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David G. Scalise

Daniel Nugent

INTERNATIONAL INTELLECTUAL PROPERTY PROTECTIONS FOR LIVING MATTER: BIOTECHNOLOGY, MULTINATIONAL CONVENTIONS AND THE EXCEPTION FOR AGRICULTURE

David G. Scalise[*]
Daniel Nugent[**]

I. INTRODUCTION

For centuries human beings have selectively bred plants and animals to achieve superior agricultural products. This work has been painstakingly accomplished through cross fertilization and progressive plant and animal selection with the hope that the desired characteristic of the selected parent will surface in its offspring. Traditional methods represent a slow and arduous process whose results sometimes lack exactitude and require constant oversight to maintain stability.[1]

The biotechnological revolution of the 1980s and 1990s has enabled scientists to isolate the genetic material of living organisms and induce

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[*] Professor Of Business Law at the McLaren School of Business, University of San Francisco. Member of the California State Bar since 1973. Current research and publishing interests include international business law and intellectual property issues. Sixteen years private practice with a concentration in domestic business law.

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[**] Joint JD/MBA graduate from the University of San Francisco class of 1994 and graduate of Occidental College (A.B. 1990). Member of the California State Bar since 1994. Research interests include domestic and international business law, intellectual property and sports representation.

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[1] Also, after the desired characteristics were achieved, there existed an inherent tendency for the characteristic to fade over generations, a process termed "genetic drift." Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1071 (1988).

precise modifications so organisms portray and carry desired genetic traits. This ability is expected to revolutionize agriculture by developing genetically superior plants and animals. Biotechnologists are already developing plants that will be less reliant on toxic pesticides and fertilizers and capable of surviving on less water, and will likely possess higher nutritional values, improved taste and better appearance.[2] Animal-related research has already achieved more productive dairy cows and anticipates livestock that will provide higher yields of more nutritional meat that is lower in fat and cholesterol.[3] When one considers that total agribusiness revenues in the U.S. alone topped $1 trillion in 1992, one can begin to conceive of the immense financial opportunities in the agricultural-biotechnology industry (ag-biotech).[4]

History bears out that heedless progress inevitably destroys something of value. The most daunting illustration of this tradeoff is the splitting of the atom, which yielded humanity an almost inexhaustible supply of relatively clean-burning fuel while giving us the power to atomize ourselves.[5] Manipulation of the gene is not immune from the potential for such tramplings. The hypothetical "parade of horribles" articulated by those opposed to genetic research expresses fears of cloning people, engineering super-humans, releasing pathogenic microbes and numerous other misapplications of science.[6]

More tangible concerns regarding the biotechnological revolution will be realized within the agricultural community, both within the U.S. and internationally. The combination of biotechnology and corporate farming will achieve productivity and economies of scale that will make less efficient family and subsistence farmers unable to compete. Consequently,

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[2] VICE PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY, at 3 (Feb. 19, 1991). Among the scores of foods to be expected are cross-species products such as juice made from tomatoes spliced with an Arctic-flounder gene to inhibit frost, and potatoes carrying a chicken gene to improve disease resistance. Tim Sandler, *Brave New Foods; Some Consumer Land Mines Await Biotech Products*, PACIFIC SUN, Oct. 13-19, 1993, at 12.

[3] Al Gore, *Federal Biotechnology Policy: The Perils of Progress and the Risks of Uncertainty*, 20 U. MICH. J.L. REF. 965, 969 (1987). The introduction of bovine growth hormones has already resulted in cows that can produce 40% more milk. The article also discusses efforts underway to achieve multiple and more rapid birth rates, and animals with a higher resistance to disease. *See also* Edmund J. Sease, *From Microbes, To Corn Seeds, To Oysters, To Mice: Patentability of New Life Forms*, 38 DRAKE L. REV. 551, 566 (1989).

[4] Joan C. Hamilton et al., *The Country Cousin Is Blossoming, Too*, BUS. WK., Mar. 2, 1992, at 72.

[5] Gore, *supra* note 3, at 967.

[6] Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980).

there are domestic concerns that ag-biotech applications will jeopardize the future of the small family farmer, and international opinion is concerned about the further depredation of developing nations.[7]

To combat this danger, many implore the inclusion into intellectual property law a special right for farmers (farmers' privilege) to make use of agriculturally related patent and breeders' rights.[8] But such an addition amounts to a compulsory license, free from obligations to compensate inventors and immune from intellectual property infringement. Most of the world's jurisdictions yield some form of farmers' privilege exemption ranging from a limited right to replant and breed protected plants and animals to an outright refusal to recognize inventors' rights in living matter.[9] In carving out such special exemptions, individual nations and international bodies must remain conscious of the incentive -- money, that drives industry to achieve new and beneficial discoveries in the biosciences.

This article examines international intellectual property rights for the protection of living matter. It analyzes multinational convention efforts, the recurring issue of farmers' privilege and their impact upon the biotechnology industry. Section II discusses intellectual property laws in the U.S. and provides a framework and understanding from which to analyze the issues presented by farmers' privilege. It begins by addressing the rationale for vesting inventors with the right to exclude others from using their inventions, and the forms of intellectual property protections available to inventors of new or modified living organisms under U.S. law. Next, it focuses on the legislative exemptions for farmers' privilege recognized within the U.S. Finally, it explores the issue of whether intellectual property laws are an appropriate forum within which to create such an exemption.

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[7] Gore, *supra* note 3, at 970. "The yield on a large farm in Iowa is forty times that of a subsistence farm in Nigeria . . . ." *Id.*

[8] "Farmers' privilege" is used as a generic term that includes all forms of special use rights granted to farmers within all jurisdictions of the world. *See* David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 1030 (1993).

[9] *See infra* notes 46-48 and accompanying text; 7 U.S.C. § 2543 (1988) for a discussion of this legislation. The self-reproducing nature of animals introduces some ambiguities even into U.S. law. Although the intentional breeding of protected animals clearly infringes upon the owner's intellectual property rights, incidental mating in normal pen or cage conditions between protected animals can hardly be controlled. This led one commentator to conclude that incidental breeding would not support an infringement suit if the event lacked a culpable mental state. Merges, *supra* note 1, at 1068-69.

Section III provides an international perspective of farmers' privilege. It also discusses international treaties and conventions addressing international intellectual property rights and the failure to resolve the conflict between the interests of private industry in industrialized countries and the needs of developing countries.

The conclusion addresses alternatives for achieving an international sharing of technology while avoiding the deleterious effects upon the biotechnology industry of globally recognized farmers' privilege.

II. UNITED STATES LAW ADDRESSING BIOTECHNOLOGY AND FARMERS' PRIVILEGE

The concept of farmers' privilege with respect to intellectual property rights is analogous to an easement in real property. An easement entitles its holder to the limited use and enjoyment of another's land free from obligation to compensate the landowner and immune from prosecution for such use. Similarly, farmers' privilege allows farmers to use inventors' intellectual property for the limited purposes of breeding or replanting free from obligation to pay subsequent licensing fees. It also insulates farmers from prosecution for infringement.

The nature of farmers' privilege removes from inventors' rights a certain dimension of ownership in their intellectual property. Therefore, to fully comprehend the impact of such an exemption, we must become familiar with the basics of recognizing exclusive rights for inventors. Then we may begin to analyze the implications of curtailing those rights through special exemptions.

A. Exclusive Rights to Invention

Two generally accepted rationales support recognition of exclusive rights to invention. Exclusive rights create the incentive to invent and facilitate the dissemination of useful information. The first element, creating the incentive to invent, is fostered by states that grant innovators of new and useful products or processes the right to exclude others from using the new technologies.[10] Affording innovators this right enables

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[10] Thomas M. Keane, *The Patentability of Biotechnological Inventions*, IR. LAW TIMES 139 (1992).

At first, "the right to exclude others from using" may seem phrased unnecessarily in the negative. However, contrary to popular perception, a patent does not create the inherent right to use the patented invention, only the "right to exclude others from making, using, or selling the invention." 35 U.S.C. § 154 (1988). To illustrate, inventor B receives a patent for technology that incorporates prior technology subject to the patent of inventor A. B cannot use B's technology without a license from A, i.e., no

them to recover the research and development costs of producing new technologies and to obtain reasonable profits, which reward innovative thought and stimulate the entrepreneurial spirit. Absent such legal protections, others could duplicate end products and, by eliminating the research and development costs incurred by original developers, undercut their prices. In an environment without inventors' rights, investors would be unwilling to commit capital resources to develop new ideas, knowing there was scant opportunity to realize a reasonable return on their investments. And without adequate capital investment, progress would stagnate.

Facilitating the dissemination of useful information is the second element. Absent adequate legal protections, inventors would be likely to shroud their new ideas in secrecy while they attempt to realize the commercial value.[11] This secrecy would result in inefficient, duplicative research and a reluctance to share ideas, which so often lead to further developments and new applications. Although current patent laws protect inventors' rights, they require full disclosure of patented products or processes. Patented information becomes freely available to the public and enters the public domain when the patent expires.[12] In the meantime, other inventors may use information from prior patents to develop derivative inventions, although they must pay royalties to the patent holders.

"The grant or denial of patents on micro-organisms is not likely to put an end to research or to its attendant risks," but the rate of progress in an environment without intellectual property rights certainly will not approach the rate with protections.[13] This is particularly true for capital-intensive industries like biotechnology, in which long-term cash commitments are necessary to finance protracted research and development cycles. As an illustration, it is estimated that one ag-biotech concern committed more than $900,000 over several years to develop a more durable and productive maize hybrid, and another approximately $600,000 for a soybean variety with similar characteristics.[14] Without adequate

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right to use. B can, however, prevent anyone from making use of B's patented technology — hence the right to exclude.

See also U.S. CONST. art. I, § 8, cl. 8. "The Congress shall have the power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." *Id.*

[11] Keane, *supra* note 10, at 139.

[12] *See* 35 U.S.C. § 111 (1988). The Act requires the inventor to provide a complete description of the new invention, indicating how it works and the best means by which to reproduce it. *Id.*

[13] *Chakrabarty*, 447 U.S. at 317.

[14] Robin Waite & Nigel Jones, *Biotechnological Patents in Europe - The Draft*

legal protections it is improbable that private industry would commit such resources to develop the new technologies that will ultimately benefit all society.

B. Intellectual Property Rights for New Agricultural Technologies

Prior to 1970 the only intellectual property rights available to protect new inventions pertaining to living matter were contained in the Plant Patent Act of 1930 (PPA),[15] which recognized exclusive rights in a restricted class of asexual or vegetative reproducing plant life.[16] In 1970 Congress enacted the Plant Variety Protection Act (PVPA),[17] which extended protections for development of new varieties of sexually reproduced plants and expanded coverage to the most valuable commercial agricultural crops.[18] The PVPA became much more valuable for commercial agriculture because the bulk of commercial crops are sexually reproduced, thus the exclusive domain of the PVPA.

The concept of farmers' privilege was introduced into U.S. law within the PVPA. It authorized qualifying farmers to sell and replant seed varieties protected under the PVPA free from obligation to pay royalties to the PVPA certificate holder.

Prior to the PVPA there was no need for a special farmers' exemption, because before 1970 there was no form of property rights that would protect sexually reproducing plant life. Rights under U.S. patent laws were withheld from subject matter involving living organisms under the judicially conceived principle known as the products of nature doctrine (see following sections). Consequently, plant breeders could protect their discoveries only through qualification under the PPA or PVPA.

This area of intellectual property law was dramatically altered by the

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Directive, 11 EUR. INTELL. PROP. REV. 145, 146 (1989).

[15] Plant Patent Act, ch. 312, 46 Stat. 376 (1930) [hereinafter Plant Patent Act].

[16] Asexual reproduction encompasses all forms of vegetative propagation, including grafting, budding, air layering and reproduction through the use of tissue cultures. *See* 2 ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 476 (1971); Otto E. Landman, *Inheritance of Acquired Characteristics Revisited*, 43 BIOSCIENCE 696 (1993); Howard M. Lenhoff & Sylvia G. Lenhoff, *Trembly's Polyps*, 258 SCI. AM. 108 (1988).

[17] *See* Plant Variety Protection Act (1970), Pub. L. No. 91-577, *reprinted in* 1970 U.S.C.C.A.N. 5082, 5083 [hereinafter Plant Variety Protection Act].

[18] *See* 35 U.S.C. §§ 161-164 (1988); 7 U.S.C. §§ 2401-03, 2543 (1988). The PVPA expressly excluded from plant variety protection fungi and bacteria. 7 U.S.C. § 2402 (1988).

Sexual reproduction involves the use of seed. Seed is the ripened ovule of a plant that is created when pollen is transferred from the stamen (the male organ of the flower) to the ovule (the female organ of the flower).

landmark Supreme Court case *Diamond v. Chakrabarty*.[19] Delivered by the Supreme Court in 1980, the *Diamond* decision purported to overturn the products of nature doctrine and to recognize plant life as protectable subject matter under a standard utility patent. The following discusses these developments in detail.

1. The Standard Utility Patent

U.S. patent law dates back more than two hundred years to the passage of the first patent act in 1790. Thomas Jefferson, instrumental in enacting that legislation, is also credited as the architect of Article I, section 8, clause 8 of the U.S. Constitution, which authorizes Congress to make laws that "promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[20] The framers of the Constitution understood the need to encourage inventors to invest in new technologies by offering temporary protections against those who would infringe.

Although the patent laws were amended several times, the most recent version, the Patent Act of 1952, preserves the three tenets that have governed since the inception of patent protection: novelty, utility, and nonobviousness of the invention. Title 35, codifying the Patent Act of 1952, states, "[w]hoever invents or discovers any *new* and *useful* process, machine, manufacture, or composition of matter, or any *new* and *useful* improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title (emphasis added)."[21] The term "new" is enlarged in §§ 102 and 103, which combine to deny patents when the invention is "known or used by others" (novelty) or is a mere extension of knowledge obvious to a person learned in the art (nonobviousness).[22]

The language that follows the "new" and "useful" elements in § 101 defines the scope of patentable subject matter to encompass any "process, machine, or composition of matter . . . " Subsequent judicial doctrine has narrowed this scope by identifying several classes of nonpatentable inventions to exclude scientific principles, laws of nature, physical phenomena, abstract ideas and products of nature.[23] The exclusion of prod-

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[19] *Chakrabarty*, 447 U.S. at 303.

[20] U.S. CONST. art. I, § 8, cl. 8.

[21] 35 U.S.C. § 101 (1988).

[22] *Id.* at §§ 102-103.

[23] Elizabeth Joy Hetch, Note: *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1030 (1992).

ucts of nature from patentable subject matter is at the core of this paper.

2. The Products of Nature Doctrine

The products of nature doctrine is derived from the inherent truth that something cannot be new if it already exists in nature.[24] Discovery of a previously unknown plant variety or animal species is certainly new by dictionary definition; however, to be patentable, the applicant must take an inventive step. To illustrate this requirement, suppose a scientist discovers a previously unknown plant in the South American rain forest that, in its natural form, counteracts Alzheimer's disease. Although the discovery is unquestionably valuable, it lacks the necessary inventive step for patentability. To satisfy the novelty requirement, the scientist must contribute something to the plant that alters its natural qualities and renders something new.

Although the products of nature doctrine appears to be rather straightforward, the courts have a history of manipulating its application to reject the patentability of higher life forms. Their decisions precariously defined the degree of intervention, — that inventive step — that transforms the subject matter from a product of nature into a patentable organism.[25] The Court's quandary and ambiguity are well-illustrated by *American Fruit Growers, Inc. v. Brogdex.*[26]

In this case, Brogdex won a patent infringement action against American Fruit Growers (AFG), alleging that AFG made unlawful use of Brogdex's patented process of impregnating orange rinds with small amounts of borax, thereby rendering the fruit resistant to destructive blue mold decay. AFG appealed the case to the Supreme Court, arguing that Brogdex's patent defined nothing more than a natural fruit and therefore was an unpatentable product of nature. Brogdex, relying upon the circuit court's rationale, asserted that borax did not naturally collect in orange rinds and therefore was not a "composition of matter" found in nature.

The Supreme Court rejected Brogdex's claims and reversed the district court and court of appeals, asserting that the "addition of Borax to the rind of natural fruit does not produce . . . an article for use which possesses a new or distinctive form, quality or property." The Court concluded, "there is no change in the name, appearance, or general character of the fruit."[27] The Court's analysis seemed indefensible, and

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[24] Sease, *supra* note 3, at 554.

[25] *Id.*

[26] American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1 (1931).

[27] *Id.* at 11. The Supreme Court quoted a portion of the circuit court's opinion: "[t]he product is a combination of the natural fruit and a boric compound carried by

many have commented that "there was little logic in the decision."[28] The borax-impregnated orange undeniably possessed a new and distinct quality in that it was resistant to the ruinous blue mold decay, a quality that changes the general character of the fruit.

The products of nature doctrine was applied with equal bafflement to reject patent applications covering advancements in animal husbandry.[29] As exemplified in *American Fruit Growers,* the courts appeared willing to transcend the boundaries of logic to repudiate the patentability of a complex living organism. As a consequence, plant breeders were reduced to the illusory rights available under the PPA while animal breeders were denied any substantive rights for their developments.

3. The Plant Patent Act of 1930

In addition to the obstacle represented by the products of nature doctrine, plant breeders seeking patent protection under 35 U.S.C. § 101 were confronted with an exacting written description requirement. Prior to the birth of biotechnology, plant breeding was an indeterminate science whose developments were more easily observed than explained. When a new plant differed from the old only in color, scent or texture, it was almost impossible to satisfy the written description requirement. Consequently, plant breeders were denied substantive protection for their discoveries, derailing innovation in this field.[30]

Recognizing the inadequacies of the patent laws, Congress enacted the PPA in 1930 to "afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry."[31] The PPA states, "[a]ny person who has *invented* or

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the rind or skin in an amount sufficient to render the fruit resistant to decay. The complete article is not found in nature and is thus an article of manufacture." *Id.*

[28] Sease, *supra* note 3, at 555.

[29] For an illustration see *Ex parte* Grayson, 51 U.S.P.Q. (BNA) 413 (PTO Bd. App. 1941), in which the court rejected a patent claim covering a fresh shrimp from which the head and sand vein had been removed. Despite the increased commercial value of this improved shrimp, the court determined that the resulting product was still a natural shrimp and therefore precluded from patent protections under the products of nature doctrine.

[30] "Prior to the Plant Patent Act of 1930, there was very little private plant breeding done aside from that performed by a handful of amateurs or hobbyists. Since then [1930], and today [1970], some 2,700 plant patents have been issued, largely to commercial breeders." Plant Variety Protection Act, *supra* note 17, at 5083.

[31] *Hearing Before the Subcommittee on Departmental Operations of the Committee on Agriculture,* 91st Cong., 2d Sess. 7 (1970) (statement of Allenby White, Chairman, Breeders' Rights Study Committee, American Seed Trade Association, quoting S. REP.

discovered and asexually reproduced any *distinct* and *new* variety of plant . . . may obtain a [plant] patent . . . (emphasis added)."[32] Furthermore, to address the issue of written description, the PPA proclaims, "No plant patent shall be declared invalid for non-compliance with section 112 of this title if the description is as complete as is reasonably possible."[33]

Under the PPA, the elements of invents or discovers, distinct and new, are loosely analogous to the elements of novelty, utility and nonobviousness required for a standard utility patent. A distinct plant variety will possess at least one significantly different characteristic that may be physiological (e.g., immunity to disease, resistance to cold) or anatomical (e.g., size, shape or color) and need appear only in some portion of the plant (root, stem, leaf or fruit). "Newness" and "invents or discovers" simply require that the plant possess a heretofore unappreciated characteristic and that the breeder possess the foresight to asexually reproduce the plant.[34] The requirements for obtaining a plant patent, therefore, are substantially more liberal than those mandated for a standard utility patent.

The PPA was not an unqualified victory for plant breeders. By the terms of the statute, plant patents are available only for asexually reproducing plants with the express exclusion of "tuber propagated plants" and "plants found in an uncultivated state."[35] Subsequent judicial interpretation further removed newly discovered bacteria[36] and tissue cultures used to create a plant variety[37] because they were each found not to be plants within the meaning of the PPA. Moreover, because the PPA protects only asexually reproducing plants, the patentee may exclude others only from asexual reproduction of the plant or from the use or sale of the protected plant that was asexually reproduced.[38] The net result of this legislation was a mechanism that offered narrow protections for plant breeders and awakened a measurable amount of research activity in this area. However, the narrow scope of the PPA neglected those plant species that comprise the bulk of U.S. commercial agriculture, rendering the legislation largely

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No. 315, 71st Cong., 2d Sess. (1930)) [hereinafter *Hearing Before the Subcommittee on Departmental Operations*].

[32] Plant Patent Act, *supra* note 15.

[33] *See* 35 U.S.C. §§ 161-164 (1988). *See also Hearing Before the Subcommittee on Departmental Operations*, *supra* note 31, at 7.

[34] PETER D. ROSENBERG, 1 PATENT LAW FUNDAMENTALS § 6.01[4][a] (2d ed. Supp. 1994).

[35] *See* 35 U.S.C. § 161 (1988).

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

[37] *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (P.T.O Bd. App. & Int. 1985).

[38] *See* 35 U.S.C. § 163 (1988).

unavailing to breeders engaging in the most beneficial research.[39]

4. The Plant Varieties Protection Act of 1970

The PPA was a qualified boon to the science of plant breeding, as evidenced by the 2,700 plant patents issued between its enactment, in 1930, and 1970. Its success was qualified, however, because the PPA excluded major U.S. cash crops such as cotton, wheat, barley, soybeans, oats and rice, which could not be vegetatively propagated. Researchers in private industry consequently subordinated those crops. By 1964, Western Europe had enacted laws to invigorate its plant breeding industry[40] and was fully appreciating the benefits of recognizing inventors' rights in sexually reproducing new plant varieties.[41] This progress placed U.S. agriculture at a competitive disadvantage because U.S. farmers lacked improved seed varieties being developed and protected by Western European nations. In response to this inauspicious trend, Congress passed the PVPA in 1970.

(a) Certification of a Plant Variety

The PVPA established a mechanism whereby "the breeder of any *novel variety* of *sexually reproducing* plants (except fungi, bacteria, and hybrids) . . . is entitled to plant variety protections,"[42] wherein a sexually reproducing plant is identified as any plant reproduced by seed (emphasis added).[43] Like the PPA, the PVPA contains the liberal written description requirement: the applicant need only specify that the claim is "as complete as is reasonably possible."[44]

The required showing to obtain a certificate covering a novel plant

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[39] *Hearing Before the Subcommittee on Departmental Operations*, *supra* note 31.

[40] *See, e.g.*, Convention for the Establishment of the European and Mediterranean Plant Protection Organisation, Apr. 18, 1951, U.K.T.S. 44; International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, 815 U.N.T.S. 89 [hereinafter the International Convention for the Protection of New Varieties]; Plant Varieties and Seeds Act of 1964 (U.K.).

[41] *See* Plant Variety Protection Act, *supra* note 17, at 5083. In 1964, England enacted its Plant Varieties and Seeds Act to come into compliance with the Western European plant breeders rights convention.

[42] 7 U.S.C. § 2402 (1988).

[43] *Id.* at § 2401(f).

[44] *Id.* at § 2422(2). The uncertainty of nongenetic-based inventions in the science of plant breeding denied plant breeders access to utility patents, because the disclosure requirements of a utility patent could not be achieved with the necessary specificity. *See infra* note 30 and accompanying text.

variety is laid out in title 7 U.S.C. § 2401. Subsection (a) defines a "novel variety as one [1] *differing* in any characteristic from all prior varieties, [2] possessing *uniformity* to the extent that any variations are predictable and commercially acceptable, and having reasonable stability (emphasis added)." The distinctiveness and newness elements contained in the PPA are preserved in the PVPA by this definition, which requires that a patentable plant "differs in any characteristic from all prior varieties."

The second element, pertaining to "uniformity," supplants the "invents or discovers" element within the PPA, which requires that the breeder asexually reproduce the new variety. The offspring of an asexually reproduced plant contains the identical genetic material as its sole parent; hence the resultant offspring is a uniform product. Sexual reproduction, however, requires two parents that will not possess the same genetic composition and whose offspring may exhibit traits of either parent. Plant breeding with sexually reproducing plants is a capricious endeavor whose results are often difficult to explain. Hence, the PVPA's uniformity requirement exists as a quality control mechanism to ensure that farmers receive a somewhat predictable and stable seed crop.

(b) Farmers' Privilege

The PVPA was enacted with two unique exemptions, one for researchers[45] and another for farmers.[46] The research exemption is a narrow privilege that permits the use and reproduction of a protected variety for bona fide research purposes. This is not perceived as a substantial curtailment of the certificate holder's rights, because the monetary returns from sales to research facilities are insignificant. The farmers' privilege, on the other hand, represents a major encroachment upon inventors' rights because farmers represent the principal purchasers of new plant varieties.

Section 2543 of title 7 defines the scope of farmers' privilege for two general classes of agriculturists. The first class applies to all farmers, permitting them (1) to sell crops produced from a protected variety for other than reproductive purposes and (2) to save seed from their protected crops for future use or for planting on the farm.[47] Although the rights of

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[45] 7 U.S.C. § 2544 (1988).

[46] *Id.* at § 2543.

[47] [I]t shall not infringe any right hereunder for a person to save seed produced by him from seed obtained, or descended from seed obtained, by authority of the owner of the variety for seedling purposes and use such saved seed in the production of a crop for use on his farm, or for sale as provided in this section. . . . It shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged, for reproductive purposes . . . .

farmers to market their crops is a logical and necessary privilege, the economic impact of the right to save seed is substantial. The developer of a new plant species can exact only a one-time license fee from a farmer for the farmer's use of seed in perpetuity. This presents difficult, yet not insurmountable, marketing and pricing considerations.

The second class applies only to those farmers "whose primary occupation is the growing of crops for sale for other than reproductive purposes," and permits the sale of saved seed for reproductive purposes to others engaged in farming as their primary occupation.[48] This exemption provides for a wide distribution of certified seed without plant breeders receiving compensation for their "protected" products. In just one crop cycle developers of new plant varieties have essentially lost all exclusive rights to market and sell their innovation.

These broad exemptions create substantial disincentives to investment in developing new plant varieties; consequently, one wonders if the PVPA is an appropriate place to legislate farm support programs. Additionally, neither the PPA nor the PVPA recognizes any rights for protecting advancements in the art of animal breeding. The net result is an odd collection of laws that, in the aggregate, fail to provide sufficiently extensive rights for those engaged in the agricultural sciences.

5. *Diamond v. Chakrabarty*: Patenting Living Matter

Prior to 1980, the U.S. Patent and Trademark Office (PTO) and the lower federal courts engaged in a seemingly determined effort to reject the patentability of living matter. Despite anomalous patents, such as that issued to Louis Pasteur in 1873 for his purified culture of yeast,[49] the courts invariably rejected patents that pertained to living matter. Their most effective weapon was the products of nature doctrine, as discussed in the *American Fruit Growers* case.[50] When that doctrine failed, the PTO and private plaintiffs relied upon the plant protection acts of 1930 and 1970 as evidence that Congress intended that only living organisms qualifying under one of the acts were to be afforded intellectual property rights.[51] Hence, plant and animal breeders and biotechnologists faced a

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Id. "Future use" would encompass use as livestock feed, replanting and most other dispositions of the seed that do not involve the sale for reproductive purposes.

[48] *Id.*

[49] Robert B. Kambic, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URB. L. J. 441, 449 (1988).

[50] *See supra* notes 26-29.

[51] *In re* Bergy, 596 F.2d 952, 965 (C.C.P.A. 1979). The companion case to

legal environment hostile to developments in their respective sciences.

In 1980, the Supreme Court issued an opinion in what is unequivocally heralded as the landmark case in biotechnology-related patent law.[52] The action was originated by a microbiologist challenging a ruling by the PTO that denied his application to patent a genetically engineered strain of bacteria capable of breaking down multiple components of crude oil. Chakrabarty's invention was a process for introducing specific plasmids, each capable of breaking down one of the four components of the oil molecule, into a host Pseudomonas bacteria.[53] The unaltered, naturally occurring Pseudomonas had no capacity for degrading oil; however, the modified Pseudomonas had substantial value for treating oil spills.[54]

PTO examiners denied Chakrabarty's application on the duel analysis that microorganisms are nonpatentable products of nature and that as living things they are per se nonpatentable subject matter. The products of nature argument was subsequently rejected by the Patent Office Board of Appeals (Board) after they recognized that Pseudomonas possessing the special characteristics of Chakrabarty's bacterium are not naturally occurring.[55] The Board, however, affirmed the PTO ruling on the second argument, explaining that Congress's special provisions under the PPA was conclusive evidence that § 101 was not intended to cover living things. The Supreme Court granted review on the issue of "whether respondent's [Chakrabarty's] micro-organism constitutes a 'manufacture' or 'composition of matter' within the meaning of [35 U.S.C. § 101]."[56]

Step one of the Court's analysis required defining the concepts "manufacture" and "compositions of matter." The term "manufacture" was given its dictionary definition to mean "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combination, whether by hand-labor or machinery."[57] A composition of matter was cited in prior case law as including

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Chakrabarty, *In re Bergy*, held that a biologically pure culture of microorganisms was patentable subject matter. The PTO argument, urging that the PPA and the PVPA evidenced a Congressional intent to remove plant life from coverage under the patent laws, was rejected by the Court of Customs and Patent Appeals. *Id.*

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

[53] A plasmid is any inclusion in a cell that has a genetic function but is not located in the nucleus. *See* 16 TABER'S CYCLOPEDIC MEDICAL DICTIONARY 1415 (1989).

[54] *Chakrabarty*, 447 U.S. at 305.

[55] *Id.* at 306 n.3. *See also In re Bergy*, 596 F.2d at 971 (rejecting the PTO's argument regarding the products of nature doctrine).

[56] *Chakrabarty*, 447 U.S. at 306, 308.

[57] *Id.* at 308. Oddly enough, this definition was quoted from the *American Fruit*

"all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gasses, fluids, powders or solids."[58]

Step two involved reading these terms in their statutory context. The Court proclaimed that the combination of such expansive terms as "manufacture" and "composition of matter" modified by the all-inclusive "any" was indicative of Congress's intention that the patent laws be broadly read. The Court also referred to committee reports from the 1952 recodification of the patent laws, which announced that it is Congress' intent that the statutory subject matter include "anything under the sun that is made by man."[59] In conclusion, the Court held that the language of § 101 fairly embraced Chakrabarty's invention of the Pseudomonas organism, thus dispelling the notion that living matter is not patentable.

With this decision the Supreme Court unveiled to U.S. science and industry a vast new world of opportunity. Initially, many waited to see if Congress would accept the Supreme Court's invitation to enact regulations covering the area of life patents.[60] However, as the resulting legislative paralysis became apparent, a rush into genetic research ensued. *Chakrabarty's* broad interpretation of patentable subject matter provided U.S. companies with the promise of patents to protect their investments into new technologies. As a result, U.S. industry greatly expanded its commitment to genetic engineering, establishing an early position of world dominance it has yet to yield.

6. The Legacy of *Diamond v. Chakrabarty*

Despite the sweeping construction of the *Chakrabarty* opinion — that patentable subject matter should include "anything under the sun that is made by man" — many questions remained. In a limited reading, the Supreme Court had expressly authorized only the grant of a patent for a

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Growers case, discussed previously. Certainly, the impregnation of the orange rind with borax seems to have given the fruit a "new quality or property" because of Brogdex's inventive labor.

[58] *Id. See also* Shell Development Co. v. Watson, 149 F. Supp 279, 280 (D.C. 1957).

[59] In 1952 Congress recodified the patent laws, the original language of which was written by Jefferson. The recodification appears in 35 U.S.C. beginning with § 101 as the present U.S. patent law.

See also Chakrabarty, 447 U.S. at 309; S. REP. NO. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. REP. NO. 1923, 82d Cong., 2d Sess., 6 (1952).

[60] "Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. . . . Or it may choose to craft a statute specifically designed for such living things." *Chakrabarty*, 447 U.S. at 318.

microorganism that was not contemplated by either of the plant protection acts. The question remained regarding whether the PTO and the courts would sanction patent protections encompassing complex living organisms such as plant and animal life, as *Chakrabarty* had decreed.

The first test occurred in 1985 in the case of *Ex parte Hibberd*, heard before the PTO's Board.[61] *Hibberd* concerned the patentability of a corn plant engineered to possess an abnormally high level of amino acids.[62] The PTO had rejected Hibberd's application on the basis that the existence of the PVPA meant that plants do not qualify for the standard utility patent under 35 USC § 101. The Board rejected this argument, recognizing "that neither the PPA nor the PVPA expressly excludes any biological subject matter from protection under Section 101 [utility patent]." The Board further recognized the inconsistency of allowing utility patent protections for certain hybrid seeds, hybrid plants and bacterium (*Chakrabarty*) that are expressly excluded from coverage under the PPA or PVPA, but that are no less members of the plant kingdom.[63]

The 1987 case of *Ex parte Allen*, represented the next step for *Chakrabarty* and the patentability of higher life forms. Allen challenged the PTO examiners' denial of a patent application covering both a process for inducing polyploiding in Pacific oysters and the end product oyster. The examiner rejected Allen's application on the duel grounds of unpatentable naturally occurring subject matter and obviousness.[64]

The Board ultimately upheld the PTO examiner's refusal to grant a patent on the grounds that "prior art" (previous discoveries) disclosed the methods of polyploiding other species of oysters, — thus Allen's was an obvious oyster.[65] Yet, despite this basis for disposing of Allen's appeal, the Board went out of its way to affirm *Chakrabarty* and reject the PTO examiner's reliance on the antiquated products of nature doctrine. "The

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[61] *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (P.T.O. Bd. App. & Int. 1985).

[62] Amino acids are principal components of protein and, consequentially, an essential element of the human diet. *See* 16 TABER'S CYCLOPEDIC MEDICAL DICTIONARY 64-75 (1989). Therefore, the presence of higher amino acid levels in corn creates an inexpensive and accessible source of the necessary building materials of the human body. 1 INTERNATIONAL DICTIONARY OF MEDICINE AND BIOLOGY 92 (1986).

[63] *Hibberd*, 227 U.S.P.Q. (BNA) at 444 n.1, 445.

[64] Polyploiding of oysters entailed the maintenance of specific temperatures during fertilization and incubation in addition to the application of predetermined levels of hydrostatic pressure on the fertilized eggs. The result is an oyster that possesses an additional set of chromosomes, rendering it sterile and capable of growing much larger with a much higher meat content because of the absence of reproductive activity. *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (P.T.O. Bd. App. & Int. 1987).

[65] *Id.* at 1427.

examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man" and as "non-naturally occurring manufactures or compositions of matter are within the confines of patentable subject matter under 35 U.S.C. 101."[66]

Only days after the Board delivered the decision in *Allen*, the PTO issued its renowned capitulatory Notice of April 7, 1987.[67] The Notice unequivocally stated that the examiner's office intended to live by the terms of *Chakrabarty* and properly issue patents for "anything under the sun that is made by man." The notice stated in part:

> The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty* . . . as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. . . .
>
> Accordingly, the Patent and Trademark Office is now examining claims directed to multi-cellular living organisms, including animals. To the extent that the claimed subject matter is directed to non-human "non-naturally occurring manufacture or composition of matter — as product of human ingenuity," (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. § 101 as being directed to nonstatutory subject matter.[68]

This controversial statement withstood subsequent challenges in the courts and in Congress, and paved the way for the first patent covering a multi-cellular living mammal, the Harvard Mouse, patent issued April 12, 1988.[69]

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[66] *Id.*

[67] 1077 OFFICIAL GAZ. PAT. OFFICE 24, 31 (April 21, 1987).

[68] *Id.*

[69] The case of *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991) considered a challenge to the PTO's authority to issue its Notice of April 7, 1987, on the dual grounds that (1) the PTO had violated procedural requirements for issuing the notice without providing public notice and an opportunity for public comment, and (2) that patenting animals threatened the breach of a variety of animal protection laws. *Id.* at 923-924. The Appellate Court dismissed it on the ground that the Animal Legal Defense Fund lacked standing to sue because it had suffered no legally cognizable injury. *Id.* at 925. Despite these grounds for dismissal, the court could not resist commenting on *Diamond* and the scope of patentable subject matter: "[t]he issue, in our view, in determining whether the claimed subject matter is patentable under Section 101 is simply whether that subject matter is made by man."

7. Usurpation of the Plant Protection Acts

The *Chakrabarty* decision and its legacy substantially supplanted both plant protection acts because of the flawed foundation upon which the acts were constructed: that the scientific world could somehow be divided into two classes (the micro-biological world of simple matter such as bacteria and parasites, and a macro-biological world of complex living organisms such as plants and animals).[70] This simplistic and antiquated view of the biological world was shattered by the science of biotechnology. Bioscientists have demonstrated that through exacting alterations at the micro level of an organism's structure, one can obtain predictable macro level changes. Hence, the biotech engineer has merged the two previously postulated worlds, forcing the legal environment to confront and obstruct science or to progress with it.

The pragmatic result of *Chakrabarty* is that now the inventor of a new plant variety propagated by genetic engineering can pursue legal protections through the PPA, the PVPA or a standard utility patent. Qualification for a standard utility patent remains conditioned upon satisfaction of the stringent disclosure requirements, precluding all but genetically engineered plants and animals.[71] However, for qualified subject matter the benefits of a utility patent far exceed those provided by either the PPA or the PVPA and are free from the numerous and burden-

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Id. at 928 (citing *Ex Parte* Allen, 2 U.S.P.Q.2d (BNA) 1425, 1426 (1987)).

Following the judicial activity addressing life patents in 1987, Congress responded with a flurry of bills. The proposed legislation ranged from efforts to impose a moratorium on the patenting of living matter, [H.R. 3119, 100th Cong., 1st Sess. (1987)] to more narrowly tailored bills that proposed the creation of farmers' privilege applicable to patented transgenic plants and farm animals [The Transgenic Patent Reform Act of 1988, H.R. 4970, 100th Cong., 2d. Sess. (1988) and The Transgenic Patent Reform Act of 1989, H.R. 1556, 101st Cong., 1st Sess. (1989)]. Although these bills provoked a substantial amount of public interest and debate, none were adopted. Consequently, the biotechnology industry continued in its pursuit of new technologies unimpeded by Congressionally imposed limitations upon the patentablity of their products.

[70] *See* LESLIE WILLIAM MELVILLE, 2 FORMS AND AGREEMENTS ON INTELLECTUAL PROPERTY AND INTERNATIONAL LICENSING § 13.03[6] (1994).

[71] The process of genetic engineering entails isolating the DNA molecule that represents a desired characteristic and replacing that molecule with new DNA material that contains the living code for reproducing said characteristic. This is an exact science, subject to precise descriptions of replication. Conversely, the art of plant breeding involves the blending of two plants and is not subject to the type of exacting specifications required for a utility patent. 2 INTERNATIONAL DICTIONARY MEDICINE AND BIOLOGY 1189 (1986).

some exceptions found in the PVPA. Therefore, prudent inventors should pursue legal protection via a utility patent whenever they qualify.[72]

Inextricably bound with the demise of the PVPA as the legal mechanism of choice for protecting botanical inventions is the fate of farmers' privilege. The PVPA is the exclusive domain of farmers' privilege because neither the standard utility patent nor the PPA provides an exemption for agriculture. As the utility patent becomes the method of choice for protecting new bio-engineered plant varieties, the question becomes whether farmers' privilege should be incorporated into the standard utility patent. A secondary question is also raised: whether farmers' privilege contained within the body of patent law should expand to encompass an exemption for genetically engineered livestock.

C. *Analysis of Farmers' Privilege*

Ideally, the desirability of any legislation is determined by weighing the cost of furnishing the legislation against the benefits to be derived from it. We use this approach to examine farmers' privilege and begin by analyzing the policy objectives that support including an agricultural exemption within the patent laws. Next, we address the societal costs of providing farmers' privilege, focusing on who bears the burden of paying for the exemption and the consequences for the biotechnology industry. Lastly, we begin to expand discussion of farmers' privilege to encompass the international perspective, contrasting policy objectives of the U.S. with those of the world community.

1. Policy Objectives

The argument in support of farmers' privilege focuses largely upon the plight of small, family-owned farms. Advocates of farmers' privilege realize that the contributions of biotechnology will enable agriculture to make enormous leaps in productivity. However, they also realize that the high development costs of bioengineered plants and animals will largely preclude small farmers from participating in the new technologies. Only large corporate agriculture, capable of spreading the costs among vast economies of scale, will be able to afford the technologies.[73] Productivity gains realized from the combination of biotechnology and corporate agriculture will, without intervention, jeopardize the cherished institution of small, family-owned farms.

Although the focus of farmers' privilege debates seems inexorably

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[72] Sease, *supra* note 3, at 567.

[73] Kambic, *supra* note 49, at 461. *See also* Gore, *supra* note 3, at 969.

drawn into a discussion of the small, family-owned farm, one must recognize that many classes benefit from farmers' privilege. The exemption within the PVPA grants farmers the right to save seed produced from a protected variety (second generation seed) for future planting and in certain instances for resale to other farmers.[74] The crop exemption lowers the cost of new and improved plant varieties to farmers who can acquire second generation seed from other farmers at a fraction of the original price. Providing lower cost access to improved seed and livestock will certainly help the small farmer remain competitive with corporate agriculture. However, the lower production costs realized by all farmers will ultimately pass to consumers in the form of lower food prices.[75]

This examination exposes important considerations regarding an exemption for agriculture. Although the primary intention of farmers' privilege is to protect the institution of the small, family-owned farm, the principal beneficiary is the consumer who profits from lower prices and a stabilized food supply.[76] Yet, the burden of paying for it is borne by inventors who are denied the exclusive right to sell their technologies and thereby obtain a fair return on investment. This generates controversy regarding whether intellectual property laws are the appropriate forum from which to legislate agricultural support programs and prompts investigation into the consequences of forcing the financial burden upon the biotechnological industry.

2. Societal Costs

In pursuit of the goal of making agriculturally related technologies available to small, family-owned farms, one must remember the fundamental rationales for granting intellectual property rights. The purpose

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[74] 7 U.S.C. § 2543 (1988). *See also* Plant Variety Protection Act, *supra* note 28, § 113.

[75] Agricultural product markets are close to perfectly competitive markets. A perfectly competitive market is defined by four characteristics: (1) numerous participants, (2) homogeneity of product, (3) freedom of entry and exit and (4) perfect pricing information. Under these conditions the individual firms (farmers) are price takers, having no choice but to accept the price that has been determined in the market. Consequently, if simultaneous productivity increases and reductions in production costs are realized, the supply of agricultural output would be expected to increase. If supply goes up, market prices will fall and consumers will reap the benefits of lower food prices. WILLIAM J. BAUMOL & ALAN S. BLINDER, ECONOMICS; PRINCIPLES AND POLICY 468-482 (3d ed. 1985).

[76] Through the use of more durable and more plentiful varieties, more food can be cultivated on less land. Economic fundamentals teach that if the supply of food increases, *certerus paribus*, the price must decrease. *Id.* at 482.

of the patent system is to promote the progress of science by securing for inventors the exclusive rights to their discoveries for a limited time. Through the grant of property rights to inventions, inventors are able to profit from their ingenuity, which, in turn, fosters the advancement of science and technology.[77] It would therefore follow that curtailment of inventors' property rights, which impedes their ability to profit, would diminish their incentive to invent.

The concern of adequate return on investment is particularly acute among biotechnology companies that invest enormous amounts of time and money to bring a genetically engineered product to market. Calgene Fresh, Inc., a California-based biotech concern, has invested ten years and $20 million into engineering a genetically superior tomato, the Flavr Savr MacGregor tomato. The Flavr Savr has a ninety percent longer vine-and-shelf life than the ordinary tomato, the result of Calgene's reversing the gene that causes spoilage. The Flavr Savr is among the first successes of the ag-biotech industry and provides tangible evidence of the forthcoming benefits of genetically engineered foods.[78] Unfortunately, private industry will not continue to fund these projects if intellectual property rights are eroded by exemptions such as farmers' privilege, thus full commercial exploitation of new ideas will be inhibited.

Tampering with patent laws to achieve public policy should be used only as a last resort. Options, such as government intervention through regulation or as a market player, should be exhausted before beginning to abridge inventors' rights. Indeed, governments are capable of achieving the objectives of farmers' privilege through alternative methods of intervention, which accomplish a more logical and practical solution. Fundamental economics teach that when society as a whole benefits from regulatory intervention, government, which represents the whole, should bear the burden of providing those benefits or market distortions will occur.[79] Transferring the burden to a select segment of private industry, like ag-biotech and plant breeders, undermines the incentive for those parties to invest in the new ideas from which we all benefit.

The existence of farmers' privilege shows that the U.S. government wants to assist farmers by making new technologies accessible, particularly to the small, family farmer who could otherwise not afford it.[80] To achieve this goal wealthy governments possess regulatory options that do not distort the economic incentives of investing in new technologies.[81]

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[77] *See* U.S. CONST. art I, § 8, cl. 8. *See also* Keane, *supra* note 10, at 139.

[78] Sandler, *supra* note 2, at 12.

[79] BAUMOL & BLINDER, *supra* note 75, at 550-551.

[80] Kambic, *supra* note 49, at 461.

[81] *See generally id.* (discussing the U.S. patent system's encouragement of innova-

Examples of such legislation include enabling farmers to purchase new technology through subsidized government loans, providing financial incentives such as tax breaks for patent owners who sell below market price, or direct government purchases. These forms of intervention could also be tailored to promote only small farmers, if that is the principal concern of government. Thus, farmers' privilege using patent or plant variety protected subject matter is neither a necessary nor a desirable exemption for developed nations when less distortive alternatives exist.

3. Alternative Legislation

Agriculture in developing countries is often largely performed on a subsistence basis in which the farmers' exclusive function is to supply food for personal or local consumption. Land is typically parceled out into small and underproductive plots, which precludes those countries from realizing the economies of scale that corporate farms in developed countries are capable of achieving. Consequently, farmers cannot afford the expensive seeds, feeds, fertilizers and pesticides that increase productivity. The absence of such agricultural catalysts inhibits the ability of underdeveloped countries to feed their populations and to provide their people with an opportunity to earn a living producing raw materials.

For countries that lack the public financing necessary to provide alternative means of agricultural support, farmers' privilege is a popular concept. Consequently, the leaders and proponents of underdeveloped countries promote a multinational treaty that would create an internationally recognized farmers' privilege. The efforts to achieve such an international convention have thus far been unsuccessful because of strong opposition from countries that believe their economic future is in developing biotechnological sciences.

Although the debate appears to be a return to the age-old conflict of the haves attempting to protect their property, intellectual or otherwise, from the have-nots, there is a much more significant question to consider. The issue is whether international farmers' privilege would discourage investment in new agricultural technologies by undermining the ability to profit from one's innovation. In essence, this is an analysis of the "[r]ight to save seed/crop exemption" contained within the PVPA but on an international scale.

If the world fails to fully compensate inventors of new and improved plant varieties, then the optimal level of investment in developing improved seed, feed and livestock will not be achieved. This concern must be carefully addressed within any multinational convention that purports

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tion through invention protection).

to create farmers' exemption. The second half of this Article examines international efforts, discusses their workability and proposes alternative solutions to the dilemma of farmers' privilege.

III. INTERNATIONAL TREATIES AND CONVENTIONS ADDRESSING BIOTECHNOLOGY PATENTS AND FARMERS' PRIVILEGE

The international markets for goods and services have become increasingly important, focusing much attention upon constructing a unified standard of international commercial laws. The need for a unifying convention is particularly acute in the area of patent law: presently 179 international jurisdictions grant patents, each with its procedures and substantive peculiarities. Obtaining multinational patent rights in this chaotic environment can be expensive and time consuming, if not impossible. The primary obstacle for the inventor is the thousands of dollars required per jurisdiction in filing costs and attorney fees, even though the inventor may receive patents in only a fraction of these jurisdictions.[82]

The proposition that a uniform system for recognizing international patent rights would reduce a great deal of the waste and inefficiency is unchallenged, but an impassioned debate has arisen regarding the scope of protections which could be achieved by a supranational convention. Private industry in developed countries prefers the most expansive bundle of property rights possible to protect its new technologies. Developing countries are demanding that private industry in developed countries surrender certain rights in consideration for the benefits to be realized under a universal patent system. Among the developing nations' concerns is the exclusion of living organisms from the scope of protectable subject matter. This demand is not wholly unreasonable, considering that a significant percentage of genetic material used in bioengineering new plants and animals is native to their countries.

Despite numerous attempts within several international fora, developed and developing countries have thus far failed to reach a compromise. The remainder of this Article discusses the international conventions that have attempted to establish a globally recognized patent and analyzes why each ultimately failed or appears doomed to fail.

A. *World Intellectual Property Organization*

The World Intellectual Property Organization (WIPO)[83] was founded

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[82] The 179 jurisdictions include 176 countries and 3 supranational bodies. *See* Edward J. Raldo, *Recent Developments Affect International Patent Harmony*, L.A. DAILY J., Aug. 25, 1993, at 7.

[83] Convention Establishing the World Intellectual Property Organisation, July 7,

on July 14, 1967, as a specialized agency of the U.N. WIPO was conceived as an administrative body to oversee the Paris Union on the Protection of Industrial Property and to provide a forum for future revisions in order to harmonize international intellectual property laws.[84] The basic rights and obligations under the Paris Union are threefold: (1) national treatment - each member agrees to provide foreign applicants the same access to intellectual property rights as domestic applicants receive, (2) right of foreign priority - each member agrees to recognize for priority purposes the original date of a foreign application and (3) unfair competition - each member must enact basic legislation pertaining to unfair competition in international trade.[85]

The provisions of the Paris Union benefit foreign inventors by ensuring equal access to the intellectual property laws of member nations and by securing an internationally recognized priority date from the first patent application regardless of where the application is filed. However, inventors are still exposed to the administrative burden and expense of individually pursuing property rights in each country in which they desire protections. Furthermore, the Paris Union is not a harmonization treaty. It obligates member nations only to recognize reciprocal rights for foreign inventors, thereby permitting each jurisdiction to maintain its idiosyncratic laws which are replete with substantive and procedural peculiarities. Consequently, not only is obtaining property rights an uncertainty for inventors, but also enforcing those rights in 179 independent jurisdictions is a logistical impracticability.

WIPO was quick to recognize the gross inadequacies of the 1967 version of the Paris Union, and it resolved to seek a revision creating a unitary system of minimal patent protections that would be established

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1967, 828 U.N.T.S. 3.

[84] The Paris Union for the Protection of Industrial Property was established in 1883 to end the practice of discrimination against foreign patent applications. WIPO is also delegated similar authority with respect to the Berne Convention for the Protection of Copyrights. Convention for the Protection of Industrial Property, Mar. 20, 1883, U.S.T.S. 379. *See also* COOPERS & LYBRAND, EC COMMENTARIES: INTELLECTUAL PROPERTY 84, § 15.1 (Nov. 26, 1992) [hereinafter COOPERS & LYBRAND, EC COMMENTARIES].

[85] ROSENBERG, *supra* note 34, § 18.05. Point one is in essence an agreement not to discriminate against foreign applicants. It does not require that a country recognize rights in certain intellectual property, but if the nation does recognize certain rights it must make them available to foreign applicants equally.

Point two prevents a person from obtaining property rights when that person copies an application in country A and is the first to file the same patent in country B. Country B is obligated to recognize the priority date of the original inventor's application in country A.

when one universal application was filed and approved. In 1970 WIPO convened its first diplomatic conference to begin that work. WIPO has convened three additional diplomatic conferences, in which very little was accomplished.[86] WIPO is currently circulating a new proposal in preparation for a fifth diplomatic conference.[87] Speculation is that WIPO's latest efforts will meet with little more success than the previous attempts.

In theory, the developed nations of North America, Europe and Asia should emphatically endorse WIPO's efforts. Yet, they do not. The reason is attributable to the organization's foundations. As a subsidiary organization of the U.N., WIPO embodies a strong proclivity toward the plight of developing nations, who comprise a majority of U.N. membership.[88] Therefore, private industry in developed nations is inherently suspect of WIPO's efforts. Industry would rather have these issues addressed in a more favorable forum — like the General Agreement on Tariffs and Trade (GATT) — over which it wields much stronger influence.[89]

The principal discord is WIPO's attempt to include provisions that would require technology transfers to developing nations, authorize compulsory licensing of protected technology, and other substantive limitations upon the rights of patent holders, which benefit developing nations at the expense of private industry.[90] WIPO continually refuses to include new plant varieties within the scope of patentable subject matter, choosing instead to force plant-related protections within the unsavory competence of the International Union for the Protection of New Plant Varieties (UPOV).[91] These policies substantially undermine adequate intellectual property protection for biotechnology advancements. In essence, WIPO amounts to an expansive farmers' privilege, which allows the use of technology while it excuses the obligation to compensate the developer, thereby denying biotechnology companies the opportunity to obtain a fair return for their investments in new technologies.

One should not expect that WIPO will be the forum within which a patent harmonization treaty is achieved in the near future. Its allegiances are too transparent, such that developed nations are reluctant to make it the forum of choice. These beliefs are echoed by the organization's director general, who recently stated, "[a]t present, WIPO does not intend

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[86] COOPERS & LYBRAND, EC COMMENTARIES, *supra* note 84, § 15.1.

[87] Alex Barnum, *Proposed Treaty on Patents Under Fire*, SAN FRAN. CHRON., Dec. 20, 1993, at B1.

[88] *Cf.* COOPERS & LYBRAND, EC COMMENTARIES, *supra* note 84, § 14.3.

[89] Kevin Watkins, *Battle for the Rights to Life*, THE GUARDIAN, Feb. 7, 1992, *available in* LEXIS, News Library, GUARDN File. *See* Section D *infra.*

[90] COOPERS & LYBRAND, EC COMMENTARIES, *supra* note 84, § 15.1.

[91] *See* Section B *infra.*

to provoke changes in national legislation; it only wants to make governments more aware [of developments and the problems to be solved]."[92] Hence, WIPO has for the present assumed a role as consultant to achieving an international patent harmonization treaty while passing its baton to those promoting the Convention on Biological Diversity.[93]

B. Union for the Protection of New Plant Varieties

The UPOV[94] was conceived along the lines of the Paris Union as an international convention for the purpose of coordinating protections for plant breeders that would transcend national boundaries. Similar to WIPO, UPOV requires signatory countries to provide (1) national treatment - affording foreign applicants of member nations the same plant breeders' rights available to domestic breeders, although no minimum level of protections is required to qualify for membership, (2) right of foreign priority - recognizing the filing date of first application within a member nation for priority purposes and (3) independent jurisdiction - granting rights in a country only when an applicant files with that nation's independent examiner's office.[95] Consequently, the same obstacles of cost and substantive incongruities burden UPOV applicants.

At present UPOV consists of twenty-one nations, all classified as developed or rapidly developing nations.[96] That few developing nations belong is predictable. Most developing nations lack legislation protecting plant breeders' rights, and enactment of such laws is not politically feasible for two reasons: (1) how could the government of a poor, agriculturally based economy enforce laws that would deprive its farmers of needed technologies for cultivating their subsistence crops?[97] and (2) what forms of punishment or deterrence could be exercised against such infringers?

UPOV's first drawback is that limited participation undermines its

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[92] Whaite & Jones, *supra* note 14, at 146, 147 nn. 32-33.

[93] *See* Section C *infra.*

[94] International Convention for the Protection of New Varieties, *supra* note 40.

[95] ROSENBERG, 3 PATENT LAW FUNDAMENTALS *supra* note 34, § 18.05, 18-13.

[96] The membership of the UPOV includes all members of the European Economic Community (Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Turkey and the U.K.) as well as several non-EC nations (Hungary, Israel, Japan, New Zealand, South Africa, Sweden, Switzerland and the U.S.). *See Will Patents Keep Up with Developments in Plant Science?,* BIOTECHNOLOGY BUSINESS NEWS, May 8, 1992, *available in* LEXIS, News Library, BIOBUS File [hereinafter *Will Patents Keep Up*].

[97] *Cf.* John H. Barton, *Patenting Life,* SCI. AM., Mar. 1991, at 40, *available in* LEXIS, News Library, ASAPII File. *See also Will Patents Keep Up, supra* note 96.

effectiveness for protecting large investments into plant-related biotechnologies. Second is its authorization that a member nation may provide farmers' privilege within its domestic laws and may subject foreign applicants to the farmer's privilege exemption.[98] Accordingly, a developing nation could become a signatory and simply provide expansive privileges for its domestic farmers to make use of protected plant varieties. Despite this capability, UPOV contains no mechanism for compulsory sharing of plant breeding technologies, and nothing prohibits private enterprise in a member nation from refusing to do business with another member nation if the lack of substantive protections discourages such commerce.

A third drawback are the 1991 amendments to the convention, which its membership is ratifying and adopting. The amendments divide plant breeders' rights and patent rights and permit member nations to withhold reciprocal recognition of plant breeders' rights for biological organisms that have been patented in another country.[99] To illustrate this provision, we revisit the case of *American Fruit Growers v. Brogdex.* Assuming that Brogdex had been awarded a U.S. patent for its borax-impregnated oranges, under the UPOV's 1991 amendments, the other member nations could reject a subsequent application seeking reciprocal national plant breeders' rights.

Biotech concerns in the U.S. will invariably choose the more comprehensive protections available under domestic patent laws for reasons discussed in Section One. Therefore, the ability of UPOV members to deny plant variety protections for patented biological material renders this convention potentially meaningless for the biotechnology industry.

Finally, regarding the needs of the biotechnology industry, UPOV is materially incomplete. This deficiency is inherent within UPOV's narrow scope — to provide intellectual property protection for new botanic plant varieties. UPOV does not address the need for protections for microorganisms and complex nonbotanical living matter, thereby ignoring the majority of biotechnological applications such as biochemicals, pharmaceuticals, biorational pesticides, bioremedial environmental cleanup organisms and genetically engineered animals. Because UPOV offers only limited protections for those engaged in plant breeding, it is a declining influence among international intellectual property harmonization efforts.

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[98] *Will Patents Keep Up, supra* note 96.

[99] International Convention for the Protection of New Varieties of Plants of March 1991, *opened for signature* Mar. 19, 1991.

C. *The Convention on Biological Diversity*

In the summer of 1992 the international community focused its attention upon Rio de Janeiro, Brazil, the site of the multinational conference on biodiversity. Its objective was the adoption of the biodiversity treaty, which promoted (1) the conservation of biological diversity, (2) the sustainable use of biological components and (3) the fair and equitable sharing of benefits arising out of genetic resources.[100] Despite President Bush's refusal to adopt the treaty, it achieved a qualified success: 162 nations signed. Since then the treaty was ratified by the requisite number of nations and entered into force on December 29, 1993.[101]

The reason the U.S. did not sign the treaty is largely attributable to the ambiguous concept of the "equitable share." This concept was born out of the concern that biotechnological and pharmaceutical corporations from developed nations are using the flora and fauna native to, and subject to the sovereign rights of, underdeveloped nations to engineer their discoveries.[102] The resultant products are then protected and sold

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[100] United Nations Draft Convention on Biological Diversity, May 22, 1992, art. I, *reprinted in* 15 Int'l Envtl. Rep. (BNA) No. 11, at 372 (June 3, 1992) [hereinafter Draft Convention on Biological Diversity].

[101] United States: Declaration Made at the United Nations Environment Programme Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity. May 22, 1992.

> 3. It is deeply regrettable to us that — whether because of the haste with which we have completed our work or the result of substantive disagreement — a number of issues of serious concern in the United States have not been adequately addressed in the course of this negotiation. As a result, in our view, the text is seriously flawed in a number of important respects.
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> 4. As a matter of substance, we find particularly unsatisfactory the text's treatment of intellectual property rights; finances; including, importantly, the role of the Global Environmental Facility (GEF); technology transfer and biotechnology.

Id. See also Stalling on Biodiversity, CALGARY HERALD, Mar. 22, 1993, at A4, *available in* LEXIS, News Library, BUSDTL File.

The terms of the treaty provided that the document would enter into effect ninety days after it had been ratified by thirty nations. On October 1, 1993, Mongolia became the thirtieth nation to ratify, enabling the treaty to enter into effect on December 29, 1993. To date more than forty nations have ratified the treaty, including: Bahamas, Barbados, Belarus, Burkina Faso, Canada, Czech Republic, Ecuador, Mexico, Mongolia, Nauru, Nepal, New Zealand, Peru, the Philippines, Sweden, Uganda and Uruguay. *See Rio Treaty Has 29 Ratifications*, Int'l Envtl. Daily (BNA) (Sept. 28, 1993); *Hotline*, ENV'T WATCH LATIN AM., Nov. 1993, at 16; *Treaty Enters Into Force 18 Months After Its Signing At 1992 Earth Summit*, Int'l Envtl. Daily (BNA) No. 248, at D-5 (Dec. 30, 1993).

[102] *Stalling on Biodiversity*, *supra* note 101. *See also* Draft Convention on Biological

in the global marketplace at a substantial profit. Hence, foreign companies exploit and profit from the resources of developing nations, which lack both the infrastructure for capitalizing on those resources and the economic wherewithal to purchase the benefits derived from the new technologies whose raw materials originated in their countries.[103]

Article 16 of the Treaty, entitled "Access to and Transfer of Technology," states, "[e]ach contracting party shall . . . provide access to and transfer of technology [to fellow contracting parties] . . . including technology protected by patents and other intellectual property rights."[104] The vague terminology within this article is subject to an interpretation that would require private industry in developed nations to surrender its protected technologies without assurances of compensation. As Richard Godown, president of the Industrial Biotechnology Association, commented, "[i]t would call upon us to give away our inventions by not providing for adequate protections."[105]

The Association of Biotechnology Companies, a U.S. organization that promotes the interests of biotech concerns, believed that the treaty would be substantially detrimental to those in ag-biotech.[106] The treaty expressly provides that engineers of new agricultural-related technologies must provide "access to and transfer of technologies . . . that make use of genetic resources . . . to developing countries."[107] This broad language is susceptible to an interpretation that a super-farmers' privilege has been created — not only a right to use but a power to compel the relinquishing of agriculturally related biotechnology patents.

The treaty furthermore provides that the technology innovator in a developed nation must share "the benefits arising from the commercial and other utilization of genetic resources with the . . . [country] . . . providing such resources."[108] This provision clearly contemplates inventors transfering their technologies to developing nations without compensation. It also suggests that income earned from sales of the technology be shared with the country that contributes the biological material. Again, the treaty's ambiguous language creates the potential for sweeping forfeiture of intellectual property rights.

Diversity, *supra* note 100, arts. 3, 16

[103] *See* Draft Convention on Biological Diversity, *supra* note 100, at arts. 15, 16 para. 3.

[104] *Id.* at art. 16.

[105] Therese Poletti, *Biotech, Drug Industry Defend Bush on Biodiversity*, REUTERS FINANCIAL WIRE, June 10, 1992, *available in* LEXIS, News Library, REUFIN File.

[106] *Id.*

[107] Draft Convention on Biological Diversity, *supra* note 100, at art. 16, paras. 1, 2.

[108] *Id.* at art. 15, para. 7.

Despite the treaty's ambiguous language and possible biotechnology-related intellectual property rights problems, the Clinton Administration genuinely believed in the treaty's aspirations. President Clinton said that ensuring the conservation of biological diversity and the sustainable use of biological resources "is critically important to the future of the world."[109] Furthermore, he perceives U.S. participation as a critical component of the treaty's ultimate success. To procure that success, the Clinton Administration drafted a letter of interpretation that clarified the U.S. understanding of the agreement's vague provisions pertaining to the protections of biotechnology.[110] This letter will be submitted, along with U.S. ratification, as an understanding of this nation's rights and obligations arising out of the treaty.

To ensure the support of the biotech industry, Clinton enlisted the help of the State Department to assist in drafting the letter of interpretation. Known as Treaty Document 103-20, this letter emphasizes that a company has the exclusive rights to the technology it owns.[111] It details four principal areas of concern: (1) the treaty is not retroactive, (2) transfer of technology must be voluntary and must take into account companies' exclusive rights to the technologies they own, (3) there will be no compulsory licensing and (4) biosafety protocol on the handling of biotechnology products is not necessary.[112]

Regarding the controversial "equitable share" concept, the letter stated,

> The United States interprets this to mean that [fair and equitable sharing] must take fully into account exclusive rights to technology that a party may possess, and that transfers of proprietary technology will occur only at the discretion of, and with the voluntary consent of, the owner of the technology.

Regarding Article 16: "The United States interprets 'fair and most favor-

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[109] *Biodiversity Treaty to be Sent to the Senate Before Congressional Recess, McGinty Says*, Daily Env't Rep. (BNA) (Oct. 28, 1993) [hereinafter *Biodiversity Treaty to be Sent to Senate*].

[110] *Id.*

[111] MESSAGE FROM THE PRESIDENT OF THE UNITED STATES TRANSMITTING THE CONVENTION ON BIOLOGICAL DIVERSITY, WITH ANNEXES, DONE AT RIO DE JANIERO JUNE 5, 1992, AND SIGNED BY THE UNITED STATES IN NEW YORK, JUNE 4, 1993, S. TREATY DOC. 20, 103d Cong., 1st Sess. (1993) [hereinafter MESSAGE FROM THE PRESIDENT].

[112] *Biotechnology Industry Endorses Administration Interpretation of Treaty*, Daily Rep. for Executives (BNA), at A226 (Nov. 26, 1993) [hereinafter *Biotechnology Industry Endorses Administration Interpretation*].

able terms' to mean terms that are voluntarily agreed to by all parties to the transaction. . . . In particular, the Convention does not provide a basis for the use of compulsory licensing laws to compel private companies to transfer technology."[113]

The Administration signed the treaty on June 4, 1993, and submitted it and the letter of interpretation to Capital Hill on November 20, 1993. The Senate must advise and consent for U.S. ratification.[114] Clinton's consensus building has achieved the coveted support of private industry. Richard Godown stated, "[w]e have been working with the Administration, and we are very, very pleased at the prospects."[115]

The international community, however, is not happy with the letter of interpretation. International commentators accuse the U.S. of attempting to unilaterally obtain the terms it was unable to procure in treaty negotiations.[116] To counter such opposition, the U.S. has sent its letter of interpretation to industrialized nations in Europe and Asia, encouraging them to file similar statements of interpretation with their ratifications.[117] But by unilaterally renegotiating the treaty's terms, the industrialized nations appear to be imposing their desires over the will of developing nations.

The treaty will not affect international biotechnology protections any time soon. It is merely a framework that remains to be completed through subsequent international negotiations. Considering the interpretive statement filed by the U.S. and the perturbed reactions of developing nations, the parties seem no closer to resolution than they were in the summer of 1992.

The apparent failure of the treaty, at least for the immediate future, is perhaps the most favorable outcome for the biotechnology industry. This Article has repeatedly touched upon the theme that compulsory uncompensated sharing of technology, although reaping short-term benefits for those afforded access, has negative long-term consequences. The amount of resources invested into the development of new ideas is directly correlated with the expected returns of achieving a breakthrough. If industry perceives low economic returns for an investment in ag-biotech because of an international convention, such as the biodiversity treaty, then little money will be invested in that area. Therefore, despite

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[113] MESSAGE FROM THE PRESIDENT, *supra* note 111, at XI, XII, XIII.

[114] *Id.* at V.

[115] *Biodiversity Treaty to be Sent to Senate*, *supra* note 109. *See also Biotechnology Industry Endorses Administration Interpretation*, *supra* note 112.

[116] *Biodiversity Treaty to be Sent to Senate*, *supra* note 109.

[117] *Policy on Environment, Trade Nexus Expected From Administration in June*, [Jan.-June] Int'l Trade Rep. (BNA) No. 18, at 756 (May 5, 1993).

resentment against the U.S. and other industrialized nations for drafting their letters of interpretation, U.S. rejection of compulsory licensing and technology transfers is a fundamentally sound position.

D. General Agreement on Tariffs and Trade

The GATT was conceived in 1947 as a provisional instrument to resolve trade disputes pending adoption of the more complete International Trade Organization (ITO). In 1948, when the U.S. rejected ITO, GATT emerged as the principal vehicle for implementing liberalized international trade policy. Since its inception, GATT has sponsored eight rounds of multilateral negotiations relating to tariffs and other trade barriers. The most recent series, the Uruguay Round, began in 1986 to address trade issues pertaining to services, foreign investment, and intellectual property rights — in addition to former topics.[118] It concluded on December 15, 1993, the last day of a U.S.-imposed deadline, but not before the agreement was nearly derailed because of disagreements over the disposition of biotechnology and other intellectual property rights.[119]

The portion of GATT that addresses intellectual property issues is called the agreement on Trade Related Intellectual Property Rights (TRIPs). The principal proponent of the TRIPs initiative was the U.S., which loses an estimated $60 billion annually as a consequence of patent violations alone by developing nations.[120] Japan, the EC and other developed nations joined with the U.S. in its push for a universally accepted system of intellectual property protections.

In April 1990, TRIPs proponents presented the GATT commission with a draft legal text for an international agreement on intellectual property protections.[121] Without question the most controversial section authorized patents for living organisms and biological processes, encompassing microorganisms, seeds, plants and animals.[122]

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[118] Kenneth W. Abbott, *Introduction and Bibliography in Regulation of International Trade: The General Agreement on Tariffs and Trade*, 1 BASIC DOC. OF INT'L ECON. LAW (1990), *available in* LEXIS, INTLAW Library, BDIEL File.

[119] *A Guide to the GATT; What's at Stake in the General Agreement on Tariffs and Trade*, WASH. POST, Dec. 6, 1993, at A16. December 15, 1993, was the expiration date of special "fast-track" legislation enacted by Congress, which enabled the Clinton Administration to negotiate a GATT agreement that would not be subject to congressional line-by-line review. It was generally agreed that if GATT were not adopted prior to the expiration date, it could not survive Congressional review. *Id.*

[120] Watkins, *supra* note 89.

[121] COOPERS & LYBRAND, EC COMMENTARIES, *supra* note 84, § 14.1.

[122] Watkins, *supra* note 89.

Developing nations opposed covering patent issues within the GATT negotiations, which they perceived as subservient to the interests of industrialized nations. They contended that a trade agreement was an improper forum within which to incorporate intellectual property rights.[123] Some environmental organizations have advocated that such issues should be resolved within the competence of WIPO or the biodiversity treaty, which have traditionally dealt with those issues and in which developing nations are heard.[124]

To obtain the developing nations' support, necessary to affirm the TRIPs accord, supporters conceded to the removal from patentable subject matter microorganisms, nonbiological processes for the production of plants and animals and microbiological processes for the production of plants and animals.[125] The result is that only living organisms and biological processes that are achieved by traditional breeding methods are protectable — a stance consistent with UPOV. In the words of Pfizer Pharmaceutical's president, TRIPs "excludes the critical class of biotechnological inventions with the greatest potential commercial gain."[126]

GATT was an unqualified defeat for the biotechnology industry and particularly for those engaged in agricultural genetic engineering. The efficiencies of a universally recognized patent remain unavailable to developers of biotechnological inventions. Instead, the industry must continue to pursue patent protections in each of 179 jurisdictions in which it desires to market its products. The betrayal felt within the biotechnology industry led many to clandestinely hope that the Uruguay Round would fail and cause the U.S. government to pursue unilateral actions. These sentiments were confirmed by Mark Ritchie of the Agricultural Policy Institute: "They [biotech companies] now believe their interests will be better served by recourse to unilateral trade threats and sanctions than by a multinational accord."[127]

E. Bilateral Trade Accords and Unilateral Trade Sanctions

Although the U.S. has failed to attain a universal convention for

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[123] *U.S. 'TRIPS' Plan Would Allow Monopoly of Genetic Resources, Greenpeace Says*, [1990] Int'l Trade Rep. (BNA) No. 47, at 1805-06 (Nov. 28, 1990).

[124] COOPERS & LYBRAND, EC COMMENTARIES, *supra* note 84, § 14.1.

[125] *Concern Over GATT Patent Proposals*, BIOTECHNOLOGY BUS. NEWS, Feb. 14, 1992, *available in* LEXIS, News Library, BIOBUS File.

"Non-biological processes" are defined as those which neither occur in nature nor correspond to classical breeding processes. *Id.*

[126] Watkins, *supra* note 89.

[127] *Id.*

harmonizing international laws protecting biotechnology, the government and private industry have achieved success with bilateral trade agreements. The U.S. is among the wealthiest nations in the international community and is the nerve center of many of the world's richest multinational corporations. Developing nations covet both access to U.S. markets and the ability to attract U.S. foreign investment as the keys to unlocking their economic potential. These privileges equip the U.S. and its private sector with powerful leveraging tools they have used to extract favorable treatment for biotechnology. The following two examples illustrate this point.

1. Merck - Costa Rica Accord

In 1991, Merck, the multinational pharmaceutical corporation, stunned many around the world when it announced a landmark biodiversity accord with Costa Rica. Merck agreed to pay $1 million to the Costa Rican government in exchange for access to their biological material and information about rainforest life forms. The biological materials are to be collected and inspected under the direction of a Costa Rican government agency, a comprehensive undertaking expected to employ many Costa Ricans.[128] If Merck develops a commercially practical product derived from Costa Rican materials or information, the Costa Rican government will be entitled to royalty payments.[129]

In essence, the Merck-Costa Rica accord is a mini-biodiversity treaty. Costa Rica receives valuable compensation for providing biological resources and information to Merck, thereby providing Costa Rica with the incentive to preserve its biological diversity in the hopes of realizing future royalties. Through the accord, Merck purchases access to Costa Rica's natural resources without compromising its property rights in new technologies derived from the rainforests.

2. The Brazilian Experience with Unilateral Trade Sanctions

Many governments understand that stronger protections for intellectual property promotes international competitiveness by attracting capital investment and facilitating the flow of technology.[130] For those govern-

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[128] *See Treaty Interferes With Principals of Patent Protection, U.S. Official Says,* Int'l Envtl. Daily (BNA) 406, (June 17, 1992) [hereinafter *Treaty Interferes With Principals of Patent Protection*]. *See also Rio Update: MNC's Help Shape Green Policy Worldwide,* CROSS BORDER MONITOR, June 30, 1993, *available in* LEXIS, News Library, BUSINT File.

[129] *Treaty Interferes With Principals of Patent Protection, supra* note 128.

[130] *Brazilian Conference Examines IP Protection in South America,* Int'l Bus. Daily

ments that fail to reach this resolution, the U.S. has not hesitated to intervene. At the disposal of the U.S. government are two popularly propounded trade sanctions: Special 301 of the Omnibus Trade and Competitiveness Act[131] and § 337 of the Tariff Act of 1930.[132]

The effectiveness of Special 301 and § 337 are illustrated by the recent conflict between the U.S. and Brazil arising over Brazil's lack of adequate intellectual property protections. When Brazil's proposal for intellectual property reform emerged from its House of Deputies in May 1993, only to be held up by the Brazilian Senate, U.S. trade representatives began preparing a list of retaliatory measures.[133]

The first level of action proposed the removal of Brazil from our Generalized System of Preferences, which grants duty-free entry of certain goods from developing countries like Brazil. If this action were deemed insufficient, the U.S. could begin imposing higher import duties on selected Brazilian goods to spurn quicker action. When one considers that the U.S. consumes twenty-two percent of all Brazilian exports, these proposed trade sanctions could dramatically deepen Brazil's already severe recession.[134]

Brazil's is not an uncommon experience among developing nations, especially those within the sphere of U.S. influence. The enormous economic strength of the U.S. provides it the leverage to influence change in almost every nation. This type of coercive action is discouraged by U.S. trading partners and the collective voice of GATT; consequently, it is reserved for the worst offenders. Nevertheless, as the biotech industry emerges as a strategic component of U.S. international trade, developing nations should anticipate the aggressive use of Special 301 and § 337 unless a harmonizing convention is achieved that includes protection for biotechnological innovations.

IV. CONCLUSION

The enormous amount of energy expended attempting to achieve international patent law harmony pertaining to biotechnologies has thus far generated few results. An impasse divides the interests of developed and developing nations. Developed countries bring to the negotiating table valuable technology from private industry, which they refuse to divulge to developing nations without adequate protections. Developing nations,

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(BNA) (Dec. 24, 1991).

[131] *See* 19 U.S.C. § 2901 (1993).

[132] *See id.* at § 1337 (1993).

[133] *Brazil's Patent Protection Bill Remains Stalled in Congress*, Int'l Trade Rep. (BNA) at 1944 (Nov. 17, 1993).

[134] *Id.*

not without their bargaining chips, possess large potential markets for the technology, the possibility of a universally recognized patent system and the threat that absent a resolution of the issues they will continue to pirate those technologies when possible. At stake is the evolution of the biotechnology industry and the untold progress and prosperity it promises to bestow upon the world.

The authors do not perceive negotiations as a zero-sum game; rather, through compromise there is a synergy whose benefits can be shared by all parties. With a unified system of international patent protections for biotechnology, private industry will save countless resources that otherwise would be wasted on filing and enforcing applications in 179 independent jurisdictions. Similarly, by contributing reasonable licensing fees, developing countries will gain from new technologies that will help them feed their populations, cure disease and increase their general welfare. This relationship will then generate new capital investment that will fuel future advancements in biotechnology.

If the international community desires an equitable sharing of wealth and technology with developing nations, it should not use the mechanism of an intellectual property convention to achieve that goal. Forcing the financial burden upon the biotech industry creates a disincentive to future investment and consequently sacrifices the progress of technology.

To resolve this issue the authors propose a two part-solution. First, to help developing nations share in the technology, industrialized nations should contribute to a U.N. supervised fund, similar to the World Bank or the International Monetary Fund, that would provide subsidized loans and other direct assistance to nations with demonstrated need. Second, to help developing nations share in the benefits derived from the natural resources of those nations, the international community should facilitate relationships like that between Costa Rica and Merck. These relationships not only would compensate countries for preserving their natural resources, but also can be structured to provide transfers of technology. The advantages of this solution are that it (1) benefits those who need assistance, in contrast to sweeping exemptions that allow any nation a free ride, (2) creates the opportunity for those who contribute valuable natural resources to profit from their contributions and (3) shifts the burden of providing financial assistance to governments, thereby removing the disincentive created with a single industry.

This solution suggests only a broad approach to resolve the conflict between private industry and developing nations. However, we view this solution as a workable foundation upon which the international community can begin constructing a new multinational convention dedicated to assisting developing nations, preserving biological diversity and harmonizing biotechnology patent laws.