposals, the most recent of which (UPOV 91) included more rigorous protection, restricted farmers' rights of use, and permitted the coexistence of alternate regulatory systems for seed protection. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 33 U.S.T. 2703 (as revised at Geneva on Mar. 19, 1991), *available at* http://www.upov.org/en/publications/conventions/1991/pdf/act1991.pdf. *See* Gallo & Kesan, *supra* note 12, at 574–76.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

endorsed the 1991 UPOV Convention.[179] In fact, the United States has been promoting UPOV as if it were the only permissible sui generis system, by including UPOV provisions in bilateral Free Trade Agreements that elevate levels of intellectual property protection and are seen as "TRIPS-plus."[180] The United States exerts economic pressure by utilizing Section 301 of the Trade Act of 1974[181] and threatening retaliatory sanctions through the WTO.[182] Moreover, developing countries are increasingly pressured politically and economically to hastily craft domestic laws to protect intellectual property at least at a TRIPS level and even beyond.[183] For developing countries, this protection of transnational corporate interests at the expense of their citizens may fall within the rubric of the International Covenant on Economic, Social, and Cultural Rights (CESCR), which mandates that its members work to ensure the right to the highest attainable standard of health care and other socioeconomic rights, including the right to food.[184]

In the aftermath of TRIPS, there has also been a movement for developing countries to transport intellectual property issues into other settings with the assistance of non-governmental organizations and occasionally officials of intergovernmental organizations:

> This strategy has resulted in the drafting of new treaties, the reinterpretation of existing agreements, and the creation of new nonbinding declarations, guidelines, and recommendations. Many of these developments criticize the TRIPS Agreement (both for what it includes and what it excludes) as well as other intellectual property protection standards.[185]

Facilitated by the CBD's sovereignty and access rules for diverse biological resources, developing countries have outlined acquisition terms and limits on genetic resources in an explosion of national access laws[186] and Material Transfer

---

[179] Straub, *supra* note 73, at 207.

[180] *Id.* at 207–08.

[181] The Trade and Tariff Act of 1984 makes IP protection actionable under section 301 of the Trade Act of 1974 if characterized as "unjustifiable" or "unreasonable" trade practices. Trade and Tariff Act of 1984, 15 U.S.C. § 2007.8 (1994); Trade Act of 1974, 19 U.S.C. § 2411 (1974). *See* Spectar, *supra* note 114, at 261–62; *see also* Stein, *supra* note 15, at 172–73.

[182] *See* Stein, *supra* note 15, at 172–73. As the "most strident enforcer" of intellectual property rights, the United States in an alliance between the U.S. Trading Representative and large businesses "has filed more TRIPS complaints in the WTO than all other WTO countries combined." *Id.* at 173.

[183] Straub, *supra* note 73, at 208. One such example occurred in India, where the revision of its intellectual property rights legislation under pressure from the WTO and the United States went well beyond TRIPS, shifting its system from one that recognized their farmers' rights to save and swap seed and sell or share their harvest, to a more stringent system that brings criminal liability for the acts of these farmers. *Id.* at 208–210.

[184] International Covenant on Economic, Social, and Cultural Rights (CESCR), art. 2(1), Dec. 16, 1966, 6 I.L.M. 360, 361, *available at* www.unhchr.ch/html/menu3/b/a_cescr.htm (ratified by the United States on Oct. 5, 1977). *See* Straub, *supra* note 73, at 187, 188–89.

[185] Helfer, *supra* note 137, at 27–28.

[186] In the wake of the CBD, more than 30 mostly developing nations have developed or are considering adopting laws delineating third party access to their diverse biological resources. Helfer, *supra* note 137, at 31 & n.128; *see also* MICHEL PETIT ET AL., WHY GOVERNMENTS CAN'T MAKE POLICY: THE CASE OF PLANT GENETIC RESOURCES IN THE INTERNATIONAL ARENA 49 & 80 n.1 (2001).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

Agreements (MTAs).[187] While the CBD encourages these states to design intellectual property rights protection, they must do so in a way that does not contradict the biodiversity objectives of the CBD.[188]

D. FAO Undertaking as an International Initiative

One such initiative on behalf of the international community came from the Food and Agriculture Organization (FAO) Commission on Plant Genetic Resources, which serves as the world forum for discussing the "'use, control, and conservation of' germplasm."[189] The Commission adopted the International Undertaking on Plant Genetic Resources (FAO Undertaking), a nonbinding declaration which aims to remedy the inequity in exchanges of plant genetic resources.[190] The Undertaking declared "the universally accepted principle" that all plant genetic resources are "a heritage of mankind and consequently should be available without restriction."[191] It stated as its objective "to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes."[192] Broad categories of "plant genetic resources" fall within its scope, including cultivated plant varieties "in current use or newly developed varieties," naturally occurring plants or "wild and weed species," and plant materials held in genetic storage banks.[193] In a clear reference to the food products of biotechnology, the Undertaking "relates to the plant genetic resources . . . of all species of economic and/or social interest, particularly for agriculture at present or in the future, and has particular reference to food crops."[194] Thus, all plant genetic materials were to be freely available to all—the commercially bred lines of the North, as well as the traditionally bred varieties and germplasm from the South.

However, in practice that broad objective was tempered by the restrictions of international trade and the need to reconcile with other treaties. Because the

---

[187] Material Transfer Agreements (MTAs) "consist of enforceable agreements between the provider and recipient of the transferred genetic materials which create specific rights and obligations for each party." Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing, Second Session, Geneva, Dec. 10–14, 2001, para. 4, WIPO Doc. WIPO/GRTKF/IC/2/3 (Sept. 10, 2001).

[188] CBD, *supra* note 19, art. 16(5). For the full text of this provision and further discussion, see *supra* notes 144–53 and accompany text; *see also* Helfer, *supra* note 137, at 31–32.

[189] *See* Spectar, *supra* note 114, at 243; Neil D. Hamilton, *Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources*, 28 TULSA L.J. 587, 600 (1993).

[190] FAO Res. 8/83, *International Undertaking on Plant Genetic Resources*, UN Food and Agriculture Organization, 22nd Sess., Annex 1, Agenda Item 16, U.N. Doc. C/83/REP (1983) [hereinafter FAO Undertaking]. Over one hundred countries signed the FAO Undertaking, but the United States did not. Spectar, *supra* note 114, at 243, n.97.

[191] FAO Res. 8/83, *supra* note 190, art. 1.

[192] *Id.*

[193] *Id.* art. 2, para. 2.1(a). In defining "collections of plant genetic resources," the FAO Undertaking includes: "a collection of seed stock or vegetative propagating material . . . held for long-term security in order to preserve the genetic variation for scientific purposes and as a basis for plant breeding" as well as "a collection from which seed samples are drawn for distribution, exchange and other purposes such as multiplication and evaluation." *Id.* art. 2, para. 2.1(b), (c).

[194] *Id.* art. 2, para. 2.2.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

common heritage approach threatened to encroach upon patent protection of new plant varieties, the United States maintained that the agreement violated basic private property rights and U.S. treaty obligations.[195] With the intellectual property rights of the biotechnology industry at stake, many industrial countries refused to sign it.[196] Most fundamentally, it conflicted with plant breeders' rights as protected in the UPOV.[197] In response to their objections, the Undertaking was revised to state that plant breeders' rights as protected by the UPOV were "not incompatible" with the common heritage principle.[198] As a result, the initial effect of the Undertaking was to open up the germplasm of the South to the biotechnology companies of the North without imparting the capital necessary for the South to obtain agricultural technology; this concept of "common heritage" served only the industry's commercial interests by allowing them "to turn public domain items into private intellectual property."[199]

To remedy this disparity, developing countries integrated three additional principles into this system: farmers' rights, national sovereignty, and a ban on intellectual property protection for genetic material held in international seed banks.[200] The revisions took place in stages: the first two annexes in 1989 affirmed farmers' rights and plant breeders' rights, with the understanding that legal protection for patented new plant varieties was permissible.[201] Third World farmers were recognized for their development and preservation of genetically diverse resources; to that end, the FAO established the International Fund for Plant Genetic Resources (IFPGR).[202] Lastly, the third annex in 1991 asserted that "nations have sovereign rights over their plant genetic materials," which made the rights to the resources represented in the Undertaking subject to this state sovereignty.[203] As a result, these countries could now exchange access to genetic resources for compensation or technology transfers.[204] With regard to the final principle (plant materials in seed banks), an international network of agricultural research centers

---

[195] Spectar, *supra* note 114, at 244.

[196] *Id.*; *see also* Hamilton, *supra* note 189, at 602.

[197] *See supra* notes 177–180 and accompanying text for a discussion of the UPOV. The most recent set of rights contained in the 1991 UPOV Convention strengthens the property rights granted to breeders and limits famers' rights; as a consequence, most developing countries have declined to endorse it.

[198] Agreed Interpretation of the International Undertaking, Res. 4/89, FAO Conference, 25th Sess., para. 1 (1989). *See* Helfer, *supra* note 137, at 36.

[199] Spectar, *supra* note 114, at 245, citing Aoki, *supra* note 105, at 46.

[200] *See* Helfer, *supra* note 137, at 36–39. For example, the national sovereignty issue was pursued particularly strongly by developing nations in the Latin American and Caribbean Group regarding their nations' control over the genetic resources in their region. *Id.*

[201] F.A.O. Res. 4/89, International Undertaking on Plant Genetic Resources, amended 1989, 1991, U.N. Food and Agriculture Organization, 25th Sess., Annex I: Agreed Interpretation of the International Undertaking (1989); F.A.O. Res. 5/89, International Undertaking on Plant Genetic Resources, amended 1989, 1991, U.N. Food and Agriculture Organization, 25th Sess., Annex II: Farmers' Rights (1989); *see also* Michael Blakeney, *Protection of Plant Varieties and Farmers' Rights*, 24 EUR. INTELL. PROP. REV. 9, 9–11 (2002) (discussing the problem that individual farmers' traditional cultivation efforts were not subject to intellectual property protection).

[202] Blakeney, *supra* note 201, at 9–11. However, the IFPGR has suffered from a lack of funding. Spectar, *supra* note 114, at 246.

[203] F.A.O. Res. 3/91, International Undertaking on Plant Genetic Resources, amended 1989, 1991, U.N. Food and Agriculture Organization, 26th Sess., Annex III (1991).

[204] *See* Helfer, *supra* note 137, at 38.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

arose, known as the Consultative Group on International Agricultural Research (CGIAR).[205] Under agreements between CGIAR and FAO, the genetic materials in these gene banks are held "in trust for the benefit of the international community" with the proviso that ownership of intellectual property rights not be permitted for these research centers or for any third parties who access the germplasm.[206] As the culmination of this process, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR) further clarified the level of intellectual property protection available for banked seeds that are subsequently modified by the recipient: "Recipients 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."[207] Presumably, then, patenting would be available for the modifications if they substantially changed the form, although this determination remains purposefully ambiguous.[208] In any event, through this partnership between the public and private sectors,[209] at least part of the world's genetic heritage will remain "protected" in the public domain.

V. FROM TRADE TO PUBLIC INTEREST

Quite remarkably, since property rights became attached to genetically engineered plant material, the focus of international dialogue has not shifted from trade to public health. The uncertainty of science has thus far proven it to be too shaky a foundation on which to build such a fortress to safeguard future generations. Perhaps through the same lens of intellectual property rights, however, the paradigm can be shifted from international trade to the public interest.

---

[205] CGIAR, a system of sixteen international research centers, is "perhaps the biggest player on public seed access on the international front." Stein, *supra* note 15, at 176; *see also* Consultative Group on International Agricultural Research: CGIAR Online, http://www.cgiar.org (last visited Aug. 8, 2008).

[206] Agreement Between [name of Centre] and the Food and Agriculture Organization of the United Nations (FAO) Placing Collections of Plant Germplasm Under the Auspices of FAO, art. 3(b) (1994), *reprinted in* Booklet of CGIAR Centre Policy Instruments, Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights 2, 3 (Version 2, July 2003). However, disputes have arisen over patenting of genetic material from CGIAR banks once genetic modifications have been made; the inquiry focuses on whether enough of a change has been made to justify granting this exclusive intellectual property protection to the private breeder. *See* Helfer, *supra* note 137, at 39; *see also* GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 50 (2000).

[207] International Treaty on Plant Genetic Resources for Food and Agriculture, art. 12.3(d), Nov. 3, 2001, http://www.fao.org/ag/cgrfa/itpgr.htm.

[208] The precise phrases used were the subject of much contentious debate, with the phrase "in the form" surviving into the official version. However, governments and commentators are divided as to its application, i.e., whether the act of extracting a gene from a seed is a sufficient alteration of the seed's genetic material to longer be "in the form received." In the final round of the negotiations, the United States, Canada, Japan, and Australia attempted to strengthen their construal by appending interpretative statements that nothing in this language is inconsistent with TRIPS or national patent statutes. *See* Helfer, *supra* note 137, at 41 & n. 179.

[209] Another example of a public/private partnership in this area is the Public Intellectual Property Resource for Agriculture (PIPRA), created to facilitate access for the public sector to the IP needed to develop improved crops. PIPRA is working with the USDA and foreign agencies to establish a database of all patented agricultural technologies. *See* Stein, *supra* note 15, at 177 (arguing that the pro-business approach by the USTR inhibits progress for developing nations and encouraging public/private partnerships for a more productive international IP policy).

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

From a global perspective, plants' genetic material and other aspects of the natural environment may not lend themselves to the standard form of intellectual property protection. As international trade hurdles have been increasingly dismantled by the WTO, opposition is mounting. One solution might be to limit these GMO property rights by interpreting TRIPS in a more restrictive manner, or to address these contradictions openly in the international community through the treaty process. Concern for the sanctity and control of resources supported by treaties—including those that provide for other intellectual property protection—may ultimately prevail over the pressures of international trade.

An alternate approach would be to recognize the inevitability and importance of international trade and shift the focus onto a new paradigm: constructive innovation for the public benefit. Under this model, the international community should use international trade to promote socially responsible technology. This could be characterized as innovation that stimulates the economy but with socioeconomic benefits. Instead of increasing only shareholder value, socially responsible technology would take into account the multitude of stakeholders, including consumers, suppliers, the local community, the global community, the natural environment, and posterity.

As essential stakeholders, developing countries should be viewed not as "customers" but as joint venturers. This shift would acknowledge their essential role as gatekeepers of "rich" and precious natural resources. This regime would give developing countries a way to benefit economically, as well as to contribute and to increase sustainability and economic independence without changing their culture (i.e., small farmers, multi-crop) or biodiversity.

Such a model would, in fact, be consistent with the objectives of the TRIPS Agreement, which states that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.[210]

Recognizing intellectual property rights that contribute to developing countries economically, without contradicting their culture or harming the environment, would value the social and economic welfare of all. Moreover, this technological innovation must be positive in order to inure to the benefit of the users of the technology, the multitude of stakeholders including farmers and consumers of the end product. Ensuring the safety of the global food supply thus fits within the objectives of intellectual property protection.

Equally important is the need to establish a process to ascertain whether this technology meets the goals of safety and efficacy, not just economically, but for the public benefit, as well as to determine the proper international organization to oversee this regime. Opening the process to peer review by the multiple stakeholders would encourage a positive redundancy and consensus on universal

---

[210] TRIPS Agreement, *supra* note 18, art. 7.

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

standards like those set forth by the Codex Alimentarius Commission for the safety of foods derived from modern biotechnology.[211] While the Codex Standards have been a useful reference point in WTO disputes, this very link to the trade organization and its process of principle making may limit its appropriateness as a purely scientific body.[212] In this regard, the WTO is not the proper organization to spearhead these efforts, since its focus is solely on international trade and economics.[213] Moreover, by failing to take into account cultural values,[214] and excluding consideration of public health and environmental issues, the WTO has arguably legislated beyond the regulatory scope of international trade and undermined its credibility in the international community.[215] In contrast, the WHO has recognized the importance of giving consideration to human health issues, traditional knowledge protection, and equitable benefit sharing.[216] But the WHO is not an ideal candidate either, due to a lack of resources and effective enforcement mechanisms.[217]

The World Intellectual Property Organization (WIPO) has shown some potential in this area as an international organization that is "fairly easy to engage" and through which "getting observer status is not too difficult."[218] Despite its focus

---

[211] The principles adopted by Codex Alimentarius Commission set a uniform standard for assessing food safety for foods derived from modern biotechnology that has been incorporated into international treaties. *See supra* note 169.

[212] *See generally* Diahnna L. Post, *The Precautionary Principle and Risk Assessment in International Food Safety: How the World Trade Organization Influences Standards*, 26 RISK ANALYSIS 1259, 1263–65 (2006) (examining how its process of principle making has been influenced by the WTO and represents a compromise among competing interests of the disputing parties). On the other hand, as an international organization Codex has been successful in openly including relevant stakeholders in its process and thereby achieving consensus. *See id.* at 1271 ("Because politics inevitably enters the decision-making process, it is best to be explicit about this and take transparent steps to include the afflicted parties.").

[213] As a trade body with no expertise in science and the environment, the WTO "views regulations strictly in a framework designed to facilitate trade, not to realize public or environmental health objectives." Strauss, *Impact of the WTO*, *supra* note 3, at 822, citing Press Release, Institute for Agriculture and Trade Policy, WTO Ruling on Genetically Engineered Crops Would Override International, National and Local Protections: Preliminary Ruling Favors U.S. Biotech Companies Over Precautionary Regulation (Feb. 7, 2006), http://www.iatp.org/iatp/library/admin/uploadedfiles/WTO_Ruling_on_Genetically_Engineered_Crops_Wou.pdf.

[214] "[W]hen policing the use of subsidies for local producers and differentiating between legitimate concerns and artificial trade barriers, the WTO has no mechanism in place to consider social values or preferences. Allowing only limited restrictions based on food safety premised on scientific assessments, the WTO has favored market access. More often than not, it has found trade barriers to exist." Zurek, *supra* note 175, at 361, 362 (concluding that the WTO is incapable of resolving the complex debate over GM foods because it "lacks the institutional capacity to consider non-market values" and fails to "give weight to important cultural values in competition with free trade").

[215] Due to its exclusive focus on trade and limited ability to assess scientific information or to consider environmental treaties, the credibility of the WTO has been severely undermined, particularly in the eyes of developing countries and environmental organizations. *See* Strauss, *Impact of the WTO*, *supra* note 3, at 821–25.

[216] *See, e.g.*, WHO Traditional Medicine Workshop, Bangkok, Thailand, Dec. 6–8, 2000, Report of the Interregional Workshop on Intellectual Property Rights in the Context of Traditional Medicine, WHO/EDM/TRM/2001.1 (2000).

[217] Although the WHO has been instrumental in studying the risks of GMOs to human health and the environment, the organization has had limited capacity beyond reporting its findings. *See* WHO Study, *supra* note 103.

[218] Catherine Saez, *IP and Genetically Modified Organisms: A Fateful Combination, Activists Say*, INTELLECTUAL PROPERTY WATCH, Dec. 2, 2008, http://www.ip-

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

on conventional intellectual property, WIPO has demonstrated its ability and willingness to take into account the needs of developing countries in its study of traditional knowledge.[219] According to Ahmed Abdel Latif, program manager for intellectual property at the International Centre for Trade and Sustainable Development (ICTSD):

> From this perspective, the WIPO Development Agenda represents a positive development toward ensuring that the advice provided to developing countries to implement their international obligations integrates flexibilities contained in the TRIPS Agreement, including areas such as plant variety protection, where the choice of protection approach by developing countries should be primarily guided by their development levels, priorities and needs.[220]

As a well-funded organization with the function of "promoting the strategic use of IP for development" as well as facilitating international filings of patent applications, WIPO is a logical candidate to continue to play a central role in the intellectual property regime.[221] However, WIPO—operating through a rigidly prescribed framework with a predominantly economic focus—presently does not go far enough.[222]

Ultimately, a combination of international organizations might be able to overcome the inherent limits of each. For example, the Codex, the FAO and the WHO could work together to establish labeling guidelines that would serve as risk management tools and provide consumers with more information on the presence of genetically modified ingredients along with warnings about potential allergens.[223] If

---

watch.org/weblog/index.php?p=1342.

[219] For example, WIPO recently established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), which recognizes human rights, cultural diversity, and environmental protection and biodiversity; the IGC is currently drafting policy objectives and core principles for the protection of traditional knowledge and traditional cultural expressions against misappropriation. *See* WIPO, WORLD INTELLECTUAL PROPERTY ORGANIZATION: AN OVERVIEW 11, 31 (2007), *available at* http://www.wipo.int/freepublications/en/general/1007/wipo_pub_1007.pdf; *see also* WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge Holders, Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998–1999), *supra* note 115 ("As the United Nations specialized agency responsible for the promotion of the protection of IP, WIPO undertook the FFMs [fact-finding missions] as part of a new programme of activities, initiated in 1998, to explore and study current approaches to, and future possibilities for, the protection of the IP rights of holders of TK [traditional knowledge]").

[220] Saez, *supra* note 218, quoting Ahmed Abdel Latif, program manager for intellectual property at the International Centre for Trade and Sustainable Development.

[221] *See, e.g.*, WIPO, WORLD INTELLECTUAL PROPERTY ORGANIZATION: AN OVERVIEW, *supra* note 219, at 40–41 (stating that revenue from its registration and filing services accounted for ninety percent of its funding).

[222] To the extent the purpose of WIPO is to advocate for the rights of patent holders, its charge may potentially conflict with the public interest. *See* Convention Establishing the World Intellectual Property Organization, art. 3(i), July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 (stating its objective "to promote the protection of intellectual property throughout the world through cooperation among States and, where appropriate, in collaboration with any other international organization").

[223] *See* Zurek, *supra* note 175, at 366 (noting that the Codex Alimentarius Commission, created by the FAO and the WHO to establish international food safety standards, is currently developing guidelines for labeling of genetically modified foods); Strauss, *Importing Caution*, *supra* note 1, at 189–95. *See generally* Codex Alimentarius Commission, FAO & World Health Organization [WHO], Report of the Thirty-Fourth Session of the Codex Committee on Food Labelling, Ottawa, Canada, May

By permission of the Board of Trustees of the Leland Stanford Junior University,
from the Stanford Journal of International Law at 45 STAN. J. INT'L L. 287 (2009).
For information visit http://sjil.stanford.edu.

the collaboration of already established international organizations is insufficient, perhaps a new regulatory body could be established in the future to incorporate both the economic and scientific aspects of GMOs into its policies. There must also be one or more independent scientific bodies that have the ability to focus on safety and efficacy apart from policy, akin to how the European Food Safety Authority functions as the scientific counterpart to the European Community policy division.[224]

To be sure, it will be difficult to develop a global consensus on standardized policies and regulations. As one commentator has noted:

> In light of the contingent nature of environmental risk, it is unrealistic to expect a fully harmonized global standard for biosafety regulation to emerge. The Cartagena Protocol, the world's first and only multilateral treaty to deal with GMO trade, has gone some way towards coordinating national policies, but by establishing a devolved system of precautionary risk regulation, it has acknowledged the inherent limits to regulatory harmonization in this policy area.[225]

Nor has the United States' aggressive approach proven the most appropriate or effective way to gain acceptance of its biotech products; instead of pushing its view of patents on GMOs on the international community, the United States would be better advised to reexamine this use of intellectual property.[226]

Policymakers must realize that the objective is not simply a matter of removing barriers to trade, but promoting trade in a way that would benefit the public. In doing so, we can achieve both a secure global food supply and a more appropriate role for intellectual property rights in the international arena.

1–5, 2006.

[224] In May 2003, the European Union created the European Food Safety Authority (EFSA) to serve as a "food safety watchdog." Unlike its U.S. counterpart, the EFSA handles only the science of risk assessment, while FDA also handles the policy decisions involved in risk management. The European Parliament wanted an organization that gave "genuinely objective, independent and public advice," leaving the policy judgments to the European Commission. *See* Geoffrey Podger, *European Food Safety Authority Will Focus on Science*, 5 EUR. AFF. (2004), *available at* http://www.europeanaffairs.org/current_issue/2004_winter/2004_winter_77.php4; Strauss, *Importing Caution*, *supra* note 1, at 180–81.

[225] Robert Falkner, *The Global Biotech Food Fight: Why the United States Got It So Wrong*, 14 BROWN J. WORLD AFF. 107, 108 (2007).

[226] *See id.* at 108.