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WHEN TWO WORLDS COLLIDE: OWNERSHIP OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

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I. *Introduction*

The rapid growth of the biotechnology industry over the past two decades led many countries to recognize the vast economic potential of their genetic resources and indigenous knowledge.[1] Pharmaceutical companies and plant breeders increasingly rely upon these resources to engineer plant-derived drugs, disease-resistant crops, and biotechnical production processes.[2] With increasing demand for new biotechnological products, the global community is struggling to strike a balance between the interests of host countries, who seek remuneration for supplying genetic resources and traditional knowledge, and biotechnological inventors, who are pressing for free access, open markets, and stronger intellectual property rights protection.

The last decade of the twentieth century witnessed the advent of conflicting and often uncoordinated treaty regimes that sought to address the regulation of genetic resources and traditional knowledge.[3] These treaties reflected the increasingly polarized views of the international community

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[1] Ajay Sharma, *The Global Loss of Biodiversity: A Perspective in the Context of the Controversy over Intellectual Property Rights*, 4 U. BALT. INTELL. PROP. L.J. 1, 4 (1995).

[2] Kerry ten Kate & Sarah A. Laird, *Bioprospecting Agreements and Benefit Sharing with Local Communities*, *in* POOR PEOPLE'S KNOWLEDGE, PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES, 133, 134 (J. Michael Finger & Philip Schuler eds. 2004) ("Annual global markets for products in the healthcare, agriculture, horticulture, and biotechnology sectors derived from genetic resources lie between U.S. $500 billion and U.S. $800 billion . . . in the case of healthcare, there are still sales of between US$75billion and US$150 billion of pharmaceuticals and between U.S. $20 million and U.S. $40 billion worth of botanical medicines derived from genetic resources each year.").

[3] Sean D. Murphy, *Biotechnology and International Law*, 42 HARV. INT'L L.J. 47, 60 (2001) ("The advent of modern biotechnology has already generated various concerns in the transnational sphere that the global community is

towards intellectual property rights. Industrialized countries, seeking to maintain incentives for new innovations through a strong intellectual property rights regime,[4] viewed many developing countries' wishes to assert sovereign control over their resources as barriers to free trade.[5] The United States, for example, resisted treaty regimes that appeared to emphasize technology transfer and benefits-sharing over strengthened intellectual property rights.[6] In contrast, many developing countries viewed intellectual property rights as a tool for industrialized countries and multinational corporations to gain free access to their resources without sharing in the benefits derived from these resources.[7] Consequently, developing countries began to assert their sovereign right to control the resources within their territorial jurisdictions.[8]

Due to these deep-rooted disagreements, new strategies for regulating the raw materials needed for biotechnology are necessary to promote a global exchange of genetic resources on fair and equitable terms. These strategies include: (1) increased use of material transfer agreements between suppliers and users of genetic resources; (2) unilateral amendments to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Convention on Biological Diversity (CBD) with a view towards integration; (3) proposed national legislative reforms; and, (4) the establishment of a fund or financial mechanism to aid developing countries in the requisite capacity-building to develop local biotechnological capabilities.

This Note analyzes divergent views on the proper role of intellectual property rights and international treaty regimes in the biotechnology trade, and surveys proposals for providing an equitable means for developing countries to share in the wealth derived from genetic resources. The discussion will

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struggling to address through disparate and largely uncoordinated treaty regimes. Although some success has been achieved, the rapid development of biotechnology applications will place increasing stress on traditional regulatory regimes.").

[4] *See, e.g.,* Sharma, *supra* note 1, at 15-17 (explaining the industrialized countries' support of strengthened intellectual property rights to protect "incentives for scientific innovation" and investment in the developing world).
[5] *See, e.g., id.* at 19-20.
[6] *See, e.g.,* Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 262-63 (1998) (explaining the United States' opposition to Article 16 of the Convention on Biological Diversity).
[7] W. LESSER, SUSTAINABLE USE OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY 4 (1998).
[8] *See, e.g.,* Sharma, *supra* note 1, at 13-14.

begin with a general background on trade in genetic resources, biotechnology, and the increasingly important role of intellectual property rights on the inputs and outputs of the biotech industry. In Section III, this Note will address the sources of conflict between developed and developing countries over the imposition of intellectual property rights regimes on their resources. Sections IV and V will discuss the CBD and the TRIPS Agreement respectively, highlighting their objectives and approaches to biotechnology trade. Finally, this Note will discuss various strategies for facilitating the sharing of benefits between buyers and sellers of genetic resources.

II: *Bio-Prospecting, Biotechnology, and the Influence of Intellectual Property Rights*

The exchange of biological materials and the concomitant disputes arising from these exchanges are not unknown to history. For millennia, civilizations have engaged in extensive trading of genetic materials such as food crops.[9] Biological resources were traditionally treated as community property to be dispersed with at will or, alternatively, as personal property that could be freely exchanged.[10] Free exchange of these biological materials was the norm and took place with little government involvement.[11] Moreover, the use of these resources usually took place without compensation to the sovereign power from which these resources originated.[12] The "common heritage approach" continued into the modern era, enabling many multinational corporations from industrialized countries to accumulate vast gene and seed banks,[13] often without compensating the original supplier of these materials. Since the 1980s, the common heritage approach to biological resources has progressively unraveled as a new system of property rights emerged.[14]

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[9] *See generally* LESSER *supra* note 7, at 14-21 (detailing the historical background to the trade in biological materials). *See also Implementing the Convention on Biodiversity: Genetic Resources*, GRZ Website, http://www2.gtz.de/biodiv/english/genres.htm (last visited Oct. 12, 2004).
[10] *See generally* LESSER *supra* note 7, at 18.
[11] *Id.* at 19.
[12] *Id.* at 181-82.
[13] *See, e.g.,* David Downes, *New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity,* 4 TOURO J. TRANSNT'L L. 1, 8-14 (1993).
[14] *Id.* at 19-21 (describing the treatment of *ex situ* genetic resources and the rejection of the common heritage approach).

Significant developments in biotechnology transformed the global community's conception of natural resources in the 1980s. Plant-derived pharmaceuticals, genetically modified crops, and other products derived from genetic materials fueled demand for biodiverse genetic resources.[15] Consequently, these developments led to a resurgence in biodiversity prospecting activities.[16] Biodiversity prospecting ("bio-prospecting"), which refers to the search and collection of biological materials to be used for commercial purposes,[17] places a premium on the natural resources of countries rich in biological diversity. In recent years, annual global markets for biologically-derived products in healthcare, agriculture, horticulture, and other biotechnology sectors averaged between $500 billion and $800 billion.[18] The sheer size of these markets is testament to the increased interplay between biological resources and economic trade that took place during the 1980s and 1990s.

The elevated demand for biological resources during the 1980s and 1990s marked a transitional period during which global perceptions of the value of these resources evolved. Biological materials, once treated as a common resource for humankind, began to be viewed as a form of property.[19] Pharmaceutical companies, which had invested substantial sums into bio-prospecting and research, sought intellectual property protections for biological processes that were traditionally not afforded protection.[20] In 1986, the first U.S. patent for a genetically engineered variety of corn was granted.[21] The transition from a common resource conception to one of intellectual property rights is attributed to the rising economic value of these resources due in part to the growing demands of biotechnology industries.[22] As

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[15] *See Implementing the Convention on Biodiversity: Genetic Resources*, GRZ Website, http://www2.gtz.de/biodiv/english/genres.htm (last visited Oct. 12, 2004).
[16] WALT REID et al., *A New Lease on Life, 6-7, 12-18, in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT (W. Reid et al., eds., 1993).
[17] DARRELL A. POSEY & GRAHAM DUTFIELD, BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES 227 (1996).
[18] Kate, *supra* note 2, at 134.
[19] *See, e.g.,* VANDANA SHIVA, PROTECT OR PLUNDER? UNDERSTANDING INTELLECTUAL PROPERTY RIGHTS 44-45 (2001).
[20] KEITH E. MASKUS, INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY 222 (2000) (noting that the first U.S. patent for a genetically engineered microorganism was finally granted after a U.S. Supreme Court decision in 1980. Diamond v. Chakrabarty, 447 U.S. 303 (1980)).
[21] Carlos Scott Lopez, *Intellectual Property Reform for Genetically Modified Crops: A Legal Imperative*, 20 J. CONTEMP. HEALTH L. & POL'Y 367, 370 (2004).
[22] LESSER *supra* note 7 at 19-20 ("[P]roperty rights are typically created in response to rises in value.").

genetic materials shifted away from being viewed as a common resource and toward becoming a form of property, the stage was set for intellectual property rights to be applied to biologically-derived products produced in the biotechnology industry.

Biotechnology placed substantial stress on traditional views of property rights that did not recognize intellectual property in life forms. As patents were applied to new biological processes and products, many of these viewpoints gave way to increasing acceptance in the United States and elsewhere. The United States now recognizes patent eligibility in practically every life form, save for cloned humans.[23] The European Union recognizes patent protection for micro-biotechnological inventions, processes, and microorganisms, while several upper-income developing countries, such as Singapore and South Korea, recognize patents for biological inventions.[24] In these countries, intellectual property rights provide important economic protection for the blossoming biotechnology industry, which enjoys hefty returns on their investments.

The recognition of intellectual property protection served a variety of essential functions in the evolution of the biotechnological industry. First, intellectual property rights were perceived as a means to stem the tide of lost revenue due to piracy.[25] Second, intellectual property rights sought to provide incentives for scientific research.[26] Despite these beneficial functions, many countries and industries lacking technological resources voice skepticism about intellectual property rights when applied on a global scale.[27] Indeed, the perception among many developing countries is that strong intellectual property protection only benefits the exporters of biotechnological products.[28]

III: *The Controversy over Intellectual Property, Genetic Resources, and Traditional Knowledge*

[23] MASKUS, *supra* note 20, at 223.
[24] *Id.*
[25] *Id.* at 58.
[26] Sharma, *supra* note 1, at 16-17.
[27] Victoria E. Spier, *Finder's Keepers: The Dispute Between Developed and Developing Countries over Ownership of Property Rights in Genetic Materials*, 7 WIDENER. L. SYMP. J. 203, 211-12 (2001).
[28] *Id.*

The increasing application of intellectual property rights toward genetic resources fanned the flames of a global controversy. Among scholarly and political circles, the appropriate role of intellectual property rights in the global biotechnology industry is a popular subject of discourse. Some argue that the application of intellectual property rights mechanisms to genetically engineered life forms and other products of biotechnology constitute a form of "colonialism" over the natural resources of developing countries.[29] Others posit that strong intellectual property rights generate larger returns for creative activity, create incentives for additional invention, and expand investment in developing countries.[30] The most accurate assessment of the efficacy of intellectual property rights in biotechnology lies somewhere between these views.

Throughout the legal systems of the industrialized world, intellectual property rights are the primary means of protecting inventors' interests.[31] Serious concerns arise when applying these systems to countries where the primary source of economic wealth consists of indigenous knowledge and genetic materials. These assets seldom qualify for patent or copyright protection, but are nevertheless essential to the invention of new biotechnological products. Not surprisingly, a growing consensus believes that conventional intellectual property rights are woefully inadequate.

The conflict over intellectual property rights is partially the result of an unequal distribution in the location and wealth of the world's global biodiversity.[32] As a general rule, the richness in biodiverse natural resources is inversely related to latitude.[33] Thus, the majority of the world's biological wealth is concentrated in the temperate regions of the globe.[34] Estimates indicate that nearly eighty percent of the

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[29] VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 4-5 (1997).
[30] *See, e.g.,* MASKUS, *supra* note 20, at 6-7 (discussing the potential consequences and benefits of applying intellectual property rights protections on a global scale).
[31] Chidi Oguamanam, *Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge*, 11 IND. J. GLOBAL LEGAL STUD. 135, 135-36 (2004).
[32] Biodiversity is an umbrella term for the degree of nature's variability among organisms and ecological complexes. *See, e.g.,* Sharma, *supra* note 1, at 1. Article II of the Convention on Biological Diversity defines biodiversity as "the variability among living organisms . . . and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems." United Nations Convention on Biological Diversity, June 5,1992, S. TREATY DOC. 20 (1993), reprinted in 31 I.L.M. 818.
[33] Ashish Kothari, *Beyond the Biodiversity Convention: A View From India* in BIODIPLOMACY: GENETIC RESOURCES AND INTERNATIONAL RELATIONS 67-72, (V. Sanchez & C. Juma, eds., 1994).
[34] *Id.*

raw genetic inputs used in biotechnology are from tropical developing countries.[35] Exacerbating the effects of this uneven distribution of biological wealth are uneven distributions of scientific knowledge, technology, and buying power. Countries with abundant genetic wealth are substantially underdeveloped compared to the genome-poor industrialized countries, which possess the majority of the world's technological knowledge.[36]

The uneven distribution of the earth's biological resources, coupled with the superior technology, economic leverage, and scientific knowledge of developed countries, has resulted in serious inequities in the global biotechnology trade. For example, nearly one-fourth of all prescription pharmaceuticals sold in the United States contain active ingredients extracted or derived from plants, the sales of which amounted to $15.5 billion in 1990 alone.[37] Globally, over one hundred prescription drugs are made from plants, seventy-four percent of which come from knowledge derived from the oral traditions of indigenous communities.[38] Unfortunately, most countries supplying these genetic resources and indigenous knowledge have not profited from the exploitation of their resources.[39] One report from the United Nations estimated that losses to developing countries as a result of the utilization of genetic materials without compensation approach $5.4 billion per year.[40] These losses have translated to profits for many industries in industrialized countries. For example, statistics show that the market for the American soybean crop has seen an annual increase of $3 billion over the past 60 years, largely the result of biotechnology.[41]

One of the more dramatic examples illustrating the disparities in benefits received globally as a result of biotechnology is the famous case of the rosy periwinkle, a plant native to Madagascar.

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[35] Joseph Straus, *Biodiversity and Intellectual Property*, CASRIP PUBLICATION SERIES: RETHINKING INT'L INTELLECTUAL PROPERTY 142 (2000) *available at* http://www.law.washington.edu/casrip/Symposium/Number6/Straus.pdf (last visited September 14, 2005).
[36] *See generally* Jim Chen, *Diversity and Deadlock: Transcending Conventional Wisdom on the Relationship between Biological Diversity and Intellectual Property*, CASRIP PUBLICATION SERIES: RETHINKING INT'L INTELLECTUAL PROPERTY, 171 (2000), *available at* https://www.law.washington.edu/casrip/Symposium/Number6/Chen.pdf (last visited September 14, 2005).
[37] McManis, *supra* note 6, at 273-74.
[38] *Id.*
[39] *See, e.g.,* Straus*, supra* note 36, at n.12.
[40] *Id*.
[41] *Id.* at n.13.

According to Charles R. McManis, Eli Lilly, the U.S. pharmaceutical company, developed two cancer-fighting alkaloids in the 1960s that derived its active ingredients from the rosy periwinkle.[42] Eli Lilly obtained patents on the materials it developed and marketed the alkaloids as a drug. By the time the patents had run out, Eli Lilly reportedly earned several hundred million dollars without providing any compensation to impoverished Madagascar.[43] Although the rosy periwinkle represents an extreme example of the biotechnology trade gone awry, it highlights the inequities that can result between host countries and biotechnological industries. This example also provides insight into the contentious issues of patent law and other intellectual property rights as applied to the global biotechnology trade.

Traditional intellectual property rights have proven quite difficult to apply to the raw genetic resources and indigenous knowledge found in developing countries.[44] The incompatibility of traditional intellectual property rights with the inputs of biotechnology can be illustrated through patents. Patents enable patent holders to prohibit the use or production of a product by non-patent holders.[45] Although patents and other intellectual property rights mechanisms are creatures of national legislation and may vary from country to country,[46] the eligibility of an item for patentability typically depends on three criteria. The three criteria for determining patent eligibility require the invention to: (1) be novel or previously unknown; (2) contain an inventive step that is non-obvious to one skilled in the area of technology it represents; and, (3) be useful or have industrial application.[47] It should be noted, however, that mere discoveries of a use are not patentable under traditional intellectual property regimes.[48]

Given the criteria of (1) novelty (2) inventive step, and (3) industrial applicability, most of the wealth possessed by the developing world is not eligible for patent protection.[49] For example, the bulk of

[42] McManis, *supra* note 6, at 273-74.
[43] *Id.*
[44] *See* LESSER, *supra* note 7, at 182 ("Traditional IPR mechanisms by which products or outputs of biotechnology are protected indicates they are seldom applicable to inputs.").
[45] *Id.* at 21.
[46] *Id.*
[47] MASKUS, *supra* note 20, at 39.
[48] LESSER, *supra* note 7, at 23.
[49] *Id.*

all genetic resources lack known uses,[50] while the traditional knowledge of indigenous peoples, including knowledge about the medicinal qualities of particular genetic resources, is likewise ineligible for patent protection.[51] Since most developing countries possess an abundance of patent-ineligible material and lack the technological capabilities found in industrialized countries, it is not surprising that these countries hold a disproportionately small number of the world's patents and enjoy substantially little of the wealth derived from patented products.[52]

Given that a large amount of the natural resources and indigenous knowledge that went into the development of biotechnological products originated from developing countries, many of these countries voiced disillusionment with the lack of remuneration from the developed world.[53] Several countries expressed the view that intellectual property rights protect only innovations and not the biological germplasm that these countries possessed in abundance.[54] Indeed, many host countries view patents of biotechnological products as an impediment to their economic and technological development.[55] The controversy over intellectual property rights, genetic resources, and remuneration became a major issue in the negotiation and eventual outcome of the CBD.

IV: *The Convention on Biological Diversity*

The CBD represents a global framework aimed at protecting biodiversity. Although this agreement is largely an international treaty aimed at promoting the sustainable use of environmental resources, it also possesses important economic aspects that impact the application of intellectual property

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[50] *Id.*
[51] Daniel Wüger, *Bioprospecting Agreements and Benefit Sharing with Local Communities*, *in* POOR PEOPLE'S KNOWLEDGE, PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES 183, 192 (J. Michael Finger & Philip Schuler eds., 2004).
[52] *Id. See also*, MASKUS, *supra* note 20, at 174-75 (illustrating that patent holders in developing countries are overwhelmingly foreign. In Mexico, for example, of the total number of patent applications filed in 1996, 30,000 were filed by foreign residents, while only 389 were from domestic residents).
[53] *See, e.g.*, Spier, *supra* note 27, at 211-12.
[54] Sharma, *supra* note 1, at 16.
[55] Spier, *supra* note 27, at 211-12.

rights on the inputs of the biotechnological industry.[56] The following discussion on the CBD highlights the implications of this agreement on biotechnology and intellectual property rights.

The CBD approaches conservation based on the theory that what is perceived as having economic value tends to be used more efficiently, thus promoting the sustainable use of depletable resources.[57] Consequently, the CBD seeks to conserve resources through economic incentives and other market mechanisms. Article I sets forth the three objectives of the CBD: (1) the conservation of biodiversity; (2) the sustainable use of its components; and, (3) the fair and equitable sharing of the benefits that arise out of utilizing genetic resources.[58] Article I goes on to indicate that "equitable sharing of benefits" includes access to genetic resources and "the appropriate transfer of relevant technologies . . ."[59] As indicated in Article I, the sharing of benefits arising out of utilization of genetic resources is a central objective of the CBD. This necessarily entails the transfer and trading of biotechnological products, many of which may be patented or protected by other mechanisms under intellectual property law.

Articles 15 through 21 of the CBD establish the necessary components for "fair and equitable" sharing of benefits arising out of utilizing genetic resources. Most controversial among these articles are Articles 15 and 16. Article 15 recognizes the sovereign rights of countries to control access to their resources and further stipulates that parties to the CBD shall "facilitate access to genetic resources for environmentally sound uses."[60] Moreover, this provision stipulates that member countries obtaining resources from other members do so on "mutually agreed terms" after obtaining the "prior informed consent" of the host country.[61] Article 15 also suggests that the buyers of genetic resources facilitate the sharing of the benefits gained from these genetic resources.[62]

Article 16 creates an obligation to provide for and facilitate the transfer of technologies relevant to sustainable use of biodiversity and genetic resources. This provision is the most explicit section of the

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[56] LESSER, *supra* note 7, at 4-5.
[57] *Id.*
[58] Convention on Biological Diversity, *supra* note 32.
[59] *Id.*
[60] Convention on Biological Diversity, *supra* note 32, art. 1.
[61] *Id.*
[62] Sharma, *supra* note 1, at 20-21.

CBD in regards to the interface between the protection of genetic resources and intellectual property rights.[63] Taken together, Articles 15 and 16 form the crux of the controversy between the developed and developing worlds and therefore merit further attention.

Article 16 outlines what constitutes appropriate access to and transfer of technology between member states. Article16(2) provides that "access to and transfer of technology . . . to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed . . .".[64] This section also indicates that the transfer of technology shall be "consistent with the adequate and effective protection of intellectual property rights," but conditions this statement by stipulating that access to and transfer of the benefits derived by biotechnology are necessary to meet the goals of the CBD.[65] Article 16(3) grants host countries, especially developing countries, access to technology that makes use of their biological resources,[66] including biotechnology that may be patented. Controversially, Article 16(5) acknowledges the importance of intellectual property rights but seems to give priority to the transfer of technology.[67]

International response to the CBD was often dominated by the divergent perspectives voiced by developed and developing countries. The United States initially refused to sign the CBD during the negotiations, stating that the CBD's treatment of intellectual property rights and technology transfer was unsatisfactory.[68] The first Bush administration argued that the CBD contained language that could potentially force the transfer of technology abroad while relieving developing countries of the burden to provide patent protection to U.S. biotechnology corporations.[69] The Administration argued that Article

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[63] McManis, *supra* note 6, at 261.
[64] Convention on Biological Diversity, *supra* note 32, art. 16.
[65] *See, e.g.,* Sharma, *supra* note 1, at 22.
[66] *Id.*
[67] *Id.* at 22-23; *see also* Convention on Biological Diversity, *supra* note 33, art. 16(5). Article 16(5) provides:
> "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

[68] Michael D. Coughlin, Jr., *Using the Merck-InBio Agreement to Clarify the Convention on Biological Diversity*, 31 COLUM. J. TRANSNAT'L L. 337, 344-47 (1993) (describing the United States' response to the Convention on Biological Diversity in the early 1990s).
[69] *Id.*

16 treated intellectual property rights as a constraint to technology transfer rather than a prerequisite.[70] Moreover, the Administration expressed concern that the CBD would hurt the competitiveness of the U.S. biotechnology firms by allowing developing countries to copy U.S. inventions. Other industrialized countries shared similar concerns, favoring strong international protection of intellectual property rights in order to create incentives for technological development.[71] In addition, these countries feared that the CBD, by reaffirming the sovereign rights of countries to control access to their biological wealth, gave developing countries the power to entirely exclude access to vital biodiverse resources.[72]

Interestingly, many U.S. biotech companies once opposed to signing the CBD softened their position, fearing that a refusal to sign could lead to their exclusion from lucrative bio-prospecting opportunities.[73] Partially as a result of this change in position, the Clinton Administration eventually signed the CBD, but conditioned final ratification on an "interpretative statement" that would spell out the concerns of protecting intellectual property rights. Ever since, efforts to ratify the CBD disappeared from the U.S. legislative agenda.[74]

The developing countries, by contrast, generally opposed strong intellectual property rights protection and asserted their sovereign rights to control access to their genetic resources.[75] Many countries argued that strong intellectual property protection hindered technological development by granting firms of industrialized countries monopoly power that enabled them to out-compete developing countries in their own markets.[76] Others pointed to perceived injustices resulting from the imposition of intellectual property rights on biotechnological products, such as the royalty payments many developing countries paid on biotech products developed from their own raw materials.[77] Malaysia and India in

[70] Chen, *supra* note 36, at 206-07.
[71] Coughlin, *supra* note 68, at 344-47.
[72] Sharma, *supra* note 1, at 19-20.
[73] McManis, *supra* note 6, at 256-57.
[74] *Id.*
[75] *See, e.g.,* Coughlin, *supra* note 68, at 344-47.
[76] *Id.*
[77] Sharma, *supra* note 1, at 16.

particular urged an interpretation of Article 16 that would justify exceptions to intellectual property protection if such exceptions were "in the interest" of preserving biodiversity.[78]

The concerns of developed and developing countries resulted in various concessions that are reflected throughout the text of the CBD. In Article 16, for example, the CBD consistently acknowledges the importance of intellectual property rights and stipulates that these rights be honored.[79] Nevertheless, Article 16 places conditions on adherence to intellectual property rights by requiring mandatory technology transfer and benefits-sharing obligations when necessary to meet the goals of the CBD. The end result was an international agreement that arguably fell short of meeting the expectations of both developed and developing countries because of its compromised and often ambiguous language.[80]

Despite the shortcomings of the CBD, the agreement marked a crucial starting point for addressing the concerns of intellectual property rights and the trade of biotechnological products. By acknowledging the importance of intellectual property rights and the goal of equitably sharing the benefits derived from utilizing the genetic materials of developing countries, the CBD came close to striking a balance between the divergent views of the developed and developing world. Nevertheless, the strong dissatisfaction of developed countries with the CBD's protection of intellectual property rights strengthened the force of a second international agreement that many consider to be fundamentally at odds with the CBD: the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

V: *The Agreement on Trade-Related Aspects of Intellectual Property Rights*

Against the backdrop of growing dissatisfaction with global regulation of intellectual property, industrialized countries pushed for a stronger uniform system of intellectual property rights. Due in part to the pressures exerted by industrialized countries, a specific agreement on the availability and

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[78] Coughlin, *supra* note 68, at 348.
[79] Convention on Biological Diversity, *supra* note 32, art. 16. See in particular Articles 16(3) and 16(5) for the intricate balance the CBD seeks to strike between the protection of intellectual property rights and the transfer of technology.
[80] MASKUS, *supra* note 20, at 225 (opines that the CBD is a "vague and confusing document with strictly exhortatory powers."); *see also* Michael A. Gollin and Sarah A. Laird, *Global Policies, Local Actions: The Role of National Legislation in Sustainable Biodiversity Prospecting*, 2 B.U. J. SCI. & TECH. L. 16 (1996) (stating that the CBD outlined a blue print for activity but failed to fully detail all necessary provisions).

enforcement of intellectual property rights became part of the final negotiations of the General Agreement on Tariffs and Trade (GATT),[81] the predecessor to the World Trade Organization (WTO). The resulting agreement, known as the "TRIPS" agreement, represents the most comprehensive multilateral instrument on intellectual property rights.[82]

TRIPS encompasses a broad range of issues and goals, the breadth of which is beyond the scope of this article. It was negotiated under the WTO and thus represents a binding commitment for all existing WTO members.[83] TRIPS establishes minimum standards for systems of intellectual property rights protection for member countries.[84] One of these standards requires members to award patents for any invention, including products and processes, in all fields of technology.[85] To be eligible for a patent, the invention must involve "an inventive step" and have "industrial application."[86] Of particular relevance to biotechnology is the fact that TRIPS does not explicitly obligate members to patent plants and animals other than micro-organisms.[87] However, Article 27(3) stipulates that should a member country opt not to provide patents for these genetic resources, the country must provide an "effective *sui generis* system."[88] Thus, TRIPS does not excuse member states from providing protection to biotechnological products.

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[81] CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPS AGREEMENT AND POLICY OPTIONS 1-2 (2000).
[82] *Id. See also* MASKUS, *supra* note 20, at 2 ("The TRIPS agreement…is the first multilateral trade accord that aims at achieving partial harmonization in an extensive area of business regulation.").
[83] Meetali Jain, *Global Trade and the New Millennium: Defining the Scope of Intellectual Property Protection of Plant Genetic Resources and Traditional Knowledge in India*, 22 HASTINGS INT'L & COMP. L. REV. 777, 780-81 (1999); *see also* Emily Taylor, *The Havana Club Saga: Threatening More than Just "Cuba Coke"*, 24 NW. J. INT'L L. & BUS. 513, 521-24 (2004). Thus, WTO membership imports several fundamental principles that guide the provisions of the TRIPS agreement, including Nondiscrimination and Most-Favored Nation status. The Nondiscrimination principle requires members to treat their citizens and the citizens of other member states on equal terms with regard to access and protection of intellectual property rights. The Most-Favored Nation principle, in comparison provides, that any benefits a member country bestows on its own citizens must likewise be afforded to nationals of other member countries. *See generally* DAVID R. DOWNES, INTEGRATING IMPLEMENTATION OF THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE RULES OF THE WORLD TRADE ORGANIZATION ix-xi (1999). These two principles play roles in defining the general obligations one member country must provide others in order to promote the WTO's overall goal of trade liberalization.
[84] MASKUS, *supra* note 20, at 225.
[85] Chen, *supra* note 36, at 202.
[86] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, art. 20(2), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS-RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994).
[87] Chen, *supra* note 36, at 203.
[88] *Id.* According to Black's Law Dictionary, *sui generis*, a Latin phrase meaning "of its own kind," is a term used in intellectual property law "to describe a regime designed to protect rights that fall outside the traditional patent,

Articles 66 and 67 address the obligations between developing and developed countries regarding technology transfer. Article 66 imposes an obligation on developed countries to provide incentives for their enterprises and institutions to transfer technology to developing countries so that they may establish a sound technological base.[89] Article 67 requires industrialized countries to cooperate in financial and technical matters, including assistance to developing countries in the implementation of the legal infrastructure for intellectual property rights protection.[90] These provisions thus commit industrialized countries to use best efforts in identifying measures to encourage technology transfer and to promote the building of technological capacities of other members, especially the least-developed countries.[91]

Despite the obligations of developed countries to aid in the transfer of technology to developing countries, these efforts have largely amounted to nil.[92] As a result, many countries expressed concern that industrialized countries and biotechnological corporations do not intend to use TRIPS in a manner that facilitates the stated objectives of the agreement. In particular, concerns that intellectual property rights could be used to support highly restrictive licensing arrangements for important public-health products, such as pharmaceuticals, have raised the ire of countless member countries.[93] This argument gains some legitimacy when one considers that the cost of acquiring drugs in many developing countries increased after the TRIPS Agreement took force in 1995.[94]

Despite many countries' reservations over TRIPS, the past decade witnessed a strengthening of intellectual property rights legislation in developing countries. Although dissent over the role of

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trademark, copyright, and trade-secret doctrine." An example would include a database that may not be eligible for protection under copyright law but could be protected under a *sui generis* statute. BLACK'S LAW DICTIONARY 1475 (8th ed. 2004).

[89] Coenraad J. Visser, *Making Intellectual Property Laws Work for Traditional Knowledge*, *in* POOR PEOPLE'S KNOWLEDGE, PROMOTING INTELLECTUAL PROPERTY IN DEVELOPING COUNTRIES, 207, 208 (J. Michael Finger & Philip Schuler eds., 2004).

[90] *Id.* at 208-09.

[91] MASKUS, *supra* note 20, at 223-24.

[92] *Id.*

[93] *Id. See also* Mark Ritchie, et al., *Intellectual Property Rights and Biodiversity: The Industrialization of Natural Resources and Traditional Knowledge*, 11 ST. JOHN'S J. LEGAL COMMENT 431, 441-42 (1996) (arguing that the TRIPS Agreement will permit pharmaceutical companies to create monopolies resulting in extremely high prices for medicines in developing countries).

[94] Jennifer May Rogers, *The TRIPS Council's Solution to the Paragraph 6 Problem: Toward Compulsory Licensing Viability for Developing Countries*, 13 MINN. J. GLOBAL TRADE 443, 443-44 (2004).

intellectual property rights continues, strengthened intellectual property regimes appear to be the wave of the future, due in part to national commitments under TRIPS.[95] Some attribute this trend to external pressures from the United States and the European Union to force intellectual property legislation in other member states.[96] In some instances, developing countries were admonished to strengthen their intellectual property rights in complying with TRIPS under threat of trade sanctions.[97]

The impact of strengthened intellectual property rights systems in developing countries varies considerably. Several countries experienced increases in foreign direct investment (FDI). For example, after implementing strong intellectual property legislation in Singapore, many foreign computer companies that once refused to conduct business entered into joint ventures with domestic companies.[98] However, strengthened intellectual property rights did not lead to increased FDI in other developing countries adopting similar legislation, including many countries in Eastern Europe and Sub-Saharan Africa.[99] The correlation between patents and inward FDI is positive in the larger, more advanced developing countries, but not in the least-developed countries.[100] Consequently, strengthened intellectual property rights regimes in developing countries have led to skewed results in attracting FDI.

The varied impacts of strengthened intellectual property rights on FDI undoubtedly have an influence on the transfer of technology and the capacity of developing countries to cultivate biotechnological development domestically. Jean Raymond Homere posits that strong intellectual property rights under the TRIPS Agreement are capable of stimulating domestic innovation and inducing greater research in developing countries.[101] Intellectual property rights also provide incentives for

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[95] LESSER, *supra* note 7, at 197 (describing the worldwide trend of strengthened intellectual property rights legislation, even in countries such as Brazil and India, both of which were vocal critics against intellectual property rights).
[96] MASKUS, *supra* note 20, at 4.
[97] Jean Raymond Homere, *Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries,* 27 COLUM. J.L. & ARTS 277, 285 (2004).
[98] *Id.* at 287.
[99] *Id.* at 287-88.
[100] Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INTL'L ECON. L. 279, 289 (2004) (arguing that economies with low income and technological capacity provide little incentives for attracting technology transfer).
[101] Homere, *supra* note 97, at 288-89.

domestic firms to innovate, knowing their investments in research will be adequately protected.[102] In the case of Brazil, Homere's hypothesis is supported where unprotected biotechnological products discouraged foreign investment.[103]

Despite optimistic predictions that TRIPS would lead to increased technological transfer and economic stimulation in developing countries, experience has shown that TRIPS tends to promote the importation of biotechnological products, not processes, into developing countries. Large pharmaceutical corporations from developed countries often apply for patents in developing countries but will not physically establish production facilities or research labs inside host countries.[104] Patented products, not the technology needed to create them, tend to be transferred, thus defeating the capacity-building goals of Article 66.[105] Many large biotechnological firms expressly precondition granting patent licenses on a host country's promise not to establish research facilities domestically.[106] While these business practices may provide limited protection to large biotechnology firms, they inhibit the overall transfer of scientific knowledge and technology envisioned under Articles 66 and 67. Many agreements between foreign biotechnological firms and host countries charge excessive royalties or force developing countries' firms to purchase inputs from the patent holder exclusively.[107] This likewise imposes additional costs on the developing world that may inhibit local development and increase prices of crucial biotechnological products, such as pharmaceuticals and certain crops.[108]

Of particular relevance in discussing the impact of TRIPS compliance on developing countries is Article 34. Under Article 34, if a patent protects a production process, a country developing a process for

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[102] *Id.*
[103] *See* Maskus, *supra* note 100, at 298.
[104] Ritchie, *supra* note 93, at 439.
[105] *Id.* Statistics indicate that 95% of foreign-held patents in developing countries are not utilized domestically. Moreover, the importation of products, and not processes, hinders the transfer of technology into the developing world, thus increasing the costs of purchasing drugs and other biotechnological products.
[106] *See id.* at 440.
[107] *Id.*
[108] MASKUS, *supra* note 20, at 191 (arguing that net importers of technology will find costs rising as a result of TRIPS). *See also* Ritche, *supra* note 93, at 441-42 (arguing that Article 33 of TRIPS permits pharmaceutical corporations to create monopolies for a minimum of 20 years, which has resulted in developing countries having to pay increased prices for valuable life-saving medicines).

the same product has the burden of proving that the two processes are different.[109] Consequently, if a firm in a developing country seeks to develop a more efficient or innovative process for producing a biotechnological drug, for example, the entrant must prove the new process is truly unique and an inventive step. This process can be expensive and burdensome for many small firms in developing countries, thus inhibiting them from entering the market and inventing new production processes. Furthermore, many large technological corporations require licensees of patented processes to grant patent rights on any further technological developments produced by the licensee back to the company. Consequently, many small firms in developing countries have little incentive to innovate, knowing that the fruits of their research will be granted back to the biotechnological corporation in the developed world.[110]

Not surprisingly, many developing countries remain reluctant to strengthen their intellectual property rights protections for a variety of reasons. First, increased prices for life-saving pharmaceuticals and other products have prompted many countries to thwart the patent provisions of the United States and the European Union by producing essential medicines locally.[111] For instance, in Argentina, domestic drug manufacturers often market generic drugs domestically at prices 15%-80% lower than the global market price.[112] Moreover, TRIPS-compliance often imposes huge burdens on developing economies. To comply formally with the TRIPS Agreement, countries must establish industrial property registries, develop enforcement mechanisms, combat piracy, and prosecute criminals.[113] Recent statistics provided by the United Nations Conference on Trade and Development (UNCTAD) estimate the costs of complying with TRIPS in various countries.[114] In Bangladesh, for example, the fixed cost of establishing a TRIPS-compliant administration for intellectual property rights is estimated at $250,000, with annual costs for judicial work, equipment, and enforcement estimated at $1.1 million. These costs do not include

[109] Ritche, *supra* note 93, at 438-40.
[110] *Id.*
[111] *Id.* at 441-42.
[112] *Id.*
[113] Visser, *supra* note 89, at 208.
[114] MASKUS, *supra* note 20, at 173-74.

the costs of training.[115] While these statistics may not appear substantial, to many developing countries with limited budgets, TRIPS-compliance is an expensive proposition.

In sum, the TRIPS Agreement made many promises for facilitating the equitable transfer of technology to developing countries. Although strengthened intellectual property protection enabled a handful of developing countries to obtain greater FDI than before the TRIPS Agreement, the overall impact of TRIPS on technology transfer has been dismal. Despite the predictions of many economists and scholars alike that increased intellectual property protection will result in technological development both domestically and abroad, the fruits of this transfer have yet to provide any substantial gains for most developing countries. Consequently, the net effect of Articles 66 and 67 has resulted in little effective technology transfer and benefits-sharing to developing countries.[116]

VI: *Proposals for Facilitating Technology Transfer and Benefits-Sharing*

Although the CBD and TRIPS have admirable goals, both fail to achieve an equitable balance between the interests of industrialized and developing countries. To foster the global exchange of genetic resources, technology, and indigenous knowledge on fair and equitable terms, a host of different strategies and reforms may be considered. The following section presents various proposals and strategies for fostering these objectives. For convenience, these strategies are subdivided into benefits-sharing and technology-transfer strategies. Benefits-sharing strategies include (1) the utilization of Plant Breeders' Rights and geographic indicators to protect plant varieties in host countries, (2) the creation of a centralized financial mechanism to aid developing countries in developing and implementing Plant Breeders' Rights and geographic indicators, (3) unilateral amendments to expand the scope of geographic indicators under the TRIPS Agreement, and (4) employing trade secrets to protect the indigenous knowledge used in creating specialized plant varieties through traditional cross-breeding. Technology-transfer strategies include (1) material transfer agreements between suppliers and users of genetic

[115] *Id.* These estimates also predict that Chile will spend approximately $718,000 in additional fixed costs with annual recurrent costs of $837,000. An expert in Egypt recently estimated one-time fixed costs to be approximately $800,000, with additional training costs of $1 million per year.
[116] *Id.* at 239.

resources, (2) regional and national legislative initiatives controlling the terms on which bio-prospecting may be conducted, and (3) disclosure requirements for patent applications in industrialized countries.

A. *Initiatives for the Sharing of Benefits on Fair and Equitable Terms*

The utilization of intellectual property rights as a means of promoting the fair and equitable exchange of genetic resources promises to be a major challenge in coming years. While many developing countries argue that intellectual property rights hinder benefits-sharing by providing monopolies for multinational corporations, international intellectual property rights systems are unlikely to disappear in the near future. Some scholars have argued that with the correct approach, intellectual property rights could act as a tool for protecting the interests of indigenous communities in host countries.[117] Consequently, new approaches adapting intellectual property regimes to the interests of developing countries are indispensable.

The success or failure of an international intellectual property rights system that takes into account the interests of both the users and providers of genetic material depends on appropriate governmental initiatives. One strategy for promoting the equitable sharing of benefits utilizes the existing intellectual property laws shared by many industrialized countries. The key to this strategy is to find a means to make the genetic constitution of plants and fungi eligible for intellectual property protections currently recognized by parties to the TRIPS Agreement. By utilizing existing intellectual property laws, this approach would not entail ground-breaking legislative reforms, nor would the economic feasibility of these reforms deter countries from implementing this strategy.

If the genetic inputs of biotechnology are to be eligible for intellectual property rights protection, a distinction must be made between *phenotypes* and *genotypes*. A *phenotype* refers to the outward physical manifestation of an organism, including its parts, cells, structures, tissues.[118] The concept of

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[117] *See generally* David R. Downes, *How Intellectual Property Rights Could Be a Tool to Protect Traditional Knowledge*, 25 COLUM. J. ENVTL. L. 253, 256 (2000) ("Many aspects of IPRs appear to be more or less neutral, but some aspects may in fact be contributing to the problem of knowledge loss, while others have the potential to help solve it.").

[118] *See, e.g., Genotype and Phenotype: Definition,* Science at a Distance, *at* http://www.brooklyn.cuny.edu/bc/ahp/BioInfo/GP/Definition.html (last visited Oct. 29, 2004).

phenotypes can be analogized to the legal concept of chattels in that it refers to a definitive structural object.[119] A *genotype* refers to the internal code of inheritable information carried by living organisms.[120] Organisms thus have dual capacities as both chattels and carriers of genetic information.[121]

The current controversy surrounding the protection of genetic resources focuses not on the value of living organisms as chattels, but as a source of genetic information.[122] In general, *phenotypes* are ineligible for intellectual property protection under the existing laws of most states, while *genotypes* are amenable to various forms of proprietary protection.[123] This distinction thus separates claims to valuable genetic information from claims to the chattel to which this information is embedded.[124] An appropriate analogy is found in property rights protection for music records. While a person can have a proprietary claim over a particular record, its purchase or sale does not transfer the copyrighted information contained within the record.[125]

The patentability of *genotypes* in their natural state does not typically fall under the purview of most countries' existing intellectual property laws or under TRIPS. However, indigenous communities and traditional farmers in host countries often manipulate plant varieties to produce traits distinct from their natural form. Consequently, a variety of intellectual property rights other than patents or copyrights could provide a viable means to protect these countries' interests in their biodiversity. An effective national strategy should provide a channel for recognizing and enforcing intellectual property rights protection for specific *genotypes* of plants bred by indigenous communities.

Long before the advent of modern genetic engineering and biotechnology, indigenous communities and traditional farmers began crop experimentation using conventional cross-breeding or

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[119] *See, e.g.,* Chen, *supra* note 36, at 187 ("Edible seed—the phenotype—is a mere chattel . . . ").
[120] *See, e.g., Genotype and Phenotype: Definition, supra* note 119.
[121] *See, e.g.,* Chen, *supra* note 36, at 188.
[122] *Id.*
[123] Chen, *supra* note 36, at 187.
[124] *Id.*
[125] *See, e.g., Forward v. Thorogood*, 985 F.2d 604 (1st Cir. 1993). *See also* Chen, *supra* note 36, at 187.

open-pollination methods.[126] These conventional methods produced unique varieties of plants and agricultural crops that continue to be developed in the modern era. As an illustration, Andean potato farmers developed through traditional farming a variety of frost-resistant crops for growing in flatlands where frost was common.[127] The *genotypes* of these plants are often the product of indigenous knowledge handed down over generations. Both the *genotype* and the indigenous knowledge that produced the plant variety may be eligible for certain types of intellectual property protection.

One strategy for protecting the interests of host countries is to provide Plant Breeder's Rights (PBR) protection for unique crop varieties. PBRs are a patent-like system for cultivated plants developed under the International Union for the Protection of New Varieties of Plants (UPOV).[128] PBRs give the breeder exclusive rights to produce, sell, and import seed varieties.[129] Instead of the traditional criteria for patent eligibility, PBRs use (1) distinctiveness, (2) uniformity, and (3) stability. Stability and uniformity are measures of reproducibility among successive generations of specimens. Distinctiveness is the more critical test and requires that the plant variety be clearly distinguishable from all known varieties.[130]

Under the revised standards of UPOV, a plant variety determined to be "dependent" on an initial variety protected by PBR cannot be commercialized without the prior consent or permission of the PBR owner.[131] Dependency is found where the plant variety at issue is "predominantly derived" from the initial variety. Derivation can be determined through specifically identified procedures, such as genetic transformation or cross-breeding.[132] Under Article 27, TRIPS mandates that member countries provide either patents or a *sui generis* system, such as PBRs. Consequently, this form of intellectual property right could provide a means for local communities to obtain some control and remuneration for their unique plant varieties.

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[126] June Starr, *Not by Seeds Alone: The Biodiversity Treaty and the Role for Native Agriculture*, 12 STAN. ENVTL. L. J. 85, 111-12 (1993).
[127] Ritchie, *supra* note 93, at 448-49.
[128] LESSER, *supra* note 7, at 165.
[129] MASKUS, *supra* note 20, at 57.
[130] LESSER, *supra* note 7, at 165.
[131] *Id.* at 166.
[132] *Id.*

Empirical data on the impact of PBRs is largely unavailable. However, Argentina, Chile, and Uruguay have adopted PBR systems that have greatly benefited private farmers.[133] In these Latin American economies, PBRs have improved the ability of private breeders to control local seed markets and prevent unauthorized trade. Moreover, these countries have witnesses increased accessibility to foreign seed as a result of PBRs, since foreign plant breeders are more willing to market their products in these countries.[134]

Although PBRs have the potential to provide an effective means to protect unique plant varieties developed by traditional farmers in host countries, PBRs have historically been utilized by large commercial plant breeders in developed countries.[135] Much like patents, traditional farmers in host countries often find it difficult to obtain protection under PBRs. The criteria of stability and uniformity are often traits bred by large agribusiness, while traditional farmers typically breed crops for adaptability.[136] Thus, PBRs do not always lend themselves to developing countries. A second drawback of PBRs is that they still permit others to utilize the *genotype* of a protected variety for private use, thus limiting the ability of PBRs to provide the same level of protection or potential remuneration as patents.[137] Finally, PBRs are not uniformly recognized around the globe, since only a handful of states belong to UPOV.[138]

To obtain the advantages of PBRs and less of the drawbacks, Article 27 of TRIPS theoretically provides developing countries the flexibility to implement a *sui generis* system of intellectual property rights.[139] Countries such as India, Thailand, and Columbia have already begun devising intellectual property systems that are friendlier to traditional farmers.[140] Developing countries could also create a

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[133] MASKUS, *supra* note 20, at 223.
[134] *Id.*
[135] Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of Scientific and Technical Knowledge of Indigenous and Local* Communities, 17 MICH. J. INT'L L. 919, 940-42 (1996).
[136] *Id.* at 941-42.
[137] *Id.*
[138] *See generally* LESSER, *supra* note 7, at 165.
[139] *See* Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 86, art. 27.
[140] *See, e.g.,* Roht-Arriza, *supra* note 135, at 954.

form of intellectual property rights that restrict the granting of private uses for *genotypes* so as to better protect their unique plant varieties.

In order to assist developing countries facing the enormous cost of devising an effective PBR system or a *sui generis* functional equivalent, a funding mechanism could help subsidize the establishment of infrastructures for developing, implementing, and enforcing these intellectual property systems.[141] These funds could be partially derived out of the profits earned from their own genetic resources. This approach would simultaneously promote benefits-sharing and strengthen intellectual property rights, as required under TRIPS. In addition, the CBD's funding mechanism, the Global Environment Facility (GEF), could be employed if further financial assistance is needed.[142] Joint collaboration with the CBD would likely have the added benefit of increasing the political legitimacy of the CBD, promoting good-will between the developed and developing countries, and allaying the fears of the United States and other industrialized countries that the CBD does not provide adequate intellectual property rights protections.

TRIPS also contemplates utilizing geographic indicators as a means of protecting the intellectual property of member states. Geographic indicators are defined under Article 22 as "indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."[143] Article 22 mandates that members must prohibit the registration of a good that misrepresents its geographical origin. Article 23 provides additional protection for wines and spirits, reflecting the relatively narrow scope of geographic indicators under the TRIPS Agreement. The special protection provided for wines and spirits—largely a luxury good—provoked criticism that many of the TRIPS

[141] Straus, *supra* note 35, at n.76 (describing the "Biotic Fund" proposed by Thomas Eisner).
[142] *See, e.g.,* G. Kristin Rosendal, THE CONVENTION ON BIOLOGICAL DIVERSITY AND DEVELOPING COUNTRIES 165 (2000) (describing the establishment of the GEF as the interim financial mechanism for the CBD under Article 21).
[143] Agreement on Trade-Related Aspects of Intellectual Property Rights, *supra* note 86, art. 22.

provisions were devised without adequate consideration of the interests of developing countries.[144] Indeed, geographic indicators are largely confined to limited applications under TRIPS.[145]

Geographic indicators are akin to trademarks in that they are not intended to reward innovation.[146] Instead, geographic indicators reward members of an established community for adhering to traditional communal or cultural practices. Throughout the globe, geographic indicators have been recognized in wines as well as certain food products produced in France, Spain, Italy, and Portugal.[147] These intellectual property rights thus have the potential to create economic rewards for producers who utilize indigenous knowledge in the production of their products.

Some developing countries have recognized the potential benefits of utilizing geographic indicators as a means to protect native products otherwise ineligible for patent protection. Developing countries have pressed for the inclusion of certain food products, such as Basmati rice or Darjeeling tea, under Article 22 of TRIPS.[148] If these countries' efforts prove successful, geographic indicators could provide protection against unauthorized commercial exploitation of a wide array of products. For example, a broadened scope of geographic indicators under TRIPS could provide a means for certain varieties of traditionally bred plants to obtain protection that might otherwise be unavailable. However, in a recent press release, the United States is resisting efforts by the European Union to add geographic indicators protections for products other than wine and spirits.[149] The United States is taking the position that the costs of expanding the scope of geographic indicators would far outweigh the benefits, especially for developing countries.[150]

The concerns of the United States are an ironic development in light of its traditional stance favoring strengthened intellectual property rights protection. Nevertheless, its position highlights a

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[144] *See, e.g.* MASKUS, *supra* note 20 at 239 (describing the frustration over the inadequate consideration of developing countries' participation in geographic indicators).
[145] *Id.*
[146] *How Intellectual Property Rights Could Be a Tool to Protect Traditional Knowledge, supra* note 117, at 259.
[147] *Id.*
[148] *Id.*
[149] *U.S. Seeks Voluntary System on Wine, Spirits Naming Rights*, USINFOR.STATE.GOV, *at* http://usinfo.state.gov/ei/Archive/2004/Jan/06-428636.html (last visited Oct. 31, 2004).
[150] *Id.*

legitimate logistical concern over the expansion of intellectual property rights in developing countries. For geographic indicators to properly function, countries must be able to develop appropriate legal structures to register traditional cultural practices and determine if they qualify for protection. These legal structures may require appropriate capacity-building in terms of training, education, and domestic legislation. An international registry for all members of the CBD and TRIPS could provide a solution that would alleviate some of the financial and logistical burdens on developing countries. The WTO or the CBD Secretariat could potentially coordinate these registry systems. A central registry would also facilitate the sharing of information between countries while protecting developing countries' rights to ensure that the original suppliers of genetically-derived domestic products produced through traditional methods are remunerated.

In addition to plant varieties, indigenous knowledge may likewise be eligible for intellectual property protection if appropriate national legislation is adopted. One potential method of providing indigenous knowledge adequate intellectual property protection is through trade secrets. Trade secrets may consist of patterns or compilations of information used in one's business which give the holder a competitive advantage over those without the same knowledge.[151] Trade secrets may also include chemical formulas, a process of manufacturing, treating, or preserving materials, and patterns for machines.[152] The object of trade secrets is to prevent undisclosed, commercially valuable information from being acquired or used by others without the consent of the property right holder.[153]

If benefits-sharing is to be promoted through trade secrets, the persons who stand to benefit must recognize the commercial value of their indigenous knowledge. The awareness of the rights and potential benefits of trade secret protection is crucial.[154] Once acknowledged, trade secrets can be protected by agreements among indigenous populations to protect these types of property. Domestic governments may aid in this endeavor by assisting local communities in recognizing the value of trade secret protections

[151] Chen, *supra* note 36, at 190-91.
[152] *Id.*
[153] Srividhya Ragavan, *Protection of Traditional Knowledge*, 2 MINN. INTELL. PROP. REV. 1, 20-21 (2001).
[154] *Id.*

and enforcing infringements. This strategy would thus require many developing countries to strengthen their existing intellectual property legislation and enforcement capacities.

Indigenous communities in developing countries have tried to use trade secrets to protect communal knowledge that had been passed down through several generations. For example, a small tribe in Peru sought to protect its genetic resources and communal traditions from unauthorized expropriation.[155] Shaman Pharmaceuticals, a United States corporation, attempted to obtain information and materials from the tribe that could be useful in the development of plant-derived medicines. The tribe demanded that Shaman enter into a contractual agreement with them to ensure that the tribe obtained benefits from the expropriation. Although the corporation did not share the rights to co-ownership of any patents or proceeds from any commercial product derived through the tribe's assistance, Shaman agreed to pay royalty payments if a product was placed on the market and to provide aid to the tribe in the form of public health assistance and forest conservation efforts.[156]

Through trade secrets or a *sui generis* equivalent, savvy indigenous communities, such as the tribe in Peru, can utilize intellectual property protections to share in the benefits of their genetic resources. However, even when trade secrets or a *sui generis* system are adopted, the country or tribe must anticipate challenges to their property rights. Were a dispute to arise over the unauthorized utilization of a trade secret, governments of developing countries could enforce these rights directly or refuse to deal with the violator in the future. As always, necessary financial and legal mechanisms may be necessary to aid developing countries in strengthening the skills and facilities to process, register, or enforce these rights. Moreover, a potential drawback of trade secrets is that they do not protect fair and independent discoveries of the same product or process.[157] Enforcement mechanisms may therefore prove tricky and burdensome for many of the least-developed countries. Countries trading in biotechnological resources should look into strategies that could coordinate the efforts of NGOs or provide a centralized mechanism that could aid in dispute settlements.

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[155] *Id.*
[156] *Id.* at 21-22.
[157] Chen, *supra* note 36, at 191.

The right combination of intellectual property rights and private agreements may provide developing countries greater leverage in protecting rights to their resources while facilitating the sharing of benefits on fair and equitable terms. PBRs and geographic indicators provide potential intellectual property alternatives to patents by protecting the *genotypes* of plants and the indigenous knowledge that developed them. Nevertheless, using geographic indicators under TRIPS would require an expansion of Article 22 that encompasses certain plant varieties meeting the established criteria. Finally, the use of trade secrets as a means for protecting indigenous knowledge should be explored by those countries providing the genetic resources for foreign biotechnological companies.

B. *Initiatives for Technology Transfer*

Despite the poor track record of license and process agreements, other bilateral agreements between multinational corporations and host countries have shown promise for facilitating the technology transfer goals of the CBD and the TRIPS Agreement. Additional efforts on the part of both biotechnological corporations and host countries should be employed in facilitating the transfer of technology to developing countries through such private arrangements. These agreements could also provide a means to enjoin foreign firms from requiring developing countries to grant all subsequent innovations derived from a product or process back to the foreign firm.

Private agreements designed specifically to address access to the genetic resources of a host country are often referred to as "material transfer agreements" (MTAs).[158] These agreements apply when the owners of the materials/host countries are identifiable and are willing to grant permission to use the genetic material or indigenous knowledge to a foreign buyer.[159] One of the most publicized MTAs was the agreement between Merck Pharmaceuticals, among the largest pharmaceutical corporations in the world, and Costa Rica's Institutio Nacional de Biodiversidad (InBio), a non-profit organization granted authority by the Costa Rican government to use national parks and conservation areas in efforts to

[158] LESSER, *supra* note 7, at 29.
[159] *Id.*

facilitate sustainable development.[160] In this agreement, InBio agreed to provide approximately 2,000 samples of various genetic materials to Merck over a two-year period.[161] Merck paid InBio $1,135,000, which was to be used in taxonomic activities, genetic resource conservation, scientific training, and acquiring equipment for specimen collection. If Merck was able to successfully commercialize a product derived from Costa Rica's natural resources, Merck agreed to make royalty payments. Finally, the agreement also provided that Merck would employ local scientists for its bio-prospecting.[162]

This agreement thus met several objectives of both the CBD and TRIPS. First, by providing up-front remuneration to InBio and the Costa Rican government, the host country shares a stake in innovations developed out of their biological resources. Second, by including a provision whereby Merck would provide royalty payments for any future commercialized product, the host country shares in the benefits of any profits derived through biotechnological development. Third, the agreement facilitated technology transfer by employing local scientists in bio-prospecting.

The Merck-InBio agreement marked an important development in the global exchange of genetic resources and biotechnology. Nevertheless, the agreement has also been criticized on a number of fronts. Such an agreement would be inapplicable to a majority of developing countries because few possess institutions such as InBio that oversee the country's natural resources. Moreover, agreements of this type would have limited applicability to countries populated by indigenous communities that should, in all fairness, share in any benefits derived from their knowledge. This quandary presents a formidable problem for MTAs, as these agreements may provide remuneration to developing countries' governments without compensating the indigenous tribe that originally supplied the materials and information used in developing the product.

Shaman Pharmaceuticals, the corporation that entered into an agreement with tribes in Peru, utilized an innovative approach towards bio-prospecting that provides insight into how contracts can facilitate technology transfer. Shaman developed a program to compensate communities that assist in

[160] *See, e.g.,*Spier*, supra* note 27, at 220-21.
[161] LESSER, *supra* note 7, at 29.
[162] *Id.*

identifying and retrieving genetic materials that could be used in developing new pharmaceuticals.[163] This program paid indigenous communities royalties on any successful commercial products derived from their resources. However, because the likelihood of a particular genetic resource having a commercial application is approximately 1 in 10,000, [164] Shaman also provided short- and medium-term benefits to address the immediate needs of the indigenous community.[165] These benefits included training local scientists in using new technologies, providing scientific software, and supplying certain biotechnological equipment.[166] Finally, Shaman established the Healing Forest Conservancy, a non-profit institution which distributes the profits from commercial products among the regional communities from which the commercialized product was sourced.[167]

Shaman's program created considerable excitement and speculation about the efficacy of private agreements in facilitating the transfer of technology to indigenous communities. However, Shaman faced substantial financial hurdles in implementing this program.[168] In 1994, Eli Lilly, Shaman's primary source of research funds, did not renew its research contract.[169] Moreover, Shaman was unable to turn a profit by the time Eli Lilly withdrew.[170] The financial troubles of Shaman eventually led the company to withdraw from bio-prospecting altogether.[171] Shaman's demise as a leader in providing technology transfer and benefits-sharing for indigenous communities thus calls into question the efficacy of these programs as a viable business model. Nevertheless, Shaman's bio-prospecting activities illustrate the

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[163] LESSER *supra* note 7, at 33-34.
[164] *See* Scott Shahverdian, *Bioprospecting: Successes, Failures and Viability as a Global Regime*, (2004) *at* http://www.colby.edu/personal/s/smshahve/bio%20web%20page%20final.htm (last visited September 14, 2005).
[165] Donald E. Bierer, et al., *Shaman Pharmaceuticals: Integrating Indigenous Knowledge, Tropical Medicinal Plants, Medicine, Modern Science and Reciprocity into a Novel Drug Discovery Approach,* Networkscience.org, *at* http://www.netsci.org/Science/Special/feature11.html (last visited Oct. 31, 2004).
[166] *Id.*
[167] David B. Vogt, *Protecting Indigenous Knowledge in Latin America*, 2 OR. REV. INT'L L. 12, 26-27 (2001).
[168] Erin B. Newman, *Earth's Vanishing Medicine Cabinet: Rain Forest Destruction and its Impact on the Pharmaceutical Industry*, 20 AM. J.L. & MED. 479, 496 (1994).
[169] *Id.*
[170] By 1995, Shaman Pharmaceuticals had still been unable to earn any profits. *See, e.g.,* Curtis M. Horton, *Protecting Biodiversity and Cultural Diversity Under Intellectual Property Law: Toward a New International System*, 10 J. ENVTL. L. & LITIG. 1, 32 (1995).
[171] LESSER *supra* note 7, at 34.

potential of private contractual agreements between biotechnology corporations and indigenous communities to facilitate technology transfer to the developing world.

In addition to MTAs, national and regional initiatives aimed at facilitating technology transfer constitute another option that countries should explore in achieving the aims of the CBD and TRIPS. In 1996, the Andean Pact, consisting of Bolivia, Columbia, Ecuador, Peru, and Venezuela, adopted the "Common System on Access to Genetic Resources" (Access System) to consolidate and develop domestic technological and scientific capabilities.[172] Under this system, a centralized national authority is designated by each member country to provide genetic resources, inspect or sign access contracts, carry out the decisions of the Pact, and ensure compliance by foreign bio-prospectors. The Access System requires potential bio-prospectors to obtain the prior informed consent of these national institutions in order to gain access to the host country's resources. Non-compliance with these access regulations gives rise to possible cancellation of intellectual property rights conferred to foreign bio-prospectors. Finally, the Access System requires the national legislatures of each member country to adopt appropriate secondary laws to comply with these obligations.

The Andean Pact's Access System represents the most formal arrangement for recording contributions to inventions and controlling access to genetic resources in the developing world.[173] Prior to the approval of this system, such access was unrestricted.[174] Member countries could not obtain their fair share of resulting economic benefits. The Access System sought to enable member countries to obtain benefits from biotechnological products derived from their resources by facilitating technological training, research, development, and transfers through state access contracts.[175]

The Access System is still in its infancy and has yet to offer the results necessary to analyze its successes or failures. Progress has been made in each member state, although the system is undergoing a

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[172] *See, e.g.,* Straus*, supra* note 35, at 158.
[173] *See, e.g.,* Weeraworawit, *Formulating an International Legal Protection for Genetic Resources, Traditional Knowledge and Folklore: Challenges for the Intellectual Property System*, 11 CARDOZO J. INT'L & COMP. L. 769, 775 (2003).
[174] Victor Tafur-Dominguez, *International Environmental Harmonization – Emergence and Development of the Andean Community*, 12 PACE INT'L L. REV. 283, 306-07 (2000).
[175] *Id.*

review process focusing on practical implementation problems.[176] Notably, one of the main problems of implementation is the high cost of operation.[177] Consequently, an equivalent system might not be a viable option in the least-developed countries that lack the funds or trained personnel necessary to manage such a complex infrastructure. Despite this drawback, however, the Access System could be a useful tool for governing access to the genetic resources of host countries and providing a legislative mechanism for the transfer of technologies to the developing world.

Problems with the Access System could arise if foreign bio-prospectors from industrialized countries are able to circumvent the system by failing to meet the prior informed consent and contract requirements of each nation. Although the Access System contains a provision providing for the revocation of any intellectual property rights granted to a foreign bio-prospector in their own territory, illicit bio-prospectors can still obtain a patent in their home countries. One example is the case of the neem tree, which traditionally has been used as a pesticide in India.[178] W.R. Grace, a United States corporation, obtained a United States patent on pesticides derived from the tree. Activists protested, claiming that the tree had been used as a pesticide for generations. The United States Patent Office was statutorily prohibited from considering foreign public knowledge as part of the patent application and was thus unable to revoke the patent.[179] As a result of this problem, scholars have proposed a variety of disclosure systems whereby the grant of a patent application requires the prior informed consent of the nation of origin.[180]

Through the use of private contract agreements and legislative initiatives, the transfer of technology to developing countries and indigenous communities could be accomplished on mutually agreed terms. The material transfer agreements utilized by Merck and Shaman illustrate methods that

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[176] Manuel Ruiz, et al., *The Protection of Traditional Knowledge in Peru: A Comparative Perspective,* 3 WASH. U. GLOBAL STUD. L. REV. 755, 769 (2004).
[177] *Id.*
[178] Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 680 (2003).
[179] *Id.; see also* 35 U.S.C. 102.
[180] *See, e.g., How Intellectual Property Rights Could Be a Tool to Protect Traditional Knowledge, supra* note 117, at 256.

host countries can employ to facilitate access to genetic resources while determining the terms of the transaction. These terms may include obligations by foreign biotechnology corporations to train domestic scientists, transfer biotechnological equipment, and employ local biologists in prospecting activities. National and regional initiatives such as the Andean Pact likewise provide a means for host countries to dictate the terms of trade by conditioning access on state contractual agreements. Much like material transfer agreements, legislative initiatives represent another tool that can be used to set the terms of trade and foster the objectives of technology transfer under the CBD and TRIPS. In the coming years, the appropriate combination of these strategies could prove to be a potent combination for countries to increase their bargaining power.

Conclusion*:*

The biotechnology industry has fundamentally altered the economic potential of genetic resources and traditional knowledge found in developing countries. Pharmaceutical corporations and Agribusiness increasingly rely upon these resources to engineer new drugs and genetically modified crops for sale in the international market. Developing countries, home to over eighty percent of the world's biodiversity,[181] have become hotbeds for bio-prospectors searching for the next big breakthrough in medicine or agriculture. As a result of the high stakes involved in this multi-billion dollar industry, the global community, in seeking to facilitate the equitable sharing of benefits, is struggling to strike a balance between the interests of biological suppliers and biotechnological inventors.

The Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights mirror the conflicting views of industrialized and developing countries concerning intellectual property rights. Industrialized countries view the CBD with a suspicious eye, as it precariously balances the sovereign rights of states with intellectual property protections. In turn, developing countries often viewed TRIPS as a tool for affording multinational corporations access to their

[181] Straus, *supra* note 35, at 142.

resources without sharing in the benefits derived from them. Despite these differences, both the CBD and TRIPS utilize benefits-sharing, technology transfer, and intellectual property rights protection as methods of promoting the fair and equitable sharing of benefits derived from biotechnology.

Benefits-sharing and technology transfer remain lofty goals under the CBD and TRIPS. Nevertheless, a number of strategies and proposals should be considered to achieve these ends. Through the use of Plant Breeders' Rights and geographic indicators, developing countries can obtain benefits for plant varieties developed through traditional knowledge. Trade secrets could be employed to protect the indigenous knowledge sought by biotechnological corporations. The use of contracts between suppliers and users of genetic resources would facilitate technology transfer to host countries. These agreements could also be a component in legislative and regional initiatives designed to control access to genetic resources and encourage the transfer of technology from foreign bio-prospectors. Finally, developed countries should consider proposals to include a disclosure requirement in patent applications to prevent unauthorized use of genetic materials.

The global community is just beginning the process of reconciling the application of intellectual property rights to genetic resources and traditional knowledge. In their efforts to forge a path to a solution, the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights often cross paths in areas of great controversy. Despite these tensions, both treaties ultimately foster economic development through recognition of the role intellectual property rights play in protecting the interests of users and consumers of genetic resources. Through a studied application of new and existing forms of intellectual property rights, biotechnology may someday make all countries winners in the eyes of the global economy.