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Introduction: Biodiversity, Biotechnology, and the Legal Protection of Traditional Knowledge

Charles R. McManis
Washington University School of Law

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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.