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Abstract

This article addresses the corrosive interplay between the patent-based and the sovereign- based systems of ownership of genetic material. In patent-based systems, genetic material is increasingly "owned" by corporations or research institutions which obtain patents over such material. In sovereign-based systems, the national government owns or extensively controls such material. As more patents issue for synthesized genes in developed countries through the patent system, more raw genetic material is legally enclosed by the governments of developing nations, which house most of the world's wild or raw genetic material. This interactive spiral of increased enclosure results in the sub-optimal utilization, conservation and improvement of vital genetic material.

This article adds to the scholarship that critiques the patenting of genetic material in the United States by focusing on the international collateral damage occasioned by overbroad patenting in this area. In addition, it takes the first comprehensive critical look at the sovereign-based system. It argues that sovereign ownership or extensive control over genetic material (i) risks creating an anticommons in raw genetic material (ii) threatens the liberty and autonomy of individuals and indigenous communities whose property contains such material and (iii) is premised on a flawed approach in international law that has led to broad and unenforceable regimes that will increase tensions between nations. Moreover, the interaction between the patent-based and the sovereign-based systems risks setting off a major trade dispute under the TRIPS Agreement.

To repair this situation, I propose a framework for a more open system for genetic material. I recommend that the United States take into account the adverse

reaction of other countries when determining as a utilitarian matter whether and, if so, to what extent to allow patents for genetic material. Expansive patent rights over genetic material can cause innovation in the biotechnology field to fall to suboptimal levels because they cause sovereigns in the world's most genetically diverse nations to curtail access to the raw material that contributes to such innovation. For their part, genetically-rich developing countries should, inter alia, adopt more selective and value-added approaches to enclosure.

HYPEROWNERSHIP IN A TIME OF BIOTECHNOLOGICAL PROMISE: THE INTERNATIONAL CONFLICT TO CONTROL THE BUILDING BLOCKS OF LIFE

By Sabrina Safrin[*]

"Hyperownership" describes in a word the present international legal landscape with respect to genetic material. At issue is who should own or control access to the subcellular genetic sequences that direct the structure and characteristics of all living things, or, in popular usage, nature's or God's blueprints for life.[1] Traditionally, genetic material belonged to a global commons or open system. No one exclusively owned this material and countries freely shared it. In sharp contrast, today exclusive ownership and restrictions on the sharing of genetic material are the international norm.

This legal enclosure of genetic material has two components. First, developed countries, most extensively and consequentially the United States, have pressed the reaches of the patent system. They are extending patent protection to a wide and increasing array of genetic material.[2] By mid-2000, the U.S. Patent and Trademark Office (PTO) had issued over six thousand patents on full-length genes isolated from living organisms and were considering over twenty thousand gene-related patent applications.[3] Second, in response to the privatization of genes through the patent system, developing countries—which house most of the world's wild or raw genetic material—are pushing the boundaries of sovereignty. They are asserting sovereign ownership or extensive national government control over a wide and increasing range of raw genetic material in their countries. Since 1993, approximately twelve nations have passed laws that greatly restrict access to raw genetic material within their borders.[4] At least thirty others are in the process of doing so.[5]

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[1] Briefly, the cells of all living things contain genes. Genes code for proteins, and proteins determine the structure and characteristics of life forms. MATT RIDLEY, GENOME 6–9 (1999).

[2] Jasemine Chambers, *Patent Eligibility of Biotechnological Inventions in the United States, Europe and Japan: How Much Patent Policy is Public Policy?* 34 GEO. WASH. INT'L L. REV. 223, 237–39 (2002); Sean D. Murphy, *Biotechnology in International Law*, 42 HARV. INT'L L.J. 47, 62–65 (2001); Lawrence Fisher, *The Race to Cash in on the Genetic Code*, N.Y. TIMES, Aug. 29, 1999, §3, at 1. While a gene or a genetic sequence in its natural state cannot be patented, a patent may issue if the naturally occurring gene is synthesized from its original state and ascribed a useful function. Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 359 (2002). Patenting is discussed more fully in parts I and V *infra*.

[3] Demaine & Fellmeth, *supra* note 2, at 359. "Over a sixth of these patents cover whole human genes and many of their significant alleles." *Id.*

[4] Lyle Glowka, *Bioprospecting, Alien Invasive Species, and Hydrothermal Vents: Three Emerging Legal Issues in the Conservation and Sustainable Use of Biodiversity*, 13 TUL. ENVTL. L.J. 329, 330–31 (2000) (reporting that ten nations have passed such laws). Since Glowka's article appeared, at least two other nations, Brazil and India, have put access-restricting regimes into place.

[5] *Id.* at 331.

This article addresses the corrosive interplay between the patent-based and the sovereign-based systems of ownership of genetic material. As more patents issue for synthesized genes, more raw genes are legally enclosed by developing nations.[6] This interactive spiral of increased enclosure, or hyperownership, results in the suboptimal utilization, conservation, and improvement of vital genetic material. It generates tensions between nations and threatens individuals and indigenous communities. The global commons is being subjected to a global tug of war over genetic material at the expense of the global common good.

Recently, a great deal of legal scholarship has been produced in the patent field questioning aspects of the U.S. grant of patents to genes or genetic sequences.[7] In criticizing or defending the privatization of genes through the patent system, however, scholars have largely failed to take into account the responsive and growing overseas phenomenon of sovereign ownership or extensive sovereign control of naturally occurring genetic material.

This article fills this lacuna by focusing on the international collateral damage occasioned by overbroad patenting of genetic material in the United States. In addition, for the first time in the legal literature, this article takes a comprehensive critical look at the sovereign-based system. In particular, it argues that sovereign ownership or extensive sovereign control over genetic material (1) risks creating an anticommons[8] in raw genetic material, (2) threatens the liberty and autonomy of individuals and indigenous communities whose property contains such material, and (3) is premised on a flawed approach in international law that has led to broad and unenforceable regimes that will increase tensions between nations. It concludes that *collectively* the developed countries' patent-based systems and the developing countries' sovereign-based systems have overreached in permitting or asserting ownership rights over genetic material.

While this article does not recommend a return to a comprehensive open system for genetic material, it proposes a novel framework for reform that would move toward a more open system. Such a framework would entail reciprocal, though not identical, steps by the United States, on the one hand, and developing countries, on the other. With respect to the United States, this article calls for an "international regarding" aspect to U.S. patent policy formulation in the

[6] *See, e.g.*, MICHAEL F. BROWN, WHO OWNS NATIVE CULTURE? 138–39 (2003) (noting that the expansion of patents in the area of biotechnology research eventually made it increasingly difficult for ethnobotanists to collect wild plant specimens). The enclosure systems of developed and developing countries are not identical. Developing nations restrict access to raw or unimproved genetic material existing in the wild. Patents, in contrast, issue for worked or improved genetic material. However, the amount of human improvement involved in a patented gene can be rather small, consisting of isolating the gene and identifying its useful function. In this case, each system encloses material either in or close to its natural state.

[7] *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 U. ILL. L. REV. 173, 192–94; *see also* Demaine & Fellmeth, *supra* note 2; Philippe Jacobs & Geertrui van Overwalle, *Gene Patents: A Different Approach*, 23 EUR. INTELL. PROP. REV. 505 (2001) (arguing that patents should not be granted for DNA but only for downstream medical goods). *But see* Eric Mauer, Comment, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter*, 95 NW. U. L. REV. 1057, 1090 (2001). Others, while accepting the patent eligibility of isolated naturally occurring genes, have proposed a series of mechanisms, such as a broader experimental use exemption and compulsory licensing, to diminish the reach and innovation-inhibiting effects of such patents. Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and A Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623 (2001) (suggesting such mechanisms for human DNA sequences); Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 735 (2000) (proposing an ASCAP system for genes, whereby all would have access to registered isolated and identified genes upon payment of a fixed fee); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001). In contrast, some maintain that the system by and large is not broken and that the United States should "steady the course." Richard A. Epstein, Steady the Course: Property Rights in Genetic Material 22–26 (John M. Olin Law & Econ. Working Paper (2d ser.) No. 152, rev. Mar. 2003), *available at* <http://www.law.uchicago.edu/Lawecon/index.html> (discussing and criticizing "middle of the road" proposals described above and proposing an "all or nothing" approach where some genetic substances, like "express sequence tags," should be left in the public domain, but everything else should be governed by the usual rules of patent protection). *But see* Rochelle Cooper Dreyfuss, Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's *Steady Course* 1 (NYU Public Law and Legal Theory Research Paper No. 59, Apr. 2003), *available at* <http://ssrn.com/abstract_id-394000> (disagreeing with Epstein).

[8] An anticommons can occur when multiple individuals or entities have rights of exclusion to a given resource. *See* text at note 84 *infra*.

biotechnology field. By this I mean that the PTO, Congress, and/or the courts should take into account, or "internationally regard," the reaction of other countries, particularly developing countries that are rich in genetic diversity, when determining as a utilitarian matter whether and, if so, to what extent to allow patents for genetic material. With respect to genetically rich developing countries, this article proposes a set of steps to reduce sovereign enclosure of genetic material. These steps include changing the international normative assumption about sovereign enclosure of genetic material and more selective approaches to enclosure. These reforms are possible because the patent system[9] and the sovereign system[10] are evolving. Opportunity exists to influence line-drawing activity in both systems.

Before I proceed, a few clarifying notes regarding the focus of this piece are appropriate. First, this article focuses on the interplay between the patenting of genetic material in the United States and the response to such patenting by developing countries that enjoy a wealth of genetic diversity. While other developed countries, particularly members of the European Union and to a lesser extent Japan, have permitted the patenting of genetic material and life forms, the United States is the proverbial "thousand-pound gorilla" in this regard. It is the world's largest producer of bioengineered goods.[11] It allows the patenting of genetic material to a greater degree than any other country.[12] Finally, the United States assumed the leadership role in pressing for the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which requires countries to extend patent protection to bioengineered goods with the potential imposition of trade sanctions if they do not.[13] The United States is the primary actor responded to by other countries when it comes to the ownership of genetic material. Second, this article approaches the issue of ownership over genetic material from a utilitarian rather than a moral perspective.[14] Third, it focuses on nonhuman genetic material. Discussion of human genetic

[9] The rules establishing how much and under what circumstances genetic material may be patented are presently being drawn and refined. Rebecca S. Eisenberg, *How Can You Patent Genes? in* WHO OWNS LIFE? 117 (David Magnus, Arthur Caplan, & Glenn McGee eds., 2003) (although people have been obtaining patents on genetic sequences for twenty years, the system is still struggling to clarify the ground rules for acquiring them).

[10] Genetically rich countries and those engaged in international work under the auspices of the Convention on Biological Diversity are currently determining and refining how much control sovereigns should assert over raw genetic material. *See* Decision 26, Fifth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Doc. UNEP/CBD/COP/5/26A (2000) (providing for the development of access and benefit-sharing guidelines as a fall-back where countries lack "comprehensive legislation and national strategies for access and benefit-sharing" and establishing two experts panels and one working group to develop such guidelines and other measures to provide for access and benefit sharing). Such guidelines may also assist countries that are developing access legislation. Both the Organization of African States and the Association of South East Asian Nations have drafted model legislation on restricting access to raw genetic material. *See* part II *infra,* notes 108–16 and corresponding text.

[11] Chambers, *supra* note 2, at 225 (the United States generates 75% of the world's agricultural bioengineered products alone). U.S. biotechnology is a $13 billion a year industry, and more than fourteen thousand biotechnology patent applications are filed in the United States each year. *Id.* at 224.

[12] Other developed countries, like the EU membership and Japan, while allowing the patenting of genetic material, allow for the denial of such patents on public policy grounds. *Id.* at 232, 239; Gitter, *supra* note 7, at 1644–49. They subject such patents to an experimental use exemption from infringement. *Id.* at 1689. On the whole, they appear to apply a somewhat stricter standard for nonobviousness than the United States. Chambers, *supra* note 2, at 241 (worldwide U.S. patent law provides the broadest protection of biotechnological innovations); Carlos M. Correa, *Internationalization of the Patent System and New Technologies*, 20 WIS. INT'L L.J. 523, 530 n.40 (2002); Gitter, *supra*, at 1677 (noting that European scholars and policymakers emphasize that the European criterion of an inventive step might soon become impossible to meet for any DNA sequence as sequencing becomes increasingly routine and obvious).

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 27, Annex 1C of Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, *in* WORLD TRADE ORGANIZATION, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999) [hereinafter TRIPS]. For the proposition that the United States assumed the leadership role in pressing for the TRIPS Agreement and the obligations that TRIPS places on countries to patent biotechnological inventions, see Frederick M. Abbott, *TRIPS in Seattle: The Not-So-Surprising Failure and the Future of the TRIPS Agenda,* 18 BERK. J. INT'L L. 165, 168 (2000); Murphy, *supra* note 2, at 68–69, 99; Kal Raustiala & David G. Victor, *The Regime Complex for Plant Genetic Resources*, 58 INT'L ORG. 277, 284 (2004).

[14] There is an expansive body of literature exploring the moral issues raised by the patenting of genetic material. *See, e.g.,* LEON R. KASS, TOWARD A MORE NATURAL SCIENCE: BIOLOGY AND HUMAN AFFAIRS 149–50 (1985); Gitter, *supra* note 7, at 1649–50 (summarizing moral objections to the patenting of genes); Mark J. Hanson, *Patenting Genes and Life: Improper Commodification? in* WHO OWNS LIFE? *supra* note 9, at 161.

material is included for the limited purposes of illustrating the reaches of the patent system and flagging the implications for human genetic material of sovereign ownership or control of nonhuman genetic material.

Part I traces the roots of hyperownership of genetic material. It describes the shift in international law and the laws of developed and developing countries from a global commons or open system to the present system of extensive ownership rights.

Part II takes a comprehensive critical look at the sovereign system. It argues that the sovereign-based control regimes risk creating an anticommons in raw genetic material and threaten the autonomy and liberty of individuals and indigenous communities whose property contains such material.

Part III asserts that the international trend of granting sovereigns ownership or extensive control over genetic material is based on a flawed approach in international law that treats genes as a tangible resource like oil when in fact they are more akin to an intangible resource like information. It explains how this flawed approach leads to overbroad and unenforceable regimes that increase tensions between nations.

Part IV argues for a more open system for genetic material and part V proposes a bilateral framework for such a system.

I. THE SHIFT FROM AN OPEN SYSTEM TO ENCLOSURE OF GENETIC MATERIAL

In the Beginning: A Global Genetic Commons

The community of nations first spoke in a legal context about the ownership of genetic material over twenty years ago. In 1983 approximately one hundred nations adopted the International Undertaking on Plant Genetic Resources (Undertaking), a nonbinding agreement negotiated under the auspices of the United Nations Food and Agriculture Organization. The Undertaking reflected the traditional international paradigm that genetic material formed part of a global commons. It began by stating that it "is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction."[15]

Although the Undertaking applied only to plant genetic resources, an area in which the concept of a global genetic commons ran especially strong, all genetic material had traditionally been viewed as part of a global commons.[16]

As part of a global commons, genetic resources were available in principle for the use of all (often referred to as open access).[17] As such, like information in the public domain, they were a freely accessible good.[18] Most important, as part of a global commons, genetic resources, like

[15] International Undertaking on Plant Genetic Resources for Food and Agriculture, Nov. 23, 1983, Art. 1, *available at* <http://www.fao.org/ag/cgrfa/iu.htm> [hereinafter Undertaking]. Eight developed countries, including the United States, expressed reservation to this language out of concern that it might conflict with intellectual property protections that they were extending to plant breeders under the UPOV Convention, *infra* note 29. *See* Raustiala & Victor, *supra* note 13, at 288; note 27 *infra* and corresponding text.

[16] Edgar J. Asebey & Jill D. Kempenaar, *Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention*, 28 VAND. J. TRANSNAT'L L. 703, 718 (1995); Michael I. Jeffrey, *Bioprospecting: Access to Genetic Resources and Benefit-Sharing Under the Convention on Biological Diversity and the Bonn Guidelines*, 6 SINGAPORE J. INT'L & COMP. L. 747, 758 (2002); John R. Adair, *The Bioprospecting Question: Should the United States Charge Biotechnology Companies for the Commercial Use of Public Wild Genetic Resources?* 24 ECOLOGY L.Q. 131, 141 (1997) (noting that access to wild genetic resources had traditionally been open); Cary Fowler, *Protecting Farmer Innovation: The Convention on Biological Diversity and the Question of Origin*, 41 JURIMETRICS 477, 480 (2001); Raustiala & Victor, *supra* note 13, at 284 ("For most of human history, the rule of common heritage governed [plant genetic resources].").

[17] PATRICIA W. BIRNIE & ALAN E. BOYLE, INTERNATIONAL LAW AND THE ENVIRONMENT 141 (2d ed. 2002) (qualifying that under international law, the use of global common property must be legitimate and reasonable).

[18] *Id.* The concept of common property or a global commons in international law is similar to the concept of a commons or public good in traditional property law. As Jeremy Waldron explains, a commons is an area or a resource whose organizing premise is that it is available in principle for the use of every person. JEREMY WALDRON, THE RIGHT TO PRIVATE PROPERTY 32 (1988). Typical examples include air, rainwater, public parks, and the intangible resource of information in the public domain.

the living resources of the high seas, were not subject to the sovereignty of or appropriation by any state.[19]

In practice, the global genetic commons allowed researchers to collect samples of genetic material freely, with two exceptions. The open system did not grant researchers and scientists the right to trespass on private or state property to obtain genetic samples. Researchers had to obtain any consent normally required before entering such property. Also, researchers would pay collectors of such material for this kind of service.[20] But they were not obligated to obtain national government approval for sampling activities or to compensate the country where the material was found.[21] As a global commons resource, genetic material was not the exclusive preserve of any single user or nation. No one commanded an *exclusive* right to prevent others from exploiting the resource generally.[22]

The Expansion of Intellectual Property Rights over Genetic Material

The traditional paradigm that genetic resources formed part of a global commons was eroded by the extension of patents to living organisms and later to genetic material.[23] In most developed countries, patents now issue for microorganisms, genetically modified plants and animals, and isolated and purified genes and genetic sequences.[24] Patents will not be granted for genetic material as found in nature, such as a gene while in a plant or a fish. A patent, however, can be obtained when that gene has been removed and isolated, and a useful function for it identified.[25] An isolated and purified gene does not exist in that form in nature. Thus, a patent could

[19] BIRNIE & BOYLE, *supra* note 17, at 141. Although the terms are often used interchangeably, the concept of common property in international law should not be confused with the international law concept of the common heritage of mankind. *Id.* at 143; KEMAL BASLAR, THE CONCEPT OF THE COMMON HERITAGE OF MANKIND IN INTERNATIONAL LAW (1998). The "common heritage of mankind" is expressed in certain post–World War II international treaties. These include the Agreement Governing the Activities of States on the Moon and Other Celestial Bodies of 1979 and, most important, the United Nations Convention on the Law of the Sea of 1982. Scholars, drawing on these two treaties, have identified five elements of the international common heritage of mankind: (1) exemption of the common area, such as the moon or the deep seabed and its resources, from appropriation by national governments; (2) international management of the area or resource through an international authority; (3) the sharing of benefits derived from the use of the area and its resources; (4) use of the area or resource solely for peaceful purposes; and (5) an obligation to protect the area or resource for future generations. BASLAR, *supra,* at 209; BIRNIE & BOYLE, *supra,* at 143–44. The international concept of common property and the concept of international common heritage of mankind share the principle of nonsovereignty over the resource in question. They differ, however, in that the concept of the common heritage of mankind envisions a strong international authority to govern the resource. It also involves the sharing of the benefits of the property concerned by all states, even if they are unable to participate in the actual extraction. *Id.* Despite sporadic use of the term "common heritage of mankind" in FAO documents and other references related to the Undertaking, most scholars have concluded or assumed that genetic resources were treated as international common property rather than common heritage of mankind property. *See, e.g.*, BASLAR, *supra*, at 307–10; *see also* note 16 *supra*. Genetic resources were not subject to control by an international body or to international benefit-sharing arrangements.

[20] Asebey & Kempenaar, *supra* note 16, at 719.

[21] *Id.*; Jeffrey, *supra* note 16, at 758.

[22] BIRNIE & BOYLE, *supra* note 17, at 141 (speaking about international common property in general and not genetic material in particular). Once reduced to possession by taking, however, individual resources, such as a fish caught on the high seas, could become property. *Id.*

[23] Diamond v. Chakrabarty, 447 U.S. 303 (1980) (allowing a patent on a genetically engineered bacterium and holding that patents could issue on living things). In 1985 the grant of a utility patent to genetically modified seed was upheld. *Ex parte* Hibbard, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Interferences 1985); *see also* Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Agric. Supply, Inc., 200 F.3d 1274 (Fed. Cir. 2000) (patents may be granted to seeds and seed-grown plants). In 1988 the first patent for a genetically modified animal was issued to Harvard University for a mouse engineered for susceptibility to cancer, U.S. Patent No. 4,736,866.

[24] Murphy, *supra* note 2. Under TRIPS, countries must extend patent protection for microorganisms. Parties have discretion whether to grant patents to plants and animals. Most developed countries have extended patents for plants and animals. Countries that have refused to extend patent protection to plants and animals include Brazil, India, and Norway. *See* Correa, *supra* note 12, at 548; Emily Marden, *The Neem Tree Patent: International Conflict over the Commodification of Life*, 22 B.C. INT'L & COMP. L. REV. 279, 293 (1999); *The Complex Realities of Sharing Genetic Assets*, 392 NATURE 525 (1998); Colin Macilwain, *When Rhetoric Hits Reality in Debate on Bioprospecting*, 392 NATURE 535 (1998).

[25] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir.), *cert. denied sub nom.* Genetics Inst. v. Amgen, Inc., 502 U.S. 856 (1991); Rebecca S. Eisenberg, *Re-examining the Role of Patents in Appropriating the Value of DNA*

issue for a gene that enables a flounder to resist frost, provided that the "inventor" has isolated and purified that gene and identified its role in frost resistance. The ability to patent such genes is significant because the holder of a patent on an isolated and purified gene can prevent all others from making or using that gene.[26]

The traditional paradigm that genetic resources formed part of a global commons was also adversely affected by the increased assertion and expansion of other forms of intellectual property rights over plants, known as plant breeders' rights.[27] In 1989 certain developed countries successfully pressed for the addition of Annex I[28] to the Undertaking to make clear that the Undertaking's common heritage of mankind concept did not affect the rights of plant breeders to exclude others from using their new and distinct varieties under the International Convention for the Protection of New Varieties of Plants (UPOV Convention).[29] Two years later, the UPOV Convention was revised to expand these breeders' rights by curtailing exceptions that had been allowed for the free replanting, exchange, and use for breeding purposes of protected varieties and their propagating material.[30] These exceptions had reflected aspects of an open system because they had allowed protected varieties to be used for a range of purposes without the original breeders' authorization. By the early 1990s, not only were biological goods subjected to a range of intellectual property rights, but developing countries were facing pressure, particularly from the United States, to extend intellectual property protection to such goods in their own countries.[31]

Developing Countries Assert Sovereign Rights over Genetic Material

In response to the patenting of plants, animals, and their genetic material, the expansion of plant breeders' rights, and the growing belief that raw genetic material might prove valuable, developing countries sought to assert sovereign rights over such material. Developing countries constitute most of the nations that hug the equatorial line where large numbers of different life forms are concentrated.[32] As a result, they harbor the greatest amount of the world's genetic

Sequences, 49 EMORY L.J. 783, 785–86 (2000); Murphy, *supra* note 2, at 64; Nicholas Thompson, *Gene Blues*, WASH. MONTHLY, Apr. 2001, at 9.

[26] Eisenberg, *supra* note 25; Thompson, *supra* note 25.

[27] The rise of intellectual property rights over plants evolved over time. For a thorough discussion of the rise and expansion of these rights, see LAURENCE R. HELFER, INTELLECTUAL PROPERTY RIGHTS IN PLANT VARIETIES: INTERNATIONAL LEGAL REGIMES AND POLICY OPTIONS FOR NATIONAL GOVERNMENTS 14–21 (UN Food and Agriculture Organization, 2004); Raustiala & Victor, *supra* note 13, at 286–93.

[28] FAO Res. 4/89, *available at* <http://www.fao.org/ag/cgrfa/iu.htm>.

[29] International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961, *as revised* Oct. 23, 1978, Arts. 5(1), 6(1), 33 UST 2703, *available at* <http://www.upov.int>. Member states are expected to grant and protect these rights at the national level.

[30] UPOV Convention, *supra* note 29, *as revised* Mar. 19, 1991, Arts. 14(1), 14(5), 15(1)(iii), 15(2), S. TREATY DOC. NO. 104-17 (1995), *available at* <http://www.upov.int>. Under the UPOV Convention, as revised in 1978, a farmer could replant seeds from the crop produced by protected seeds for his own subsequent use, as well as exchange seeds with other farmers without paying additional royalties to the breeder. The 1991 revisions no longer allowed for the free exchange of seeds and imposed limitations on their replanting. HELFER, *supra* note 27, at 19. The UPOV Convention, as revised in 1978, also allowed breeders to use a protected variety to create new varieties without the prior authorization of the original breeder. The 1991 revisions, while recognizing this right, limited it to new varieties that are not "essentially derived" from protected varieties. While this limitation was intended to prevent second-generation breeders from making mere cosmetic changes in a protected variety, controversy exists over the amount of genetic distance required before a second-generation variety does not "essentially derive" from the first. The overall effect of the amendment has been to narrow the exemption and expand the rights of first-generation breeders. *Id.* at 19.

[31] Raustiala & Victor, *supra* note 13, at 287, 290. The TRIPS Agreement, *supra* note 13, negotiated in the early 1990s and adopted in 1994, requires that biotechnological innovations, with certain exceptions, and plants receive intellectual property protection.

[32] Columbia University, School of International and Public Affairs, Access to Genetic Resources: An Evaluation of the Development and Implementation of Recent Regulation and Access Agreements 3 (Environmental Policy Studies Working Paper No. 4, 1999) (unpublished manuscript), *available at* <http://www.bionet-us.org> [hereinafter Columbia Access Paper]. Developed countries also destroyed much of their genetic diversity when they destroyed natural habitats, such as forests, to make room for factories, homes, etc.

diversity.[33] Why, these countries asked, should individuals and companies from gene-poor developed countries obtain genetic material free of charge from gene-rich developing countries when they then patent these genes and at times sell them back to the country where the genetic material originated?[34] Should not such material be treated like oil or coal for which source countries receive compensation?[35] As the president of Tanzania said, "[M]ost of us in developing countries find it difficult to accept the notion that biodiversity should [flow freely to industrial countries] while the flow of biological products from the industrial countries is patented, expensive and considered the private property of the firms that produce them. This asymmetry . . . is unjust."[36]

Consequently, developing countries began taking steps to enclose raw genetic material. At the end of 1991, they successfully pressed for the adoption of Annex III to the Undertaking. The annex stated that the Undertaking's heritage of mankind concept was "subject to sovereignty of the states over their plant genetic resources" and that "nations have sovereign rights over their plant genetic resources."[37] This assertion of sovereign rights over raw genetic material represented the death knell of the core concept of a global commons, namely, that sovereigns would not claim or appropriate something in that commons as exclusively their own.[38]

By 1992, the concept of a global commons or open system for genetic resources had been relegated to a coffin. At the 1992 Earth Summit in Rio de Janeiro, nations hammered the nails into this coffin. The Convention on Biological Diversity (CBD or Convention), adopted at that summit, begins its discussion of genetic resources by proclaiming not the common heritage of such resources but, rather, the sovereignty of nations over them.[39] Article 15(1) of the Convention states, "Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." The Convention broadly defines "genetic resources" as "any material of plant, animal, microbial or other origin containing functional units of heredity" of "actual or potential value."[40] Although earlier proposals had employed the "common heritage of mankind" language, most developing countries emphatically rejected such language.[41] Consequently, the

[33] LILY LA TORRE LÓPEZ, ALL WE WANT IS TO LIVE IN PEACE 208 (Int'l Union for the Conservation of Nature [IUCN], 1999) (90% of the world's biodiversity is found in the tropical and subtropical regions of developing countries); Macilwain, *supra* note 24; *see also* J. M. Spectar, *Patent Necessity: Intellectual Property Dilemmas in the Biotech Domain & Treatment Equity for Developing Countries,* 24 HOUS. J. INT'L L. 227, 231 (2002) (stating that major centers of genetic diversity or centers of origin of the world's economically important crops are located in the tropics or subtropics); Christopher Hunter, Comment, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles to Conserve Raw Medicinal Materials,* 25 B.C. ENVTL. AFF. L. REV. 129, 131, 136 (1998) (approximately 50% of all species reside in the tropical forests, including nearly half of the 250,000 species of the world's higher plants).

[34] BIODIVERSITY PROSPECTING 23 (Walter V. Reid et al. eds., 1993). *See generally* Keith Aoki, *Neocolonialism, Anticommons Property, and Biopiracy in the (Not-So-Brave) New World Order of International Intellectual Property Protection,* 6 IND. J. GLOBAL LEGAL STUD. 11, 47 (1998) (summarizing the objections of Vandana Shiva, Ruth Gana [Okediji], Rosemary Coombe, James Boyle, Jack Kloppenberg, and others who have written about the "Great Seed Ripoff" made possible by international conventions that allowed plant breeders to use traditional indigenous varieties of seeds and "improve them" via minor genetic alterations without compensating the countries where those seeds originated); James O. Odek, *Bio-piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 141 (1994) (explaining that developing countries now "passionately" protest the prospecting for plant species in their tropical forests by scientists from multinational corporations who are "protecting their discoveries" through intellectual property rights. "To developing countries, these practices constitute uncompensated exploitation of their 'plant genetic resources' in the name of intellectual property rights.").

[35] BIODIVERSITY PROSPECTING, *supra* note 34, at 23.

[36] Statement of President Ali Hassan Mwinyi of Tanzania, UN Doc. A/CONF. 151/26/Rev.1, at 36 (1993), *quoted in* Craig D. Jacoby & Charles Weiss, *Recognizing Property Rights in Traditional Biocultural Contribution*, 16 STAN. ENVTL. L.J. 74, 89 (1997).

[37] FAO Res. 3/91, *available at* <http://www.fao.org/ag/cgrfa/iu.htm>.

[38] *See* Raustiala & Victor, *supra* note 13, at 288, 290 (core notion of the 1983 Undertaking was that no nation owned plant genetic material).

[39] Convention on Biological Diversity, June 5, 1992, Art. 15(1), 31 ILM 818, 823 (1992) [hereinafter CBD]. As of October 2004, 188 states had ratified or acceded to the Convention. The United States has signed but not joined the Convention. Parties to the Convention on Biological Diversity, *at* <http://www.biodiv.org> (last modified Oct. 12, 2004).

[40] CBD, *supra* note 39, Art. 2.

[41] Clare Shine & Palitha T. B. Kohona, *The Convention on Biological Diversity: Bridging the Gap Between Conservation and Development*, 1 RECIEL 278, 282 (1992).

preamble to the Convention pointedly refers to genetic resources as the "common concern" rather than the "common heritage" of humankind.[42]

The Convention on Biological Diversity, after acknowledging sovereign rights[43] over genetic resources, requires parties to "endeavour to create conditions to facilitate access" to such resources.[44] The trend of genetically rich countries, however, has been the opposite: to restrict and encumber access to raw genetic material within their borders, largely in response to the increased patenting of genetic material and bioengineered goods since the conclusion of the CBD.[45] These countries particularly object to developed countries' granting of patents to genes isolated from material that was taken from or originated in developing countries.[46] They view such patenting as colonial-style taking or theft.[47] As activist Vandana Shiva states: "The freedom that transnational corporations are claiming through intellectual property rights protection . . . is the freedom that European colonizers have claimed since 1492."[48] Colonization, the taking of minerals, timber, and other resources from the developing world, has "now been extended to the interior spaces, the 'genetic codes' of life-forms from microbes and plants to animals, including humans."[49] Thus, as corporations from developed countries, particularly the United States, increasingly obtain patents over genetic material and biotechnological innovations,[50] developing countries increasingly enclose their raw genetic material.

In addition, the environmental community has encouraged developing countries to pass legislation restricting access to genetic material. Environmentalists hope that making money from genes will give developing countries' governments an incentive to preserve threatened natural

[42] CBD, *supra* note 39, pmbl.

[43] The existence of sovereign rights over a nation's territory, including its natural resources, is a fairly well established principle in international law. Carlos M. Correa, Sovereign and Property Rights over Plant Genetic Resources 2 (Background Study Paper, Comm'n on Plant Genetic Resources) (1994) (citing Resolution 1803 of the UN General Assembly, UN GAOR, 17th Sess., Supp. No. 17, at 15, UN Doc. A/5217 (1962), which provides in paragraph 3 that due care should be taken "to ensure that there is no impairment, for any reason, of the State's sovereignty over its natural wealth and resources"). Each nation has the authority to regulate extraction of its natural resources. Christopher D. Stone, *What to Do About Biodiversity: Property Rights, Public Goods, and the Earth's Biological Riches*, 68 S. CAL. L. REV. 577, 602 n.63 (1995) (citing GA Res. 3281, UN GAOR, 29th Sess., Supp. No. 31, at 50, UN Doc. A/9631 (1974); GA Res. 3171, UN GAOR, 28th Sess., Supp. No. 30, at 52, UN Doc. A/9030 (1973); GA Res. 1803, *supra*).

[44] CBD, *supra* note 39, Art. 15(2).

[45] *See generally* Aoki, *supra* note 34, at 49.

[46] *See generally* Correa, *supra* note 12 (many developing countries, like Brazil, have explicitly excluded existing biological materials from patentability unless they are genetically altered). The furor over a patent application on a cell line cultivated from a Guayami woman's blood illustrates this objection. In the early 1990s, U.S. researchers took blood samples from members of the Guayami tribe to check for a propensity for hairy-cell leukemia. In 1991 researchers applied for a patent on a cultivated cell line, identifying Dr. Jonathan Kaplan as the "inventor" of the cell line. When news of the application reached the press, indigenous communities were outraged. Aoki, *supra* note 34, at 53.

[47] Assurances by some that the patenting of genes isolated from an individual or a plant or animal does not preclude those donors from using their own genes provide little comfort. *See, e.g.*, Eisenberg, *supra* note 9. If anything, these assurances appear to highlight the breadth of the taking as the patent holder apparently enjoys the right to exclude uses of the patented gene, with the exception of its biological action in the host's body.

[48] VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 2 (1997). Although made in the context of objecting to the TRIPS Agreement, these statements reflect the general views of activists and many developing countries on the relationship between intellectual property rights and raw materials taken from those countries.

[49] *Id.* at 3.

[50] For a general discussion, see Andrew Pollack, *Patenting Life: A Special Report: Biological Products Raise Genetic Ownership Issues*, N.Y. TIMES, Nov. 26, 1999, at A1. *See also* Peter Drahos, *Biotech Patents, Markets and Morality*, 21 EUR. INTELL. PROP. REV. 441, 442–43 (1999). The expansion of patent protection to an increasing array of genetic material and biotechnological innovations has resulted not only from the acceleration of such activity in the United States, but also from the internationalization of some of these protections through the TRIPS Agreement. Under Article 27 of the TRIPS Agreement, *supra* note 13, member states of the World Trade Organization must extend patent protection to biotechnological innovations. While countries need not extend patent protection to plants, they must provide for a *sui generis* system that offers some intellectual property protection for plants. Raustiala & Victor, *supra* note 13, at 292, note that throughout the TRIPS review process, "developing countries, sometimes joined by the EU, sought to limit the scope of protection for improved plant genetic resources but the United States generally sought the widest possible ambit for intellectual property protection."

habitats and biological diversity.[51] In this way, gene-laden threatened species can essentially pay their own way to continued survival.

Today, the appropriateness of national government ownership or extensive national control over raw genetic material to achieve compensation or "benefit sharing" represents the prevailing perspective in international law.[52] Article 15(7) of the CBD specifies that access to genetic resources shall be gained only with the "prior informed consent of the Contracting Party providing such resources," unless that country provides otherwise. As a result, international work on implementation of the CBD includes model legislation prescribing sovereign ownership or extensive control over genetic resources.[53] As stated earlier, since the adoption of the CBD, over forty nations have passed or are in the process of passing laws that greatly restrict access to raw genetic material within their borders.[54]

What are these sovereign-based access-restricting regimes? How do they work? They tend to be lengthy, complex, and varied. In the main, they declare or regard genetic resources as national patrimony. As such, these resources essentially belong to the national government or at least are subject to extensive national government control. Before considering the problems raised by such regimes, analysis of two influential access-restricting regimes—that of the Andean community (an early regime) and that of India (a recent one)—may convey the flavor of how such regimes operate.

Andean common system on access to genetic resources. One of the most important and influential regimes restricting access to raw genetic material is the regional Common System on Access to Genetic Resources (Common System) promulgated by the Andean Pact nations of Bolivia, Colombia, Ecuador, Peru, and Venezuela.[55] Together these five countries may "harbor the largest proportion of the world's biological diversity."[56] In addition, they play a significant role at international negotiations addressing access to genetic resources issues.[57] Consistently with their own practice, at international meetings these nations advocate comprehensive legislative regimes to restrict access to genetic material, demand international funding for the development of such regimes, and seek to incorporate aspects of the Common System into international agreements or resolutions addressing access to genetic resources issues.[58] Moreover, as one of the earliest

[51] *See generally* Raustiala & Victor, *supra* note 13, at 289; Christopher D. Stone, *New Issues for a New Century: Land Use, Biodiversity, and Ecosystem Integrity*, 27 ECOLOGY L.Q. 967, 991–92 (2001) (describing approach aimed at achieving conservation by solidifying the property interests of the nation in which the resource originated).

[52] *See* Raustiala & Victor, *supra* note 13, at 293; *see also* Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 927 (1996) (to achieve fair and equitable benefit sharing for the use of biological resources and the conservation of biological diversity, the CBD "vests sovereign rights" to genetic resources in the state). The CBD represents the principal international forum for the definition of rules pertaining to access to and benefit sharing of genetic resources. The Food and Agriculture Organization (FAO), by Resolution 7/93, renegotiated the International Undertaking on Plant Genetic Resources to "harmonize" it with the CBD. See the home page of the Undertaking, <http://www.fao.org/ag/cgrfa/iu.htm>.

[53] Raustiala & Victor, *supra* note 13, at 290. The International Union for the Conservation of Nature, for example, prepared a guide outlining basic elements for a draft access and benefit-sharing system for use by governments in drafting access and benefit-sharing legislation. LYLE GLOWKA, A GUIDE TO DESIGNING LEGAL FRAMEWORKS TO DETERMINE ACCESS TO GENETIC RESOURCES (IUCN Envt'l Pol'y & Law Paper No. 34, 1998). This guide was used by the Andean Pact nations of Bolivia, Colombia, Ecuador, Peru, and Venezuela in developing their common access regime. Achim Seiler & Graham Dutfield, Regulating Access and Benefit Sharing: Basic Issues, Legal Instruments, Policy Proposals, Doc. UNEP/CBD/WG–ABS/1/INF/4, at 69 (2001), *available at* <http://www.biodiv.org/doc/meetings/abs/abswg-01/information/abswg-01-inf-04-en.pdf>.

[54] *See supra* notes 4, 5 and corresponding text.

[55] Andean Pact, Common System on Access to Genetic Resources, Decision 391 (July 2, 1996), *available at* <http://www.comunidadandina.org/ingles/treaties/dec/d391e.htm> [hereinafter Common System].

[56] Columbia Access Paper, *supra* note 32, at 34. Colombia, in particular, is said to account for 10% of the world's terrestrial species of plants and animals.

[57] For example, Peru served as cochair of one of the CBD sub–working groups of the Access and Benefit Sharing Working Group. Venezuela served as chair of the negotiating group for the International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, *available at* <http://www.fao.org/ag/cgrfa/itpgr.htm> [hereinafter PGR Treaty].

[58] For example, Colombia insisted for many years that the PGR Treaty govern access not only to genetic resources, but also, as does the Common System, *supra* note 55, Arts. 1, 2, access to derivatives of such resources

attempts to restrict access to genetic material, the Common System has influenced other access regimes.[59]

Under the Common System, ownership of raw genetic material and derivatives of such genetic resources, such as molecules, effectively vests with the nation-state, i.e., the national government (hereinafter the State), rather than with the individual or indigenous community whose land or property houses the relevant genetic resource.[60] Under the Common System, the State either expressly owns or exercises virtually complete control over such resources.[61] The State also ostensibly owns the genetic material of migratory species, such as migrating birds, in their territories.[62] State ownership applies to genetic material for which the states are countries of origin.[63] Under the Common System, this classification broadly includes material found *in situ* (i.e., in natural habitats) in that country, as well as material taken from *in situ* sources in that country and maintained *ex situ*, such as in museums, zoos, and collections of plant germ plasm.[64]

Although the State effectively owns all nonhuman genetic material in its territory, the Common System provides that such ownership is without prejudice to the ownership of the biological resource or land containing the genetic material.[65] Thus, while a person in Colombia might own a plant or cow, the national government owns the genetic makeup of that plant or cow.[66] To access genetic material (a practice referred to as "bioprospecting") within an Andean Pact country, a researcher or institution must obtain the consent of the national government and enter into an agreement prescribing benefits to be received by that country for the accessed material.[67] Only the State can authorize such access.[68] Only the State is a party to the benefit-sharing agreement with the bioprospector.[69] The Common System applies not only to foreigners seeking

(i.e., the molecular products of gene expression). The CBD's access and benefit-sharing provisions do not extend to units as small as a molecule, which does not contain "functional units of heredity." Including such derivatives would substantially increase restrictions on access to genetic material. *See* Seiler & Dutfield, *supra* note 53, at 70.

[59] The Andean Pact adopted the Common System in 1996, a mere three years after the entry into force of the CBD. For the influence of the Common System, see for example, UGANDA WILDLIFE SOCIETY AND ENVIRONMENTAL LAW INSTITUTE, LEGAL AND INSTITUTIONAL OPTIONS FOR GOVERNING ACCESS TO GENETIC RESOURCES IN UGANDA 10–11, 29 (Environmental Law Institute, 1999) (citing the Andean Pact regime as a potential model in certain respects for Uganda's regulations on access and benefit sharing). The Andean model has also been included in virtually all case studies on access and benefit-sharing legislation.

[60] Columbia Access Paper, *supra* note 32, at 39 (the Common System "grants ownership of genetic resources and derivatives to the member nation or state"). Common System, *supra* note 55, Art. 6 ("The genetic resources and their byproducts which originated in the Member Countries are goods belonging to or the heritage of the Nation . . . as stipulated in their respective national legislation."). The Colombian legislature declared that "genetic resources . . . belong to the nation, as they are part of the natural resources or riches." Columbia Access Paper, *supra*, at 40.

[61] Columbia Access Paper, *supra* note 32, at 40; *see infra* note 65.

[62] *See* Common System, *supra* note 55, Arts. 3, 6.

[63] *Id.*

[64] Common System, *supra* note 55, Arts. 1, 3, 6. Article 2 of the CBD, *supra* note 39, defines "*in-situ* conditions" as "conditions where genetic resources exist within ecosystems and natural habitats, and in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties." Article 1 of the Common System largely mimics this definition.

[65] Common System, *supra* note 55, Art. 6; Seiler & Dutfield, *supra* note 53, at 74. The Common System distinguishes between biological resources, which contain genetic resources, and genetic resources. Consistently with this approach, Article 14 of the Common System provides that the system shall not impede the use and free movement of biological resources, such as fish, plants, or fauna, within the Andean area, "provided that there is no access to the genetic resources contained in the biological resources." Similarly, the fourth complementary provision, adopted by the Andean Pact, requires that certain exports of biological resources bear the inscription "Use of this product as a genetic resource is not authorized." KERRY TEN KATE & SARAH A. LAIRD, THE COMMERCIAL USE OF BIODIVERSITY 33 n.1 (1999). Moreover, the State does not claim ownership to the knowledge of indigenous communities associated with genetic resources, such as knowledge relating to the healing property of plants. Common System, *supra*, Art. 7.

[66] Common System, *supra* note 55, Art. 7; Columbia Access Paper, *supra* note 32, at 39–40.

[67] Common System, *supra* note 55, Art. 17; Seiler & Dutfield, *supra* note 53, at 70–71, 73.

[68] Columbia Access Paper, *supra* note 32, at 39; Seiler & Dutfield, *supra* note 53, at 71.

[69] Seiler & Dutfield, *supra* note 53, at 70–71. To obtain this consent, the researcher must provide the national government with all information concerning the genetic resource at issue, including its actual and potential uses, its derivatives, and the risks that could arise from accessing it. *Id.* at 70. The applicant need not provide this information to any other stakeholder. *Id.* The Common System does provide for "accessory" contracts between researchers

access to genetic resources in an Andean Pact country, but also to Andean Pact nationals and local institutions.[70]

India. In December of 2002, India passed comprehensive legislation restricting access to genetic material in its territory.[71] India's law broadly prohibits any foreign person[72] or foreign corporation[73] from "obtain[ing] any biological resource[74] occurring in India or knowledge associated thereto" for research, survey, or commercial utilization[75] without the prior approval of India's National Biodiversity Authority.[76] Regulation of bioprospecting by Indian resident citizens and Indian corporations is left to subnational (state) biodiversity boards and appears less restrictive.[77] The statute further prohibits any foreign person or corporation from "transfer[ring] the results of any research relating to biological resources occurring in, or obtained from, India" without the prior approval of the National Biodiversity Authority.[78] Moreover, even if the National Biodiversity Authority approves the obtainment or transfer of any such resource or information, the applicant may not subsequently transfer that resource or information without the authority's consent.[79]

The law, in turn, requires the National Biodiversity Authority to secure equitable benefit sharing for the use of "accessed biological resources, their by-products, . . . and knowledge relating thereto."[80] Where a biological resource or associated knowledge has been acquired from a specific individual, group, or organization, the authority may, but need not, direct payment of moneys collected to such individuals, groups, or organizations.[81] The law does not require bioprospectors to obtain the consent of affected individuals or groups before obtaining biological resources. However, the National Biodiversity Authority must consult with specially created local committees when making decisions "relating to the use of biological resources" and associated knowledge.[82] Finally, the law prohibits any person, whether foreign or Indian, from applying for any intellectual property right in or outside India "for any invention based on any research or information

and the owners or administrators of the property on which the bioprospecting is to take place. *Id.* at 71. These contracts, however, are subject to the agreement between the State and the researcher. *Id.*

[70] Columbia Access Paper, *supra* note 32, at 43.

[71] Biological Diversity Act, 2002, No. 18, Feb. 5, 2003, *available at* <http://envfor.nic.in/divisions/biodiv/act/bio_div_act.htm>.

[72] This refers to any person who is not a resident citizen of India. *Id.* §3(2).

[73] Foreign corporation refers to any "body corporate, association or organization . . . not incorporated or registered in India" or "which has any non-Indian participation in its share capital or management." *Id.*

[74] "Biological resource" broadly encompasses "plants, animals and micro-organisms or parts thereof, their genetic material and by-products . . . with actual or potential use or value." *Id.* §2(c). Biological resources do not include "products which may contain portions or extracts of plants and animals in unrecognizable and physically inseparable form." *Id.* §2(c), (p).

[75] *Id.* §3(1). "Commercial utilization" refers to end uses of biological resources for commercial purposes, such as for drugs, food flavors, cosmetics, colors, and "genes used for improving crops and livestock through genetic intervention." *Id.* §2(f).

[76] *Id.* §3. The National Biodiversity Authority is a national interagency body. *Id.* §8.

[77] The Biological Diversity Act, *supra* note 71, §22, authorizes states within India to create state biodiversity boards. These boards may regulate, prohibit, and restrict the "commercial utilization," "bio-survey," and "bio-utilization" of any biological resource by Indians, but not by foreigners. The Biological Diversity Act, §§7, 24, requires Indian resident citizens and Indian corporations to give "prior intimation" (undefined but seems to mean prior notification) to the state biodiversity board before engaging in such activities. They need not, however, obtain the approval of the National Biodiversity Authority before engaging in such activities.

[78] *Id.* §§4, 19(1).

[79] *Id.* §20(1).

[80] *Id.* §21. The law refrains from requiring the payment of royalties or fees in all cases. It does, however, consistently mention such royalties and fees in connection with bioprospecting approval, ostensibly assuming that the National Biodiversity Authority will usually require such payments. *Id.* §§6(2), 19(1), 19(3), 20(3).

[81] *Id.* §21(3).

[82] *Id.* §41(2). India's law requires that every local municipality create a biodiversity management committee. *Id.* §§41(1), 2(h). These local committees may levy collection fees from any person accessing or collecting biological resources from areas within their territorial jurisdiction. *Id.* §41(3). The National Biodiversity Authority must notify the public of any of its approvals. *Id.* §§19(4), 20(4).

on a biological resource obtained from India" without the prior approval of the National Biodiversity Authority.[83]

II. Risks Posed by Sovereign Ownership or Control of Genetic Material

Most access-restricting regimes are breathtaking and unprecedented in scope. They purport to cover the export of all nonhuman living things and the parts of all nonhuman living things down to the genetic and, in some cases, molecular level. Some, like the regimes of the Andean Pact nations, Brazil, and to a lesser extent India, even control the domestic use of raw genetic material. Nations, lured by the prospect of becoming a genetic Saudi Arabia, promulgate these regimes in an attempt to capture monetary and other benefits.

These increasingly popular national access-restricting regimes pose two risks. First, they risk creating an anticommons in raw genetic material. Second, they risk infringing on the autonomy and interests of individuals and indigenous communities whose land or property contains the genetic material to which the sovereign stakes claim. A seemingly irreconcilable tension exists between an access-restricting regime that protects the interests of all potential stakeholders (individuals, local communities, the State, and even interested civil society) and a regime that avoids an anticommons by limiting the number of involved stakeholders and thereby facilitates access to genetic material and benefit sharing. I predict that national government and international work on access and benefit sharing will face the difficult task of choosing between protecting the interests of all stakeholders and providing economic remuneration to the nation-state. Furthermore, this tension will probably become more severe as nations and international organizations eventually grapple with the issue of access to the human genome.

The Anticommons Trap

What is an anticommons? Michael Heller, introducing the concept, explains an anticommons property "as the mirror image of commons property."[84] A tragedy of the commons exists when too many individuals have the right to use a scarce resource, such as fisheries, and overuse that resource potentially to its complete depletion.[85] An anticommons can occur when too many individuals or entities have rights of exclusion to a given resource.[86] A tragedy of the anticommons arises when these individuals or entities employ their rights to veto the use of a given resource and in so doing waste the resource by its underconsumption compared with a social optimum.[87] Both tragedies represent "group action" problems in economic terms.

Heller points to unused storefronts in Moscow as an example of an anticommons tragedy. In the 1990s, as the former Soviet Union made the transition to a free-market economy, previously state-owned stores remained empty, "while flimsy metal kiosks, stocked full of goods, mushroomed up on Moscow streets."[88] Why? Heller explains that transition regimes "failed to endow any individual with a bundle of rights" representing "full ownership of storefronts or other scarce resources."[89] They gave a broad assortment of stakeholders, including private or quasi-private enterprises, workers' collectives, and local, regional, and federal governments, rights to prevent the use of a storefront.[90] As a result, entrepreneurs preferred to sell their wares on the

[83] *Id.* §6(1).

[84] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 621, 622 (1998).

[85] Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244–45 (1968). In addition to depleted fisheries, traditional examples of this tragedy include air pollution, overgrazed fields, the extinction of species, and marine pollution.

[86] Heller, *supra* note 84, at 622, 677.

[87] *Id.* at 677.

[88] *Id.* at 622–23.

[89] *Id.* at 623.

[90] *Id.*

street rather than undertake the burdensome and uncertain task of obtaining the consent of all stakeholders. As Heller notes, the Russian government did not intentionally create an anticommons. However, by giving too many individuals and entities property rights and decision-making authority over the use of a given resource, it unwittingly created an anticommons tragedy.[91]

Scholars identify another anticommons tragedy in the proliferation of patent rights in the United States on basic discoveries in the biotechnology field.[92] Patent claims are currently staked to upstream research results, such as the isolation and identification of genetic sequences, that traditionally would have been made freely available as part of the public domain.[93] Consequently, a broad range of upstream patent holders over early biomedical and genetic research results can prevent others from developing downstream medical treatments and therapeutics that build upon these results.[94] In this anticommons environment of fragmented property rights, proceeding with a particular gene therapy or downstream bioengineered good entails high search and negotiation costs to locate and bargain with the many rights owners whose permissions are necessary to complete broader development.[95] In addition, a single holdout can completely stymie a project.[96] The tragedy is that upstream research results are underutilized and downstream medical treatments, therapeutics, and other potentially helpful goods remain undeveloped.

Not all agree that an anticommons exists or risks emerging in the biotechnology field.[97] Nevertheless, it may be emerging in a related and to-date largely uncontroversial area of government restriction of access to genetic material. Multiple ownership interests or rights of exclusion in raw genetic material risk creating an anticommons. For example, let us imagine that Grandma owns a petunia plant, but the government owns the plant's genetic makeup. In addition, Grandma's local community holds a stake in the plant's genetic makeup because many members of the community have similar petunia plants on their windowsills. If each of these stakeholders has the right to prevent the extraction of the petunia's genes, it will be extremely difficult and costly to access and utilize that material.

There are signs that access-restricting legislation that legitimately tries to protect the interests of all parties is creating an anticommons problem. One example is the Philippines access-restricting regime, with its multiple consent requirements. This regime broadly encompasses all "research, collection and utilisation of biological genetic resources" within the Philippines "for purposes of applying the knowledge derived therefrom for scientific or commercial purposes."[98] Navigating the regime is arduous. It requires the bioprospector to go through multiple layers of national government review and consent.[99] In addition, the bioprospecting applicant

[91] *Id.* at 625.

[92] Heller & Eisenberg, *supra* note 7 (pointing to anticommons problems in basic medical research); Rai, *supra* note 7, at 192–94 (upstream patents in biotechnology can deter innovation).

[93] Heller & Eisenberg, *supra* note 7, at 698; Rai, *supra* note 7, at 192–94.

[94] Ostensibly to spur and support the biotechnology industry, the U.S. Patent and Trademark Office has adopted a fairly generous approach to granting patents in the biotechnology area. It has granted patents for gene discoveries that border new useful technologies, traditionally eligible for the patent grant, and basic research results, traditionally precluded from the patent grant. *Id.*

[95] *See generally* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1611 (2003) (summarizing effects of an anticommons).

[96] *Id.*

[97] John Doll, 280 SCIENCE 700 (1998); John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Work Through the Patent Problem*, 299 SCIENCE 1021 (2003) (concluding that strong patent protection in the area of research tools has rarely thwarted innovation); *see also* Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 297 n.47 (2003) (discussing patent thicket but that companies' response has been to put things into the public domain); Epstein, *supra* note 7, at 20. *But see* Burk & Lemley, *supra* note 95 (concluding that the biotech industry is particularly susceptible to anticommons problems).

[98] TEN KATE & LAIRD, *supra* note 65, at 19; *see* Philippines Exec. Order No. 247 (May 18, 1995), *available at* <http://law.nus.edu.sg/apcel/dbase/filipino/primary.html>.

[99] The bioprospecting applicant must first submit a letter of intent along with a research proposal and a filing fee to the national Inter-Agency Committee on Biological and Genetic Resources (IACBGR). The IACBGR is a national regulatory body established under section 6 of the executive order to enforce and implement its provisions. If the research proposal passes an initial screening by the committee's Technical Secretariat, the applicant

must obtain written prior informed consent from indigenous communities for bioprospecting within their ancestral lands[100] or from other appropriate local authorities.[101] The applicant must also obtain written prior informed consent from any affected private landowner.[102] In addition, it must notify the public of the proposed project through, for example, media advertisements.[103] It must also engage in and document "sector consultation," which involves a "community assembly" to discuss the project.[104] The applicant must agree to pay royalties or other forms of compensation to the national government and to the indigenous or local community or individual concerned,[105] as well as enter into a host of other benefit-sharing arrangements.[106] Not surprisingly, as of October 2001, only two out of thirty-seven proposed projects had garnered all the necessary approvals.[107]

Model legislation approved by the fifty-three-member Organization of African Unity (OAU) similarly risks creating an anticommons. The model legislation is to serve as a basis for national legislation and an Africa-wide convention for restricting access to genetic material.[108] The legislation requires a bioprospector to obtain the prior informed consent from both the national government[109] and concerned local communities.[110] In addition, collectors may not transfer obtained biological resources or their derivatives to any third party without prior authorization from the national competent authority and the concerned local community or communities.[111]

The potential for an anticommons can further be seen in the yet-to-be-adopted Framework Agreement on Access to Biological and Genetic Resources[112] of the Association of South East

submits, inter alia, a formal application, an institutional profile, an environmental impact assessment, and a processing fee. After the IACBGR considers the project and the benefit-sharing agreement, it submits its recommendation to yet another government agency for approval or disapproval. Upon approval of the application, the applicant pays a bioprospecting fee as determined by the IACBGR. TEN KATE & LAIRD, *supra* note 65, at 30.

[100] *Id.* at 28 (citing Exec. Order No. 247, *supra* note 98, §2); Columbia Access Paper, *supra* note 32, at 57. Section 2.1(w) of the Philippine Implementing Rules and Regulations defines prior informed consent as

> the consent obtained by the applicant from the Local Community, IP [Indigenous Cultural Communities or Indigenous Peoples], PAMB [Protected Area Management Board] or Private Land Owner concerned, after disclosing fully the intent and scope of the bioprospecting activity, in a language and process understandable to the community, and before any bioprospecting activity is undertaken.

Philippines Dep't of Env't & Nat. Res., Admin. Order No. 20 (July 9, 1996), *available at* <http://law.nus.edu.sg/apcel/dbase/filipino/regs/phrbio.html> [hereinafter Phil. Regulations].

[101] Phil. Regulations, *supra* note 100, §§6.1.3, 7.1. Appropriate local authority refers to "Indigenous Cultural Communities or Indigenous Peoples," municipal or city mayor of the local government unit, or Protected Area Management Board. *Id.* §2.1(w).

[102] *Id.* §§2.1(w), 6.1.3, 7.1.

[103] *Id.* §7.2.1.

[104] *Id.* §7.2.2. The applicant then submits the signed prior informed consent certificate(s) and proof of public notification and sector consultation to the Technical Secretariat. *Id.* §7.3. The Technical Secretariat evaluates the application and documents and submits its evaluation to the full IACBGR. *Id.*

[105] Exec. Order No. 247, *supra* note 98, §5(e); WILLIAM LESSER, SUSTAINABLE USE OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY: EXPLORING ACCESS AND BENEFIT SHARING ISSUES 57 (1998).

[106] Foreign applicants must agree to conduct research in collaboration with Philippine scientists from Philippine institutions, Phil. Regulations, *supra* note 100, §8.1.12. Applicants must also make technologies developed from research on Philippine endemic species available royalty-free for commercial and local uses to the national government, *id.* §8.1.9, and make available commercial products derived from Philippine resources to the national government and local communities concerned, *id.* §8.1.13.

[107] Columbia Access Paper, *supra* note 32, at 55.

[108] OAU, African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Materials (2000), *available at* <http://www.grain.org> [hereinafter OAU Model Legislation]; Seiler & Dutfield, *supra* note 54, at 88. This regional model will become or influence the law of some, if not many, of the OAU member states.

[109] OAU Model Legislation, *supra* note 108, Art. 5(1).

[110] *Id.*

[111] *Id.*, Art. 8 (1)(iv). Other requirements include, inter alia, depositing duplicates of biological specimens along with complete field information with designated governmental agencies, and immediately informing the national competent authority and the concerned local community or communities of all findings from the research and development pertaining to the resource. *Id.*, Art. 8 (1)(ii), (iii).

[112] ASEAN, Framework Agreement on Access to Biological and Genetic Resources (draft text Feb. 24, 2000), *available at* <http://www.grain.org> [hereinafter ASEAN Agreement]. The Framework Agreement aims at "ensur[ing]

Asian Nations (ASEAN).[113] The agreement provides that access to genetic resources in an ASEAN nation requires the prior informed consent of that nation,[114] implicitly at both the national government and local levels.[115] It further states that "all resource providers, particularly indigenous peoples and local communities . . . , shall be actively included in the negotiation of benefits . . . arising from the use of the resource."[116]

In August of 2001, Brazil adopted a provisional measure (Measure) to restrict access to genetic material within its territory. The Measure also appears at risk, albeit to a lesser extent than other access regimes, of creating an anticommons.[117] The Measure requires national government authorization for "access to components of the genetic heritage"[118] of any nonhuman organism within Brazil.[119] Such authorization, however, may be granted only with the prior consent of the indigenous community involved, where access occurs on indigenous territory.[120] Where access occurs on private land, authorization requires the private landowner's prior consent.[121] In addition, the consent of the owners of the tangible property involved, such as the plant containing the sought genetic resources, must be secured.[122] Where there is a prospect of commercial use, access to the components of the genetic heritage requires a benefit-sharing contract.[123] The national government may, but need not, be a party to the contract. However, all contracts must be submitted to the national government for registration and approval.[124] Where the national government is not a party to the contract, "it shall be assured where applicable of a share in the benefits."[125]

The above analysis of existing and proposed access-restricting regimes illustrates their potential, as a matter of legislative design, to create an anticommons in raw genetic material. The collapse in 2001 of a bioprospecting project in Chiapas, Mexico, provides a case study of the emerging anticommons problem in the bioprospecting area. In September 1998, the International Cooperative Biodiversity Group (ICBG), a U.S. government initiative that includes the National Institutes of Health (NIH), granted $2.5 million dollars for a project aimed at drug

that access regulations within the ASEAN region are uniform and consistent in accordance with identified minimum requirements as set out in this Framework Agreement." *Id.*, Art. 2.

[113] ASEAN is composed of Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam.

[114] ASEAN Agreement, *supra* note 112, Art. 10. The agreement directs member states to establish legally binding procedures to require such consent.

[115] *Id.*

[116] *Id.*, Art. 11. The agreement stipulates a minimum set of benefit-sharing requirements. These include "[t]he participation of nationals in research activities; [t]he sharing of research results, including all discoveries; . . . [f]ees, royalties and financial benefits." Required benefit sharing also includes the deposit of a complete set of all voucher specimens in national institutions, "access by nationals to all national specimens deposited in international *ex-situ* collections," and the "donation to national institutions of equipment used as part of research." *Id.*

[117] Brazil, Provisional Measure No. 2.186-16 (Aug. 23, 2001), *available at* <http://www.grain.org/brl/brazil-tk-2001-en.cfm> [hereinafter Brazil Measure].

[118] *Id.*, Arts. 2, 16. The Measure broadly defines genetic heritage as "information of genetic origin contained in samples . . . of plant, fungal, microbial or animal specimens," whether living or dead, encountered *in situ* in Brazil or maintained in *ex situ* collections after *in situ* collection within Brazil. *Id.*, Art. 7(I). "Within Brazil" includes collections done within Brazil's national territory, on its continental shelf, or in its oceanic exclusive economic zone. *Id.* A nation's exclusive economic zone extends 200 miles off its coast.

[119] *Id.*, Art. 3. The Measure requires national government authorization where access is sought for scientific research, technological development, or exploratory activity to identify components of the genetic heritage with potential commercial uses. *Id.*, Art. 7(IV), (VII). The Measure creates a national Council for the Management of Genetic Resources to authorize access to genetic material within Brazil and associated traditional knowledge. *Id.*, Arts. 10, 11(IV), 15(III). The national council is within the Ministry of Environment.

[120] *Id.*, Arts. 16, §9, 11(IV)(b).

[121] *Id.*, Art. 16, §9. Where access occurs in a protected area, such as a park, authorization requires the prior consent of the relevant competent body. *Id.*

[122] *Id.*, Art. 11(IV)(a).

[123] *Id.*, Art. 16, §4. Where the "potential for economic use . . . in either a product or process" based on accessed genetic heritage or derived from traditional knowledge is identified after the collection was authorized and for which a contract was never signed, "the benefiting institution" must contact the management council to execute such a contract. *Id.* §5.

[124] *Id.*, Art. 29.

[125] *Id.*, Art. 24. Benefits may include division of profits, royalties, technology transfer, unrestricted licensing of products or services, and training of persons. *Id.*, Art. 25.

discovery from plants and microfungi widely used by the highland Maya in Mexico.[126] The University of Georgia, the Colegio de la Frontera Sur of Mexico, and a Welsh pharmaceutical company led the project.[127] Mexican law requires a special government permit for "biotechnological" collections in Mexico and provides for the issuance of permits only if the requester has obtained prior informed consent from, and negotiated an access and benefit-sharing agreement with, the owner or legal possessor of the land where sample collecting takes place.[128] The implicated communities in this case involved approximately eight thousand villages and some nine hundred thousand Mayan-speaking people.[129]

The ICBG team first held a national forum on Mexican bioprospecting experiences.[130] It then invited Mayan community members to a general information assembly, distributed flyers in native languages, and ran radio spots to inform the communities of the project and to obtain their feedback.[131] The ICBG team also presented a play about the project in communities and answered questions.[132] The play, performed in native languages, showed the project's aims and methods, its short- and long-term benefit-sharing elements, and the low probability of the discovery of a commercially successful drug.[133] Community members who wished to participate in the project were to sign a general memorandum of understanding indicating their interest.[134] The benefit-sharing terms included provision for the creation of a new nonprofit organization to represent the highland Maya, a trust fund to distribute any financial benefits that emerged from the project, and a proviso that the new nonprofit organization would receive a joint ownership interest in any patents that emerged from the project.[135] In a year and a half, forty-six of the forty-seven visited communities in fifteen municipalities agreed to participate in the project.[136]

The project, however, met vigorous opposition from a confederation of local healers' organizations, Consejo de Médicos y Parteras Indígenas Tradicionales de Chiapas (COMPITCH), which claimed that they had not been given the opportunity to voice their opinions about the project.[137] One of their main concerns was "that pharmaceutical companies would collect something that has always been readily available and free, synthesize it, slap a patent on it, and sell it as a new 'drug' accessible only to the rich."[138] Another concern was the opportunity cost—namely, that other researchers who might offer greater benefits would not seek to duplicate the ICBG effort.[139] The Rural Advancement Foundation International (RAFI), an international nongovernmental organization, further objected to the project because private companies, including GlaxoSmithKlein, would have benefited from the research. A RAFI researcher stated that "[w]e think it is completely wrong to use public money to fund research for private companies."[140] In the face of objections from these groups, the requisite bioprospecting permit did not issue, and the project collapsed in 2001.[141]

[126] Christopher Locke, *Forest Pharmers Go Bioprospecting*, RED HERRING, Apr. 1, 2001, at 84, 86, *available at* <http://www.redherring.com>; Joshua Rosenthal, Politics, Culture and Governance in the Development of Prior Informed Consent and Negotiated Agreements with Indigenous Communities 12 (Sept. 4, 2003) (final draft of paper prepared by deputy director, Fogarty International Center, Nat'l Insts. of Health).

[127] Locke, *supra* note 126, at 86.

[128] Rosenthal, *supra* note 126, at 12–13.

[129] *Id.* at 14.

[130] *Id.* at 15.

[131] *Id.*

[132] *Id.* The ICBG would perform the play in a given community only if invited by a municipal president or community representative.

[133] *Id.*

[134] *Id.*

[135] *Id.* at 18–19.

[136] *Id.* at 15.

[137] *Id.* at 16; Locke, *supra* note 126, at 86.

[138] Locke, *supra* note 126, at 86.

[139] Rosenthal, *supra* note 126, at 16. No other researchers, however, had expressed interest in such a project. *Id.* The opportunity cost was a phantom or, at best, uncertain. Moreover, it is hard to see how the Mayan ICBG experience would entice others to venture into its failed wake.

[140] Locke, *supra* note 126, at 86.

[141] *Id.;* Rosenthal, *supra* note 126, at 17–18.

The above incident does not reflect an anticommons tragedy in the strictest legal sense. The two most powerful voices objecting to the project, COMPITCH and RAFI, did not technically enjoy veto power over the project under Mexican law. As a de facto matter, however, at least in the case of COMPITCH, they did. Their objections ultimately carried greater weight than the consent of the Mayan communities participating in the project and the involvement of a local university.[142] This incident reflects the anticommons environment in which bioprospectors now operate in much of the developing world.[143] The objections of any one group, whether legally, culturally, or politically empowered, can prevent the other groups from going forward with a project potentially beneficial to themselves and to human health.

The ICBG spent thousands of dollars and nearly two years trying to obtain the prior informed consent of the groups in whose land it wished to bioprospect. As a U.S.-taxpayer-funded enterprise with a commitment to exploring and developing models of ethical research, the ICBG could develop expensive, multiyear efforts to garner multiple prior informed consents and negotiate agreements.[144] This, however, is a privileged situation. It is not the reality for the vast majority of projects sponsored by government, academic, or industrial organizations.[145]

While numerous access-restricting regimes are now in place and scores more in the offing, rather than engendering impressive economic gains, the CBD and the laws that it inspired are driving companies away from bioprospecting activities.[146] They are leading to the underutilization of genetic resources due to their complexity and the difficulty of achieving the consent of all interested parties. For every bioprospecting success story, there are dozens of cases where the projects never got off the ground.[147] A study conducted by Columbia University unearthed few successful examples of bioprospecting.[148] Many of those that did occur involved the ICBG initiative, a project funded by U.S. taxpayers, rather than private enterprise or individual scientists.[149]

While bioprospecting has not ground to a halt in the wake of the CBD, access and benefit-sharing arrangements are taking place at a relatively slow rate, well below the level anticipated at the time of the CBD's adoption and at international negotiations on access and benefit sharing since then.[150] Patent scholars note that where an anticommons arises in a particular area, researchers may simply avoid the area rather than navigate the anticommons.[151] A similar problem appears to be occurring in the area of bioprospecting. Rather than navigate the access regimes and attempt to garner the consent or approval of multiple rights-holders, researchers are simply refraining from bioprospecting in the first place.[152] For example, after spending one million dollars and two years attempting to navigate Colombia's access regime, BioAndes, a private

[142] Rosenthal, *supra* note 126, at 17–18.

[143] *See infra* note 146.

[144] Rosenthal, *supra* note 126, at 21–22.

[145] *Id.*

[146] David Labrador, *Refining Green Gold*, SCI. AM., Dec. 2003, at 38; Macilwain, *supra* note 24 (reporting how the anticipated post-CBD "gold rush" of scientists hurrying to developing countries to bioprospect has failed to materialize); *see* TEN KATE & LAIRD, *supra* note 65, at 300–01. As of 1999, not a single access agreement had been negotiated with any Andean Pact nation. Columbia Access Paper, *supra* note 32, at 35–43. Since then, a small handful have been concluded. Telephone interview with Joshua Rosenthal, deputy director, Fogarty Institute, NIH (July 7, 2003).

[147] Locke, *supra* note 126, at 84.

[148] Columbia Access Paper, *supra* note 32.

[149] *Id.* A three-hundred-page book by Kerry ten Kate and Sarah Laird, *supra* note 65, on the commercial use of biological diversity discusses surprisingly few nongovernment bioprospecting projects involving access to specimens of genetic material for potential application in a commercial good, since the adoption of the CBD. A large percentage, if not the majority, of the "benefit-sharing" cases discussed occurred earlier and involved U.S. government subsidies or traditional payment for the extraction of bulk raw materials that are used as inputs for end products rather than genetic sampling. An example of bulk raw material is the bulk cultivation of Kava for export.

[150] Bioprospecting projects are taking place, *see* BROWN, *supra* note 6, at 139–40; TEN KATE & LAIRD, *supra* note 65, but at relatively low levels, *see* notes 146 and 147 *supra*, and note 153 *infra* and corresponding text.

[151] *See* Rai, *supra* note 7, at 192–93.

[152] *See* note 146 *supra*; *see generally* TEN KATE & LAIRD, *supra* note 65, at 32 (noting that access regimes are elaborate and that many domestic and foreign scientists and companies report finding them cumbersome, time-consuming, and costly to follow).

joint venture between a U.S. pharmaceutical company and a Colombian concern, abandoned its efforts not only in Colombia, but also in the entire Andean Pact region.[153]

In the alternative, researchers and companies may brave the anticommons quagmire only in rare cases involving genetic material with a high probability of value. For example, bioprospecting continued in Cameroon after it promulgated a national access regime. In that case, scientists already knew that a valuable plant existed in the Cameroonian rain forest and they continued relationships built before the CBD.[154] However, the Cameroonian access regime that is now in place increases the difficulty of making similar discoveries in the future.

Fixing an anticommons once it emerges presents no easy task. Heller warns that undoing an anticommons can be "brutal and slow" and even thwarted entirely by transaction costs, holdouts, and those seeking rents disproportionate to their contribution.[155] The easiest solution to an anticommons problem is to vest ownership or ownership's core right, the right to exclude, in a single entity. The more recent access regime of India reflects this trend, centralizing control in a national entity.[156] While Brazil's access-restricting Measure requires the consent of multiple stakeholders, it also centralizes control over bioprospecting in the national government. The problem with this temptingly easy fix is the risks that such centralization poses to the interests of individuals and indigenous communities whose property contains the genetic material that the sovereign has claimed or granted access to in exchange for remuneration.

Risks to Individuals and Indigenous Communities

Robust sovereign rights over raw genetic material threaten the autonomy and interests of individuals and indigenous communities in two ways. First, in the case of access regimes where the national government owns genetic material (e.g., Colombia), the refusal by an individual or an indigenous community to consent to a particular bioprospecting project obstructs the government's ability to profit from and use its own property. In such a situation, the State may pressure the individual or indigenous community to grant consent. In the alternative, the State may simply access its genetic property by force. International law provides insufficient protection to individuals and indigenous communities in those circumstances. The International Labour Organization's Convention Concerning Indigenous and Tribal Peoples in Independent Countries provides that where the State retains ownership of resources related to indigenous lands, it must merely "consult" with indigenous peoples before permitting the exploration or exploitation of such resources.[157] It does not require the State to abide by the wishes of the indigenous communities concerned.

I have been unable to find any reported incidents in which governments physically forced individuals or indigenous communities to part with genetic material contained on their lands or in their property. However, the potential for such actions exists.[158] Brazil's access-restricting regime, for example, expressly allows the national government to authorize entry onto private land for the taking of samples of "genetic heritage," without the consent of the owners of the material or land, "[i]n the event of relevant public interest" as determined by the national government.[159] As a general matter, researchers report tensions between those who view their countries'

[153] Columbia Access Paper, *supra* note 32, at 35–43. In addition, a Colombian national abandoned a bioprospecting project altogether after realizing the ramifications of the application process. *Id.* at 43.

[154] Benefit-Sharing Case Studies: *Aristocladus korupensis* and *Prunus africana*, Doc. UNEP/CBD/COP/4/Inf.25, at 6, 7, 10–14 (1998), *available at* <http://www.biodiv.org/doc/case-studies/abs/cs-abs-aristo-pdf>.

[155] Heller, *supra* note 84, at 622, 677, 688.

[156] *See* notes 71–83 *supra* and corresponding text.

[157] Convention Concerning Indigenous and Tribal Peoples in Independent Countries, No. 169, June 27, 1989, Art. 15(2), 28 ILM 1382 (1989), *reprinted in* ILO, INTERNATIONAL LABOUR CONVENTIONS AND RECOMMENDATIONS 1919–1991, at 1436 (1992).

[158] Indeed, human rights scholarship is replete with examples of sovereign abuse of individuals and indigenous communities to further national government political and economic objectives. *See, e.g.*, Judy Mayotte, *Civil War in Sudan: The Paradox of Human Rights and National Sovereignty*, 47 J. INT'L AFF. 497 (1994).

[159] Brazil Measure, *supra* note 117, Art. 17.

flora and fauna as national patrimony and indigenous communities who consider such resources their own.[160]

One situation that may result in coercive action by a government involves the recent approval by the Chinese government of a bioprospecting project to locate microbes in Tibet.[161] The proceeds of the project will go to the Chinese government. Local Tibetan communities were not consulted, and they are not expected to reap benefits from the project.[162] It is hard to imagine that the Chinese government will allow local opposition to prevent the undertaking. Indeed, indigenous rights groups are calling on the outside researchers to protect the interests of indigenous communities, asserting that the Chinese government will not do so.[163] In the case of oil, a much less pervasive resource than the genetic material of all nonhuman living things, history abounds with examples of coercive actions by sovereigns that have claimed oil located on indigenous lands.[164] Since genetic material can be extracted without relocating entire populations, the most extreme kinds of coercion that have occurred with regard to oil are unlikely to occur with regard to raw genetic material. What is more likely is that governments will suppress those who object to a given project and disregard the concerns of indigenous groups and individuals affected by a bioprospecting project that promises to generate revenue.[165]

As for the second kind of threat posed by robust sovereign rights in this context, even if the State does not assert an exclusive ownership interest over genetic material but, rather, as in Brazil and India, centralizes control over genetic material in the national government to ensure benefit sharing for the nation, this paternalism necessarily diminishes the ability of individuals and indigenous communities to control the genetic resources in question for themselves.[166] This problem becomes particularly acute where there is a conflict between the government's interests and those of the individuals and indigenous communities. Such conflict seems likely given that the government's primary motivation is to obtain benefit sharing for itself and the country. The individuals or indigenous communities concerned may or may not share this goal and might have other goals that they consider more important. In fact, indigenous communities tend to stress control over resources and related knowledge above compensation.[167] Ironically, in the paternalistic regimes, indigenous communities have effectively lost direct control over genetic material, the thing they most care about, as a result of the State's drive to garner compensation for the nation.

[160] BROWN, *supra* note 6, at 160. *See generally* Traci L. McClellan, Note and Comment, *The Role of International Law in Protecting the Traditional Knowledge and Plant Life of Indigenous Peoples*, 19 WIS. INT'L L.J. 249 (2001) (discussing struggle of indigenous people to obtain the right to control resources).

[161] David Cyranoski, *Microbe Hunt Raises Doubts over Local Benefits of Bioprospecting*, 420 NATURE 109 (2002).

[162] *Id.*

[163] *Id.*

[164] Indigenous communities have been relocated and their lands expropriated, and governments have used force to suppress their objections to oil exploration. *See* Judith Kimerling, *'The Human Face of Petroleum': Sustainable Development in Amazonia*, 10 RECIEL 65, 73 (2001); Amazon Watch, Burlington's Oil Projects vs. Indigenous Communities and Rainforest Protection (2003), *at* <http://www.amazonwatch.org/amazon/EC/burling/>; Pipob Udomittipong & Tyler R. Giannini, Expanding Oil in Collapsing Markets? South East Asia, *at* <http://www.ran.org/oilreport/seasia.html> (visited Sept. 24, 2004); Pipob Udomittipong & Tyler R. Giannini, Offshore Boom, Onshore Impact: Central Africa, *at* <http://www.ran.org/oilreport/africa.html> (visited Sept. 24, 2004).

[165] In the case of oil, the government of Nigeria suppressed those who opposed oil drilling on indigenous lands even to the point of executing noted activist Kenneth Saro Wiwa. *See, e.g.*, Logan Michael Breed, Note, *Regulating Our 21st-Century Ambassadors: A New Approach to Corporate Liability for Human Rights Violations Abroad*, 42 VA. J. INT'L L. 1005, 1010 (2002).

[166] In both India's and Brazil's access legislation, the government grants consent for the bioprospecting project, and it is the job of the government to obtain any necessary consent from local communities or engage in the watered-down obligation of "consultation" with them.

[167] Roht-Arriaza, *supra* note 53, at 955 ("The goal is not simply to receive money in exchange for access to knowledge and resources, but to control whether, and how, such knowledge is commercialized, while also leaving it available for noncommercial uses."). *See generally* Rosemary J. Coombe, *Intellectual Property, Human Rights & Sovereignty: New Dilemmas in International Law Posed by the Recognition of Indigenous Knowledge and the Conservation of Biodiversity*, 6 IND. J. GLOBAL LEGAL STUD. 59, 100–03 (1999) (emphasizing the need for indigenous communities to be able to say no to the use of their resources); Lakshmi Sarma, Note, *Biopiracy: Twentieth Century Imperialism in the Form of International Agreements*, 13 TEMP. INT'L & COMP. L.J. 107 (1999) (stressing the importance to indigenous people of controlling their resources).

The extent of government intrusion into the liberty of individuals and indigenous communities is illustrated by the extension of government control, in the paternalistic model adopted by Brazil and India, not only over genetic material, but also over indigenous knowledge about the uses of such material.[168] This is not surprising since the object of these regimes is to obtain remuneration for the country, and traditional knowledge of the raw material's uses often gives value to the raw material itself.[169] Under these countries' regimes, foreigners may not obtain either genetic material or knowledge about the healing or other uses of such things as plants or animals from shamans, individuals, or indigenous communities, without the Indian or Brazilian government's consent.[170] These restrictions effectively curtail the liberty of those individuals and communities who may wish to share their knowledge.

States, with several notable exceptions,[171] have not generally protected the rights or interests of indigenous or traditional communities but, instead, have often facilitated their destruction. Moreover, there is little reason to believe that the State will use funds negotiated on behalf of individuals or indigenous communities for their benefit.[172] Given the choice between respecting the wishes of indigenous communities and individuals and potentially enhancing their countries' technological development and resource-starved coffers, national governments may and, if history is a guide, generally will choose the latter over the former.[173] Vesting the sovereign with rights over genetic material in order to protect individuals and indigenous communities from bioprospectors may be likened to having the proverbial fox guard the henhouse.

To avoid the specter of sovereigns compelling individuals or indigenous communities to part with genetic material, one might create a system (as exemplified by that of the Philippines, the OAU model legislation, and others) in which all interested parties must agree to a given bioprospecting project before it may proceed. This solution does not address the second issue of the curtailment of the liberty of individuals and communities to alienate genetic material against the government's wishes, but it does reduce the risk that the government will force individuals or communities to part with genetic material. However, as discussed above, this multiconsent approach creates an anticommons problem.

The tension between fixing or avoiding an anticommons and protecting the interests of stakeholders will likely become more pronounced as nations and the international community eventually grapple with controlling access to what portends to be the most lucrative genetic material: human genetic material. The human genome holds greater potential for drug development than the genes of plants and animals.[174] The "genetic gold" is less likely to lie in the genetic makeup of a frog in the Amazon than in the genetic makeup of isolated indigenous communities.[175]

Researchers seeking genetic links to diseases and drugs to cure them prize access to DNA from unusually homogeneous and isolated populations.[176] DNA samples from a relatively uniform

[168] Brazil's Measure, *supra* note 117, provides in Article 8(II) that traditional knowledge associated with Brazil's genetic heritage forms part of Brazil's "cultural heritage."

[169] *See* Roht-Arriaza, *supra* note 53, at 928 (noting that "by consulting indigenous peoples, bioprospectors can increase the success ratio in trials for useful substances from one in 10,000 samples to one in two"). While estimates like this may be too optimistic, government agencies and the private sector have used indigenous knowledge of the applications of plants and other organisms to lead them to raw material helpful for drug development. *See* BROWN, *supra* note 6, at 104, 125–32, 140–41; TEN KATE & LAIRD, *supra* note 65, at 61; 7 PHARMACEUTICAL BIOLOGY 5 (Joshua Rosenthal ed., 1999).

[170] Biological Diversity Act, *supra* note 71, §§3(1), 4; Brazil Measure, *supra* note 117, Arts. 8, 11(IV)(b), 12, 16.

[171] Canada, for example, recently vested indigenous communities with a range of natural resources.

[172] Roht-Arriaza, *supra* note 53, at 948.

[173] *See* BROWN, *supra* note 6, at 99 (reporting that Peru threatened to take away land given to indigenous communities if those communities did not commercially develop the lands but, rather, continued to use them for subsistence agriculture).

[174] Cindy Hamilton, *The Human Genome Diversity Project and the New Biological Imperialism*, 41 SANTA CLARA L. REV. 619, 621–22 (2001); *see, e.g.*, TEN KATE & LAIRD, *supra* note 65, at 45 (global net sales of human proteins developed by rDNA techniques reached $7.7 billion in 1993 alone); Fisher, *supra* note 2.

[175] Hamilton, *supra* note 174, at 621– 22.

[176] George J. Annas, *Rules for Research on Human Genetic Variation—Lessons from Iceland*, 342 NEW ENG. J. MED. 1830 (2000); *Gene Prospecting in Remote Populations*, SCIENCE, Oct. 24, 1997, at 565; Hamilton, *supra* note 174, at 623;

gene pool facilitate identification of genetic deviations that may cause medical disorders.[177] Genetic researchers have thus targeted the relatively homogeneous populations of Estonia, Finland, Iceland, Tonga, and certain groups in China,[178] as well as isolated and relatively homogeneous populations in mountain villages in Italy[179] and on the small island of Tristan da Cunha.[180] In the United States, researchers have shown particular interest in Native American populations.[181]

At present, the laws and draft laws that restrict access to genetic material to obtain remuneration for the nation exclude human genetic material from their ambit.[182] This being said, uneasiness over the use of human genetic resources for scientific or commercial purposes has been growing.[183] These concerns often mirror those raised in the context of bioprospecting in the nonhuman context. Many object to the unfairness of permitting companies to profit from patented genes or goods utilizing such genes without compensating the donors of the underlying genetic material.[184] When human genetic material comes from developing countries, concerns about the fair and equitable sharing of benefits between developed and developing countries arise as well.[185] In addition, many object to the patenting of human genetic material.[186]

David Dickson, *Back on Track: The Rebirth of Human Genetics in China*, 396 NATURE 303, 304 (1998); John Pomfret & Deborah Nelson, *In Rural China, a Genetic Mother Lode*, WASH. POST, Dec. 20, 2000, at A1.

[177] Annas, *supra* note 176, at 1830.

[178] *See, e.g., id.;* Dickson, *supra* note 176; Henry T. Greely, *Iceland's Plan for Genomics Research: Facts and Implications*, 40 JURIMETRICS, Winter 2000, at 153; *Mining a Rich Seam of Genetic Diversity*, *supra* note 176; Michael Specter, *Decoding Iceland*, NEW YORKER, Feb. 18, 1999, at 40; Wim Weber, *Tonga Sells Genetic Heritage to Australian Firm*, LANCET, Dec. 2, 2000, at 1910, *available in* 2000 WL 9007333.

[179] James Charles, *Lost Village Could Hold Key to Cures*, DAILY EXPRESS, Jan. 3, 2001, at 1, *available in* 2001 WL 13273533; Tom Hundley, *Remote Italian Town on the Map for Geneticists: Clues to Disease Are Sought*, CHI. TRIB., Dec. 31, 2000, at 1.

[180] Greely, *supra* note 178, at 164; Rural Advancement Foundation International [RAFI, now ETC Group] Communiqué, *Companies Step up Efforts to Sample Remote Populations* (Nov. 12, 1997), *available at* <http://www.etcgroup.org>; RAFI Communiqué, *Gene Hunters in Search of "Disease Genes" Collect Human DNA from Remote Island Populations* (May 30, 1995), *available at* <http://www.etcgroup.org/article.asp?newsid-207>. The populations of the Pacific islands of Pingelap and Norfolk are also targets for genetic research. Patrick Barkham, *Faraway Tonga Cashes in on Its Gene Pool Secrets*, GUARDIAN, Nov. 23, 2000, *available in* 2000 WL 29681585.

[181] Telephone conversation with Mervyn Tano, executive director, International Institute for Indigenous Resource Management (June 2001). Mr. Tano estimated that the Cherokee Nation had already received some thirty applications for studies on the genetic makeup of its population and that the Navajo Nation had received numerous such requests.

[182] GLOWKA, *supra* note 54, at 33; TEN KATE & LAIRD, *supra* note 65, at 17. India's national law excludes human genetic material, *see* Biological Diversity Act, *supra* note 71, Art. 1(c), as does the ASEAN Agreement, *supra* note 112, Art. 4. Access to human genetic material for research or commercialization, with several exceptions, remains largely unregulated. TEN KATE & LAIRD, *supra,* at 17.

[183] *See, e.g.*, WHO, GENOMICS AND WORLD HEALTH: REPORT OF THE ADVISORY COMMITTEE ON HEALTH RESEARCH §§7.1–7.6 (2002) [hereinafter WHO REPORT], *available at* <http://www3.who.int/whois/genomics/genomics_report.cfm>; Hamilton, *supra* note 174; RAFI Communiqué, *Phase II for Human Genome Research: Human Genetic Diversity Enters the Commercial Mainstream* (Jan. 21, 2000), *available at* <http://www.etcgroup.org/article.asp?newsid-230> [hereinafter RAFI, *Phase II*]; RAFI Communiqué, *The Human Tissue Trade; The Global Traffic and Market in Human Biomaterials* (Jan. 30, 1997), *available at* <http://www.etcgroup.org/search.asp?page-3&type-communique>; RAFI, *Gene Hunters*, *supra* note 180; Pomfret & Nelson, *supra* note 176; *Human Rights Movement Condemns Gene Research in Tonga*, PAC. ISLANDS BROADCASTING ASS'N NEWS SERV., Nov. 28, 2000, *available in* 2000 WL 18811901.

[184] *See* WHO REPORT, *supra* note 183, §§7.5, 7.4.4 (indicating that patenting of genetic material of indigenous people is increasing opposition to population genetic studies and including suggestions for increased attention to benefit sharing). Article 4 of the Universal Declaration on the Human Genome and Human Rights, which was adopted by the UNESCO General Conference in 1998, states that "the human genome in its natural state shall not give rise to financial gains." 29 C/Res. 16, UNESCO Gen. Conf., 1 Res., at 41 (1998). However, it is argued that where genomics research gives rise, for example, to profitable drugs, "it is not unreasonable for individuals who allow access to their DNA to consider themselves as owners of a resource and to demand fair compensation, which is considered to be in the region of 50% of net profits and royalties." WHO REPORT, *supra*, §7.5; *see also* Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990) (patenting of cell line obtained from a patient); Jon F. Merz, *Discoveries: Are There Limits on What May Be Patented? in* WHO OWNS LIFE? *supra* note 9, at 99 (describing furor over patenting of the gene responsible for Canavans disease, where members of the affected Jewish community donated tissue samples used to identify the patented gene). *See generally* Julia D. Mahoney, *The Market for Human Tissue*, 86 U. VA. L. REV. 163 (2000).

[185] WHO REPORT, *supra* note 183, §§7.4.4, 7.5.

[186] *Id.* §7.4.4, Box 7.2.

Despite a decision of the Parties to the Convention on Biological Diversity to exclude human genetic material from the Convention's treatment of natural resources,[187] a trend toward viewing human genetic material as a natural or national resource is apparent. For example, reports on human genetic research in China trumpet the importance of ethnic diversity as a national resource, describing the distinct characteristics of China's numerous ethnic groups as a "goldmine" for population geneticists.[188] In fact, entire populations are seen as "treasure" or "valuable resources" that open up an opportunity for "mining a rich seam of genetic diversity."[189] An article reporting on a proposed deal between Tonga and an Australian biotechnology firm, which would have given the firm access to the DNA of Tongans, explains how that isolated Pacific archipelago would "add DNA to its more usual trade in fish, coconuts and coffee."[190] In the words of another article, "selling its DNA secrets" is one of the ways that "Tonga's constitutional monarchy is obtaining hard currency in the modern global economy."[191]

Concerns about the export of human genes prompted China to promulgate national rules governing access to human genetic material.[192] The rules require that "[a]ny institution or individual who discovers or holds important pedigrees and [human] genetic resources" in certain regions must immediately report them to the relevant national departments.[193] The rules also state that "[n]o institution or individual may sample, collect, trade, export human genetic resources or take them outside the territory of the People's Republic of China, or provide them to other countries" without government permission.[194] Separate legislation requires national identity cards to include an eighteen-digit code referencing each person's genetic code.[195] This code is derived from a required sample of the person's blood, tissue, or hair.[196] Thus, China will now have a DNA sample or at least a record of a DNA sample of every citizen's genetic makeup. Such samples or records may be cross-referenced on the basis of nationality, family, and locality, and potentially alienated by the government.[197]

While present legal regimes distinguish between human and nonhuman genetic resources, this distinction may not hold over time. The rules and approaches currently being laid down, both nationally and internationally, regarding national government ownership and control of nonhuman genetic resources so as to obtain financial and other benefits for the nation can probably be expected to apply to or materially affect future legal regimes governing access to

[187] The Second Meeting of the Parties to the CBD "reaffirmed that human genetic resources are not included within the framework of the Convention." Decision II/11, para. 2, Doc. UNEP/CBD/COP/2/19, at 22 (1996).

[188] Dickson, *supra* note 176, at 305.

[189] *Id.* at 304; *see also* Lisa Belkin, *Chasing Bad Genes to the Ends of the Earth: The High-Tech Future of Medicine Is in the Blood of Remote Peoples,* N.Y. TIMES, Apr. 26, 1998, §6 (Magazine), at 46, 52.

[190] Dawn Sugimoto, *Isolated Tonga Sells Its DNA Info to Science*, LETHBRIDGE HERALD, Nov. 25, 2000, *available in* 2000 WL 27467389.

[191] Barkham, *supra* note 180.

[192] China, General Office of the State Council, Interim Measures for the Administration of Human Genetic Resources (June 10, 1998), *in* U.S. Embassy Beijing, New PRC Human Gene IPR Rules (Sept. 1998), *at* <http://www.usembassy-china.org.cn/sandt/geneipr.htm>.

[193] *Id.*, Art. 4.

[194] *Id.* For an international collaborative project involving the human genetic resources of China, the application documents must include an "[i]nformed consent form of the donor of the human genetic material and/or his (her) legal representatives." *Id.*, Art. 12. The rules' consent requirements, however, do not appear to apply to genetic material secured by the Chinese government. For a discussion of international rules for the protection of individuals, see note 204 *infra*.

[195] Transfert.net, *La Chine passera à la carte d'identité électronique à partir de janvier 2004* (Sept. 1, 2003), *at* <http://www.transfert.net>. The card, which is required for all citizens over sixteen, also includes the person's nationality, address, and place of birth.

[196] *Id.*

[197] The proviso in the Universal Declaration on the Human Genome and Human Rights, *supra* note 184, that "the human genome in its natural state shall not give rise to financial benefits" does not appear to restrict such alienation. Presumably a gene, once removed, is no longer in its natural state. Also, the declaration refers to the entire human genome rather than individual genes. For potential limitations on government actions, see *infra* note 204.

human genetic material as well.[198] Indeed, some are already suggesting that the CBD govern or the parties otherwise address access to human genetic material.[199] Others, while not going that far, point to the CBD as a model. A 2002 report by an advisory committee to the World Health Organization on genomics and world health, for example, expressly includes a detailed discussion of the CBD's approach to benefit sharing as a potential guide for such sharing in the human genetics area.[200] Admittedly, humans differ from trees. Yet developed countries quickly moved from patenting the microbe to patenting human genes. The U.S. Supreme Court handed down its seminal *Chakrabarty* decision, which allowed the patenting of genetically engineered microbes, in 1980. Within a few years, the U.S. Patent and Trademark Office was granting patents on human genes,[201] and in 1991 the U.S. Court of Appeals for the Federal Circuit upheld such patenting.[202] Thus, in less than a decade, the United States moved from patenting the microbe to patenting the human gene. Moreover, in the celebrated case of *Moore v. Regents of the University of California*, the California Supreme Court upheld the University of California's ownership of Moore's cell line.[203] If the University of California, a state institution, can own an individual's cell line, cannot the national government of China or another country own the cell lines of their populations? National governments, having gained comfort from their ownership or extensive control of nonhuman genetic resources to obtain benefits for the nation, can make the jump to human genetic material, as the patent system has done, with the attendant risks to human liberty and autonomy.[204]

[198] The ASEAN Agreement, *supra* note 12, Art. 4, prohibits the prospecting of genetic material of human origin and urges "the establishment of a multilateral process to effectively regulate the access, use, and commercialization of human genetic materials." *See also* WHO REPORT, *supra* note 183 (discussing potential need for international guidelines to help national governments negotiate with multilateral corporations for the sharing of benefits arising out of the use of human genetic material).

[199] *See, e.g.*, Hamilton, *supra* note 174, at 636–39; *see also* RAFI, *Phase II*, *supra* note 183, at 15 (asserting that the CBD Conference of Parties should seek an advisory opinion from the International Court of Justice clarifying its responsibility with respect to human genetic diversity); RAFI News Release, US Funding of Human Biodiversity Collections Carries on Despite Contrary Scientific Advice 3 (Nov. 14, 1997) (stating that the CBD parties have been inadvertently ceded a role in addressing issues concerning human biodiversity and should bring the issue of collection of human genetic material before the UN human rights commissioner and the ICJ). The Convention on Biological Diversity does not necessarily distinguish between human and other genetic resources. TEN KATE & LAIRD, *supra* note 65, at 17, 45. Articles 1, 2, and 15 of the Convention, *supra* note 39, which set forth its objectives, definitions, and provisions on access to genetic resources, respectively, do not exclude human genetic resources from their terms. Article 2 of the Convention broadly defines "genetic material" as "any material of plant, animal, microbial *or other origin* containing functional units of heredity" (emphasis added). The term "or other origin" could be understood to include genetic material of human origin. Articles 15(1) and 15(5) of the Convention, which recognize the right of national governments to control genetic resources, could apply to human genetic resources as well. Although the Second Meeting of the Parties to the Convention "*[r]eaffirmed* that human genetic resources were not included within the framework of the Convention," the parties can revisit the issue. Decision II/11, *supra* note 187, para. 2. The Conference of the Parties has at times shown little regard for the jurisdictional limits of the Convention. For example, the CBD does not retroactively apply to genetic resources collected prior to its entry into force. CBD, *supra*, Art. 15, para. 3. This did not stop the Fourth Meeting of the Conference of the Parties from embarking on a work program that encompassed collections of material acquired prior to the CBD's entry into force. Decision IV/8, para. 2, Doc. UNEP/CBD/COP/4/27, at 109 (1998).

[200] WHO REPORT, *supra* note 183.

[201] *See, e.g.*, U.S. Patent No. 4,370,417,1026 (issued Jan. 25, 1983) (patent for DNA sequence for plasminogen activator protein); U.S. Patent No. 4,703,008,1083 (issued Oct. 27, 1987) (patent for DNA sequence for erythropoietin). For the Supreme Court's decision, see Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[202] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).

[203] Moore v. Regents of Univ. of Cal., 793 P.2d 479 (Cal. 1990).

[204] The nonbinding UNESCO Declaration on the Human Genome and Human Rights of 1998, *supra* note 184, and the nonbinding International Declaration on Human Genetic Data, Oct. 16, 2003, *available at* <http://www.unesco.org>, provide some protections for individuals. Article 5 of the 1998 declaration requires researchers to obtain the free and informed consent of participants in genetic research. The 2003 declaration stipulates that genetic material should be extracted from humans only with their prior informed consent and that such material should not be used for an incompatible different purpose without their consent. The State, however, may decide to do away with this requirement for "compelling reasons by domestic law consistent with the international law of human rights." 2003 declaration, *supra*, Art. 8(a). In addition, material given for one reason may be used for another without the person's consent if the "use proposed is in the public interest" or where data are unlinked to any particular person. *Id.*, Art. 16(a). For a discussion of controls and the limits of such controls on the conduct of human genetic research, see Henry T. Greely, *The Control of Genetic Research: Involving the "Groups Between,"*

III. International Law's Mishandling of Genetic Material and Its Implications

The Convention on Biological Diversity essentially takes the position that genetic material is the same as any tangible natural resource, such as oil and timber, over which sovereigns exercise control and even ownership.[205] But is it? While genes have a tangible component (i.e., a minuscule combination of chemicals), they share more in common with an intangible good like information than they do with a typical tangible natural resource like oil.[206] What holds value and is really being sought is not so much a particular physical cell as the information, the blueprint, contained in that cell and, in fact, in millions of similar cells.[207] Moreover, as with information, the use of genetic material is largely nonrivalrous in that its use by one person generally does not diminish its availability for use by others.[208] One need not fell a forest to access its genetic material, and removed genes can be replicated. This feature puts it into sharp contrast with oil, minerals, and timber, whose use is rivalrous.[209] The exploiter of the latter goods is after the raw physical substance, not the information it contains.[210] Their taking by one person renders them unavailable for the use of others.[211]

This perspective on the similarity of genes to an intangible good did not make its way into international law. The Convention on Biological Diversity and national and international measures promulgated pursuant to the Convention largely assume that sovereigns should exercise similar rights over the subcellular genetic sequences of all nonhuman living things within their jurisdiction to those they exercise over oil or timber. In some ways, the Convention encourages sovereigns to exercise more control over genetic material, stipulating government consent for access to such material so that nations can benefit from its use.[212] This approach has led nations on a quixotic quest to control the extraction of genetic material from within their borders in an effort to prevent any potentially valuable information it may contain from escaping. A rough analogy would be if sovereigns decided to take control of the removal of written words from their countries, under the theory of sovereign rights over the paper within their borders, so that information conveyed by those words could not leave their territory.

This flawed approach is likely to exacerbate already high tensions between nations over ownership of genetic material. First, since what is really being sought is the information represented by genetic sequences, the ownership of this information becomes a fundamental question. This problem is particularly acute when, as often happens, the genetic sequence may appear in more than one nation. The CBD stipulates that the "country of origin" providing the genetic material is the one that must consent to its access and ostensibly receive benefits arising from its use.[213]

33 Hous. L. Rev. 1397, 1406 (1997); Shira Prada-Frank, *Human Genomics: A Challenge to the Rules of the Game of International Law*, 40 Colum. J. Transnat'l L. 613 (2002).

[205] CBD, *supra* note 39, Art. 15(1). *But see* note 212 *infra*.

[206] *See generally* Stone, *supra* note 44, at 597.

[207] *Id*.

[208] *Id*.

[209] *Id*.

[210] *Id*.

[211] *Id*.

[212] Some commentators argue that the Convention distinguishes genetic resources from other natural resources because it stipulates that national governments should facilitate access to genetic resources. *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. Transnat'l L. 1, 8–9 (1993). This position is largely undercut by the language of Article 15(1) of the Convention, which plainly likens genetic material to other natural resources. Moreover, the Convention's requirement that countries facilitate access to genetic material is weak, requiring them solely to "endeavour" to create conditions to facilitate access. CBD, *supra* note 39, Art. 15(2). This weak obligation is further eroded by other provisions, which encourage countries to obtain "benefit sharing" for the use of genetic resources (Art. 1) and specify that access to genetic material normally requires the prior informed consent of the national government (Art. 15(5)). Such controls are not normally prescribed by treaty for other natural resources. Not surprisingly, nations in the aftermath of the CBD have not promulgated laws to enable and facilitate access to genetic material but, rather, to curtail access to such material to obtain monetary and other benefits.

[213] CBD, *supra* note 39, Arts. 15(5) ("Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party."), 15(3) ("For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this

The country of origin, in turn, is defined as the country which possesses those genetic resources within "ecosystems and natural habitats, . . . and, in the case of domesticated or cultivated species," such as most agricultural goods, "in the surroundings where they have developed their distinctive properties."[214] Ascertaining where a given gene acquired its distinctive properties can be both difficult and controversial.[215] Whether a gene "naturally occurs" in a given country may also provoke controversy.[216] Fights between countries are likely to arise as they quarrel over which gene "originated" where and which nation should rightfully capture any benefits arising from its use.

Second, simply to state the goal of controlling the extraction of all potentially valuable subcellular genetic sequences is to highlight obvious enforcement problems. The extraction of oil, minerals, and timber tends to be fairly visible, often requiring expensive structures and continuous activity.[217] Violation of laws restricting such extraction can readily be seen. Enforcement challenges are manageable.[218] The same cannot be said about the extraction of genetic material. Genes are contained in a twig, a leaf, a spoonful of soil, a butterfly wing. They can be removed easily, making the cost of policing high.[219]

To the extent that genes have a tangible component, that component is renewable, largely abundant rather than scarce, and amenable to discrete extraction. The challenge presented to developing countries by the CBD is how to take a nonrivalrous, abundant resource and make it exclusive. How can nations prevent most, let alone all, genetic sequences of potential value from leaving their borders? They cannot.[220]

Developing countries, therefore, are increasingly turning to patent systems to enforce their access-restricting regimes.[221] The access-restricting regimes of India and Brazil, as well as the model laws of the ASEAN nations and the OAU, reflect the enforcement link being made by developing countries to this effect. As mentioned above, India's law prohibits any person from applying for any intellectual property right anywhere to inventions based on research or information on a biological resource obtained from India without the prior approval of the National Biodiversity Authority.[222] The authority may impose a benefit-sharing fee and/or royalty as a condition of approval.[223] The Brazilian Measure stipulates that Brazil's grant of any intellectual property right "for a process or product obtained using samples of components of the genetic

Article . . . , are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention."). I note that, as is often the case, the CBD's provisions are somewhat confusing and not entirely consistent with each other. Article 2 appears to define the "country providing genetic resources" more broadly than solely the country of origin as stipulated in Article 15(3). Under Article 2, the "country providing genetic resources" is the one "supplying genetic resources collected from *in-situ* sources . . . or taken from *ex-situ* sources, which may or may not have originated in that country."

[214] *Id.*, Art. 2.

[215] *See generally* Fowler, *supra* note 16, at 484–86 (generally discussing this problem for purposes of benefit sharing under the CBD). While Dr. Fowler limits his discussion to plant genetic resources, I believe that the problems that he has identified will arise with respect to other genetic resources as well.

[216] Without providing guidance, the CBD defines "habitat" as "the place or type of site where an organism or population naturally occurs." What does it mean for something to occur naturally in a place? For example, do species that have been transported by human beings from one country to another "naturally occur" in the new country?

[217] Stone, *supra* note 52, at 984.

[218] *Id.*

[219] *Id.*; Jacoby & Weiss, *supra* note 36, at 93 (predicting that policing and patrolling borders to control the flow of genetic resources would be difficult and expensive).

[220] *See* Stone, *supra* note 44, at 605.

[221] Rosemary J. Coombe, *The Recognition of Indigenous People's and Community and Traditional Knowledge in International Law*, 14 ST. THOMAS L. REV. 275 (2001) (discussing proposals to disclose origin of genetic resources in patent application); Glowka, *supra* note 4, at 332 (calling for shifting enforcement burdens from source countries to user countries); Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Plant Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000).

[222] Biological Diversity Act, *supra* note 71, §6(1).

[223] *Id.* §6(2).

heritage is contingent on the observance" of the Measure.[224] Applicants for patents and other forms of intellectual property protection in Brazil must "specify the origin of the genetic material and the associated traditional knowledge," presumably in their applications for such protections.[225] Costa Rica's access regime, as well as that of the Andean Pact, also links the granting of intellectual property rights to compliance with the source countries' access laws.[226] The OAU model legislation prohibits a collector from applying for any form of intellectual property protection over the collected biological resource, its parts, or its derivatives without the prior informed consent of the original providers.[227] While not mentioning intellectual property rights in particular, the ASEAN Framework Agreement stipulates that, as part of the benefit-sharing arrangement, resource providers shall receive, without payment of a royalty, all technologies developed from research on the provided materials.[228]

In conformity with their own practice of linking the patent application and the patent grant to compliance with their access-restricting regimes, developing countries are increasingly demanding that the United States and other developed countries require patent applicants to disclose the country of origin of any genetic material used to develop the item sought to be protected.[229] In addition, they are demanding that developed countries either refuse to enforce or refrain from granting patents to innovations, such as synthesized genes and bioengineered goods, that utilize material that came from developing countries, unless it was obtained in compliance with the country of origin's access-restricting laws. For example, in connection with the 2003 meeting of the TRIPS Council, Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, India, Peru, Thailand, and Venezuela proposed amending the TRIPS Agreement to require, as a condition of patent acquisition, (1) the disclosure of the source and country of origin of genetic resources used in the invention, (2) evidence that the country of origin had consented to its extraction and use, and (3) "evidence of fair and equitable benefit sharing under the relevant national regime."[230] They further proposed that failure by an applicant to provide this information should render the patent unenforceable.[231] They argued that these amendments were "imperative to implement the TRIPS Agreement and the CBD in a mutually supportive and complementary way."[232] The African Group, which consists of all African nations that belong to the WTO, proposed a similar amendment to the TRIPS Agreement,[233] arguing that the Agreement "has not provided adequate and equitable means to prevent patents mainly in developed

[224] Brazil Measure, *supra* note 117, Art. 31.

[225] *Id.*, Art. 31. Violation of the Measure triggers a menu of potential penalties. These include confiscation of products derived from samples of the genetic heritage or associated traditional knowledge, suspension of the sales of such products, and suspension or cancellation of any patent related to such samples or associated traditional knowledge. *Id.*, Art. 30. In addition, a person or a corporation that economically exploits a product or process developed from samples of components of Brazil's genetic heritage or associated traditional knowledge accessed in violation of the Measure is subject to a penalty of 20% of the gross amount obtained from selling or licensing the product or process. *Id.*, Art. 26.

[226] Jeffrey, *supra* note 16; Pires de Carvalho, *supra* note 221.

[227] Seiler & Dutfield, *supra* note 54, at 90.

[228] *Id.*

[229] *See, e.g.*, World Trade Organization, TRIPS: Reviews, Article 27.3(B) and Related Issues, Background and the Current Situation, *at* <http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm> (last modified June 24, 2004).

[230] World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge, WTO Doc. IP/C/W/403, paras. 1, 9 (June 24, 2003). In addition, China, Pakistan, Zambia, and Zimbabwe had made a similar proposal to the TRIPS Council in 2001. *Id.*, para. 1 & n.2. The WTO documents cited here and below are available online at <http://www.wto.org>.

[231] WTO Doc. IP/C/W/403, *supra* note 230, para. 14.

[232] *Id.*, para. 21.

[233] World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement, WTO Doc. IP/C/W/404 §III(D) (June 26, 2003). The African Group proposed that Article 29 of the TRIPS Agreement be amended as follows: "Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin."

Members that have amounted to and resulted in the misappropriation of genetic resources . . . . from developing Members."[234]

The United States and other developed countries did not agree to these demands.[235] They will probably continue to refuse to condition the patent grant or its enforcement on the disclosure of information indicating the applicant's compliance with access-restricting regimes.[236] Doing so would involve the consideration of criteria unrelated to the requirements of patentability.[237] Traditionally, the patent system has steadfastly declined to serve as a vehicle for enforcing any nonpatent regulatory scheme.[238] The demands of the developing countries that the patent system help enforce their access-restricting laws and the likely hostility of developed countries, particularly the United States, to such demands will exacerbate tensions between these nations regarding genetic material and bioengineered goods.

In addition, the linkage that most access-restricting regimes make between compliance with their terms and the grant (or the enforcement) of patents portends a TRIPS dispute of massive proportions. A country will run afoul of the TRIPS Agreement if it refuses to issue a patent to an otherwise patentable invention, such as a drug, because the genetic material used in it was obtained in violation of the access rules of that country or of another country.[239] Article 27.1 of the TRIPS Agreement stipulates that "patents shall be available for any inventions, . . . provided that they are new, involve an inventive step and are capable of industrial application." Whether genetic resources were acquired in compliance with a country's access-restricting regime has no bearing on these criteria for patentability.[240]

Through the TRIPS Agreement, developed countries sought to prevent the widespread copying of patented goods, such as pharmaceutical products, that was occurring in developing countries.[241] Thus, if countries like Brazil and India begin to deny or refuse to enforce patents to a

[234] *Id.* §I.

[235] Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L. 1, 68 (2004); *see, e.g.*, World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from the European Communities and Their Member States, WTO Doc. IP/C/W/383, para. 54 (Oct. 17, 2002) (expressing the Communities' general objections to such requirements as part of the patent process); DAVID HUNTER, JAMES SALZMAN, & DURWOOD ZAELKE, INTERNATIONAL ENVIRONMENTAL LAW AND POLICY 967–68 (1998) (reciting U.S. objections that such requirements would be a legal and administrative "nightmare"); Jeffrey, *supra* note 16, at 773 (discussing U.S. opposition to such demands).

[236] The European Communities and Switzerland offered a compromise in response to developing country demands for additional disclosure rules. This compromise fell far short of meeting those demands and developing countries rejected it. The EC compromise called for the negotiation of "a self-standing disclosure requirement." This requirement would not function as a new eligibility criterion for patent eligibility or the enforcement of patents but, in the words of the proposal, "would allow WTO Members to keep track . . . of all patent applications with regard to genetic resources for which they have granted access." Helfer, *supra* note 235, at 68–69. Switzerland indicated its receptivity to allowing nations to require disclosure of the source of genetic material in patent applications but refused to require such disclosure as a matter of international law or condition the patent grant on such disclosure. World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Switzerland, WTO Doc. IP/C/W/400/Rev.1 (June 18, 2003).

[237] These are that the invention be new, nonobvious, and useful and be disclosed to the public in the patent application.

[238] *See, e.g.*, Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999) (noting that it is not the task of the Patent and Trademark Office to serve as arbiters of deceptive trade practices or to determine whether drugs are safe, or otherwise to exercise the police powers of the states); Pires de Carvalho, *supra* note 221, at 372; *see also* TRIPS, *supra* note 13, Art. 27.2 (although members may exclude certain inventions from patentability to protect *ordre public* or morality, "such exclusion [shall not be] made merely because the exploitation is prohibited by their law").

[239] Pires de Carvalho, *supra* note 221, at 372, 379–89.

[240] *Id.* Indeed, some developed countries are aware of the apparent conflicts between access-restricting legislation and the TRIPS Agreement. *See, e.g.*, World Trade Organization, Council for Trade-Related Aspects of Intellectual Property Rights, Communication from Brazil, WTO Doc. IP/C/W/228, para. 24 (Nov. 24, 2000) (pointing to conflicts between the CBD and TRIPS "at the implementation level"). Pires de Carvalho suggests that, while a refusal to grant a patent under such circumstances would violate the TRIPS Agreement, a country's refusal to enforce a patent for failure to disclose that genetic material was acquired without the country of origin's consent would not. Analysis of this untested approach is the topic of a separate article.

[241] *See* MARTIN J. ADELMAN ET AL., CASES AND MATERIALS ON PATENT LAW, 2D at 60 (2003) (highlighting the importance of TRIPS for the pharmaceutical industry); Martin J. Adelman & Sonia Badia, *Prospects and Limits of the Patent Provision in the TRIPS Agreement: The Case of India,* 29 VAND. J. TRANSNAT'L L. 507, 524, 532 (1996) (Prior to

range of drugs because their development involved or allegedly involved genetic material taken without their consent, these drugs could once again be freely manufactured and sold in developing countries. Developed countries would lose some of the important gains that they achieved through the TRIPS Agreement at considerable cost to their industries.[242] Consequently, if such denials or refusals to enforce patents begin to occur, they could be transformed into a major trade dispute.[243]

IV. The Argument for a More Open System for Genetic Material

There are three principal reasons why the community of nations should temper the present twin systems of ownership of genetic material and take steps toward establishing a more open system for such material. First, the sovereign-based and the patent-based systems of ownership suffer from multiple problems. Second, these problems and the corrosive interplay between the two ownership systems are leading to the underutilization of genetic material with the commensurate opportunity cost of potentially beneficial biotechnological goods. Third, a more open system for genetic material would encourage innovation, promote conservation of such material, and facilitate collaboration between developed and developing countries.

The preceding parts identify three major problems related to the sovereign-based ownership system for genetic material: (1) it is creating an anticommons in raw genetic material; (2) it threatens the autonomy and liberty of individuals and indigenous communities; and (3) it is based on a flawed approach in international law that has led to unenforceable regimes destined to increase tensions between nations and threatens to lead to a major TRIPS dispute. For all of its problems, the sovereign-based system boasts few benefits. The best argument for extensive sovereign control over genetic material is to obtain benefits for the nation of origin. Arguably, such control is necessary to prevent individual actors from providing easy access to the material, undercutting the ability of the nation and its citizens to generate revenue from it. However, the access-restricting regimes have not generated, nor appear likely to generate, much revenue, let alone enough to convince countries to preserve natural habitats as environmentalists had hoped.[244] If anything, the Convention on Biological Diversity and the laws that it inspired have driven companies away from bioprospecting.[245] Moreover, these regimes are costly to administer and enforce.[246]

As stated at the outset, this article focuses on the sovereign-based system, but the patent system in the genetics area is also flawed. In the United States, it too is, or at a minimum risks, creating an anticommons in genetic material that deters innovation.[247] Dan Burk and Mark Lemley summarize the current unhappy situation as follows: "Patentees have acquired thousands of patents on DNA sequences that cover specific genes or in some cases fragments of genes. . . . Any particular gene therapy requires the simultaneous use of many of these patents, leading

TRIPS, countries like India widely manufactured drugs that were patented in developed countries. TRIPS prevents this practice and therefore is extremely important to the pharmaceutical industry.).

[242] *See generally* ADELMAN ET AL., *supra* note 241, at 60.

[243] The 1996 TRIPS dispute between the United States and the European Union against India illustrates how quickly a country's failure to protect pharmaceutical products properly can create a trade dispute. India failed to comply with the TRIPS requirement that it provide a "mailbox mechanism" through which patent applicants could deposit their claims during the transitional period that applies to developing countries. In less than two years, the United States filed claims against India before the WTO and the European Union joined as a third participant. India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, Doc. WT/DS50/AB/R (adopted Jan. 16, 1998).

[244] *See* Stone, *supra* note 52, at 1000 (admitting that the prospective use values for biodiversity, particularly the pharmaceutical potential, have been "conveniently exaggerated" by well-intentioned academics).

[245] Labrador, *supra* note 146; *accord* Stone, *supra* note 52, at 991 (pointing to "evidence that as national efforts become more stringent, the interest of bioprospecting firms may wane, resulting in fewer prospecting agreements").

[246] *See* note 219 *supra* and corresponding text.

[247] *See* notes 92–97 *supra* and corresponding text.

to anticommons problems."[248] It is estimated, for example, that scientists in creating the celebrated "golden rice," a strain genetically engineered for enhanced vitamin A, may have infringed as many as seventy patents.[249] The scientists who created the rice, which might prevent thousands of cases of blindness a year, report that they could not have done so had they attempted to identify and secure the consent of all implicated patent holders.[250]

In addition to anticommons problems, genetic patenting may be leading to a related problem of patent thickets.[251] In contrast to an anticommons, which requires the aggregation of multiple inputs to create a single product, patent thickets occur when multiple overlapping patents cover the same technology and can choke an industry.[252] In a patent thicket environment, holders of patents can prevent each other from fully utilizing the corresponding rights, as each holder's right overlaps with, and hence infringes upon, a right held by another.[253]

Not all agree that the present U.S. system for patenting genetic material is flawed.[254] Most scholars, however, seem to believe that the patent system in the genetics area has overreached and is inhibiting innovation. As Dreyfuss notes, "[T]he literature questioning aspects of genomic patenting and proposing all sorts of interventions" to limit the innovation-inhibiting aspects of such patenting, such as compulsory licensing, experimental use defenses, and condemnation proceedings, is growing "large" and "fast."[255]

Patents on little-improved genetic material may not even be needed to encourage researchers and companies to discover the functions of genes.[256] Companies have a built-in incentive to discover the functions of genes so they can develop potentially lucrative downstream products such as drugs and therapeutics dependent upon the upstream gene discovery. Granting patents to isolated and identified genes presumably fosters the disclosure of their identity and function. However, in view of the advances in through-put technology that enable more rapid identification of genes and the "race" between companies to identify the functions of genes, the advantages of disclosure may not be that substantial.[257] They may be insufficient to warrant the broad right granted to a patent holder to control all uses of the isolated gene for almost twenty years.

As described earlier, the sovereign enclosure regimes are deterring companies and researchers from bioprospecting in genetically rich countries.[258] The emerging response of developing countries to the low levels of such activity and the disappointing revenue flows and benefit-sharing arrangements is to tighten their grip over genetic material even further by linking the patent application or patent grant to compliance with their access-restricting regimes.[259] One can expect that companies and research institutions will avoid engaging in behavior that might

[248] Burk & Lemley, *supra* note 95, at 1625–26 (footnote omitted). Proceeding with a particular gene therapy or downstream bioengineered good involves high costs in locating and bargaining with the holders of patents on these various genes and gene fragments. *See generally id.* at 1611 (summarizing effects of an anticommons). Any one patent holder can thwart a project by refusing to license its individual genetic component unless paid a "bribe" to do so. *Id.* The problem is exacerbated even further by "reach-through" licenses, whereby the owners of upstream patents seek control of and royalties on the downstream uses of their patented genes. *Id.* at 1626. But see note 97 *supra* for those who disagree that an anticommons is emerging.

[249] PETER PRINGLE, FOOD, INC. 20, 33 (2003).

[250] *Id. (*quoting the developer of the golden rice as saying he had to ignore the patents while experimenting with the rice "or I couldn't move at all").

[251] Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust,* 16 BERKELEY TECH. L.J. 813, 842 (2001).

[252] Burk & Lemley, *supra* note 95, at 1627.

[253] *Id.*

[254] Epstein, *supra* note 7; *see also* Mauer, *supra* note 7, at 1090 (favoring a broad interpretation of patentable subject matter).

[255] Dreyfuss, *supra* note 7, at 1; *see supra* note 7.

[256] *See generally* Burk & Lemley, *supra* note 95, at 1678.

[257] Gitter, *supra* note 7, at 1677 (discussing how easy it is to isolate genes with computer-assisted high-throughput sequencing); Walter V. Reid, *Technology and Access to Genetic Resources, in* ACCESS TO GENETIC RESOURCES 53 (Mugabe et al. eds., 1997); *see* Thompson, *supra* note 25 (describing race to isolate and discover functions of genes).

[258] *See* notes 146, 152, & 153 *supra* and corresponding text.

[259] *See* notes 221–28 *supra* and corresponding text.

imperil or encumber their ultimate ability to obtain a patent. Consequently, the emerging linkage between the patent grant and the enforcement of access-restricting regimes will likely further deter companies from prospecting in genetically rich developing countries. Companies will also likely avoid interactions with scientists from developing countries for fear of facing accusations of having obtained genetic resources in violation of national access-restricting regimes.

Companies and research institutions are coping by adopting strategies that will likely be continued in the future. Thus, rather than turning to nature for potentially valuable genes, they have relied more heavily on *ex situ* collections;[260] and in the face of increasingly restricted access to raw genetic material, they have depended upon, searched for, and invested more heavily in technological solutions to meet their needs. Such solutions include both combinatorial chemistry, which enables the building of "designer genes" from scratch through the assembling of amino acids that make up genes,[261] and the manipulation of genes within a species rather than transferring them between species.[262] Instead of inserting a frost-resistant gene from a unique flounder into a tomato, scientists might manipulate the tomato's existing genes to achieve frost resistance.

Despite their promise, technical advances or fixes do not eliminate the value of *in situ* natural genetic material.[263] Such material offers time-tested survival templates.[264] Moreover, scientists consistently report the continued value of natural resources and the need to return to nature for new inputs.[265] Thus, the minimization, and in many cases abandonment, of the search for and use of natural genetic material in the wake of the enclosure regimes is harmful.

Finally, the present international norm of excessive enclosure of raw or little-improved genetic material by either the private sector or sovereigns forgoes the benefits of more open systems. Society benefits when certain places and goods, like thoroughfares, air, and information in the public domain, are available to all.[266] This holds particularly true when the resources in question, like genes and language, are building blocks. If the building blocks themselves are not accessible, people cannot build, and innovation is hampered.

In the case of genetic material, the open system that predated the CBD had numerous advantages. Samples of biological resources containing genetic material, such as seeds, soil, leaves, and animals, were freely exchanged both within and between nations. This widespread international sharing facilitated the conservation and improvement of genetic material, as well as fostered international scientific collaboration.

Some resources benefit from being shared, creating "a more, the merrier effect."[267] The more the resources are shared, the more they are preserved. Genetic resources are this type of good.[268] In contrast to engendering a tragedy of the commons, where a common resource is used to depletion, the sharing of genetic material under an open system increases the global genetic

[260] TEN KATE & LAIRD, *supra* note 65, at 302.

[261] Macilwain, *supra* note 24; Stone, *supra* note 52, at 974 ("reliance on laboratory-concocted 'designer genes' is reducing the need to scout up natural samples").

[262] Conversation between author and deputy director of the Genomics Institute, University of Illinois, Champagne-Urbana (Nov. 2001); Virginia Gewin, *While Industrial Agrobiotech R & D Falters, Opportunities in Plant Biology in the Public Sector Are Growing*, 419 NatureJobs 4, 5 (Oct. 10, 2002), *at* <http://www.naturejobs.com>.

[263] John Harte, *Land Use, Biodiversity, and Ecosystem Integrity: The Challenge of Preserving Earth's Life Support System*, 27 ECOLOGY L.Q. 929, 959 (2001).

[264] *Id.*

[265] PHARMACEUTICAL BIOLOGY, *supra* note 169, at 19–20.

[266] *See generally* BASLAR, *supra* note 19, at 40–41 (citing Roman belief that sharing certain basic resources would further the common interest); JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS 9–10, 119 (1996) (arguing that intellectual property regimes "can actually *slow down* scientific progress, *diminish* the opportunities for creativity, and *curtail* the availability of new products"); LAWRENCE LESSIG, THE FUTURE OF IDEAS (Vintage Books 2002) (2001).

[267] *See generally* Carol M. Rose, *The Several Futures of Property: Of Cyberspace and Folk Tales, Emission Trades and Ecosystems*, 83 MINN. L. REV. 129, 181–82 (1998).

[268] *See* Stone, *supra* note 44, at 597–98.

pool, as it ensures the maintenance of genetic material in multiple locations.[269] The open system that predated the expansion of intellectual property rights and sovereign rights over genetic material accounts for the widespread distribution and preservation of crops and crop varieties away from their places of origin.[270] The maintenance of genetic material in multiple countries and locations has benefited all. For example, under the open system, grape seedlings from France were brought to the United States.[271] Later a blight destroyed many French vineyards and the United States sent seedlings back to France.[272] Just as the American wine industry bases itself in part on grape seedlings from France, so the French wine industry bases itself in part on repatriated grape seedlings from the United States.

In addition, the open system produced *ex situ* international and national structures to conserve, share, and improve biological and genetic material. These included zoos and national collections of plant and other material. Such collections have facilitated the conservation of plants and animals as well as promoted research related to them.

The work of the Consultative Group on International Agricultural Research (CGIAR) constitutes an excellent example of the international conservation and collaborative activity that flourished under the open system. The CGIAR system consists of sixteen international research centers that hold and improve seed and other plant material collected from around the world.[273] Its purpose is to collect, conserve, improve, and facilitate the worldwide sharing of plant genetic resources for food and agriculture.[274] Breeders can request samples of seeds from the CGIAR system to breed crops that, for example, might resist a pest or blight, or use less water.[275] It is unlikely that as open a system of worldwide conservation and sharing of genetic material could be created anew in the present international environment of hyperownership. Indeed, in the aftermath of the CBD's adoption, the challenge has been to preserve the CGIAR system.[276]

The open system facilitated not only the conservation of genetic material in multiple places, but also the improvement of such material. For example, the semidwarf varieties of wheat and

[269] Stephen B. Brush, *Genetically Modified Organisms in Peasant Farming: Social Impact and Equity*, 9 IND. J. GLOBAL LEGAL STUD. 135, 157 (2001) ("Genetic resources retain their viability partly because they are shared so widely . . ."). An open system for genetic material does not harm the resource itself or appear to pose a great risk of overutilization. Genetic resources are renewable, largely abundant, and access to a limited sample of the resource generally satisfies research objectives.

[270] *Id.*

[271] *See generally* GEORGE ORDISH, THE GREAT WINE BLIGHT (1972).

[272] *Id.*

[273] Geoffrey Hawtin & Timothy Reeves, *Intellectual Property Rights and Access to Genetic Resources in the Consultative Group on International Agricultural Research*, *in* INTELLECTUAL PROPERTY RIGHTS III: GLOBAL GENETIC RESOURCES: ACCESS AND PROPERTY RIGHTS 41 (Steve A. Eberhart et al. eds., 1998). These centers are located in Colombia, Indonesia, Mexico, Peru, Syria, the Philippines, Kenya, India, the United States, Sri Lanka, Nigeria, Italy, the Netherlands, and Côte d'Ivoire. *Id.* at 53–54.

[274] *Id.* at 41; PEOPLE, PLANTS, AND PATENTS 92–93 (Crucible Group, 1994) (noting that the CGIAR holds the "world's largest international collection of crop and forest germplasm—more than 500,000 accessions. . . . The CGIAR has trained more than 50,000 agricultural researchers and has worked with national agricultural research services to feed at least 500 million people in the South who would not otherwise be fed.")

[275] PEOPLE, PLANTS, AND PATENTS, *supra* note 274, at 92 (the CGIAR centers make about "600,000 accessions and breeding lines . . . available free of charge to researchers every year, mostly in developing countries").

[276] *See generally* Hawtin & Reeves, *supra* note 273, at 41–42 (describing creation of CGIAR system in 1971 as outgrowth of the common heritage environment that allowed for the free collection and sharing of samples of genetic material, and challenge to CGIAR system of increased intellectual property rights and assertion of sovereign rights that marked the 1980s and 1990s). The renegotiation of the Undertaking, *supra* note 15, sought in part to preserve the international germ plasm system. The new PGR Treaty, *supra* note 57, that emerged from these negotiations succeeds in protecting the international germ plasm collections to a large extent. It also creates a limited open system for sharing a select group of plant genetic resources of core staple crops for food and agriculture. Such collections, however, no longer operate as openly as they once did. They are required to create detailed records on the source of new materials contributed, subject provided materials to certain conditions, and make their collections available only for certain purposes. The new PGR Treaty entered into force on June 29, 2004. As of that date, fifty-five nations had ratified the Treaty and fifty more had signed it. For a discussion of the Treaty, see Laurence R. Helfer, *Using Intellectual Property Rights to Preserve the Global Genetic Commons: The International Treaty on Plant Genetic Resources for Food and Agriculture*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (J. H. Reichman & Keith Maskus eds., forthcoming 2005).

rice that formed the bedrock of the Green Revolution were created from raw genetic material freely obtained from Japan.[277] These improved semidwarf varieties, in turn, were rapidly shared throughout the world thanks to the open system, which prevailed at that time.[278] Moreover, the open system facilitated informal collaboration between scientists of different countries, who could collaborate without having to clear their actions with national government authorities or worry about infringing upon a range of patents. They could also pursue genetic research in their own countries without navigating an extensive regulatory maze.

Notwithstanding its benefits, establishing a comprehensive open system for raw genetic material, even if it could be proved empirically desirable,[279] is unrealistic. Moreover, the present system of excessive enclosure of genetic material is unlikely to self-correct or at least to do so readily. First, too many believe that genetic material will produce windfall profits for developing countries or represent a justified reward for corporations. As Michael Heller and Rebecca Eisenberg noted, drawing upon the literature of psychology, individuals and entities tend to overstate the value of their contribution and such overstated beliefs are difficult to dislodge.[280] Second, groups, individuals, and interested civil society are unlikely to give up their right to control, or to have input into decisions on, whether access to genetic material should be granted to ameliorate anticommons problems. Third, the memory of the colonial experience makes developing countries particularly wary of permitting the extraction of resources without compensation. Fourth, in a time of declining foreign assistance budgets, tremendous pressure is being applied to find alternative funding sources for developing countries. The prospect of genetic gold or genetic petroleum may be too seductive to pass up entirely.

Finally, the developing country reaction described earlier was not only a product of perceived aggressive patenting in the genetics area, but also a response to the patenting of improved genetic material that took place in the wake of *Chakrabarty*.[281] If developed countries would place improved genetic material in the public domain, developing countries have maintained that they would completely open up access to raw genetic material within their borders.[282] Developed countries are not about to exclude all bioengineered organisms and improved genetic material from the patent grant, nor do I argue for such a step. Given this reality, implementation of a comprehensive open system for raw or little-improved genetic material is unrealistic at present.

To reach this conclusion does not mean that the international community should continue to pursue the present-day hyperownership approach to genetic material. Rather, part V suggests a framework of reciprocal intermediate steps to be taken by the United States and gene-rich developing countries that would reduce both private and sovereign enclosure of genetic material and move the global community toward a more open system. A thorough exploration

[277] PRINGLE, *supra* note 249, at 32, 40.

[278] Brush, *supra* note 269.

[279] The difficulty of empirically proving the benefits of open systems over closed ones is a classic problem. Despite the existence of patent laws for centuries, their comparative efficacy over public domain systems in promoting innovation has yet to be empirically proven. *See* WORLD BANK, KNOWLEDGE FOR DEVELOPMENT—WORLD DEVELOPMENT REPORT 1998/1999, at 34–35 (1999) (no systematic empirical evidence confirms the positive impact of intellectual property rights on increasing research and development; and while tighter intellectual property rights "may actually slow the overall pace of innovation," systematic empirical evidence proving this is similarly lacking); BOYLE, *supra* note 266 (pointing to lack of empirical proof that intellectual property rights in aggregate increase the overall amount of innovation); Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), THOMAS JEFFERSON, WRITINGS 1286 (Merrill D. Peterson ed., 1984), *available at* <http://www.temple.edu/lawschool/dpost/mcphersonletter.html> (noting that the lack of patent laws in other countries did not appear to reduce their comparative ability to innovate).

[280] Heller & Eisenberg, *supra* note 7; *see* Stone, *supra* note 52 (noting the general overvaluation of genetic resources).

[281] *See* notes 34–36, 45 *supra* and corresponding text.

[282] *See* PEOPLE, PLANTS, AND PATENTS, *supra* note 274, at 93–94 (noting position that raw material provided under the CGIAR system should be freely available only if improved varieties are made freely available); Odek, *supra* note 34. This position was repeatedly taken by many developing countries during the renegotiation of the International Undertaking on Plant Genetic Resources that took place between 1996 and 2001. (I participated in the negotiations as legal counsel to the U.S. delegation and personally heard such proposals.)

of each prong of this framework is beyond the scope of this article, whose purpose is limited to critically analyzing the current global situation of hyperownership over genetic material and to proposing an overall framework for reform.

V. A NOVEL FRAMEWORK FOR A MORE OPEN SYSTEM FOR GENETIC MATERIAL

A Call for "International Regarding" in U.S. Patent Policy on Biotechnology

U.S. patent law and its implementation are not ossified. A rich body of scholarship and ongoing debate have considered many aspects of the patent system. For example, scholars, Congress, the Patent and Trademark Office, and the courts have grappled with the questions of what ought to be patent-eligible subject matter,[283] how strictly or liberally to apply the requirements of patentability,[284] and what exceptions should be made to the patent grant.[285] The debate as to where and how the lines for patenting should be drawn has been particularly acute with respect to genetic material, and the system is still struggling to clarify the relevant ground rules.[286]

The determination by Congress, the PTO, and to a lesser degree the courts of whether, under what circumstances, and to what extent patents should be granted often has a policy component.[287] The touchstone for such policy determinations is whether and how patents will encourage or discourage innovation.[288] This touchstone flows from the utilitarian nature of patent law. As widely agreed, patents are granted to encourage innovation and should be granted only to the extent necessary to achieve that end.[289] Scholars and decision makers have at times considered various factors when ascertaining whether patents in certain areas encourage innovation. These include whether the particular area of innovation involves high research and development costs, the ease of imitation, and the availability of alternative incentives for innovation.[290]

This section argues that policy determinations on the patenting of genetic material in the United States should include an "international regarding" component, meaning that Congress, the PTO, and/or the courts should take into account the reaction of other countries when deciding as a policy matter whether to expand or restrict patent rights over genetic material in the United States.[291] They should consider the impact of this international reaction upon innovation.[292] At present, a vigorous discussion is being waged in the patent literature as to whether the PTO, Congress, or the courts serve as the best forum to air and act upon policy and

[283] *See* Burk & Lemley, *supra* note 95, at 1597; Gitter, *supra* note 7, at 1624–25; Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 VAND. L. REV. 2081, 2083–84 (2000); Dreyfuss, *supra* note 7, at 1; Epstein, *supra* note 7.

[284] *See* Burk & Lemley, *supra* note 95, at 1597; Eisenberg, *supra* note 283, at 2085–98; Gitter, *supra* note 7, at 1625; Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

[285] *See* Eisenberg, *supra* note 283; Gitter, *supra* note 7; Dreyfuss, *supra* note 7; Epstein, *supra* note 7.

[286] *See supra* notes 7, 9.

[287] Burk & Lemley, *supra* note 95, at 1668–96.

[288] *See* note 320 *infra; see, e.g.*, Brenner v. Manson, 383 U.S. 519 (1966) (majority and dissenting opinion each focus on the effect that setting the utility bar would have on innovation and disclosure of innovation, the majority holding that scientific development would be better served with a utility rule that did not allow the issuance of patents to processes that produced chemical compounds whose usefulness had not been shown and the dissent reaching the opposite conclusion).

[289] Burk & Lemley, *supra* note 95, at 1599; Mark A. Lemley, *Romantic Authorship and the Rhetoric of Property*, 75 TEX. L. REV. 873, 888–90 (1997) (pointing to innumerable court decisions, statutory provisions, and commentators for this proposition).

[290] *See generally* Burk & Lemley, *supra* note 95, at 1581–95.

[291] The international regarding calculus that I propose has application beyond the patenting of genetic material. A broader discussion of this issue is the subject of a separate law review article.

[292] The international regarding calculus that I propose should not be confused with the usual determinations of whether actions contemplated by the United States violate U.S. obligations under international law. *See, e.g.*, Graeme B. Dinwoodie & Rochelle Cooper Dreyfuss, *Preserving the Public Domain of Science Under International Law*, *in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (J. H. Reichman & Keith Maskus eds., forthcoming 2005) (discussing whether proposed cures to overpatenting in the genomics area would violate provisions of the TRIPS Agreement), *available at* <http://ssrn.com/abstract_id-478961>.

innovation considerations that bear on line drawing in the patent law area.[293] The Federal Circuit, which adjudicates patent cases, has shied away from expressly considering policy factors in its decisions.[294] Nonetheless, it has set different standards for patenting in the biotechnology area than in the software and mechanical areas.[295] The scope of this article does not extend to determining which branch of government is best suited for this function; rather, it seeks to add the international regarding dimension to the list of policy and innovation factors that merit consideration in patenting-policy decisions. The discussion below does offer examples of how each branch of government could take the reactions of other countries into account in this regard. Overall, inclusion of the international regarding component favors steps to create a more open system for genetic material.

The United States has spent considerable energy in pressing developing countries to promulgate patent systems similar to its own system.[296] Through the TRIPS Agreement, the United States has essentially required developing countries to protect U.S. biotechnological (and other) innovation and to internalize U.S. values and concerns.[297] Yet the United States has failed to acknowledge developing country concerns and the implications of such concerns for innovation in the interpretation and evolution of U.S. patent law. The policy discussion within the PTO, Congress, and, to the extent it takes place, the courts on whether, when, and to what extent the United States should extend patents to genetic material is largely an insular exercise.[298] Similarly, the ever-increasing body of literature questioning aspects of genomic patenting and proposing all sorts of interventions usually fails to take into account the reactions of other countries to U.S. line drawing in the genetics area.[299] To the extent that this literature references other countries' approaches or concerns, it tends to be limited to consideration of how other developed countries, particularly members of the European Union, treat genetic material, or addresses the different issue of whether U.S. policies and proposed interventions comply with the TRIPS Agreement.[300]

This omission is problematic because where the United States draws its lines with respect to the patenting of genetic material has repercussions on the availability of raw genetic material that contributes to biotechnological innovation. As explained earlier, enclosure of genetic material by the United States, particularly when it has been little improved, begets enclosure of raw genetic material by developing countries. The easier it is to patent genes in the United States, the harder it will be to obtain genetic samples that contribute to biotechnological innovation from genetically rich source countries. Because raw genetic material contributes to innovation, responsive enclosure by sovereigns to the liberal patenting of genetic material by the United States is likely to hinder innovation or at least cause it to rest at a suboptimal level.

Moreover, where the United States draws its lines with respect to the patenting of genetic material affects the general climate for scientific cooperation between developed and developing countries. Overall, liberal patenting of genetic material in the United States makes it more difficult for U.S. scientists to collaborate with scientists in developing countries. Enclosure laws in developing countries, promulgated in large part in response to the patenting of genetic material

[293] *See* Arti K. Rai, *Engaging Facts and Policy: A Multi-institutional Approach to the Patent System Reform*, 103 COLUM. L. REV. 1035 (2003).

[294] Burk & Lemley, *supra* note 95; Rai, *supra* note 293.

[295] Rai, *supra* note 293.

[296] *See supra* note 13.

[297] *Id.*

[298] Notable exceptions include Demaine & Fellmeth, *supra* note 2 (considering international resolutions on genetic patents in the human genome area), and, although not specifically in the genetics area, BOYLE, *supra* note 266; Margo A. Bagley, *Patently Unconstitutional: The Geographical Limitation on Prior Art in a Small World*, 87 MINN. L. REV. 679, 688–90 (2003) (arguing that U.S. should include foreign prior uses as patent-defeating prior art and asserting that the "[§]102 geographical limitation facilitates the 'pirating' of . . . genetic resources from developing countries, exacerbating feelings of ill will toward the United States for its hypocritical stance in this area").

[299] *See, e.g.*, Burk & Lemley, *supra* note 95; Rebecca S. Eisenberg, *Intellectual Property at the Public-Private Divide: The Case of Large-Scale cDNA Sequencing*, 3 U. CHI. L. SCH. ROUNDTABLE 557 (1996); Holman & Munzer, *supra* note 7, at 774; Dreyfuss, *supra* note 7; Epstein, *supra* note 7.

[300] *See, e.g.*, Gitter, *supra* note 7 (considering the patenting of human genetic material in the United States and the European Union); Dinwoodie & Dreyfuss, *supra* note 292.

in the United States, affect the ability of scientists in those countries to share information and material related to biotechnological innovation with U.S. scientists without obtaining government consent and arranging benefit-sharing agreements.[301]

The recent seven-year international exercise to renegotiate the International Undertaking for Plant Genetic Resources to promote global food security illustrates this problem. During the renegotiation of the Undertaking, developing countries repeatedly criticized the patenting of little-improved genetic material in the United States.[302] They asserted unwillingness to share genetic material from their countries and even objected to the sharing of genetic material held in international agricultural research centers, on the ground that such material, once shared, would be patented or "fenced in" by developed countries, especially the United States.[303]

Inclusion of an international regarding calculus when shaping patent law comports with the widely acknowledged utilitarian purpose of the patent system.[304] Its omission is inconsistent with that purpose. Any policy analysis into the innovative character of genetic patenting, and how standards for such patenting should be set and construed to maximize innovation, that omits the transnational variable as part of its calculus will yield incomplete and suboptimal conclusions. The justification for patenting isolated genes is to encourage the identification and disclosure of their functions.[305] Yet some of that allegedly innovation-promoting effect is offset by the responsive curtailment by source countries of access to a wealth of raw and, at times, unique genetic material that contributes to innovation in both genetics and biotechnology. While granting patents to little-improved genetic material might promote the discovery and disclosure of the functions of some genes in the short term, it may impede overall biotechnological innovation in the long run as researchers find themselves unable to obtain valuable genetic material in the wild.

How would the international regarding calculus that I propose work? I am not suggesting that patent examiners assess the foreign response to each and every patent application, or that federal courts entertain a host of potential foreign implications when adjudicating a wide range of patent infringement cases. An international regarding calculus would operate at the policy or line-drawing level. It should be included in the mix of factors to be taken into account and balanced against each other when making these policy determinations.[306]

For example, the Patent and Trademark Office could take international implications into account when exercising its discretion in setting the guidelines for patent examiners regarding genetic material.[307] The PTO's recent revision of the utility guidelines that it applies to biotechnological innovations and the attendant academic discourse illustrate the insularity of U.S. line-drawing activity, as well as demonstrate how international implications could have been considered. The granting by the PTO of patents to isolated naturally occurring genetic material where

[301] See, for example, the laws of India, Brazil, and the Andean Pact discussed *supra* in parts I and II.

[302] *See* note 282 *supra*.

[303] Indeed, one of the last terms of the renegotiated Undertaking that nations agreed upon was a provision limiting the ability of a breeder who obtained genetic material from the international system to patent such genetic material "in the form received." PGR Treaty, *supra* note 57, Art. 12.3(d). This term reflects the core concern of developing countries that freely given genetic material should not be enclosed. I believe the debate on this issue will continue as nations will likely disagree as to the meaning of "in the form received." Developed countries will understand this term to encompass genes isolated from germ plasm samples. Consistently with its practice of allowing the patenting of isolated genetic material, the United States will likely interpret this term as not encompassing genetic material isolated from received germ plasm since the material was not received in its isolated form. If genes isolated from germ plasm obtained from the international system are patented, one can expect less sharing of germ plasm and a retreat to enclosure.

[304] Burk & Lemley, *supra* note 95, at 1597 (citing, inter alia, John Shepard Wiley Jr., *Copyright at the School of Patent*, 58 U. CHI. L. REV. 119 (1991); Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–30 (1989); and a slew of Supreme Court cases).

[305] *See, e.g.*, Prada-Frank, *supra* note 204, at 654–55 (supporting patent protection for human genes as an incentive to improve health care).

[306] A detailed discussion and analysis of the precise way that an international regarding calculus would operate is the subject of a separate law review article. The discussion that follows provides an entry point into the concept and its implications.

[307] *See generally* Rai, *supra* note 293, at 1131–32 (pointing out the line-drawing function exercised by the U.S. PTO when it sets its guidelines, as well as the limits of its power).

the "inventor" had failed to identify a specific utility for that gene or gene fragment (so-called express sequence tags, or ESTs, which essentially serve as a research probe for the rest of the gene) generated considerable criticism.[308] That criticism alleged that the PTO had set the standard for utility too low in the genetic patenting area.[309] The PTO, critics argued, was issuing patents to genetic fragments or genes of little or no demonstrated use and such patents would chill research.[310] Interestingly, the extensive criticism leveled in the U.S. legal literature against a low utility bar and its innovation-inhibiting side effects did not reference international or transnational considerations that bolster these concerns.[311] In particular, it ignored the general hostility of source countries to the patenting of little-improved genetic material and the growing reaction engendered by that hostility.[312]

In response to this extensive criticism, the PTO revised the utility guidelines that it applies to the biotechnology area.[313] It posted interim guidelines in 1999 and received numerous comments on them.[314] Several comments reflected developing country concerns over the patenting of genes and genetic sequences.[315] Most specifically, one commentator argued that the PTO should not grant patents to ESTs because "it will exacerbate tensions between indigenous peoples and western academic/research communities and because it will undermine indigenous peoples' own research and academic institutions."[316] The PTO summarily rejected this comment, stating that "[u]nder United States law, a patent applicant is entitled to a patent when an invention meets the patentability criteria of title 35."[317] Other commentators raised the oft-mentioned objection of developing countries that genes are products of nature or in the alternative discoveries, which should not be eligible for patenting.[318] This objection was similarly brushed aside.

Obviously, the PTO administers U.S. law, but it enjoys a certain amount of latitude in interpreting and applying that law.[319] The PTO's discretion involves interpreting the statutory requirements for patentability of "utility," "novelty," and "nonobviousness." The legal literature that tries to shape these decisions focuses on the impact that a given line or standard will have on innovation.[320] The promulgation of new utility guidelines, in response to domestic criticism that the PTO was issuing patents for genetic sequences too liberally, which would deter rather than promote innovation, reflects this latitude. The United States engaged in a public discourse on where

[308] *See* Rebecca S. Eisenberg & Robert P. Merges, *1995 Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 AM. INTELL. PROP. L. ASS'N Q.J. 1 (1996); Eisenberg, *supra* note 299; Richard A. Epstein, *Property Rights in cDNA Sequences: A New Resident for the Public Domain*, 3 U. CHI. L. SCH. ROUNDTABLE 575 (1996) (arguing against the patenting of ESTs); Martin Enserink, *Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196, 1197 (2000); Elliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCIENCE 643 (1996). For an in-depth discussion of ESTs and the controversy surrounding them, see Holman & Munzer, *supra* note 7.

[309] *See* sources cited *supra* note 308; *see also* Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

[310] *See* sources cited *supra* notes 308, 309.

[311] *See* sources cited *supra* notes 308, 309.

[312] *See* sources cited *supra* notes 308, 309.

[313] U.S. Patent and Trademark Office, Examination Guidelines for the Utility Requirement, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001); Enserink, *supra* note 308.

[314] *See* 66 Fed. Reg. 1092 (Jan. 5, 2001).

[315] Several commentators urged that genes should not be patentable because they are discoveries, not inventions, or because they are products of nature or define something as basic as what it means to be a human being. *Id.* at 1092–93.

[316] Comment (6), *id.* at 1094.

[317] Response to comment (6), *id*.

[318] Comment (2), *id.* at 1093. For developing country concerns, see *infra* note 339.

[319] Burk & Lemley, *supra* note 95, at 1575, 1644–46, 1696; Merges & Nelson, *supra* note 284, at 840–41.

[320] *See, e.g.,* Burk & Lemley, *supra* note 95 (generally pointing to courts' discretion in implementing and interpreting patent law, specifically taking line drawing for the nonobviousness standard as an example); Holman & Munzer, *supra* note 7, at 774–814 (analyzing innovation-inhibiting or -promoting effects of granting or refusing patents to ESTs); Jacobs & van Overwalle, *supra* note 7; Merges & Nelson, *supra* note 284, at 840–68, 884–916 (PTO's discretion in determining patent scope and even broader discretion of courts in determining patent scope, and innovation-inhibiting or -promoting impacts of such determinations); Epstein, *supra* note 7, at 37–40, 51–57 (economic consequences of allowing patents on ESTs and genetic materials in general).

and how the lines should be drawn. That discourse, however, largely ignored or glibly closed the door to developing country concerns that bear on this line drawing, which it did not have to do. Arguments that granting patents to genes with little identified function deters innovation were bolstered by the contribution of such patents to a reciprocal spiral of increased enclosure of raw genetic material, also inhibiting innovation.[321]

Similarly, Congress could and should take the reactions of other countries into account when deciding whether and how to amend the patent statutes with respect to biotechnological innovations. Burk and Lemley point out that "[w]hile patent law has historically been uniform, with a single set of legal standards" to cover all types of innovation, Congress has increasingly demonstrated a willingness to tailor the law to meet the needs of particular industries.[322] Scholars have suggested numerous ways of tailoring the patent law to loosen or restrict standards in the biotechnology area.[323] These include proposals to relax the disclosure requirements or nonobviousness standards that apply to such patents or to restrict the scope of genetic sequence patents.[324] In fact, in 1995 Congress, ostensibly in an effort to help the biotechnology industry, lowered the nonobviousness bar for biotechnological processes,[325] making it easier to patent them. The merits of proposals to amend the patent statute and the compatibility of such proposals with the TRIPS Agreement are subject to debate.[326] However, should Congress again consider enacting biotechnology-specific legislation, it should take into account the likely reactions of other countries to such legislation. In particular, legislation that makes it easier to patent genetic material, especially little-improved genetic material, could fuel responsive enclosure by sovereigns over genetic material in their countries.

Like the PTO, courts have a certain amount of discretion in interpreting the words "utility," "nonobviousness," and "novelty." In addition, the courts, particularly the Supreme Court, serve as the primary arbiter of whether or not something constitutes a discovery of nature, which cannot be patented.[327] The U.S. patent statute gives little guidance with respect to the latter inquiry. In determining whether a gene constitutes an innovation or a discovery of a product of nature, courts could consider how other countries view this issue. They might also consider the extent to which other countries require improvement to an isolated gene when determining whether that gene overcomes the nonobviousness or utility hurdle. While the views of others should not necessarily be determinative,[328] they need not be ignored. They could perform a useful role in helping U.S. courts reach the best decision. Several Supreme Court justices have pointed to the benefits of considering the conclusions reached by other countries on issues similar to those confronted by the Court.[329] Justice Stephen Breyer, pointing to the human rights area, noted

[321] Its aggressive approach to patenting isolated the United States at the renegotiation of the International Undertaking for Plant Genetic Resources, as well as contributed to U.S. isolation at international discussions under the rubric of the Convention on Biological Diversity.

[322] Burk & Lemley, *supra* note 95, at 1631.

[323] *Id*. at 1632–33.

[324] *Id.* at 1633.

[325] 35 U.S.C. §103(b) (2000).

[326] Burk & Lemley, *supr*a note 95, at 1634–38; Dinwoodie & Dreyfuss, *supra* note 292.

[327] *See, e.g.,* Diamond v. Diehr, 445 U.S. 926 (1980) (determining that a computer algorithm could be patented); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (deciding that a collection of seeds was a product of nature).

[328] While not speaking to patent law in particular, Justice Antonin Scalia points to the dangers of using other countries' approaches to guide the decisions of U.S. courts. Antonin Scalia, *Keynote Address: Foreign Legal Authority in the Federal Courts,* 98 ASIL PROC. 305 (2004).

[329] *See, e.g.*, Sandra Day O'Connor, *Broadening Our Horizons: Why American Judges and Lawyers Must Learn About Foreign Law,* INT'L JUD. OBSERVER, June 1997, at 2 (stating that "American judges and lawyers can benefit from broadening our horizons" and explaining how her own experience on the Court has suggested that "we often have a lot to learn from other jurisdictions"); Sandra Day O'Connor, *Keynote Address,* 96 ASIL PROC. 348, 350 (2002) (suggesting that "conclusions reached by other countries and by the international community should at times constitute persuasive authority"); Stephen Breyer, *Keynote Address*, 97 ASIL PROC. 265 (2003) (expressing his own view of the relevance of other countries' approaches and citing Justices Ruth Bader Ginsburg, David Souter, and John Paul Stevens, who have also at times referred to comparative foreign experience). *But see* Scalia, *supr*a note 328 (criticizing, with several exceptions, the use of foreign materials in U.S. judicial decision making). *See also Agora: The United States Constitution and International Law*, 98 AJIL 42 (2004).

that it is especially beneficial when different countries apply somewhat similar legal phrases to somewhat similar circumstances.[330] Given the increasingly global nature of patent law by virtue of the TRIPS Agreement, which essentially internationalizes concepts of novelty, utility, and nonobviousness, consideration of other countries' approaches seems particularly appropriate. Its appropriateness is bolstered by the increasing international trade in patented goods and the tensions that can arise when an item is allowed to be patented in one country but not in another.[331]

What are the overall implications of an international regarding calculus for the patenting of genetic material? Let us consider two of the issues currently debated in the academic literature. The first involves the question mentioned in the preceding paragraph, whether patent rights should extend to little-improved genetic material or more generally to what some are calling discoveries close to the lab bench.[332] Some argue that patents should not be granted for little-improved genetic material, as it constitutes a discovery of nature.[333] Discoveries of nature, like Einstein's theory of relativity or the discovery of a plant or mineral, have traditionally been excluded from patent protection. Linda Demaine and Aaron Fellmeth argue that for a gene to warrant a patent, the inventor ought to have substantially improved it.[334] Isolating and purifying the gene and identifying its function are not enough. Those taking the opposite position argue that patents serve a useful role in encouraging the isolation and purification of genes into a useful form.[335] They further argue that patents have been granted for the isolation of chemical compounds, and that genes are simply a type of chemical compound.[336]

Some, while believing that the United States has issued patents over genetic material too liberally, are not prepared to go as far as Demaine and Fellmeth. They support the patenting of isolated genes, provided that the function of the gene has been identified so that the utility requirement is satisfied and the isolation and identification of the gene's function are not obvious in light of the prior art.[337] They would thus find naturally occurring genes eligible for patenting but argue for strict, rather than liberal, application of the patentability requirements of utility and nonobviousness.[338]

When one takes into account the international consequences of such line-drawing determinations, they argue against allowing the patenting of little-improved genetic material. In the alternative, they favor strict construction of the patent requirements in genetics, particularly with respect to utility and nonobviousness. First, the majority of countries in the world do not agree with the U.S. standards for the patenting of little-improved genetic material, finding them too lax. Many consider such material more akin to discoveries or products of nature.[339] Other developed countries, like the EU members and Japan, while permitting the patenting of genetic material, exempt from patent infringement experimental uses of such material, allow for the denial of this kind of patent on public policy grounds in certain situations, and apply slightly stricter patentability requirements.[340] Second, liberal patenting requirements in the United States,

[330] Breyer, *supr*a note 329, at 266.

[331] The import into the United States of a product that has been patented in the United States but not overseas constitutes infringement of the U.S. patent. 35 U.S.C. §271(a) (2000).

[332] *See generally* ADELMAN ET AL., *supr*a note 241, at 148; Rai, *supra* note 309, at 77.

[333] Demaine & Fellmeth, *supra* note 2.

[334] *Id.*

[335] *See* Eisenberg, *supra* note 9, at 119–20; Epstein, *supra* note 7, at 44–51.

[336] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991) (allowing patents over naturally occurring, yet isolated genes as akin to chemical compounds); Eisenberg, *supra* note 9, at 119–20; Epstein, *supra* note 7, at 44–51.

[337] *See, e.g.,* Burk & Lemley, *supra* note 95, at 1644–45, 1681–82; Eisenberg, *supra* note 299; Enserink, *supra* note 308; Epstein, *supra* note 7, at 51–57.

[338] *See, e.g., supra* note 326.

[339] GEOFF TANSEY, TRADE, INTELLECTUAL PROPERTY, FOOD AND BIODIVERSITY 8 (1999) (noting that many developing countries oppose the patenting of genetic material; examples include Argentina, Brazil, and the Andean Pact countries); Murphy, *supra* note 2 (making same point).

[340] *See supra* note 12.

which essentially enable greater private enclosure of genetic material, engender reciprocal enclosure of raw genetic material by sovereigns in gene-rich countries. To the argument that too many patents in upstream genetic materials deter innovation because researchers cannot use these discoveries for downstream applications,[341] an international regarding component adds that too many patents on upstream materials further deter innovation because the developing countries retaliate by making it difficult for researchers in the United States to obtain the raw genetic material that contributes to innovation.

International regarding also has some bearing on whether Congress should enact a broader experimental use exemption than currently allowed for genetic innovations in particular, or for research in general.[342] Such an exemption would allow researchers to use patented genetic material, including substantially improved genetic material, freely for research.[343] It could ameliorate some of the anticommons problems that currently stymie research in the United States. To these benefits, international regarding would add the benefit of enabling U.S. researchers to collaborate more easily with scientists overseas. Moreover, such an exemption could modestly improve the climate for a more open system for genetic material internationally. Genetically rich countries might respond to a broader experimental use exemption by similarly exempting research uses of raw genetic material from their enclosure regimes. Some already do so.

Congress and the U.S. Supreme Court have considered the approaches of other countries and the implications of those approaches when making certain decisions regarding the scope of intellectual property rights under U.S. law. In *Eldred v. Ashcroft*, the Supreme Court found that Congress's expansion of the copyright term by twenty years did not violate the constitutional restriction of those terms to "limited periods of time." According to the Court, Congress had not exceeded its constitutional authority by enacting the extension in part because it was seeking to harmonize U.S. copyright terms with those of the European Union.[344] If consideration of other countries' practices favors broader intellectual property rights in some cases, so do such practices, views, and their implications favor narrower construction of those rights in others. For the reasons mentioned above, genetic patenting appears to be such an area.

Overall, adding an international regarding component to the mix of factors that are considered for genomic patenting (1) lends support to construing the isolation and identification of genetic material as products of nature rather than patent-eligible subject matter, (2) supports high-utility and nonobviousness standards in the biotechnology field, and (3) supports an experimental use exemption. It generally favors the creation of a more open system for genetic material.

Were the practice of patenting isolated and identified genetic material stopped, the motivation of developing countries to assert commensurate ownership rights over raw genetic material in their countries would decrease. While such actions would not eliminate all the reasons that caused sovereigns to assert ownership rights over raw genetic material, they would create a more fertile environment for enhancing access to it.

[341] *See* notes 247–55 *supra* and corresponding text; *see also* Jacobs & van Overwalle, *supra* note 7 (arguing that patents should not be granted for DNA but only for downstream medical goods); Matthew Erramouspe, Comment, *Staking Patent Claims on the Human Blueprint: Rewards and Rent-Dissipating Races,* 43 UCLA L. REV. 961, 998 (1996) (arguing for stricter limits on gene patentability).

[342] *See* Dinwoodie & Dreyfuss, *supra* note 292, at 12–20; Gitter, *supra* note 7, at 1684–92 (in the context of human DNA sequences); Mueller, *supra* note 7. On experimental use or fair use generally, see Eisenberg, *supra* note 304; Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law,* 100 COLUM. L. REV. 1177, 1205 (2000).

[343] For a discussion of whether research exemptions comply with the TRIPS Agreement, see Dinwoodie & Dreyfuss, *supra* note 292, at 12–20.

[344] Eldred v. Ashcroft, 537 U.S. 186, 188, 206 (2003). According to the official summary:

> A key factor in the [expansion of the copyright term] was a 1993 European Union (EU) directive instructing EU members to establish a baseline copyright term of life plus 70 years and to deny this longer term to the works of any non-EU country whose laws did not secure the same extended term. By extending the baseline United States copyright term, Congress sought to ensure that American authors would receive the same copyright protection in Europe as their European counterparts.

Reducing Sovereign Enclosure of Genetic Material

As stated earlier, internationally, the appropriateness and desirability of sovereign ownership or extensive control of raw genetic material represents the prevailing wisdom. However, just as fluidity can be found in the patent system vis-à-vis how much and under what circumstances patents should extend to genetic material, so, too, can fluidity be found in the international system vis-à-vis how much control sovereigns should extend over raw genetic material and under what circumstances. Many nations have already adopted laws and rules governing access to genetic material within their borders, but even more are doing so. In addition, debate and the implementation of guidelines on access and benefit sharing regarding genetic material are taking place under the auspices of the Convention on Biological Diversity.[345] The meaning of the CBD's terms and the manner of their implementation are evolving.[346] Opportunity therefore exists for shaping the laws, rules, and guidelines that define sovereign enclosure of raw genetic material.

As discussed earlier, establishment of a comprehensive open system for raw genetic material is not realistic; but that does not mean the international community should continue to pursue an aggressive sovereignty approach. Instead, this article suggests three intermediate steps that would reduce sovereign enclosure of raw genetic material and move the global community toward a more open system for such material. The first step would flip the current normative assumption of enclosure with nonenclosure as the exception, to a norm of nonenclosure with sovereign enclosure as the exception. The second step involves two key considerations for determining when sovereign enclosure is more justifiable and when less so. The third step calls for a shift in sovereign focus from stressing the obtainment by developing countries of remuneration for raw genetic material to stressing their opportunities to add value to such material.

A flip in the normative assumption of sovereign enclosure. The first step would reverse the normative assumption with respect to sovereign enclosure of genetic material. Today, the global community begins with the assumption of enclosure[347] and has to justify nonenclosure. This norm is reflected in Article 15(7) of the CBD, which requires the prior informed consent of the source country, unless it provides otherwise. The recent negotiation of the International Treaty on Plant Genetic Resources for Food and Agriculture exemplifies this current state. Nations began their discussion of access to these resources for food and agriculture by broadly asserting state sovereignty over them.[348] Having done so, they then spent seven grueling years developing distinct carve-outs for a more open system.[349] Enclosure is the rule. Access is the exception.

Instead, nations and international work addressing access to genetic material should begin with the normative assumption of an open system and then justify sovereign ownership or enclosure.[350] In this respect, such a system of sovereign enclosure would resemble the patent system. Despite its excesses, the patent system assumes that most information falls within the public domain. Those seeking a patent have to justify enclosure by proving that they have met the requirements of novelty, nonobviousness or inventiveness, and utility.[351] They must also disclose

[345] See the Web site of the CBD, <http://www.biodiv.org>, for a list of the various working groups and expert panels on access to genetic resources and benefit sharing. *See also* Report of the Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Doc. UNEP/CBD/COP/6/20, at 254 (2002) (setting up international guidelines for access and benefit sharing).

[346] *See* Jeffrey, *supra* note 16 (the meaning of the CBD's terms will evolve over time). *See generally* Melinda Chandler, *The Biodiversity Convention: Selected Issues of Interest to the International Lawyer,* 4 COLO. J. INT'L ENVTL. L. & POL'Y 141 (1993) (noting the general ambiguity of the CBD's terms and provisions).

[347] Raustiala & Victor, *supra* note 13, at 295.

[348] PGR Treaty, *supra* note 57, Art. 10 (which begins by proclaiming sovereign rights over plant genetic resources and then tries to create a more open system).

[349] *Id.*, Arts. 10–13,15, 16; *see also A Treaty on Plant Genetic Resources,* AGRICULTURE 21 (Dec. 2001), *available at* <http://www.fao.org/ag/magazine/0112sp3.htm> (discussing the seven years of difficult negotiations).

[350] Such a change in international assumption would not necessarily require an amendment to the CBD because the Convention allows countries to refrain from asserting sovereign rights. CBD, *supra* note 39, Art. 15(7).

[351] 35 U.S.C. §§101–103 (2000); TRIPS, *supra* note 13, Art. 27(1).

their innovation to the public.[352] In addition, unlike sovereign ownership rights, the patent grant is of limited duration so that, after a prescribed period of time, the innovation enters the public domain.[353] Admittedly, the bar for patenting raw or little-improved genetic material has been set too low, and this author and others believe that such patents have been granted wrongly.[354] However, the debate over whether, under what circumstances, and to what extent a patent should apply to genetic material operates within a system that makes the applicant justify enclosure against an overall ethos of openness or public domain.[355] This is an appropriate starting point for sovereigns as they confront the as-yet untapped, and to a large extent unidentified, value of the genetic resources within their borders.

When sovereign enclosure is justifiable and when it is less so. Were a flip in the normative assumption adopted, the question of what circumstances would or would not justify sovereign enclosure or ownership would become more pronounced. What is enclosed? What remains open? This question brings us to the second part of my proposed approach: two key considerations to determine when sovereign enclosure is more justifiable and when it is less so.

The first consideration would avoid, to the extent possible, the balkanization of property interests in a given *res*. It would argue against the assertion of a sovereign ownership interest distinct from the ownership interest of the tangible property that houses the genetic material in question. Under this consideration, the owner of a frog would own that particular frog's genetic material. Thus, the frog's owner could freely alienate that frog and its genes as he or she pleases. The owner would not have to obtain the national government's consent or remit a portion of any proceeds to the government as compensation for its ownership interest in the frog's genetic makeup. Similarly, the owner could refuse to alienate the frog or its genetic material without raising the prospect of being seen as obstructing the sovereign's ownership interest in that material.

The same would hold true for property interests secured by indigenous communities, which have struggled and continue to struggle for rights over land and resources.[356] In some cases they have succeeded in obtaining such rights. Canada, for example, recently decided to vest indigenous groups with considerable natural resources.[357] To the extent that an indigenous community obtains such rights, they should not be encumbered by the national sovereign's assertion of a residual or newly imposed ownership interest in the genetic component of those resources. Under the nonbalkanization approach, an indigenous community would enjoy the same right to alienate or to object to the alienation of the genetic component of its resources as it has to alienate the resource that contains that material. A nonbalkanization approach would eliminate the risks to human autonomy and dignity discussed earlier. It would also reduce, if not eliminate, anticommons pressure by vesting the owner of the resource that houses the genetic material with full ownership rights over the genetic component of the resource and the commensurate right to consent to its extraction.

Before the adoption of the Convention on Biological Diversity, scholars engaged in debate over who should own raw genetic material. Some argued that ownership should vest with sovereigns as being in the best position to negotiate lucrative deals for raw genetic material.[358] It was further argued that, if sovereigns owned genetic material, they would have an incentive to conserve it.[359]

[352] 35 U.S.C. §112; TRIPS, *supra* note 13, Art. 29.

[353] The usual term for a patent is twenty years from the time of application. 35 U.S.C. §154(a)(2); TRIPS, *supra* note 13, Art. 33.

[354] *See supra* notes 7, 308, 309.

[355] In the United States, the conception of the patent as an exception to the general concept that ideas form part of the public domain finds vivid expression in the writings of Thomas Jefferson, who characterized patents as an "embarrassment." Letter from Thomas Jefferson, *supra* note 279. The Supreme Court, in *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989), reiterated that patents are an exception to the general rule that information should form part of the public domain.

[356] *See supra* note 167.

[357] *See supra* note 171.

[358] *See* Odek, *supra* note 34, at 175–76 (citing JACK R. KLOPPENBURG & DANIEL L. KLEINMAN, THE USE AND CONTROL OF PLANT GENETIC RESOURCES 171, 194, 199 (1988)).

[359] Raustiala & Victor, *supra* note 13, at 289.

Others contended that indigenous communities should own genetic material, as they were the ones who had traditionally conserved it.[360] Still others believed that individuals should own genetic material.[361] Not surprisingly, when sovereigns negotiated the answer to this question internationally, they effectively claimed the ownership interest or its core right—the right to exclude—for themselves. This article suggests that the answer to the question of ownership of raw genetic material should have been: whoever owns the *res* that contains the genetic material. The owner will differ in different situations.

Applying the nonbalkanization consideration, sovereign enclosure would be justified where the sovereign owns the tangible property that houses the genetic material. Public parks exemplify this situation. Because of their pristine or special nature, these areas are likely to contain unique genetic material. The discovery in Yellowstone National Park of *thermus aquaticus*, a heat-resistant bacterium with extensive commercial application, serves as an example.[362] In addition, bioprospecting in national parks, in comparison to other areas, is less likely to raise anticommons and individual autonomy problems. Because the national government owns the park and its resources, multiple consents need not be secured. Similarly, alienating resources in such a situation would not ordinarily infringe on the rights of individuals or indigenous communities, as they do not have an ownership interest in the property that houses the material.[363] Moreover, given the nexus between the bioprospecting activity and the park, sums received from that activity might have a greater chance of being used for conservation connected with the park or with a national system of protected areas than sums received from bioprospecting that is unconnected with an established conservation effort.[364]

If national governments marketed their parks or public lands for their bioprospecting potential, these sites should appeal to commercial concerns. In view of the lack of overlapping multiple ownership interests, they would offer the advantage of uncontested property rights to the genetic material obtained. By the same token, they should involve a lesser administrative burden than prospecting on nongovernment land. Indeed, if national access regimes sought to facilitate bioprospecting in national parks and on public land, they could create an attractive alternative to the regulatory maze that currently deters corporations from venturing into many countries. Both the United States and Costa Rica have successfully adopted such an approach. The Diversa Corporation entered into an agreement with the U.S. National Park Service to prospect in Yellowstone National Park.[365] Costa Rica has entered into multiple agreements with corporations to provide them with genetic samples taken exclusively from public lands.[366]

A second consideration in determining the justifiability of sovereign enclosure would involve an assessment of the likely economic benefits and costs of an access-restricting regime. For example, in deciding how much genetic material to enclose, governments would assess the abundance of a genetic resource or class of genetic resources. Governments ought not to waste scarce regulatory and enforcement resources in attempting to capture the value of genetic material available in multiple countries. The numerous sources of supply decrease the likelihood that provision of such material will prove lucrative. In addition, enforcement problems can be expected to prove more difficult, as any given genetic sample could have come from a multitude of countries. Finally, conflicts between countries are likely to arise over identification of the source country of the various genes. In contrast, sovereign enclosure would be more justified where the country is home to unique or rare genetic material. As with all genetic material, while the

[360] Odek, *supra* note 34, at 175–76.

[361] Raustiala & Victor, *supra* note 13.

[362] For a discussion of this discovery, see Adair, *supra* note 16.

[363] Were indigenous communities living in such parks, the situation would be more complex.

[364] Sums received from bioprospecting in national parks in both Costa Rica and the United States have been used to promote conservation activities.

[365] Columbia Access Paper, *supra* note 32, at 61.

[366] Correspondence between Sabrina Safrin and legal counsel of the Instituto Nacional de Biodiversidad (INBIO) (Feb. 2004) (on file with author); *see, e.g.*, TEN KATE & LAIRD, *supra* note 65, at 253–57 (describing Diversa-INBIO agreement); Columbia Access Paper, *supra* note 32, at 18 (describing Merck-INBIO agreement).

likelihood is slim that unique or rare material would yield a commercially lucrative product, at least any value derived from it would not be further eroded by the presence of multiple suppliers or conflicting claims and contests between nations.

Similarly, governments should assess the suitability of certain classes of genetic material for enclosure. For example, access to plant germ plasm for food and agriculture has traditionally yielded rather low returns.[367] Many have said that the costs of regulating access, in terms both of the creation of a regulatory system and of the opportunity cost of less innovation in developing new foods, exceed the potential proceeds from any access regime over agricultural genetic resources.[368] Such genetic material, therefore, does not appear particularly well suited to enclosure.[369]

This consideration represents a tailored or selective approach to enclosure. Malaysia has adopted such an approach. In 1994 one of Malaysia's states, Sarawak,[370] passed legislation requiring written authorization from the director of forests before the removal of any tree or extract from a tree from Sarawak for research aimed at developing pharmaceutical or medicinal compounds.[371] This legislation adopted an uncommonly tailored approach. It covers only trees and then only with respect to their use in pharmaceutical or medicinal compounds.

A selective or tailored approach has usually not been favored on the grounds that one can never anticipate for certain which gene might prove valuable.[372] Thus, observers have criticized Malaysia's tailored approach.[373] This criticism has apparently led, at least in part, to consideration by Malaysia's national government of broader national legislation that would require bioprospectors to obtain a national government license for "all activities relating to prospecting, collection, research, utilisation and development of genetic resources."[374] At present, the prevailing response to uncertainty is to control or enclose most genetic material. Such an approach, however, does not take into account the administrative cost of omnibus control. Similarly, it fails to take into account the chilling effect of comprehensive regimes on informal exchanges between local and foreign scientists. While a selective approach would leave some genetic material that might ultimately prove valuable unenclosed, it would enable more successful regulation of access to the genetic material that is enclosed.

Would a selective approach address the anticommons and human autonomy risks that I have raised? It would not rectify these problems directly, but it might do so indirectly. If a government enclosed less, it would reduce the administrative burden of total enclosure and enable it to husband and focus its administrative and enforcement resources. It could do a better job of creating a system where the consent of material stakeholders is efficiently secured before a bioprospecting project goes forward. Moreover, because selective regimes would target the resources most likely, though not certain, to hold value, they might attract bioprospecting projects that are more lucrative, hence better able to support the costs of securing the consent of multiple stakeholders. Tailored, efficient systems would probably do a better job of attracting bioprospecting projects than the omnibus, burdensome systems currently in place and under way. In addition, because under a selective approach the national government would enclose less genetic material, a smaller

[367] Brush, *supra* note 269, at 135 (agricultural bioengineered products are less profitable than bioengineered organisms in the pharmaceutical and chemical industries); Fowler, *supra* note 16, at 487.

[368] *See, e.g.,* Fowler, *supra* note 16, at 487.

[369] The PGR Treaty, *supra* note 57, creates a more open system for plant genetic resources for core staple crops for food and agriculture. This model may warrant repetition in other areas, such as some human genetic resources.

[370] Malaysia has a strong federal system comprising thirteen states, each with its own legislature and extensive powers over natural resources. KERRY TEN KATE & ADRIAN WELLS, BENEFIT-SHARING CASE STUDY: THE ACCESS AND BENEFIT-SHARING POLICIES OF THE UNITED STATES NATIONAL CANCER INSTITUTE: A COMPARATIVE ACCOUNT OF THE DISCOVERY AND DEVELOPMENT OF THE DRUGS CALANOLIDE AND TOPOTECAN 18 (1998). Access to genetic resources within Malaysia is regulated as much by the states as by the federal government. Bioprospecting activities in Malaysia will often require both federal and state approval. *See generally id.* at 18–20.

[371] Forests Ordinance of Apr. 1994, §65A(b), *reprinted in* TEN KATE & WELLS, *supra* note 370, at 19 n.50.

[372] TEN KATE & WELLS, *supra* note 370, at 20; Stone, *supra* note 51, at 992 (discussing uncertainty of determining which gene will prove valuable). He does not propose a comprehensive approach.

[373] TEN KATE & WELLS, *supra* note 370, at 20 (suggesting that observers have made such criticism).

[374] *Id.* at 19–20 (quoting the proposed amendment). The proposal under consideration remains somewhat tailored in that it excludes plants and microbial genetic resources from its scope. *Id.* It also applies only to foreigners.

universe of material and stakeholders would face anticommons and human autonomy and dignity problems. The problems, in short, would exist under a selective approach but to a lesser extent than under the prevailing comprehensive enclosure systems.

Value-added approach. The third step of my proposed approach involves a change in focus by national governments and the international community from one that stresses the obtainment of remuneration by developing countries for genetic material in its raw state to one that stresses opportunities for developing countries to add value to such material. Conceptually, this change in focus would be patterned not on a model of an export commodity like petroleum but, rather, on a value-added industry such as eco-tourism. Eco-tourism has enabled countries to generate revenue in connection with the preservation of natural resources. It represents perhaps the best example of the sustainable use of natural resources, whereby countries generate revenue from nature without destroying it. To attract tourists, nations must conserve the natural environment that the tourists come to enjoy. They generate revenue by providing value-added services in connection with the tourist industry, ranging from lodging, to transportation, food, entertainment, and guides. Eco-tourism requires countries to take a proactive approach, as they must develop and provide infrastructure and services for the tourist industry, as well as market their country as an eco-tourist destination.

Several commentators have noted the benefits of value-added approaches to bioprospecting.[375] Under these approaches, source countries do not obtain remuneration simply by providing access to raw genetic material. Rather, they provide services in connection with such material or otherwise add value to it.[376] For example, a source country or an institution in that country can add value to raw genetic material by offering assaying services for such material.

Costa Rica is the country must often cited for the successful regulation of access to genetic material.[377] In contrast to most gene-rich developing countries, Costa Rica has concluded multiple benefit-sharing arrangements with corporations. It has adopted a value-added approach to genetic material and created a national organization, INBIO, to provide initial assaying services for raw genetic material. Under benefit-sharing arrangements with corporations like Merck and Diversa, the corporations make lump-sum up-front payments to INBIO and agree to pay royalties in the event a downstream product is developed. INBIO, rather than the corporations or their agents, searches for potentially valuable genetic material and gives the corporations a selection of such material. Costa Rica's approach also includes the nonbalkanization model, as INBIO conducts its bioprospecting solely on public lands where genetic material is not subject to multiple ownership rights.[378] Following the value-added model of eco-tourism rather than the commodity export model of oil, Costa Rica has successfully and affirmatively marketed itself as an attractive place to obtain assayed genetic material.[379]

INBIO's agreement with Merck is the most heralded and often-cited bioprospecting agreement.[380] It was concluded prior to the adoption of the CBD and inspired countries to include terms on access to genetic resources in the Convention, as it served as the primary example of the value of genetic resources and their money-making potential.[381] Unfortunately, the subtler aspects of the Costa Rican approach, which stress adding value to raw genetic material and limiting collection to public lands, are not reflected in the CBD or the numerous national laws that

[375] *See* BIODIVERSITY PROSPECTING, *supra* note 34; Reid, *supra* note 257, at 62; Seiler & Dutfield, *supra* note 54, at 110.

[376] Reid, *supra* note 257, at 62–63; Seiler & Dutfield, *supra* note 54, at 110.

[377] Costa Rica's agreement with Merck is mentioned in most articles or books that deal with access and benefit sharing regarding genetic resources. *See, e.g.*, BIODIVERSITY PROSPECTING, *supra* note 34; TEN KATE & LAIRD, *supra* note 65; Adair, *supra* note 16; Asebey & Kempenaar, *supra* note 16; Shayana Kadidal, Note, *Plants, Poverty and Pharmaceutical Patents*, 103 YALE L.J. 223 (1993); Locke, *supra* note 126, at 84; Columbia Access Paper, *supra* note 32, at 18 (Merck-INBIO is probably the most famous of access and benefit-sharing arrangements); Seiler & Dutfield, *supra* note 54.

[378] Correspondence between Sabrina Safrin and INBIO legal counsel, *supra* note 366.

[379] *See* INBIO Web site, <http://www.inbio.ac.cr/>.

[380] *See supra* note 375.

[381] *Id.; see also* Raustiala & Victor, *supra* note 13, at 289.

have emerged in its wake. Rather, both the CBD and the laws that it inspired are based on the faulty assumption that genes are a resource like oil, which can and should be comprehensively controlled to generate windfall profits. The framework proposed above argues against this assumption and suggests a set of concrete steps for considerably narrower sovereign enclosure of genetic material.

VI. Conclusion

Both the patent system and the sovereign-based system have overreached in permitting or asserting ownership rights to genetic material. This article has shown that the sovereign-based system (1) is or risks creating an anticommons in raw genetic material, (2) threatens the liberty and autonomy of individuals and indigenous communities whose property contains such material, and (3) is premised on a flawed approach in international law leading to broad and unenforceable regimes that will increase tensions between developed and developing nations and may set off a major TRIPS dispute. Meanwhile, the overprivatization of genetic material through the patent system is or, at a minimum, risks creating an anticommons in genetic material that inhibits innovation.

These twin systems of hyperownership interact in a corrosive fashion. Sovereigns, in response to the patenting of genetic material, have been enclosing genetic material. Corporations and research institutions, in turn, are avoiding potentially valuable bioprospecting opportunities or pursuing such opportunities at suboptimal levels. In response, developing countries are tightening their control over genetic material by using the patent system to enforce their access-restricting regimes. This article predicts that corporations and research institutions will further avoid interactions with genetically rich countries.

This reciprocal spiral of increased enclosure of genetic material hinders the eventual enjoyment, by citizens of both economically developing and developed nations, of the as-yet largely unrealized potential of these resources. It generates tensions between nations and threatens individuals and indigenous communities. It diminishes opportunities to conserve, expand, and improve the global genetic pool.

To repair this situation, this article has suggested a bilateral framework of steps to be taken by the United States and by gene-rich developing countries that would reduce both private and sovereign enclosure of genetic material and create a more open system. It proposes that the United States take into account or internationally regard the adverse reaction of other countries, particularly developing countries that are rich in genetic diversity, when determining as a utilitarian matter whether and, if so, to what extent to allow patents for genetic material. Expansive patent rights can ultimately cause innovation in the biotechnology field to fall to suboptimal levels because they cause sovereigns in the world's most genetically diverse nations to curtail access to the raw genetic material that contributes to such innovation. Application of an international regarding calculus therefore argues for measures to limit the patenting of genetic material and thus to create a more open system for such material.

For their part, gene-rich developing countries and those engaged in international work involving access to genetic resources should take steps to reduce sovereign enclosure of genetic material. First, they should change their normative assumption of sovereign enclosure and nonenclosure as an exception, to the reverse. Second, they should avoid severing the ownership interest in genetic material from the ownership interest in the property containing the material and should adopt more selective approaches to enclosure. Third, they should focus on value-added approaches to enable their countries to benefit from genetic material.

The earlier paradigm in international law, an open system in which genetic resources were readily shared by all and exclusively owned by no one, while far from perfect, was not without its advantages. Rather than continuing their companion hyperownership approaches, developed and developing countries, as well as those conducting international work on genetic resources issues, should strive to achieve a more open system.