NatAgLaw@uark.edu · (479) 575-7646

An Agricultural Law Research Article

# Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge

By

Charles R. McManis

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# Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge

## Introduction

Charles R. McManis*

This symposium volume is composed of five articles that were originally presented as papers at a conference, held at Washington University School of Law on April 4–6, 2003, on the general topic, "Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge,"[1] as well as a concluding article in which I discuss an important post-conference development here at Washington University School of Law. Like the conference itself, these articles address the three general topics that are implicit in the title of the conference and this symposium volume.

### BIODIVERSITY: WHAT ARE WE LOSING AND WHY—AND WHAT IS TO BE DONE?

The first article, by Jim Chen, was presented at the first session of the conference, the topic for which was "Biodiversity: What Are We Losing and Why—and What Is to Be Done?" In this Article, "Across the Apocalypse on Horseback: Imperfect Legal Responses to

* Thomas and Karole Green Professor of Law; Director, Intellectual Property & Technology Law Program.

1. For the conference agenda, video clips, and conference papers, see http://law.wustl.edu/centeris/pastevents/biodivsp02.html

Biodiversity Loss," Professor Chen, who is on the law faculty at the University of Minnesota, notes that although biodiversity loss has reached apocalyptic proportions, neither legal responses to the crisis nor the accompanying legal scholarship address the distinct sources of human influence on evolutionary change. In an effort to remedy at least the scholarly gap, Chen notes that the engines of extinction can be described in equine terms, beit as the four horsemen of the ecological apocalypse—habitat destruction, overkill, introduced species, and secondary extinctions—or in terms of Edward O. Wilson's acronym, HIPPO, derived from the Greek word for horse: *H*abitat destruction, *I*nvasive species, *P*ollution, *P*opulation, and *O*verharvesting.[2]

According to Professor Chen, the problem with current national and international environmental efforts is that they address the causes of biodiversity loss in precisely the reverse order of their current relative significance—focusing more attention on the primary cause of diversity loss in Paleolithic times—namely over-harvesting of large and endangered mammalian and avian life—than on wide-scale habitat destruction, which was first set in motion by the rise of Neolithic agriculture and the spread of sedentary human settlements across much of the globe and is now the leading cause of biodiversity loss. Having explained how the law has failed to keep pace with the scientific understanding of biodiversity loss, Chen suggests a modest agenda for meaningful legal reform. First, he proposes that international policymakers develop a joint framework for the regulation of commercial bioprospecting (the topic of the final session of the conference). Second, he proposes that the international community facilitate the professionalization of "parataxonomy," especially in the developing world, by enlisting indigenous and local communities in the labor-intensive task of classifying the millions of species that currently inhabit the globe. Chen concludes by reminding us that *in situ* preservation of ecosystems remains the only effective way to save biodiversity, and that the academic community has a singularly immense responsibility to educate the public on the importance of realigning environmental law with the scientific

2. *See* EDWARD O. WILSON, THE FUTURE OF LIFE 50–51 (2002).

understanding of biodiversity loss, a task, he notes, that promises its own epiphany—a more spiritually satisfying understanding of the biosphere at its fullest and most diverse.

## AGRICULTURAL BIOTECHNOLOGY: PART OF THE SOLUTION OR PART OF THE PROBLEM—OR BOTH?

The second article, by Neil D. Hamilton, was presented at the second session of the conference, the topic for which was "Agricultural Biotechnology: Part of the Solution or Part of the Problem—or Both?" In his article, "Forced Feeding: New Legal Issues in the Biotechnology Policy Debate," Professor Hamilton, who is on the law faculty at Drake University Law School and is Director of its Agricultural Law Center, provides an update on the legal and policy issues shaping America's approach toward agricultural biotechnology, the role biotechnology will play in the world's food and agricultural systems, and how policy and law will be asked to shape that future. In so doing, he builds on an earlier article of his, entitled "Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms."[3] Since the publication of that article, at least five new developments suggests that such an update is in order—the StarLink controversy, an ultimately unsuccessful ballot referendum in Oregon to mandate labeling of GM food products, the decision on the part of the U.S. Food and Drug Administration (FDA) not to require such labeling, as well as its restrictions on the ability to label food as being free of GMOs, the continuing, indeed escalating, conflict between the U.S. and the European Union over European resistance to accepting unlabeled GM foods, which is now before a World Trade Organization dispute settlement panel,[4] and the growing controversy

3. Presented at a meeting of the American Agricultural Law Association in St. Louis in 2000, 6 DRAKE J. AGRIC. L. 81 (2001), and later receiving the AALA's Award of Excellence for Professional Scholarship.

4. *See* WTO DS 291, http://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm#2004. On May 20, 2003, one month after the Washington University conference, the U.S. filed a formal request for consultations with the WTO; on March 3, 2004, the U.S. requested the establishment of a dispute panel. A panel decision is expected by the end of June 2005.

over pharma-crops—that is, traditional commodity crops that have been genetically modified to create traits and products with pharmacological value.

In the United States, at least, Professor Hamilton believes that the future for agricultural biotechnology is relatively bright. Whether it remains so, says Hamilton, depends on how the legal issues in eight separate categories play out: (1) The sudden injection of the U.S.-EU conflict over labeling of GM products into a potentially inflammatory international debate over the role of GM products in combating famine in sub-Saharan Africa; (2) continuing consumer acceptance of GM foods and acquiescence in the FDA's decision not to require labeling of GM foods, voter resistance to state ballot initiatives such as the one unsuccessfully mounted in Oregon in 2002, and resolution of continuing consumer and scientific concerns over the use of gene-altered fish and mammals for food production; (3) the fallout from the StarLink controversy, which simultaneously exposed serious regulatory inadequacies in the approval of a corn product for feed but not food purposes, a rather cavalier attitude on the part of seed companies and farmers with respect to the use of GMOs, and a tendency on the part of the agricultural biotech industry to try to shift legal liability for such debacles onto producers; (4) the more recent debate over pharma-crops, and the potential risks of contamination that such crops create with respect to the food crops and products; (5) the impact of the Supreme Court decision confirming that utility patents are available for plant varieties,[5] as well as lower court rulings upholding the enforceability of contracts on seed product labeling restricting the ability of purchasers to save and replant seeds; (6) the continuing debate over pollen drift and liability for contamination; (7) the resolution of international GMO disputes, such as the pending dispute between the U.S. and the E.U.; and (8) the effectiveness of resistance management regulations designed to prevent the development of pest resistance to bio-pesticides by requiring farmers to set aside acreage for the planting of non-GMO refuges for pests. Professor Hamilton concludes that, unless some new incident raises new safety concerns, the U.S. marketplace will

5. J.E.M. Ag Supply v. Pioneer Hi-Bred Int'l, Inc., 534 U.S. 124 (2001).

continue to welcome GM foods, but the tension between the U.S. and E.U. will continue to cloud prospects on the international front.

## TRADITIONAL KNOWLEDGE: WHAT IS IT AND HOW (IF AT ALL) SHOULD IT BE PROTECTED?

The third article, by Stephen B. Brush, was presented at the third session of the conference, the topic for which was "Traditional Knowledge: What Is It and How (if at All) Is It to Be Protected?" In his article, "Protecting Traditional Agricultural Knowledge," Professor Brush, who is on the faculty of the Department of Human and Community Development at the University of California-Davis, discusses whether the protection of traditional agricultural knowledge, particularly in cradle areas of crop domestication, evolution and diversity (Vavilov Centers), where plant genetic resources have customarily been treated as common pool resources, according to a set of practices loosely labeled as "common heritage," is best accomplished through a form of bioprospecting that replaces common pool management with a system of private ownership that is in line with the principle of national sovereignty over genetic resources enunciated in the Convention on Biological Diversity. Specifically, Professor Brush addresses two issues relating to the demise of the common heritage regime: (1) What role does common heritage play in the management of crop genetic resources; and (2) What steps are available to protect crop genetic resources in the public domain and to recognize the stewardship of farmers who maintain those resources?

In his article, Professor Brush first explains what is meant by Vavilov Centers, why they are important, and how crop genetic resources have been diffused from these original cradles of origin. Next, he discusses how, historically, common heritage has been the implicit system for managing the diffusion of crop genetic resources, from the informal movement of crops in prehistoric times to the formal national and international framework of crop exploration and conservation agencies exemplified in the international network of agricultural research organizations, called the Consultative Group for International Agricultural Research (CGIAR), the U.N. agency known as the Food and Agricultural Organization (FAO), and the

FAO's now superceded 1983 International Undertaking on Plant Genetic Resources for Food and Agriculture. Next, he discusses the role of traditional agricultural knowledge and innovation in the common heritage regime and in the promotion of *in situ* conservation of crop genetic resources, followed by a discussion of the closing of the genetic commons, with the promulgation of the Convention on Biological Diversity in 1992, followed by the establishment of the World Trade Organization, which was given authority to implement and enforce, among other international trade agreements, the new Agreement on Trade-Related Aspects of Intellectual Property Rights. Finally, he discusses the recent resurgence of common heritage as the underlying principle of a new international framework for managing access to crop genetic resources, the new FAO International Treaty for Plant Genetic Resources for Food and Agriculture, which was negotiated in 2001, and has now been signed by over seventy-nine countries, including the U.S., and went into force on June 29, 2004.

As Brush explains, while states retain sovereign rights over their genetic resources, including the right to designate genetic material and whole plants as intellectual property, the core provisions of the Treaty place the resources of thirty-six genera of crops and twenty-nine genera of forages in the public domain and guarantee access to these resources for breeding and research. Germplasm from the multilateral system will be available under the terms of a Material Transfer Agreement that may include provisions for benefit sharing in the event of commercialization. The Treaty states that "[r]ecipients shall not claim any intellectual property or other rights that limit facilitated access to plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System." It also specifies a procedure for benefit sharing by stipulating that commercialization of a new plant variety will trigger a financial contribution to the multilateral system. However, the level, form, and conditions of payment is not resolved in the Treaty itself and will be subject to further negotiations within the governing body of the Treaty. Brush also notes that the Treaty moves away from an initial strategy of creating binding international resolution to create Farmers' Rights, as a counterweight to internationally recognized Breeders' Rights, as the Treaty states that realizing Farmers' Rights rests with national governments, while

admonishing national governments to do so through measures that will promote (a) the protection of traditional knowledge relevant to plant genetic resources for food and agriculture; (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture. Brush concludes by examining two models for implementing Farmers' Rights at the national level and identifying weaknesses in the FAO Treaty itself in failing to set out obligations of industrialized and developing countries alike to support conservation of crop resources beyond funds raised in connection with commercializing improved crop varieties.

## ETHNOBOTANY AND BIOPROSPECTING: THINK GLOBALLY, ACTING LOCALLY

The next two articles in this volume were presented at the fourth and final session of the conference, the topic for which was: "Ethnobotany and Bioprospecting: Thinking Globally, Acting Locally." These two articles respectively provide a summary of the latest global thinking and a discussion of an international effort to provide affordable legal representation for traditional knowledge holders and other potential clients in the developing world to ensure an equitable sharing of the benefits of genetic resources and traditional knowledge utilized in local ethnobotanical and bioprospecting research activities. My own concluding article will describe a second complementary effort to provide affordable legal representation for traditional knowledge holders and other potential clients in the developing world.

The first article, entitled "From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent," by Dr. Nuno Pires de Carvalho, who is Deputy Director and Head of the Industrial Property Section, Economic Development (Intellectual Property Law) Sector, of the World Intellectual Property Organization (WIPO), offers the latest global thinking on the protection of traditional knowledge. In his article, Dr. Carvalho

builds on an earlier article, "From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?"[6] in which he argued that the road is not so tortuous or obstacle-strewn as is commonly believed, that various other elements of indigenous knowledge might be protected by resorting to the traditional mechanisms of intellectual property, such as copyright and related rights, patents, trademarks, geographical indications and trade secrets, but that it also might be possible to develop a *sui generis* regime of protection of the contents of indigenous knowledge databases, which would provide effective protection of indigenous knowledge and yet would permit their holders to describe and register their knowledge in its entirety, without the need to disaggregate it. The purpose of the present article is to take stock of what has been done since 1999 to build the road that the shaman will walk from his hut to the patent office, examining the evolution of legal concepts and strategies providing for effective protection of traditional knowledge, with particular reference to the work of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

Specifically, Carvalho first provides a working definition of traditional knowledge (TK), discusses the economic importance of TK, and it spells out the different economic and non-economic reasons that should compel governments to look at the issue of TK protection seriously. Next, he examines and evaluates measures taking a "defensive" approach to the protection of TK, that is, those attempting to prevent third parties from unwarrantedly claiming rights to elements of TK. As he explains, those measures can be of two types. The first would be to collect and organize elements of TK in databases in a manner so as to permit their retrieval by patent and trademark examiners to take TK into consideration as prior art or otherwise as bars to registration when examining patent applications and trademark registrations. The second would be to establish a requirement that patent applicants disclose the origin of genetic resources and evidence of the prior informed consent of TK holders where genetic resources and/or TK were utilized as a starting point

6. Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office: How Long and Winding is the Road?*, 41 REV. ABPI [Brazilian Association of Intellectual Property] 3 (1999).

for the inventive process—a requirement that Carvalho has discussed in more detail in an article published in a previous volume of this Journal.[7] Next, Carvalho examines and evaluates various measures taking a "positive" approach to the protection of TK, that is, those enabling TK-holders to assert exclusive, property rights. Here, too, he notes that governments have thus far taken two different paths: some have utilized traditional mechanisms of intellectual property in order to protect some elements of TK; other governments have preferred to establish a *sui generis* legal regime adapted to the special characteristics of TK. In the final two parts of his article, Carvalho concludes that while the construction roads from the shaman's hut to the national patent office are well advanced in some places, there is still some major construction work to be done, the most important task being the construction of roads across national borders. Accordingly, Carvalho identifies three essential standards that an international treaty on the protection of TK should contain so as to achieve international coherence and yet permit contracting countries to keep a certain level of freedom at the national level. He also inventories various existing international treaties, finding only one, surprisingly the United Nations Convention to Combat Desertification, to provide a useful existing framework for discussing the legal protection for TK.

The article entitled "Answering the Call: Public Interest Intellectual Property Advisors," by Michael A. Gollin, who is a practicing patent attorney with the Venable Law Firm in Washington, D.C., offers a salient example of how intellectual property lawyers might "act locally" to contribute to the legal protection of traditional knowledge, and in that way, to the preservation of biodiversity. In this article, Gollin discusses an organization established by an international association of concerned individuals, including Gollin himself, called Public Interest Intellectual Property Advisors (PIIPA),[8] which has been incorporated as a non-profit, tax-exempt global *pro bono* initiative to provide intellectual property-related

7. Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications Without Infringing the TRIPS Agreement: The Problem and The Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000).

8. *See* http://www.piipa.org.

legal services for governments, agencies and research organizations in developing countries and other public interest clients. In Part I of his article, Gollin describes the growing need for intellectual property-related legal and professional assistance for developing countries, and in the public interest. In Part II, he discusses how PIIPA was founded and organized to address these needs. In particular, he discusses how PIIPA will pursue its principal goal of improving access to intellectual property services through two basic activities: (1) Matching prospective clients with professionals able to provide intellectual property services, including counseling, negotiation, protecting intellectual property, and challenging intellectual property rights; and (2) strengthening intellectual property counseling and management resources in developing countries through training, monitoring, and collaborative arrangements. Gollin also discusses how PIIPA proposes to deal with the legal, ethical and political dimensions involved in these two basic activities. In Part III, Gollin addresses the on-going development of PIIPA, including illustrative cases, current challenges, such as developing criteria for screening potential clients and IP professionals, and developing a funding strategy, and concludes with a discussion of future directions.

This volume concludes with a brief article of my own, designed as a companion piece to foregoing article by Michael Gollin, and is entitled "Answering the Call: The Intellectual Property & Business Formation Legal Clinic at Washington University." In this article, I describe a complementary example of how intellectual property legal clinics such as the one recently established here at Washington University can "act locally," in conjunction with Michael Gollin's Public Interest Intellectual Property Advisors, to provide legal protection for traditional knowledge holders and promote the preservation of biodiversity.

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# Across the Apocalypse on Horseback: Imperfect Legal Responses to Biodiversity Loss

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# Across the Apocalypse on Horseback: Imperfect Legal Responses to Biodiversity Loss

Jim Chen*



> *I looked, and there was a pale green horse. Its rider was named Death, and Hades accompanied him. They were given authority over a quarter of the earth, to kill with sword, famine, and plague, and by means of the beasts of the earth.*[1]

## I. HEARING THE HOOVES OF THE ECOLOGICAL APOCALYPSE

Life on earth overcomes mass extinction events on a temporal scale spanning millions of years. By this measure, "the loss of genetic and species diversity" is probably the contemporary crisis "our

* Associate Dean for Faculty and James L. Krusemark Professor of Law, University of Minnesota Law School <chenx064@maroon.tc.umn.edu>. This paper benefited from a faculty workshop on April 17, 2003, at the University of Minnesota Law School. Daniel A. Farber, Alexandra Glynn, Gil Grantmore, Jamie A. Grodsky, David McGowan, and Susan M. Wolf provided helpful comments. Special thanks to Kathleen Chen.

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1. *Revelation* 6:8 (New American Bible).

descendants [will] most regret" and "are least likely to forgive."[2] Biodiversity loss is the "scientific problem of greate[st] immediate importance for humanity."[3] If indeed biodiversity loss has reached apocalyptic proportions, it is fitting to describe the engines of extinction in equine terms. Jared Diamond characterizes the deadly horsemen of the ecological apocalypse as an "Evil Quartet" consisting of habitat destruction, overkill, introduced species, and secondary extinctions.[4] Edward O. Wilson prefers an acronym derived from the Greek word for horse. HIPPO represents *H*abitat destruction, *I*nvasive species, *P*ollution, *P*opulation, and *O*verharvesting.[5] Although conservation biologists have identified the leading causes of biodiversity loss, legal responses to the crisis do not address distinct sources of human influence on evolutionary change. Not surprisingly, legal scholarship tends to ignore the distinctions among causes of biodiversity loss. This Article takes a modest step toward remedying at least the latter shortcoming.

Such "environmental and land-use ethics" as are codified in law today stem from an "era when the human population, at one-tenth its present size, tamed wilderness with axe and ox."[6] Before the rise of Neolithic agriculture and the spread of sedentary human settlements across much of the globe, Wilson's deadly HIPPO took the reverse sequence: OPPIH. The transmogrification of OPPIH to HIPPO over time frames the human impact on evolution in historical as well as biological terms. In Paleolithic times, the overharvesting of large mammals and flightless birds had a greater ecological impact than what was then "a still proportionately small amount of habitat destruction."[7] In North America, for instance, the sudden

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2. *Toward a Lasting Conservation Ethic: Hearing Before the S. Comm. on Envtl. Pollution*, 97th Cong. 366 (1981) (statement of Edward O. Wilson, Baird Professor of Science, Harvard University).

3. EDWARD O. WILSON, THE DIVERSITY OF LIFE 254 (1992).

4. *See* Jared Diamond, *"Normal" Extinctions of Isolated Populations*, *in* EXTINCTIONS 191 (Matthew H. Nitecki ed., 1984); Jared Diamond, *Overview of Recent Extinctions*, *in* CONSERVATION FOR THE TWENTY-FIRST CENTURY 37, 39–41 (David Western & Mary C. Pearl eds., 1989).

5. *See* EDWARD O. WILSON, THE FUTURE OF LIFE 50–51 (2002).

6. David Tilman, *Causes, Consequences and Ethics of Biodiversity*, 405 NATURE 208, 210 (2000).

7. WILSON, *supra* note 5, at 50.

disappearance of large mammals such as mammoths and ground sloths 11,000 to 12,000 years ago, after the continent's megafauna had survived twenty-two glacial cycles, strongly suggests that this mass extinction was attributable to "blitzkrieg."[8] The settlement of Polynesia, beginning 3,500 to 3,000 years before the present, introduced three domesticated species of Eurasian provenance—pigs, dogs, and chickens—that simultaneously dictated the arc of economic development on each island and spelled doom for many of the islands' endemic species.[9] Today, "the principal cause of biodiversity loss is the fragmentation, degradation, and destruction of ecosystems and habitats through conversion of land to economically productive uses, especially agriculture, forestry, mineral and fossil fuel extraction, and urban development."[10]

Thanks to a pair of prominent controversies over the constitutionality of endangered species protection under federal law,[11] most jurists and legal scholars understand, at a minimum, the utilitarian rationales for protecting biodiversity.[12] The law fails, however, to calibrate its remedies according to the severity of the biological threat. Perversely enough, the legal understanding of

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8. *See* Jared M. Diamond, *Quaternary Megafaunal Extinctions: Variations on a Theme by Paganini*, 16 J. ARCHEOLOGICAL SCI. 167 (1989). *See generally* QUATERNARY EXTINCTIONS (Paul S. Martin & Richard G. Klein eds., 1984). The extent to which human colonization affected the ecology of North America is fiercely debated. *See, e.g.*, TIM FLANNERY, THE ETERNAL FRONTIER (2001); SHEPARD KRECH III, THE ECOLOGICAL INDIAN (1999); TED STEINBERG, DOWN TO EARTH (2002).

9. *See* JARED DIAMOND, GUNS, GERMS, AND STEEL 60 (1997). The enduring prominence of the words for pigs, dogs, and chickens in the Hawaiian language—*pua'a*, *'īlio*, *moa*—pays linguistic homage to the centrality of animal husbandry in Polynesian culture before European contact. For further discussion of the effects of European contact on island culture, see SALLY ENGLE MERRY, COLONIZING HAWAI'I 221–42 (Sherry B. Ortner et al. eds., 2000); PATRICK VINTON KIRCH, ON THE ROAD OF THE WINDS (2000).

10. Bradley C. Karkkainen, *Biodiversity and Land*, 83 CORNELL L. REV. 1, 7 (1997) (internal citations omitted).

11. *See* Gibbs v. Babbitt, 214 F.3d 483 (4th Cir. 2000); Nat'l Ass'n of Home Builders v. Babbitt, 130 F.3d 1041, 1053 (D.C. Cir. 1997). *See generally* Christine A. Klein, *The Environmental Commerce Clause*, 27 HARV. ENVTL. L. REV. 1 (2003); Bradford C. Mank, *Protecting Intrastate Threatened Species: Does the Endangered Species Act Encroach on Traditional State Authority and Exceed the Outer Limits of the Commerce Clause?*, 36 GA. L. REV. 723 (2002); John Copeland Nagle, *The Commerce Clause Meets the Delhi Sands Flower-Loving Fly*, 97 MICH. L. REV. 174 (1998); Omar N. White, *The Endangered Species Act's Precarious Perch: A Constitutional Analysis Under the Commerce Clause and the Treaty Power*, 27 ECOLOGY L.Q. 215 (2000).

12. *See generally* WILSON, *supra* note 3.

extinction mechanisms remains frozen in time, like an insect in amber or, more appropriately, a cave dweller in ice. The legal enterprise of preventing extinctions is likelier to succeed if it addresses the most powerful causes of biodiversity loss today. Habitat destruction and alien invasive species should figure more prominently than overkill in the law of biodiversity protection.

As the balance of this Article will show, however, the few laws that do address biodiversity loss take primary aim at overkill and the marketing of products derived from endangered species. Part II of this Article describes how the law seeks to preserve biodiversity by deterring overkill, habitat destruction, and the introduction of alien invasive species. The law imposes its clearest and harshest sanctions precisely where the drivers of extinction are weakest: when humans take conscious steps to capture or kill other living things. Part III concludes that the lack of congruence with conservation biology impedes legal efforts to preserve biodiversity.

## II. HORSE-WHIPPED: LEGAL RESPONSES TO VECTORS OF BIODIVERSITY LOSS

### *A. Overkill*

The Edwardian excess of Joseph Conrad's *Heart of Darkness*[13] retains its firm grip on the conservationist imagination. The 1916 treaty at issue in *Missouri v. Holland*,[14] perhaps one of the first legal enactments in the United States (or anywhere else in the world) to treat biodiversity conservation as "a national interest of very nearly the first magnitude,"[15] focused exclusively on "the killing, capturing or selling . . . of . . . migratory birds."[16] At a certain level, we have never recovered from witnessing the spectacular slaughter of the Carolina parakeet and the passenger pigeon.[17] These birds,

13. JOSEPH CONRAD, HEART OF DARKNESS (1902).
14. 252 U.S. 416 (1920).
15. *Id.* at 435.
16. *Id.* at 431.
17. At least with respect to the passenger pigeon, this is true in a very tangible sense. By eliminating the principal predator of ticks in northern forests, the extermination of the passenger pigeon may be fairly blamed for the recent prominence of Lyme disease. *See* David E. Blockstein, *Lyme Disease and the Passenger Pigeon?*, 229 SCIENCE 1831 (1998); David E. Blockstein,

respectively the only parrot native to North America and what is thought to have been not only the most abundant bird but also the most abundant terrestrial vertebrate, became extinct at the Cincinnati Zoo four years apart. Martha, the last passenger pigeon, died on September 1, 1914; Incas, a male Carolina parakeet and the last of his kind, died on February 21, 1918.[18] The paradigmatic act of converting wildlife to personal property through capture and slaughter[19] remains the central focus of laws designed to protect endangered species. In the United States, section nine of the Endangered Species Act of 1973 (ESA)[20] flatly prohibits the taking of any protected species.[21] "The term 'take' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct."[22] Section nine so unequivocally condemns the harvesting of protected organisms that few if any litigated ESA cases discuss this aspect of the statute. One of the most prominent reported cases involving an attempt to harvest a member of a protected species actually arose under the Marine Mammal Protection Act of 1972[23] rather than the ESA.[24]

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*Passenger Pigeons, Lyme Disease, and Us*, BIRDING, Aug. 2001, at 302. *See generally* A. W. SCHORGER, THE PASSENGER PIGEON (1955).

18. *See* CHRISTOPHER COKINOS, HOPE IS THE THING WITH FEATHERS (2000); SCOTT WEIDENSAUL, THE BIRDER'S MISCELLANY (1991). *See generally* ERROL FULLER, EXTINCT BIRDS (1987). For a celebrated account of how Incas "died of grief" after the death of his mate, Lady Jane, see George Laycock, *The Last Parakeet*, AUDUBON, Mar. 1969, at 21. That these two extinctions coincided with what was then the most extravagant exercise in human slaughter is perhaps more prophetic than coincidental.

19. *See* Pierson v. Post, 2 Am. Dec. 264, 3 Cai. R. 175 (N.Y. Sup. Ct. 1805); Liesner v. Wanie, 145 N.W. 374, 376 (Wis. 1914) (awarding ownership to the hunter who fires the shot that mortally wounds a hunted animal); Young v. Hichens, 115 Eng. Rep. 228, 230 (Q.B. 1844) (Denman, C.J., dissenting) (proposing to award possession where a fisherman has attained "actual power over the fish"); *cf.* Geer v. Connecticut, 161 U.S. 519, 529–31 (1896) (recognizing the traditional police power of the states over hunting and fishing). *See generally* 2 WILLIAM BLACKSTONE, COMMENTARIES *391 (describing common law precedent before the nineteenth century on the ownership of wild animals); Dhammika Dharmapala, *An Economic Analysis of "Riding to Hounds":* Pierson v. Post *Revisited*, 18 J.L. ECON. & ORG. 39 (2002).

20. Pub. L. No. 93-205 § 9, 87 Stat. 884, 893–95.

21. 16 U.S.C. § 1538 (2000).

22. *Id.* § 1532(19).

23. 16 U.S.C.S. §§ 1361–1421h (2005).

24. *See* United States v. Hayashi, 22 F.3d 859 (9th Cir. 1993). *But see* United States v. McKittrick, 142 F.3d 1170 (9th Cir. 1998) (upholding ESA penalties levied against a rancher who shot and decapitated a gray wolf).

The Endangered Species Act reveals an overt bias, preventing direct takings of large, charismatic fauna over all other threats to biodiversity. The Act excludes certain insects from its protective aegis,[25] even though they are essential to human welfare: if "land-dwelling arthropods . . . were to disappear, humanity probably could not last more than a few months."[26] Moreover, even though "[t]he biological differences between animals and plants . . . offer no scientific reason for lesser protection of plants,"[27] the Act significantly undervalues plants.[28] Threatened and endangered plants are protected only insofar as they appear on federal land or are destroyed in knowing violation of state law.[29] Plants receive far fewer critical habitat designations than do threatened and endangered animals.[30] In so doing, the ESA perpetuates the common law's baneful treatment of plants as private property merely because they dwell on private land.[31]

Traffic in goods derived from endangered species remains the single act of biodiversity destruction on which international law has reached a punitive consensus. The Convention on International Trade in Endangered Species (CITES),[32] now in its fourth decade, would

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25. *See* 16 U.S.C. § 1532(6) (2000) (excluding from "[t]he term 'endangered species' . . . a species of the Class *Insecta* determined . . . to constitute a pest whose protection . . . would present an overwhelming and overriding risk to man").

26. WILSON, *supra* note 3, at 133. *See generally* THE NEW ENCYCLOPEDIA OF INSECTS AND THEIR ALLIES (Christopher O'Toole ed., 2003). On the concept of ecosystem services, see generally NATURE'S SERVICES (Gretchen C. Daily ed., 1997); PEAST PANEL ON BIODIVERSITY & ECOSYSTEMS, TEAMING WITH LIFE (1999); Graciela Chichilnisky & Geoffrey Heal, *Economic Returns from the Biosphere*, 391 NATURE 629 (1998); Janet S. Herman et al., *Groundwater Ecosystems and the Service of Water Purification*, 20 STAN. ENVTL. L.J. 479 (2001); H. A. Mooney et al., *Biodiversity and Ecosystem Functioning*, *in* GLOBAL BIODIVERSITY ASSESSMENT 275, 282 (V.H. Heywood & R.T. Watson eds., 1995); James Salzman, *Valuing Ecosystem Services*, 24 ECOLOGY L.Q. 887 (1997); Barton H. Thompson, Jr., *People or Prairie Chickens*, 51 STAN. L. REV. 1127, 1136–37 (1999).

27. NAT'L RESEARCH COUNCIL, SCIENCE AND THE ENDANGERED SPECIES ACT 90 (1995).

28. *See* Sandra B. Zellmer & Scott A. Johnson, *Biodiversity in and Around McElligot's Pool*, 38 IDAHO L. REV. 473, 481–82 (2002).

29. *See* 16 U.S.C. § 1538(a)(2)(B) (2000).

30. *See* Conservation Council for Hawaii v. Babbitt, 2 F. Supp. 2d 1280, 1281 (D. Haw. 1998) (noting that critical habitat designations covered only twenty-four of approximately seven hundred plant species listed in 1998).

31. *See* Holmes Rolston III, *Property Rights and Endangered Species*, 61 U. COLO. L. REV. 283, 293 (1990).

32. Convention on Int'l Trade in Endangered Species of Wild Fauna & Flora, Mar. 3–Apr. 30, 1973, 20 U.S.T. 1087, 993 U.N.T.S. 243.

represent a major step toward conserving biodiversity as long as one is willing to overlook the fact that it does not work. The extension of CITES during the 1980s to "all aspects of trade and research" in orchids "immediately increased the desire for the plants, raised their market value dramatically, and led to even more collecting of rare orchid species from the wild."[33] Nothing in CITES stops developers and farmers who would "flood [critical] habitat with a hydroelectric dam, log it, level the hillsides of a road, build a golf course on the site, or burn the jungle to the ground for agricultural purposes."[34] Not surprisingly, "no reliable data [show] that CITES and similar efforts ha[ve] reduced smuggling, saved any orchid species from extinction, helped protect orchid habitats, or even salvaged orchid plants facing . . . certain destruction."[35] Controlled harvests for profit outperform direct regulation under CITES in deterring the poaching of elephants.[36] As with the American alligator,[37] the elephant's salvation may lie in commercialization. The focus on politically visible but environmentally secondary acts of overkill and commercial exploitation has rendered CITES tragically impotent.

### *B. Alien Invasive Species*

In an increasingly interconnected world,[38] human ecological mismanagement often takes the form of introducing an invasive species.[39] "[M]ost invasions have a weak impact," but on occasion

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33. ERIC HANSEN, ORCHID FEVER 67 (2000).

34. *Id.* at 17.

35. *Id.* at 262–63.

36. *See* EDWARD BARBIER ET AL., ELEPHANTS, ECONOMICS AND IVORY 132–38 (1990); FRANCES CAIRNCROSS, COSTING THE EARTH 132–41 (1992); Michael J. Glennon, *Has International Law Failed the Elephant?*, 84 AM. J. INT'L L. 1 (1990).

37. *Cf.* Gibbs v. Babbitt, 214 F.3d 483, 495 (4th Cir. 2000) (noting the successful recovery of the American alligator from the United States endangered species list in 1975 to a return to a contemporary market for its hides); Catharine L. Krieps, *Sustainable Use of Endangered Species Under CITES: Is It a Sustainable Alternative?*, 17 U. PA. INT'L ECON. L. 461, 479–80 (1996) (describing the creation of a market in alligator products as a spur for the conservation of alligators and their habitats). *See generally* SARA J. SCHERR ET AL., MAKING MARKETS WORK FOR FOREST COMMUNITIES (2002); *Pulp Friction*, ECONOMIST, Mar. 16, 2002, at 80.

38. *See, e.g.*, Theodore C. Foin et al., *Improving Recovery Planning for Threatened and Endangered Species*, 48 BIOSCIENCE 177, 180–81 (1998); David S. Wilcove et al., *Quantifying Threats to Imperiled Species in the United States*, 48 BIOSCIENCE 607, 608–09 (1998).

39. *See generally* GEORGE W. COX, ALIEN SPECIES IN NORTH AMERICA AND HAWAII

"an invasive species [is] capable of precipitating monumental changes to an ecosystem."[40] For example, introducing the Nile perch into Lake Victoria devastated endemic cichlids.[41] Exotics have suppressed or eliminated native, often endemic, species in the Everglades, the Great Lakes, the Hawaiian Islands, and Guam.[42] Starlings, a scourge to many native birds, entered North America by virtue of a single man's perverse obsession with importing all birds mentioned by Shakespeare.[43] Feral cats, perhaps 100 million strong, constitute "a non-native predator that is creating havoc for certain native [bird] species" in the United States.[44] Barnacles, mollusks, worms, and hydroids leaving warmer seas on a flotilla of wooden fragments and buoyant pumice threaten the integrity of Arctic and Antarctic waters.[45]

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(1999); CHARLES S. ELTON, ECOLOGY OF INVASIONS BY ANIMALS AND PLANTS (1958); MARK WILLIAMSON, BIOLOGICAL INVASIONS (1996); Andrew N. Cohen & James T. Carlton, *Accelerating Invasion Rate in a Highly Invaded Estuary*, 279 SCIENCE 555 (1998); David M. Lodge, *Biological Invasions: Lessons for Ecology*, 8 TRENDS ECOLOGY & EVOLUTION 133 (1993); M. Jake Vander Zanden et al., *Stable Isotope Evidence for the Food Web Consequences of Species Invasions in Lakes*, 401 NATURE 464 (1999).

40. Kevin Shear McCann, *The Diversity-Stability Debate*, 405 NATURE 228, 232 (2000). *See generally* Mark Williamson & Alastair Fitter, *The Varying Success of Invaders*, 77 ECOLOGY 1661 (1996).

41. *See* TIJS GOLDSCHMIDT, DARWIN'S DREAMPOND (Sherry Marx-Macdonald trans., 1996); Peter N. Reinthal & George W. Kling, *Exotic Species, Trophic Interactions and Ecosystem Dynamics: A Case Study of Lake Victoria*, *in* THEORY AND APPLICATION IN FISH FEEDING ECOLOGY 296 (Deanna J. Stouder et al. eds., 1994).

42. *See, e.g.*, ROBERT DEVINE, ALIEN INVASION (1998); WILLIAMSON, *supra* note 39, at 77, 142–43, 145–48; Julie A. Savidge, *Extinction of an Island Forest Avifauna by an Introduced Snake*, 68 ECOLOGY 660 (1987); Don C. Schmitz & Daniel Simberhoff, *Biological Invasions*, ISSUES IN SCI. & TECH., Summer 1997, at 33; Eric Biber, Note, *Exploring Regulatory Options for Controlling the Introduction of Non-Indigenous Species to the United States*, 18 VA. ENVTL. L.J. 375, 380 (1999).

43. *See* ANNIE DILLARD, PILGRIM AT TINKER CREEK 37 (1974) (recounting the story of Eugene Schiffelin); *cf.* WILLIAM SHAKESPEARE, THE FIRST PART OF KING HENRY THE FOURTH, act I, sc. 3, ll. 218–24, *in* THE OXFORD SHAKESPEARE 453, 459 (Stanley Wells & Gary Taylor eds., 1988) ("[The king] Forbade my tongue to speak of Mortimer; / But I will find him when he lies asleep, / And in his ear I'll hollo 'Mortimer!' / Nay I'll have a starling shall be taught to speak / Nothing but 'Mortimer,' and give it him / To keep his anger still in motion."). Efforts to reverse the damage by exterminating starlings have failed. *See* DILLARD, *supra*, at 38–39.

44. James Gorman, *Bird Lovers Hope to Keep Cats on a Very Short Leash*, N.Y. TIMES, Mar. 18, 2003, at F3.

45. *See generally* David K. A. Barnes, *Biodiversity: Invasions by Marine Life on Plastic Debris*, 416 NATURE 808 (2002).

As overall biological diversity decreases, the environmental impact of invasive species will probably increase. If "simplified communities are more vulnerable to invasion," then "we should also expect an increase in frequency of successful invaders as well as an increase in their impact."[46] Repeated cycles of extirpation and invasion, whether intentional or inadvertent, "can, and eventually will, invoke major shifts in community structure and dynamics."[47] In this game of ecological roulette, the disturbances with the "greatest ecological impact frequently incur high societal costs."[48]

Existing law offers few, if any, ways to address the problem of invasive species. Laws targeting the animal and plant pests[49] do enable the Department of Agriculture to constrict the movement of organisms known or suspected to have an adverse effect on agriculture.[50] Such laws, however, serve more to regulate the proposed releases of genetically modified crops than to provide broad-based authority to restrain the diffusion of invasive species.[51]

The National Environmental Policy Act of 1970 (NEPA)[52]—a statute whose procedural requirements are analogous to those of the ESA[53]—provides a somewhat broader platform for legal intervention. One federal court of appeals has used NEPA to require a federal agency to address how dam construction could introduce zebra

46. McCann, *supra* note 40, at 233.

47. *Id.*

48. F. Stuart Chapin III et al., *Consequences of Changing Biodiversity*, 405 NATURE 234, 239 (2000). On the economic impact of alien invasive species, see generally UNITED STATES OFFICE OF TECHNOLOGY ASSESSMENT, HARMFUL NON-INDIGENOUS SPECIES IN THE UNITED STATES (1993); David Pimentel et al., *Environmental and Economic Costs of Nonindigenous Species in the United States*, 50 BIOSCIENCE 53 (2000).

49. *See* Animal and Plant Health Inspection Act, 7 U.S.C. §§ 150aa–jj (2000); Plant Quarantine Act, *id.* §§ 151–67; *see also* 7 C.F.R. §§ 319.8–.77, 340.0–.9 (2005).

50. *See generally* 7 C.F.R. §§ 340.0–.9 (2005).

51. *See, e.g.*, Availability of Determination of Nonregulated Status for Genetically Engineered Canola Notice, 59 Fed. Reg. 55,250, 55,250–51 (Nov. 4, 1994) (declining to restrict genetically engineered laurate canola varieties containing "sequences . . . derived from the plant pathogens *A. tumefaciens* and cauliflower mosaic virus" once it had been determined that these plants were no likelier than comparable, traditionally bred varieties to become weeds, to confer weedy characteristics on canola's wild relatives, or to harm agriculturally beneficial organisms "such as bees or earthworms").

52. 42 U.S.C. §§ 4321–70d (2000).

53. Thomas v. Peterson, 753 F.2d 754, 764 (9th Cir. 1985).

mussels into previously uninfested waters.[54] More typically, however, NEPA proves impotent to curb invasions. Rejecting arguments that airport expansion could dramatically increase the rate at which commercial flights (especially from Asia) would introduce alien species into Maui, the Ninth Circuit declined to find a NEPA violation.[55] That court took refuge in the vagaries of airport demand projections,[56] the multiplicity of invasion vectors,[57] and the impossibility of determining *ex ante* which species would become established and, among those, which would become "economic pests."[58]

No single country can contain the menace posed by alien invasive species. Within the inherently global project of biodiversity conservation, any hope of addressing the scourge of alien invasive species demands especially vigorous international cooperation.[59] The Convention on Biological Diversity exhorts its contracting parties, "as far as possible and as appropriate," to "[p]revent the introduction of, control or eradicate those alien species which threaten ecosystems, habitats or species."[60] The United States' persistent refusal to sign the Convention, however, effectively short-circuits international law's potential to spur domestic legal change.[61]

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54. *See* Hughes River Watershed Conservancy v. Glickman, 81 F.3d 437, 445 (4th Cir. 1996). *See generally* PATRICK MCCULLY, SILENCED RIVERS: THE ECOLOGY AND POLITICS OF LARGE DAMS (1996); Christine A. Klein, *Dam Policy: The Emerging Paradigm of Restoration*, 31 ENVTL. L. REP. 10,486 (2001); Christine A. Klein, *On Dams and Democracy*, 78 OR. L. REV. 641 (1999).

55. *See* Nat'l Parks & Conservation Ass'n v. U.S. Dep't of Transp., 222 F.3d 677 (9th Cir. 2000).

56. *Id.* at 680.

57. *See id.* at 680 & n.3.

58. *Id.* at 681.

59. *See* 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, 333–49 (2000); *cf.* Steven A. Wade, *Stemming the Tide: A Plea for New Exotic Species Legislation*, 10 J. LAND USE & ENVTL. L. 343 (1995) (urging similar efforts at the domestic level).

60. United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, art. 8(h), 31 I.L.M. 818 [hereinafter CBD].

61. *See generally* Robert F. Blomquist, *Ratification Resisted: Understanding America's Response to the Convention on Biological Diversity, 1989–2002*, 32 GOLDEN GATE U. L. REV. 493 (2002).

### *C. Habitat Destruction*

Among the drivers of biodiversity loss, habitat destruction is by far the deadliest.[62] Contracting the physical range of endangered species spurs their extinction.[63] Island biogeography posits that a ninety-percent reduction in the area of a biological island—which may consist of an island in the geographic sense or merely an isolated patch of wildlife habitat—dictates a fifty-percent reduction in biological carrying capacity as measured by the number of distinct species that can be sustained.[64] An area as large and diverse as Centinela, a diverse forest ridge in Ecuador, can fall victim to cacao cultivation.[65] As typified by California's Hetch Hetchy Reservoir,[66] Egypt's Aswan High Dam,[67] and China's Three Gorges Dam,[68] large-scale damming can erase multiple ecological niches. Destroying large

62. *See, e.g.*, Paul R. Ehrlich, *The Loss of Diversity: Causes and Consequences*, *in* BIODIVERSITY 21 (E. O. Wilson ed., 1988); P. A. Matson et al., *Agricultural Intensification and Ecosystem Properties*, 275 SCIENCE 504, 504 (1997) (describing the conversion of land to agricultural use as "one of the most significant human alterations to the global environment"); *cf.* Larry E. Morse et al., *Native Vascular Plants*, *in* OUR LIVING RESOURCES: REPORT TO THE NATION ON THE DISTRIBUTION, ABUNDANCE, AND HEALTH OF U.S. PLANTS, ANIMALS, AND ECOSYSTEMS 205, 208 (Edward T. Lavoe et al. eds., 1995) (describing "[h]abitat alteration and incompatible land use" as larger threats than overcollecting, global climate change, and sea-level rise).

63. *See, e.g.*, Rob Channell & Mark V. Lomolino, *Dynamic Biogeography and Conservation of Endangered Species*, 403 NATURE 84 (2000); John H. Lawton, *Population Dynamics Principles*, *in* EXTINCTION RATES 147 (John H. Lawton & Robert M. May eds., 1995); Bruce A. Wilcox & Dennis D. Murphy, *Conservation Strategy: The Effects of Fragmentation on Extinction*, 125 AM. NATURALIST 879 (1985).

64. *See, e.g.*, ROBERT H. MACARTHUR & EDWARD O. WILSON, THE THEORY OF ISLAND BIOGEOGRAPHY (1967); Daniel Simberloff, *Experimental Zoogeography of Islands: Effects of Island Size*, 57 ECOLOGY 629 (1976); Donald R. Whitehead & Claris E. Jones, *Small Islands and the Equilibrium Theory of Island Biogeography*, 23 EVOLUTION 171 (1969). The most elementary mathematical formula expressing this relationship is $N = k \cdot A^{.27}$, where $N$ represents the number of species, $A$ represents the area, and $k$ represents an empirically determined constant. For a skeptical assessment of island biogeography's strongest claims, see Charles C. Mann, *Extinction: Are Ecologists Crying Wolf?*, 253 SCIENCE 736 (1991).

65. *See* C.H. Dodson & A.H. Gentry, *Biological Extinction in Western Ecuador*, 78 ANNALS MO. BOTANICAL GARDEN 273 (1991); *see also* WILSON, *supra* note 3, at 243 (arguing that the name Centinela "deserves to be synonymous with the silent hemorrhaging of biological diversity").

66. *See, e.g.*, RICHARD WHITE, IT'S YOUR MISFORTUNE AND NONE OF MY OWN 412–15 (1991).

67. *See, e.g.*, TOM LITTLE, HIGH DAM AT ASWAN (1965); Gilbert F. White, *The Environmental Effects of the High Dam at Aswan*, 30:7 ENV'T 5 (1988).

68. *See, e.g.*, VACLAV SMIL, CHINA'S ENVIRONMENTAL CRISIS (1993).

chunks of the earth's physical infrastructure within a temporal frame that by geological standards is effectively instantaneous significantly accelerates the rate of evolutionary change attributable to humans.

1. Private Land

The prohibition against the taking of any species protected by the ESA[69] has been interpreted to extend to the destroying or significantly modifying critical habitat.[70] The Supreme Court's first ESA decision reflected the Justices' understanding of the potential of habitat destruction to disrupt breeding and eliminate indispensable food sources.[71] As the example of orchids illustrates, however, similar sophistication has not migrated from American law to the international sphere. The use of section nine against habitat destruction triggers other provisions of the ESA. Section ten authorizes incidental take permits upon submission and approval of a habitat conservation plan (HCP).[72] In turn, approval of an HCP triggers the federal government's obligation under section seven to "insure [sic] that any action" it undertakes "is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of" critical habitat.[73] This provision has been interpreted as imposing an affirmative obligation to pursue an active species conservation policy.[74]

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69. *See* 16 U.S.C. § 1538 (2000).

70. *See* 50 C.F.R. § 17.3 (2005); Babbitt v. Cmtys. for a Great Or., 515 U.S. 687 (1995); *see also* 16 U.S.C. § 1533(a)(3)(A) (2000) (authorizing the designation of "critical habitat" for endangered or threatened species).

71. *See* Tenn. Valley Auth. v. Hill, 437 U.S. 153, 162, 166 n.16 (1978).

72. *See* 16 U.S.C. § 1539(a) (2000).

73. *Id.* § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b) (2005); Friends of Endangered Species, Inc. v. Jantzen, 760 F.2d 976, 984–85 (9th Cir. 1985); Nat'l Wildlife Fed'n v. Babbitt, 128 F. Supp. 2d 1274, 1286 (E.D. Cal. 2000). Section 4(d) of the Act, 16 U.S.C. § 1533(d), may also be used to establish the functional equivalent of HCPs for threatened species. *See* Robert L. Fischman & Jaelith Hall-Rivera, *A Lesson for Conservation from Pollution Control Law: Cooperative Federalism for Recovery Under the Endangered Species Act*, 27 COLUM. J. ENVTL. L. 45, 94–109 (2002).

74. *See* Carson-Truckee Water Conservancy Dist. v. Clark, 741 F.2d 257, 262 (9th Cir. 1984); Fla. Key Deer v. Stickney, 864 F. Supp. 1222, 1237–38 (S.D. Fla. 1994); J.B. Ruhl, *Section 7(a)(1) of the "New" Endangered Species Act*, 25 ENVTL. L. 1107, 1137 (1995).

Before HCPs became a familiar fixture of ESA enforcement, developers and farmers facing potential section nine liability often resorted to the "scorched earth" technique of preemptively clearing wildlife habitat.[75] Clinton-era enforcement transformed the "previously obscure and rarely used permit provision" of section ten into "the centerpiece of . . . endangered species and ecosystem conservation policy."[76] Threatened section nine liability became merely "the opening gambit in a prolonged bargaining process."[77] HCPs today represent "perhaps the most visible example of a consensus-based, multi-stakeholder approach to resource management."[78]

The strategy has its limits. Like the ESA as a whole, HCPs proceed species by species, and only after an individual species has

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75. Michael J. Bean, *Overcoming Unintended Consequences of Endangered Species Regulation*, 38 IDAHO L. REV. 409, 415 (2002) (quoting NAT'L ASS'N OF HOMEBUILDERS, DEVELOPER'S GUIDE TO ENDANGERED SPECIES REGULATION 109 (1996)); *see also* George Cameron Coggins & Anne Fleishel Harris, *The Greening of American Law?: The Recent Evolution of Federal Law for Preserving Floral Diversity*, 27 NAT. RESOURCES J. 247, 297 (1987). Scholars debate just how inflexible section nine is in practice. *Compare* Christopher A. Cole, *Species Conservation in the United States: The Ultimate Failure of the Endangered Species Act and Other Land Use Laws*, 72 B.U. L. REV. 343, 350–54 (1992) (arguing that the Act, at least as enforced without resort to HCPs, is unduly harsh and ineffective), *with* Karin P. Sheldon, *Habitat Conservation Planning: Addressing the Achilles Heel of the Endangered Species Act*, 6 N.Y.U. ENVTL. L.J. 279 (1998) (arguing that landowners historically did not treat their chances of receiving incidental take permits under section ten as sufficiently serious to warrant the making of HCP proposals). For one account of the feared economic consequences of the listing of an endangered species (the northern spotted owl) and the designation of its critical habitat, see Seattle Audubon Soc'y v. Moseley, 80 F.3d 1401, 1403–04 (9th Cir. 1996).

76. Bradley C. Karkkainen, *Adaptive Ecosystem Management and Regulatory Penalty Defaults: Toward a Bounded Pragmatism*, 87 MINN. L. REV. 943, 970 (2003). For details of how section ten arose from efforts to reconcile preservation of the remaining habitat of the endangered Mission Blue butterfly with commercial development on San Bruno Mountain on the San Francisco peninsula, see Friends of Endangered Species, Inc. v. Jantzen, 760 F.2d 976, 982–83 (9th Cir. 1985); S. REP. NO. 97-418, at 10 (1982); H.R. REP. NO. 97-835, at 31–32 (1982), *reprinted in* 1982 U.S.C.C.A.N. 2872–73; MICHAEL J. BEAN ET AL., RECONCILING CONFLICTS UNDER THE ENDANGERED SPECIES ACT: THE HABITAT CONSERVATION PLANNING EXPERIENCE 52–55 (1991); Jamie A. Grodsky, *The Paradox of (Eco) Pragmatism*, 87 MINN. L. REV. 1037 (2003); Albert C. Lin, *Participants' Experiences with Habitat Conservation Plans and Suggestions for Streamlining the Process*, 23 ECOLOGY L.Q. 369, 375–76 (1996).

77. Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297, 317 (1999). For further discussion of environmental law as a process of public-sector negotiation among interested groups, see David A. Dana, *The New "Contractarian" Paradigm in Environmental Regulation*, 2000 U. ILL. L. REV. 35.

78. Jody Freeman, *The Contracting State*, 28 FLA. ST. U.L. REV. 155, 194 (2000).

begun to decline. Despite well-founded doubts about the territorial and institutional suitability of states as participants in ecosystem management,[79] state-law restrictions on land use can enhance the effectiveness of federal HCPs.[80] California law facilitates natural community conservation plans that provide "large-scale, multi-species equivalents of HCPs."[81] That state's active intervention is crucial because it is home to the California floristic province, the hottest of biological "hotspots" in the continental United States.[82] Ultimately, however, the ESA only indirectly addresses habitat loss and altogether ignores "other causes" of biodiversity loss "such as the invasion of exotic species and air and water pollution."[83] The Act as a whole falls far short of "promot[ing] the conservation of ecosystems on the geographic scale necessary to promote biodiversity generally."[84]

2. Public Land

Although "[t]he Endangered Species Act of 1973 was motivated in part by the need to . . . regulat[e] beyond the limited confines of federal land,"[85] a significant degree of habitat conservation takes

79. *See* Bradley C. Karkkainen, *Collaborative Ecosystem Governance: Scale, Complexity, and Dynamism*, 21 VA. ENVTL. L.J. 189, 216 (2002).

80. *See* Marc J. Ebbin, *Is the Southern California Approach to Conservation Succeeding?*, 24 ECOLOGY L.Q. 695, 696–97 & n.7 (1997); 16 U.S.C. § 1535 (2000) (authorizing cooperative species conservation agreements between states and the federal government); *cf.* A. Dan Tarlock, *Biodiversity Federalism*, 54 MD. L. REV. 1315 (1995) (asserting that biodiversity conservation will not succeed absent state-federal cooperation).

81. A. Dan Tarlock, *Biodiversity Conservation in the United States*, 32 ENVTL. L. REP. 10,529, 10,539 (2002) [hereinafter Tarlock, *Biodiversity Conservation*]; *see also* Natural Communities Conservation Act, CAL. FISH & GAME CODE §§ 2800–40 (West 2003). *See generally* John M. Gaffin, *Can We Conserve California's Threatened Fisheries Through Natural Community Planning?*, 27 ENVTL. L. 791 (1997). For further discussion of the role of state tort law in biodiversity conservation, see A. Dan Tarlock, *Local Government Protection of Biodiversity: What Is Its Niche?*, 60 U. CHI. L. REV. 555 (1993).

82. *See* Ryan Carlsbeek et al., *Patterns of Molecular Evolution and Diversification in a Biodiversity Hotspot: The California Floristic Province*, 12 MOLECULAR ECOLOGY 1021 (2003).

83. Tarlock, *Biodiversity Conservation*, *supra* note 81, at 10,537; *see also* Elaine K. Harding et al., *The Scientific Foundations of Habitat Conservation Plans: A Quantitative Assessment*, 15 CONSERVATION BIOLOGY 488 (2000).

84. Tarlock, *Biodiversity Conservation*, *supra* note 81, at 10,540.

85. Gibbs v. Babbitt, 214 F.3d 483, 494 (4th Cir. 2000); *see also* Davina Kari Kaile, Note, *Evolution of Wildlife Legislation in the United States: An Analysis of the Legal Efforts to Protect Endangered Species and the Prospects for the Future*, 5 GEO. INT'L ENVTL. L. REV. 441 (1993);

place under the aegis of public land management. The law of public lands rests on the primary premise of "multiple use," defined as a range of uses "including, but not limited to, recreation, range, timber, minerals, watershed, wildlife and fish, and natural scenic, scientific and historical values."[86] Because "[m]ultiple use posits that all uses from commodity extraction and production to biodiversity are equal," this principle "both supports and hinders biodiversity conservation."[87]

When it first appeared, the concept of "multiple use" represented a substantial improvement in federal land management policy. "[I]ncreased competition for forage" among cattle and sheep ranchers during the nineteenth and early twentieth centuries led to overgrazing, diminished profits, and open hostility among forage competitors."[88] The Federal Land Policy and Management Act of 1976 (FLPMA)[89] explicitly adopted two statutory principles: "multiple use" for recreation, range, timber, mineral extraction, wildlife and fish habitat, and natural, scenic, scientific, and historical uses;[90] and "sustained yield" of renewable resources.[91] At the same time, FLPMA retained "first priority" for existing grazing-permit holders as long as federal land-use planning continued to leave land "available for domestic livestock grazing."[92]

Although a statutory commitment to multiple use may theoretically "provide[] the legal foundation for a management decision to preserve biodiversity,"[93] disputes over federal land management expose a bias favoring commercialization over

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*cf.* Conservation Council for Haw. v. Babbitt, 2 F. Supp. 2d 1280, 1281 (D. Haw. 1998) (invalidating a decision not to designate critical habitat insofar as that decision was based solely on a claim that some of the species at issue were located on private land, without determining whether a decision not to designate might be appropriate when a species exists solely on private land).

86. 43 U.S.C. § 1702(c) (2000); *see also id.* § 1701(a)(7) (directing that "management [of public land] be on the basis of multiple use and sustained yield unless otherwise specified by law").

87. Tarlock, *Biodiversity Conservation*, *supra* note 81, at 10,540–41.

88. Pub. Lands Council v. Babbitt, 529 U.S. 728, 732 (2000). *See generally* DEBRA L. DONAHUE, THE WESTERN RANGELAND REVISITED: REMOVING LIVESTOCK FROM PUBLIC LANDS TO CONSERVE NATIVE BIODIVERSITY (Gordon Morris Bakhen et al. eds., 1999).

89. Pub. L. No. 94-579, 90 Stat. 2744 (codified as amended at 43 U.S.C. §§ 1701–1785 (2000)).

90. 43 U.S.C. § 1702(c) (2000).

91. *Id.* § 1702(h).

92. *Id.* § 1752(c) (2000).

93. Tarlock, *Biodiversity Conservation*, *supra* note 81, at 10,541.

conservation.[94] When the Interior Department tried in 1995 to "accelerate restoration" of rangelands by making its managerial approach "more compatible with ecosystem management,"[95] incumbent ranchers argued in response that the Department was legally obliged to safeguard livestock interests' reliance on the perpetuation of grazing privileges.[96] This argument ran squarely against an explicit statutory proviso that neither "the creation of a grazing district [n]or the issuance of a permit . . . shall . . . create any right, title, interest, or estate in or to the lands."[97]

Other decisions have demonstrated the willingness of federal land management agencies to favor grazing and other historically privileged land uses. A federal district court was forced to remind federal land managers in 1985 that grazing "[p]ermittees must be kept under a sufficiently real threat of cancellation or modification in order to adequately protect the public lands from overgrazing or other forms of mismanagement."[98] In spite of its statutory mandate to maintain "final control and decisionmaking authority over livestock grazing practices on the public lands," the federal government had all but ceded jurisdiction over grazing permits.[99]

On the whole, federal land management policy concentrates its habitat preservation efforts on tracts designated as "wilderness." "A wilderness, in contrast with those areas where man and his own works dominate the landscape, is . . . an area where the earth and its community of life are untrammeled by man, where man himself is a visitor who does not remain."[100] Unlike other public lands, wilderness areas fulfill their function solely by virtue of remaining "in their

94. *See, e.g.*, United States v. State, 23 P.3d 117, 128 (Idaho 2001) (arguing that reservation of water for a wildlife refuge would unfairly "subordinate" rights to "water intended to be stored and regulated by colossal federal projects for the past 98 years" for the primary purpose of "reclamation").

95. *See* Grazing Administration—Exclusive of Alaska, 60 Fed. Reg. 9894, 9900–06 (Feb. 22, 1995) (codified at 43 C.F.R. pt. 4, 1780, 4100).

96. *See* Public Lands Council v. Babbitt, 529 U.S. 728, 741 (2000).

97. 43 U.S.C. § 315b (2000); *see Public Lands Council*, 529 U.S. at 741–42.

98. Natural Resources Def. Council, Inc. v. Hodel, 618 F. Supp. 848, 871 (E.D. Cal. 1985).

99. *Id.* at 871; *see also* 43 U.S.C. §§ 1901–08 (2000).

100. 16 U.S.C. § 1131(c) (2000); *cf.* Or. Natural Desert Ass'n v. Singleton, 47 F. Supp. 2d 1182, 1192 (D. Or. 1998) holding that "the explicit 'protect and enhance' language of" the Wild and Scenic Rivers Act "requires that watersheds be maintained in a primitive condition and the waters kept unpolluted").

natural condition."[101] Wilderness preservation helps ensure "that an increasing population, accompanied by expanding settlement and growing mechanization, does not occupy and modify" the entire physical surface of the earth.[102]

Cold and high-elevation wilderness areas, however, cannot anchor a comprehensive and effective biodiversity program.[103] Biodiverse "hot spots," rich in species, typically live up to their name: most such locales lie in the tropics.[104] The National Park Service—which is directed to "conserve the scenery and the natural and historic objects and the wild life" in the most spectacular federal lands[105]—was designed to preserve geological wonders, not to serve broader ecological purposes.[106] Wilderness policy, in microcosm, reveals the weakness of the overall legal response to biodiversity loss. Laws designed to prevent biodiversity loss behave like a twisted version of Wee Willie Keeler—aiming environmental law "where they ain't."[107]

## III. A MODEST AGENDA FOR FORESTALLING APOCALYPSE NOW

This brief survey shows how the law has failed to keep pace with the scientific understanding of biodiversity loss. Advances in the field of conservation biology have had little or no legal impact. Federal courts routinely decline to treat innovations in conservation biology

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101. 16 U.S.C. § 1131(a) (2000).

102. *Id.*

103. *See* Jonathan S. Adams et al., *Biodiversity: Our Precious Heritage*, *in* PRECIOUS HERITAGE: THE STATUS OF BIODIVERSITY IN THE UNITED STATES 1, 17 (Bruce A. Stein et al. eds., 2000); Tarlock, *Biodiversity Conservation*, *supra* note 81, at 10,542.

104. *See* John Charles Kunich, *Preserving the Womb of the Unknown Species with Hotspots Legislation*, 52 HASTINGS L.J. 1149, 1157–58 (2001); Norman Myers, *The Biodiversity Challenge: Expanded Hot-Spots Analysis*, 10 ENVIRONMENTALIST 243 (1990); Norman Myers, *Threatened Biotas: "Hot Spots" in Tropical Forests*, 8 ENVIRONMENTALIST 187 (1988).

105. 16 U.S.C. § 1 (2000) (directing the Service to "provide for the enjoyment of the same in such manner and by such means as will leave them unimpaired for the enjoyment of future generations"); *see also* Nat'l Park & Conservation Ass'n v. Stanton, 54 F. Supp. 2d 7, 17 (D.D.C. 1999).

106. *See* RICHARD WEST SELLARS, PRESERVING NATURE IN THE NATIONAL PARKS: A HISTORY 2–3 (1997).

107. Wee Willie Keeler amassed a career batting average of .341 from 1892 to 1910 by hitting the ball "where they ain't." *See* Geoffrey C. Ward, *Our Game: Beginnings to 1900*, *in* BASEBALL: AN ILLUSTRATED HISTORY 52 (1994).

as "a necessary element of diversity analysis."[108] In a case assaulting the government's failure to consider "population dynamics, species turnover, patch size, recolonization problems, fragmentation problems, edge effects, and island biogeography,"[109] the Seventh Circuit ultimately held that these concepts of conservation biology were uncertain in application and that the Forest Service could therefore ignore them in managing national forests.[110] Even a valid "general theory," the court held, "does not translate into a management tool unless one can apply it to a concrete situation."[111] A federal district court similarly declined to endorse specific techniques for managing "distinct geographic ecosystems . . . inhabited by grizzly bears."[112] That court seemed to treat complexity as a legal excuse in its own right. The possibility that "science or circumstances" might change, the court reasoned, relieved the agency of any obligation to prepare an "exhaustively detailed recovery plan."[113] As a result, the court rejected a claim that the Endangered Species Act required "linkage zones between ecosystems inhabited by grizzlies."[114]

Cases of this nature suggest that conservation biology, until further notice, will not govern American environmental law until federal land management agencies and the agencies charged with implementing the Endangered Species Act decide that it does. In the meanwhile, federal judges take frequent refuge in the maxim that "a reviewing court must generally be at its most deferential" when an agency "is making predictions, within its area of special expertise, at the frontiers of science."[115] Administrative and judicial passivity bode

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108. Sierra Club v. Marita, 46 F.3d 606, 620 (7th Cir. 1995).
109. *Id.* at 618.
110. *Id.* at 622–23.
111. *Id.* at 623.
112. Fund for Animals v. Babbitt, 903 F. Supp. 96, 106 (D.D.C. 1995).
113. *Id.* at 107.
114. *Id.* at 109–10.
115. Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc., 462 U.S. 87, 103 (1983); *see also* Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607, 656 (1980) (plurality opinion); *id.* at 705–06 (Marshall, J., dissenting); Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992) (stating that "[t]he rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise"); Envtl. Def. Fund, Inc. v. Costle, 578 F.2d 337, 339 (D.C. Cir. 1978) ("[I]n an area characterized by scientific and technological uncertainty . . . this court must proceed with particular caution, avoiding all temptation to direct the agency in a

ill for biodiversity conservation. An even more potent driver of ecological ruin and evolutionary change may lurk in global climate change, whose consequences defy description, much less prediction.[116] The failure to coordinate the law with scientific knowledge threatens to consign yet another environmental crisis requiring transnational cooperation to the perdition of zero-sum politics.[117]

In the meanwhile, "[t]hose of us who love nature, and who would like to ensure that nature persists for future generations to love, need to think about saving ordinary places and ordinary things."[118] Without abandoning the admittedly implausible prospect of comprehensively reconfiguring domestic and international environmental law to address habitat destruction and alien invasive species, advocates of biodiversity conservation can pursue a more modest agenda for reform. First, international policymakers should develop a joint framework for the regulation of commercial bioprospecting. International coordination on commercial exploitation of biodiversity can improve the very process of collecting rare specimens. If even casual hiking affects the distribution and population of wildlife,[119]

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choice between rational alternatives."); Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 177 (D.D.C. 2000).

116. *See* Camille Parmesan & Gary Yohe, *A Globally Coherent Fingerprint of Climate Change Impacts Across Natural Systems*, 421 NATURE 37 (2003); Robert L. Peters, *Conservation of Biological Diversity in the Face of Climate Change*, *in* GLOBAL WARMING AND BIOLOGICAL DIVERSITY 15, 21–22 (Robert L. Peters & Thomas E. Lovejoy eds., 1992); Terry L. Root et al., *Fingerprints of Global Warming on Wild Animals and Plants*, 421 NATURE 57 (2003); *cf.* Herman E. Daly, *Ecological Economics*, 254 SCIENCE 358 (1991) (suggesting that global warming can threaten even *homo sapiens* by destabilizing the human food supply). See *generally* Osvaldo E. Sala et al., *Global Biodiversity Scenarios for the Year 2100*, 287 SCIENCE 1770 (2000) (describing the potential ecological impact of land use, proliferation of exotic speciès, climate change, and the continued escalation of $CO_2$ and $N_2$ levels). For speculation on the possibility of legal recourse against human agents of climate change, see Myles Allen, *Liability for Climate Change*, 421 NATURE 891 (2003).

117. *See generally* NEIL CARTER, THE POLITICS OF THE ENVIRONMENT 232–44 (2002); MATTHEW PATERSON, GLOBAL WARMING AND GLOBAL POLITICS (1996); Peter Newell, *Who "CoPed" Out in Kyoto? An Assessment of the Third Conference of the Parties to the Framework Convention on Climate Change*, 7 ENVTL. POL. 153 (1998); Peter Newell & Matthew Paterson, *A Climate for Business: Global Warming, the State and Capital*, 5 REV. INT'L POL. ECON. 679 (1998).

118. Holly Doremus, *The Special Importance of Ordinary Places*, 23 ENVIRONS ENVTL. L. & POL'Y J. 3, 4 (2000).

119. *See* Mausolf v. Babbitt, 125 F.3d 661, 669–70 (8th Cir. 1997) (upholding snowmobiling restrictions in Voyageurs National Park on the basis of biological opinions that showed adverse

purposeful bioprospecting leaves a dramatically deeper human footprint. Bioprospectors, anthropologists, or journalists may even engage in deliberate misconduct.[120] Even though the collapse of global fisheries has shaken public confidence in official efforts to achieve "sustainability,"[121] bitter experience teaches that the lack of coordination would be worse. The slash-and-collect approach of Victorian orchid harvesters would probably prevail.[122] Rationalized harvesting would limit instances of "the wonderfully unusual accomplishment of discovering and eradicating in the same instant a new species."[123]

In addition, the international community should facilitate the professionalization of parataxonomy,[124] especially in the developing world. Millions of species await collection and classification by properly trained field biologists. Transnational cooperation can help translate ethnobiological knowledge into terms understood by the global scientific community. Its economic impact is simple and immediate. Scientific research, to put it bluntly, generates jobs.[125] The science of systematics is so labor-intensive that the task of classifying ten million species would require twenty-five thousand

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impacts from snowmobiling on gray wolves). *See generally* David S. May, *Tourism and the Environment*, 14 NAT. RESOURCES & ENV'T 57 (1999). Realizations of this sort have motivated the establishment of the National Wildlife Preservation System within the United States. *See* 16 U.S.C. § 1132 (2000).

120. *See* PATRICK TIERNEY, DARKNESS IN EL DORADO: HOW SCIENTISTS AND JOURNALISTS DEVASTATED THE AMAZON (2000).

121. *See, e.g.*, MICHAEL HARRIS, LAMENT FOR AN OCEAN (1998); CARL SAFINA, SONG FOR A BLUE OCEAN (1998); LISA SPEER ET AL., NAT'L RES. DEF. COUNCIL, HOOK, LINE & SINKING (1997); H. Scott Gordon, *Economics and the Conservation Question*, 1 J.L. & ECON. 110 (1958); H. Scott Gordon, *The Economic Theory of a Common-Property Resource: The Fishery*, 62 J. POL. ECON. 124 (1954); Bob Holmes, *Biologists Sort the Lessons of the Fisheries Collapse*, 264 SCIENCE 1252 (1994); Donald Ludwig et al., *Uncertainty, Resource Exploitation, and Conservation: Lessons from History*, 260 SCIENCE 17 (1993); Alison Rieser, *Property Rights and Ecosystem Management in U.S. Fisheries: Contracting for the Commons?*, 24 ECOLOGY L.Q. 813 (1997); Anthony Scott, *The Fishery: The Objectives of Sole Ownership*, 63 J. POL. ECON. 116 (1955); Barton H. Thompson, Jr., *Tragically Difficult: The Obstacles to Governing the Commons*, 30 ENVTL. L. 241, 247–49 (2000).

122. *See* HAROLD KOOPOWITZ & HILARY KAYE, PLANT EXTINCTION: A GLOBAL CRISIS 199–205 (1983); SUSAN ORLEAN, THE ORCHID THIEF 62–67 (1998).

123. BILL BRYSON, A WALK IN THE WOODS: REDISCOVERING AMERICA ON THE APPALACHIAN TRAIL 92 (1998).

124. *See* CHRISTOPHER JOYCE, EARTHLY GOODS: MEDICINE-HUNTING IN THE RAINFOREST 118–21 (1994).

125. Gibbs v. Babbitt, 214 F.3d 483, 494 (4th Cir. 2000).

professional lifetimes.[126] Whether framed as cooperative bioprospecting or north-to-south technology transfer for the enrichment of parataxonomy, commercially oriented initiatives satisfy the Convention on Biological Diversity's exhortation that the international community should "adopt economically and socially sound measures . . . as incentives" to conserve biodiversity and to contribute to its sustainable development.[127]

Willingness to pursue a more modest agenda, however, does not weaken the need for more aggressive conservation measures. *In situ* preservation remains the only effective way to save biodiversity. The larger the tract of land set aside for conservation, the better.[128] Zoos, gene banks, and other *ex situ* strategies fall far short of the mark.[129] Despite consuming a significant portion of the capital expended on conservation, *ex situ* efforts have protected a trivial amount of biodiversity.[130] *Ex situ* conservation cannot preserve the adaptive and evolutionary value of individual species, let alone entire ecosystems.[131] By introducing criteria designed to suit human tastes and preferences, *ex situ* preservation exerts selective pressure on those species that are targeted for protection.[132] Only *in situ* conservation can effectively preserve the "conditions where genetic resources exist with ecosystems and natural habitats," or at least the surroundings where "domesticated or cultivated species . . . have developed their distinctive properties."[133]

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126. WILSON, *supra* note 3, at 318.

127. CBD, *supra* note 60, art. 11.

128. *See* Karkkainen, *supra* note 10, at 10–12.

129. *See* Holly Doremus, *The Rhetoric and Reality of Nature Protection: Toward a New Discourse*, 57 WASH. & LEE L. REV. 11, 54–57 (2000).

130. *See* Roger A. Sedjo, *Property Rights, Genetic Resources, and Biotechnological Change*, 35 J.L. & ECON. 199, 203 (1992).

131. *See, e.g.*, EDWARD C. WOLF, ON THE BRINK OF EXTINCTION 44 (1987); Matthew B. Hamilton, Ex Situ *Conservation of Wild Plant Species: Time to Reassess the Genetic Assumptions and Implications of Seed Banks*, 8 CONSERVATION BIOLOGY 39 (1994); G. Ledyard Stebbins, *Why Should We Conserve Species and Wildlands?*, *in* CONSERVATION BIOLOGY: THE THEORY AND PRACTICE OF NATURE CONSERVATION, PRESERVATION AND MANAGEMENT 453, 463 (Peggy L. Fiedler & Subodh K. Jain eds., 1992); Mark A. Urbanski, Note, *Chemical Prospecting, Biodiversity Conservation, and the Importance of International Protection of Intellectual Property Rights in Biological Materials*, 2 BUFF. J. INT'L L. 131, 181 (1995).

132. *See* Holly Doremus, Comment, *Patching the Ark: Improving Legal Protection of Biological Diversity*, 18 ECOL. L.Q. 265, 284 (1991).

133. CBD, *supra* note 60, art. 2.

Finally, the academic community bears a singularly immense responsibility to educate the public. A country whose citizens lead the developed world in rejecting the Darwinian account of natural history[134] is hardly well equipped to reorient the primary focus of biodiversity conservation from preventing overkill to preserving habitat and slowing the flux of alien species. Ours, after all, is a legal culture where at least one member of the highest court in the land condemns habitat preservation because it allegedly "imposes unfairness to the point of financial ruin—not just upon the rich, but upon the simplest farmer who finds his land conscripted to national zoological use."[135] The same jurist even derives perverse pleasure from mocking "the much beloved secular legend of the Monkey Trial" and thereby delivers rhetorical succor to the enemies of biological enlightenment.[136]

Among creation myths vying to satisfy the human need for a compelling story of origins, especially in an emotionally challenging "age of globalization," "none is more solid and unifying for the species than evolutionary history."[137] No other story of human beginnings boasts a more expansive narrative scope or enjoys greater scientific support.[138] Realigning environmental law with the scientific understanding of biodiversity loss produces its own epiphany, its own spiritually satisfying path toward detecting an "echo of the infinite, a glimpse of its unfathomable process, a hint of the universal law."[139] "[I]ntense spiritual feelings" arise from the "unfathomable complexity and . . . sublime beauty" of the biosphere at its fullest and

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134. *See* Eugenie C. Scott, *Antievolution and Creationism in the United States*, 26 ANN. REV. ANTHRO. 263, 263–64 (1997) (reporting a 1996 survey conducted by the National Science Board that found that forty-four percent of Americans do not believe in an evolutionary explanation of human origins); see Nicholas D. Kristof, *God, Satan and the Media*, N.Y. TIMES, Mar. 4, 2003, at A27 (reporting that "Americans are more than twice as likely to believe in the devil (68 percent) as in evolution (28 percent)").

135. Babbitt v. Cmtys. for a Great Or., 515 U.S. 687, 714 (1995) (Scalia, J., dissenting).

136. Tangipahoa Parish Bd. of Educ. v. Freiler, 530 U.S. 1251 (2000) (Scalia, J., dissenting from denial of cert.).

137. WILSON, *supra* note 5, at 133.

138. *See* David Christian, *The Case for "Big History,"* 2 J. WORLD HIST. 223, 235 (1991) (describing history, at least if studied across the whole of time, "as a form of modern 'creation myth'" that "reflects the best attempts of our society to answer questions about origins").

139. Oliver Wendell Holmes, *The Path of the Law*, 10 HARV. L. REV. 457, 478 (1897), *reprinted in* 110 HARV. L. REV. 994, 1009 (1997).

most diverse.[140] Training the law to harness, perchance to halt, the horses of our ecological apocalypse should help us recapture the "beauty and mystery that seized us at the beginning."[141]

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140. DAVID TAKACS, THE IDEA OF BIODIVERSITY 255 (1996).
141. EDWARD O. WILSON, CONSILIENCE 237 (1998).

An Agricultural Law Research Article

# Forced Feeding: New Legal Issues in the Biotechnology Policy Debate

By

Neil D. Hamilton

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# Forced Feeding: New Legal Issues in the Biotechnology Policy Debate

Neil D. Hamilton*

## INTRODUCTION: LOOKING BACK TO MOVE AHEAD

In the fall of 2000, I presented a paper, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*,[1] at the American Agricultural Law Association annual meeting in St. Louis. The paper inventoried the legal and policy issues shaping America's approach toward biotechnology and was designed to serve as a tool for understanding the ongoing debate. Thirty months have passed and the pace of consideration of issues relating to society's acceptance of biotechnology has not slowed. Just as the article was being finished, the StarLink fiasco was beginning. That episode alone has provided the grist for numerous lawsuits and other policy debates.[2]

In the intervening thirty months, several issues have become more settled. For example, except for skirmishes such as the failed ballot referendum in Oregon to mandate food labels,[3] American consumers appear for the most part to accept the Food and Drug Administration's decision not to require labeling on the use of genetically modified ingredients. In light of the obstacles the FDA placed in the way of anyone trying to label a food as being free of

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* Professor Hamilton is the Dwight D. Opperman Chair of Law and Director, Agricultural Law Center, Drake University Law School, Des Moines, Iowa.

1. Neil Hamilton, *Legal Issues Shaping Society's Acceptance of Biotechnology and Genetically Modified Organisms*, 6 DRAKE J. AGRIC. L. 81 (2001). This article subsequently received the American Agricultural Law Association's Award of Excellence for Professional Scholarship at the association's October 2002 meeting.

2. *See* Kramer v. Aventis Crop Sci. USA Holding, Inc., 212 F. Supp. 2d 828 (N.D. Ill. 2002).

3. *See, e.g.*, Philip Brasher, *Oregon Voters Reject Food-Labeling Measure*, DES MOINES REG., Nov. 8, 2002, at 1D.

Genetically Modified Organisms (GMO), it may not be surprising the issue has subsided.[4] Other issues, such as the continuing conflict between the United States and the European Union over European resistance to accepting unlabeled GMO foods and the legality of such action under the World Trade Organization (WTO) rules, remain topics of current public debate.[5] Predictably, several new issues have emerged which were not addressed in the original article, the most significant being the controversy over planting pharma-crops, traditional commodities genetically modified to create traits and products with pharmacological value.[6]

What follows is an effort both to update many of the issues discussed in the previous article and to make the analysis more timely and complete. In doing so, the article will share whatever insights and observations are possible concerning the role that biotechnology will play in our food and agriculture system and how policy and law will be asked to shape that future.

## RECENT DEVELOPMENTS IN BIOTECHNOLOGY POLICY—WHAT HAS WORKED AND WHAT HASN'T

Before discussing recent policy developments relating to agricultural biotechnology, it may be helpful to start with a brief summary of events from the last two years. On the domestic front, the public acceptance of biotechnology has continued with only a few minor interruptions. From the standpoint of farms, the continued and rapid adoption of genetic modification (GM) technology—especially in the form of Roundup Ready soybeans and *Bacillus thuringiensis* (Bt) corn—is remarkable.[7] This seems especially so in light of the

4. *See* Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4839 (Jan. 18, 2001), *available at* http://www.cfsan.fda.gov/~dms/biolabgu.html.

5. *See, e.g.*, Philip Brasher, *Biotech Ban Tries Patience of U.S.*, DES MOINES REG., Mar. 4, 2003, at 1D (concerning Trade Representative Robert Zoellick's frustration that current geopolitical forces relating to U.S. plans to invade Iraq have for now led the U.S. to delay its plans to file a formal WTO complaint against E.U. policy on GMO foods).

6. *E.g.*, Philip Brasher, *U.S. Tightens Rules for Growing Pharma Crops*, DES MOINES REG., Mar. 7, 2003, at 1D.

7. *See, e.g.*, *ERS Research Identifies Benefits, Costs to Farmers of Using GE Crops*, FEEDSTUFFS, Aug. 26, 2002, at 3 (discussing the recent report by United States Department of Agriculture economists documenting the rapid adoption of genetically engineered crops,

continuing uncertainty whether some foreign markets will accept the crops. In particular, the resistance of European consumers to accepting gene-altered food appears to have hardened, perhaps as a method of resisting what is seen as America's attempted political and economic hegemony.[8] Around the world the use and development of biotechnology continues to progress, with Asia being an especially active region.[9] The continued development of new crop products by the biotech sector, such as the recently approved version of Bt corn for use with corn root-worm, a major pest in the United States, promises a continued flush of new products for use by farmers.[10]

As to the actual farm-level use of biotechnology, the main focus is on three issues: resistance management for Bt crops,[11] lingering concerns about how to resolve liability conflicts between biotech and non-biotech crops such as organic grain, and the potential use and regulation of pharma-crops.[12] From a legal perspective, recent litigation involving the StarLink episode has begun to provide some of the legal guidance that will be needed to resolve the unavoidable conflicts between production of biotech crops and non-GMO crops.[13] From an industry perspective, the resolution of intellectual property

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including sixty-one percent of the U.S. soybean crop and fifty-six percent of the cotton crop in 2001).

8. *See* Lizette Alvarez, *Consumers in Europe Resist Gene-Altered Foods*, N.Y. TIMES, Feb. 11, 2003, at A3.

9. *See* David Barboza, *Development of Biotech Crops Is Booming in Asia*, N.Y. TIMES, Feb. 21, 2003, at A3 (reporting that China, India, and Indonesia are already planting millions of acres of GMO crops and are investing heavily in developing locally adapted GM products).

10. *See* Philip Brasher, *EPA Gives Final OK to New Corn*, DES MOINES REG., Feb. 26, 2003, at 1D; Andrew Pollack, *U.S. Approves Type of Corn That May Cut Pesticide Use*, N.Y. TIMES, Feb. 26, 2003, at C10.

11. *See, e.g.*, *Growers Must Follow Bt Planting Guidelines or Be Denied Seed*, IOWA FARM BUREAU SPOKESMAN, Nov. 23, 2002, at H10.

12. The USDA has announced much-awaited rules for the planting of pharma-crops. *See* Philip Brasher, *U.S. Tightens Rules for Growing Pharma Crops*, DES MOINES REG., Mar. 7, 2003, at 1D; Andrew Pollack, *U.S. Imposes Stricter Rules for Genetically Modified Crops*, N.Y. TIMES, Mar. 7, 2003, at A23. These rules, which include enhanced on-farm inspections requirements and limitations on the ability to rotate food crops on fields recently planted with pharma-crops, may have the effect of limiting the use of the technology in Midwestern states like Iowa. Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11,337 (Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340).

13. An excellent example of the costs and complexities involved in managing the inherent conflicts between these production systems can be seen in the recent $110 million settlement of claims by non-StarLink growers. *See* Non-StarLink Farmer Litigation, *at* http://non-starlinkfarmerssettlement.com (last visited Nov. 14, 2004).

rights issues means the real legal and policy issues will relate to how the federal government proceeds with implementation of new regulations on farmers' use of the products—such as the required refuges to manage resistance and limitations on producing pharma-crops in rotation. In summary, the horizon is relatively bright with only a few clouds looming to challenge the continued growth and acceptance of biotechnology in American agriculture and our food system. Farmers are planting, American consumers are eating, and most foreign customers are buying. At least for now everything is relatively peaceful. Whether the future proves to be so tranquil will depend in part on how the legal issues summarized in the following eight categories play out.

### *I. African Famine Provides New Opportunity to Attack Biotech Opponents—If We Don't Use It, People Will Die!*

The international development that provided perhaps the strongest opportunity for proponents of biotechnology to argue its benefits, and perhaps as importantly to castigate its opponents, came from an unlikely source: the need for increased food aid to relieve famines in southern Africa.[14] As America and other grain producing nations mobilized to respond to the need for grain, several potential recipient nations questioned whether the food aid, in particular corn in seed form rather than ground as meal, would contain GMOs. The debate brought into focus the contrast between American attitudes toward the safety of the crops and the further trade related impact of the leakage of seeds into production. Because the United States grain marketing system does not segregate or identify the type of corn, and given the increased prevalence of the planting of GMO seeds, the assumption would have to be that American food aid would contain GMOs. The issue for several African nations then became whether the risk of accepting the food aid—knowing at least some of the corn would be diverted and saved for seed and replanted—would lead to

14. *See, e.g.*, Henri E. Cauvin, *Between Famine and Politics, Zambians Starve*, N.Y. TIMES, Aug. 30, 2002, at A6; Henri E. Cauvin, *Zambian Leader Defends Ban on Genetically Altered Foods*, N.Y. TIMES, Sept. 4, 2002, at 6; Marc Lacey, *Engineering Food for Africans*, N.Y. TIMES, Sept. 8, 2002, at A16.

the presence of GMO corn in future crops.[15] The concern was how this development might affect a nation's status as "GMO free" for purposes of future sales to European countries and other countries concerned about GMOs.

The debate over these issues mushroomed into an international incident which illuminated several ethical issues. For instance, could a nation such as Zambia refuse food aid knowing that people might die rather than accept GMO crops, which have no known food safety risks for consumers?[16] On closer study, the food shortages appear to have subsided, except in Zimbabwe.[17] But the underlying conflict provided rich fodder for American policy makers and biotechnology promoters looking for an argument to throw back at Europeans resisting the use of GMOs.[18] Rather than simply alleging that the European Union's resistance stems from trade preferences or anti-technology elitism, United States officials, most notably Trade Representative Robert B. Zoellick, are now able to accuse the Europeans of callous disregard and active culpability in starving poor Africans solely to protect their sensitivities over eating GMOs. For example, Mr. Zoellick was quoted as saying, "I find it immoral that people are not being able to be supplied food to live in Africa because people have invented dangers about biotechnology."[19] While the Europeans protested they had not pressured African nations and do not promote starvation, the moral issue was joined.[20]

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15. *See supra* note 14.

16. *See, e.g.*, Rekha Basu, *Africans' Logical Fear of GM Corn*, DES MOINES REG., Dec. 8, 2002, at 30; Danna Harman, *Some Africans Prefer Hunger to Biotech Corn*, DES MOINES REG., Nov. 20, 2002, at A1.

17. *See, e.g.*, Rachel L. Swarns, *African Food Shortages Ending Everywhere Except Zimbabwe*, N.Y. TIMES, Jan. 31, 2003, at A16.

18. *See, e.g.*, Philip Brasher, *Activists Push Fear of Food*, DES MOINES REG., Aug. 31, 2002, at 1A. The situation created great opportunity for sermonizing by U.S. proponents of biotechnology on the theme of how could a country choose to let its citizens starve rather than accept this wonderful gift from the West. *See, e.g.*, Tim Burrack, *Safe, GM Food Can Save Starving Africans*, DES MOINES REG., Nov. 8, 2002, at 13A.

19. *See* Elizabeth Becker, *U.S. Threatens to Act Against Europeans over Modified Food*, N.Y. TIMES, Jan. 10, 2003, at A4.

20. *Id.*

## *II. Consumer Acceptance of GMOs—So Far So Good, but What About These Fish*

The most significant story relating to the consumption of GMO foods in the United States is, in many regards, the lack of a story. For the most part, American consumers don't seem to mind or care. When the FDA in January 2001 rejected for the latest and probably last time requests to require mandatory labeling of GMO foods, what little steam remained went out of this effort.[21] Instead, much of the attention of GMO opponents has shifted to fighting a rear-guard action to protect at least the availability of a food supply that is as free as possible of the presence of GMOs. The final approval of the USDA's national organic program standards and labeling requirements provided the focus for efforts to develop and expand this "alternative" food stream. Because the rules do not allow the use of biotechnology for organics, this provides an outlet for consumers seeking these foods.[22] From the perspective of American law, the FDA action rejecting labels for GMO foods flows from the agency's view of the purpose of food labels and the legal conclusion that this information is not material and labels not containing it are not misleading.[23]

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21. Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 & 592). For a general discussion of U.S. regulation of GM foods, see Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181 (1998).

22. National Organic Program, 7 C.F.R. § 205 (2004); *see also* Elizabeth Becker, *Organic Gets an Additive: A U.S.D.A. Seal to Certify It*, N.Y. TIMES, Oct. 21, 2002, at A10; *A New Organic Era*, N.Y. TIMES, Oct. 21, 2002, at A18. Unfortunately, in recent weeks the integrity of the new national organic program has been placed in jeopardy because of a rider in the 2003 omnibus spending bill, inserted at the request of Congressman Nathan Deal of Georgia. This rider would allow meat to be labeled as organic even if the animals were not fed organic feed, even though the price of organic feed is more than double the price of conventional feed. The inclusion of this loophole has triggered a new wave of concern and support for protecting the organic food label and could produce a backlash that will reignite concerns about the presence of GMOs in the food supply. *See, e.g.*, *Staying Organic*, N.Y. TIMES, Mar. 5, 2003, at A22.

23. For a detailed analysis and criticism of the U.S. approach toward the regulation and labeling of GMO foods, see Thomas McGarity & Patricia I. Hansen, *Breeding Distrust: An Assessment and Recommendations for Improving the Regulation of Plant Derived Genetically Modified Foods* (Jan. 11, 2001), *available at* http://biotech-info.net/breeding_distrust.html (Jan. 11, 2001).

The most contentious episode in the United States over GMO labels was a ballot initiative in Oregon, where a coalition of consumer advocates and environmentalists placed a proposal to mandate labeling for GMO foods sold in Oregon on the fall 2002 ballot.[24] The food and biotech industry waged a multi-million dollar campaign to defeat the initiative and the United States government took the unprecedented step of warning the state that it believed such a law would interfere with the operation of the national food system.[25] The combination of ads, warnings, confusion, and other uncertainty no doubt helped contribute to the overwhelming defeat for the proposal.[26] Assuming that the law had passed, food manufacturers likely would have challenged it on First Amendment grounds as well as claiming federal preemption. Their challenge would have been similar to the successful fight waged by the food industry to defeat Vermont's 1994 attempt to require labeling of milk produced with bovine growth hormone.[27] In that case, the Second Circuit Court of Appeals ruled that the First Amendment prohibited the state from compelling this type of commercial speech from dairies.[28] The court observed that consumers concerned about health issues could purchase bovine-somatotropin-free milk from producers who voluntarily labeled their products as not containing the additive.[29]

But the assumption that producers who choose to employ alternative production techniques are free to communicate this fact on

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24. For a discussion of the contents of the proposed Oregon law and its potential impact on the food industry, see Patricia Callahan, *Oregon May Require Labels on Genetic Food*, WALL ST. J., Sept. 30, 2002, at B1; Elizabeth Weise, *FDA Tries to Remove Genetic Label Before It Sticks*, USA TODAY, Oct. 9, 2002, at 7D (concerning a letter from the acting commissioner of the FDA to the Governor of Oregon).

25. Brasher, *supra* note 3.

26. *Id.*

27. Int'l Dairy Foods Assoc. v. Amestoy, 92 F.3d 67 (2d Cir. 1996).

28. *Id.* at 72.

29. The court stated:

> Absent, however, some indication that this information bears on a reasonable concern for human health or safety or some other sufficiently substantial governmental concern, the manufacturers cannot be compelled to disclose it. Instead, those consumers interested in such information should exercise the power of the their purses by buying products from manufacturers who voluntarily reveal it.

*Id.* at 74.

public's attention.[39] In addition to lingering concerns about the wisdom of using GM technology in meat animals, there was at least one reported incident that raised concerns about possible food safety, or at least animal safety, of GM technology. In the summer of 2002, an interesting story emerged from Iowa concerning the possible relationship between fertility problems in swine and the usage of certain strains of Bt corn in feed.[40] Opponents looking for the smoking gun of health problems from using GMO crops hoped the story would prove to be a major controversy.[41] For scientists, the controversy raised several difficult and perhaps unanswerable questions. But the official response was that the problems were caused by the farmers, not the crops.[42]

### *III. StarLink—Biotech's Self-Inflicted Black Eye Illustrates Limits of Regulatory Structures*

The one incident in the last two years that most clearly illustrates the legal and policy dimensions of the biotechnology age is the StarLink affair. What begin as a minor incident of some GM corn appearing in taco shells blossomed into a major episode that brought into focus a range of significant issues, including, among others:

- the research and marketing decisions of biotech companies;

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39. *See* Andrew Pollack, *F.D.A. Says Food Supply May Contain Altered Pigs*, N.Y. TIMES, Feb. 6, 2003, at A26; Elizabeth Weise, *Research Piglets Sold as Food Hard to Find*, USA TODAY, Feb. 7, 2003, at A3.

40. *See, e.g.*, Tom Block, *More Iowa Sow Herds Experiencing Breeding Problems*, IOWA FARM BUREAU SPOKESMAN, May 18, 2002, at 1; Tom Block, *Pseudopregnancies Puzzle Swine Producer*, IOWA FARM BUREAU SPOKESMAN, Apr. 29, 2002. John Otte, *Swine Pseudopregnancy Mystery*, HOG PRODUCER, June 2002, at H1. For the biotech, industry the issue was a concern, but for conspiracy theorists who believe GMO foods are a serious health threat, the story was heaven-sent. Even in light of what appears to be growing acceptance of the safety of GMO foods, some organizations continue to point out that questions remain. *See, e.g.*, Justin Gillis, *FDA Policies for Gene-Altered Foods Faulted in Report*, WASH. POST, Jan. 7, 2003, at A5 (discussing the recent report by the Center for Science in the Public Interest concerning gaps in the regulatory system relating to biotechnology).

41. For example, Friends of the Earth, which had been responsible for exposing the StarLink contamination of corn products, took a special interest in this controversy and the disposition of a supply of corn from an Iowa farm. *See* http://foe.org/camps/comm/safefood/gefood/iowa (last visited Jan. 5, 2004).

42. *See Researchers Dispute Claims Against Corn*, DES MOINES REG., Oct. 11, 2002, at 2A.

- the adequacy of the U.S. regulatory system for marketing GMO products;
- the cavalier attitudes some seed companies and farmers have toward use of GMOs;
- the ability of the legal system to develop and apply rules for allocating liability in cases of unintentional product contamination;
- the difficulty of developing marketing systems to segregate products not approved for use throughout America's food system;
- the role that the government should play in protecting the integrity of the grain supply;
- the inherent tension between the interests of the food industry and the interests of the biotech community over the use and proliferation of products that raise regulatory and consumer acceptance risks; and
- the impact of such products on export markets for American crops.

The list of issues triggered by the StarLink affair shows how this area of American law and policy is still developing. The legacy of the StarLink affair can be seen in the court rulings and litigation allocating the costs and damages from the incident, proposals for state legislation to address GMO contamination, and new regulatory proposals to restrict the use of similar technologies.[43]

When boiled down to its essence, the StarLink affair resulted from the combination of a foolish (and in retrospect incredibly costly) decision by Aventis to bring to the market a corn product not approved for both food and feed uses and the unreasonable decision of the Environmental Protection Agency (EPA) to allow such split registration. These two actions were especially unfortunate in light of the inability of the grain market to provide for the segregation of the crops, and the apparent unwillingness of some of the companies marketing the technology to communicate and enforce the limitations

43. For an article discussing many of the possible legal theories available to resolve pollen drift related damages akin to the StarLink affair, see Amelia P. Nelson, *Legal Liability in the Wake of StarLink: Who Pays in the End?*, 7 DRAKE J. AGRIC. L. 241 (2002).

on its use to farmers. Given this background it was entirely predictable that StarLink corn would find its way into the food supply. When the history of the StarLink affair is written, it will reveal many lessons. One important lesson is that without the brave actions of lawyers in the Iowa Attorney General's Farm Division, who stepped in to prevent the seed companies' initial attempts to unreasonably allocate the costs and liabilities to the "offending" farmers (many of whom had never seen the restrictive terms of the product approval) the whole episode may have evolved quite differently. These and other lessons should make the StarLink episode a powerful and highly instructive moment for all concerned. Whether we will be wise enough to be so educated is yet to be seen.

A key question raised by the StarLink episode is whether we will take additional steps to insure that crops not approved for use in certain markets will in fact be kept from them. The current approach relied on by biotech companies is to place most of this responsibility on the producers. This is done by placing language in the technology transfer agreement to make producers responsible for post harvest "channeling." For example, the provision used in the Grower's Copy of the "2002 Monsanto Technology/Stewardship Agreement" provides, in part:

> Channeling: Grain/commodities harvested from Roundup Ready corn, YieldGard Corn Borer with Roundup Ready corn, Roundup Ready canola and Roundup Ready sugarbeets are approved for U.S. food and feed use, but not yet approved in certain export markets where approval is not certain to be received before the end of 2002. As a result, the grower is required to direct such grain/commodities to the following approved market options: feeding on farm, use in domestic feed lots, elevators that agree to accept the grain, or other approved uses in domestic markets only.[44]

In the "you agree" portion of the contract, the grower agrees "[t]o channel grain produced to domestic use as necessary to prevent

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44. *See* 2002 Monsanto Technology / Stewardship Agreement (on file with author).

movement to markets where the grain has not yet received regulatory approval for import."[45]

### *IV. Pharming—New Crops Present Practical Challenges to Protecting the Food Supply and Promise New Round of Legal Issues*

No doubt the biggest story in the last year in agricultural biotechnology circles has been the attention given to the idea of pharming: the production of genetically modified crops engineered to express some form of a pharmaceutically useful product. This "new" form of biotechnology has received considerable attention in the farm press and has generated a seemingly unrealistic set of economic expectations by Midwestern farmers and politicians.[46] From a legal standpoint, the development of pharming raises a whole new set of legal and policy issues, primarily because of legitimate concerns about the food safety risks of using food crops to produce drugs and the liability issues this will produce. Because of the nature of the risks, pharming has helped illuminate some of the fault lines that exist in the larger food system, perhaps as best illustrated by the tensions between food manufacturers (who remember well the costs and public relations impact of the StarLink episode) and the farming and biotech communities, both of which appear to have never met a technology they don't think should be widely available and utilized.[47] To date, the food sector has been supportive of the development and use of agricultural biotechnology. Perhaps this is due to its own doctrinal resistance to government regulation. Remarkably, the pharma-crop situation has led the National Food Processors

45. *Id.*

46. *Id.* The hoped for economic returns to farmers from pharma-crops may run aground on three shoals of industrialized agriculture: the number of acres actually needed for their production may be limited; the increased prices paid to farmers may be minimal because they did not contribute to the invention of the technology, but instead are only providing land and services; and the additional costs and risks associated with raising the crops and meeting the regulatory requirements for production will reduce the benefits. The reality is that there is little reason to expect pharma-crops to provide returns any larger than conventional crops.

47. For example, a General Mills executive speaking on a biotech panel in Chicago warned that food manufacturers receive no benefit from the current technology, noting, "candidly, we have told the biotech industry that we are in a perilous situation until consumer benefits arrive." Ameet Sachdev, *Biotech "Perilous" for Food Industry*, DES MOINES REG., June 20, 2002, at 1A.

Organization to propose a moratorium on the use of the technology until the possible risks of contamination of the food supply can be addressed.[48] This came after the surprising offer by the biotechnology industry to limit the use of the technology in large parts of the country.[49]

The public debate over the production of pharma-crops and the adequacy of their regulations began in the summer of 2002, when a coalition of environmental groups, GE Food Alert, raised concerns about the safety of the technology and the adequacy of the USDA's effort to police the field experiments underway.[50] After these concerns became public, rumors of possible government actions against companies that raised the crops under experimental field permits emerged. The issue revolved around whether the companies followed agency guidelines that were designed to insure that no pollen from the crops drifted into neighboring fields and that precautions were taken to see that volunteer crops did not emerge the next year.[51]

While these rumblings were heard in farm country, the biotech industry stunned its supporters in the Midwest, especially in Iowa, by launching what amounted to a pre-emptive strike in an attempt to head off public concerns about possible contamination of the food supply with drugs. In late October, the Biotechnology Industry Organization (BIO) members announced a voluntary agreement to redline much of the Midwestern corn belt and not plant pharma-corn in these areas to avoid possible contamination within the food supply.[52] The surprise announcement caused difficulty for Governor

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48. *See* Anne Fitzgerald, *Coalition Urges More Attention to Food Safety*, DES MOINES REG., Feb. 8, 2003, at D1. This article concerns the coalition led by the Grocery Manufacturers of America and their petition to the FDA for stringent regulation of pharma-crops, using the same approach as with brick and mortar drug manufacturing facilities. Their proposal included requests that the FDA prohibit the use of corn and other food crops for production of plant based drugs and a request that the USDA stop issuing field trial permits for the crops. *Id.*

49. *See, e.g.*, Philip Brasher, *Iowa Denied New "Drug" Corn*, DES MOINES REG., Oct. 23, 2002, at 1A.

50. *See, e.g.*, Anne Fitzgerald, *Critics: Altered Crops Pose Risk to Health*, DES MOINES REG., July 12, 2002, at 1D.

51. *See, e.g.*, Anne Fitzgerald, *Pioneer Fined for Violating Biotech Corn Permits*, DES MOINES REG., Dec. 13, 2002, at 1D (concerning fines the EPA assessed to Pioneer and Dow AgroSciences for violation of requirements on growing experimental crops).

52. *See* Brasher, *supra* note 49.

Vilsack in his Iowa re-election campaign and illustrated the split between the food manufacturers and the biotech industry.[53] The sudden action by the biotechnology industry led to editorials and a public relations campaign to get the policy reversed.[54] The industry action brought into question the future of biotech plantings and research at universities like Iowa State, which had made considerable investments in its Plant Sciences Institute.[55] The industry eventually agreed to lift the moratorium and comply with the federal government's new enhanced rules.[56] But the adequacy of the federal rules on pharma-crops next came into focus in what came to be known as the ProdiGene incident.

In late 2002, the enforcement of federal rules on the planting of biotech crops was brought into focus in a pharming case involving the Texas company ProdiGene.[57] Facts indicate that the company had failed to adequately enforce its field cleanup requirements on two sites in Nebraska and Iowa. This led the government to assess a three million dollar fine against the company, part of which was to cover the cost of the 500,000 bushels of contaminated grain the government had to purchase and incinerate.[58] The dispute, following on the heels of the BIO "redlining" proposal, brought extra focus on the adequacy of the federal regulatory structure.[59] As a result of the ProdiGene incident, the FDA took a renewed interest in the adequacy of its rules and, in mid-November, announced plans to increase the monitoring of the companies involved in pharming research.[60]

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53. *See, e.g.*, Editorial, *Lift the Moratorium*, DES MOINES REG., Oct. 25, 2002, at 14A.

54. *See, e.g.*, *Lift the Moratorium*, DES MOINES REG., Oct. 25, 2002, at 14A.

55. *See* Philip Brasher, *ISU Vows Biotech Research Will Go On*, DES MOINES REG., Oct. 25, 2002, at 1A.

56. *See, e.g.*, Philip Brasher, *Biotech Group Lifts Corn Ban*, DES MOINES REG., Dec. 4, 2002, at 1A; *Bring on "Biopharming"*, DES MOINES REG., Dec. 5, 2002, at 12A.

57. Press Release, United States Department of Agriculture, USDA Announces Actions Regarding Plant Protection Act Violations Involving Prodigene, Inc. (Dec. 6, 2002), *available at* http://www.usda.gov/news/releases/2002/12/0498.htm (last visited Nov. 7, 2004).

58. *See* Andrew Pollack, *U.S. Investigating Biotech Contamination Case*, N.Y. TIMES, Nov. 13, 2002, at C7; Philip Brasher, *Biotech Corn May Have Tainted Soybeans*, DES MOINES REG., Nov. 13, 2002, at 1A.

59. *See, e.g.*, Philip Brasher, *Prodigene Must Pay $3 Million in Corn Case*, DES MOINES REG., Dec. 7, 2002, at 1A; Justin Gillis, *Tiny Shoots Lead to Big Biotech Headache*, DES MOINES REG., Dec. 29, 2002, at M1; Andrew Pollack, *Spread of Gene-Altered Pharmaceutical Corn Spurs $3 Million Fine*, N.Y. TIMES, Dec. 7, 2002, at A15.

60. *See* Philip Brasher, *FDA to Tighten Biotech Crop Inspection*, DES MOINES REG., Nov.

### *V. Intellectual Property Rights and Agriculturally Important Genetic Material—Supreme Court Clears Last Doubt*

When I wrote the article in 2000, one cloud on the horizon of the application of intellectual property protections to plant genetic material was an Iowa case involving a fight between Pioneer Hi-Bred International and an agricultural retailer over infringement of Pioneers' patent rights in its corn varieties. The case raised the issue of whether the language of the Plant Variety Protection Act (PVPA) preempted the ability of the Patent Office to grant patent protection for plant varieties such as the corn in dispute. The district and appellate courts predictably upheld the patents and ruled that the PVPA does not prevent their issuance.[61] The courts held that there was no conflict and patents on varieties were legal.[62] Surprisingly, the United States Supreme Court decided to take certiorari in the case and hear further arguments.[63] To make a long story short, the Court heard the case, considered the issues, and in a six to two decision reaffirmed what the seed and biotech communities believed all along—the PVPA does not preempt granting patents on plant varieties.[64] This case is significant because it shows that the Court is not going to revisit the larger issue concerning the wisdom or legality of granting patents on living materials. While other policy issues of trade, pollen drift, and regulatory enforcement continue to engage the public, the inside baseball aspect of biotechnology continues with fights over intellectual property rights between the major players over ownership and control of significant parts of the technology.[65]

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20, 2002, at 1D; *Set Tough Rules for Biofarms*, DES MOINES REG., Nov. 14, 2002, at 18A.

61. Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 49 U.S.P.Q.2d 1813 (N.D. Iowa 1998), *aff'd* 200 F.3d 1374 (Fed. Cir. 2002).

62. *Id.*

63. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., 534 U.S. 124 (2001).

64. *Id.*; *see also* Kevin M. Baird, Recent Development, *Patent Protection of Plants Grows Under the Supreme Court's Latest Decision*, 2002 U. ILL. J.L. TECH. & POL'Y 269 (2002); Anne Hazlett, *Supreme Court Holds Utility Patents May Be Issued for Plants*, AGRIC. L. UPDATE, Jan. 2002, at 4, 4–5; Mark D. Janis & Jay P. Kesan, *Intellectual Property Protections for Plant Innovation: Unresolved Issues After J.E.M. v. Pioneer*, 20 NATURE BIOTECH., Nov. 2002, at 1161.

65. *See, e.g.*, David Elbert, *Pioneer Sues Rival Over Patent*, DES MOINES REG., Oct. 18, 2002, at 1D; Andrew Pollack, *Dispute Ends for Monsanto and DuPont*, N.Y. TIMES, Apr. 3, 2002.

From a farmer's perspective, the most immediate intellectual property rights issue is the impact of technology transfer agreements and product labeling on the ability to save and replant biotech crops. The bottom line is that biotech crops are only marketed under arrangements that comprehensively prevent this opportunity (because they do not allow leakage of the technology). The legality of these agreements has been debated in connection with the Roundup Ready technology agreement, but there is little doubt about their enforceability. In the last year some of the first court cases illuminating the issue have been decided.[66] The cases present few surprises and hold that the language of the planting restrictions is enforceable.[67] Of the court cases involving seed patent infringement and possible pollen drift, the fight between Canadian farmer Percy Schmeiser and Monsanto of Canada concerning his alleged infringement on Roundup Ready canola has received the greatest attention in the international press.[68] The Canadian district court ruled that Mr. Schmeiser had infringed upon Monsanto's rights, rejecting Mr. Schmeiser's theory that the canola came onto his property through drift or other unintentional sources.[69] In September 2002, the Canadian Court of Appeals upheld the decision.[70] The case may still go up for further appeal.

### *VI. State Initiatives to Allocate Responsibility and Liability for Pollen Drift—Who Pays for "Adventitious" Presence?*

In my 2000 article, I commented that "[g]enetic pollution or "pollen drift' is perhaps the most intellectually interesting legal issue relating to biotechnology."[71] I still believe this is true, although the

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66. *See, e.g.*, Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002); Monsanto v. Swann, 308 F. Supp. 2d 937 (E.D. Mo. 2003).

67. *See, e.g.*, David Moeller, *Monsanto Gets Injunction Against Seed-Saving Farmer*, 17 FLAG NEWSLETTER (Farmers Legal Action Group), Fall 2002, at 9; Donald Uchtmann, *Can Farmers Save Roundup Ready Beans for Seed? McFarling and Trantham Cases Say "No"*, AGRIC. L. UPDATE, Oct. 2002, at 4–5.

68. Information about this dispute can be found at http://percyschmeiser.com (last visited Jan. 5, 2005).

69. *See* Monsanto Canada, Inc. v. Schmeiser, 2001 FCT 256.

70. *See* Schmeiser v. Monsanto Canada, Inc., 2002 FCA 309.

71. Hamilton, *supra* note 1, at 103.

development of legal precedent addressing this issue has been limited.[72] The StarLink litigation and settlement is perhaps the most significant development because it establishes responsibility for damages resulting from the use of the technology. However, because the case involved a violation of the regulatory approval of the product, it may not serve as controlling precedent in the more difficult case where the lawful use of an approved product results in measurable commercial damages to a non-compatible crop. As a result, courtroom battles to resolve conflicts over pollen drift from the production of GMO crops and the potential liability from contaminating neighboring non-GMO crops still loom on the legal horizon.[73]

State attempts to regulate the actual planting and use of biotech crops is another legal front on which several developments have occurred. For example, in March 2001, the North Dakota legislature considered, but rejected, a proposal prohibiting the planting of GMO wheat for two years.[74] In 2002, the Indiana legislature passed legislation designed to inject state law into the questions of liability and responsibility for use of biotech crops.[75] In 2003, the Iowa General Assembly introduced a new legislative approach to addressing pollen drift damages by creating a "Grain Integrity Indemnity Fund."[76] This idea, based on the state's grain indemnity fund, which protects farmers who store or sell grain from financial losses, would assess a small fee or excise tax on each bushel of grain sold in the state to fund a twenty-five million dollar indemnity fund to cover validated claims of damages from pollen contamination. While the idea can be criticized for failing to allocate the financial liability to either the developers of the technology or the actual users, the approach has the major benefit of providing an accessible pool of

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72. For an excellent discussion of many of the dimensions of this issue, as influenced by the StarLink affair, see Thomas P. Redick & Christina G. Bernstein, *Nuisance Law and the Prevention of "Genetic Pollution": Declining a Dinner Date with Damocles*, 30 ENVTL. L. REP., May 2000, at 10,328.

73. *See, e.g.*, Anne Fitzgerald, *Specialty Pollen Concern Blowin' in Wind*, DES MOINES REG., Mar. 7, 2002, at 1D.

74. *See* Andrew Pollack, *Proposal to Bar Altered Wheat Seems Doomed*, N.Y. TIMES, Mar. 31, 2001, at A9.

75. H.B. 1119, 112th Gen. Assemb., 2d Reg. Sess. (Ind. 2003).

76. H.F. 80-108, 1st Sess. (Iowa 2003).

funds for compensating injured growers. Instead of requiring each dispute to become a courtroom battle over proof of causation and the measurement of damages, the indemnity fund approach would give farmers what they need most: a way to cover their damages.

### *VII. International Trade Restraints on Marketing GMO Crops—When Will We Be Heard?*

The most contentious area of the biotechnology debate continues to be the relationship between the United States and the European Union and the issue of European regulations on the importation and labeling of American-raised GM crops. While the European Union has made progress in developing new standards, perhaps the best way to describe the situation in the winter of 2003 was mounting tensions moving inexorably toward a WTO trade war.[77] The only problem from the United States perspective was that another, more important, war moved onto center stage. It was politically and diplomatically difficult to bash the Europeans over GMO policy while trying to motivate them to support our efforts to wage war on Iraq.[78] As a result, the drumbeat for a trade war with the Europeans over GMO policy, which many see as a much-needed test of the resolve and efficacy of WTO rules and processes and a defense of sound science, has had to take a back seat to more pressing geo-political concerns.[79] Even among those nations embracing biotechnology there exists issues relating to free trade in the technology and efforts to protect domestic economic opportunities. The situation in China is perhaps the best example of this schizophrenic situation: the nation embraces the use of biotechnology but uses an uncertain regulatory environment to chill the ability of Western companies to export crops to the country.[80] While Chinese regulations on biotechnology

77. *See, e.g.*, Philip Brasher, *Fear Threatens U.S. Crop Sales in Europe*, DES MOINES REG., Nov. 11, 2002, at 1A.

78. *See* Elizabeth Becker, *U.S. Delays Suing Europe over Ban on Modified Food*, N.Y. TIMES, Feb. 5, 2003, at A6.

79. *See* Philip Brasher, *Biotech Ban Tries Patience of U.S.*, DES MOINES REG., Mar. 4, 2003, at 1D.

80. *See* Joseph Kahn, *The Science and Politics of Super Rice*, N.Y. TIMES, Oct. 22, 2002, at C1.

continue to evolve and raise concerns for United States exports, some American companies have been able to develop plans for moving forward with China.[81]

*IX. Resistance and GMOs—Refuges, Roundup and Resistant Weeds*

From a technological standpoint, one significant issue related to the widespread adoption of GMO technology is how its use will eventually lead to the development of resistance in the target pest. From a regulatory perspective, this concern is most directly at issue in the regulation of bio-pesticides such as Bt corn. The regulatory focus is on the need for farmers to follow resistance management plans, which include planting non-Bt refuges. The counter-intuitive nature of requiring farmers not to use an effective technology and the unwelcome task of actually enforcing regulations relating to refuges help complicate this topic. In late November 2002, the EPA announced a "two-strikes" policy concerning farmer compliance with the field refuge requirements for planting Bt corn, including roles for companies to aid in the enforcement.[82] The issue of resistance management took another turn early in 2003, when new research was reported indicating the increased appearance of weeds resistant to the use of Roundup.[83] The significance of the story was emphasized when it became the subject of a somewhat surprising editorial, entitled "Too Much Roundup."[84]

## CONCLUSION: THE FUTURE OF LAW AND BIOTECHNOLOGY

This article provides a concise update of many of the significant legal and policy issues shaping American law as relates to agricultural biotechnology. Some issues, such as the international bio-safety protocol and the recent completed international agreements

81. *See, e.g.*, Anne Fitzgerald, *Joint-Venture to Produce, Sell Seed Corn to Chinese Farmers*, DES MOINES REG., Dec. 12, 2002, at 1D (concerning a recent agreement between Pioneer Hi-Bred International and a major Chinese seed corn company).

82. *See* Philip Brasher, *Rules Govern Biotech Planting*, DES MOINES REG., Nov. 27, 2002, at D1.

83. Philip Brasher, *Roundup-Resistant Weeds Are Cropping Up All Over*, DES MOINES REG., Jan. 10, 2003, at A1.

84. *Too Much Roundup*, INT'L HERALD TRIB., Feb. 20, 2003, at 8.

on plant genetic resources, were beyond the scope of this discussion. Other areas of ongoing litigation, such as the StarLink settlement, could be the basis for their own lengthy treatment. What is clear from this discussion is that a series of significant legal and policy questions will continue to shape how agricultural biotechnology will be accepted in America. As the article makes clear on the issue of food safety and consumer acceptance, unless some new incident occurs to provide evidence of safety concerns, the marketplace will continue to welcome GMO foods. In the near term, one of the most significant issues is whether genetically altered salmon will be marketed, and if so, what type of environmental restrictions will be placed on its production. From the perspective of farmers and state legislators, the future of pharma-crops will offer both promise and problems. It will be interesting to see whether the market reality for the crops can match the expectations they appear to be generating. On the international front, the tension between the United States and the European Union over GMOs will remain a source of conflict that may or may not be addressed when the European Union approves its long-promised policy on the production of GMO crops. Biotechnology is a powerful and elegant technology that will undoubtedly play a role in the future of world agriculture. The complex social issues relating to biotechnology will test the ability of the legal system to develop rules and mechanisms to guide its use.

An Agricultural Law Research Article

# Protecting Traditional Agricultural Knowledge

By

Stephen B. Brush

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# Protecting Traditional Agricultural Knowledge

Stephen B. Brush*

Conservationists have advanced various proposals to protect farmer knowledge and engender the farmer participation necessary for continued crop evolution that generates plant genetic resources for food and agriculture. These proposals include increasing the demand for traditional crops by farmers and consumers,[1] enhancing the supply of those crops,[2] and negotiating a monetary value for crop resources.[3] While achieving *in situ* conservation is possible without changing farmers' customary management of crops as common pool resources, an alternative approach is to negotiate a contract with providers of the resource that involves direct payment and royalties. This bioprospecting mechanism implies a change in the customary treatment of crop genetic resources as common pool goods and is in line with national ownership mandated by the Convention on Biological Diversity (CBD).[4] Until the end of the last century, crop genetic resources were managed as public domain goods according to a set of practices loosely labeled as "common heritage." The rise of intellectual property for plants, the commercialization of seed, the increasing use of genetic resources in crop breeding, and the

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1. Valeria Negri & Nicola Tosti, *Phaseolus Genetic Diversity Maintained On-Farm in Central Italy*, 49 GENETIC RESOURCES & CROP EVOLUTION 511, 518–19 (2002); Margaret E. Smith et al., *Participatory Plant Breeding with Maize in Mexico and Honduras*, 122 EUPHYTICA 551, 552 (2001).

2. MAURICIO R. BELLON, DEMAND AND SUPPLY OF CROP INFRASPECIFIC DIVERSITY ON FARMS 1–2 (Economics Program of the International Maize and Wheat Improvement Center (CIMMYT), Mexico, D.F., Working Paper No. 01-01, 2001).

3. Paul J. Ferraro & Agnes Kiss, *Direct Payments to Conserve Biodiversity*, 298 SCIENCE 1718, 1719 (2002).

4. CBD (1992), *available at* http://www.biodiv.org/convention.

declining availability of crop genetic resources have contributed to extensive revisions to the common heritage regime. Changes include specifying national ownership over genetic resources and use of contracts in the movement of resources between countries.

This article explores the impact of these changes in cradle areas of crop domestication, evolution and diversity (Vavilov Centers) where farmers continue to grow diverse populations of crops that serve as stores of genetic resources and sources for new resources. The question posed here is whether protection of traditional knowledge is best accomplished through a form of bioprospecting that replaces common pool management by private ownership. The article addresses two issues relating to the demise of the common heritage regime:

1. What role does common heritage play in the management of crop genetic resources?
2. What steps are available to protect crop genetic resources in the public domain and to recognize the stewardship of farmers who maintain those resources?

The article discusses these issues in reference to the flow of genetic resources between traditional farming systems of Vavilov Centers and the commercial and public crop breeding sectors in developed countries.

## I. VAVILOV CENTERS AND THEIR CROP RESOURCES

The uneven distribution of crop diversity among geographic regions was one clue used by nineteenth-century naturalists such as Alphonse DeCandolle and Charles Darwin to identify centers of domestication for different crops.[5] The contrasts between centers of origin and other regions where crops are cultivated are still impressive. A single province in the Peruvian Andes has more potato diversity than all of North America.[6] Likewise, the cassava diversity found in a single Amerindian village in Guyana has been found to be greater than the diversity in core collection of the international gene

5. STEPHEN B. BRUSH, FARMERS' BOUNTY 24 (2004).

6. C.F. Quiros et al., *Biochemical and Folk Assessment of Variability of Andean Cultivated Potatoes*, 44 ECON. BOTANY 254, 264–65 (1990).

bank of the crop.[7] Early in the twentieth century, Nikolai Vavilov added a second clue, the presence of wild relatives, to solve the problem of locating centers of crops' origins.[8] Vavilov's accomplishment is recognized among crop scientists by the concept of a Vavilov Center to designate the geographic regions where a particular crop was domesticated and initially evolved under cultivation.[9] Although the idea of "center" has been debated[10] and crop centers are redefined according to new data,[11] the current consensus among crop scientists is that cradle areas of crop domestication are identifiable and reasonably well known.[12] While genetic resources are found in all farming systems, they are particularly valuable and abundant in Vavilov Centers. Concern for conservation and protection of traditional knowledge associated with them is appropriately focused on these centers. Vavilov Centers are critical locations for genetic resources of the world's crops because of their on-going processes of crop evolution, such as gene flow between wild relatives and cultivated types and decentralized selection by farmers.

Just as uneven distribution reveals origin, it also is evidence of diffusion and the fact that farmers and consumers elsewhere are beneficiaries of the resources derived from Vavilov Centers. Thus, maize and cassava farmers in Africa and Asia rely on crop genetic resources that originated in MesoAmerica (maize) and the Amazon Basin (cassava); and New World farmers who grow rice, an Asian domesticate, or sorghum, from Africa, draw on resources from the Old World. The flows of genetic resources in public breeding programs, diffusion of improved crops, and commercial seed also evidence a contemporary dependence on genetic resources from

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7. M. Elias et al., *Assessment of Genetic Variability in a Traditional Cassava (*Manihot esculenta *Crantz) Farming System, Using AFLP Markers*, 85 HEREDITY 219, 226 (2000).

8. N.I. Vavilov, *The Origin, Variation, Immunity, and Breeding of Cultivated Plants*, 13 CHRONICA BOTANICA 1, 45 (1949/1950).

9. JOHN GREGORY HAWKES, THE DIVERSITY OF CROP PLANTS 65 (1983).

10. *See* JACK R. HARLAN, CROPS AND MAN 51 (2d ed. 1992).

11. *See* David L. Lentz et al., *Prehistoric Sunflower (*Helianthus annuus *L.) Domestication in Mexico*, 55 ECON. BOTANY 370, 374 (2001).

12. HAWKES, *supra* note 9, at 52.

Vavilov Centers that is perhaps greater than in times when crop diffusion was informal.[13]

The flow of crop genetic resources has occurred in different spatial and organizational frameworks since the beginning of agriculture. Indeed, some crop scientists speculate that domestication occurred because the wild ancestors of crops were moved beyond their original habitats.[14] The diffusion of crops beyond their original cradle areas starts with the exchange of seed among farmers and is a dominant pattern of crop evolution.[15] This diffusion was accomplished through the incessant movement of human populations and the constant quest for new crops and crop varieties to meet the obstacles of crop production and to satisfy the urgings of human curiosity and palate. Long before the "Columbian Exchange"[16] connected the Old and New Worlds and before European imperial ambitions moved crops here and there,[17] the patterns of long-distance and trans-continental crop diffusion existed. In the prehistoric New World, maize, beans, avocados, and chili pepper, among other crops, migrated from MesoAmerica in the Northern Hemisphere to South America, and cassava, tomatoes, and tobacco moved in the opposite direction. In the prehistoric Old World, wheat, cabbage crops (*Brassica oleracea*) among others moved eastward from the Fertile Crescent and the Mediterranean to the far reaches of Asia, while rice and stone fruits (e.g., peaches, apricots) moved westward to the Atlantic.[18] Similar patterns are evident in Africa and Oceania, for

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13. *See generally* Robert E. Evenson & Douglas Gollin, *Genetic Resources, International Organizations, and Improvement in Rice Varieties*, 45 ECON. DEV. & CULTURAL CHANGE 471 (1997) (evaluating the effect of international organizations and programs on improvements in rice varieties); Cary Fowler et al., *Unequal Exchange? Recent Transfers of Agricultural Resources and Their Implications for Developing Countries*, 19 DEV. POL'Y REV. 181 (2001) (examining current patterns of gene flows and finding that developing countries are major net recipients of germplasm samples); MELINDA SMALE ET AL., THE DEMAND FOR CROP GENETIC RESOURCES (International Food Policy Research Institute, Environment and Production Technology Division (EPDT) Discussion Paper No. 82, 2001) (recognizing that germplasm samples distributed by the U.S. National Germplasm System favor developing countries).

14. HAWKES, *supra* note 9, at 30.

15. LLOYD T. EVANS, CROP EVOLUTION, ADAPTATION AND YIELD 113 (1993).

16. ALFRED W. CROSBY, JR., THE COLUMBIAN EXCHANGE: BIOLOGICAL AND CULTURAL CONSEQUENCES OF 1492, at 64 (1972).

17. LUCILE H. BROCKWAY, SCIENCE AND COLONIAL EXPANSION: THE ROLE OF THE BRITISH ROYAL BOTANIC GARDENS 6, 37 (1979).

18. JONATHAN D. SAUER, HISTORICAL GEOGRAPHY OF CROP PLANTS 27, 116, 207, 218

instance in the diffusion of sorghum south of the Sahara and taro across the Pacific.[19] More formal mechanisms for diffusing crop resources appear to have complemented informal methods since antiquity. The biogeography of rice was recognized in China at least 2000 years ago,[20] and expeditions that included the collection of new crops and crop varieties are reported for the Sumerians in 2500 BC.[21]

Beginning in the fifteenth century, the colonial expansion and global migration of Europeans changed the scale and nature of crop diffusion in two ways. First, the amount and rapidity of diffusion were greatly augmented by the Iberian linkage between Europe, Africa, and the New World.[22] This connection changed the agricultural landscape on all continents. Second, crop exploration and diffusion were formalized and eventually institutionalized.[23] Naturalists and plant explorers accompanied expeditions that had colonial or imperial intentions, and the collection and diffusion of medicinal, industrial, and food crops played a visible role in the European expansion between the sixteenth and twentieth centuries.[24] Indeed, plant collection and exchange was seen as a normal part of diplomatic and economic intercourse among nations,[25] an idea that was immortalized in Thomas Jefferson's aphorism, "[t]he greatest service which can be rendered any country is, to add a useful plant to its culture".[26]

By the early twentieth century, plant collection, conservation and introduction had become a formalized government activity in the United States, Russia, and Australia.[27] Responding to the discovery

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(1993); DANIEL ZOHARY & MARIA HOPF, DOMESTICATION OF PLANTS IN THE OLD WORLD 15, 84, 172, 181 (2d ed. 1993).

19. SAUER, *supra* note 18, at 84; EVANS, *supra* note 15, at 73.

20. F. Bray, *Agriculture, Vol. VI Pt. 2, in* J. NEEDHAM, SCIENCE AND CIVILIZATION IN CHINA 487 (1984).

21. C. LEONARD WOOLLEY, THE SUMERIANS 79 (1928).

22. CROSBY, *supra* note 16, at 73.

23. JOHN GASCOIGNE, SCIENCE IN THE SERVICE OF EMPIRE: JOSEPH BANKS, THE BRITISH STATE AND THE USES OF SCIENCE IN THE AGE OF REVOLUTION 130 (1998).

24. BROCKWAY, *supra* note 17.

25. Knowles A. Ryerson, *History and Significance of the Foreign Plant Introduction Work of the United States Department of Agriculture*, 7 AGRICULTURAL HISTORY 110 (1933).

26. *Services of Jefferson (1800), in* IX THE WORKS OF THOMAS JEFFERSON 65 (Paul Leicester Ford ed., 1905).

27. Ryerson, *supra* note 25, at 121.

of the principles of inheritance in genetics,[28] national crop breeding programs grew out of the foundations of informal plant exploration and introduction. The young science of genetics changed crop resources from a possible source of new production to a probable source. Vavilov was one of the first crop scientists to recognize and promote this idea.[29] International programs for collection, conservation, evaluation, and use of genetic resources further changed the scope and nature of the movement of crop genetic resources among human communities and across great distances. Establishing effective crop breeding programs for international development followed the path blazed by Vavilov and others in assembling, evaluating, and utilizing large national collections of genetic resources from many places but principally from cradle areas of crop domestication.[30]

## II. THE COMMON HERITAGE REGIME

"Common heritage" has historically been the implicit system for managing the diffusion of crop genetic resources, from the informal movement of crops in prehistoric times to the formal national and international framework of crop exploration and conservation agencies. Common heritage refers to the treatment of genetic resources as belonging to the public domain and not owned or otherwise monopolized by a single group or interest. Defining common heritage is similar to belated and sometimes last-ditch efforts to demarcate the public domain after the expansion of private property.[31] Just as the public domain is most easily defined when its constituent parts are appropriated and privatized,[32] common heritage

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28. John M. Poehlman, *How Crop Improvement Developed, in* THE LITERATURE OF CROP SCIENCE 1, 9 (Wallace C. Olsen ed., 1995).

29. Vavilov, *supra* note 8, at 15.

30. DONALD L. PLUCKNETT ET AL., GENE BANKS AND THE WORLD'S FOOD 7–8 (1987); Ryerson, *supra* note 25, at 123 (discussing U.S. expeditions to Europe, Asia, and North Africa in the early twentieth century to bring myriad genetic resources from those countries to the United States).

31. *See generally* Jessica Litman, *The Public Domain*, 39 EMORY L.J. 965 (1990) (examining the public domain and copyright law).

32. *See generally* ROSEMARY J. COOMBE, THE CULTURAL LIFE OF INTELLECTUAL PROPERTIES (1998) (analyzing the constitutive role intellectual property plays in law and society).

is made visible when exchange and use of biological resources are restricted and privatized. An obstacle to understanding and appreciating common heritage is its inherently implicit nature, but roots of the concept are visible in the free exchange of seed among farmers, the long history of diffusion through informal and formal mechanisms, established scientific practices, and the application of the term to other resources in the international arena. Moreover, the robust debate about common property[33] was likely to have triggered the use of the term by crop scientists. Reference to crop genetic resources as a common heritage appeared in the 1980s in association with the establishment of the Commission on Plant Genetic Resources at the Food and Agricultural Organization of the United Nations (FAO) and the launching of the International Undertaking of Plant Genetic Resources.[34] The 1983 conference establishing the FAO Commission and International Undertaking affirmed a resolution stating that "plant genetic resources are a heritage of mankind and consequently should be available without restriction".[35]

Common heritage for plant resources implies open access to seeds and plants from farmers' fields, with due recognition of prior informed consent and the importance of farmers' need for seed and undisturbed fields. Common heritage reflects common property regimes described by anthropologists and other social scientists.[36]

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33. *See* Garret Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968); Duncan Kennedy & Frank Michelman, *Are Property and Contract Efficient?*, 8 HOFSTRA L. REV. 711 (1980).

34. Resolution 8/83 of the Twenty-second Session of the FAO conference recognized that "plant genetic resources are a heritage of mankind . . . ." Food and Agriculture Organization of the United Nations (FAO) Res. 8/83, International Undertaking on Plant Genetic Resources for Food and Agriculture, U.N. FAO Commission on Genetic Resources for Food and Agriculture (CGRFA), 22d Sess. [hereinafter Res. 8/83] pt. (a), at 1 (1983). Resolution 5/89 of the Twenty-fifth Session of the FAO conference recognized that "plant genetic resources are a common heritage of mankind . . . ." FAO Res. 5/89, Farmers' Rights, U.N. FAO, 25th Sess., pt. (a), at 1 (1989); *see also* CARY FOWLER, UNNATURAL SELECTION 189 (1994); ROBIN PISTORIUS & JEROEN VAN WIJK, THE EXPLOITATION OF PLANT GENETIC INFORMATION 10–15 (1999).

35. Res. 8/83, *supra* note 34, Annex, at 2 (1983).

36. Bonnie J. McCay & James M. Acheson, *Human Ecology of the Commons*, *in* THE QUESTION OF THE COMMONS 1 (Bonnie J. McCay & James M. Acheson eds., 1987); *see also* Fikret Berkes, *Common-Property Resource Management and Cree Indian Fisheries in Subarctic Canada*, *in* McCay & Acheson, *supra*; Arun Agrawal, *Common Property Institutions and Sustainable Governance of Resources*, 29 WORLD DEV. 1649 (2001) (examining common property-based resource management).

Like these common property regimes, common heritage implies open access; but whereas common property regimes often imply "club goods"[37] that are openly accessible only to members, common heritage for genetic resources tends to involve fuzzy and permeable boundaries and lack of concern about access. This contrasts with the clear boundaries and control of access that are usual for more tangible and finite common property assets such as pastures, irrigation systems, and wood lots.[38] The universal processes of diffusion and dispersal and the historical practice of reciprocity, which are all in the nature of crop genetic resources, provide the logical foundation for common heritage, but not for drawing sharp boundaries that define ownership. Crop genetic resources derive originally from the natural and amorphous processes of crop evolution: mutation, natural selection, exchange, and decentralized selection. Because no person or group controls crop evolution, it is inappropriate for anyone to claim authorship or ownership. Likewise, the tangled history of diffusion and dispersal not only obscures points of origin but suggests that all farmers benefit from fluid movement of seed. Farmers who openly provide seed expect to receive it in the same manner, and the same is true for crop breeders.

Neither common heritage nor common property imply a lack of rules governing the use and management of common assets,[39] a fact that has been often misunderstood.[40] Rather, community management involves regulated access to common resources and reciprocity among users. One implicit principle in common heritage of genetic resources is the principle of reciprocity: those taking seeds are expected to provide similar access to crop resources. Open access is balanced by generalized reciprocity among farmers and plant breeders across economic sectors and national borders. Reciprocity by plant collectors and breeders becomes evident in three ways. First,

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37. RICHARD CORNES & TODD SANDLER, THE THEORY OF EXTERNALITIES, PUBLIC GOODS, AND CLUB GOODS 33 (2d ed. 1996).

38. ELINOR OSTROM, GOVERNING THE COMMONS 90 (1990).

39. Stephen B. Brush, *Is Common Heritage Outmoded?*, *in* VALUING LOCAL KNOWLEDGE: INDIGENOUS PEOPLE AND INTELLECTUAL PPROPERTY RIGHTS 143 (Stephen B. Brush & Doreen Stabinsky eds., 1996); *see also* OSTROM, *supra* note 38, at 92; CORNES & SANDLER, *supra* note 37.

40. McCay & Acheson, *supra* note 36, at 8; Hardin, *supra* note 33.

plant collectors who gather material that is freely exchanged within farming communities continue this free exchange with crop breeders everywhere.[41] Second, collectors and crop breeders have historically worked under the ethos of public sector research in which the free dissemination of improved crops and the availability of genetic resources from gene banks represents reciprocity to farmers and countries that provide genetic resources. The wide diffusion of modern crop varieties from international breeding programs is one indication of the extent of reciprocity under common heritage.[42] Third, plant variety protection, the most widely used form of Breeders' Rights, includes farmers' and researcher's exemptions which allow farmers to replant and researchers to reuse certified seed without paying royalties to the certificate holder.[43] Illustrating the reciprocity principle in practice, Shands and Stoner enumerate the multiple ways that the U.S. National Germplasm System honors its obligations in the global flow of crop resources. These include donor support to foreign and international conservation and crop improvement programs, cooperative breeding programs, access to USDA collections, repatriation of germplasm, training, and scientific exchange.[44]

The exchange of seed among farmers and the lack of explicit proprietary rules governing specific crop types, traits, or germplasm appear to be common to agriculture before the twentieth century. It remains the dominant approach to seed management for the large majority of farmers around the world. The occasional prohibitions on the export of seed or plant cuttings, such as the nineteenth-century embargo by Peru and Bolivia on the export of *Chinchona* seedlings[45]

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41. Henry L. Shands & Allan K. Stoner, *Agricultural Germplasm and Global Contributions*, *in* GLOBAL GENETIC RESOURCES 97, 97–98 (K. Elaine Hoagland & Amy Y. Rossman eds., 1997).

42. Derek Byerlee, *Modern Varieties, Productivity, and Sustainability*, 24 WORLD DEV. 697, 697 (1996).

43. David J. Houser, *Exemptions Under Patents and Certificates Covering Plants and Comments on Material Transfer Agreements*, *in* INTELLECTUAL PROPERTY RIGHTS: PROTECTION OF PLANT MATERIALS 107, 108 (P. Stephen Baenziger et al. eds., 1993).

44. Shands & Stoner, *supra* note 41, at 101.

45. BROCKWAY, *supra* note 17, at 115–16; TOBY MUSGRAVE & WILL MUSGRAVE, AN EMPIRE OF PLANTS 154 (2000).

or Ethiopia's more recent embargo on coffee,[46] cannot be interpreted as negating the custom of treating genetic resources as public goods. The age-old and continuing diffusion of crops through informal and formal mechanisms, without restrictions on the use of progeny, also supports the argument that genetic resources historically have been defined as part of the public domain.

The crop scientists who articulated the idea of common heritage for crop resources were acculturated in science as a social system without proprietary relations over its basic resources: theories, algorithms, or methodologies.[47] The sociology of science in this context was described by Merton as the Communism of science in which concern for authorship did not imply exclusive rights.[48] Accordingly, most crop scientists who helped establish the international framework for plant genetic resources worked in public breeding programs that released their products as public goods.

Crop scientists also adopted the concept of common heritage from the international discourse about caring for the global environment.[49] The search for ways to confront degradation in extra-territorial regions such as the open seas led to the concept of common heritage[50] and to international legal frameworks such as the Antarctic Treaty (1959) and the U.N. Convention on the Law of the Sea (1982). Five elements of common heritage emerged from these negotiations:[51]

1. Areas defined as common heritage would not be subject to appropriation by private or public interests;
2. All people would share in the management of common territory;

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

47. ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE 293 (Norman W. Storer ed., 1973).

48. *Id.* at 274.

49. Francis X. Cunningham, *The Common Heritage*, FOREIGN SERV. J., July/Aug. 1981, at 13.

50. Christopher C. Joyner, *Legal Implications of the Concept of the Common Heritage of Mankind*, 35 INT'L & COMP. L.Q. 190 (1986).

51. *Id.*

3. Economic benefits from the exploitation of common territory would be shared internationally;
4. Common territory would only be used for peaceful purposes; and
5. Scientific research in common territory would be freely and openly accessible.

These principles were never explicitly applied to crop genetic resources, perhaps because of ambiguity about the exact definition of these resources. If resources are defined as wild relatives of crops or cultivated populations of farmers' varieties (landraces) that cannot be attributed to one farmer or specific point of origin, then these common heritage principles are appropriate. If resources are defined as all genetic material of crops, then the first three of these principles are violated by the plant patenting and plant variety protections (Breeders' Rights) that were in place in industrial countries before 1980. Some used common heritage to argue against the right of breeders to protect their products,[52] while others saw common heritage and Breeders' Rights as co-existing.[53] The central vagueness in defining common agricultural heritage is whether it applies to all genetic material or just to material that is in nature and unclaimed as property. This ambiguity has had devastating consequences for the continued practice of relatively easy and open access to genetic resources.

Common heritage management of genetic material that is not claimed as intellectual property remains conspicuous at two extremes: in farming communities of Vavilov Centers and in the flow of germplasm through international gene banks. The exchange of crop material among farmers within and between communities appears to be ubiquitous and perhaps a necessary part of agriculture.[54] Seed exchange is necessitated and promoted by many factors. Seeds have finite viability because of the constantly changing natural

52. P.R. MOONEY, THE LAW OF THE SEED 45 (1983).

53. C. Mastenbroek, *Plant Breeders' Rights, An Equitable Legal System for New Plant Cultivars*, 24 EXPERIMENTAL AGRIC. 15, 22–24 (1988).

54. Stephen B. Brush, *Bioprospecting the Public Domain*, 14 CULTURAL ANTHRO. 535 (1999).

environment, especially pests and pathogens. Seed becomes infested with disease organisms, such as viruses. Human tastes are notoriously fickle, especially when reflected in markets. Households lose seed in bad years or to rot and vermin. These factors and many others lead to common folk admonitions to change seed often,[55] while other forces result in a constant commingling of individual farmers' material.[56] Commingling of genetic material within and among villages occurs on common threshing floors, in the exchange of gifts of seed, wage payment in kind to agricultural labor, and in regional trade of commodities and seed.[57] This commingling poses a high barrier to any other form of seed management than common heritage.

Case studies of rice turnover in Thailand[58] and maize seed flow in Mexico[59] illustrate the significance of farmer-to-farmer seed exchange. Dennis found that Thai rice farmers relied mostly on traditional varieties and grew an average of 1.7 varieties per farm, but variety turnover was high.[60] Variety lists from 1950 to 1961 indicate eighty-nine types of rice in the study region, and in 1982–83, only fifteen of these were still present among the total of 122 varieties. Dennis found that average projected turnover time for upland rice was thirty to forty-eight years, while the time for lowland, irrigated rice was thirteen years.[61] Traditional and local varieties were subject to turnover as well as modern varieties. In sum, variety turnover is a regular part of traditional Thai rice agriculture, and traditional varieties are not necessarily local varieties.

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55. A.C. Zeven, *The Traditional Inexplicable Replacement of Seed and Seed Ware of Landraces and Cultivars*, 110 EUPHYTICA 181, 181–82 (1999).

56. Stephen Brush et al., *Potato Diversity in the Andean Center of Crop Domestication*, 9 CONSERVATION BIOLOGY 1189 (1995) (examining diversity and population structure of potato landraces to better conserve genetic resources).

57. Stephen B. Brush et al., *Dynamics of Andean Potato Agriculture*, 35 ECON. BOTANY 10 (1981); Hugo Perales R. et al., *Dynamic Management of Maize Landraces in Central Mexico*, 57 ECON. BOTANY 21 (2003).

58. John Value Dennis, Farmer Management of Rice Variety Diversity in Northern Thailand 123 (1987) (unpublished Ph.D. dissertation, Cornell University) (on file at University Microfilms, Ann Arbor, MI).

59. D. Louette, *Traditional Management of Seed and Genetic Diversity: What is a Landrace?*, *in* GENES IN THE FIELD 109 (Stephen Brush ed., 1999).

60. Dennis, *supra* note 58, at 194.

61. *Id.* at 124.

Similarly in Mexico, a Vavilov Center like Thailand, the flow of maize germplasm also appears significant among farming communities. Louette found that farmers in Cuzalapa, Jalisco regularly change the seed lots of their maize landraces and acquire seed of existing varieties and new varieties from outside their community.[62] She found that fifteen percent of the seed lots in the study period were from outside. Perales found a similar pattern in the Chalco and Cuautla Valleys of central Mexico, where farmers frequently purchase seed in urban market places and where seed of maize landraces moves between different states.[63] Both Louette and Perales describe the genetic base of maize landraces as an open system. This description has likewise been applied to potato landraces found in Quechua farmers' fields in the Cusco area.[64] With better information about farmer seed management in traditional farming systems, we now think of landraces as metapopulations or networks of individual populations that are linked through seed flow among farmers and communities.

Moving from farmers' fields in Vavilov Centers to the flow of crop germplasm through international gene banks and crop breeding programs, we also see an open system. Duvick argued that a distinguishing characteristic between traditional and modern farming systems was the locus of diversity in each.[65] According to this view, diversity in traditional farming systems was found on individual farms and in farming communities, while in modern systems diversity was shifted to a network of gene banks and breeding programs. We have modified our thinking about traditional farming to recognize the importance of metapopulations and seed systems, but we can accept Duvick's description of modern agriculture as an interdependent network of seed and germplasm sources.[66] Very few

62. Louette, *supra* note 59.

63. Hugo Rafael Perales Rivera, Conservation and Evolution of Maize in Amecameca and Cuatla Valleys of Mexico 230 (1998) (unpublished Ph.D. Dissertation, University of California Davis) (on file at University Microfilms, Ann Arbor, MI).

64. Karl S. Zimmerer, *The Ecogeography of Andean Potatoes*, 48 BIOSCIENCE 445, 452 (1998).

65. Donald N. Duvick, *Genetic Diversity in Major Farm Crops on the Farm and in Reserve*, 38 ECON. BOTANY 161 (1984).

66. *Id.*

countries or farming systems in the world today do not rely to some degree on the international system that moves crop germplasm, breeding lines, improved varieties, and commercial seed across international borders. Studies of breeding programs show that developing countries, including those within Vavilov Centers, are heavily dependent on international flows of germplasm and more dependent than developed countries.[67] Rejesus et al. examined wheat breeding and found that in West Asia, the Vavilov Center for wheat, wheat breeders' use of their own landraces and advanced lines accounted for 34.2% of the breeding material in their programs compared to 37.9% from international sources.[68] For rice, Evenson and Gollin document the flow of germplasm in Asia and the dependence of Asian countries on germplasm obtained from the International Rice Research Institute (IRRI).[69] Vavilov Center countries (e.g., India, Burma, Bangladesh, Nepal, Vietnam) depended on IRRI for between 65.0% (India) and 98.1% (Vietnam) for the rice material in their breeding programs. This compared to 13.6% in U.S. rice breeding. Fowler et al. estimate that 89.8% of the rice samples distributed from IRRI go to developing countries.[70] The international exchange of crop germplasm is similar to exchange among farmers in being an open system.[71]

Both farmer seed exchange and international crop germplasm flows evolved originally as common heritage regimes. Common heritage is logical within farming communities where land and other natural resources are communally owned, seed is exchanged or shared, invention is collective, provenance is ambiguous, and natural and artificial selection are intertwined. Because of the transaction costs of proprietary management of seed, common heritage arguably is the best way to satisfy the frequent necessity to change or acquire seed in non-market economies. Privatization of land and the development of a market for labor do not necessitate the privatization

67. SMALE ET AL., *supra* note 13.

68. R.M. Rejesus et al., *Wheat Breeders' Perspectives on Genetic Diversity and Germplasm Use*, 9 PLANT VARIETIES & SEEDS 129, 132 (1996). The origin of the remainder of parent material in wheat breeders' crossing blocks was not clearly identified. *Id.*

69. Evenson & Gollin, *supra* note 13, at 481.

70. Fowler et al., *supra* note 13, at 192.

71. *Id.* at 190.

of genetic resources. Intellectual property for plants was a rather recent change[72] that lagged far behind the development of markets for land and labor. Plant patenting and other forms of intellectual property in plants has been willingly embraced in some countries but resisted in many others.[73]

Likewise, a common heritage approach for international exchange is sensible because it lowers transaction costs that are inherent in defining and defending property over genetic resources.[74] These costs include negotiation, pre-distribution tracking, and post-distribution tracking[75] as well as the conventional transaction costs (e.g., exclusion, information, and communication), identified by economists.[76] An example of information costs associated with crop genetic resources is how to ascertain the true "source" of collections. Germplasm collecting existed for many decades before it was more formally organized in the 1970s with the creation of world collections and the International Board for Plant Genetic Resources to facilitate collection and exchange. The United States received germplasm from many sources, including missionaries, diplomats, and plant explorers. The original collections that established the U.S. national gene bank (National Seed Storage Laboratory) included material that had only the country of origin.[77] These U.S. collections were duplicated and distributed to other national and international gene banks, such as the Italian National Gene Bank at Bari and the International Center for Agricultural Research in the Dry Areas (ICARDA), thus multiplying the material without detailed provenience in gene banks around the world.[78] A 1984 review of the status and use of gene banks by Peeters and Williams reports that passport data was wholly lacking for sixty-

72. FOWLER, *supra* note 34, at 73.

73. Martin Khor, *Third World*, 37 RACE & CLASS 73, 74 (1996).

74. BERT VISSER ET AL., GLOBAL FORUM ON AGRICULTURAL RESEARCH (GFAR), DOC. NO. GFAR/00/17-04-04, TRANSACTION COSTS OF GERMPLASM EXCHANGE UNDER BILATERAL AGREEMENTS 2–3 (2000), *available at* http://www.egfar.org/documents/02_-_meetings/conferences/gfar_2000/session_2/gf170404.pdf.

75. *Id.* at 3.

76. Ronald H. Coase, *Notes on the Problem of Social Cost*, *in* THE FIRM, THE MARKET, AND THE LAW 157–86 (1988).

77. Conversation with Ardeshir B. Damania, Genetic Resources Conservation Program, University of California, Davis (Jan. 15, 2003).

78. *Id.*

five percent of the samples in the active international network of gene banks.[79] This percentage has probably decreased as more systematic collection has added to inventories, but the FAO reports that only thirty-seven percent of the material in national collections has passport data.[80]

Plant explorers often cover large territories and reduce collection times by collecting in markets and other central places such as schools. Even if collections come directly from farmers, the seed may be a recent acquisition from another farmer or village. Assigning a territorial designation may also be problematic because of the frequency of migration and the transitory nature of political boundaries. Assuring that source information adheres to collections also incurs cost. Imposing transaction costs associated with privatization onto the international exchange crop germplasm is defensible if the benefits of privatization, such as improved access and conservation are realized, but whether these benefits will indeed result is yet to be demonstrated.

In contemporary parlance, common heritage means that genetic resources are an international public good[81] used by crop scientists to produce other public goods. Common heritage is a rational system of managing crop genetic resources in the international system that was principally organized as a way to facilitate public breeding programs. The public good nature of this system is embodied in the practice of open exchange of crop germplasm among crop breeders and in the research exemption of plant variety protection systems.[82] The period of common heritage management provided an international benefit of immeasurable proportions. The availability of crop resources outside of their original hearths provided food sources that altered human

79. J.P. Peeters & J.T. Williams, *Towards Better Use of Genebanks with Special Reference to Information*, 60 PLANT GENETIC RESOURCES NEWSL. 22, 24 (1984).

80. UNITED NATIONS FOOD AND AGRICULTURE ORGANIZATION, THE STATE OF THE WORLD'S PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (1997) [hereinafter STATE OF THE WORLD], *available at* http://www.fao.org/waicent/faoinfo/agricult/agp/agps/pgrfa/pdf/swrfull.pdf.

81. RAVI KANBUR ET AL., THE FUTURE OF DEVELOPMENT ASSISTANCE: COMMON POOLS AND INTERNATIONAL PUBLIC GOODS (1999); Inge Kaul et al., *Defining Global Public Goods*, *in* GLOBAL PUBLIC GOODS 2, 13 (Inge Kaul et al. eds., 1999).

82. Houser, *supra* note 43, at 108.

history. The "Columbian Exchange"[83] not only benefited Europeans but it also made new staples, such as maize, beans, sweet potatoes, and potatoes, available to Africa and Asia. More recently, the collection of genetic resources under common heritage led directly to increasing food availability around the world through breeding high yielding varieties whose pedigrees include germplasm from numerous countries.[84]

## III. CLOSING THE GENETIC COMMONS

Following the successful initiatives of the 1970s to organize an international framework for conserving crop genetic resources, the common heritage approach for managing access came under increasing, erosive pressure. Factors that combined to threaten the common heritage approach include the increasing value of genetic resources, the expansion of Breeders' Rights in industrial countries, the liberal policy formulation for agricultural development, the North/South political discourse, and the rise of the environmental movement. These strands converged in the early 1990s to produce the CBD, and when taken together with the Global Agreement on Trade and Tariffs, they point to the demise of common heritage. By the beginning of the twenty-first century, however, common heritage had regained status as the underlying principle of a new international framework for managing access to crop genetic resources.

Genetic resources gained value throughout the twentieth century by virtue of increasing demand and decreasing supply. The discovery of the principles of inheritance provided impetus for the creation of systematic crop breeding, an endeavor that required a supply of genetic material.[85] Public and private crop breeding expanded its role throughout the twentieth century, first in the rapidly industrializing countries of Europe and North America,[86] and then internationally

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83. CROSBY, *supra* note 16, at 185–88 (describing the importance of New World crops to Africa).

84. Byerlee, *supra* note 42, at 697; Melinda Smale, *The Green Revolution and Wheat Genetic Diversity: Some Unfounded Assumptions*, 25 WORLD DEV. 1257, 1257 (1997).

85. Ryerson, *supra* note 25, at 123–24.

86. DEBORAH FITZGERALD, THE BUSINESS OF BREEDING: HYBRID CORN IN ILLINOIS, 1890–1940 (1990). Fitzgerald chronicles the rise of private corn breeding on the foundations of

into the developing countries.[87] While organized crop breeding increased the demand for genetic resources, genetic erosion that accompanied agricultural modernization threatened the supply of those resources.[88] The creation of an international network of over 1300 national and regional germplasm collections in addition to eleven international gene banks managed by CGIAR institutions, and with six million accessions is evidence of increased value of genetic resources.[89]

The rise of crop breeding also contributed to the demise of common heritage by changing perceptions about crop breeders and ownership of living matter. After 1900, crop breeders emerged as another type of inventor who manipulated common goods into novel and more useful ones,[90] so it is not surprising that intellectual property protection for plant breeders soon followed the rise of systematic crop improvement. A progression of different forms of Breeders' Rights ensued, the U.S. Plant Patent Act in 1930, and since this Act, Breeders' Rights have been expanded both in terms of what products are eligible for protection as intellectual property and in the strength of protection afforded to breeders. Utility patents on new crops, their component parts, and processes have thus been added to plant patents and plant variety certificates.[91] The U.S. Supreme Court reaffirmed the legitimacy of utility patents for crops in *J.E.M. Ag Supply v. Pioneer Hi-Bred International*.[92] Moreover, less developed countries have increasingly adopted Breeders' Rights to stimulate crop improvement and in response to international pressure. Perhaps most importantly, Breeders' Rights are included in the Trade-Related

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public science. *See, e.g.*, DEBORAH FITZGERALD, *The Uses of Science: History of the Funk Brothers Seed Company*, *in* FITZGERALD, THE BUSINESS OF BREEDING, *supra*; JACK RALPH KLOPPENBURG, JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 1492–2000, at 105–16 (1988); HENRY A. WALLACE & WILLIAM L. BROWN, CORN AND ITS EARLY FATHERS, (Iowa State University Press rev. ed. 1988).

87. LLOYD T. EVANS, FEEDING THE TEN BILLION 133 (1998).

88. O.H. Frankel, *Genetic Conservation in Perspective*, *in* GENETIC RESOURCES IN PLANTS—THEIR EXPLORATION AND CONSERVATION 469, 474 (O. H. Frankel & E. Bennett eds., 1970); Jack R. Harlan, *Our Vanishing Genetic Resources*, 188 SCIENCE 618, 619 (1975).

89. STATE OF THE WORLD, *supra* note 80, at 98, 107.

90. FOWLER, *supra* note 34, at 89.

91. Nicholas J. Seay, *Intellectual Property Rights in Plants*, *in* INTELLECTUAL PROPERTY RIGHTS, *supra* note 43, at 61, 66.

92. 534 U.S. 124, 130 (2001).

Aspects of Intellectual Property Rights (TRIPS) Agreement[93] and are part of the package of national policies required for membership in the World Trade Organization (WTO).[94] While the TRIPS agreement allows countries to fashion their own (*sui generis*) approach to Breeders' Rights,[95] the need to conform to international standards encourages adoption of a system resembling the International Union for the Protection of New Varieties of Plants (UPOV) approach.

The development of plant breeding, the expansion of Breeders' Rights, and the recognition of genetic erosion as a social cost of agricultural development seemed to portend the inevitable demise of common heritage. The apparent failure of the common heritage system to contain the degradation of crop genetic resources conforms to the Tragedy of the Commons scenario.[96] This failure is attributed to the open access quality of the common heritage system that allowed breeders to benefit from using resources without bearing the cost of maintaining them. Hardin[97] and others[98] argued that privatizing common pool resource was the way to arrive at socially acceptable levels of use and conservation, and this argument was easily extended to genetic resources.[99]

The North/South political discourse took up the availability of Breeders' Rights in industrialized countries and their absence elsewhere as evidence of an imbalance in the stream of benefits flowing from genetic resources.[100] Breeders were accorded the right

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93. GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS, TRADE AND BIODIVERSITY 78 (2000); MARTIN A. GIRSBERGER, BIODIVERSITY AND THE CONCEPT OF FARMERS' RIGHTS IN INTERNATIONAL LAW 135 (Thomas Cottier ed., 1999); Dan Leskien & Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a* Sui Generis *System*, ISSUES IN GENETIC RESOURCES NO. 6 (International Plant Genetic Resources Institute (IPGRI), June 1997, at 2.

94. Carlos A. Primo Braga & Carsten Fink, *Reforming Intellectual Property Rights Regimes*, 1 J. ECON. INT'L L. 537, 539 n.3 (1998).

95. Leskien & Flitner, *supra* note 93, at 48.

96. Hardin, *supra* note 33, at 1243.

97. *Id.*

98. Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347 (1967).

99. Roger A. Sedjo, *Property Rights and the Protection of Plant Genetic Resources*, *in* SEEDS AND SOVEREIGNTY 293 (Jack R. Kloppenburg, Jr. ed., 1988).

100. Jack R. Kloppenburg, Jr. & Daniel Lee Kleinman, *Seeds of Controversy: National Property Versus Common Heritage*, *in* SEEDS AND SOVEREIGNTY, *supra* note 99, at 173, 173–74.

to tangible, private benefits while farmers had to rely on indirect, public benefits. The reciprocity of the common heritage system functioned through providing public goods such as new crop varieties, education, and development infrastructure rather than in private goods that directly connected the farmer and crop breeder. The critical ambiguity of whether common heritage should apply to all genetic resources or only to those in fields and farm stores became a political liability. The relatively low visibility of the reciprocity provided a basis for claims of exploitation under the label "biopiracy."[101] Odek's definition of biopiracy as the "uni-directional and uncompensated appropriation" of genetic resources[102] pointedly ignored the reciprocity of the international system of collecting, conserving, using, and redistributing crop genetic resources. More generally, this reciprocity was undervalued by arguments that contractual collection arrangements are needed to ensure equitable returns.[103] Finally, the rise of the "neo-liberal" policy agenda in international development after 1980[104] and the increasing pressure for more participatory and non-governmental programs[105] favored market solutions to development problems such as conserving crop resources.

By 1992, these strands had converged to create conditions for a bold move against common heritage, and a potential *coup de grâce* was delivered in the 1992 CBD that defined genetic resources as belonging to nation states. The initialing of the CBD at the 1992 U.N. Conference on the Environment and Development (UNCED) in Rio de Janeiro marks a watershed in the management of crop genetic resources.[106] UNCED sought to forge a new framework for

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101. VANDANA SHIVA, BIOPIRACY: THE PLUNDER OF NATURE AND KNOWLEDGE 5 (1997).

102. James O. Odek, *Bio-Piracy: Creating Proprietary Rights in Plant Genetic Resources*, 2 J. INTELL. PROP. L. 141, 145 (1994).

103. WORLD RESOURCES INSTITUTE (WRI), WORLD CONSERVATION UNION (IUCN), UNITED NATIONS ENVIRONMENT PROGRAMME (UNEP), GLOBAL BIODIVERSITY STRATEGY: GUIDELINES FOR ACTION TO SAVE, STUDY, AND USE EARTH'S BIOTIC WEALTH SUSTAINABLY AND EQUITABLY 94 (1992).

104. John Williamson, *The Washington Consensus Revisited*, *in* ECONOMIC AND SOCIAL DEVELOPMENT INTO THE XXI CENTURY 48 (Louis Emmerji ed., 1997).

105. R. CHAMBERS, RURAL DEVELOPMENT: PUTTING THE LAST FIRST 168 (1983).

106. Lyle Glowka et al., Int'l Union for the Conservation of Nature, *A Guide to the Convention on Biological Diversity*, ENVTL. POLICY AND LAW PAPER NO. 30, 1994, at 1.

confronting environmental problems.[107] This new framework intended to defuse increasing North/South polarization of the pre-UNCED era with a cooperative approach involving unbinding ("soft law") agreements such as Agenda 21, community based forms of action, inclusion of non-governmental organizations (NGOs), and voluntary reporting.[108] UNCED also followed a period of heightened awareness of the trans-national nature of environmental problems and somewhat fitful attempts to negotiate individual, legally binding conventions, such as the U.N. Convention on the Law of the Sea.[109]

The post-UNCED system for managing crop genetic resources was characterized by national ownership of crop resources overlying professional practices inherited from the pre-UNCED (common heritage) period and the creation of management tools that would be appropriate to the UNCED principles of sovereign ownership and equitable sharing of benefits from the use of biological resources. Two contradictory pressures, however, are evident in the spirit of UNCED. The emphasis on sovereign ownership suggested a move to regulate access to national resources through bilateral contracting mechanisms that became know as bioprospecting agreements.[110] The second pressure in UNCED was to eschew legally binding international conventions[111] in favor of a more cooperative "soft law" approach[112] based on voluntary mechanisms.

These pressures have had different effects in reshaping access to genetic resources depending whether pharmaceutical and natural product resources or crop resources are involved. Access to resources

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107. Jacqueline Roddick, *Earth Summit North and South*, 7 GLOBAL ENVTL. CHANGE 147, 147 (1997).

108. DARRELL A. POSEY & GRAHAM DUTFIELD, BEYOND INTELLECTUAL PROPERTY 120 (1996); *see also* Roddick, *supra* note 107.

109. *See generally* U.N. DIV. FOR OCEAN AFFAIRS & THE LAW OF THE SEA, THE LAW OF THE SEA (1997) (reproducing the text of the agreement with index and excerpts from the Final Act of the Third United Nations Conference on the Law of the Sea).

110. Walter V. Reid et al., *A New Lease on Life*, *in* BIODIVERSITY PROSPECTING: USING GENETIC RESOURCES FOR SUSTAINABLE DEVELOPMENT 1 (Walter V. Reid et al. eds., 1993); Sarah A. Laird & Kerry ten Kate, *Biodiversity Prospecting: The Commercial Use of Genetic Resources and Best Practice in Benefit-Sharing*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE: EQUITABLE PARTNERSHIPS IN PRACTICE 241, 243 (Sarah A. Laird ed., 2002).

111. Roddick, *supra* note 107, at 156.

112. Francesco Mauro & Preston D. Hardison, *Traditional Knowledge of Indigenous and Local Communities*, 10 ECOLOGICAL APPLICATIONS 1263, 1266 (2000).

for pharmaceutical development tended toward regulation by bilateral contracts while access to resources for crop development has tended toward open, multilateral mechanisms.[113] Three differences between these two genetic resources explain this outcome. First, pharmaceutical resources tend to involve relatively discrete traits and perhaps single genes while crop resources involve quantitative traits that are controlled by multiple genes. Second, crop resources are dependent on human stewardship and have resulted from collective management and selection. Third, pharmaceutical resources lacked the international infrastructure of collection, conservation, public breeding, and exchange that was developed for crop resources.[114] The Merck/InBio contract[115] epitomized bioprospecting contracts for pharmaceutical and natural product development. Comparable agreements between suppliers and users of crop genetic resources are rare, but in their place, suppliers of crop resources have promoted the use of material transfer agreements.[116] These mechanisms are sometimes informational rather than financial contracts. For instance, the instruments developed by the international gene banks of the CGIAR system inform the recipient of germplasm that it is for research and breeding purposes only and inveigh him/her to forgo future claims of intellectual property.[117] These mechanisms retain

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113. Brendan Tobin, *Biodiversity Prospecting Contracts*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE, *supra* note 110, at 287; COMMISSION ON INTELLECTUAL PROPERTY RIGHTS (CIPR), INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 69 (2002), *at* http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf.

114. Perhaps because of the extremely large number of species kept at botanical collections and herbariums, their policy is to make specimens available to researchers. *See, e.g.*, Royal Botanic Gardens, Kew: Collections: Herbarium (last visited Dec. 26, 2004), *at* http://www.rbgkew.org.uk/collections/herbcol.html. No comparable system exists for plant resources for pharmaceuticals to the one for crop resources, which involves the exchange of seed as well as information about the accessions. *See* BIODIVERSITY IN TRUST: CONSERVATION AND USE OF PLANT GENETIC RESOURCES IN CGIAR CENTRES (Dominic Fuccillo et al. eds., 1997); PLUCKNETT ET AL., *supra* note 30.

115. Reid et al., *supra* note 110, at 2.

116. John H. Barton & Wolfgang E. Siebeck, *Material Transfer Agreements in Genetic Resources Exchange—The Case of the International Agricultural Research Centres*, ISSUES IN GENETIC RESOURCES NO. 1, May 1994, at 11; *see also* Michael A. Gollin, *Elements of Commercial Biodiversity Prospecting Agreements*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE, *supra* note 110, at 310, 313.

117. *See, e.g.*, CENTRO INTERNACIONAL DE AGRICULTURA TROPICAL (CIAT), MATERIAL TRANSFER AGREEMENT (2001), *available at* http://www.ciat.cgiar.org/pgr/mta.htm.

common heritage aspects of the pre-UNCED era and avoid moving to more rigid contractual agreements that specify benefit flows that are found in bioprospecting agreements for pharmaceutical and other natural products.[118] In other cases, however, countries have turned to the Mutual Transfer Agreement (MTA) as a contractual mechanism to transfer genetic resources. An example of this is the use of MTAs by the National Biodiversity Institute of Costa Rica that accompany the transfer samples to partner organizations and have contractual power recognized by national law.[119]

Civil society organizations, nations, regional coalitions, and international agencies have responded to the closure of the biological commons with a variety of programs and implements aimed at protecting the public domain. On program is to register traditional knowledge practices and innovations and thereby define them as a prior art so that they cannot be directly appropriated as intellectual property. The American Association for the Advancement of Science has initiated the Traditional Ecological Knowledge * Prior Art Database where plant names and associated knowledge can be registered.[120] At the international level, the negotiation of the International Treaty for Plant Genetic Resources for Food and Agriculture represents the culmination of an enduring effort to maintain crop resources as common pool goods.

## IV. THE INTERNATIONAL TREATY FOR PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Besides material transfer agreements, the international crop resource system responded to national sovereignty with negotiations that eventually reconfirmed the principles of relatively unfettered and uncompensated germplasm exchange. Negotiations involving the Consultative Group for International Agricultural Research (CGIAR),

118. Reid et al., *supra* note 110.

119. Jorge Cabrera Medaglia, *Costa Rica: Legal Framework and Public Policy*, *in* SANTIAGO CARRIZOSA ET AL., ACCESSING BIODIVERSITY AND SHARING THE BENEFITS 101 (2004).

120. AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (AAAS), AAAS PROJECT ON TRADITIONAL ECOLOGICAL KNOWLEDGE, *at* http://shr.aaas.org/tek (last visited Sept. 20, 2004).

the FAO Commission on Plant Genetic Resources for Food and Agriculture, and numerous nations resulted in two international agreements that confirmed common heritage. In 1994, the collections of the international gene banks of the CGIAR centers were placed under the auspices of the FAO, to be managed as an international public good by the gene banks, excepted from intellectual property claims, and freely available to crop breeders.[121] Second, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was negotiated in 2001[122] and has now been signed by seventy-eight countries, including the U.S.[123] Having reached the required number of national instruments of ratification, acceptance, approval or accession, the treaty went into force on June 29, 2004.[124]

The ITPGRFA takes a multilateral approach that reaffirms common heritage for the crop genera that are included in list of crops covered by the pact. States retain sovereign rights over their genetic resources, including the right to designate genetic material and whole plants as intellectual property. The core provisions of the ITPGRFA (Articles 10–12) place the resources of thirty-six genera of crops and twenty-nine genera of forages in the public domain and guarantees access to these resources for breeding and research. Germplasm from the multilateral system will be available with an MTA that may include provisions for benefit sharing in the event of commercialization. The Treaty stipulates that

> Recipients shall not claim any intellectual property or other rights that limit the facilitated access to plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System.[125]

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121. PISTORIUS & VAN WIJK, *supra* note 34; CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH (CGIAR) SYSTEM-WIDE GENETIC RESOURCES PROGRAMME, 1999 ACTIVITIES (2000), *at* http://sgrp.cgiar.org/1999activities-policy.html.

122. International Treaty on Plant Genetic Resources of Food and Agriculture (ITPGRFA), Commission on Genetic Resources for Food and Agriculture, U.N. Food and Agricultural Organization (FAO) (2001), *at* ftp://ext-ftp.fao.org/ag/cgrfa/it/itpgre.pdf.

123. ITPGRFA, U.N. FAO Legal Office (last visited Dec. 26, 2004), *at* http://www.fao.org/legal/treaties/033s-e.htm.

124. *Id.*

125. ITPGRFA, *supra* note 122, art. 12.3.d.

The phrase "in the form received" may be interpreted as allowing intellectual property claims once significant, inventive manipulation has occurred.[126] The interpretation of this issue and others will be negotiated by parties to the treaty that will comprise the Governing Body of the International Undertaking. The FAO serves as the proprietor of the international crop collections that are held in trust by the CGIAR, and the CGIAR system has repeatedly confirmed its adherence to open access to these collections.[127]

Article 13 of the ITPGRFA lays out a procedure for benefit sharing by stipulating that commercialization of a new plant variety will trigger a financial contribution to the multilateral system. Again, the approach is multilateral rather than contractual between the genetic resource provider and the person who commercialized a product using that resource. The level, form, and conditions of payment (for instance, whether small farmers are exempt) is not resolved in the treaty and will be subject to further negotiations within the Governing Body of the International Undertaking.[128] The benefit-sharing mechanism of the ITPGRFA faces serious logistical difficulty because of the long lag time between access to genetic resources and commercialization. Moreover, identifying the contribution of a specific resource within the complex pedigree of an improved crop variety poses a major obstacle to negotiating benefit sharing. Nevertheless, the treaty provides a mechanism for negotiating these obstacles while access to crop resources remains open. Another obstacle is the increasing propensity of commercialization of crop varieties based on patents of transgenic components such as *Bacillus thuringiensis* (Bt) and tolerance to glyphosate herbicides.[129] Because these traits do not derive from

126. CIPR, *supra* note 113, at 69.

127. Susan Bragdon & David Downes, *Recent Policy Trends and Developments Related to the Conservation, Use and Development of Genetic Resources*, ISSUES IN GENETIC RESOURCES NO. 7 (IPGRI), June 1998, at 17, *available at* http://www.ipgri.cgiar.org/policy/igr7.pdf.

128. The terms of benefit sharing are to be determined by the Governing Body of the treaty, comprised of all contracting parties. *See* ITPGRFA, *supra* note 122, art. 13.2.d.ii.

129. *See, e.g.*, Greg Graff et al., *Agricultural Biotechnology in Developing Countries*, *in* PERSPECTIVES IN WORLD FOOD AND AGRICULTURE 2004, at 417, 423–24 (Colin G. Scanes & John A. Miranowski eds., 2004); Janice A. Kimpel, *Freedom to Operate*, 37 ANN. REV. OF PHYTOPATHOLOGY 29, 38 (1999). Moreover, besides reliance on intellectual property in agricultural biotechnology, there is evidence of increasing concentration in this research sector.

traditional agricultural knowledge, commercialization of crops based on these traits may not contribute to the multilateral system developed by the ITPGRFA.[130]

This treaty grew out of nearly two decades of negotiation at the FAO concerning an international system for managing crop genetic resources.[131] Following UNCED, the system of international germplasm exchange faced the rise of bilateral agreements which the CBD sovereignty clause invited, but four factors pushed treaty negotiation toward a multilateral framework. First, replacing the open system with one defined by bilateral contracts would entail steep transaction costs that might exceed the value of the resources.[132] Second, the process of creating a new access regime based on bilateral contracts posed the threat of interrupting germplasm exchange because of an anti-commons[133] resulting from the claims of different parties to control over access.[134] Third, increasing evidence suggested heavy dependence by poor countries on outside germplasm resources,[135] contradicting the conclusion that industrial countries were more dependent on germplasm from developing countries.[136] Fourth, accessions from large and valuable collections of the CGIAR network and industrial countries, such as the National Seed Storage

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James F. Oehmke & Christopher A. Wolf, *Measuring Concentration in the Biotechnology R&D Industry*, 6 AGBIOFORUM 134, 135 (2003).

130. Article 11.2 of the ITPGRFA specifies that "[t]he Multilateral System . . . shall include all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain." ITPGRFA, *supra* note 122, art. 11.2. Agbiotech components, such as the Bt and herbicide tolerance traits, are transgenes that are inserted into crop plants outside the context of national and privately owned gene banks. *See* Gerald C. Nelson, *Traits and Techniques of GMOs*, *in* GENETICALLY MODIFIED ORGANISMS IN AGRICULTURE 7 (Gerald C. Nelson ed., 2001).

131. FOWLER & MOONEY, *supra* note 46, at 187.

132. VISSER ET AL., *supra* note 74.

133. *See generally* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 HARV. L. REV. 622 (1998) (introducing the anticommons as a tool in property theory and showing how awareness of anticommons can shape legal policymaking); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998).

134. *See* POSEY & DUTFIELD, *supra* note 108, at 128; CARLOS M. CORREA, OPTIONS FOR THE IMPLEMENTATION OF FARMERS' RIGHTS AT THE NATIONAL LEVEL (Instituto Agronomico per l'Oltremare (IAO), Working Paper No. 8, Dec. 2000).

135. Evenson & Gollin, *supra* note 13; Fowler et al., *supra* note 13.

136. Jack Kloppenburg, Jr. & Daniel Lee Kleinman, *The Plant Germplasm Controversy*, 37 BIOSCIENCE 190, 190 (1987).

Laboratory of the U.S., remained openly available to crop breeders.[137] As long as these germplasm collections were managed as common heritage resources, bilateral contracts for the same type of resources were untenable.

Uncertainty over whether a new international order for crop genetic resources reconfirmed or undermined common heritage as plant breeders understood had bogged down negotiations about the International Undertaking at the FAO.[138] The ITPGRFA finally overcame the conflict by shifting emphasis toward open-access to crop resources and away from the issue of compensation. Avoiding the long-term disputes about patenting life forms and gene sequences also aided the agreement on the status of international collections. Finally, by separating the issue of gene bank access from Farmers' Rights and accepting the co-existence of Breeders' Rights and common-pool rights, the ITPGRFA gained acceptance from over 100 countries and avoided any specific national opposition.[139]

## V. FARMERS' RIGHTS

The FAO Commission's International Undertaking on Plant Genetic Resources provided a forum for negotiating three different international goals: (1) conserving crop germplasm, (2) ensuring its exploration and availability, and (3) addressing equity interests of farmers in developing nations.[140] A primary strategy for meeting the last goal was the movement to create a program of Farmers' Rights. These were conceived as a way to address the imbalance between genetic and economic wealth found in industrial and developing countries;[141] but at their inception, Farmers' Rights were also linked

137. The history of germplasm distribution from CGIAR center gene banks is documented in Fowler et al., *supra* note 13. The U.S. policy is described in Shands & Stoner, *supra* note 41. *See also* Allan K. Stoner, *Celebrating a Century of Plant Exploration*, 46 AGRIC. RES. MAG. 2 (1998).

138. FOWLER & MOONEY, *supra* note 46, at 197.

139. Earth Negotiations Bulletin, Sixth Extraordinary Session of the Commission on Genetic Resources for Food and Agriculture, June 25–30, 2001, *at* http://www.iisd.ca/biodiv/excgrfa-6.

140. *See* Bragdon & Downes, *supra* note 127, at 13.

141. FOWLER, *supra* note 34, at 201; *see also* José Esquinas-Alcázar, *Farmers' Rights*, *in* AGRICULTURAL VALUES OF PLANT GENETIC RESOURCES 207, 209 (Robert E. Evenson et al. eds., 1998).

to an agenda to curtail Breeders' Rights. FAO Commission Resolution 8/83, which established the International Undertaking on Plant Genetic Resources in 1983, had stressed the common heritage principle that plant genetic resources should be available without restriction. It provides a sweeping definition of genetic resources as incorporating not only wild and weedy crop relatives and farmers' varieties, but also newly developed "varieties" and "special genetic stocks (including elite and current breeders' lines and mutants)."[142] In classifying all types of crop genetic resources as a single category, this formulation suggested that the International Undertaking was a vehicle to challenge Breeders' Rights. NGOs presented the idea of Farmers' Rights to the FAO Commission in 1985.[143] The authors of the Farmers' Rights idea were antagonistic to Breeders' Rights,[144] believing perhaps that international acceptance of Farmers' Rights would undermine individual rights.[145]

The gambit to undermine Breeders' Rights through a binding international resolution[146] endorsing unrestricted access to all genetic material failed because of political, practical, and conceptual problems. Politically, Farmers' Rights were opposed by states that provided for Breeders' Rights.[147] The availability of large stocks of genetic resources in open collections[148] used by nations in Vavilov Centers[149] undercut the possibility of financing Farmers' Rights through restricting the flow of crop genetic resources. Dutfield discusses conceptual problems in defining the term "farmer" in relation to Farmers' Rights, ambiguity in who might hold these rights, and inconsistency in the fact that not all traditional farmers or farming communities conserve genetic resources.[150] In addition, the possible reliance on a contractual mode of defining Farmers' Rights

142. Res. 8/83, *supra* note 34, Annex, art. 2.1.2.v.

143. Pat Mooney, *Viewpoint of Non-Governmental Organisations*, *in* AGROBIODIVERSITY AND FARMERS' RIGHTS 40 (M.S. Swaminathan ed., 1996).

144. *Id.*

145. FOWLER, *supra* note 34, at 187.

146. DUTFIELD, *supra* note 93, at 103 (2000).

147. Pat Roy Mooney, *The Law of the Seed Revisited: Seed Wars at the Circo Massimo*, 1 DEV. DIALOG 1985, at 139, 150 (1985).

148. Stephen B. Brush, *Valuing Crop Genetic Resources*, 5 J. ENV'T & DEV. 416 (1996).

149. Fowler et al., *supra* note 13, at 189.

150. DUTFIELD, *supra* note 93, at 104.

may well exclude numerous farmers who create, maintain, and exchange crop genetic resources.[151] The future of Farmers' Rights, therefore, depended on accepting the coexistence of different rights for farmers and breeders. FAO Resolution 5/89 concluded that the two types of rights were not incompatible, and defining Farmers' Rights as:

> [R]ights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in centres of origin/diversity ... [T]hese rights are vested in the International Community as trustees for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.[152]

Like intellectual property, Farmers' Rights were justified as a mechanism to encourage the creation of socially valuable goods (plant genetic resources). Farmers' Rights differed from Breeders' Rights in that they were to be vested in the "International Community" rather than in individuals. However, in not specifying what genetic materials were covered or who could claim ownership, the FAO definition created a problematic category. Even though the Farmers' Rights idea was carried into Agenda 21, negotiations for implementing the CBD, and the Global Plan of Action for the Conservation and Sustainable use of Plant Genetic Resources for Food and Agriculture (the 1996 Leipzig Conference),[153] the idea has remained an elusive goal. Its early association with the anti-Breeders'-Rights agenda, and its ambiguities regarding materials and holders of the rights thwarted its acceptance as an international principle or program. Following the ITPGRFA negotiation, the fate of Farmers' Rights will be determined at the national level.

The U.K. Commission on Intellectual Property Rights observes that Farmers' Rights are not intellectual property rights but rather

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151. Stephen B. Brush, *Bio-Cooperation and the Benefits of Crop Genetic Resources: The Case of Mexican Maize*, 26 WORLD DEV. 755, 761 (1998).

152. STATE OF THE WORLD, *supra* note 80, at 278.

153. *Id.* at 312; GIRSBERGER, *supra* note 93, at 183.

represent a mechanism to counterbalance Breeders' Rights.[154] Farmers' Rights differ from intellectual property by the rights conferred, the title holder, subject matter, and duration,[155] and they are ambiguous for three of these criteria. The nature of the rights conferred by Farmers' Rights hinges on the economic benefit that connected recognition of resources provided in the past and benefit sharing in the future. While these goals are embedded in the justification for Farmers' Rights, no estimate of value or widely accepted method to estimate value of crop genetic resources are available. Consequently, the right to compensation for past contributions and benefit sharing for current and future use is largely metaphorical. Estimating value is obstructed by the absence of methods and data to assess the historic economic contribution of farmers' varieties from Vavilov Centers and the lack of calculations of the cost of conserving them on-farm. Estimating the historic contribution of farmers' varieties ideally requires one to separate the economic contribution of germplasm from other factors such as the development of physical infrastructure and human capital. The difficulty in doing this relegates the estimate to anecdotal evidence.[156] Likewise, estimating the cost of Farmers' Rights is hampered by the lack of a program for how the stream of benefits to farmers might be used to achieve conservation goals.[157] How holders of individual rights plan to use the benefits from intellectual property is not an issue because finite monopoly rights are expected to encourage more invention. If continued stewardship is the goal of Farmers' Rights, then the recipients of an international stream of benefits who are acting on behalf of farmers need a plan. Bioprospecting contracts[158] to overcome the lack of economic valuation are inappropriate for crop genetic resources. These contracts are likely to be ineffective

154. CIPR, *supra* note 113, at 68.

155. *See* CORREA, *supra* note 134.

156. Rural Advancement Foundation International (RAFI) of the U.N. Development Programme, Conserving Indigenous Knowledge—Integrating New Systems of Integration, (1995), *available at* http://www.undp.org/csopp/cso/newfiles/dociknowledge.html.

157. *See* STEPHEN B. BRUSH, FOOD AND AGRIC. ORG. OF THE U.N, PROVIDING FARMERS' RIGHTS THROUGH IN SITU CONSERVATION OF CROP GENETIC RESOURCES (Aug. 1994), *available at* ftp://ext-ftp.fao.org/ag/cgrfa/bsp/bsp3e.pdf.

158. Tobin, *supra* note 113, at 287.

conservation tools and may have detrimental economic effects. Because collecting genetic resources tends to be "single shot,"[159] collecting fees are unlikely to have a long-term conservation effect. I have written that contracts are likely to arbitrarily favor single communities or regions who have no special claim to crop germplasm.[160] Barrett and Lybbert argue that bioprospecting windfalls may be exclusionary or even regressive.[161] The reaction of groups who were excluded from bioprospecting agreements confirms that exclusion is a liability.[162]

Possible titleholders of Farmers' Rights include farming communities and states.[163] The diffuse and obscure origin of most crop resources in Vavilov Centers can lead to challenges of one community's claims for rights to a specific landrace or other crop resource by other communities. Transaction costs to settle such disputes may be higher than the value of the right, and arbitrary allocation presents ethical problems of favoring one community over others.[164] If conceived as a market situation between community "sellers" and seed company "buyers," Farmers' Rights exist in a monopsony environment in which a multitude of farmers with genetic resources face an extremely limited set of potential "buyers." Mendelsohn observes that this situation leads to market failure and argues that a monopoly acting on behalf of farmers is necessary.[165] Because preexisting agreements such as the CBD and the ITPGRFA recognize state ownership of genetic resources, Farmers' Rights will logically be held by the state. Because Vavilov Centers cross national boundaries, a broad definition of protected material under Farmers'

159. Christopher B. Barrett & Travis J. Lybbert, *Is Bioprospecting a Viable Strategy for Conserving Tropical Ecosystems?*, 34 ECOLOGICAL ECON. 293 (2000); Brush, *supra* note 151, at 759–60.

160. Brush, *supra* note 151, at 760.

161. Barrett & Lybbert, *supra* note 159.

162. Ronald Nigh, *Maya Medicine in the Biological Gaze: Bioprospecting Research as Herbal Fetishism*, 43 CURRENT ANTHRO. 451 (2000).

163. *See* CORREA, *supra* note 134.

164. Brush, *supra* note 151, at 760.

165. Robert Mendelsohn, *The Market Value of Farmers' Rights*, *in* AGRICULTURE AND INTELLECTUAL PROPERTY RIGHTS 121 (Vittorio Santaniello et al. eds., 2000).

Rights confronts the likelihood of disputes between countries. This possibility gave rise to a consortium approach by Andean nations.[166]

The subject matter of Farmers' Rights is equally ambiguous. The most commonly used term to describe crop genetic resources that are managed by farmers is "landrace," but no widely accepted definition exists.[167] Characterization of landraces with gene bank collections is limited, and much of the material is stored without adequate documentation to identify farmers who might be considered as the sources.[168] Defining knowledge rather than genetic resources as the subject matter of Farmers' Rights is equally problematic because farmers' knowledge is local, widely shared, changeable, and orally transmitted. Lastly, the concept does not specify whether wild relatives of crops, which have provided valuable traits to crop improvement but are not known or used by farmers, are covered by Farmers' Rights. Examples of wild crop relatives that have provided valuable germplasm include wild tomatoes in Peru[169] and wild rice in Mali.[170]

The final criterion that distinguishes Farmers' Rights from intellectual property is their duration.[171] The monopoly right of a grant of the intellectual property is made to be temporary as a way to balance the goal of increased invention over the goal of open competition. The unlimited duration of Farmers' Rights foregoes this balance, a policy of dubious merit if other communities or nations have valuable genetic resources or prove to be more effective conservationists.

In specifying national sovereignty, the CBD does not *per se* recognize or value the contributions of farmers in maintaining or providing genetic resources nor provide a vehicle for transferring

166. Liliana M. Davalos et al., *Regulating Access to Genetic Resources Under the Convention on Biological Diversity*, 12 BIODIVERSITY & CONSERVATION 1511, 1514 (2003); *see also* Manuel Ruiz, *Decision 391: The Common Regime on Access to Genetic Resources in the Andean Pact*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE, *supra* note 110, at 379.

167. A.C. Zeven, *Landraces: A Review of Definitions and Classifications*, 104 EUPHYTICA 127, 129 (1998).

168. Peeters & Williams, *supra* note 79, at 24–25.

169. Hugh H. Iltis, *Discovery of No. 832: An Essay in Defense of the National Science Foundation*, 3 DESERT PLANTS 175 (1982).

170. Pamela C. Ronald, *Making Rice Disease-Resistant*, 227 SCI. AM. 100, 101 (1997).

171. *See* CORREA, *supra* note 134.

value to communities where crop resources existed. However, prior to the CBD, Farmers' Rights had run as a subtext beneath negotiations about regulating access to crop genetic resources,[172] and farming communities' interests were recognized in Agenda 21's discussion of rural development that precedes the section on biodiversity conservation.[173] Nevertheless, in the 2001 final draft of the ITPGRFA, Farmers' Rights remained largely programmatic and without specific implementing instruments. These rights survive in Article 9 of the ITPGRFA as an acknowledgement of the contributions of farmers to the welfare of humankind. The ITPGRFA moves away from the initial strategy of a binding international resolution to create Farmers' Rights and confirms that realizing Farmers' Rights rests with national governments. The treaty inveighs on its Contracting Parties to provide for these rights in three ways:

> (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
>
> (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture; and
>
> (c) the right to participate in making decisions, at the national level on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.[174]

As in the *ex ante*, common heritage period, farmers are not granted a favored status as owners of genetic resources that they have inherited and maintained. The ITPGRFA does not vest farmers with a property right allowing them to exclude others from using or benefiting from crop resources.

Negotiating Farmers' Rights at the national level faces obstacles that were not critical in the international arena, such as political

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172. *See, e.g.*, Final Consensus Report: Global Initiative for the Security and Sustainable Use of Plant Genetic Resources, Keystone International Dialogue Series on Plant Genetic Resources, Oslo Plenary Session (1991).

173. Secretary General of the Conference, *Promoting Sustainable Agriculture and Rural Development*, UNCED Doc. A/CONF.151/PC/100/Add.19, *in* AGENDA 21 & THE UNCED PROCEEDINGS 397 (Nicholas A. Robinson ed., 1992).

174. ITPGRFA, *supra* note 122, art. 9.2(a)–(c).

weakness of the traditional farming sector, urban and consumer demand for low cost commodities, and the need to promote agricultural development. Although the CBD does not distinguish crop genes as a special category of biological resource, negotiations for Farmers' Rights will have to separate crop genes and acknowledge the regime established by the ITPGRFA. We have gained appreciation of traditional farmers' varieties, or landraces, as collective inventions and metapopulations rather than as assets that are privately derived and managed.[175] Significant proportions of most nations' agricultural sectors have benefited from adopting new technology, including new crop varieties, but landraces still meet farmers' needs in specific agricultural niches.[176] The demand for crop genetic resources is greatest in developing countries,[177] while in industrial countries it is modest and satisfied by resources that have already been collected.[178] Finally, a large number of parties have direct interest and influence in negotiating a new regime for biological resources.[179] For crop genetic resources these interests crosscut national boundaries, public and private sectors, and rural and urban communities. At the very least, the parties who are direct stake holders in the issue include subsistence and commercial farmers, crop breeders in the public and private sectors, national and international gene banks, the agricultural development service sector, private seed companies, and crop scientists.

Experience gained in research and negotiation about possible mechanisms to protect farmers' knowledge offer four guidelines for crafting national Farmers' Rights programs:

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175. *See* Louette, *supra* note 59; KARL S. ZIMMERER, CHANGING FORTUNES: BIODIVERSITY AND PEASANT LIVELIHOOD IN THE PERUVIAN ANDES 113 (1996).

176. Stephen B. Brush, *In Situ Conservation of Landraces in Centers of Crop Diversity*, 35 CROP SCI. 346 (1995); *see also* David A. Cleveland et al., *Do Folk Crop Varieties Have a Role in Sustainable Agriculture?*, 44 BIOSCIENCE 740, 745 (Dec. 1994).

177. SMALE ET AL., *supra* note 13.

178. D.R. Marshall, *Limitations to the Use of Germplasm Collections*, *in* THE USE OF GERMPLASM COLLECTIONS 105–20 (A.H.D. Brown et al. eds., 1989); *see also* John P. Peeters & Nick W. Galwey, *Germplasm Collections and Breeding Needs in Europe*, 42 ECON. BOTANY 503 (1988).

179. Charles V. Barber et al., *Developing and Implementing National Measures for Genetic Resources Access Regulation and Benefit-Sharing*, *in* BIODIVERSITY AND TRADITIONAL KNOWLEDGE, *supra* note 110, at 363, 385.

1. The goals of Farmers' Rights are to balance Breeders' Rights and encourage farmers to continue as stewards and providers of crop genetic resources.
2. Farmers' Rights are held collectively rather than by individual farmers or communities.
3. Farmers' Rights are not exclusive or meant to limit access to genetic resources.
4. Mechanisms are needed to share benefits received by the international community from genetic material from farmers' fields or international collections.

These principles frame the ITPGRFA and they are evident in two models for implementing Farmers' Rights: India's Act No. 53, for the Protection of Plant Varieties and Farmers' Rights[180] and the Organization of African Unity's African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources.[181]

## VI. FARMERS' RIGHTS AT THE NATIONAL LEVEL

GRAIN reports that six countries[182] (Bangladesh, Brazil, India, Panama, Peru, and the Philippines) and the Organization of African Unity (OAU) have drafted legislation or model legislation relating to Farmers' Rights. Bangladesh, India, and the OAU envision these rights as part of national systems for plant variety protection, while Brazil, Panama, Peru, and the Philippines envision special rights for traditional knowledge that possibly includes crop materials as collective property. In some instances, such as Costa Rica's[183]

180. The Protection of Plant Varieties and Farmers' Rights Act, India Act 53 (2001) [hereinafter India Act], *available at* http://grain.org/brl_files/india-pvp-2001-en.pdf.

181. OAU, AFRICAN MODEL LEGISLATION FOR THE PROTECTION OF THE RIGHTS OF LOCAL COMMUNITIES, FARMERS AND BREEDERS, AND FOR THE REGULATION OF ACCESS TO BIOLOGICAL RESOURCES (2000) [hereinafter AFRICAN MODEL LEGISLATION], *available at* http://grain.org/brl_files/oau-model-law-en.pdf.

182. Genetic Resources Action International (GRAIN), Farmers' Rights (Sept. 9, 2004), *at* http://grain.org/brl/?typeid=45.

183. Ley de Protección de los Derechos de los Fitomejoradores, Costa Rica Law 15.487 (2003) [hereinafter Costa Rica Law]; India Act, *supra* note 180.

proposed Law for the Protection of Plant Breeders' Rights,[184] Farmers' Rights are provided by following policies in plant variety protection[185] that allow farmers the right to re-sow, exchange, segregate, and sell the produce from protected varieties described in the 1978 version of the UPOV system.[186] In other instances, such as India's Protection of Plant Varieties and Farmers' Rights Act,[187] Farmers' Rights are expanded beyond this to include the right to benefits from collection and use of landraces to produce commercially registered varieties. Collective rights systems, such as those in Panama[188] and Peru,[189] regulate use of collective property through national registers and in the case of Peru through licensing of collectively owned biological resources. The collective rights approach is primarily aimed at protecting folklore, artistic expression, and plant knowledge associated with natural products and medicines rather than crops per se.

India's Act No. 53, Article 16d, affirms that farmers or a community of farmers may petition to register a new variety as the breeder, but it goes beyond this logical extension of Breeders' Rights to recognize Farmers' Rights in four ways. First, farmers' roles as keepers of genetic resources and sustainers of crop evolution are to be recognized and rewarded through a National Gene Fund. This

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184. John H. Barton, *Acquiring Protection for Improved Germplasm and Inbred Lines*, *in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY 19, 22 (Frederic H. Erbisch & Karim M. Maredia eds., 1998); *see also* Silvia Salazar, *Costa Rica*, *in* INTELLECTUAL PROPERTY RIGHTS IN AGRICULTURAL BIOTECHNOLOGY, *supra*, at 179, 184; Costa Rica Law, *supra* note 183.

185. UPOV, the International Union for the Protection of New Varieties of Plants (Union Pour la Protection des Obtentions Vegetales) is an intergovernmental organization with headquarters in Geneva (Switzerland). UPOV was established by the International Convention for the Protection of New Varieties of Plants, adopted in Paris in 1961 and it was revised in 1972, 1978 and 1991. Barton, *supra* note 184; *see also* Robert E. Evenson, *Intellectual Property Rights, Access to Plant Germplasm, and Crop Production Scenarios in 2020*, 39 CROP SCI. 1630, 1631 (1999).

186. UPOV, The UPOV System of Plant Variety Protection (2002), *at* http://www.upov.int/en/about/upov_system.htm.

187. India Act, *supra* note 180.

188. Regimen Especial de Propriedad Intelectual Sobre los Derechos Colectivos de los Pueblos Indigenas, Panama Law No. 20 (June 26, 2000), *translation available at* http://grain.org/brl/?docid=461&lawid=2002.

189. Propuesta de Regimen de Protección de los Conocimientos Colectivos de los Pueblos y Comunidades Indígenas Vinculados a los Recursos Biológicos, Peru Law 27,811 (June 10, 2002), *translation available at* http://grain.org/brl/?docid=81&lawid=2041.

Fund will be used for benefit sharing and to support *in situ* and *ex situ* conservation, and it will be financed by annual fees levied on breeders of registered varieties, depending on the value of the royalty earned from a registered variety. Benefit sharing to communities that provided germplasm used in a registered variety will be determined according to the extent and nature of the use of genetic material in the registered variety and the commercial value of the variety.[190] Second, India's Act No. 53 establishes the farmers' exemption that was present in early plant variety protection regimes of the U.S. and UPOV,[191] allowing farmers to "save, use, sow, resow, exchange, share or sell his farm produce including seed of a variety protected under this Act in the same manner as he was entitled before the coming into force of this Act."[192] Third, breeders are required to disclose in their application for registration information regarding tribal or rural families' use of genetic material used in the breeding program. Failure to disclose this information is grounds for rejecting an application for variety registration. Fourth, any interested party may file a claim on behalf of a village or local community stating its contribution to the evolution of a registered variety. If this claim is substantiated, the breeder is required to pay compensation to the National Gene Fund.

The African Model Legislation establishes Farmers' Rights in four ways. First, it allows farmers to certify their varieties as intellectual property without meeting the criteria of distinction, uniformity, and stability that breeders must meet. This certificate provides farmers with "the exclusive rights to multiply, cultivate, use or sell the variety, or to license its use."[193] Second, farmers are given the right to "obtain an equitable share of benefits arising from the use of plant and animal genetic resources."[194] The African Model Law Article 66 establishes a Community Gene Fund to accomplish benefit sharing and to be financed by royalties fixed to registered breeders'

190. India Act, *supra* note 180, art. 26(5).

191. David J. Houser, *Exemptions Under Patents and Certificates Covering Plants and Comments on Material Transfer Agreements*, *in* INTELLECTUAL PROPERTY RIGHTS, *supra* note 43, at 107, 108.

192. India Act, *supra* note 180, art. 39(iv).

193. *African Model Legislation*, *supra* note 181, art. 25.

194. *Id.* art. 26.

varieties. Third, farmers are guaranteed an exemption to Breeders' Rights restrictions to "collectively save, use, multiply and process farm-saved seed of protected varieties."[195] Fourth, farmers' varieties are to be certified as being derived from "the sustainable use [of] a biological resource."[196] This certificate does not imply financial reward.

A pattern for Farmers' Rights is evident in the provisions of the ITPGRFA, India's Act No. 53, and the African Model Legislation. All three accept the co-existence of Breeders' Rights along with Farmers' Rights, and all intend to accomplish benefit sharing through a centralized funding mechanism and the duties levied on income streams from Breeders' Rights. This same benefit sharing mechanism is present in the Genetic Resources Recognition Fund (GRRF) of the University of California that imposes a licensing fee on the commercialization of patented plant material involving germplasm from Developing Countries.[197] The ITPGRFA and GRRF envision this mechanism as a generic tool for reciprocity rather than one to reward specific farmers or communities. The African Model Legislation goes furthest in signifying individual communities as the beneficiaries. India's Act No. 53 combines both the generic and specific uses of compensation through the centralized gene fund. Farmers' Rights are also provided in farmers' exemptions to restrictions embedded in Breeders' Rights. Contradicting the view that Farmers' Rights are not a form of intellectual property,[198] the Model African Law goes beyond the ITPGRFA and India's Act No. 53 in granting exclusive rights to farmers over their varieties.

Implementation of national systems for Farmers' Rights is still untested, although the Indian plan has been passed by both houses of the Indian Parliament and received the President's support.[199] The

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195. *Id.* art. 26(1)(f).

196. *Id.* art. 27(1).

197. Pamela Ronald & Stephen Brush, *Genetic Resources Recognition at the University of California, Davis*, 35 IN VITRO REP. 8 (2001); KERRY TEN KATE & AMANDA COLLIS, THE UNIVERSITY OF CALIFORNIA, DAVIS, BENEFIT-SHARING CASE STUDY, *available at* http://www.biodiv.org/doc/case-studies/abs/cs-abs-ucdavis.pdf (last visited Dec. 26, 2004).

198. W. Lesser, *Intellectual Property Rights Under the Convention on Biological Diversity*, *in* AGRICULTURE AND INTELLECTUAL PROPERTY RIGHTS, *supra* note 165, at 35; *see also* CIPR, *supra* note 113.

199. Asha Krishnakumar, *For Farmers' Rights*, FRONTLINE, Feb. 16–Mar. 1, 2002,

success of rights set forth in India's Act No. 53, the ITPGRFA, and the African Model Legislation hinge on the value of certified crop varieties that use germplasm obtained from farmers and the transaction costs of determining which farmers should be beneficiaries.

The value of certified varieties is not fully known in India or Africa, but two factors indicate that their value will offer meager resources to finance Farmers' Rights. First, the experience of Western, industrialized countries shows that plant variety certificates have relatively low or negligible value. Lesser looked at the value of plant variety certificates for soybeans in New York State, determined that the price premium associated with certified seed was only 2.3%, and concluded that this form of protection is too weak to be an incentive to breeders.[200] A similar result in India would not generate any appreciable revenue to fund Farmers' Rights. It is possible that "stronger" intellectual property means, such as utility patents, would increase revenue, but both India and the OAU reject patenting of plants. Second, modern breeding programs increasingly are dependent on the use of "elite" breeding lines that are several generations removed from farmers varieties and show increasingly complex pedigrees involving crop genetic resources from many sources.[201] Although India is a net exporter of landraces as breeding material, foreign landraces are as important to India's rice program as are national landraces.[202] Because African agriculture is heavily dependent on crops originating in other regions, dependence on international germplasm is high. For instance, in Nigeria's rice breeding program, 180 out of 195 landrace progenitors used in breeding were borrowed from other countries.[203] Estimating the contribution of a single landrace or collection to the value of a

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*available at* http://www.flonnet.com/fl1904/19040800.htm.

200. W. Lesser, *Valuation of Plant Variety Protection Certificates*, 16 REV. AGRIC. ECON. 231 (1994).

201. M. Smale et al., *Dimensions of Diversity in Modern Spring Bread Wheat in Developing Countries from 1965*, 42 CROP SCI. 1766 (2002).

202. Douglas Gollin & Robert E. Evenson, *An Application of Hedonic Pricing Methods to Value Rice Genetic Resources in India*, *in* AGRICULTURAL VALUES OF PLANT GENETIC RESOURCES 139 (Robert E. Evenson et al. eds., 1998).

203. Douglas Gollin, *Valuing Farmers' Rights*, *in* AGRUCULTURAL VALUES OF PLANT GENETIC RESOURCES 233 (Robert E. Evenson et al. eds., 1998).

modern variety has not been accomplished and is likely to become more difficult as pedigrees become more complex.[204]

Transaction costs in determining which farmers or communities should receive compensation through the national gene funds are equally problematic to financing Farmers' Rights. If equity is a concern, it is inappropriate to simply assign rights to the community where collection occurred because of the metapopulation aspect of landraces.[205] Exclusionary rights have proven to be politically unacceptable because of this issue.[206] Even if an arbitrary recognition of rights is made, farmers who are excluded but who have the same resources may offer their resources at competitive prices setting off a downward price spiral that is unfavorable to farmers and conservation.[207] Transaction costs can be lowered by establishing a national monopoly[208] but this contradicts the terms of India's Act No. 53 and the African Model Legislation.

In sum, Farmers' Rights are a moral but largely rhetorical recognition of the contribution of farmers to the world's stock of genetic resources. They provide only a limited mechanism to share the benefits of using crop genetic resources or to promote their conservation.

## VII. TRADITIONAL AGRICULTURAL KNOWLEDGE

The interplay between biological variation and its control through selection makes crop and natural evolution similar to one another, but the two differ by virtue of the role of "artificial" selection by humans in crop evolution.[209] Darwin laid out the basic framework of crop evolution that distinguishes two types of human selection: methodical and unconscious.[210] According to Darwin, unconscious selection is

204. Gollin & Evenson, *supra* note 202.
205. Brush, *supra* note 151, at 760–61.
206. Nigh, *supra* note 162, at 462.
207. Mendelsohn, *supra* note 165; Barrett & Lybbert, *supra* note 159.
208. Mendelsohn, *supra* note 165.
209. HAWKES, *supra* note 9; C. M. Donald & J. Hamblin, *The Convergent Evolution of Annual Seed Crops in Agriculture*, 36 ADVANCES IN AGRONOMY 97, 99–100 (1983).
210. 20 CHARLES DARWIN, *Variation of Animals and Plants Under Domestication, Volume II*, *in* THE WORKS OF CHARLES DARWIN 153 (Paul H. Barrett & R.B. Freeman eds., New York University Press 1988).

inadvertent and arises when people generally favor a superior cultivar without specific selection for individual traits.[211] More recent models of crop evolution re-label unconscious selection as "nonspecific selection."[212] Methodical, or conscious selection, which is methodical and specific, is the more important contribution of humans to the evolution of crops.[213] For the vast majority of crop evolution, conscious selection has been decentralized and managed by farmers. In the past century, the organization of crop breeding programs has centralized selection and given an important role in crop evolution to scientists, public agencies, and seed companies.[214]

Conscious selection by farmers implies the use of knowledge systems about the crop and its environment, which are subsets of more general traditional and indigenous knowledge systems.[215] While "traditional knowledge" and "indigenous knowledge" are not synonymous, they share many attributes, such as being unwritten, customary, pragmatic, experiential, and holistic. The terms are frequently used in the same context to distinguish the knowledge of traditional and indigenous communities from other types of knowledge, such as the knowledge of scientific and industrial communities.[216] Indeed, the primary distinction between traditional and indigenous knowledge pertains to the holders rather than the knowledge *per se*. Traditional knowledge is a broader category that includes indigenous knowledge as a type of traditional knowledge held by indigenous communities.[217]

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211. *Id.*

212. *See, e.g.*, Daniel Zohary, *Unconscious Selection and the Evolution of Domesticated Plants*, 58 ECON. BOTANY 5 (2004); EVANS, *supra* note 15, at 267.

213. HARLAN, *supra* note 10, at 127; David Rindos, *Darwinism and its Role in the Explanation of Domestication*, *in* FORAGING AND FARMING 27, 29 (David R. Harris & Gordon C. Hillman eds., 1989).

214. Poehlman, *supra* note 28.

215. Roy Ellen & Holly Harris, *Introduction*, *in* INDIGENOUS ENVIRONMENTAL KNOWLEDGE AND ITS TRANSFORMATIONS 1, 7 (Roy Ellen et al. eds., 2000); Paul Sillitoe, *The Development of Indigenous Knowledge*, 39 CURRENT ANTHRO. 223, 226–29 (1998).

216. Arun Agrawal, *Dismantling the Divide Between Indigenous and Scientific Knowledge*, 26 DEV. & CHANGE 413, 422 (1995); Nuno Pires de Carvalho, *From the Shaman's Hut to the Patent Office*, 17 WASH. U. J.L. & POL'Y 111 (2005); Manuel Ruiz, *The International Debate on Traditional Knowledge as Prior Art in the Patent System* (Center for International Environmental Law 2002), *at* http://ciel.org/Publications/PriorArt_ManuelRuiz_Oct02.pdf; Sillitoe, *supra* note 215.

217. John Mugabe, *Intellectual Property Protection and Traditional Knowledge*, *in* World

While traditional knowledge has emerged in international discourse on new legal mechanisms,[218] indigenous knowledge is a term long in use by anthropologists and other investigators of non-industrialized societies;[219] because of this history, indigenous knowledge enjoys a more elaborated discussion and definition than the more inclusive term. Nevertheless, apart from the designation of the type of holder, the definitions applied to indigenous knowledge apply also to traditional knowledge. While Kongolo observes that "[t]raditional knowledge is rarely defined within the national, regional, and international frameworks,"[220] indigenous knowledge has been extensively analyzed by ethnobotanists and others,[221] so it behooves us to utilize the analysis of indigenous knowledge to grapple with traditional knowledge. Both are associated with folk nomenclatures and taxonomies of plants[222] and the environment[223] and in practical domains such as disease etiology[224] and agricultural practices.[225] Distinguishing between indigenous knowledge and other knowledge systems has proven to be problematic,[226] but anthropologists and others argue that a number of criteria can be used to differentiate indigenous knowledge from other knowledge systems. Indigenous knowledge's distinguishing characteristics include (1)

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Intellectual Property Organization (WIPO), INTELLECTUAL PROPERTY AND HUMAN RIGHTS 97 (1999).

218. Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge*, 1 J. INT'L ECON. L. 555, 561–68 (1998); Pires de Carvalho, *supra* note 216; W.B. Wendland, *Intellectual Property, Traditional Knowledge and Folklore: WIPO's Exploratory Program*, 33 INDUS. PROP. & COPYRIGHT L. 485 (2003).

219. Sillitoe, *supra* note 215, at 223.

220. Tshimanga Kongolo, *Towards a More Balanced Coexistence of Traditional Knowledge and Pharmaceuticals Protection in Africa*, 35 J. WORLD TRADE 349, 357 (2001).

221. BRENT BERLIN, ETHNOBIOLOGICAL CLASSIFICATION 4 (1992); Sillitoe, *supra* note 215.

222. BRENT BERLIN ET AL., PRINCIPLES OF TZELTAL PLANT CLASSIFICATION 25–28 (1974); Scott Atran et al., *Folkecology and Commons Management in the Maya Lowlands*, 96 PROC. NAT'L ACAD. SCI. USA 7598, 7600 (1999).

223. *See, e.g.*, Deirdre M. Birmingham, *Local Knowledge of Soils: The Case of Contrast in Côte d'Ivoire*, 111 GEODERMA 481, 484 (2003); Jeffery W. Bentley & Gonzalo Rodríguez, *Honduran Folk Entomology*, 42 CURRENT ANTHRO. 285, 289–95 (2001).

224. *See, e.g.*, ELOIS ANN BERLIN & BRENT BERLIN, MEDICAL ETHNOBIOLOGY OF THE HIGHLAND MAYA OF CHIAPAS, MEXICO: THE GASTROINTESTINAL DISEASES 54 (1996).

225. MARGOT BEYERSDORFF, LEXICO AGROPECUARIO QUECHUA (1984); ROBERTO J. GONZÁLEZ, ZAPOTEC SCIENCE 130–54 (2001).

226. *See* Agrawal, *supra* note 216, at 425.

localness, (2) oral transmission, (3) origin in practical experience, (4) emphasis on the empirical rather than theoretical, (5) repetitiveness, (6) changeability, (7) being widely shared, (8) fragmentary distribution, (9) orientation to practical performance, and (10) holism.[227] These same characteristics apply to traditional knowledge.

Traditional agricultural knowledge is understandably responsible for guiding the past and present accomplishments of most of the world's farmers. The primary development of crops and cropping systems occurred before the relatively recent discoveries of agricultural chemistry and crop biology,[228] and most of the world's farmers still rely on traditional knowledge rather than on formal, scientific knowledge. The hyperbolic growth of agricultural production may now rely on formal science, but it is built on foundations developed by traditional farmers.

Traditional knowledge for crop genetic resources has both cognitive and biological aspects. The cognitive aspect is embodied in the nomenclatures, classificatory systems, and cultural practices of farmers, while the biological aspect is embodied in crop germplasm from generations of observation, election, exchange, and maintenance. Both aspects of traditional knowledge have fuzzy boundaries because of their protean and fragmented nature. Traditional knowledge has been described for numerous farming systems,[229] and its value is evident in such specific activities as designing and managing irrigation,[230] coping with marginal farming environments,[231] enhancing production with local inputs,[232] and developing crop diversity.[233]

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227. Ellen & Harris, *supra* note 215, at 4–5.

228. EVANS, *supra* note 87, at 90.

229. *See* GONZÁLEZ, *supra* note 225, at 130ff.

230. FRANCESCA BRAY, THE RICE ECONOMIES 68 (1986).

231. PEDRO A. SANCHEZ, PROPERTIES AND MANAGEMENT OF SOILS IN THE TROPICS 377 (1976); Karl S. Zimmerer, *Soil Erosion and Labor Shortages in the Andes with Special Reference to Bolivia, 1953–91*, 21 WORLD DEV. 1659, 1661 (1993).

232. GENE C. WILKEN, GOOD FARMERS: TRADITIONAL AGRICULTURAL RESOURCE MANAGEMENT IN MEXICO AND CENTRAL AMERICA 46–69 (1987) (describing soil management using organic amendments).

233. Daniela Soleri & David A. Cleveland, *Farmers' Genetic Perceptions Regarding Their Crop Populations: An Example with Maize in the Central Valleys of Oaxaca, Mexico*, 55 ECON. BOTANY 106 (2001).

While the existence and accomplishments of traditional agricultural knowledge are unquestioned, its defining characteristics pose severe obstacles for its valuation and protection by farmers and outside interests such as conservationists, indigenous rights activists, and rural development agencies. Indeed, outside efforts to value, promote, and protect traditional knowledge appear inevitably to distort it and its social context.[234] A severe obstacle to valuation and protection is the disarticulation of different types of knowledge when that information is local, orally transmitted, practical, and fragmentary in distribution. Agricultural knowledge is comprised of numerous substantive domains such as soil types, pests, pathogens, and crop genotypes, domains for environmental conditions such as rainfall and temperature patterns, and management domains such as irrigation techniques, soil amendments, planting patterns, pest control, weed control, and crop selection. Brookfield and Stocking add organization as a third domain that includes tenure arrangements, resource allocation, and dependency on alternative production spheres.[235] These domains are demarcated by distinct lexicons and nomenclatures such as crop variety names or terminology for management practices. Traditional knowledge is rife with "covert categories"[236] and unlabeled, intermediate domains[237] that may link substantive and management domains but require intensive research to understand. These substantive and management domains are logically articulated in the minds and memories of individual farmers, but they may appear disarticulated in a wider social context and to outsiders.

Capturing the knowledge in a single domain by collecting its nomenclature, such as crop variety names, is relatively easy but of limited use. The content of a single domain may be ordered taxonomically, but revealing taxonomy requires elaborate analysis similar to biological systematics that sift and winnow the clutter and

234. Michael R. Dove, *Center, Periphery, and Biodiversity*, *in* VALUING LOCAL KNOWLEDGE 41 (Stephen B. Brush & Doreen Stabinsky, eds., 1996).

235. Harold Brookfield & Michael Stocking, *Agrodiversity: Definition, Description and Design*, 9 GLOBAL ENVTL. CHANGE 77, 79 (1999).

236. BERLIN, *supra* note 221, at 176.

237. Stephen B. Brush, *Ethnoecology, Biodiversity, and Modernization in Andean Potato Agriculture*, 12 J. ETHNOBIOLOGY 161, 163–67 (1992).

noise of variation.[238] Folk nomenclatures are unevenly distributed and disparate among individuals and localities.[239] Because traditional knowledge is most developed when a domain's salience is high,[240] nomenclature for crops and agriculture is often embellished, for instance, in the wealth of variety names found in small regions.[241] Unfortunately, the elaboration of folk nomenclature for crops is greatest at the variety (infra-specific) level that is often judged as having dubious value by botanists[242] and ethnobotanists.[243] Since variety names are orally transmitted, repetitive, widely shared, and fragmentary, name lists cannot be used directly to estimate genetic diversity or population structure above the farm level.[244] Synonyms may, in fact, be known to some farmers but not marked or widely recognized. Problems of over- and under-classification of genetic variation can only be resolved by careful agronomic and genetic characterization, a step that would seem to obviate the need to collect folk names. The fact that traditional knowledge is orally transmitted and changeable creates problems in identifying truly local and autochthonous knowledge.[245] The fact that traditional knowledge is local, empirical, and holistic suggests that indigenous people do not have to worry about consistency over wider areas, as plant collectors and geneticists must if they are trying to find traits that are locally abundant but not widespread.[246]

Linking nomenclatures of substantive domains to one another and to management domains is complicated by the inherent qualities of localness, oral transmission, and fragmented distribution. The best studies showing linkage between different domains (e.g., crop

238. BERLIN, *supra* note 221.

239. Quiros et al., *supra* note 6.

240. BERLIN, *supra* note 221, at 255.

241. Brush, *supra* note 237; HAROLD C. CONKLIN, HANUNÓO AGRIGULTURE: A REPORT ON AN INTEGRAL SYSTEM OF SHIFTING CULTIVATION IN THE PHILIPPINES 112–13 (1957) (reporting over ninety rice varieties among the Hanunoo of the Philippines).

242. *See* B.L. Burtt, *Infraspecific Categories in Flowering Plants*, 2 BIO'L J. LINNEAN SOC'Y 233 (1970).

243. BERLIN, *supra* note 221, at 34.

244. Brush et al., *supra* note 56, at 1191; Quiros et al., *supra* note 6, at 256.

245. Dove, *supra* note 234.

246. D.R. Marshall & A.H.D. Brown, *Optimum Sampling Strategies in Genetic Conservation*, *in* CROP GENETIC RESOURCES FOR TODAY AND TOMORROW 53 (O.H. Frankel & J.G. Hawkes eds., 1975).

diversity and local ecological conditions or disease etiology and ethnobotany) are executed in single communities or micro-regions.[247] Linking multiple domains, such as crop type, soils, and plant diseases, or showing how domains are linked across regions are daunting tasks and generally not attempted in research on traditional agricultural systems. Of course, formal science overcomes the linkage problem by institutionalizing knowledge through educational curricula, instruction and examination, technical manuals, peer review, publication, and intellectual property.

These characteristics and problems of traditional knowledge have limited its use by crop scientists and others outside of local farming systems. Because detailed information on farmer knowledge is usually not part of the passport data accompanying crop resources and may be difficult to interpret or verify, crop scientists who are looking for particular traits test collections according to ecological background or, more commonly, use well known germplasm ("elite breeding lines") developed in experiment station research. Wellhausen et al., who pioneered research on maize diversity in MesoAmerica, opined that indigenous people had consciously contributed little to the evolution of maize under domestication.[248] Only recently have plant collectors and crop conservationists begun to collect traditional knowledge along with other ecological information.[249] Usually only the local name is collected as part of the passport data that accompanies collections.[250]

## VIII. PROTECTING TRADITIONAL AGRICULTURAL KNOWLEDGE

Agricultural development, through the expansion of crop land, improved management, inputs to crop production, and increasing yield potential, has allowed exponential population growth without a

247. BERLIN & BERLIN, *supra* note 224; Mauricio R. Bellon & J. Edward Taylor, *"Folk" Soil Taxonomy and the Partial Adoption of New Seed Varieties*, 41 ECON. DEV. & SOC. CHANGE 763 (1993).

248. E. J. WELLHAUSEN ET AL., RACES OF MAIZE IN CENTRAL AMERICA 29 (1957) (National Academy of Sciences, National Research Council, Publication 511).

249. IPGRI, *Indigenous Knowledge Documentation* (2001), *at* http://www.ipgri.cgiar.org/regions/apo/ik.html.

250. IPGRI, *Multi-Crop Passport Descriptors* (2005), *available at* http://www.ipgri.cgiar.org/publications/pubfile.asp?id_pub=124.

Malthusian calamity. However, projected global population expansion to ten billion people is likely to exceed historic and important sources of agricultural growth, such as the addition of crop land and irrigation.[251] Consequently, satisfying demand for additional agricultural production will depend on enhancing the biological capacity of major crops.[252] The two most important sources of crop genes for this enhancement will be gene banks and farmers' fields where traditional crops and crop evolutionary processes continue. Crop scientists and agricultural developers have prepared for this exigency by assembling large collections of genetic resources in gene banks and making them available for crop improvement.[253] By 1970, an international framework for collection, conservation, utilization, and exchange was in place. This framework was epitomized by the creation of the International Board for Plant Genetic Resources, world collections of principal crops at international agricultural research centers such as the International Rice Research Institute, and national collections such as those of the National Seed Storage Laboratory in Fort Collins, Colorado.[254]

Both the cognitive and biological aspects of traditional agricultural knowledge are endangered in the contemporary world by such processes as population growth, market development, technology diffusion, and cultural change. We have long accepted the notion that traditional agricultural knowledge is valuable and worth saving, and individuals, nations, and international groups have invested in conserving that knowledge for future generations.[255]

Achieving the goal of protecting traditional agricultural knowledge may mean either protecting the cognitive or the biological aspects of crops. For most crops, protection against loss of traditional agricultural knowledge has given almost exclusive priority to *ex situ* (off-farm) measures for conserving germplasm in gene banks,

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251. EVANS, *supra* note 15, at 368; Paul E. Waggoner, *How Much Land Can Ten Billion People Spare for Nature?*, 17 TECH. IN SOC'Y 17 (1995).

252. NATIONAL RESEARCH COUNCIL (NRC), MANAGING GLOBAL GENETIC RESOURCES: AGRICULTURAL CROP ISSUES AND POLICIES (1993).

253. STATE OF THE WORLD, *supra* note 80, at 140.

254. *Id.* at 83; PISTORIUS & VAN WIJK, *supra* note 34, at 98; PLUCKNETT ET AL., *supra* note 30, at 110.

255. STATE OF THE WORLD, *supra* note 80, at 53, 60ff.

breeders' collections, and botanical gardens.[256] While *ex situ* conservation has become institutionalized at both national and international levels,[257] crop scientists increasingly recognize the need to conserve crop genetic resources *in situ* in the habitats where they have evolved.[258] Because elemental processes of crop evolution, such as selection, exchange, and dispersal, are guided by farmers' knowledge, the preservation of farmers' knowledge systems is essential to ongoing crop evolution.

Conserving the cognitive aspects of traditional agricultural knowledge takes on added value because crop scientists and conservationists now accept the idea that crop genetic resources and crop evolutionary processes should be conserved *in situ* (on-farm).[259] *In situ* conservation for crop resources takes place on farms and with the management of crop populations by farmers through selection, use, exchange, and bequest. *In situ* conservation is distinguished because it is dynamic, decentralized, and aimed at conserving dynamic crop evolutionary processes rather than a static inventory of crop types.[260] Rather than preserve diversity *per se*, *in situ* conservation aims to preserve decentralized selection, farmer seed production and exchange, and gene flow among crop varieties and with wild relatives. While *in situ* conservation and the preservation of traditional agricultural knowledge may be seen as synonymous, it is erroneous to imagine that traditional agricultural knowledge can be preserved as a given inventory of information, nomenclature, or local understandings of crops and crop ecology. Because both crops and knowledge systems are dynamic, *in situ* conservation can preserve

256. David Wood & Jillian M. Lenné, *The Conservation of Agrobiodiversity On-Farm*, 6 BIODIVERSITY & CONSERVATION 109, 110 (1997); Brian D. Wright, *Crop Genetic Resource Policy*, 41 AUSTRALIAN J. AGRIC. & RES. ECON. 81, 87 (1997).

257. Garrison Wilkes, *Germplasm Collections*, *in* INTERNATIONAL CROP SCIENCE I 445 (D.R. Buxton et al. eds, 1993).

258. NRC, *supra* note 252, at 117; N. Maxted et al., *Complementary Conservation Strategies*, *in* PLANT GENETIC CONSERVATION 15, 17 (N. Maxted et al. eds., 1997).

259. STATE OF THE WORLD, *supra* note 80, at 351.

260. M.S. Swaminathan, *The Past Present and Future Contributions of Farmers to the Conservation and Development of Genetic Diversity*, *in* MANAGING PLANT GENETIC DIVERSITY 23, 26 (Johannes M.M. Engels et al. eds., 2002); P.K. Bretting & D.N. Duvick, *Dynamic Conservation of Plant Genetic Resources*, 61 ADVANCES IN AGRONOMY 1, 4 (1997); N. Maxted et al., *Towards a Methodology for On-Farm Conservation of Plant Genetic Resources*, 49 GENETIC RES. & CROP EVOLUTION 31, 32–33 (2002).

the context of practice of traditional knowledge rather than the knowledge itself.

However, institutions or programs similar to those that have been established for *ex situ* conservation are either lacking or underdeveloped for protecting *in situ* resources. Crop scientists and others have made initial but important steps toward developing methods for achieving *in situ* conservation.[261] These steps include means to increase the value of traditional crops to farmers through collaborative plant breeding and market development and improving the supply of traditional varieties and seed through diversity fairs and farmer networks. Numerous pilot research and conservation projects have been implemented in Vavilov Centers with financial support from private foundations, such as the McKnight Foundation's Collaborative Crop Research Program[262] and international agencies such as the Global Environmental Facility.[263] *Ex situ* conservation agencies, such as the International Plant Genetic Resources Institute[264] have moved to support *in situ* conservation as part of the overall effort to protect crop resources, and several counties have adopted the goal of promoting *in situ* conservation of crop resources as part of their national biodiversity agenda.[265] Nevertheless, protecting the cognitive aspect of traditional agricultural knowledge is ad hoc, tentative and programmatic rather than institutionalized. Funding a broad and institutionalized program of *in situ* conservation will most likely be accomplished through conventional bilateral and multilateral mechanisms that have successfully managed international

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261. T.M. Worede et al., *Keeping Diversity Alive: An Ethiopian Perspective*, *in* GENES IN THE FIELD: CONSERVING PLANT DIVERSITY ON FARMS 143, 152 (Stephen B. Brush, ed., 1999); Mauricio R. Bellon et al., *Participatory Landrace Selection for On-Farm Conservation: An Example from the Central Valleys of Oaxaca, Mexico*, 50 GENETIC RES. & CROP EVOLUTION 401 (2003).

262. McKnight Foundation Collaborative Crop Research Program (CCRP), About the CCRP (Dec. 8, 2004), *at* http://mcknight.ccrp.cornell.edu/about.

263. GLOBAL ENVIRONMENTAL FACILITY (GEF), GEF OPERATIONAL PROGRAM #13 ON CONSERVATION AND SUSTAINABLE USE OF BIOLOGICAL DIVERSITY IMPORTANT TO AGRICULTURE, *available at* http://gefweb.org/operational_policies/operational_programs/op_13_english.pdf (last visited Dec. 26, 2004).

264. D. Jarvis & T. Hodgkin, *Farmer Decision Making and Genetic Diversity*, *in* GENES IN THE FIELD: ON-FARM CONSERVATION OF CROP DIVERSITY 261 (Stephen B. Brush ed., 1999).

265. Worede, *supra* note 261.

agricultural development in the past.[266] The bioprospecting alternative is too limited in the number of farmers and duration to be adequate for the needs of national *in situ* conservation in Vavilov Centers or elsewhere.

## IX. CONCLUSION

Numerous parties and participants have struggled with the issue of protecting traditional agricultural knowledge and crop resources through binding international resolutions, formal contracting, and non-contractual benefit sharing mechanisms. The impetus for this was the recognition that resources and knowledge were eroding under the pressures of modernization, such as rapid population growth and commercialization of agriculture, but it also grew out of the North/South dialog of the mid-twentieth century. The move to end common heritage as a management scheme for genetic resources is understandable as both a liberal ideology to overcome the Tragedy of the Commons[267] and an anti-colonialist tool to stop uncompensated acquisition of resources from the South.[268] However, both of these sources for justifying the closure of the genetic commons are problematic because they are based on inaccurate caricatures of traditional resource managers and the international crop germplasm system. The Tragedy of the Commons overlooks successful and long-lived systems of managing common pool resources,[269] and the North/South dialog assumes that farmers are barefoot equivalents of crop breeders, overlooking incremental, collective invention,[270] networks of interdependence among farming communities,[271] and farmers' links to a global flow of crop material.[272] Moreover, the

266. Robert W. Herdt, *Assisting Developing Countries Toward Food Self-Reliance*, 95 PROC. NAT'L ACAD. SCI. USA 1989, 1990 (1998); Bruce Trotter & Ann Gordon, *Charting Change in Official Assistance to Agriculture*, 25 FOOD POL'Y 115, 120 (2000).

267. Hardin, *supra* note 33.

268. MOONEY, *supra* note 52; Thomas Cottier, *The Protection of Genetic Resources and Traditional Knowledge*, 1 J. INT'L ECON. L. 555, 559 (1998).

269. OSTROM, *supra* note 38, at 58.

270. Robert C. Allen, *Collective Invention*, 4 J. ECON. BEHAV. & ORG. 1 (1983).

271. D. Louette, *Traditional Management of Seed and Genetic Diversity: What Is a Landrace?*, *in* GENES IN THE FIELD: ON-FARM CONSERVATION OF CROP DIVERSITY 109 (Stephen B. Brush ed., 1999).

272. Gollin, *supra* note 203.

North/South dialog understates the value of global public goods[273] and international cooperation involving both North/South and South/South transfers.

Arguably, it is time to move beyond both the Tragedy of the Commons and North/South dialog as bases for developing mechanisms to protect traditional agricultural knowledge and crop resources. This conclusion is embedded in the negotiated settlement of the ITPGRFA that returns to common heritage for the world's most important crops. The weakness of that treaty, however, is that it does not give proper emphasis to the obligations of industrial countries and developing countries alike to support conservation of crop resources beyond funds raised in connection to commercializing improved crop varieties. This mechanism faces the same limitations as the Indian and OAU gene funds and is likely to be inadequate for meeting conservation budgets that are already inadequate.[274] Rather, benefit sharing must come from a more traditional transfer of international capital: development assistance focused on programs to improve rural incomes in Vavilov Centers. An assortment of tools now exist to use those funds in a way that increases production and income without replacing traditional crop populations.[275] Bilateral and multilateral development assistance that funds rural development activities and benefits the stewards of the world's crop resources can be justified as part of the reciprocal obligations of industrial nations to developing nations. Multilateral efforts such as the Global Environmental Facility's Program on Conservation and Sustainable Use of Biological Diversity Important to Agriculture[276] and the McKnight Foundation's Collaborative Crop Research Program[277] embody reciprocity through international financial assistance. The irony of this conclusion is that it reverts to tools and principles that were established before the assault on common heritage.

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273. Inge Kaul et al., *Introduction*, *in* GLOBAL PUBLIC GOODS xix, xxvi (Inge Kaul et al. eds., 1999).

274. NRC, *supra* note 252, at 117.

275. Jan Engeles & Bert Visser, *Strategies and Methodologies in Genetic Diversity Conservation*, *in* ENCOURAGING DIVERSITY 26, 27 (Conny Almekinders & Walter de Boef eds., 2000); Swaminathan, *supra* note 260, at 26.

276. GEF, *supra* note 263.

277. CCRP, *supra* note 262.

# From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent

By

Nuno Pires de Carvalho

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# From the Shaman's Hut to the Patent Office: In Search of a TRIPS-Consistent Requirement to Disclose the Origin of Genetic Resources and Prior Informed Consent

Nuno Pires de Carvalho*

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* J.D., LL.M, S.J.D., Federal University of Minas Gerais, Brazil; LL.M., S.J.D., Washington University. The author is Deputy Director and Head of the Industrial Property Law Section, Economic Development (Intellectual Property Law) Department, of the World Intellectual Property Organization (WIPO), Geneva, Switzerland. All views expressed are the author's and not necessarily those of WIPO and/or its Member States.

## I. INTRODUCTION

The introduction in patent statutes of a requirement to disclose the origin of genetic resources and prior informed consent of the use of traditional knowledge in claimed inventions (hereinafter "the Requirement") has been at the center of an international debate for the last few years. Many developing, biodiversity-rich countries consider that the Requirement is an essential component of a broader approach to patent law, which should be informed by considerations of economic development.[1] At the other end of the spectrum, a few industrialized countries believe that the Requirement is not only incompatible with current international law, in particular the TRIPS Agreement,[2] but that it also undermines the value of patents as titles that secure private property rights because it unnecessarily

1. *See Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/11 (Aug. 27, 2004). That proposal has received the support of the delegations of South Africa, Bolivia, Cuba, Ecuador, Iran, Kenya, Sierra Leone, Tanzania and Venezuela. *See also Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO.* WIPO Doc. WO/GA/31/13 (Sept. 27, 2004); *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO Doc. WO/GA/31/14 (Sept. 28, 2004). All WIPO treaties and documents cited in this Article are available on the WIPO's website, at http://www.wipo.int. *See infra* Part III.F for a brief report of ongoing multilateral discussions.

2. *See infra* notes 38 and 53 and accompanying text.

complicates the already complex patent procurement procedures and reduces legal certainty.[3]

Actually, the debate on the Requirement has caused international discussions on the advancement of standards of patentability to stall,[4]

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3. *See Working Group on Reform of the Patent Cooperation Treaty*, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004). The United States delegation said that the Swiss proposal to include a provision in the PCT Regulations allowing PCT Parties to adopt the Requirement

> would not achieve its stated goals of achieving timely solutions to access to genetic resources and traditional knowledge as well as the sharing of the benefits derived from such access. Rather, the proposal would sanction provisions in national laws to deny patent rights and challenge granted patents under prescribed circumstances, which would increase litigation, create a disincentive for innovation, and reduce any benefits that may be shared. The Delegation could thus not support the proposal .... The Delegation of the United States of America noted that Switzerland compared its proposal to disclosure requirements which were based upon fundamental principles of patent law or required as a practical matter to facilitate patent examination, but in the Delegation's view the disclosure requirement proposed by Switzerland was directed to matters falling outside patent laws such as access and benefit sharing. The Delegation expressed the view that patent laws were not the appropriate means for addressing matters of misappropriation of genetic resources and traditional knowledge, or other matters of general misconduct. Such thinking might lead States to attempt to advance other non-patent related goals, such as a tax reporting requirement, through the patent laws.

*Id.* at 17. Nevertheless, the United States has its own statutory provisions with a disclosure requirement that advances non-patent goals. In contrast with the Swiss proposal, however, the U.S. statutory provisions are consistent with international law because they are dictated by concerns over material (or proprietary) interests in the patents. *See infra* Part IV.D.

4.

> Although the work of the SCP [WIPO Standing Committee on the Law of Patents] has produced some useful results, the lack of progress at recent SCP sessions clearly demonstrates that the current model for discussion is not workable. Indeed, discussions in the SCP have degenerated to the point that the SCP was unable to agree to a further work program at its most recent session of May 10–14, 2004. There are several reasons for this lack of progress .... Beyond this, the draft treaty documents contain several provisions that have been extremely controversial and of a high political sensitivity, leading to postponement of discussions on some provisions and protracted debates with little resulting progress on others.

*Proposal by the United States of America and Japan for Establishing a New Work Plan for the Standing Committee on the Law of Patents (SCP)*, WIPO Doc. WO/GA/31/10 (Aug. 27, 2004). That proposal was submitted to the WIPO 31st Ordinary (15th Extraordinary) General Assembly, of 2004. As described *infra*, in Part III.F, the United States and Japan have attempted to insulate the current work of the SCP on a draft Substantive Patent Law Treaty (SPLT) by separating topics that are of a more technical nature (such as novelty and inventiveness, or non-obviousness) from the debate of the adoption of the Requirement. That attempt, as noted *infra*, even if correct from a technical point of view, has not been successful in the SCP. The major concern of developing countries is, naturally, an eventual TRIPS

to the prejudice of the interests of inventors and the society at large in obtaining titles that are more secure and less prone to challenges, thus increasing legal security of intangible assets. An objective clarification of the legal aspects of the Requirement, therefore, has become a matter of urgency. That is what this Article intends to achieve. This Article has two main objectives: to explain that the Requirement, as a condition of patentability aimed at monitoring the implementation of the Convention of Biological Diversity (CBD),[5] is incompatible with current international law, including the CBD itself; and to discuss possible ways of adopting the Requirement that are compatible with international law.

Part II of this Article describes the main objectives that biodiversity-rich developing countries want to achieve by adopting the Requirement. It also explains the formal nature of the Requirement—several international treaties against which the Requirement is to be checked treat formal and substantive requirements differently.

Part III assesses the inconsistency of the Requirement vis-à-vis the relevant international instruments, namely the TRIPS Agreement,[6] the UPOV Convention(s),[7] the Patent Cooperation Treaty (PCT),[8] the

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inconsistency of the Requirement, for it might lead to disputes under the WTO Dispute Settlement Mechanism and, ultimately, the risk of commercial sanctions. Developing countries expect that, if they were able to include language in support of their view in the SPLT, they would be closer to a consensus on the adoption of the Requirement in the WTO framework.

5. The Convention on Biological Diversity, Dec. 29, 1993, *available at* http://www.biodiv.org/convention/articles.asp [hereinafter CBD]. Currently, the CBD has 188 parties. The text of the Treaty as well as an introductory guide to its provisions can be found on the CBD Secretariat's website, at http://www.biodiv.org.

6. Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization (WTO), Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter the TRIPS Agreement, or, simply TRIPS]. The text of the TRIPS Agreement as well as of the WTO documents cited in this Article are available on the WTO website, at http://www.wto.org.

7. "UPOV" is the acronym of the *Union pour la Protection des Obtentions Végétales*. Two different versions of the UPOV Convention of 1961 are in force: UPOV 1978 and UPOV 1991. The texts of the International Convention for the Protection of New Varieties of Plants, of December 2, 1961, as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 can be found on UPOV's website, at http://www.upov.org. The UPOV is not about patents for inventions, but about a sui generis regime for plant varieties. Because the main concern of this Article is patent law, references in this Article to UPOV are to be understood mutatis mutandis.

8. Patent Cooperation Treaty, June 19, 1970, *available at* http://www.wipo.int/pct/en/

Patent Law Treaty (PLT)[9] and the CBD. Part III also briefly reports on the current status of international negotiations on the Requirement in the different fora (such as the TRIPS Council and several bodies of WIPO).

Recognizing that an international solution for the gridlock is not in sight in the short- or mid-term, Part IV searches for possible ways to establish a Requirement consistent with TRIPS and other international instruments. Section (a) criticizes a solution that has already been proposed: to treat traditional knowledge holders who contribute genetic resources for inventions as inventors or co-inventors. Section (b) looks at a non-statutory solution, penalizing unjust enrichment from the concealment of valuable information. Even though this solution is available, it is not cast in stone, and courts have varied in dealing with differences in the level of information between contracting parties. Section (c) revisits a solution based on the unclean hands doctrine. Section (d) analyzes a solution adopted under U.S. law and which deals with government material interests in inventions funded with federal resources. Even if the situation and the consequences of that solution are different from the Requirement, nevertheless, the U.S. solution provides a useful hint that buttresses an additional solution, proposed in section (e): governments of biodiversity-rich countries would be entitled to claim ownership in the patents covering inventions derived from genetic resources extracted from their territory without permission. Following a parallel in the regime of employees' inventions as well as in the doctrines of conversion (or the right of accession in civil code countries), the unauthorized use by inventors of materials extracted from national territories would entitle those governments to have a material claim in the resulting title. This is, under a different dosage, the solution recognized by U.S. law for inventions funded by federal resources.

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texts/pdf/pct.pdf (entered into force on Jan. 24, 1978) [hereinafter PCT]. The PCT is administered by the International Bureau of WIPO.

9. Patent Law Treaty, *opened for signature* June 1, 2000, *available at* http://www.wipo.int/clea/docs/en/wo/wo038en.html [hereinafter PLT]. The PLT, once it enters into force, will be administered by the International Bureau of WIPO.

Notwithstanding the fact that Part IV may indicate valuable solutions for adopting a TRIPS-consistent Requirement without changing the text of the international agreement, Part V brings a word of caution. It may not be that valuable to tamper with already complex procedures for obtaining patent rights and add an extra argument for challenging them. Part V concludes that patents are not certificates of good behavior: they are certificates of inventive behavior. For the sake of a reasonably efficient international patent system, they should remain so.

## II. THE OBJECTIVE AND NATURE OF THE REQUIREMENT

### *A. The Objective of the Requirement*

In the last few years a number of developing, biodiversity-rich countries have insistently requested that international patent law be modified to permit national laws to require disclosure[10] of the origin of genetic resources and prior informed consent of the use of traditional knowledge in patent applications. The Requirement has a single objective: to help stakeholders monitor compliance with the legal or contractual obligation to share benefits derived from the commercial use of genetic resources and/or associated traditional knowledge, in the light of the recommendation contained in Articles 8 and 15.7 of the CBD.[11] Article 8 provides:

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10. Patent applicants have, primarily, the obligation of disclosing "the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." TRIPS Agreement, *supra* note 6, art. 29.1. WTO Members, additionally, "may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application." *Id.*

11. A group of developing countries identified four objectives of the Requirement:

> (a) reducing instances of bad patents; (b) enabling the patent office to ascertain more effectively the "inventive step" claimed in a particular patent application; (c) enhancing the ability of countries to track bad patents in the instances where they are granted and challenge the same; (d) improving compliance with their national laws on PIC [prior and informed consent] and fair and equitable benefit sharing prior to accessing a biological resource/associated traditional knowledge.

*The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, at 2–3, WTO Doc. IP/C/W/403 (June 24, 2003). The impact of the Requirement as a tool for assessing patentability (this is, in a nutshell, the objectives listed under (a), (b) and (c)) is significant only in those cases where patents have

> Each Contracting Party shall, as far as possible and as appropriate:
>
> . . . .
>
> (j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and *encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.*[12]

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been applied for or obtained in regard to biological materials (plants, animals and micro-organisms). However, in most developing countries, only micro-organisms are patentable subject matter, as a result of implementing article 27.3(b). Other inventions concerning living organisms are not. So, the proposal of that group of developing countries could have a significant impact in developed countries rather than in their own territories. Moreover, never has a patent been granted in violation of rights and interests of traditional knowledge holders in developing countries. So far, the reports of "biosquatting" patents have only designated patents issued in the United States, Europe and Japan. It seems, therefore, that the problem of "bad patents" is exclusively one that respects developed countries. In this Article the word "biosquatting" will replace the term "biopiracy." Actually, the term "biosquatting" is more accurate than the word "biopiracy" for qualifying the appropriation (or misappropriation) of intangible components of genetic resources and/or of traditional knowledge that could be deemed in the public domain as well as the unauthorized claiming of traditional knowledge that is in control of Indigenous peoples and local communities. The reason is that the first modality is not necessarily illegal—in many cases, actually, private parties benefit from a loophole or a particular feature in the law, such as the one that only accepts written disclosure of prior art for the purposes of patent novelty assessment. Such claims, which impinge on knowledge that otherwise would be in the public domain are similar to settling "on public land in order to acquire title to the land," that is, squatting in the definition of the BLACK'S LAW DICTIONARY 1411 (7th ed. 1999). Squatting also means "entering upon lands, not claiming in good faith the right to do so by virtue of any title of his own or by virtue of some agreement with another who [one] believes to hold the title," *id.*, which corresponds to the misappropriation of TK that is in control of Indigenous and local communities. This second meaning would be closer to "piracy," but not the first one. Besides, under international intellectual property law, the word "piracy" is linked to some practices of copyright infringement. TRIPS Agreement, *supra* note 6, art. 51 n.14. Accordingly, the word "cybersquatting" has been used to designate those cases of misappropriation of third parties' names and brands as domain names over the Internet. The term "biosquatting" seems, therefore, more accurate to identify illegal or otherwise illegitimate intellectual property practices related to genetic resources and associated TK.

12. CBD, *supra* note 5, art. 8 (emphasis added).

Article 15.7 of the CBD provides:

> Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 *with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources* with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.[13]

Failure to comply with the Requirement may be sanctioned in different ways. For example, it can be stipulated that willingly omitting information on the origin of genetic resources in a patent application amounts to lack of candor in the context of relations between a private citizen and the public administration, a breach of a general duty of transparency punishable by a fine or a ban on entering into contracts with the government. But in the field of patents, the sanction that has been more frequently envisaged by governments is the rejection of the patent application or the revocation of the resulting patent, if granted.[14]

It is generally accepted that, once a piece of traditional knowledge (hereinafter "TK")[15] has been instrumental for an inventor to reach a

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13. CBD, *supra* note 5, art. 15.7 (emphasis added).

14. This Article will focus on this last modality of sanctions, unless indicated otherwise.

15. The WIPO Secretariat has explained that the term "traditional knowledge" is, actually, a misnomer, for it comprises both technical ideas, that is, knowledge, and expressions of such knowledge, in the form of expressions of folklore (EOF) or traditional cultural expressions (TCEs) (the terms EOF and TCEs are interchangeable). In other words, the term TK has two different meanings. In a broader concept, it comprises both ideas and expressions. But, in a stricter sense, TK means technical ideas (technical solutions developed by traditional communities in fields such as medicine, agriculture, and environmental protection). Therefore, TK lato sensu corresponds to the traditional idea/expression dichotomy that buttresses the general framework of intellectual property. TK lato sensu comprises two different (but intertwined) fields: EOF or TCEs are closer to the copyright regime; TK stricto sensu has a close affinity with industrial property. *See Consolidated Survey of Intellectual Property Protection of Traditional Knowledge*, ¶¶ 8–9, WIPO Doc. WIPO/GRTKF/IC/5/7 (Apr. 4, 2003). It is in this narrow sense that the term TK is employed in this Article, and which has been defined by the WIPO Secretariat as:

> ideas developed by traditional communities and Indigenous peoples, in a traditional and informal way, as a response to the needs imposed by their physical and cultural

new, creative and useful solution to a given technical problem, it is predictable that the same inventor will be able to put the invention on the market and extract revenues from it. Under Article 15.7 of the CBD and the legal or contractual instruments based thereon, the bioprospector or his/her successor is obligated to share those revenues with the TK holder. As a matter of law, that obligation arises from the TK-derived creation and the obtaining of benefits from it, not from the patent. In other words, the obligation remains regardless of whether the practical applications derived from the TK are submitted as patent applications or kept as trade secrets or simply disclosed into the public domain. A well-written TK licensing agreement will contain clauses providing for monitoring of unauthorized use of the TK, but a problem arises when there is no contractual relationship between the bioprospector and the TK supplier, and therefore the latter has no access to the former's accounting books or research records. Biosquatting then becomes a matter of breach of statutory measures (in those countries which have enacted measures on access to genetic resources and associated TK) or of breach of the law in general (as far as misappropriation of TK can be alleged).

The practical reason for some countries' insistence in keeping the Requirement is that without the voluntary[16] or mandatory disclosure it is extremely difficult, if not impossible, to assert with reasonable

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environments and that serve as means for their cultural identification; the technical scope of those ideas is therefore vast, and comprises all fields of technical application; those ideas contrast with the respective expressions, such as folk tales, poetry, and riddles, folk songs and instrumental music, dances, plays, etc.

*Id.* ¶ 8. The WIPO document explains further that handicrafts may be covered by either field of TK, or by both concomitantly, depending on their more or less utilitarian function. *Id.* ¶ 9.

16. Many patent applications do identify the origin of genetic resources used in making the invention, regardless of any legal constraint in that sense. *See generally* Asha Sukhwani, PATENTES NATURISTAS (Oficina Española de Patents y Marcas, Madrid). *See also Patents Using Biological Sources Material (I) and Mention of the Country of Origin in Patents Using Biological Source Material (II)*, WIPO Doc. WIPO/GRTKF/IC/2/15 (Dec. 13, 2001). The U.S. delegation, in its response to the questionnaire that was used as the base for the WIPO technical study on the Requirement, said: "[B]ased on experience, the USPTO is aware that patent applicants, at times, provide information about the genetic resources used in their invention, including the source of origin, in order to meet the written description, enablement or best mode requirement." *See Draft Technical Study on Disclosure Requirement Related to Genetic Resources and Traditional Knowledge*, ¶ 60, WIPO Doc. WIPO/GRTKF/IC/5/10 (May 2, 2003) [hereinafter *Draft Study*].

certainty that a given invention has been made possible because of a certain hint given to the inventor on a certain use of a plant, animal or micro-organism. Where the invention consists of the very use of the plant (or of its active component) for a practical purpose,[17] the link between the invention and the TK is more visible—if they are not actually the same, as it turned out in the turmeric patent. In that hypothesis, the TK creator should be identified as co-inventor, because his contribution was one of clearly inventive nature. But in those many countries in which new uses of known substances are not patentable subject matter *per se*, situations like the turmeric patent would never arise.[18] In most cases TK is the hint that leads bioprospectors to select plants for collection and further analysis. In these cases there is no visible link between the final product and the initial lead. The invention consists of identifying the useful components and assessing their efficacy.[19] The TK holder who gave

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17. For example, U.S. Patent No. 5,401,504 was granted for the "Use of *turmeric* in wound healing" and it was thus summarized: "Method of promoting healing of a wound by administering *turmeric* to a patient afflicted with the wound" (hereinafter designated as "the turmeric patent"). The patent was re-examined and invalidated, on grounds of lack of novelty, upon request by the Indian Council of Scientific and Industrial Research (CSIR), a government agency linked to the Indian Ministry of Science and Technology. This was a clear-cut case in which a patent was granted for a traditional invention. The patent applicants had added nothing new or creative to what they had learned from ayurvedic traditional medicine. Nevertheless, if it were not for the lack of novelty, the people of Kerala might have been better off if the CSIR had requested the transfer of the title in the U.S. patent instead of pursuing its invalidation. Information on the CSIR can be obtained at http://www.csir.res.in.

18. *See, e.g.*, Andean Community Decision No. 486 art. 21 (Sept. 14, 2000), *available at* http://www.sice.org/trade/JUNAC/decisiones/DEC486e.asp.

> Article 21.—Products or processes already patented and included in the state of the art within the meaning of article 16 of this Decision may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

Legislation and other documents of the Andean Community can be found on its website, at http://www.comunidadandina.org.

In the same sense, The Patents Act (1970) of India, provides:

> The following are not inventions within the meaning of this Act . . .
>
> (d) the mere discovery of any new property of new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Indian statutes on industrial property can be found on the Indian patent office's website, http://www.patentoffice.nic.in.

19. Frequently the identified components are useful for purposes other than those known

the hint and eventually supplied the samples of the resources to the bioprospector can be deemed instrumental to the final output of the inventive activity, but he is not a co-inventor and possibly would have a hard time trying to identify his contribution in the claimed invention. The Requirement, accompanied with effective deterrent sanctions, becomes a crucial tool to obtain compensation from the unauthorized use of TK.

### *B. The Formal Nature of the Requirement*

The Requirement is a *formal* requirement, as opposed to a *substantive* one, and thus its place in the TRIPS Agreement, if ever adopted, should be Article 29, rather than Article 27.3(b). Substantive requirements are those that concern the nature of the invention itself. Substantive, therefore, are the elements of novelty, non-obviousness and utility. Those elements are not only substantive requirements but also substantive *conditions* of patentability, because the failure to meet them is sanctioned with either the rejection of the patent application or, if *a posteriori*, with the invalidity of the patent.[20]

In contrast, formal requirements are those that concern the form in which the invention is submitted to the patent office. The main formal requirement—failure to comply with it will cause the patent application to be denied—is disclosure of the invention, which must be enabling. This formal condition is actually a consequence of the substantive conditions of patentability: it is by reading specifications that disclose the invention in an enabling manner that patent examiners make decisions on whether they find the invention new, non-obvious, and useful.

Other formal requirements that may constitute conditions of patentability relate to evidence of ownership: a document assigning

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to the TK holder.

20. Another substantive requirement—which is not a substantive condition—is the unity of invention. In general, the failure to meet this requirement, if detected during the examination of the patent application, causes the patent application to be divided, but not rejected. If detected after the patent is granted, the patent is preserved. A fourth substantive condition of patentability—the condition of alternativeness of inventions—was identified by the United States Supreme Court in at least three cases. *See* Nuno Pires de Carvalho, *The Problem of Gene Patents*, 3 WASH. U. GLOBAL STUD. L. REV. 701, 725–34 (2004).

the right to apply for the patent to the inventor's employer, for example, or a statement that the applicant is the true inventor. This formal condition is explained by the fact that some patent laws retain the principle that patent rights are originally vested in the first and true inventors. Assignees are only entitled to acquire patent rights as a result of a transfer of original rights. Patent offices generally do not examine the issues of inventorship and ownership, because their role is more a technical one, but some evidence is generally required that identifies those upon whom the law vests the patent rights (or their legitimate expectations).[21]

A third category of formal requirements is evidence of the payment of fees to patent offices. There are two categories of fees: procurement fees, which patent applicants must pay to patent offices for services rendered, and maintenance fees. Procurement fees are not referred to either in the TRIPS Agreement or in the Paris Convention for the Protection of Industrial Property, but they stem from customary administrative practices and are set as an obligation by the PCT and its Regulations.[22] They are therefore authorized by Article 1.1 of the TRIPS Agreement. Maintenance fees, in contrast, are expressly mentioned by Article $5^{bis}$ of the Paris Convention.[23] Article $5^{bis}(2)$ authorizes Paris Union Members "to provide for the restoration of patents which have lapsed by reason of non-payment of fees"—which, *a contrario*, means that Paris Union Members (as well as WTO Members, in the light of Article 2.1 of the TRIPS Agreement) may provide for the lapse of patents on grounds of non-payment of maintenance fees.

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21. As explained below, the TRIPS Agreement does not contain any provisions on ownership of inventions. It is exclusively a matter for national laws to attribute property rights to inventors or to third parties that are legally entitled to succeed to inventors because of certain material interests in the inventions (such as employers, financial sponsors, etc). The only obligation of WTO Members in this regard is stated in article $4^{ter}$ of the Paris Convention: to give inventors the right to be mentioned as such in the patent. Significantly, article $4^{ter}$ of the Paris Convention does not say that the inventor has the right to be mentioned as *owner* in the patent, but only *as such*, that is, as the creator, the author of the invention.

22. PCT, *supra* note 8, arts. 3(4)(iv). 4(2), 39(1), Regs 14–16. The PCT and its Regulations are naturally concerned with fees due in the course of the international phase of patent applications. But article 39(1)(a) of the PCT makes explicit reference to national fees.

23. Mar. 20, 1883 (last amended in 1979) [hereinafter "Paris Convention"]. The text of the Paris Convention as well as of the other Treaties administered by the WIPO Secretariat can be found on WIPO's website, at http://www.wipo.int.

Evidence concerning the origin of genetic resources and prior informed consent of TK holders is a formal requirement in the sense that it does not concern the nature of the invention, but the manner in which the application is presented to the patent office. The Requirement may assume different forms according to the specific nature of the TK involved. When the knowledge about the origin of the genetic resource or the TK used in the invention is essential for understanding the working of the claimed invention, it becomes an element of the enabling disclosure. The Requirement, in such circumstances, is already imposed by current international and national patent law as a formal condition of patentability.[24] Governments' permission to access genetic resources and TK holders' authorization to use their knowledge, and/or genetic resources incorporating their knowledge, are not technical elements: they are exclusively legal elements. A patent application may, theoretically, describe a certain genetic resource or a piece of TK without the need for identifying its origin or its holder(s). But when TK is incorporated into the claimed invention as an inventive concept in its own right (such as in the turmeric patent), then the identification of the TK holder(s) and evidence of their prior informed consent become important elements for the attribution of inventorship and/or ownership. But the Requirement has already been set by current patent law, and does not generally present those characteristics; rather, this condition of patentability results from sui generis legislation that countries have gradually introduced.[25]

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24. Of course, this is true only as far as information concerning the genetic resource or associated TK is concerned. Evidence of prior informed consent is not relevant for enabling disclosure purposes.

25. The legal treatment of the Requirement by WTO Members can be categorized into four different groups: (a) countries that have established the Requirement as a condition of patentability (thus, failure to comply will cause the rejection of the patent application and the invalidity of the patent, if granted): in this category, we can identify the statutes of Brazil, Provisional Measure No. 2.186-16, of August 23, 2001, article 31, the Member States of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela), Decision 391, of July 2, of 1996, articles 16, 26, 35 and second complementary provision and Decision 486, of September 14, 2000, articles 3 and 75, Costa Rica, Law No. 7.788, of 1998, article 81, Egypt, Law No. 82/2002, article 13, and India, The Patents Act, 1970, as amended by The Patents (Amendment) Act of June 25, 2002, Sections 10, 25 and 64; (b) countries that have accepted the Requirement but not as a formal condition for the grant and validity of patent rights: China, see *Information Provided by WIPO Member States Concerning Provisions to Ensure the Recording*

## III. THE REQUIREMENT AS A CONDITION OF VALIDITY OF INTELLECTUAL PROPERTY RIGHTS AND APPLICABLE INTERNATIONAL LAW[26]

### *A. The TRIPS Agreement*

Three provisions in the TRIPS Agreement are relevant for assessing to what extent WTO Members may establish formal requirements (such as the Requirement) as a condition of patentability.[27] First, under Article 29.1, WTO Members are obliged to impose on patent applicants the duty to disclose the invention. Also, WTO Members may impose on patent applicants the duty to identify the best mode of carrying out the invention.

The second provision is Article 32. A question may be raised whether WTO Members may revoke patents for violating rules on access to genetic resources and/or failure to obtain informed authorization by TK holders. Even though Article 32 is silent on this

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*of Some Contributions to Inventions*, Addendum, at 1, WIPO Doc. WIPO/IP/GR/00/3/Rev.1 (Apr. 14, 2000) and the 25 Members of the European Community, Directive 98/44/EC of the European Parliament and the Council of July 6, 1998, on the protection of biotechnological inventions, Recital 27; on June 2003 Norway informed the TRIPS Council that a proposal in this same sense had been submitted to its Parliament, WTO Doc. IP/C/M/40 (Aug. 22, 2003), ¶¶ 87–88; (c) countries in which the Requirement only applies in the field of patents: Egypt and India; and (d) countries in which the Requirement extends to other fields of industrial property (such as breeders' rights and, eventually, utility models and industrial designs): Andean Community, Brazil and Costa Rica.

26. The following discussion does not analyze the disclosure related provisions of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, which was adopted by the FAO Conference on November 3, 2001. The reason is that the FAO Treaty does not provide for or even imply intellectual property protection, as the FAO representative stated at the second session of the WIPO Intergovernmental Committee. *See Report*, ¶ 15, WIPO Doc. WIPO/GRTKF/IC/2/16 (Dec. 14, 2001). One commentator suggests that the Material Transfer Agreement (MTA) that the FAO Treaty provides for is a sort of a transparency measure. Nevertheless, it is not an intellectual property measure nor is it patent-related. Martin A. Girsberger, *Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge—Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing*, 7 J. WORLD INT. PROP. 451, 466 (2004). As of the date of this writing the FAO International Treaty has been signed by seventy-eight countries and accepted (or ratified, approved or acceded to) by fifty-four countries. The Treaty entered into force on June 29, 2004. The text of the Treaty is available at http://www.fao.org/legal/treaties/treaty-e.htm.

27. TRIPS Agreement, *supra* note 6, arts. 29.1, 32, 62.1. The TRIPS provisions on substantive conditions of patentability are articles 27.1 and 70.8(b).

issue, it seems that the general understanding of WTO Members, with the exception of India, is that they may not.[28]

The third provision is Article 62.1, which provides:

> Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Section 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.[29]

Formal conditions that are not explicitly mentioned by Article 29 must be a) reasonable and b) consistent with the provisions of the TRIPS Agreement. The definition of "reasonableness" is not self-evident. Because the TRIPS Agreement "occupies a relatively self-contained, sui generis status in the WTO Agreement," as the Panel in *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products*[30] put it, that is, as the TRIPS Agreement deals with intellectual property in its trade-related aspects only, one might conclude that "reasonable" means those formal conditions that help patent offices assess whether the three substantive requirements of Article 27.1 have been met.

Reasonable also means the formal conditions that help patent offices and/or courts to identify the inventors and/or their successors in title. This issue comprises two different aspects: one has to do with the identification of the *inventor*; the other has to do with the identification of the *owner*.[31] It is generally understood that those

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28. *See* NUNO PIRES DE CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, at 373–75 (2d ed. 2005).

29. TRIPS Agreement, *supra* note 6, art. 62.1.

30. WTO Doc. WT/DS50/R (Sept. 5, 1997), Panel Report, as modified by the Appellate Body Report, adopted on January 16, 1998, ¶ 7.19.

31. Because there is a distinction between the owner and the inventor (although they may be the same person), article 4 of the PCT has two separate subsections concerning the identification of the applicant (article 4(1)(iii)) and the identification of the inventor (article 4(1)(v)) in the request. Subsection 1.4 states:

> Failure to indicate in the request the name and other prescribed data concerning the inventor shall have no consequence in any designated State whose national law requires the furnishing of the said indications but allows that they be furnished at a time later than that of the filing of a national application. Failure to furnish the said indications in a separate notice shall have no consequence in any designated State

persons who contributed with their creative minds to the inventive solution of a given technical problem are entitled to the patent. The patent cannot be attributed to third persons if they do not receive it in a transfer of title. In the U.S., for example, a patent application shall be filed the inventor or by a person authorized by the inventor. Only under exceptional circumstances may the application be filed by someone other than the inventor.[32] In other countries, the application may be filed by a person other than the inventor (his/her employer, for example), provided that the applicant submits evidence of his/her legal right of succession (a labor contract, for example, or a statement by the inventor in that sense).[33] The inventor's right to the patent is both a material and a moral right, in the sense that the inventor has not only vested rights to acquire property in the fruit of his/her work, but also to be publicly acknowledged as such.[34]

The identification of the owner, in contrast with the identification of the inventor, is a necessary element for the many social purposes that stem from property, such as levying taxes, establishing rights to inheritance and providing collateral. Society at large must know what

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whose national law does not require the furnishing of the said indications.

PCT, *supra* note 8, art.4. Significantly, there is no parallel provision in the PCT regarding the applicant. This means that failure to indicate precise data on the applicant in the request does have consequences.

32. 35 U.S.C.A. §§ 111, 118 (2005).

33. *See, e.g.*, C.P.I. No. 9,279, art. 5.2 (Br.) Industrial Property Law 14/05 1996, No. 9,279, art. 6.2 (1996), which authorizes those who, by means of a labor contract or a services contract, acquired the rights from the inventor to file for patent applications on their own behalf. The English version of the Brazilian statute is available on the website of WIPO's Collection of Laws for Electronic Access, at http://www.wipo.int/clea/en.

34. For example, 35 U.S.C. § 111 deals with inventors' material rights. But where the Paris Convention says that "[t]he inventor shall have the right to be mentioned as such in the patent," it is recognizing inventors' moral rights. Paris Convention, *supra* note 23, art. 4$^{ter}$. Article 9.1 of the TRIPS Agreement excludes protection of authors' moral rights from the scope of the Agreement—the reason being that moral rights are not trade-related. One might wonder then why the TRIPS Agreement does not have a similar provision concerning inventors' moral rights, because in its absence, and under article 2.1 of the TRIPS Agreement, WTO Members are obliged to comply with article 4$^{ter}$ of the Paris Convention. The reason is that, as already explained, patent law is not necessarily about protecting *inventors*, but about appropriating *inventions*. As Bodenhausen explains, because inventors have been accorded the right, and only the right, to be mentioned "as such" (that is, as inventors, not as owners) in the patent, national law may provide for their right to waive it. G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY AS REVISED AT STOCKHOLM IN 1967, at 64 (reprinted 1991). That possibility does not exist under article 6$^{bis}$ of the Berne Convention—hence the need for article 9.1 of the TRIPS Agreement.

technologies are available for use without authorization, so as to avoid infringement. In some cases, a patent may give rise to a public interest not only as far as government use is concerned, but also in regard to exceptions to rights conferred, such as compulsory licenses. Thus, the PCT establishes that the identification of the applicant is one of the mandatory elements of the patent request (Article 4.1(iii)). Likewise, the draft Standard Patent Law Treaty (SPLT), in Article 4, says that the right to a patent shall belong to the inventor or to the successor in title of the inventor.[35]

In view of the above, it can be submitted that requiring identification of not only the owner but also other persons that may have proprietary interests in the patent is within the scope of "reasonable procedures and formalities," under Article 62.1 of the TRIPS Agreement. This is an important aspect because it explains why the government funding disclosure clause under 35 U.S.C. § 202 (which requires contractors under government funding to mention in the patent application the fact that the invention was made under federal financial assistance) is TRIPS-consistent. As explained below, consistency arises from the fact that the government funding disclosure identifies proprietary interests in the claimed invention.[36]

The same applies to requirements of procurement or maintenance fees, provided these are consistent with the provisions of the TRIPS Agreement. As explained above, both procurement and maintenance fees are accepted by the TRIPS Agreement, either as elements of WTO Members' national legal systems and practices (Article 1.1) or as Paris Convention obligations (Article 2.1).[37]

In conclusion, formal conditions that (a) have nothing to do with helping patent examiners to assess novelty, inventiveness and susceptibility of industrial application, (b) have no connection with ownership, and (c) are not aimed at evidencing the payment of fees, are ultimately TRIPS-inconsistent.[38]

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35. The draft Substantive Patent Law Treaty (SPLT) is the subject matter of discussions in the WIPO Standing Committee on the Law of Patents.

36. *See infra* Part IV.D.

37. *See supra* text accompanying notes 24–25.

38. The conflict between the Requirement (as a condition of patentability) and the TRIPS Agreement was the subject of an exchange of views by WIPO Members at the third session of the WIPO Intergovernmental Committee. The United States expressed the view that such a

It is probably because of fear of violating TRIPS that biodiversity-rich developing countries have actively pursued in the WTO an amendment either to Article 27.3(b) or to Article 29, so as to explicitly allow for the Requirement to be included in national laws.[39] Actually, requiring information on the origin of materials or the consent of persons whose knowledge has been directly or indirectly used in the development of the invention would be TRIPS-consistent only if, besides being reasonable for the purposes of Article 62, it extended to all fields of technology. To confine the Requirement to the area of biotechnological inventions is an act of discrimination as to the field of technology, under Article 27.1.[40]

The need to implement Article 15 of the CBD is no excuse, because Article 27.1 admits no exceptions other than those it specifically identifies.[41] Moreover, the CBD not being a WTO Agreement, Article XX(d) of GATT 1994 would not justify the discrimination against a field of technology in violation of the provisions of an annex to the WTO Agreement. Actually, the WTO being an Agreement about customs barriers, the WTO has Members that are not Contracting Parties to the CBD. It would not be reasonable to impose on those Members an obligation they are not bound to observe.[42]

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Requirement does not keep with the TRIPS Agreement. *Report*, ¶ 71, WIPO Doc. WIPO/GRTKF/IC/3/17 (June 21, 2002). The Dominican Republic, *id.* ¶ 70, Sri Lanka, *id.* ¶ 75, Egypt and Sudan, *id.* ¶ 76, expressed an opposed understanding.

39. *See infra* Part III.F.

40. TRIPS Agreement, *supra* note 6, art. 27.1. It should be emphasized that the discriminatory nature would not be in requiring the identification of the origin of the genetic resources, but in doing so in respect of patent applications in the field of biotechnology only. Therefore, it would not be discriminatory to impose the Requirement in regard to all patent applications, regardless of their field of technology. Of course, one might allege that the Requirement would ultimately discriminate against other sorts of raw materials, such as minerals. But article 27.1 is clear in prohibiting discrimination as to the nature of the inventions, rather than to the type of raw materials. And, secondly, it is admitted that biological resources and tangible raw materials are different in nature because what matters in the former is the genetic and chemical information they contain. The Requirement, once it addresses genetic material, is therefore tolerated as a kind of differential treatment, as opposed to a discriminatory one. *See* CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, *supra* note 28, at 168–70.

41. TRIPS Agreement, *supra* note 6, art. 27.1. As it will be explained below, actually it is CBD Contracting Parties that are under the obligation to respect international agreements on intellectual property, and not the other way around. *See infra* Part III.E.

42. One commentator has expressed his dissent with this view. Dutfield wrote:

In conclusion, WTO Members may adopt the Requirement as a mechanism for monitoring compliance with the CBD provisions on benefit sharing, but only if it does not constitute a condition for acquiring intellectual property rights which depend on registration, and provided that it is consistent with the provisions of the TRIPS Agreement, namely Articles 3, 4, and 27.1.[43]

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> There is no compelling reason at all why the compulsory submission of a document, such as a certificate of origin, would impose another substantive condition as long as it is not linked to determining the patentability of the invention. After all examination and renewal fees have to be paid by patent applicants and owners, and TRIPS does not prevent them merely because they are not mentioned in the Agreement. Similarly, the submission of documentation attesting to the fact that the applicant had complied with the relevant ABS [access and benefit sharing] regulations, such as a certificate of origin, would be just another administrative requirement.

Graham Dutfield, *Sharing the Benefits of Biodiversity—Is There a Role for the Patent System?*, 5 J. WORLD INT. PROP. 899, 921 (2002). This line of reasoning can be challenged on several grounds. Of course, there are some aspects of patent law that are not mentioned in the TRIPS Agreement. But one must distinguish between those aspects that are not mentioned because negotiators thought they were already implied, and those that negotiators did not mention because of their incompatibility with WTO principles and rules. As explained above, the requirement concerning evidence of the timely payment of fees is not similar to the Requirement because the obligation to pay procurement fees was already a legal practice in WTO Members before the entry of the TRIPS Agreement into force (namely, under PCT provisions), and therefore, it is adopted under article 1.1. Furthermore, payment of maintenance fees is subject to Paris Convention provisions, which have been incorporated by reference in the TRIPS Agreement. On the other hand, the Requirement is not a matter of "another substantive condition," but rather a formal one, because it does not concern the invention itself. And, as far as formal conditions are concerned, the controlling provisions are articles 29 and 62. A formal condition is acceptable only when it is already covered by a provision of the Agreement (such as article 29) or when it is *reasonable*. That commentator does not explain why it would be reasonable to adopt a condition that aims at implementing a treaty that is not part of the WTO. Furthermore, as explained below, it is not reasonable to adopt a formal condition of patentability that creates tension with the TRIPS Agreement with the aim of implementing the CBD, when the CBD itself requires that all measures concerning benefit sharing must comply with international treaties on intellectual property (such as the UPOV Convention, the PCT and the TRIPS Agreement itself).

43. TRIPS Agreement, *supra* note 6, arts. 3,4, 27.1. Article 27.2 of the TRIPS Agreement seems to confine measures in the field of patents aimed at generating barriers to patentability to geographical borders. But in the case of the Requirement, neither article 27.2 nor the national treatment principle would necessarily stand in its way. The reasons are that (a) the Requirement does not give rise to an exclusion from patentability, but rather to some sanctions against illegal access (which may comprise, in some countries, patent invalidation); (b) the Requirement concerns resources that may serve as raw materials for inventions, not the nationality of patent applicants. Curiously, Bolivia has once attempted to justify the consistency of the Requirement as established in the statutes of the Andean Community (see *supra* note 25) to which it is bound by invoking Article 29.2 of the TRIPS Agreement. During the review of Bolivia's implementing legislation in the TRIPS Council, Japan asked the following question:

### *B. The UPOV Convention(s)*

On the other hand, those WTO Members that are also Members of the UPOV may not revoke plant variety certificates on grounds of failure to inform the origin of genetic resources and prior informed consent. In fact, both UPOV 1978 and 1991[44] texts provide that plant varieties certificates may be annulled only when the varieties fail to meet the conditions of novelty and distinctness. Certificates may also be cancelled, but only when the varieties fail to meet the conditions of uniformity or stability as well as the following formal requirements: the breeder failed to provide the authority with the information, documents or materials deemed necessary for the maintenance of the variety (namely, its stability); the breeder failed to pay maintenance fees; the breeder did not propose a suitable denomination to replace the denomination previously submitted and which has been cancelled after the grant of the right.[45] More importantly, the grounds for annulling or canceling plant varieties certificates may not be expanded by UPOV Members.[46] This means that a breeder that develops a variety based upon a plant genetic resource unlawfully collected shall not have the respective certificate annulled or cancelled by any UPOV Member on the ground that

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Please explain the relationship between Article 29.1 of the TRIPS Agreement and Articles 26(h) and (I) of Decision 486 which oblige patent applicants to submit a copy of the contract for access to genetic resources and a copy of the documents certifying the authorization to use of traditional knowledge. Does your country consider the above-mentioned applicant's obligation as an enablement requirement which is clearly stipulated in Article 29.1 of the TRIPS Agreement, or as an additional requirement which is not stipulated in that Article?

Bolivia answered that Article 26(h) of Decision 486 "fit within [the] context" of Article 29.2 of the TRIPS Agreement (which authorizes WTO Members to require patent applicants to provide for information concerning the results of corresponding applications in other countries). TRIPS Article 29.2, *supra* note 6. But, in response to a follow-up question posed by Japan, Bolivia corrected its obviously mistaken answer and clarified that the Requirement was a matter of not allowing patents to be granted on inventions based on unlawfully obtained genetic resources. In other words, the Requirement had nothing to do with either paragraph 1 or 2 of Article 29. *See Review of Legislation (Bolivia)*, WTO Doc. IP/Q3/BOL/1 (Feb. 13, 2002), at 40–42.

44. International Convention for the Protection of New Varieties of Plants, Dec. 2, 1961 [hereinafter UPOV] (as revised on Oct. 23, 1978 and Mar. 19, 1991).

45. UPOV 1991, *supra* note 44, arts. 21–22; *see also* UPOV 1978 art. 10.

46. *Id.*

he/she has failed to comply with national laws concerning access to genetic resources. This view was affirmed by the UPOV Secretariat in a communication addressed to the TRIPS Council:

> UPOV is not opposed to the disclosure, per se, of countries of origin or geographical origin of genetic resources in any way that will facilitate the examination mentioned above, but could not accept this as an additional condition of protection.
>
> Thus, if a country decides, in the frame of its overall policy, to introduce a mechanism for the disclosure of countries of origin or geographical origin of genetic resources, such a mechanism should not be introduced in a narrow sense, as a condition for plant variety protection.[47]

In conclusion, UPOV members may adopt the Requirement, provided it does not constitute a condition for obtaining or maintaining plant breeders' rights.

### *C. The Patent Cooperation Treaty*

Parties to the PCT may not impose the Requirement, either as a condition of patentability or not, on international applications with the purpose of monitoring compliance with the CBD. Article 27.1 of the PCT (on "National requirements") provides that "[n]o national law shall require compliance with requirements relating to the form or contents of the international application *different from or additional to* those which are provided for in this Treaty and the Regulations."[48]

At the diplomatic conference of Washington, in 1970, there was a brief discussion about the meaning of the word "contents" in Article 27.1. A Canadian delegate asked whether the word "contents" (and its French version "contenu") was used with "the intent to cover

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47. *Review of the Provisions of Article 27.3(b), Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore, Information from Intergovernmental Organizations, Addendum, International Union for the Protection of New Varieties of Plants (UPOV)*, at 4, WTO Doc. IP/C/W/347/Add.3 (June 11, 2002).

48. PCT, *supra* note 8, art. 27.1 (emphasis added).

everything in the application from the point of view of substance, or simply to refer to matters that were, so to speak, treated in the application."[49] The Secretary General of the Conference replied that the latter was intended.[50] Indeed, a footnote to the Final Text of Article 27.1 of the PCT explains that:

> The requirements relating to form and contents are principally provided for in Articles 3 (The International Application), 4 (The Request), 5 (The Description), 6 (The Claims), 7 (The Drawings), and 8 (Claiming Priority), and the Rules pertaining to these Articles (mainly Rules 3 to 13). The words "form or contents" are used merely to emphasize something that could go without saying, namely, that requirements of substantive patent law (criteria of patentability, etc) are not meant.[51]

Article 27.5 of the PCT supports *a contrario* the understanding that no formal requirements other than those explicitly set out in the Treaty can be established on international applications.[52] The requirement to disclose the origin of genetic resources and to give evidence of prior informed consent, being a formal requirement, is therefore prohibited in the PCT context. Paragraph 8 of Article 27 contains exceptions to the provisions of paragraph 1,[53] but those do

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49. RECORDS OF THE WASHINGTON DIPLOMATIC CONFERENCE ON THE PATENT COOPERATION TREATY, 1970 at 553 (WIPO 1972).

50. *Id.*

51. *Id.* at 35.

52. PCT, *supra* note 8, art. 27.5. Article 27.5 of the PCT reads:

> Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, any Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications.

53. PCT art. 27.8. reads:

> Nothing in this Treaty and the Regulations is intended to be construed as limiting the freedom of any Contracting State to apply measures deemed necessary for the preservation of its national security or to limit, for the protection of the general economic interests of that State, the right of its own residents or nationals to file international applications.

not comprise the Requirement. Actually, Article 27.8 acknowledges some restrictions established by PCT Members (such as the United States) imposed on their own nationals in regard to the filing of patent applications in other countries, for reasons of national security or other reasons of national policy. Obviously, this is not a condition of patentability, but a matter of permitting the filing of patent applications. In conclusion, international patent applicants, under the PCT system, may not be required to add elements or documents to the patent applications that are designated to follow the so-called "PCT route" beyond those contained in the Treaty.[54]

In conclusion, the Requirement is not allowed under the PCT either as condition of patentability or as an additional requirement during the international phase. We will see below, however, that this rule applies in regard to the Requirement as an element for monitoring compliance with the CBD. But if the Requirement is adopted in the context of assessing proprietary interests, the PCT is no obstacle to its adoption in national laws. In that event, the Requirement ceases to be a formality aimed at assessing a certain type of disclosure—it is rather aimed at identifying the holder(s) of property rights and interests in the claimed inventions. Moreover, nothing in the PCT and its regulations stands in the way of PCT Members to adopt additional formal requirements once the application enters the national phase.[55]

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54. This same view was expressed by the delegation of Norway in the TRIPS Council:

> The PCT explicitly prohibited any requirement which was different from or additional to the requirements provided for in the PCT or its Regulations. Thus, the PCT constituted an important obstacle to the introduction of a system where an international patent application covering biotechnological inventions should contain a reference to the source of origin.

*Minutes of Meeting*, ¶ 100, WTO Doc. IP/C/M/42 (Feb. 4, 2004).

55. See, for example, 35 U.S.C. § 371(c)(4) (2000), requesting an additional document containing an oath or declaration of the inventor (or other person authorized under chapter 11 of Title 35) complying with the requirements of section 115, once an international application enters the national phase in the United States.

### *D. The Patent Law Treaty*

Article 10.1 of the PLT reads:

> Non-compliance with one or more of the formal requirements referred to in Articles 6(1), (2), (4) and (5) and 8 (1) to (4), with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention.[56]

According to Article 6.1 of the PLT,

> Except where otherwise provided for by [the PLT], no Contracting Party shall require compliance with any requirement relating to the form or contents of an application different from or additional to the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty.[57]

In other words, formal conditions of patentability that are not provided either in the PCT or in the PLT itself are not allowed by the PLT. Given that the Requirement is, as shown, inconsistent with the PCT and that the PLT has no provision approving it,[58] the Requirement is also inconsistent with the PLT.

Finally, because the PLT is complementary to the PCT, in that it applies to national and regional patent applications permitted under the PCT,[59] the conclusion is that the Requirement is inconsistent with the PLT (as a condition of patentability or not) both at the international and the national phases.

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56. PLT, *supra* note 9, art. 10.1.

57. *Id.* art. 6.

58. Additional, formal conditions of patentability, under the PLT, are that the contents of an application "which correspond to the contents of the request of an international application under the Patent Cooperation Treaty be submitted under a special request form," the payment of fees, evidence of priority, and the form and means of transmittal of communications (concerning the patent application) to the Patent Offices. PLT, *supra* note 9, arts. 6, 8.

59. PLT, *supra* note 9, art. 3.1.

### *E. The Convention on Biological Diversity (CBD)*

It is generally understood that the Requirement is necessary to help Contracting Parties to the CBD monitor compliance by bioprospectors and/or their successors with national legislation on access to genetic resources. It is also assumed that the Requirement stems logically from the provisions of Articles 8(j) and 15.7 of the CBD.[60] However, the Requirement, when adopted as a (formal) condition of patentability, is in violation of not only the TRIPS Agreement, the UPOV Convention, the PLT and, eventually, if adopted in the international phase, the PCT, but also the CBD itself.

Where Article 15.7 of the CBD suggests that Contracting Parties should take legislative measures with the aim of sharing benefits arising from the commercial exploitation of genetic resources, it says that they should do so "in accordance with Articles 16 and 19."[61] The expression "in accordance with Article 16" means two things.

First, access to genetic resources in developing countries may require technology that is in the hands of private companies in developed countries. Therefore, in order to obtain technology that will create the means for accessing their genetic resources, developing countries shall observe Article 16, which provides for measures that "facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment."[62]

It has been suggested that the reference to Article 16 "expands the potential benefits [to be shared with suppliers of genetic resources] to include: access to and transfer of technology using the genetic resources."[63] This aspect, however, is not clear. When Article 15.7 says that measures will be taken "in accordance with," it seems that it

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60. *See supra* note 11.

61. CBD, *supra* note 5, art. 15.7. Interestingly, article 15.7 advises that benefits should be shared through the financial mechanism of articles 20 and 21, which dismisses the idea of an intellectual property contract approach (under which benefits could be extracted from royalties, for example).

62. *Id.* art. 16.1.

63. LYLE GLOWKA ET AL., A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY 82 (1994).

is referring to procedural requirements that the measures must obey, and not to the scope of the benefits. If the intention were to expand the nature of benefits, the provision's language would be different. For example, the mention of the results of research and development and the benefits arising from the utilization of genetic resources could be followed by the expression "including the benefits referred to in Articles 16 and 19." This view is corroborated by the fact that Article 19 is not about concessions (access to biotechnology shall be on mutually agreed terms), but about procedures that must be respected in order to establish joint research ventures.

Second, the measures taken must be in accordance with paragraphs 2 and 3 of Article 16, which contain rules on technology transfer: "such access and transfer [and, under Article 15.7, all measures aiming at promoting benefit sharing] shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights" as well as "in accordance with international law."[64] In other words, all measures aimed at implementing Article 15.7, including measures to monitor compliance with the obligation of benefit sharing, must respect Contracting Parties' international obligations under intellectual property agreements—which, as shown above, do not permit the adoption of the Requirement as a condition for obtaining rights.[65] Therefore, any measures aimed at monitoring compliance with benefit sharing obligations that are inconsistent with international intellectual property treaties are also inconsistent with the CBD itself. It is true that Article 16.5, which invites Contracting Parties to make efforts to avoid infringing patent and other intellectual property rights, creates obstacles for the implementation of CBD objectives. However, those efforts shall be made "subject to national legislation

64. CBD, *supra* note 5, arts. 15–16.

65. UPOV 1978 and the PCT were already in force when the CBD was negotiated and agreed, in 1992. UPOV 1991 and the TRIPS Agreement, which was signed in April 15, 1994, at Marrakesh, as an Annex of the Agreement Establishing the World Trade Organization (WTO), had their terms already negotiated. Between December 21, 1991, when the Director General of the GATT communicated the results of the Uruguay Round so far reached, and April 15, 1994, only a few minor aspects of the TRIPS Agreement were changed. But the TRIPS Agreement remained essentially the same, which means that the CBD Contracting Parties in 1992 were already aware of those obligations.

and international law."[66] This means that, for Contracting Parties to be excused from observing current international obligations under intellectual property treaties, they must provide for the amendment of those treaties. But until that happens, they are obliged by the CBD itself to observe those treaties. The only conclusion possible is that countries that implement Article 15.7 through measures that are inconsistent with international treaties on intellectual property (such as adopting the Requirement as a condition of patentability) are in violation of the CBD itself. It could be argued, however, that Article 15.7 of the CBD applies to genetic resources only, in contrast with Article 8(j), which refers to knowledge, that is, to intangible assets, and which contains no parallel obligation to comply with Article 16.[67] In other words, one might argue that the CBD does not require measures aimed at monitoring compliance of contracts of TK licensing (either independently from access to genetic resources or in combination with it) with international treaties on intellectual property. But that argument would be wrong: the CBD is about tangible biological diversity and the intangible component is not defined as an integral part of genetic resources. TK, for the CBD, is complementary and accessory to genetic resources, and not an independent component, worthy of separate rules. In other words, measures taken under Article 8(j), because they are complementary and subordinated to those under Article 15.7, must likewise respect intellectual property-related international obligations.

Another argument that could be raised is that Article 15.5, which submits access to prior informed consent, makes no reference to international treaties on intellectual property. Compliance with the obligation of obtaining prior informed consent, therefore, could be monitored regardless of international obligations in the area of intellectual property. To that extent, prior informed consent would give rise to stand-alone obligations under the CBD. Such an argument, however, would be flawed. The reason is that Article 15.4 makes access subject to "the provisions of this Article," which necessarily include those of paragraph 7.[68] In other words, measures

66. CBD, *supra* note 5, art. 16.5.
67. *Id.* arts. 8, 15.
68. *Id.* art. 15.4.

aiming to implement the obligation of obtaining prior informed consent are, like those concerning benefit sharing, subject to paragraphs 2 and 3 of Article 16.

### *F. Current Multilateral Negotiations*

There have been attempts to include the Requirement in international treaties. Those attempts have two different purposes. One, obviously, is to produce effects in territories other than those from which the genetic resources and TK were extracted. As a matter of fact, although genetic resources are raw materials for all sorts of inventions in all fields of technology, they are more important in the biotechnology field. And the main markets for biotechnology processes and products are in developed countries, where most patent applications in that area are filed. It follows that limiting the application of the Requirement to developing countries does not have practical consequences. With that in mind, during the discussions in the WIPO Standing Committee on the Law of Patents (SCP), in September of 1999, on the draft Treaty on the Law of Patents (PLT), Colombia proposed the addition of the following provision:

> 1. All industrial property protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally.
>
> 2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.[69]

The SCP did not reach a consensus on this proposal,[70] and WIPO Member States subsequently revisited the issue no less than five

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69. *Protection of Biological and Genetic Resources*, WIPO Doc. SCP/3/10 (Sept. 8, 1999).

70. *See Report*, ¶¶ 202–09, WIPO Doc. SCP/3/11 (Sept. 14, 1999).

times. In November 1999, the WIPO Working Group on Biotechnology held informal discussions on Colombia's proposal and issued a questionnaire aimed at identifying the intentions of WIPO Member States as to the eventual adoption of the Requirement at the national or regional level.[71] The WIPO Meeting on Intellectual Property and Genetic Resources, held in Geneva in April 2000, discussed the responses to that questionnaire as well as other issues concerning TK, in preparation for the Diplomatic Conference for the adoption of the PLT. In that venue, Colombia softened its proposal: it no longer suggested that the provision had a mandatory nature, but rather that it merely permitted Parties to the future PLT to adopt the Requirement at the national level. Colombia's argument was that it was afraid that, without such permission, the Second Complementary Provision of Andean Community Decision No. 391[72] would be in conflict with the future Treaty. The new proposal read as follows: "When necessary, and if the invention has been obtained from genetic and/or biological resources, any Contracting Party may demand that a copy of the document issued by the competent national authority attesting the legality of access to those resources be submitted to the Office."[73] Subsequently, on the first day of the Diplomatic Conference, on May 11, 2000, WIPO Members held negotiations on Colombia's new proposal, the outcome of which was the grant of a mandate to WIPO's Director General to take the action necessary to establish a forum where Member States could exchange views on matters concerning protection of traditional knowledge, expressions of folklore and access to genetic resources. After intensive consultations, the Director General of WIPO proposed, and the Assemblies approved, in September 2000, the establishment of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (hereinafter

71. *See* WIPO Doc. WIPO/IP/GR/00/3/Rev.1, *supra* note 25.

72. *See supra* note 25.

73. WIPO Doc. WIPO/GR/00/4 (Apr. 14, 2000) (document on file with the WIPO Secretariat). Two elements in this proposal made it optional for PLT Contracting Parties: first, it could be adopted only when Members thought it was necessary (for example, necessary for implementing the CBD); and, second, the word "may" expresses an authorization, not a mandatory action.

designated as the "Intergovernmental Committee").[74] The Requirement was again discussed in WIPO after a request from the Secretariat of the CBD, conveying to the Intergovernmental Committee the invitation by the Conference of the Parties that the WIPO Secretariat prepare a study

> on methods consistent with obligations in treaties administered by the World Intellectual Property Organization for requiring the disclosure within patent applications of, *inter alia*: (a) Genetic resources utilized in the development of the claimed inventions; (b) The country of origin of genetic resources utilized in the claimed inventions; (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions; (d) The source of associated traditional knowledge, innovations and practices; and (e) Evidence of prior informed consent.[75]

The resulting WIPO study scrutinizes the Requirement and its possible technical and legal implications in a very thorough and consistent fashion, but, as a matter of course, it does not state an opinion on its compatibility with international treaties or propose new, alternative solutions.[76] The WIPO Secretariat has not such a mandate.

More recently, and again in the SCP, which is currently having discussions on a Draft Substantive Patent Law Treaty,[77] the

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74. *See Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*, WIPO Doc. WO/GA/26/6 (Aug. 7, 2000); *Report of the Twenty-Sixth (12th Extraordinary) session of the WIPO General Assembly*, WIPO Doc. WO/GA/26/10 (Oct. 3, 2000).

75. *See* WIPO Doc. WIPO/GRTKF/IC/5/10, *supra* note 16, Annex, at 3.

76. *See supra* note 16.

77. *See Draft Substantive Patent Law Treaty*, WIPO Doc. SCP/8/2 (Oct. 16, 2002); *Practice Guidelines Under the Substantive Patent Law Treaty*, WIPO Doc. SCP/8/4 (Oct. 16, 2002). The draft SPLT contrasts with the PLT in the sense that it goes beyond merely procedural provisions, and contains substantive rules of patent law, namely rules on conditions of patentability and on revocation. However, if we take the word "substantive" with its narrow meaning of standards of rights granted and protected (in other words, the standards concerning the scope of patent rights)—as the TRIPS Agreement does in section 5 of part II—then the SPLT, which is mostly concerned with the harmonization of conditions of patentability, does not cover actual substantive law. It is true that conditions of patentability do have an impact on the definition of standards of rights protected, but they are not substantive standards themselves. The only substantive provision that the current draft of the SPLT contains is article 4, on

Dominican Republic, on behalf of a group of countries,[78] proposed to amend paragraph 2 of draft Article 2 (on "General Principles"), which, after the change, would read:

> Nothing in this Treaty and the Regulations shall limit the freedom of a Contracting Party to take any action it deems necessary for the preservation of essential security interests or to comply with international obligations, including those relating to the protection of genetic resources, biological diversities, traditional knowledge and the environment.

Brazil has also suggested an amendment to Article 13 (on "Grounds for Refusal of a Claimed Invention")[79] of the draft SPLT, which would read: "[Compliance with Applicable Law on Other Matters] A Contracting Party may also require compliance with the applicable law on access to genetic resources, protection of traditional knowledge . . . ."[80] These two proposals aim at avoiding the same conflict that exists under the PCT and the PLT. In an explanatory note, however, the Dominican Republic justifies its proposal with the need to fulfill international commitments under the CBD. To that extent, therefore, the argument becomes circular: as explained above, in order to comply with the CBD, countries must comply with international agreements on intellectual property; the violation of the latter leads to the violation of the CBD itself. Therefore, in order to comply with the CBD, it is necessary to include the Requirement in intellectual property treaties. However, because the Requirement is not established in the CBD—on the contrary, unless intellectual property treaties are modified, the CBD prohibits

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inventorship/ownership—the language of which, incidentally, has been borrowed from the draft Treaty Supplementing the Paris Convention as far as Patents Are Concerned, article 9. The Diplomatic Conference convened (at The Hague, on June 3 to 28, 1991) to adopt this draft Treaty failed to reach a conclusion. Nevertheless, some of its provisions were later incorporated into section 5, part II, of the TRIPS Agreement.

78. The countries are: Chile, Colombia, Cuba, The Dominican Republic, Ecuador, Honduras, Nicaragua, Peru and Venezuela.

79. The Brazilian proposal also impacts article 14 of the SPLT, which deals with revocation of patents.

80. *See Proposals by the Delegations of the Dominican Republic and Brazil Concerning Articles 2, 13 and 14 of the Draft Substantive Patent Law Treaty*, WIPO Doc. SCP/8/5 (Nov. 5, 2002), Annexes I and II.

it—it makes no sense to amend the draft SPLT (or, for that matter, any treaty in force) to permit Contracting Parties to enact measures "in order to comply with international obligations" (as proposed by the Dominican Republic) or to impose "the applicable law on . . . access to genetic resources" (as proposed by Brazil).[81] The two proposals are, in fact, circular. Because those obligations are not explicitly stated in the CBD, they cannot be assumed. For the proposals to make sense it would be better to adopt the language proposed by Colombia during the negotiations that led to the adoption of the PLT. Or, as it will be explained below, countries can adopt the Requirement, although not as a condition of patentability with the goal of implementing the CBD, but rather as a measure for establishing proprietary interests derived from the material contributions to the inventive output. Anyway, the two proposals have already been the subject matter of discussions in the SCP,[82] but in view of the different opinions as to whether the SCP is the appropriate forum to address the issue, it was decided to include the two proposals in the text of the draft SPLT in square brackets, accompanied by the following note: "The SCP agreed at its eighth session to include the paragraphs in square brackets, but to postpone substantive discussions on these provisions."[83]

More recently, Switzerland proposed to include the Requirement in the Regulations under the PCT.[84] According to the Swiss proposal,

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81. *Id.*

82. *See Report, Eighth Session of the SCP*, ¶¶ 37–49, WIPO Doc. SCP/8/9 (Dec. 18, 2002).

83. *Id.* ¶ 49; *see also Summary by the Chair*, ¶ 11, WIPO Doc. SCP/8/8 (Nov. 29, 2002) 11. At the tenth session of the SCP, the United States, Japan and the European Patent Office proposed to focus discussions on a "first package of provisions," comprising the definition of prior art, the grace period, novelty and non-obviousness. *See Proposal from the United States of America, Japan, and the European Patent Office Regarding the Substantive Patent Law Treaty (SPLT)*, at 2, WIPO Doc. SCP/10/9 (Apr. 22, 2004), Annex. The SCP has not reached consensus on that proposal. *See Summary by the Chair*, ¶ 67, WIPO Doc. SCP/10/10 (May 14, 2004).

84. Switzerland proposed to amend Rules 51*bis*.1 (by introducing a new subparagraph (g)) and 4.17 (by introducing a new subparagraph (vi). The Swiss proposal and its justification were submitted to the Fourth Session of the Working Group on Reform of the Patent Cooperation Treaty (PCT) held on May 19 to 23, 2003. *Proposals by Switzerland Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. PCT/R/WG/4/13 (May 5, 2003). The proposal was discussed by the Working Group at that same session as well as the session it held from November 17 to 21,

the Requirement could be imposed by national laws in the national phase of international applications. The participants of the Working Group on Reform of the PCT have not reached an agreement. Some delegations would accept the proposal not only because they saw it as "constructive and pragmatic," but also because the PCT was a good starting point for changing international law because the proposal would have an impact on national patent applications.[85] Other delegations, however, said that the WIPO Intergovernmental Committee is a more adequate forum to discuss the proposal.[86] Other delegations were not convinced that the patent system was the proper context in which to address concerns of benefit sharing because implementing measures whereby patents might be invalidated for failure to comply with the requirements of disclosure of source would reduce certainty in patent rights, increase litigation, and reduce patent filings.[87] The topic continues under discussion in the Working Group.[88]

Some WTO Members have addressed the Requirement several times in discussions in the TRIPS Council—the idea would be to amend the TRIPS Agreement so as to establish the Requirement as an additional formal condition of patentability. That discussion was inaugurated by India in 1997, with a document submitted to the Committee on Trade and Environment,[89] but was soon transferred to

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2003. *See Summary of the Session by the Chair*, WIPO Doc. PCT/R/WG/4/14 (May 23, 2003), and PCT/R/WG/5/13 (Nov. 21, 2003)—at this session the Swiss proposal was re-submitted as WIPO Doc. PCT/R/WG/5/11 Rev. (Nov. 19, 2003). *See also Additional Comments by Switzerland on its Proposal Regarding the Declaration of Source of Genetic Resources and Traditional Knowledge in Patent Applications*, WIPO Doc. PCT/R/WG/6/11 (Apr. 21, 2004). The United States delegation has stated that it could not support the Swiss proposal. *See supra* note 3. For a detailed discussion of the Swiss proposal and the current status of multilateral negotiations, see generally Martin A. Girsberger, *Transparency Measures*, *supra* note 26.

85. *See Summary of the Session*, ¶ 133, WIPO Doc. PCT/R/WG/5/13 (Nov. 21, 2003).

86. *Id.* ¶¶ 131, 134.

87. *Id.* ¶ 135.

88. *Id.* ¶ 144; *see also Summary of the Session*, ¶¶ 82–104, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004).

89. For an overview of the debates on the Requirement and other TK-related issues in the WTO, see *The Relationship Between the TRIPS Agreement and The Convention on Biological Diversity—Summary of Issues and Points Made*, WTO Doc. IP/C/W/368 (Aug. 8, 2002); *Review of the Provisions of Article 27.3(b)—Summary of Issues Raised and Points Made*, WTO Doc. IP/C/W/369 (Aug. 8, 2002), and *The Protection of Traditional Knowledge and Folklore—Summary of Issues Raised and Points Made, Note by the Secretariat*, WTO Doc. IP/C/W/370

the TRIPS Council in the context of the review of Article 27.3(b) of the TRIPS Agreement. Subsequently, in the preparations for the fourth session of the WTO Ministerial Conference in Doha, several WTO Members raised the issue again.[90] The Ministerial Declaration, approved in Doha, included the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore as topics of the work program to be pursued by the Council for TRIPS under the review of Article 27.3(b).[91] But the debate has not made substantive progress since Doha. Papers were submitted by the European Communities,[92] a group of developing countries,[93] Switzerland[94] and the African Group.[95] The papers by the group of developing countries and the African Group sought the possible incorporation of the Requirement into the TRIPS Agreement. Switzerland communicated its proposal concerning the amendment of the Regulations under the PCT. And the European Communities reiterate their view that the Requirement "should not act, *de facto* or *de jure*, as an additional formal or substantial patentability criterion. Legal consequences of the non-respect of the requirement should lie outside the ambit of patent law."[96] With the purpose of giving focus

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(Aug. 8, 2002).

90. *See, e.g., The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/356 (June 24, 2002), (proposal by Brazil, China, Cuba, Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe).

91. *Ministerial Declaration*, ¶ 19, WTO Doc. WT/MIN(01)/DEC/1 (Nov. 20, 2001). It should be noted that, according to ¶ 52 of the *Ministerial Declaration*, the work program does not necessarily entail negotiations on new standards. The TRIPS Council may, therefore (and it probably will), keep its focus on TK (and, particularly, on stricto sensu TK) at the level of discussions and exchange of views.

92. *Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge and Folklore—A Concept Paper*, WTO Doc. IP/C/W/383 (Oct. 17, 2002).

93. *The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge*, WTODoc. IP/C/W/403 (June 24, 2003) (submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela).

94. *Article 27.3(b), the Relationship Between the TRIPS Agreement and the Convention of Biological Diversity, and the Protection of Traditional Knowledge*, WTO Doc. IP/C/W/400/Rev.1 (June 18, 2003).

95. *See Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement*, WTO Doc. IP/C/W/404 (June 26, 2003).

96. *Ministerial Declaration*, *supra* note 91, at 2. Norway expressed the same view in the

to the debate, a group of developing countries submitted a checklist of issues to the TRIPS Council, containing three groups of questions (in a total of fourteen questions) on the meaning and scope of the Requirement.[97] That proposal has been rejected by the delegations of the United States and Japan.[98] That same group of developing countries detailed its proposal in two subsequent papers.[99] The United States expressed their views on the inconvenience of the Requirement and proposed alternative solutions to the problem of erroneously granted patents.[100]

## IV. IN SEARCH OF A SOLUTION FOR ADOPTING THE REQUIREMENT WITHOUT UNDULY BURDENING THE PATENT SYSTEM AND/OR INFRINGING INTERNATIONAL LAW

### *A. The TK Holder: A Co-Inventor?*

It has already been proposed that the best manner to address the issue of misappropriation of traditional knowledge and unauthorized access to genetic resources is to consider traditional knowledge

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TRIPS Council. *See* WTO Doc. IP/C/M/39 (Mar. 21, 2003), ¶ 120.

97. *See The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD)—Checklist of Issues*, WTO Doc. IP/C/W/420 (Mar. 2, 2004) (submission from Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela). Subsequently, Bolivia joined the group. *See The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge—Addendum.* WTO Doc. IP/C/W/420/Add.1 (Mar. 5, 2004).

98. *See* TRIPS Council Zooms in on Disclosure Requirements, Bridges Trade BioRes, vol. 4 n.17 (Sept. 23, 2004), *at* http://www.ictsd.org/biores/04-09-23/story1.htm.

99. *See Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention*, WTO Doc. IP/C/W/429/Rev.1 (Sept. 27, 2004) (submission by Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, and Venezuela). Subsequently, Bolivia and Colombia requested to be added to the list of sponsors. WTO Docs. IP/C/W/429/Rev.1/Add.1 (Oct. 14, 2004), and Add.2 (Jan. 20, 2005). *See The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge—Elements of the Obligation to Disclose Evidence of Prior Informed Consent Under the Relevant National Regime*, WTO Doc. IP/C/W/438 (Dec. 10, 2004).

100. *See Article 27.3(b), Relationship Between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore*, WTO Doc. IP/C/W/434 (Nov. 26, 2004). In a nutshell, the United States reaffirmed that the Requirement would not be cost-effective, for it would be too cumbersome and would not accomplish its purpose. *Id.* at 2–7. The United States proposed that erroneous patents could be avoided by resorting to prior art databases, the inequitable conduct doctrine and post-grant opposition or re-examination. *Id.* at 7–8.

holders as co-authors of inventions derived from genetic resources and/or associated traditional knowledge.[101] Of course, when traditional knowledge holders inform bioprospectors of the results of their own inventive activity and those results are later claimed in a patent application, there is no doubt that the original inventors are entitled to be recognized as co-owners of the resulting patents (provided that the conditions of patentability are met). As one commentator explains:

> Patents for plant-derived drugs may be of three kinds: patents on the structure of the compound, patents on the process of isolation, and patents on specific uses of the drug. The contribution of indigenous knowledge may differ for each of these. For example, indigenous knowledge will have little contribution to patents on the structure of a compound, and, in many cases, patents on the process of isolation. Nevertheless, since the compound may very likely never have been isolated without knowledge of the existence of a particular plant and its importance in indigenous medicine, indigenous knowledge is still of critical importance in the identification and development of the drug. Where the use of the isolated drug is the same as, or very similar to, that of the source plant, it is clear that the contribution of indigenous knowledge has been essential to the development of the drug. On the other hand, where the use of the isolated compound as a drug diverges

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101. Michael J. Huft, Comment, *Indigenous Peoples and Drug Discovery Research: A Question of Intellectual Property Rights*, 89 NW. U. L. REV. 1678 (1995), says that "[i]t seems clear that there will be little difficulty in establishing the requisite level of collaboration to maintain joint inventorship in the development of plant-derived drugs using indigenous knowledge." *Id.* at 1722; *see also* Anil K. Gupta, *Rewarding Creativity for Conserving Diversity in [the] Third World: Can IPR Regimes Serve the Needs of Contemporary and Traditional Knowledge Experts in [the] Third World?*, *available at* http://www.sristi.org/pub/html (last visited Nov. 5, 2004).

> Given the high hit rate in formal research around locally identified uses of plants and other kinds of biodiversity, transaction costs of formal R and D systems in private and public systems are reduced considerably. They should in turn share the benefits that may accrue from commercialization of so protected products. In some cases local communities or individuals as the case may be should be considered co-inventors of the new value added products.

*Id.* at 4.

considerably from the use of the source plant in indigenous medicine, the contribution of indigenous knowledge is minimal at best.[102]

The contribution of TK holders to patented inventions, therefore, takes two possible forms: they inform bioprospectors of the possible use of genetic resources (thus leading to the identification of useful bioactive components) and they supply samples of the genetic resources in question.

Traditional knowledge holders are inventors of the uses of those bioactive components (even if they ignore their specific composition), where uses are sufficiently inventive.[103] As inventors

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102. Huft, *supra* note 101, at 1724 (note omitted).

103. An interesting discussion about the patentability of traditional uses of genetic resources can be found in Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co. Ltd., [1996] R.P.C. 76:

> The Amazonian Indians have known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulfate of quinine. In 1944, the structure of the alkaloid molecule ($C_{20}H_{24}N_2O_2$) was discovered. This meant that the substance could be synthesized.
>
> Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: "We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine" The Indian replies: "That is very interesting. In my tribe, we call it the magic spirit of the bark." Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine.
>
> On the other hand, in a different context, the Amazonian Indian would not know about quinine. If shown pills of quinine sulphate, he would not associate them with the cinchona bark. He does not know quinine under the description of a substance in the form of pills, and he certainly would not know about the artificially synthesised alkaloid . . . .
>
> The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial. So far I have been considering what it means to know about something in ordinary everyday life. Do the same principles apply in the law of patents? Or does patent law have a specialised epistemology of its own?

*Id.* at 88 (*per* Lord Hoffman). This text was quoted in *Defensive Protection Measures Relating*

(or co-inventors), and in accordance with internationally accepted principles of patent law, traditional knowledge holders could claim co-ownership in patents granted in any country that covered inventions derived from their inventive contributions.[104] In other words, those who omit information on the inventive contribution of traditional knowledge holders in patent applications are in violation of patent law. There is no need for an additional requirement: the requirement already exists in Article 4[ter] of the Paris Convention.

However, shamans who supply relevant, if not crucial, genetic material may provide important support for the activities of research and development of pharmaceutical and biotechnology companies, but they are not co-inventors of the products and processes obtained as ultimate derivatives of those genetic resources. This issue was already addressed by U.S. courts in at least two cases: *Moore v. Regents of the University of California*[105] and *Regents of the University of California v. Synbiotics Corp.*[106]

In *Moore*, the Supreme Court of California held that the plaintiff, from whom the spleen had been extracted and the respective cells been used for medical research, which led to a patented cell line,[107] had a cause of action against the five defendants (the physician, the owners and operators of the University's hospital, a researcher, a biotechnology institute and a pharmaceutical company) for breach of

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*to Intellectual Property, Genetic Resources and Traditional Knowledge: An Update*, at 7–8, WIPO Doc. WIPO/GRTKF/IC/6/8 (Dec. 15, 2003). The judge, however, framed his argument as an element of novelty rather than of patentable subject matter. Actually, if a patent were granted for the use of chinchona bark (or quinine, for that matter) to treat malaria and other fevers, there would be no doubt that the Peruvian communities should be designated the rightful inventors. *See generally* MARK HONIGSBAUM, THE FEVER TRAIL—IN SEARCH OF THE CURE FOR MALARIA (Pan Books, 2002), which contains a very detailed and vivid account of how chinchona bark became a staple medicine in Europe. The book also tells about the adventures of European explorers in Peru and Bolivia who, in spite of local laws banning the unauthorized exportation of chinchona bark (in order to avoid the total depletion of the chinchona trees), took enormous risks to find and collect the precious natural medicine.

104. In many countries, uses (and in particular second uses of known substances) are not patentable subject matter if they do not consist of new, inventive and useful processes formed by a series of steps. *See* CARVALHO, THE TRIPS REGIME OF PATENT RIGHTS, *supra* note 28, at 188–90.

105. 793 P.2d 479 (Cal. 1990).

106. 849 F. Supp. 740 (S.D. Cal. 1994).

107. *Moore*, 729 P.2d at 480–81.

the physician's disclosure obligations, but not for conversion.[108] One of the reasons that led the Court to refuse the allegation of conversion was that

> the subject matter of the Regent's patent—the patented cell line and the products derived from it—cannot be Moore's property. This is because the patented cell line is both factually and legally distinct from the cells taken from Moore's body. Federal law permits the patenting of organisms that represent the product of "human ingenuity," but not naturally occurring organisms. Human cell lines are patentable because "[l]ong-term adaptation and growth of human tissues and cells in culture is difficult—often considered an art" . . . and the probability of success is low. It is this *inventive effort* that patent law rewards, not the discovery of naturally occurring raw materials.[109]

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108. *Id.* at 497. Conversion, is "under tort and criminal law, the wrongful possession or disposition of another's property as if it were one's own; an act . . . of willful interference, without lawful justification, with any chattel in a manner inconsistent with another's right, whereby that other person is deprived of the use of possession of the chattel." BLACK'S LAW DICTIONARY 333 (7th ed. 1999).

109. *Moore*, 729 P.2d at 492–93 (citations omitted). In his dissent, Judge Mosk acknowledged that, as a matter of law, suppliers of materials cannot be seen as joint inventors because of the particular nature of their contributions. *Id.* at 512 (Mosk, J., dissenting). He suggested, however, that as an analogy, the plaintiff could be entitled to claim inventorship. "A patent is not a license to defraud," he said. *Id.* (Mosk, J., dissenting).

> I am aware that "patients and research subjects who contribute cells to research will not be considered inventors." Nor is such a person, strictly speaking, a "joint inventor" within the meaning of the term in federal law. But he does fall within the spirit of the law . . . . Although a patient who donates cells does not fit squarely within the definition of a joint inventor, the policy reasons that inform joint inventor patents should apply to cell donors.

*Id.* (Mosk, J., dissenting) (citations omitted). The problem with Judge Mosk's analogy is that patents are not certificates of fraud-free conduct. Patents have not been devised to certify that the inventor has a *good* character. They have been devised as certificates that someone with an *inventive* character (or with luck) has reached an *inventive* outcome. Furthermore, Judge Mosk's analogy would create serious problems of proportionality: what proportion of the patent rights should go to those who contributed with the materials? If it is accepted that without them the invention would not have arisen, then they might be entitled to the whole patent (the understanding being that the uniqueness of the invention lied in the uniqueness of the material—therefore, any other scientist might very well, if in possession of the same material, develop a similar invention). Judge Mosk, ultimately, was proposing a complete reformulation of the patent system, so that all sorts of contributions, in addition to the inventive contributions,

In *Synbiotics*, the owner of several cats that were showing some particular symptoms, took them, along with her written observations on the cats' symptoms, to be blood tested.[110] From the blood samples, scientists were able to isolate the virus (similar to the human AIDS virus), and subsequently filed for and obtained two patents.[111] The district judge refused to see an inventive nature in the act of bringing the cats and calling the scientists' attention to the cats' symptoms.[112] Because gene- and chemical-related inventions are conceived only when the inventor "has reduced the invention to practice through a successful experiment," the cats' owner could not be seen as an inventor.[113] "As a matter of law," the court said, "only those persons who contributed to the acts and events that resulted in the conception and reduction to practice are properly considered the inventors of the patents."[114] And because the cats' owner had neither been present, nor participated in any way in the events of identifying and isolating the virus, she was not a co-inventor.[115]

The same reasoning can be applied to most (but not to all) TK holders' contributions to patented inventions. Their contributions generally consist of indicating a specific use of a specific resource, or of samples of the material. Based on that information, researchers will be able: to identify the bioactive ingredient that causes the positive action identified by the TK holder; to assess and describe the properties of that ingredient; to isolate and to purify that ingredient (and, eventually to synthesize it); and to transform it into a final

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are recognized. Stretching his reasoning, where an inventor failed to pay the rent of the premises where he did his research, the landlord might as well ask for a share in the ownership of the invention. The only manner to overcome that uncertainty would be to follow the example of some provisions that deal with employees' inventions, which attribute a pre-determined, arbitrary proportion of proprietary interests to employers when inventions are made by employees not hired to invent and who used the employers' data, experience, and resources. *See infra* Part IV.E. However, contrary to Judge Mosk's view, this solution is not about *inventorship* but rather about *ownership*. Purely material contributions can never give rise to claims of inventorship.

110. *Synbiotics*, 849 F. Supp. at 742.

111. *Id.* at 741.

112. *Id.* at 742.

113. *Id.*

114. *Id.*

115. *Id.* Because she was not a co-inventor, she had no vested rights in the patent title, and therefore, she had no standing for licensing the patents to a third party—which was actually a patent infringer, not a patent licensee.

product. Obviously, the TK holder has not participated in any of these activities. Therefore, he is not one of the inventors.[116] The provision of resources, as crucial as they may be for the inventive output, is not inventive *per se*.

Therefore, where the TK holder's contribution consisted in handing over genetic resources and/or indicating their utility, the Requirement is not relevant for detecting inventorship of claims that are not limited to uses. It seeks only to establish a contractual interest in the commercial gains of an invention derived from genetic resources, in the event these resources have been extracted from a territory where there is a duty to obtain formal consent in order to have legitimate access. The Requirement, under those circumstances, is not ancillary to patent law—it is ancillary to administrative and/or contract law.

### *B. Non-Statutory Standards and the Duty of Disclosure: Unjust Enrichment and Uninformed Consent*

Because inventions derived from traditional knowledge do rely on contributions from TK holders, either in the form of knowledge or in the form of materials, or both, one could allege that the patent applicants are, directly or indirectly, benefiting from those contributions; therefore, they are being unjustly enriched if no recognition is given to the contributors. However, under current standards of international law, knowledge that is not claimed in the form of a patent application becomes a matter of public domain, and, in the absence of effective measures aimed at keeping it secret, no claim can be made as to ownership. Unpatented and disclosed ideas are free to circulate and be used without any restriction—this is the core of the patent and trade secret systems. Thus, in the absence of a

116. But, on the other hand, based on that same information, researchers may have tested and confirmed that the resource (or a bioactive ingredient in the resource) had effective results when used in the manner indicated by the TK holder (such as the use of a plant as an antibiotic). If a patent is applied for the *use* of that ingredient, the TK holder may rightfully claim that he is indeed an inventor (or a joint inventor, if the researchers have generated some additional concept to the TK holder's original invention), because in this event he was indeed the person who conceived the technical solution for the problem. But when the TK holder is the true inventor, he should be identified as such under current patent law. The Requirement, therefore, does not create a new obligation in this narrow sense.

special statutory provision obliging patent applicants to inform patent offices of the use of traditional knowledge either as a lead or as a component of the claimed invention, courts may hesitate to recognize traditional knowledge holders' legal standing to claim compensation for misappropriation of or unjust enrichment from their unpatented and disclosed knowledge. Let us take the following hypothetical example: a bioprospector obtains information from a shaman on the medicinal use of a given genetic resource; the bioprospector may then buy some samples of that resource from the shaman or may receive them as a gift, and, back in a developed country, sells the information and the collected samples to a pharmaceutical company. Guided by such information, the company identifies a bioactive component in the resource, discovers its useful properties and develops such information into a final product several years later. Eventually, the company obtains a patent on the isolated and purified bioactive component as well as on its use. The company also obtains marketing approval from the health authorities and starts commercializing the drug.

As discussed above, we have here two different situations: when the patent is obtained on the isolated and purified component, the shaman has supplied information and samples of the genetic resources, and in exchange he has received no remuneration at all or, at most, a very small amount of money, which eventually (and frequently) is not proportionate to the potential economic value of the information and materials provided; but when the patent is obtained on the use of a bioactive component, the shaman is indeed an inventor or co-inventor, because he (or one of his ancestors) was the person who created the mental concept of the solution for the technical problem (the problem was a certain illness and the solution was the use of the bioactive compound to combat the illness or its symptoms). This second situation is already dealt with by patent law, and the following discussion will not cover it. The difficulty lies in the first situation (in the absence, of course, and as noted, of a special statute). As seen before,[117] the shaman cannot be deemed a co-inventor, regardless of the importance of the raw material to the final

117. *See supra* Part IV.A.

inventive output. His contribution concerned raw material in which no inventive concept was embodied—or, if it was (for example, the breeding work that made it possible for the genetic material to acquire (or enhance) the properties in question), it did not have any influence whatsoever on the inventive work of isolating and purifying the compound. The shaman's contribution to the invention, therefore, was not of an intellectual nature.

The problem is whether the shaman can allege that the bioprospector had failed to disclose to him the potential or actual value of the genetic resource (and the associated element of traditional knowledge, which consists of the discovery of the resource's bioactive properties). Otherwise he would have requested an increased payment (or, eventually, a share in the commercial gains derived from the final output). Is the bioprospector, and his/her successors (eventually, the pharmaceutical company), liable for fraudulent concealment? Does the bioprospector (or the company) have a duty to disclose information to the shaman on the effective or potential value of his TK? Is the bioprospector, therefore, liable in the event that he/she fails to do so? If the answer is yes, traditional knowledge holders may have standing to ask U.S. courts to make biosquatters accountable for concealment.

The controlling case is *Laidlaw v. Organ*,[118] where the Supreme Court held that the buyer did not have the duty of disclosing to the seller of tobacco the news that a treaty of peace had been signed at Ghent between England and the United States, which caused the value of tobacco to rise "from 30 to 50 percent."[119] Justice Marshall wrote:

> The question in this case is, whether the intelligence of extrinsic circumstances, which might influence the price of the commodity, and which was exclusively within the knowledge of the vendee, ought to have been communicated by him to the vendor? The court is of opinion that he was not bound to communicate it. It would be difficult to circumscribe the contrary doctrine within proper limits, where the means of

118. 15 U.S. 178 (1817).
119. *Id.* at 183.

> intelligence are equally accessible to both parties. But at the same time, each party must take care not to say or do any thing tending to impose upon the other.[120]

If we extrapolate this holding into the contractual relationship between the bioprospector and the shaman, we will notice that: (1) most probably the bioprospector is not aware of the real value of the genetic resource; the information he/she controls is that eventually the genetic resource shown to him/her by the shaman has potential pharmacological value, but ultimately such a value will be assessed several years later, after much research and testing; anyway, that is already a piece of information that the shaman did not know; therefore, that is not a situation "where the means of intelligence are equally accessible to both parties," in the words of Justice Marshall; (2) the increased value of the genetic resource (as compared to the value the shaman thinks it has) is both *intrinsic* and *extrinsic* to it—it is intrinsic to the extent that it is a medicinal bioactive component of the resource that adds value to it; and it is extrinsic to the extent that the firm's activities of screening, researching, isolating, purifying and testing the pharmaceutical product, not to mention the FDA's administrative act of granting marketing approval, are the factors that increase the resource's commercial value; (3) the bioprospector's failure in disclosing to the shaman what he already knows about the resource's potential value can be deemed a misrepresentation by silence[121] and the failure in informing the shaman of the increased value as a result of the downstream activities carried out by the pharmaceutical firm could eventually be seen as continuing misrepresentation.[122]

Keeton explains that the law after *Laidlaw* was expanded and that the buyer has no duty to disclose to the vendor circumstances that make the property much more valuable, "and this is true regardless of whether the fact concealed is extrinsic or intrinsic."[123]

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120. *Id.* at 195.

121. *See* W. Page Keeton, *Fraud—Concealment and Non-Disclosure*, 15 TEX. L. REV. 1, 1 (1937).

122. *Id.* at 6.

123. *Id.* at 21. Keeton exemplifies with several cases holding that a purchaser of real estate who is aware of the existence of valuable mineral ores underlying the property has not the duty

One might argue that this is an unfair rule, to the extent that it preserves a situation of unequal information and power between the contracting parties. But, as Keeton suggests, "the law cannot hope to put all parties to every contract on an equality as to knowledge, experience, skill and shrewdness; even if it could, would such be a just and equitable law?"[124] The point is that there is no economic efficiency in promoting negligence and laziness, and, on the contrary, there is economic efficiency in rewarding those who diligently pursue information and knowledge. "It is pointed out," Keeton said, "that [the duty to disclose information to an indolent vendor] is neither just to the individual nor is it a wise social policy to follow because it tends to discourage industry and training."[125]

Based on this argument, Kronman crafted the theory that where the individual obtains information as a result of deliberate efforts, such information should be considered the subject matter of property rights.[126] Therefore, and whereas "[t]he only feasible way of assigning property rights in short-lived market information is to permit those with such information to contract freely without disclosing what they know,"[127] the bioprospector should be allowed to conceal the information about the intrinsic value of the genetic resource and associated TK from the shaman. The reason for distinguishing between knowledge that has been deliberately acquired by the bioprospector (or his/her employer—the pharmaceutical company) and knowledge that has been acquired casually is that denying protection to the latter "will have no significant effect on his future behavior. Since one who casually acquires information makes no investment in its acquisition, subjecting him to a duty to disclose is not likely to reduce the amount of socially useful information which he actually generates."[128]

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to disclose such information to the seller, even when he is aware that the seller is not in possession of such information. *Id.* at 22.

124. *Id.* at 22–23.

125. *Id.* at 23.

126. Anthony T. Kronman, *Mistake, Disclosure, Information, and the Law of Contracts*, 7 J. LEGAL STUD. 1, 14 (1978).

127. *Id.* at 15.

128. *Id.* at 15–16.

Under Kronman's approach, therefore, the duty to disclose information on the value of the genetic resource would take place only where genetic resource collection is random or ethnobotanical,[129] and when the bioprospector is actually in possession of such information, which most frequently he is not. In contrast, taxonomic collection would never be subject to the duty of disclosure, because taxonomic collection is deliberate and targeted, which leads to the presumption that knowledge about the value of the collected genetic resources has been previously acquired.

Another commentator, with the same purpose of fostering acquisition of socially useful information, stretched Kronman's idea and proposed that doctors and biotechnology firms should be allowed to lie to patients who contribute with materials extracted from their own bodies.[130] Accordingly, bioprospectors should not only be allowed to conceal information for taxonomic collection of genetic resources: they should also be allowed to lie, if asked by the shaman about their intentions as to the utilization of the resources.

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129. James Miller says that there exist three strategies for collecting plants for screening programs: random, taxonomic and ethnobotanical. *See* James S. Miller & Stephen J. Brewer, *The Discovery of Medicines and Forest Conservation*, *in* CONSERVATION OF PLANT GENES 122 (Acad. Press, 1992). "Random collecting is an attempt to sample as much taxonomic diversity as possible." *Id.* One limitation of random collecting "is that it often yields samples that are often taxonomically biased by the geographical restriction of collecting." *Id.* "Taxonomic collecting is based on the general tendency . . . for related taxa to contain related compounds." *Id.* at 123. And ethnobotanical collecting consists of selecting the plants to be collected based on their use by traditional medicine. *Id.* The use of ethnobotanical data may be applied in the study of the use of plants in traditional medicine, followed by a testing of their effectiveness. It also may be used for random screening of plants "used in traditional medicine on the assumption that they have a higher probability of yielding bioactive compounds." *Id.*

130. *See* Robert Heidt, *Maintaining Incentives for Bioprospecting: The Occasional Need for a Right to Lie*, 13 BERKELEY TECH. L.J. 667, 667–720 (1998). Bioprospecting, in Heidt's comment, means "the search for valuable cells." *Id.* at 667. Heidt addresses a single situation: a doctor extracts some material from the body of one of his patients, and he/she finds some interesting and potentially valuable properties in some cells. But because the cells did not resist the tests and perished, the doctor needs to obtain additional material. Heidt suggests that the doctor should not only be entitled to omit that information to the patient (which would have Kronman's assent), but also, if asked by the patient, he should also be allowed to lie about the real value of the cells. *Id.* at 670. For a general discussion about how patent law applies to collection of human genetic material, see generally Cynthia M. Ho, *Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries*, HOUS. J. HEALTH L. & POL'Y 107 (2002).

Keeton, however, notes that courts tend to include non-economic factors in their analysis of contractual relationships where differences in knowledge may lead to misinformed consent, or mistakes:

> In the present stage of the law, the decisions show a drawing away from this idea [that law is concerned with freedom of contract, not with morals], and there can be seen an attempt by many courts to reach a just result in so far as possible, but yet maintaining the degree of certainty which the law must have. The statement must often be found that if either party to a contract of sale conceals or suppresses a material fact which he is in good faith bound to disclose then his silence is fraudulent.
>
> [I]t would seem that the object of the law in these cases should be to impose on parties to the transaction a duty to speak whenever justice, equity, and fair dealing demand it. This statement is made only with reference to instances where the party to be charged is an actor in the transaction. This duty to speak does not result from an implied representation by silence, but exists because a refusal to speak constitutes unfair conduct.[131]

It is possible that a shaman may persuade a U.S. court to determine that a biosquatter and/or his successors must compensate the shaman for the omission in informing him of the real or potential value of a genetic resource and/or associated TK, so as to enable the shaman to request a review of the amounts paid (and eventually,

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131. Keeton, *supra* note 121, at 31 (citations omitted). Given that this issue involves fairness, and in the absence of a rule of mathematical precision to dispose of all situations, Keeton lists nine items to be checked so as to assess whether there is or is not a duty to disclose, such as the difference in degree of intelligence of the parties to the transaction, the manner in which the information is acquired, the general class to which the person who conceals the information belongs, the materiality of the fact not disclosed and the conduct of the person with knowledge of the non disclosed fact. *Id.* at 33–37. In the light of some of those items, the bioprospector would not be blamed for concealing information from the TK holder. But other items, in Keeton's view, would clearly speak in favor of the TK holder and against the bioprospector and his successors. It should be noted that Keeton's reasoning may also apply to differences in levels of information between a prospector and a government that supplies a certain genetic resource. However, in this case, the issue at stake would not be one of difference in knowledge, for the genetic resource is not knowledge in itself, but one of prospective or actual gains derived from a material contribution by the government.

where it may make economic sense, a rescission of the contract).[132] This has nothing to do, however, with patent law. What the shaman may complain about is the lack of transparency or candor by the bioprospector. The fact that a patent application does not disclose any element that may help the shaman assess the real value of the information he had provided may simply constitute an additional element for persuading the judge that the bioprospector has acted in bad faith. But the breach of the shaman's right to be informed and the act of misappropriation and fraudulent concealment took place at the moment the bioprospector received the material (and/or the information on its traditional use) from the TK holder.

### *C. Revisiting the Unclean Hands Doctrine*

When traditional knowledge is used, directly or indirectly, as a basis for creating inventive uses for genetic resources to which they are associated, and where those inventions become the subject matter of patents, society has two ways to deal with the need for ensuring the sharing of eventual benefits arising from those inventions with TK holders: one is to adopt the Requirement as a condition of patentability; the other is to adopt the unclean hands doctrine.

I have proposed elsewhere that governments could resort to the unclean hands doctrine as an alternative to adopting the Requirement as a condition of patentability:

> [C]ourts should be able to sanction the lack of candor of patent applicants who knowingly failed to disclose the source in a manner that would facilitate benefit sharing, as established by article 15 of the CBD. Actually, the determination that the concealment of information might lead to the implementation of public policies concerning benefit sharing is fraudulent is a matter of law. Consequently, any attempt to enforce patent

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132. Actually, some transfers of genetic material do require a continued supply. This is particularly true in the cosmetics and perfume industry, where synthetic materials are never as efficient as the natural ones. But in the pharmaceutical sector the same circumstances may also arise. For example, it has been reported that efforts to successfully synthesize taxol are still undergoing. The use of the bark of the Pacific yew to produce the anti-cancer drug has put serious strain in the tree's population. *See Pacific Yew: The Taxol Story*, Canadian Forest Service, *at* http://www.pfc.forestry.ca/ecology/yew/taxol_e.html (last visited Nov. 5, 2004).

rights thus obtained would be an abuse of rights. In compliance with paragraph 2 of article 8 of the TRIPS Agreement and given that infringement both direct and contributory is a tort, it can be imposed that one must have clean hands to obtain relief from an equity court. Only after a patentee abandons its unlawful practice and the effects of the misuse are completely dissipated may it sue infringers. In the case of the Requirement, this implies that patent owners would have to disclose the origin and obtain the appropriate authorizations from the appropriate stakeholders (governments, local authorities, and traditional knowledge holders) before the patent rights could be enforced against infringers.

In sum, the national or regional laws of WTO members that restrict access to the genetic resources found in their territory may require that patent applicants indicate, if known, the source of genetic resources directly or indirectly used in obtaining the invention. The lack of that indication by a patent applicant who knew or had reason to know constitutes fraud. Therefore, the enforcement of the resulting patent therefore, may be deemed an abuse of rights.

In the same vein, if one obtains the genetic resource directly or indirectly used in making a patented invention in a country that has adopted legislation requiring prior informed consent, the failure to obtain that consent constitutes fraud and, therefore, an attempt to enforce that patent may be deemed an abuse of rights. In both cases the patentee's cleaning his hands by providing the missing information and/or obtaining the required prior consent, would purge the abuse of rights.

Importantly, this proposal would not raise transaction costs to an unacceptable level, making patents ineffective. The sort of care required from patent applicants would be reasonable under the circumstances. They would be required to indicate the origin of the resources that they knew or that they had a reason to know—this is a reasonable care standard. In many cases, mere evidence of compliance with the national laws of the countries providing the genetic resources would suffice, without imposing on the patent applicants the burden of

> engaging in complicated and costly investigative efforts. On the other hand, infringers would not be able to get away with illegal practices because the burden of proving the failure by the patent owner to meet the reasonable care standard would fall upon them. If they provided no evidence, no defense would exist against the patent owner. Nevertheless, as explained before, that standard would not be impossible to meet particularly where the countries of origin had enacted laws on access to genetic resources. In these cases, assessing whether the patent owner met the standard would be almost a matter of objective fact finding.[133]

The use of the unclean hands doctrine would have advantages over the patentability condition approach:

(1) first, as a rule of enforcement, it would be compatible with the different international treaties mentioned above (namely the TRIPS Agreement, the UPOV Convention, the PCT and the PLT); several of the arguments listed in paragraph 29.74 *supra* indicate that such a rule would be fair for the purposes of Article 41.2 of the TRIPS Agreement;

(2) second, it would not affect the patentability of an invention. Actually, the idea proposed does not resort to the inequitable conduct rule, because inequitable conduct can only be alleged when the patent applicant fails to disclose to the patent office some material fact that may be (or probably is) material to the patentability; therefore, inequitable conduct, like the Requirement, is linked to the conditions of patentability. The inequitable conduct may also lead to the partial or total unenforceability of the patent, but, unlike the unclean hands doctrine, it cannot be purged.[134] To this extent, the idea of permitting the biosquatter to clean his/her hands is a mitigated inequitable conduct approach. However, when the claims contain matter that is

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133. *See* Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Applications without Infringing the TRIPS Agreement*, 2 WASH. U. J.L. & POL'Y 371, 399–400 (2000) (footnotes omitted).

134. For an overview of recent cases on the inequitable conduct doctrine, see Lisa A. Dolak, *The Inequitable Conduct Doctrine: Lessons from Recent Cases*, 84 J. PAT. & TRADEMARK OFF. SOC'Y 719, 723–40 (2002). As noted above, the inequitable conduct doctrine has been identified by the United States as an alternative solution to prevent the granting of patents that claim previously disclosed TK. See *supra* note 100.

traditional knowledge (such as the turmeric patent[135]), the obligation to disclose it is already clearly established by patent law. Likewise, when the origin of a genetic resource is relevant for enabling an appropriate description of the invention, applicants are already under the obligation to disclose it in the specifications.[136] In those two circumstances, failure to inform the patent examiner about those facts amounts to concealing elements of material importance for the assessment of the patentability. Those would be grounds for a finding of irremediable inequitable conduct.

(3) third, the unclean hands doctrine does indeed promote benefit sharing because it surprises the patent owner at the moment he/she is using the court authority to collect revenue from an infringer (in the form of damages) and/or to impose his/her exclusive rights (and maintain his/her position as exclusive user of the invention in the market by means of an injunction). Because the court will refuse to do so until the patent owner cleans his/her hands, the patent owner has no solution other than seeking a settlement with both the supplier of the genetic resources and the licensor of the associated TK.

One commentator has already discussed this point in relation to the collection of human material from patients. Commenting on Judge Mosk's dissent in *Moore*, she wrote:

> [I]n the case of failing to disclose patient contributions, unless the law changes with respect to whether patients can jointly conceive of an invention, failure to disclose the identity of patients, or even their contributions, would not rise to the level of material information for patentability purposes. Although patients believe that but for their actions, no patentable invention would have been conceived in the first instance, this information is not material to whether the ultimate invention is patentable. In addition, allowing information that is not material to the patentability analysis to be the basis for inequitable conduct runs counter to the traditional basis for such unenforceability . . . .

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135. *See supra* note 17.

136. Several countries, in their responses to the WIPO questionnaire on the Requirement, have noted that aspect. *See Draft Study*, *supra* note 16, ¶¶ 57–64.

> In addition, even if the patent laws were amended to make patents unenforceable if patient contributions were not properly disclosed to the patent office, it is unclear whether this would be an optimal approach. In particular, for patients who want to share of patent profits, creating a new rule for unenforceability would negate any such hope of profits. Nonetheless, if patients cannot be considered joint inventors, an unenforceability rule might provide a helpful bargaining platform for some patients. Accordingly, perhaps patients should advocate a new patent rule requiring all patent applicants to disclose the extent of patient contributions to the invention, as well as what compensation, if any, has been provided for such contributions.[137]

The inequitable conduct, like the Requirement (if adopted as a condition of patentability), seriously reduces the possibility of the TK holder to share benefits. Of course, it is not because the patent will become unenforceable that the inventor will completely cease to obtain gains from its exploitation. A patent is not a *sine qua non* of commercial success. Nor does the inventor cease commercially exploiting it once it is lost or expired. We can think of a very long list of inventions that continued being profitably exploited by their inventors after the expiration of the respective patents. Besides, as explained above, the obligation to share benefits under Article 15.7 does not necessarily stem from their commercial utilization. Their use for scientific or technological purposes is already sufficient ground to trigger benefit sharing—even though, in the absence of commercial gains, it may become very difficult to evaluate those benefits. Nonetheless, the expiration of the patent (or the lapse of the rights to enforce it) reduces the patentee's capacity of reaping the fruit of a commercially successful invention because nothing will prevent others from doing the same—and consequently it undermines the patentee's financial capacity of sharing benefits.

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137. Cynthia Ho, *supra* note 130, at 155–56. The commentator describes a situation that is almost exclusive to U.S. law. In most countries patents cannot be granted on cells, cell lines, genes, or gene sequences, if of human origin. *See Review of the Provisions of Article 27.3(b)—Illustrative List of Questions*, WTO Doc. IP/C/W/273/Rev.1 (Feb. 18, 2003).

The unclean hands doctrine approach has the advantage that it does not affect the enforceability of the patent—it just suspends it until the patent owner cleans his/her hands.[138]

### *D. The Duty to Disclose Relevant Material Interests in Patent Applications; The Example of the Government Funding Disclosure Clause of 35 U.S.C. § 202.*

In 1999, the WIPO Secretariat included the following question in a questionnaire on WIPO Member States' practices related to the protection of biotechnological inventions:

> Does your legislation include any special provisions to ensure the recording of contributions to inventions (such as the source of government funding, the source of genetic resources that originate or are employed in biotechnological inventions, the grant of prior informed consent to have access to those resources)?[139]

The question was deliberately drafted so as to imply that the requirement to identify the origin of genetic resources, then adopted only by Costa Rica and the Andean Community, and the obligation to inform about the use of government funding, as imposed by the United States Code, are similar. Indeed, they are similar to the extent that both are formal requirements because they concern the manner in

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138. *See* MANUEL RUIZ, SOUTH CENTRE, THE INTERNATIONAL DEBATE ON TRADITIONAL KNOWLEDGE AS PRIOR ART IN THE PATENT SYSTEM (Oct. 2002), *available at* www.southcentre.org/publications/occasional/paper09/traditionalknowledge.pdf; COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 86–87 (Sept. 2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf.

139. Actually this question was originated by the debate in the SCP on the Colombian proposal. Because of that proposal, Colombia was invited to attend the meeting of the WIPO Working Group on Biotechnology, in November 1999. *See Issues for Proposed Work Program on Biotechnology*, WIPO Doc. WIPO/BIOT/WG/99/1 (Oct. 28, 1999) (on file with the WIPO Secretariat). The responses to the questionnaire were collected and circulated and submitted to the WIPO Meeting on Intellectual Property and Genetic Resources of April 17 and 18, 2000 (*Information Provided by WIPO Member States Concerning Special Provisions to Ensure the Recording of Some Contributions to Inventions*, WIPO Doc. WIPO/IP/GR/00/3 Rev.1 (Apr. 14, 2000))—the meeting that was the precursor of the Intergovernmental Committee. The same responses can also be found in WIPO Doc. WIPO/GRTKF/IC/1/6 (Apr. 6, 2000), submitted to the first session of the Committee, from April 30 to May 3, 2001.

which the claimed invention is described, and thus they do not regard the nature of the invention. Both requirements are, therefore, *extrinsic* to the invention. But the similarity stops there. As it will be shown, unlike the Requirement, the U.S. requirement that contractors inform about government funding is consistent with international obligations, including those of the TRIPS Agreement.

Contractors, under 35 U.S.C. § 202,[140] have actually two disclosure obligations: they must disclose the very existence of the

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140. The relevant provisions of Chapter 18 ("Patent Rights in Inventions Made with Federal Assistance"), 35 U.S.C. § 202 *et seq.* read:

35 U.S.C. § 202 Disposition of rights

(a) Each nonprofit organization or small business firm may, within a reasonable time after disclosure as required by paragraph (c)(1) of this section, elect to retain title to any subject invention . . . The rights of the nonprofit organization or small business firm shall be subject to the provisions of paragraph (c) of this section and the other provisions of this chapter . . . .

(c) Each funding agreement with a small business firm or nonprofit organization shall contain appropriate provisions to effectuate the following:

(1) That the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to a contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time . . . .

(4) With respect to any invention in which the contractor elects rights, the federal agency shall have a nonexclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for on or behalf of the United States any subject invention throughout the world: *Provided*, That the funding agreement may provide for such additional rights; including the right to assign or have assigned foreign patent rights in the subject invention, as are determined by the agency . . . .

(6) An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention . . . .

35 U.S.C. § 203 March-in rights

(1) With respect to any subject invention in which a small business firm or nonprofit organization has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee, or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself . . . .

35 U.S.C. § 206 Uniform clauses and regulations

> The Secretary of Commerce may issue regulations which may be made applicable to federal agencies implementing the provisions of sections 202 through 204 of this chapter . . . .

Those regulations can be found in 37 C.F.R. § 401 (2004), and in particular in the following rules:

> § 401.3 Use of standard clauses at § 401.14.
>
> (a) Each funding agreement awarded to a small business firm or nonprofit organization . . . shall contain the clause found in § 401.14(a) . . . .
>
> § 401.14 Standard patent rights clauses.
>
> (a) The following is the standard patent rights clause to be used as specified in § 401.3(a).
>
> Patent rights (Small Business Firms and Nonprofit Organizations) . . .
>
> (b) Allocation of Principal Rights
>
> The Contractor may retain the entire right, title, and interest throughout the world to each subject invention subject to the provisions of this clause and 35 U.S.C. § 203. With respect to any subject invention in which the Contractor retains title, the Federal government shall have a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for on or behalf of the United States the subject invention throughout the world.
>
> (c) Invention Disclosure, Election of Title and Filing of Patent Application by *Contractor*
>
> (1) The *contractor* will disclose each subject invention to the *Federal Agency* within two months after the inventor discloses it in writing to *contractor* personnel responsible for patent matters . . . .
>
> (2) The *contractor* will elect in writing whether or not to retain title to any such invention by notifying the *Federal Agency* . . . .
>
> (d) Conditions When the Government May Obtain Title
>
> The *contractor* will convey to the *Federal Agency*, upon written request, title to any subject invention —
>
> (1) If the *contractor* fails to disclose or elect title to the subject invention within the times specified in (c) above, or elects not to retain title; provided that the *agency* may only request title within 60 days after learning of the failure of the *contractor* to disclose or elect with the specified times . . . .
>
> (f) *Contractor* Action to Protect the Government's Interest . . . .
>
> (4) The *contractor* agrees to include, within the specification of any United States patent applications and any patent issuing thereon covering a subject invention, the following statement, "This invention was made with government support under (identify the *contract*) awarded by (identify the Federal agency). The government has certain rights in the invention."

The provisions of 35 U.S.C. § 202 *et seq.* apply to all firms regardless of their size, in accordance with Presidential Executive Order I2,591. It should be noted that, because the march-in rights, under 35 U.S.C. § 203, amount to a compulsory license, they are subject to the

subject inventions to the funding agency; and they must inform that the subject invention was made under a funding agreement in the patent application.[141] If the contractor fails to disclose the invention to the funding Agency, the Government may acquire title to the invention. Such an acquisition, however, is not automatic—"the agency may only request title within 60 days of learning of the failure to disclose or elect within the specified times."[142] And because the provision says that the Government *may* request title, it follows that such a request depends on the discretionary authority of the governmental agency.

The purpose of the government funding requirement (hereinafter designated as "the U.S. requirement") is two-fold. On the one hand, it is aimed at informing the government itself about the existence of the invention, because the fact that the invention was publicly funded gives the government some rights in the invention, namely the right to a nonexclusive, nontransferable, irrevocable and paid-up license.[143] On the other hand, the requirement provides information to the public at large, because, if some circumstances of public interest arise, the government has march-in rights in the invention, which means that interested third parties may eventually obtain the right to use the patented invention.[144] However, the notice on the patent letter that the invention was made with Federal financial assistance is "neutral" in the sense that the actual rights that the government may have reserved are not specified thereon.[145]

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provisions of article 31 of the TRIPS Agreement. Therefore, the possibility for the U.S. government to grant "partially exclusive, or exclusive" compulsory licenses is inconsistent with article 31(d) of the TRIPS Agreement, which provides that compulsory licenses "shall be non-exclusive." TRIPS Agreement, *supra* note 6, art. 31.

141. Section 302(c)(6) states that the funding agreement shall contain the obligation "on the part of the contractor . . . to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support." Evidently, the second aspect of this provision is beyond the contractor's control. Only the Unites States Patent and Trademark Office (USPTO) can implement the obligation of including a certain language in the patent. The only thing the patent applicant can do is to inform the USPTO of the interests of the federal government in a given patent application and to request a correction if the patent is issued without such a note.

142. 37 CFR § 401.14(a)(d)(1) (2004)

143. 35 U.S.C.S. § 202(c)(4) (2004); Exec. Order No. 12, 591, 52 Fed. Reg. 13,414 (1987).

144. 35 U.S.C.S. § 203 (2004).

145. "The only concrete evidence Duke cites is the statement on each of the patents noting that the government has rights in the patents. This, however, is insufficient because these short

Secondly, § 202 *et seq.* do not provide for any mandatory action to be taken by Federal agencies. They contain no standards for courts to use to examine legality.[146]

Another important aspect of Chapter 18 is that its provisions do not set a clear entitlement to patent rights. "Though the indication is strong," said the Court of Appeals for the Eleventh Circuit in *Southern Research Institute v. Griffin Corp.*,[147] "that the government should ordinarily grant such [patent] rights, the statute admits of no considerations by which we could fairly gauge the propriety of a refusal to so grant such rights."[148] In a footnote the court noted that commentators had suggested that the Bayh-Dole Act[149] created a presumption in favor of researchers working with a government funding grant. The court, however, repeated: "[w]hile we may not disagree with this view, we note that the Act leaves us without sufficient judicial standards by which to evaluate a *refusal* to give away patent rights."[150]

What is then the consequence of failure to comply with the government funding disclosure requirement—or more specifically, what happens if the contractor fails to acknowledge in the patent application that the invention was made with public financial assistance? It seems that, according to courts, the consequence ultimately lies in the discretionary authority of the government, provided the deadlines established by 37 C.F.R § 401.14 are

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notations on the patents do not define the scope of the government's rights." Madey v. Duke Univ., 307 F.3d 1351, 1364 (Fed. Cir. 2002).

146. "The court held that Vartanian's complaint must be dismissed because (1) § 202 did not provide, either explicitly or implicitly, a private right of action regarding the ownership of inventions; (2) judicial review of the agency's purported refusal to grant ownership rights was unavailable . . . because the underlying statute, § 202, does not provide any standards for meaningful review of the agency's actions . . . . We also agree with the court that judicial review is not available because the underlying statute, § 202, provides no standards for judging the propriety of the agency's action." *See* Vartanian v. Gen. Elec. Co., No. 99-1404, 2000 U.S. App. LEXIS 6327, at *2–*3, *6 (Fed. Cir. Apr. 6, 2000) (per curiam).

147. 938 F.2d 1249 (11th Cir. 1991). The plaintiff alleged that the government was under a statutory duty to assign the rights stemming from a patent covering an invention to which SRI's employees had contributed under a federal grant.

148. *Id.* at 1254.

149. Bayh-Dole Act, 35 U.S.C.S. §§ 200–11 (2004).

150. 938 F.2d at 1254 n.10. 35 U.S.C. § 202 *et seq.* were introduced in the Patents Act (Title 35) by the Bayh-Dole Act.

complied with. In *Gen-Probe Inc. v. Center for Neurologic Study*,[151] the District Court for the Southern District of California held that section 202 provides for no private right of action.[152] The court added that, unlike sections 281 and 141–45 of the Patent Act, section 202 contains no mechanism for private enforcement.[153]

Moreover, the transfer of title does not occur automatically where the contractor failed to disclose the invention to the Federal agency or to the USPTO office. In *Jewish Hospital of St. Louis v. Idexx Laboratories*,[154] the District Court of Maine construed section 202 in the following manner:

> [n]either the statute nor the regulation results in the automatic transfer of title IDEXX asserts. The statute requires funding agreements to provide that the Government '*may* receive title' under certain circumstances . . . . Rather than automatically transferring title to the invention upon late disclosure, the

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151. 853 F. Supp. 1215 (S.D. Cal. 1993).

152. *Id.* at 1217 (citing with approval Platz v. Sloan-Kettering Inst., 787 F. Supp. 360 (S.D.N.Y. 1992)).

153.

> This conclusion [that under section 202 no private right of action exists] is supported by the fact that elsewhere in the patent statutes, Congress did explicitly grant private causes of action. *See, e.g.*, 35 U.S.C. § 281 (1988) ("a patentee shall have remedy by civil action for infringement of his patent"); 35 U.S.C. §§ 141–145 (1988) (applicant whose patent is rejected by the Patent Office on appeal may pursue his claim in the federal courts). The fact that elsewhere in the patent statutes private rights were expressly provided indicates that "when Congress wished to provide a private damage remedy, it knew how to do so and did so expressly." Likewise, that such a right was not created under § 202(c)(7)(B) suggests that no right was intended.

*Id.* at 1218 (citation omitted). This is debatable, however. True inventors are entitled to claim and enforce in courts inventorship and ownership of the patent, and yet the Patent Statute contains no provision explicitly recognizing such a right. That right stems from the principle that patents should be granted for those whom the law qualifies as the rightful patent letter addressees.

154. 973 F. Supp. 24 (D. Me. 1997). Idexx had moved to file a third amended answer and counterclaim to assert three affirmative defenses to patent infringement: (1) lack of standing or failure to join an indispensable party (the Federal government); (2) patent misuse and unclean hands; and (3) inequitable conduct. Order on Idexx's Motion to File Third Amended Answer and Counterclaim (Docket Item 202) 1, Jewish Hosp. v. Idexx Labs., 973 F. Supp. 24 (D. Me. 1997) (Civ. No. 95-290-P-H) [hereinafter Order]. The argument of Idexx was that, because Jewish Hospital had neglected to promptly communicate to the NIH the making of the patented invention under a NIH funding agreement (the communication was made after the patent was issued), the government had automatically acquired title and therefore the Jewish Hospital had no standing for enforcing rights in that patent.

> Secretary has provided in regulation 401.14(d)(1) that grant recipients like Jewish Hospital retain title to the invention unless and until the Federal agency meets two requirements. First, the Federal agency must make a "written request." 37 C.F.R. §401.14(d). Second, the Federal agency must make this request "within 60 days after learning of the failure of the [grant recipient] to disclose." 37 C.F.R. § 401.14(d)(1.)[155]

The result that title does not transfer automatically to the Government under section 202 is even clearer when its language is compared to the language of the Federal Nonnuclear Energy Research and Development Act (FNERDA). "Unlike the permissive and conditional language of the statute and regulation here [section 202 and 401.14], FNERDA clearly provides that 'title to any invention made or conceived under a FNERDA contract *shall vest* in the United States.'"[156]

Disputes involving title to the invention between the Federal agency and the funded inventor may not benefit third parties. The court said:

> Simply put, I fail to see how the allegations of improper delay, even if true, are at all material to this patent infringement case. These allegations concern the Jewish Hospital-NIH funding contract and its procurement. But whether Jewish Hospital mislead the NIH has no bearing on any legitimate issues in IDEXX's answer or counterclaims. IDEXX cannot benefit from potential disputes between Jewish Hospital and the NIH arising under the contract and procurement process.[157]

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155. Order, *supra* note 154, at 4. The court noted: "Indeed, the very title of regulation 401.14(d) is '*Conditions* When the Government *May* Obtain Title.' 37 C.F.R. § 401.14(d)."

156. *Id.* at 4 n.3 (citation omitted).

157. *Id.* at 5. These aspects of Chapter 18 represent a departure from pre-existing law. In a case involving the alleged infringement of a patented invention made under a 1974 grant from the Public Health Service (invention which was communicated to the funding agency nearly eighteen years after the grant expired), VDI Technologies, Inc. v. Price, Civil No. 90-341-M, Order of August 31, 1994 (D.N.H. 1994), the District Court of New Hampshire said that "[w]hile the regulations and reporting requirements did not automatically vest title to grant-related inventions in the United States, they did automatically vest in the government the exclusive right to determine who could obtain and exercise ownership rights and on what terms." *Id.* at 8. "For purposes of the present declaratory judgment action, Sudbury's ownership

Actually, if it is not possible to identify here a case of inequitable conduct, because the funding contract is not material to the issue of patentability, the failure to timely disclose the invention to the government and to society at large (through the notice on the patent letter) may raise a question of unclean hands—which apparently the district judge's order failed to address. The question is that the notice on the patent informs the public that the government—and, consequently, tax-payers—has interests in the patented invention, which may include the royalty-free use of the invention by the government itself, or, if some circumstances of public interest arise, march-in rights claims.[158] Even though it seems that the government, and the NIH in particular, will be parsimonious in resorting to the extreme solution of marching in private patent rights,[159] the possibility exists nonetheless. Failure to communicate to the USPTO that ownership of a certain invention made under federal funding is limited by Federal statutes and regulations may be seen as a serious omission of facts relevant to public policy; therefore, any attempt to enforce rights thus acquired might be deemed abusive.

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of the '854' patent is not established, rendering the purported case and controversy between these parties unripe, at least as to the patent related claims." *Id.* at 9. "Moreover, what Sudbury knew, or should have known, of the reporting requirements would be critical to an assessment of whether Sudbury was guilty of inequitable conduct before the Patent and Trademark Office ('PTO'). If Sudbury did know of the restrictions on patentability and deliberately withheld that information, then the '854' patent would most probably be unenforceable." *Id.* at 10 (citation omitted). "At this juncture, until the government exercises its right to determine ownership of the invention, and, the scope of those ownership rights are determined if they are awarded to Sudbury, the regulations operate to preclude its claim to record ownership of the patent and preclude its current claim of infringement." *Id.* at 11.

158. 35 U.S.C. § 206 (2000).

159. *See Determination In the Case of Petition of Cell Pro*, National Institutes of Health, Office of the Director, of August 1, 1997, *available at* www.nih.gov/news/pr/aug97/nihb_01.htm. The Director said that the NIH is

> wary . . . of forced attempts to influence the marketplace for the benefit of a single company, particularly when such actions may have far-reaching repercussions on many companies' and investors' future willingness to invest in federally funded medical technologies. . . . In exercising its authorities under the Bayh-Dole Act, NIH is mindful of the broader public health implications of a march-in proceeding, including the potential loss of new health care products yet to be developed from federally funded research.

*Id.* at 8.

On its face, the U.S. requirement is substantially distinct from the Requirement because it does not establish a condition of patentability. In other words, the Patent Office will neither reject a patent application because the applicant failed to inform about the fact that the claimed invention was made under a Federal grant, nor will a court invalidate or refuse to enforce patent rights on that ground. However, that is not the point, because, as seen above, the Requirement is not always imposed as a condition of patentability. Furthermore, even when it is not a formal condition of patentability, the Requirement is in violation of those WIPO treaties that deal with formal requirements (which are not necessarily patentability conditions), such as the PCT and the PLT. Therefore, even if it is not a formal condition of patentability, the U.S. requirement could be in violation of the United States' international obligations under the PCT and the PLT. But it is not. The government funding disclosure requirement helps the funding agency and tax payers to assess matters of attribution of rights in the invention, i.e., ownership. Patent laws in general designate inventors as the original owners of patented inventions. But ownership may as well stem from contractual arrangements between inventors and their employers[160] or funding providers.

Worried that entities benefiting from federal grants were not adequately reporting inventions made in compliance with a statutory mandate,[161] two federal agencies have already inspected the levels of actual implementation of 35 U.S.C. § 202. The first report was elaborated by the Office of Inspector General of the Department of Health and Human Services, in 1994. It specifically checked the reported disclosure of inventions made under NIH grants at the Scripps Research Institute and concluded that they were underreported.[162] The Inspector General recommended a review of patents obtained by NIH grantees (to the argument that such a review would cause too much work, the Inspector suggested that the NIH

160. *See* U.S. v. Dubilier Condenser Corp., 289 U.S. 178 (1933).

161. *See* 35 U.S.C. § 202(b)(3) (2000).

162. *See* DEP'T OF HEALTH HUM. SERVS., *Underreporting Federal Involvement in New Technologies Developed at the Scripps Research Institute* (June 1994), *available at* http://www.oig.hhs.gov/oas/reports/phs/c9300029.pdf.

take a "risk-based approach that would ensure that those grantees most likely to have inventions and file for patents are reviewed").[163]

The second report was issued by the United States General Accounting Office (GAO), in August 1999.[164] This second Report also concluded that there was not enough information on patent documents on government interests in inventions made under federal grants. Based on that conclusion, the GAO recommended Congress to consider amending the Bayh-Dole Act "to standardize, improve, and streamline the reporting process for inventions subject to both the Act and Executive Order 12591."[165] In order to achieve that, the GAO recommended:

> [t]he Congress could consider (1) requiring the Secretary of Commerce to develop standardized disclosure forms and utilization reports for federally funded inventions, (2) making the patent the primary control mechanism for reporting and documenting the government's rights and the only written instrument for confirming the government's royalty-free license, and (3) requiring the Patent and Trademark Office to provide information to the funding agencies to assist them in monitoring compliance.[166]

GAO's argument was that the

> patent database is a better source than the Government Register for determining the government's rights to federally sponsored inventions. It is more accessible than the Government Register in that the official patent records are available for inspection and a user can obtain from PTO's Internet Web site the full text of patents issued since 1976.[167]

Among the measures aiming to streamline the reporting process, the GAO had suggested a requirement that the notice on the patent application include "the name of each specific agency that funded

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163. *Id.* at 9–10.

164. U.S. G.A.O. OFFICE, REPORTING REQUIREMENTS FOR FEDERALLY SPONSORED INVENTIONS NEED REVISION (1999).

165. *Id.* at 19.

166. *Id.*

167. *Id.* at 14–15.

research, the contract or grant number(s) under which the invention was created, and a provision stipulating that the government has a nonexclusive, paid-up, royalty-free right to the use of the invention."[168] The GAO also proposed that the USPTO should keep the funding agency informed of events that might affect the government's rights during the application's prosecution (so that the funding agency could take preventive measures to protect its interests in the invention) and that the Patent Gazette include a notice on the government's interest on patents issued.[169] The GAO also proposed that the USPTO could charge applicants a fee for applications that contained a government interest notice.[170]

The USPTO agreed that the requirement, if adopted in GAO's terms, would be in compliance with the draft of the Patent Law Treaty that was then being negotiated. What the USPTO did not agree with was the increased burden on patent applicants.[171]

The GAO's recommendations were not implemented and thus the USPTO has no obligation to seek information on the nature or origin of the funds used by inventors for making claimed inventions. Interestingly, many of the proposals made by the GAO could have been subscribed to by environmental agencies of biodiversity-rich countries seeking ways and means to monitor compliance with contracts on access to genetic resources (likewise, the GAO was seeking a practical means to monitor, through patent documents, compliance with contracts of access to government funds). To the allegation that using the patent system to monitor the use of genetic resources is not efficient because it would not cover inventions kept undisclosed, the GAO would answer that that is not a problem because section 202 actually requires a patent to be filed. Therefore, in principle, all inventions made with government funding that are patentable subject matter will find their way to the USPTO. But that is not the issue, of course. The issue is that it would be wrong (however not offensive to international legislation) to use patents to verify whether contractors have complied with their contractual

168. *Id.* at 32.
169. *Id.*
170. *Id.*
171. *Id.* at 20.

obligations. The idea that patents are not certificates of good behavior does not apply to bioprospecting only, it also applies to government funding.

Anyway, the government funding disclosure requirement is consistent with the obligations of the United States under the four international agreements mentioned above.

First, it is compatible with the TRIPS Agreement, and not only because it is not a formal condition of patentability. Actually, if the US requirement were a (formal) condition of patentability, it would be nonetheless compatible with Article 62 of the TRIPS Agreement. And the reason was given above: it is indeed *reasonable* to impose any conditions necessary to identify the right to ownership of the invention. In contrast with the Requirement, as explained, under which suppliers of genetic resources or of associated TK do not have a claim of inventorship, the funding Federal agency may indeed claim property rights in the invention, in the event that the contractor fails to do so within the established period. Moreover, there are public interests involved in the notice concerning public funding because, in view of the public nature of the funding, march-in rights may be invoked by the government as per interested third parties' request. The notice on the patent, therefore, operates as a notice to society at large that the rights deriving from that particular patent are subject to some considerations and actions that may be dictated by public policy.[172] In contrast, the Requirement has the single purpose of informing stakeholders of an eventual interest in the results of the research or of the commercial exploitation of the claimed invention—results to which the patent does not contribute. If the claimed invention consists of a cloned animal cell line, for example, the

172. As the Office of Inspector General of the Department of Health and Human Services said: "[w]hen the Government is not aware of a grantee's invention, it is not able to exercise its rights and to protect the taxpayers' interest." *See* DEP'T OF HEALTH HUM. SERVS., *supra* note 160, at 7. The GAO also took note of the rationale set out by Federal Regulations:

> It is important that the Government and the contractor know and exercise their rights in inventions conceived or first actually reduced to practice in the course of or under Government contracts in order to ensure their expeditions available to the public and to enable the Government, the contractor, and the public to avoid unnecessary payment of royalties and to defend themselves against claims and suits for patent infringement.

48 C.F.R. § 27.305-1(a) (2004).

original material of which was the product of bioprospection, the fact that the Patent Office may be informed of the circumstances in which the raw material was obtained will have no consequences at all if in the country in question cloning technology may not be commercially exploited (in many countries it cannot be patented either).

The UPOV Convention is not affected by the U.S. requirement, which applies to patents only (including, eventually, plant patents). However, if the U.S. requirement were applicable to plant variety protection, again, unlike the Requirement, it would be UPOV 1991 consistent. The reason is that Article 1 of UPOV 1991 defines "breeder" as

> —the person who bred, or discovered and developed, a variety,
>
> —the person who is the employer of the aforementioned person or who has commissioned the latter's work, where the laws of the relevant Contracting Party so provide, or
>
> —the successor in title of the first or second aforementioned person, as the case may be.[173]

As a supplier of financial resources to the breeder, the Federal agency would acquire title, if the U.S. Plant Variety Act so established, provided the breeder failed to claim the right or disclose the origin of the funding, as a commissioner of the breeder's work. And since the basic obligation of the Contracting Parties to the UPOV Convention is to "grant and protect breeders' rights,"[174] it follows that Congress may impose an obligation on the precise identification of the breeder (including its employers and commissioners) within the application for a variety certificate.

The U.S. requirement is not only compatible with PCT provisions, but it is also expressly permitted by the Treaty.[175] Actually, among

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173. UPOV 1991, *supra* note 44, art. 1.

174. *Id.* art. 2.

175. Actually, the United States government itself may have thought, at some point, that the U.S. requirement could be in conflict with the PCT because it has proposed to add a new subparagraph to Rule 51*bis*.1 of the PCT Regulations (on "Certain National Requirements Allowed") as follows: "where the invention was invented as part of the work performed under a contract with the government of the designated State, any document containing a statement

the formal requirements the PCT refers to, there is a mention of the identification of "the name and other data concerning the inventor where the national law of at least one of the designated States requires that these indications be furnished at the time of filing a national application."[176] The U.S. requirement, which applies to United States patent applications only,[177] concerns the identification of the inventor—concept which comprises the funding Federal agency which, under the circumstances established in Chapter 18, may acquire the rights which originally belong to the inventor, thus becoming "the inventor" for all legal purposes.

Because the U.S. requirement has the purpose of clarifying issues of ownership, and because ownership is crucial to the patent system, the U.S. requirement is consistent with PLT provisions (which, as explained, incorporates the conditions of patentability established by the PCT) and with the draft SPLT provisions (which permits Contracting Parties to define the conditions under which third parties may succeed the inventor in his/her rights in the invention).[178]

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which indicates any government license rights in the invention and identifies the government contract." *See Proposed Amendments of the PCT Regulations and Modifications of the PCT Administrative Instructions, Relating to the Draft Patent Law Treaty*, at 12, WIPO Doc. PCT/A/28/2 (Jan. 28, 2000), Annex I. Later the U.S. Delegation withdrew this proposal,

> in light of having undertaken a review of the controlling statutory provision. That review revealed that the controlling statutory provision only imposed an obligation on a contractor-applicant to include in the application a statement as referred to in proposed (vi); it did not provide any authority for the United States Patent and Trademark Office to require such statement.

*See* Report, ¶ 11, WIPO Doc. PCT/A/28/5 (Mar. 17, 2000). Actually, the U.S. delegation was correct in concluding that there was no need for the proposed amendment, but the real reason, as explained above, is not that the USPTO has no authority to verify compliance with the statutory requirement. Actually, the PCT is not about the authority of patent offices to impose formal requirements: it is indeed about the possibility of Contracting Parties to impose those requirements, either through statutes or patent offices' administrative practices. If the PTO argument prevailed, countries could establish the Requirement as a condition of validity of patents, provided patent offices did not have the task of verifying compliance (which would be left to courts). To this extent, the U.S. requirement may indeed be scrutinized in the light of the PCT. But the reason is different: actually, the PCT allows for the U.S. requirement because it relates to the identification of third parties' ownership interests in the claimed invention.

176. PCT, *supra* note 8, art. 4.

177. 35 U.S.C. § 202(c)(6) (2000).

178. PCT, *supra* note 8, art. 4.2.

In conclusion, the U.S. requirement not only makes good sense in view of the public policy considerations that buttress it, but it is also entirely consistent with U.S. international obligations.

### *E. Another Possible Solution Under Current National and International Patent Law: Material Contributions to the Inventive Activity May Generate Material Interests in the Patent*

Several developing countries have shown reluctance to adopt a disclosure requirement that is less than a condition of patentability—even though, as we have seen, it may be inconsistent with several international agreements, including the TRIPS Agreement. The reason is one of efficiency, for illegal bioprospecting might not be deterred unless a stronger remedy is available. The question, then, is whether it is possible to impose the Requirement as a significant and effective measure—that is, with an impact at least as strong as if it were a condition of patentability—without infringing current international patent law (and without the need for amending the TRIPS Agreement, which, anyway, seems a very unlikely exercise in the short or medium term). The answer is yes, provided some fundamental aspects are taken into consideration.

Under the national law of some WTO Members, when an employee who has not been hired to invent makes an invention using resources (including raw materials) and data that belong to his/her employer, the latter is entitled to a material claim in the invention, and, consequently, in the patent. In the United States, such claim means the royalty-free right of using the invention.[179] In Brazil, the employer is entitled to ownership of half of the proprietary patent rights (that is, the employer becomes a co-owner) and to a paid, exclusive license of the other half.[180] In France, the employer may claim full ownership of the invention or an exclusive license.[181] In all cases, the employer's claim stems from its material contribution to

179. *See* Mark B. Baker & Andre J. Brunel, *Restructuring the Judicial Evaluation of Employed Inventors' Rights*, 35 ST. LOUIS U. L.J. 399 (1991).

180. *See* Brazilian Law No. 9279 of May 14, 1996, art. 91.

181. CODE DE LA PROPRIETE INTELLECTUELLE, art. L611-7, ¶ 2. The French Intellectual Property Code is available (in a searchable form), *at* http://legifrance.gouv.fr (last visited Jan. 4, 2005).

the final inventive result, and not from an inventive contribution. As the district court held in *Synbiotics*,[182] there is an essential difference between material contributions and inventive contributions. The latter leads to a share in the invention as co-inventorship, which was not the case at bar in *Synbiotics*. Nevertheless, material contributions may lead to a share in the patent, as compensation for the value of the contribution. This is an issue of civil law that is well settled in Civil Codes, under the term "right of specification"[183] or "right of accession."[184] The general rule is that when a new material is obtained from the application of an intellectual contribution to a raw material in a manner that transforms it, the new material belongs to the person who made the modification. But when the raw material (or the original material) is acquired in bad faith, the property in the resulting material goes to the owner of the raw material. A general exception occurs when the value of the labor (or the intellectual contribution) is disproportionately higher than the value of the raw material—in this case the property right belongs to the person who made the modification, but the owner of the raw material is in any event entitled to compensation. Examples of labor that are assumed as having a disproportionately high value are painting, sculpture and writing (for example, the Brazilian and the Spanish Civil Codes) and

182. *See supra* note 106 and accompanying text.

183. *See, e.g.*, Civil Code of Brazil, Law No. 10.406, of January 10, 2002, arts. 1269–71. In Brazil, the right of specification is different from the right of accession in the sense that the latter does not apply to chattels. Other than that difference in terminology, Brazilian law follows the general principles adopted in European continental countries. The text of the new Brazilian Civil Code is available at http://www.planalto.gov.br.

184. *See, e.g.*, Civil Code of France, as amended, arts. 565–74, *available at* http://legifrance.gouv.fr. The parallel of "right of accession" in common law is conversion. *See supra* note 107 and accompanying text. In *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), the acquisition of rights in the invention through conversion was rejected because of the difference of nature between the act of supplying raw material and the act of inventing. *See supra* note 107 and accompanying text. Indeed, nothing justifies converting the act of supplying raw materials (even if accompanied with information based on observation) into an act of inventing. The right of accession is based on a different rationale—the rationale that, since it is impossible for the unauthorized user of the raw material to reduce it back to its natural state, compensation for the loss of property in the raw materials is paid in the form of attribution of property rights in the invention. Neither the provisions on employees' inventions nor the Civil Codes attempt to substitute invention for supply of raw materials—to this extent, that rationale is the same rationale that the Supreme Court of California used in *Moore*.

artisanship (French Civil Code).[185] Of course, the law can stipulate otherwise, as in the case of the Brazilian Industrial Property Law (which assigns to the employer half of ownership of the patent, regardless of the value of both the materials used by the employee and the final value of the invention). The invention's final value has an impact only on the compensation to be paid for the exclusive license. Anyway, the controlling concept is intention. Was the bioprospector acting in good or bad faith? When national law contains rules on access to genetic resources, and the bioprospector willingly fails to notify the competent authorities of some collection made, bad faith may be presumed.

Likewise, national law can stipulate that where genetic resources have been incorporated into inventive outputs, the country that has provided the resources, and in the absence of a contract establishing otherwise (such as a contract of access to genetic resources), the invention is deemed to belong (partly or totally) to the national authority in charge of managing biodiversity resources. The rationale underlying such a provision would not be different from the rationale that underlies those provisions on employees' inventions mentioned above—or, for that matter, the provisions on the U.S. disclosure requirement concerning financial contributions by federal authorities.

Eventually, the person who, or entity which, by law, acquires a material interest in the invention (and, consequently, in the resulting patent rights), is entitled to renounce his/her rights and, consequently, seek the rejection of the claim or the invalidation of the patent granted. The point here is not one of opposing a patent application on grounds of failure to comply with a formal requirement: it is indeed a matter of *abandoning* a claim of proprietary rights and letting the subject matter of the claim fall into the public domain.

Would resorting to the doctrine of specification or of accession, under civil law, either in order to transfer title in inventions developed from genetic resources (and associated TK), or to seek the rejection of patent claims or the invalidation of patents, be acceptable

185. *See* Civil Code of Brazil, art. 1270, § 2; French Civil Code, arts. 570–71, as amended by Law No. 60-464, of May 17, 1960; Spanish Civil Code, art. 377. The complete text of the Spanish Civil Code is available at http://todoelderecho.com/SeccionInternacional/codigosjuridicos2.htm (last visited Jan. 4, 2005).

under the TRIPS Agreement? The answer can only be yes, on three grounds.

First, the issue now being considered is not one of implementing the CBD—which, as explained above, is outside the scope of the TRIPS Agreement—but one of affirming proprietary rights in the output of the inventive use of genetic resources. As explained above, international treaties, implicitly or explicitly, do permit (if they do not require) the national laws to clarify proprietary interests in inventions. To some extent, that is not only a matter of tolerance, but also a crucial issue that speaks to legal security and predictability.

Second, the TRIPS Agreement does not stand in the way of WTO Members' rights of addressing proprietary interests of suppliers of material contributions and assessing their importance so as to evaluate the final stake of those suppliers in the final inventive output. Of course, no one could say that the U.S., the Brazilian, and the French provisions that give employers a material interest in inventions made by employees not hired to invent are TRIPS-inconsistent. Nor, for that matter, could one say that the rules on specification or accession of the Brazilian and French Civil Codes are TRIPS-inconsistent. Attributing proprietary rights or interests in the result of inventive uses of genetic resources is a matter of national law, and the TRIPS Agreement does not establish that only inventors are entitled to the patents. As explained before, the TRIPS Agreement is not about protecting *inventors*, but about protecting *investors*. Like the U.S. government, which contributes with financial resources, and employers, who contribute with materials and data (including raw materials), governments that contribute with genetic resources may have assigned to them by law proprietary interests in the inventions.

Obviously, the matter here is not contribution of the plants or animals or micro-organisms to the inventive output, but contribution of the genetic and biological information contained therein. It is that information that has been transformed or assimilated by the inventive contribution of the inventor. In this sense, given the unique value of such information, one should not take lightly that the economic value of genetic resources is minimal as compared to the final value of the invention—particularly when the invention does nothing else other than identifying pre-existing valuable properties or uses of the genetic resources.

Third, even where the contributor of genetic resources retains the right to oppose the grant of the patent or to obtain its invalidation, and thus the proprietary interest generates an issue of patentability as a supplementary aspect of the assignment of title, that is a reasonable formal requirement in the light of Article 62.1 of the TRIPS Agreement to the extent it stems from proprietary interests in the invention. Several national laws, indeed, contain provisions making it possible to invalidate a patent when the applicant had no just title to claim property rights.[186] The Requirement, under this new approach, is not different.[187]

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186. Several countries, in their responses to the WIPO questionnaire on the Requirement, have noted that aspect. *See Draft Study*, *supra* note 16, ¶¶ 70–71. If a country acquires, under this approach, a proprietary interest in the patent, would it be interested in promoting its invalidation? Probably not, in general. Actually, it may be the case under certain exceptional circumstances, such as when the patent claims properties of genetic resources and/or associated TK that present particular cultural or religious relevance to traditional communities. In that case, the government may prefer to let the invention fall into the public domain.

187. As noted above, both the UPOV Convention (in both versions) and the PCT would accept new requirements established on grounds of proprietary interests. That issue in the context of the PCT has been thus scrutinized by the WIPO Secretariat:

> The PCT does not have a mechanism for a distinct declaration concerning source of GR/TK as a separate element of the form or content of an international application, or as an additional national requirement relating to the form or content of an international application. The PCT stipulates that it is not "intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires." This clearly applies to patentability of the invention as such. However, as has been noted several times above, the entitlement of the applicant to apply for and be granted a patent is also a matter of substantive law, distinct from the technical patentability of the invention as such, but potentially at least as important in terms of the ultimate ownership and exercise of the patent.

WIPO Doc. WO/GA/30/7/Add.1, ¶ 179. Of course, the provisions on the entitlement to apply for a patent cannot be found in article 27 of the PCT, because they are formal requirements (as explained above, they do not concern the invention itself). The provision in the PCT that allows countries to take measures concerning the identification of those who are entitled to apply for a patent (either because they are the inventors or because they are contractual or legal assignees of the right to apply for the patent) is article 9 ("The Applicant"). The result, nevertheless, is the same: the PCT does not stand in the way of national laws establishing the Requirement as a manner of identifying the person or entity legally entitled to apply for a patent on an invention directly or indirectly derived from genetic resources (or, for that matter, an invention funded with governmental resources). As far as the UPOV 1991 Convention is concerned, the permission for Contracting Parties to impose requirements concerning proprietary interests arises from the third indent of small roman (iv) of article 1 (on "Definitions"), which refers to the successor in title of the breeder or his/her employer. It is a matter for national law, therefore, to establish the conditions and terms under which succession in title occurs.

It goes without saying that, even where the Requirement is adopted as a condition of patentability in the context of the attribution of proprietary interests, its inconvenience may be the same as adopting it as a means of monitoring CBD compliance. The reason is that a shift in the purpose and the scope of the Requirement does not eliminate the complexity of proving use of a legitimately accessed genetic resource. The fact that the Requirement, if adopted as a means of establishing proprietary interests in patents and plant variety certificates, may be TRIPS-compliant, does not eliminate the problems of legal insecurity and unpredictability to which it gives rise.

## V. A WORD OF CAUTION: THE LIMITED VALUE OF THE REQUIREMENT

It is not certain that the costs generated by the implementation of the Requirement correspond to the benefits society is able to extract therefrom.[188] Actually, not all costs arising from the implementation of the CBD can be internalized by society if they are not kept at a reasonable level.[189] On the one hand, when biosquatting is the result of the claim of private property rights in knowledge that is in the public domain (as in the turmeric patent) in foreign countries (which may have legislation that is more open to patentability in the biotechnology field), the losers of unwarranted claims are not the TK holders, but the granting countries' society at large. As a matter of law, TK in the public domain can be used by anyone for free. The misappropriation of TK permits biosquatters to put a higher price on

188. To my best knowledge, the Requirement has never been applied in practice, that is, no patent application has been rejected and no patent has been invalidated because of failure to comply with the Requirement. However, where the Requirement is a condition of validity of patent rights, a situation of legal insecurity stems from its imposition because it may be alleged by third parties or the patent office *ex officio* at any time after the grant. Legal insecurity increases transaction costs and thus reduces the aggregated value of the output of enforcing and using patent rights.

189. *See* Rick Cannell, *Biodiversity's Incalculable Value*, FIN. TIMES, at 14 (July 21, 1998):

> Bioprospecting is not always quite as immediately lucrative as some have been led to believe and nations (such as the Philippines) that are imposing strict costs and conditions on those who wish to carry out bioprospecting may be rendering their biodiversity too expensive to be of any use.

products and services that otherwise would be sold for less. Moreover, unduly patented traditional knowledge cannot be incorporated into products and services of squatters' competitors, thus blocking the development of competing derivatives. But squatting of traditional knowledge does not prevent its holders to continue using it in their daily life. When the preparation of traditional knowledge databases has no other purpose than opposing patent and trademark claims, and considering the high costs that such preparation entails, it may well represent a waste of resources. On the other hand, when biosquatters claim property rights in traditional knowledge which remains under the private control of indigenous peoples and traditional communities, the enactment of measures of positive protection, such as a sui generis regime, may be much more effective tools to correct and repress situations of misappropriation. In that event, traditional knowledge holders will be in a position of enforcing their rights—rights which are recognized, if not formalized, by law. Enforcement of intellectual property rights may not be a very simple and cost-free issue, but it is always more effective than challenging the validity of patents based on traditions (which are frequently undocumented) and customary law.

Moreover, an undue burden imposed on patent applications may create serious difficulties to the management of national and international patent systems and deviate the focus of the whole patent system from contributing to the progress of useful arts to the acknowledgement of third parties' stakes in claimed inventions. The transaction costs arising from uncertainties as to ownership of traditional knowledge, in the absence of an international system of its registration, would be enormous.[190]

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190. This same point was noted by the representative of a group of users in the Working Group on Reform of the PCT:

> One representative of users stated that an essential feature of any national law requiring proof of having obtained prior informed consent would be a centralized procedure for showing that the requirement had been met. Without this, an alleged failure to obtain permission for use would become a standard attack in any country with such a provision. An applicant may have received consent from one source, but be attacked on the grounds that he should have sought permission from a different source. The consequence would be that fewer patent applications would be filed in these countries, resulting in there being no benefits for the applicant to share at all. Even if such systems were set up in countries with this type of legislation, it was

## VI. CONCLUSION: PATENTS ARE CERTIFICATES OF INVENTIVE BEHAVIOR, NOT GOOD BEHAVIOR

This Article has shown that the requirement to disclose the origin of genetic resources and prior informed consent in patent applications, as a formal condition of patentability aimed at monitoring compliance with the CBD, is not consistent with international obligations, in particular the TRIPS Agreement and the CBD itself. Because the debate on its adoption at the international level has led to the blockage of negotiations that might lead to increasing security in international patent protection, it has become a matter of urgency to identify mechanisms that permit biodiversity-rich countries to adopt the Requirement without infringing their international obligations, which could give rise to trade-related tensions, and yet keep the resulting encumbrances on patent procurement procedures at a reasonable level.

The Article has explained that a possible solution may lie in linking the granting of patents on inventions directly or indirectly derived from genetic resources with proprietary interests in the raw materials supplied—the so-called "right of accession" of civil law. That solution has two parallels in patent law: one is the possibility of employers to claim proprietary interests in the inventive output of employees (not hired to invent) where the latter have used data and materials that belong to the former; the other is the legal mechanism that ensures material interests of the U.S. government in inventions made with federal funding. The U.S. government is not necessarily entitled to property rights in the inventions in question, but it is nevertheless entitled to non-paid use and third parties may request compulsory licenses of those inventions. Under some special circumstances—both claims are, if not proprietary claims, at least material claims in property rights.

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pointed out that this would not help the case of inventions where the information was gained from a different country.

*See* Summary of the Session, WIPO Doc. PCT/R/WG/5/13 (Nov. 21, 2003), ¶ 140; Cynthia M. Ho, *Disclosure of Origin and Prior Informed Consent for Applications of Intellectual Property Rights Based on Genetic Resources: A Technical Study of Implementation Issues*, Final report, July 2003, study commissioned by the Secretariat of the CBD, and distributed in document UNEP/CBD/WG-ABS/2/INF/2 of September 29, 2003 (available on the CBD website).

Nevertheless, establishing the Requirement as a material claim by governments of countries from the territory of which genetic resources have been subtracted without permission is an issue of civil law, which does not change the essential thrust of the patent system: to attribute property rights in inventions (no matter who the owner is). The Requirement thus can be introduced so as to identify who that owner is—so that the patent is granted to whom the law indicates is the legitimate owner.[191]

Notwithstanding its eventual compliance with international obligations, the Requirement, if adopted as a condition of patentability, undermines the value of patents as effective means of securing property rights in inventions. The possibility of attacking the validity of those rights because of factors concerning conditions that are intrinsic to raw materials used, and extrinsic to the invention itself or to inventorship, would create unpredictability. Patents would lose much of their accuracy as reliable tools for measuring the invention's value, in particular in the biotechnology field, as their validity could depend on elements that have nothing to do with the invention. As said above, patents are certificates of *inventive* behavior, and is in that capacity that they perform their social function. If transformed into certificates of *good* behavior, patents cease being patents as such and become certificates of the origin of genetic materials. Incidentally, the validity of patents could also be scrutinized vis-à-vis the acquisition of other raw materials and research tools, and their purpose of securing intangible assets would necessarily become meaningless. Moreover, the Requirement, if established as a condition of patentability, does not promote benefit sharing: it simply generates information about the use of genetic resources and associated TK in the making of claimed inventions. Most patents fail to generate any economic revenue, particularly in the pharmaceutical industry, where patent applications are filed very early in the research process, and patent applicants are far away from obtaining a positive

191. As explained above, in a very limited number of cases, governments (in principle eventually entitled to succeed a biosquatter in title) may prefer to invalidate the patents where the public outrage against some practices of biosquatting disallows maintaining them, even if the title is transferred to the rightful owners. Likewise, patent laws of several countries allow for the invalidation of patents when they are not granted to those legally entitled to apply, such as the true, first inventor. *See supra* note 185 and accompanying text.

commercial outcome. Thus, as a monitoring tool, the Requirement would give TK holders information about the existence of a patented invention only. It would not inform them about the commercial exploitation of that invention, let alone the financial gains of the patent owner. Moreover, one should not underestimate the difficulties of patent applicants in identifying the origin of genetic resources, the properties of which might have found their way into a claimed invention. The Requirement might prove impossible to meet in many instances, and therefore, it would only add to the already existing complexities of the patent system.

Patents are the recognition of an inventive activity, and not of the manner in which that activity has been pursued. So, if an inventor has access to a genetic resource in a way that contradicts the legislation and the national policy of a given country, sanctions may be imposed upon the inventor. But the new and useful result of his mental activity of inventing, although resulting from the use of that genetic resource, should nonetheless entitle him to the patent. To this extent, it can be said that patents are certificates of *inventive* behavior; patents are not certificates of *good* behavior.[192] For this reason, patents should not be used to assess the legitimacy of access to genetic resources or the fairness of the treatment of traditional knowledge holders by bioprospectors. That is not the function of the patent system.

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192. The representative of the United States said in the TRIPS Council that

> with regard to the relationship between the TRIPS Agreement and the CBD, he said that the agreements could be implemented in a mutually supportive manner and that no conflict existed between them. Although he supported the objectives of the CBD, he did not favour using the patent system as a means to seek compliance with the CBD's provisions on prior-informed consent and benefit-sharing. It was the view of the United States that national systems outside patent laws were the most effective way to achieve these objectives. These regimes could have many components, including the use of permits, contractual obligations, and civil and/or criminal penalties. Patent laws were simply not intended, nor were they appropriate, to regulate misconduct, as they provided exclusive rights for a limited time in exchange for disclosures in order to further innovation. Misconduct, such as misappropriation of genetic resources, required direct regulations with enforcement by criminal or civil penalties.

*See Council Trade Related Aspects of Intellectual Property Rights—Minutes of Meeting—Held in Centre William Rappard on 18 November 2003*, ¶ 19, WTO Doc. IP/C/M/42 (Feb. 4, 2004), ¶ 109. The United States expressed the same view in the WIPO Working Group on the PCT Reform, *Summary of the Session*, ¶ 95, WIPO Doc. PCT/R/WG/6/12 (May 7, 2004).

# Answering the Call: The Intellectual Property & Business Formation Legal Clinic at Washington University

By

Charles R. McManis

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# Conclusion

## Answering the Call: The Intellectual Property & Business Formation Legal Clinic at Washington University

Charles R. McManis*

The five articles in this symposium volume have focused on specific aspects of three broad issues: (1) biodiversity loss and what is to be done about it; (2) the national and international debates over the appropriate legal protection and regulation of agricultural biotechnology in view of its potential impact on the problem of biodiversity loss; and (3) the legal protection of traditional knowledge as a means of conserving and promoting sustainable use of biological diversity. As the last of these five articles, by Michael Gollin, points out, one of the principal obstacles in responding effectively to any of these international issues is the lack of access to affordable intellectual property legal counsel in many parts of the developing world where the majority of the earth's biodiversity is located.

Just as the *pro bono* organization, Public Intellectual Property Advisors (PIIPA), that Michael Gollin was instrumental in organizing, is responding to this need by matching prospective clients with existing IP professionals and strengthening IP counseling and management resources in developing countries, so too the Intellectual Property and Technology Law Program[1] at Washington University School of Law is seeking to respond by establishing an Intellectual Property and Business Formation Legal Clinic, a primary objective of

* Thomas and Karole Green Professor of Law; Director, Intellectual Property & Technology Law Program.

1. For a description of the Intellectual Property & Technology Law Program, see http://law.wustl.edu/LLMIP/Fall2004/WashU_IPbroch.pdf [hereinafter IPTL Brochure].

which will be to develop expertise in the overlapping fields of biodiversity, agricultural biotechnology, and traditional knowledge protection and to make that expertise available, both to prospective developing-country clients and to local IP professionals who wish to participate in the *pro bono* activities of PIIPA. Funded in part by a generous grant to Washington University by the Ewing Marion Kauffman Foundation,[2] as a part of its Campus Entrepreneurship Initiative, the Intellectual Property and Business Formation Legal Clinic will begin operations on January 10, 2005.

The Clinic's activities will initially be devoted to four program areas, each of which will involve teams of two students, who will:

- Participate in interdisciplinary innovation and entrepreneurship courses at the University, such as the Senior Design Course in the Department of Biomedical Engineering,[3] and the Hatchery course in the Olin School of Business[4];
- Work with St. Louis-area business incubators, such as the Nidus Center for Scientific Enterprise[5];
- Work with non-profit organizations, such as the St. Louis Volunteer Lawyers and Accountants for the Arts[6] and Public Interest Intellectual Property Advisors[7];
- Work with two St. Louis area research organizations, the Missouri Botanical Garden[8] and the Donald Danforth Plant Science Center,[9] on international projects involving genetic

2. *See* http://www.kauffman.org. For a description of the Kauffman Campus Entrepreneurship Initiative, see http://www.kauffman.org/news.cfm/396. For a description of the Washington University grant, see http://news-info.wustl.edu/news/page/normal/599.html.

3. *See* http://biomed.wustl.edu/courses/bme_401/ bme_401.asp.

4. For a description of this course and the Skandalaris Entrepreneurship Program at the Olin School of Business, see http://www.olin.wustl.edu/entrepreneurship/PDF/SEP.pdf.

5. *See* http://www.niduscenter.com.

6. *See* http://www.vlaa.org.

7. *See* http://www.piipa.org.

8. For an introduction to the research activities of the Missouri Botanical Garden, see http://www.mobot.org/plantscience/default.asp.

9. *See* http://www.danforthcenter.org.

resources, biotechnology, and the protection of traditional medicinal and agricultural knowledge.

Each of these four program areas will enable Washington University law students, working under the supervision of an experienced intellectual property attorney who will serve as the Administrative Director of the Clinic and Lecturer in Law,[10] to develop expertise in providing early-stage legal assistance to innovators in a variety of contexts. The four teams of students and their specific activities are as follows:

1. The *Interdisciplinary Innovation Team* will provide legal expertise in two interdisciplinary innovation courses offered at Washington University. The Biomedical Engineering Design course is a capstone design experience to prepare undergraduate engineering students for engineering practice.[11] These engineering students, together with graduate business, law, and graphic design students, will work in small groups to develop an original design or redesign of a component or system of biotechnological significance. The design experience will incorporate engineering standards and realistic constraints, including consideration of economics, the environment, sustainability, manufacturability, as well as ethical, health and safety, social and political requirements. The student teams will prepare written reports and present their designs orally to a panel of faculty members and industrial representatives. Law students will be responsible for conducting patent searches and identifying other legal issues that are relevant to the design and commercialization process. The Hatchery course, which is a part of the Skandalaris Entrepreneurship Program at the Olin School of Business,[12] enables teams of students to support entrepreneurs from the St. Louis community, and will include interdisciplinary teams that will work with the University's Office of Technology Management[13] to assess

10. The Administrative Director for the Intellectual Property & Business Formation Legal Clinic is Mr. David Deal, formerly a patent attorney with the St. Louis law firm of Thompson Coburn, and a patent examiner with the U.S. Patent and Trademark Office. Mr. Deal is a graduate of the University of Missouri-Columbia School of Law, and a *magna cum laude* graduate of the University of Missouri-Columbia School of Engineering.

11. *See supra* note 3.

12. *See supra* note 4.

13. For a description of the operations of the Office of Technology Management, see

the feasibility of commercializing various of the University's scientific discoveries, including those made by the Medical and Engineering Schools. Here, too, law students will be responsible for conducting patent searches and identifying other legal issues that are relevant to the commercialization process.

2. The *Business Incubator Team* will work primarily at the Nidus Center for Scientific Enterprise, which was established in 2000 to assure the success of start-ups and early stage plant and life science companies.[14] The team will also develop and present training modules for and at the Center for Emerging Technologies,[15] a public-private-academic partnership founded in 1995 to develop specialized services and facilities to accelerate the growth of advanced technology companies in the St. Louis region. At the Nidus Center, law students will also work for BioGenerator,[16] an incubator-within-an-incubator, which is designed to fill a gap—sometimes called the valley of death or a no-man's land—in the progression, from academic research to revenue, in the creation of a company. BioGenerator will work closely with the technology transfer offices of Washington University and St. Louis University, to identify company concepts with the most potential, and then provide funding for such things as proof-of-concept tests, market research and management consultants, preparatory to applying for space at one of the St. Louis area business incubators.

3. The *Pro Bono Team* will work with the St. Louis Volunteer Lawyers & Accountants for the Arts (VLAA)[17] and the Public Interest Intellectual Property Advisors (PIIPA)[18] to provide assistance to St. Louis area attorneys who are providing pro bono legal assistance in the fields of copyright, trademark and patent law, as well as associated matters relating to business formation, contracts, and acquisition of non-profit tax exempt status, to qualifying clients. The St. Louis VLAA provides free legal and accounting assistance and sponsors a wide range of educational programs for artists and art

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http://roles.wustl.edu/OfficeTechnologyManagement.htm.

14. *See supra* note 5.
15. *See* http://www.emergingtech.org.
16. *See* http://www.biobelt.org/news/pd_110103.html.
17. *See supra* note 6.
18. *See supra* note 7.

administrators. PIIPA is an international non-profit organization that makes intellectual property counsel available for developing countries and public interest organizations seeking to promote health, agriculture, biodiversity, science, culture, and the environment. PIIPA will engage in three main activities: (1) expanding a worldwide network of IP professional volunteers (the IP Corps); (2) operating a processing center where assistance seekers can apply to find individual volunteers or teams who can provide advice and representation as a public service; and (3) building a resource center with information for professionals and those seeking assistance. Working under the supervision of the Administrative Director of the Intellectual Property & Business Formation Legal Clinic, the *Pro Bono Team* will develop, provide training modules for, and work with a St. Louis node of IP lawyers participating as PIIPA volunteers.

4. The *International Research Team* will work with the Missouri Botanical Garden[19] and the Donald Danforth Plant Science Center[20] on national and international research projects. For example, the Missouri Botanical Garden partners with a number of other research organizations, including the Donald Danforth Plant Science Center, and is currently partnering with the University of Missouri-Columbia (UMC) and the University of Western Cape (UWC) in South Africa, in The International Center for Indigenous Phytotherapy Studies (TICIPS), directed by Bill Folk (UMC) and Quinton Johnson (UWC), a new and unique project designed to test traditional South African herbal remedies in contexts ranging from in vitro assays to a clinical trial.[21] During the summer of 2004, a rising third-year Washington University Law School J.D. student, Edward Kim, served as a summer intern at the University of Western Cape, working on the Center's proposed intellectual property policy,[22] and will be a member of the Clinic's inaugural *International Research Team*. Likewise, the Donald Danforth Plant Science Center partners, not only with the Missouri Botanical Garden,[23] but also with a variety of

19. *See supra* note 8.
20. *See supra* note 9.
21. *See* http://www.mobot.org/MOBOT/research/diversity/medicinalPlants.htm.
22. *See* IPTL Brochure, *supra* note 1, at 3.
23. *See supra* note 21.

other organizations, including an organization called Public Sector Intellectual Property Resource (PIPRA),[24] an initiative by a variety of universities, foundations and non-profit research institutions to make agricultural technologies more easily available for development and distribution of subsistence crops for humanitarian purposes in the developing world and specialty crops in the developed world.[25] The *International Research Team* will work on this and other intellectual property-related projects at the Danforth Center.

The activities of the Intellectual Property and Business Formation Legal Clinic will be supported by an associated Center for Research on Innovation and Entrepreneurship, a university-wide research center, housed at the law school, and likewise initially funded by the Kauffman Campus Entrepreneurship Initiative.[26] The Center is committed to becoming a premiere research center for Washington University, the larger St. Louis research community, and other academic, government, and private sector entities interested in bridging the gap between research and development (R & D) in academia. The Center will focus its conceptual and empirical research activities on the research and development process itself to explore how optimally to "move R to D," particularly with respect to university and other early-stage public or non-profit research.

The research activities of the Center will include both directed research, in the form of periodic academic conference and workshops, and administration of a university-wide competitive grant program to support individual and collaborative group research on innovation and entrepreneurship. For its inaugural directed research project, the Center is planning a fall 2005 academic conference on the topic, "Commercializing Innovation," which will bring together leading thinkers in diverse fields to develop modern tools and strategies for improving the complex process of innovation commercialization, with a focus on both domestic and international implications.[27] As a part of its competitive grant program, the Center

24. For a description of the Danforth Center's involvement with PIPRA, see http://www.mobot.org/MOBOT/research/diversity/medicinalPlants.htm. For a more detailed description of the activities of PIPRA, see http://www.pipra.org/.

25. *See* http://www.pipra.org.

26. *See supra* note 2.

27. *See* IPTL Brochure, *supra* note 1, at 7.

recently announced the award of eight entrepreneurial research grants, the first year of funding for which totals over $140,000, to Washington University faculty members who applied for funding for a variety of individual research projects focusing on some aspect of innovation and entrepreneurship. Included among the research grants funded is a $21,250 research grant to the author for a project entitled "A Pilot Project to Collect Data and Design an Empirical Study on the Impact of Early-stage Access to Affordable Intellectual Property and Business Formation Legal Services on the Innovative Process," will utilize the experience of the Intellectual Property & Business Formation Legal Clinic to examine how early-stage access to affordable legal services (and the lack thereof) affects the innovative process. This grant will be supplemented by an additional $18,750 from undesignated directed research funds of the Center. Thus, the Clinic will not only provide valuable professional service; it will also serve as a valuable research tool to determine the effect of early-stage access to affordable legal services on the innovative process.

The Clinic will also seek outside grant funding to support exchange programs that will provide lawyers and law students from the developing world with full-tuition scholarships to enroll in the law school's Intellectual Property LLM Program,[28] and will provide Washington University law students with summer internships, similar to the experience of Washington University law student, Edward Kim, in South Africa, in the summer of 2004,[29] and Washington University alumna, Susanna E. Clark, who in the summer of 2003 arranged an internship with the Peruvian Environmental Law Society, in Lima, Peru, as a result of having participated in an international academic conference held at Washington University in April 2003,[30] which included a number of participants in the International Cooperative Biodiversity Group (ICBG)-Peru Project[31] (one of a

28. For a description of the law school's IP LLM program, see http://law.wustl.edu/LLMIP.

29. *See supra* note 22 and accompanying text.

30. For a summary of the conference agenda, video clips, and conference papers, see http://law.wustl.edu/centeris/pastevents/biodivsp02.html.

31. For a detailed description of the ICBG-Peru Project, and Washington University's leading role in it, see Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 CARDOZO J. INT'L &

number of ICBG projects funded by the National Institutes of Health,[32] including representatives of the Peruvian Environmental Law Society.[33]

The goal of the Intellectual Property & Business Formation Legal Clinic in all of its activities will be to highlight, both to law students and to the legal profession as a whole, that the purpose of national and international intellectual property law is a public one—to "Promote the Progress of Science and the useful Arts"[34]—and that the protection and enforcement of intellectual property rights "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, to a balance of rights and obligations."[35]

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COMP. L. 547, 570–76 (2003)

32. For a description of the NIH-funded ICBG projects, see *id.*, at 565-69.

33. For two published products of Ms. Clark's summer internship, see Manuel Ruiz, Isabel Lapeña & Susanna E. Clark, *The Protection of Traditional Knowledge in Peru: A Comparative Perspective*, 3 WASH. U. GLOBAL STUD. L. REV. 755 (2004); and Jorge Caillaux & Susanna E. Clark, Chapter 6, *A Brief Review of Legislation on Access to Genetic Resources and the Protection of Traditional Knowledge in Selected Megadiverse Countries*, INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES (Burton Ong, ed.) (2004).

34. U.S. CONST. art. I, § 1, cl. 8.

35. Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, December 15, 1993, 33 I.L.M. 81 (1994), *available at* http://www.wto.int.