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Battling Bills, Beans, 7& Biopiracy

by

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BATTLING BILLS, BEANS & BIOPIRACY

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I. INTRODUCTION

"Take what ye can, give nothin' back! Any man who falls behind, is left behind. Pirate's Code."

-Jack Sparrow, Pirates of the Caribbean

Article I, § 1 of the Constitution states, "[a]ll legislative [p]owers herein granted shall be vested in a Congress of the United States."[1] With each new session, the Legislature faces a plethora of bills, each of which require it to weigh the needs of the interest groups raising concerns against the impact of the legal change and the status quo. Proposed House Bill 242 was raised in the 108th Congress by Representative Darrell Issa of California.[2] As the bill's primary sponsor, he represents the economic interests of the U.S. horticultural industry, to which California contributes approximately 25% through sales income.[3] H.R. 242, revived after its fleeting appearance as H.R. 5119 in the 107th Congress, aimed to amend current U.S. patent laws, specifically 35 U.S.C. § 162.[4] Section 161 of the Plant Patent Act states:

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores [sic], mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.[5]

The "owner of the plant patent has the sole right to reproduce, sell, and use the plant."[6] In addition, he has the ability "to explore possible medicinal, agricultural, or other uses for the plant."[7] However, in order for a prospective applicant to successfully obtain a plant patent, he must establish novelty by comparing the claims in the application to the "'prior art' base," which includes "prior publications, uses, or sales."[8] In fact, "[c]urrently, all prior art that is more than one year old is valid in its ability to disprove

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[1] U.S. CONST. art. I, § 1.

[2] Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. (2003).

[3] Justin W. VanFleet, *Patenting Plants*, SCIENCE + TECHNOLOGY IN CONGRESS: AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (AAAS) (Oct. 2002), *at* http://www.aaas.org/spp/cstc/stc/stc02/02-10/plants.htm (last visited Feb. 14, 2005).

[4] H.R. 242 § 2; *see* Dave Downey, *Political File–Issa Wins Coveted Appointment*, NORTH COUNTY TIMES, Jan. 19, 2003, *at* http://www.ncti-mes.com/articles/2003/01/19/export1310.txt (last visited Feb. 14, 2005).

[5] 35 U.S.C. § 161 (2000).

[6] VanFleet, *supra* note 3.

[7] *Id.*

[8] *Id.*

novelty."[9] While 35 U.S.C. § 162 merely states that "[n]o plant patent shall be declared invalid for noncompliance with section 112 of this title if the description is as complete as is reasonably possible,"[10] H.R. 242 proposed supplementing § 162 with an additional paragraph.[11] The bill also strove to alter the status quo of plant patent eligibility by narrowing the eligible prior art base for invalidation of patent applications.[12] This was in an effort to aid the flagging horticulture industry in the wake of an abrupt policy turnaround by the United States Patent and Trademark Office ("U.S.P.T.O.") that has resulted in increased stringency during the review of plant patent applications.[13] Whether it be an unfortunate incidental impact of this bill, the result of careless legislative composing, or a deliberate smokescreen, if H.R. 242 or a similar bill were implemented, it would have the devastating effect of demolishing the prophylactic walls only recently put up by defenders of biopiracy.[14] In the narrow context of this Note, biopiracy is the misappropriation of knowledge of the medicinal qualities inherent in native plants known to the indigenous peoples of third world countries for centuries.[15]

This Note examines both the direct or incidental impact of proposed legislation upon biopiracy, whether direct or incidental. While Part I briefly introduced plant patent law and H.R. 242, Part II establishes the detailed framework and background behind plant patents regarding the present law. Part II also outlines the details of H.R. 242 and its motivations—the innocent and political motives, as well as the perhaps more shrouded motives. The author's motivation in this Note is not solely focused on H.R. 242, but rather she uses H.R. 242 as an illustrative example of proposed legislation threatening to further encroach upon biopiracy. Whether or not this bill is eventually reintroduced or defeated, legislators and the public must be made aware of smokescreen legislation, such as H.R. 242, which may intentionally or incidentally have an adverse impact on international human rights. Part III defines and discusses biopiracy, analyzing the potentially devastating impact of H.R. 242 and proposed legislation of its kind. Furthermore, Part III introduces and predicts

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[9] *Id.*
[10] 35 U.S.C. § 162.
[11] Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. §§ 2(a)–(c) (2003).
[12] *See* VanFleet, *supra* note 3.
[13] *See id.*
[14] *See id.*
[15] *Id.*

the potential impact on biopiracy of H.R. 121 of the 109th Congress, an analogous bill introduced by Congressman Issa. In conclusion, Part IV examines some possible resolutions to the severe legislative impact of bills such as the proposed H.R. 242 and H.R. 121 upon biopiracy and its victims—third world countries and their indigenous peoples.

II. Background—The Meat Behind the Legislation

"Laws are like sausages. It's better not to see them being made."
-Otto von Bismarck (1815–1898)

The Plant Patent Act of 1930 was enacted to introduce an "incentive" to researchers of plants and plant development in the United States.[16] As stated in recent Congressional testimony, "[t]he purpose of that legislation was to address a perceived inequity for plant inventors and provide them with the same opportunity to seek patent protection as their industrial inventor counterparts."[17] The Act has been successful, with an estimated "12,500 plant patents" being issued since its introduction.[18] Today, plant patent law allows for a liberal construction in accepting plant patent applications consistent with the remaining aspects of the patent laws of Title 35; however, some constraints are in place to prevent abuse of the system.[19] In order for a prospective plant patent applicant to successfully obtain a patent, he must be able to prove that the invented or discovered variety of plant is novel or new, in addition to being useful and non-obvious to someone of ordinary skill in the pertinent art, in accordance with 35 U.S.C. § 102.[20] To do this, the patent examiner must compare the claims in the application to the "prior art base," which can include "prior publications, uses, or sales."[21] The application can be invalidated if the prior art is identical to the claims.[22] Under the existing patent laws, the scope of prior art valid to dis-

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[16] *Hearing on Plant Breeders Equity Act of 2002, H.R. 5119 Before the Subcomm. on Courts, the Internet and Intellectual Property, Comm. on the Judiciary*, 107th Cong. (2002) (statement of Vincent E. Garlock, Deputy Executive Director, AIPLA), *at* http://www.aipla.org/content/contentgrou-ps/legislative_action/107th_Congress/testimony1/plantpatent.pdf (last visited Feb. 15, 2005) [hereinafter Statement of Vincent E. Garlock].

[17] *Id.*

[18] *Id.*

[19] *See id.*

[20] *Id.*; *see* 35 U.S.C. §§ 102, 103 (2000).

[21] VanFleet, *supra* note 3.

[22] 35 U.S.C. §§ 102, 161.

prove the legitimacy of a patent application is anything greater than *one year* old from the date of application.[23] H.R. 242 proposed redefining and expanding novelty by narrowing the scope of the prior art base.[24]

As stated previously, H.R. 242 was a proposed bill introduced by Rep. Darrell Issa in the U.S. House of Representatives on January 8, 2003, entitled the Plant Breeders Equity Act of 2003.[25] The bill was revived in the 108th session of Congress after it was allowed to die as a result of inaction in the 107th Congress as H.R. 5119.[26] This Act proposed an amendment to 35 U.S.C. § 162, laying out the relaxed written description requirement for plant patent applications—namely that the application it be "as complete as is reasonably possible."[27] If enacted, the H.R. 242 would have supplemented § 162 with the following paragraph:

> No plant patent application shall be denied, nor shall any issued plant patent be invalidated, on the grounds that the invention was described in a printed publication to which section 102(b) of this title applies, unless the invention was described in a printed publication in this or a foreign country more than *ten years* prior to the date of the application for patent in the United States.[28]

This would have narrowed the prior art base allowed to a patent examiner to invalidate claims in a patent application by ignoring the past *ten years* of prior art in its consideration of novelty, rather than merely ignoring the past *one year*.[29] Presently, the bill has been allowed to die silently; the last action was taken on March 6, 2003, when H.R. 242 was referred to the Subcommittee on Courts, the Internet, and Intellectual Property.[30] According to Subcommittee Chairman F. James Sensenbrenner, Jr.'s (R-WI) office, as of late January 2004, hearings were supposed to have been scheduled soon.[31] On January 4, 2005, Congressman Issa

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[23] *Id.* § 102.

[24] VanFleet, *supra* note 3.

[25] Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. § 1 (2003).

[26] *See id.*; Plant Breeders Equity Act of 2002, H.R, 5119, 107th Cong. § 1 (2002).

[27] 35 U.S.C. § 162 (2000).

[28] H.R. 242 § 2(b) (emphasis added).

[29] *Compare id. with* 35 U.S.C. § 162. *See also* VanFleet, *supra* note 3.

[30] *See* Bill Summary and Status for the 108th Congress, H.R. 242 (2004), *at* http://thomas.loc.gov/bss/d108/d108laws.html (last visited Feb. 14, 2005).

[31] Telephone Interview with Spokesperson, Chairman F. James Sensenbrenner, Jr.'s Office, in Washington D.C. (Jan. 30, 2004).

introduced H.R. 121 in the 109th Congress[32] a bill that has changed in content, but remained analogous in its impact. Since H.R. 121 has only been recently introduced, there is little commentary on the bill available at the time of this writing; however, the author of this Note will discuss her analysis of its impact on biopiracy in a Part III.

The primary supporters of Congressman Issa's bill were plant breeders with two primary arguments for enactment of H.R. 242. First, plant breeders claimed that they needed the added ten-year flexibility in prior art as compensation for lost time in the plant quarantine process.[33] When foreign plants are brought into the United States, they must be checked to assure that the plant is safe and able to adapt to growing conditions and the environment in the United States.[34] This quarantine process, the breeders claim, can take up to eight years, thereby effectively stealing at least that long from their potential profit margin, as these would have been years in which the plant breeders could have conducted research or engaged in manufacturing and sales.[35]

Second, plant breeders alleged that the current interpretation of 35 U.S.C. § 102(b) is detrimental to the horticulture industry. In January, 2001, the U.S.P.T.O. suddenly reversed a traditional view it had adopted regarding plant patent guidelines.[36] Originally, the U.S.P.T.O. had applied the idea that any publication discussing a plant variety claimed in an application was not enabling, and thus was not invalidating prior art.[37] Now, however, the U.S.P.T.O. has reversed this view and allows descriptive publications to be enabling, and therefore invalidating, as prior art.[38] The U.S.P.T.O. has begun to "reject any plant patent application

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[32] Plant Breeders Equity Act of 2005, H.R. 121, 109th Cong. (2005), *at* http://thomas.loc.gov/bss/d109/d109laws.html.

[33] *See Plant Breeders Equity Act of 2002, Hearing before the Subcomm. on Courts, the Internet, and Intellectual Property of the Comm. on the Judiciary House of Representatives*, 107th Cong. 13 (2002) (statement of Craig J. Regelbrugge, Senior Director, Government Relations, The American Nursery and Landscape Association, on behalf of the National Association of Plant Patent Owners) [hereinafter Regelbrugge].

[34] *Id.* at 12–13.

[35] *See id.* at 13; VanFleet, *supra* note 3.

[36] Regelbrugge, *supra* note 33, at 12–13.

[37] *Id.* at 15. The standard definition of the "enablement requirement" in patent law is "[t]he rule that the specification of a patent application must describe the invention so that a person with ordinary skill in the art could make and use the invention without experimenting unduly." BLACK'S LAW DICTIONARY 546 (7th ed. 1999).

[38] Regelbrugge, *supra* note 33, at 15.

where, more than one year prior to the application filing date, the claimed plant was described in a publication and the claimed plant was available to the public anywhere in the world."[39] In the blink of an eye, the U.S. shifted from having the most permissive system for protecting horticultural varieties—one where foreign publication and availability were deemed irrelevant to U.S. patentability—to the most rigid and limiting, where foreign publication and availability for more than one year are now considered an absolute bar to obtaining a U.S. plant patent.[40]

Economically, this policy change by the U.S.P.T.O. is potentially devastating to the horticultural industry. The U.S.P.T.O. has "suggested that as many as 75% of issued plant patents may be in jeopardy."[41] It is difficult to accurately estimate the economic loss because most of the affected industries are small or family-owned businesses.[42] A few examples are startlingly demonstrative of the economic debacle the industry currently faces.[43] One of the larger nursery growers in the United States estimates that the potential for sales and royalty losses will exceed $5 million annually.[44] Another U.S. company that introduces and protects "new ornamental varieties . . . conservatively estimates royalty losses of $2.4 million over ten years for just six plant groups with which they are working."[45] As another example, a large U.S. rose breeder will lose most of its $10 million in annual sales income, the majority of which is used to fund research for future breeding programs.[46] Last, but certainly not least, another rose breeder in the United States estimates "royalty losses alone at $2.9 million over the commercial life" of only sixteen varieties.[47] The loss of funds in these examples will have a devastating effect on the breeding research which can be conducted in the future.[48] These losses stem from the fact that after implementation of the policy change by the U.S.P.T.O., several plant patents were invalidated based on publications, which were previously not considered proscriptive prior

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[39] *Id.*
[40] *Id.*
[41] *Id.*
[42] *Id.*
[43] *Id.* at 15–16.
[44] Regelbrugge, *supra* note 33, at 16.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.* at 13.

art.[49] In essence, not only will these and other horticulture companies lose money in sales and royalties but, because most of the influx of profit is invested directly back into research for future development, this source of funding for research and development ("R&D") will be lost.[50] This contravenes the fundamental purpose of the Plant Patent Act—to stimulate plant R&D—because without these funds the horticulturists will not only have no incentive, they will also have no means, or at least severely reduced means, to pursue R&D, or at least severely reduced means to pursue such avenues as R&D.[51]

As the representative of California, a state representing one-quarter of all domestic horticultural sales, Congressman Issa believed that H.R. 242 was the "swiftest" way to remedy the situation and provide plant breeders with some breathing room by limiting the prior art base that can be used to invalidate these plant patents.[52] Others disagreed. Opponents of H.R. 242 argued that the proposed bill violated the essence of the patent system, which relies on rewarding novelty and the ingenuity of inventors.[53] As some critics argue, "[u]nder the proposed legislation, someone may read a journal article describing a plant that is up to ten years old and then successfully apply for a patent on the plant described in the publication."[54] In other words, passage of this bill would have suggested a future of granting patents for plants that are not new, but rather have been discovered for up to ten years.[55] Vincent E. Garlock, Deputy Executive Director of the American Intellectual Property Law Association ("AIPLA"), testified before the Subcommittee on Courts, the Internet, and Intellectual Property, a subcommittee of the Committee on the Judiciary, regarding H.R. 5119.[56] In his statements, Garlock questioned the absence of an explanation by supporters of the bill for how "providing import monopolies" on plants developed in a foreign market would advance domestic plant interests in the United States.[57] He argued that the loss of some royalties by domestic breeders of

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[49] *Id.* at 15.

[50] Regelbrugge, *supra* note 33, at 14, 16.

[51] *Id.* at 19.

[52] VanFleet, *supra* note 3.

[53] *Id.*

[54] *Id.*

[55] *Id.*

[56] *See* Statement of Vincent E. Garlock, *supra* note 16, at 8.

[57] *Id.* at 8.

foreign developed plant varieties is not sufficient to institute such a broad, sweeping change in U.S. patent law.[58]

In addition, Mike Kirk, Executive Director of the AIPLA, provided a brief summary of the AIPLA's opposition to H.R. 242 (as well as 2002's H.R. 5119).[59] First, the AIPLA felt that the ten-year grace period remedy would have been overly broad and unnecessary, especially for plants in the United States, because domestic plants do not undergo the quarantine process as it is only required for foreign plants.[60] This contradicts Congressman Issa's position that this bill would have aided domestic plant breeders because, if the purpose truly was to aid U.S. plant breeders, this bill would be meaningless as it would have only aided foreign plant breeders.[61] Furthermore, if the quarantine process is taking ten years, then the problems that lie in this quarantine process itself should be addressed, rather than implementation of an overinclusive remedy such as H.R. 242.[62]

Garlock also dismissed the ten-year grace period as too broad for three reasons. First, utility patents are not granted a ten-year grace period; therefore, plant patents should not be afforded such an unfounded advantage.[63] Once an invention has been revealed to the public and is enabling, little reason exists for such a grace period distinction for varying types of patents.[64] Second, Kirk argued that no rationale existed for why this lengthy grace period should apply to U.S. domestic breeders who are able to exert control over when publication occurs.[65] Third, this ten-year grace period would have run in contravention to the constitutional purpose of the patent laws—that is, "to promote the progress of the useful arts and sciences."[66] "The interest of the public in gaining access to new plant varieties in a reasonable period of time must be balanced against the desire of plant breeders to patent foreign developed varieties in the most convenient and inexpensive man-

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[58] *Id.* at 8–9.

[59] Telephone Interview with Mike Kirk, Executive Director, American Intellectual Property Law Association (AIPLA) (July 2003) [hereinafter Kirk Interview].

[60] *Id.*

[61] *Id.*

[62] *Id.*

[63] Statement of Vincent E. Garlock, *supra* note 16, at 9.

[64] *See id.*

[65] Kirk Interview, *supra* note 59.

[66] Statement of Vincent E. Garlock, *supra* note 16, at 9; *see also* U.S. CONST. art. 1, § 8.

ner."[67] In response to the breeders' argument that the new U.S.P.T.O. policy regarding § 102(b) undermines the horticulture industry, Garlock responded that while "the uncertainty of introducing new plant varieties into the marketplace makes the early filing of a patent application prohibitive, particularly for small growers . . . this reason [is] uncompelling."[68] This, he argued, is not a new issue—it is faced by all inventors and patent owners wishing to introduce a new product into the market.[69] These inherent complexities and uncertainties lend themselves to some given commercialization difficulties, but it is not a problem affecting only plant patent owners.[70] In general, Garlock believed that other avenues should be fully "exhaust[ed]" before resorting to such a radical change in the statute.[71] While all of these issues are valid arguments against the enactment of H.R. 242, the most overlooked, and perhaps most devastating, effect would have been the bill's impact on biopiracy.

III. Analysis

"To him that you tell your secret you resign your liberty."
-Anonymous, *Proverb*

A. Biopiracy—Its Beans and Its Victims

"Maybe the problems of two people don't amount to a hill of beans. But this is our hill. And these are our beans!"
-Lt. Frank Drebin, *Naked Gun*

Biopiracy is broadly known as the misappropriation of "indigenous traditional knowledge."[72] For the purposes of this Note specifically, biopiracy occurs when primarily U.S. pharmaceutical companies patent the natural medicinal qualities of plants as their own.[73] Typically, this is knowledge that has been common to the indigenous peoples of third world nations for centuries.[74]

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[67] Statement of Vincent E. Garlock, *supra* note 16, at 9–10.
[68] *Id.* at 9.
[69] *Id.*
[70] *Id.* at 9–10.
[71] *Id.* at 10.
[72] AAAS Science and Human Rights Program, *Report on Science and Human Rights: Patents, Traditional Knowledge, and the USPTO,* American Association for the Advance of Science, *at* http://shr.aaas.org/repo-rt/xxii/2_patent.htm (last visited Feb. 14, 2005) [hereinafter Report on Human Rights].
[73] *See id.*
[74] *See id.* (providing several examples of traditional remedies which have been subject to patenting by corporations).

Unfortunately, because these cultures consider certain plants and their beneficial effects common knowledge, they usually have not documented the information in written form.[75] In old-world cultures, this knowledge is passed down from generation to generation "through practice and oral history."[76] Due to the heterogeneity of the international intellectual property ("IP") regime, unwritten traditional knowledge is not consistent with the U.S.P.T.O. guidelines for establishing prior art, which require that the knowledge be described in a printed publication in order to preclude patentability by another.[77] Many of the U.S. corporations involved in biopiracy exploit the fact that most of these third world cultures do not possess sufficient or proper documentation to negate patentability, and, therefore, the pharmaceuticals are able to successfully obtain a patent on these plants and their centuries-old uses quite easily.[78] Owners of these plant patents have the "right to reproduce, sell, and use the plant."[79] In addition, they may "explore possible medicinal, agricultural, or other uses for the plant."[80] Since about 70% of the most profitable pharmaceutical drugs find their source in natural plant products, there is an impliedly lucrative market for biopirates to exploit the lush vegetation of underdeveloped countries.[81] The meager protections provided by the IP systems in these underdeveloped countries further entices such biopirates.

The onslaught of biopiracy, especially in recent years, has alerted international organizations, and compelled them to take action to publicly recognize the gravity of biopiracy. The United Nations ("UN"), in its International Covenant on Economic, Social and Cultural Rights ("Covenant") noted in Article 15(1)(c) that "everyone has the right to 'benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he [or she] is the author.'"[82] This has been accepted as the "human rights standard" on an international level and "is the most relevant statement in international human rights law regarding the issue of biopiracy, as it affirms the right

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[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] Report on Human Rights, *supra* note 72; *see also* VanFleet, *supra* note 3.
[79] *Id.*
[80] *Id.*
[81] *Lecture 31: Value of Biodiversity*, AOL.COM, *at* http://members.aol.com/Tenaya21/Ecology/LectureNotes/lec31.html (last visited Feb. 14, 2005).
[82] Report on Human Rights, *supra* note 72.

to intellectual property protection."[83] As applied to biopiracy specifically, the Covenant provides that these indigenous cultures "are entitled to protection" of their traditional knowledge, regardless of the absence of proper documentation.[84] Unfortunately, the United States has not ratified the Covenant and, therefore, does not recognize this international human rights standard.[85] According to a representative at FoodFirst, an institute for human rights and food policy standards, the failure of the United States to ratify the Covenant is sadly consistent with United States policy towards international poverty and welfare reform in general.[86] If the U.S. ratified this Covenant, legal causes of action could be brought against these individual pharmaceutical companies for violation of the international UN Covenant; however, because of U.S. foreign policy, ratification does not seem plausible in the near future.[87]

Biopiracy is not merely a theory; its especially recent prevalence in the third world is disquieting. Three examples include ayahuasca from South America, the Mexican Enola bean, and the nuna popping bean. Ayahuasca is a plant that has been used by indigenous Amazonian Indians for centuries to treat various sicknesses.[88] In 1986, Loren Miller obtained a U.S. patent on a variety of the vine he collected in Ecuador, which triggered public outcry and the formation of a coalition between the Amazonian Indians and other American non-governmental organizations ("NGO"), such as the Center for International Environmental Law ("CIEL") and the Coordinating Body of Indigenous Organizations of the Amazon Basin ("COICA"), to challenge the validity of Miller's patent on novelty grounds.[89] The U.S.P.T.O. invalidated the patent in 1999, but then reversed its decision upon Miller's subsequent appeal in 2001.[90]

In order to obtain a plant patent in the United States, the applicant must make a showing of novelty, utility, and nonobvious-

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[83] *Id.*
[84] *Id.*
[85] *Id.*
[86] Telephone Interview with Spokesperson, FoodFirst (July 2003).
[87] *Id.*
[88] Leanne M. Fecteau, *The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy*, 21 B.C. THIRD WORLD L.J. 69, 84–87 (2001); *see also* MICHAEL F. BROWN, WHO OWNS NATIVE CULTURE? 106–07 (2003) (discussing the controversies surrounding the Enola and nuna beans and the ayahuasca plant).
[89] BROWN, *supra* note 88, at 107; Fecteau, *supra* note 88, at 69–72, 84–88.
[90] BROWN, *supra* note 88, at 107.

ness.[91] Patents in biopiracy are a mockery of the novelty element. With ayahuasca, for instance, it is common knowledge that the patent is by no means novel, but rather it is based on the traditions of the indigenous Amazonian people.[92] Amazonian Indians have been using ayahuasca bark for centuries in medicinal drinks, yet Miller was able to obtain a U.S. patent on the plant.[93] This innate hypocrisy contradicts the basic standard of novelty.[94] Unfortunately, deficiencies in both U.S. and South American patent systems allow for the perpetuation of this exploitative biopiracy.[95] The U.S. system requires written documentation of prior art, while South American systems make no allowance for protection of traditional knowledge.[96] While this problem has been brought to the forefront of current events, and the COICA was initially successful in rescinding Miller's patent, most indigenous communities lack the money and resources to engage in costly, litigious battles against powerful U.S. entities.[97]

In general, beans are common targets for biopiracy because the United States market for beans is quite lucrative. The average annual consumption of beans in the U.S. is roughly nine pounds per person.[98] In 1998, three billion pounds of beans were harvested, amounting to a crop value of over $600 million.[99] One

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[91] 35 U.S.C. §§ 101–03 (2000).

[92] *See* Fecteau, *supra* note 88, at 69.

[93] STEPHEN A. HANSEN & JUSTIN W. VANFLEET, TRADITIONAL KNOWLEDGE AND INTELLECTUAL PROPERTY: A HANDBOOK ON ISSUES AND OPTIONS FOR TRADITIONAL KNOWLEDGE HOLDERS IN PROTECTING THEIR INTELLECTUAL PROPERTY AND MAINTAINING BIOLOGICAL DIVERSITY, AMERICAN ASSOCIATION FOR THE ADVANCEMENT OF SCIENCE (AAAS) SCIENCE AND HUMAN RIGHTS PROGRAM 14 (July 2003), *at* http://shr.aaas.org/tek/handbook/handbook_1.pdf (last visited Jan. 14, 2005) (explaining that Miller's patent on ayahuasca eventually expired in June 2003).

[94] 35 U.S.C. §§ 101–02.

[95] *See Peru Debates Law on Indigenous Peoples' Intellectual Property Rights*, GUYANA'S AMERINDIAN PEOPLES ASSOCIATION (Jan. 12, 2000), *at* http://www.sdnp.org.gy/apa/peru_debates_law.htm (last visited Feb. 15, 2005) (discussing the Peruvian government's attempts to create intellectual property laws to protect its native peoples).

[96] *See id.* (describing the differences between the proposed Peruvian intellectual property legislation and the current Bolivian intellectual property laws protecting native peoples).

[97] *Peruvian Farmers and Indigenous People Denounce Maca Patents*, ETC GROUP (July 3, 2002), *at* http://etcgroup.org/ text/txt article.asp?newsid=353 (last visited Feb. 14, 2005).

[98] U.S. DEP'T OF AGRIC., THE ECONOMICS OF FOOD, FARMING, NATURAL RESOURCES, AND RURAL AMERICA, ECONOMIC RESEARCH SERVICE (ERS), *at* http://ers.usda.gov/Briefing/DryBeans (last visited Feb. 14, 2005).

[99] *Id.*

example of bean biopiracy involves the Enola bean, a Mexican yellow bean. The owner of the patent, Larry Proctor, is the owner of the Colorado-based seed company POD-NERS.[100] On a trip to Mexico in 1994, Proctor purchased some Enola bean seeds, and less than two years later, he successfully obtained an exclusive monopoly patent.[101] The essence of his exclusive right is based on the claim of a bean with a "particular color yellow."[102] "So, in theory, anyone researching or commercializing a bean with this color has to pay royalties first, or risk being sued."[103] Proctor has already enforced his patent by suing two companies that were selling the Enola beans in the United States, alleging infringement of his patent.[104] One party to such a lawsuit is Tutuli Produce, a company in Arizona that imports beans.[105] The owner of Tutuli Produce, Rebecca Gilliland, originally dismissed the idea of a lawsuit, thinking the whole debacle to be a joke, asking "[h]ow are they going to tell me they invented a bean I've been eating for 40 years?"[106]

After Proctor received his patent, he sent a letter on behalf of POD-NERS to all Mexican bean importers in the United States informing them that if they wished to continue selling yellow beans, they would have to obtain a license from POD-NERS and subsequently pay royalties.[107] This in turn generated fear amongst all bean importers, not just those importing Mexican yellow beans.[108] Because this exclusive patent adversely impacts importers of beans in the United States, it is also economically disastrous for Mexican farmers who are exporting the beans to the Unites States companies. Miguel Tachna Felix, for example, has been exporting several yellow beans to the United States for over four years but has now lost a subsequent portion of his market.[109] Overall, the Mexican farmers suffered a drastic decrease of over

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[100] Timothy Pratt, *Patent on Small Yellow Bean Provokes Cry of Biopiracy*, N.Y. TIMES, Mar. 20, 2001, at F5.

[101] *Id.*

[102] *Id.*

[103] *Id.*

[104] *Enola Bean Patent Challenged*, CENTRO INTERNACIONAL DE AGRICULTURA TROPICAL (CIAT) (2001), *at* http://www.ciat.cgiar.org/newsroom/release_02.htm (last visited Feb. 14, 2005).

[105] *See* Pratt, *supra* note 100.

[106] *Id.*

[107] CIAT, *supra* note 104.

[108] *Id.*

[109] *Id.*

90% in export sales due to Proctor's yellow bean patent.[110] In addition, the poor farmers in Mexico now have to pay licensing fees to continue growing native crops that they have been growing for centuries—fees which most cannot afford.[111]

A second bean, the Nuna popping bean, has also been exploited by biopirates.[112] It is a popular snack food with Andean origins.[113] This bean has now been patented by yet another United States company seeking to maximize profits; however, by obtaining an exclusive patent, research on a common Andean childhood snack food has been hindered.[114] It was hoped that "research in Columbia on popping beans . . . might replace the export of illicit cocaine.[115] However, if the beans are grown on an industrial scale in the United States, small-scale Andean farmers will have little opportunity to sustain an export market," and they will get lost in the competition.[116] Therefore, not only are Andean farmers economically constrained, they are also forced back into black market industries.

The cumulative economic impact of biopiracy on third world countries is staggering. The United States has accused the third world of failing to pay royalties in two sectors.[117] In the agricultural chemicals industry, the United States alleges that the third world owes $202 million, and in the pharmaceutical industry, the United States claims that the royalties owed total $2.545 billion.[118] The Rural Advancement Foundation International ("RAFI"), now known as the ETC Group,[119] however, has shown that "if the contribution of Third World peasants and trib[es] is

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[110] *Id.*

[111] *See id.*

[112] *Nuna, The Popping Bean: Patent Pops Off Row*, NATURAL SCIENCE, May 23, 2001, *at* http://naturalscience.com/ns/news/news38.html (last visited Feb. 14, 2005).

[113] *Id.* The nuna bean "is grown in the high Andes." *Id.* It was "[f]ound at pre-Inca archaeological sites . . . [and] is a popular staple in many areas of Ecuador and Peru." *Id.*

[114] *Id.*

[115] *Id.*

[116] *Id.*

[117] Vandana Shiva, *The Turmeric Patent is Just the First Step in Stopping Biopiracy*, THIRD WORLD NETWORK (TWN) ONLINE (Oct. 1997), *at* http://www.twnside.org.sg/title/tur-cn.htm (last visited Feb. 15, 2005).

[118] *Id.*

[119] RAFI is now known as the "ETC Group: Action Group on Erosion, Technology, and Concentration." For purposes of this Note, "RAFI" will be used for actions taken when the organization was still known as RAFI, and "ETC Group" will be used for actions taken after the name change.

taken into account," it is the United States that actually owes third world countries roughly $302 million for agricultural products alone, and another $5.097 billion for pharmaceuticals.[120] "[I]n these two biological industry sectors alone, the United States owes $2.7 billion to the Third World" for its exploitation of traditional knowledge.[121] These countries will probably never see a dime.

B. The Future—Prophylactic Measures . . . But Not For Long

"We do not write because we want to; we write because we have to."
-W. Somerset Maugham (1874–1965)

In order to save themselves from the pillaging of biopiracy, some third world countries are now implementing prophylactic measures with the help of international organizations like the ETC Group. The key to Western corporate success in biopiracy is the loophole of the requisite written documentation of this traditional knowledge that is lacking by impoverished communities.[122] "As a proactive measure, [these] indigenous communities have begun documenting [their knowledge of plants] . . . to establish prior art" not because they want to, but because they have to out of necessity.[123] A project of the Science and Human Rights Program helps document traditional knowledge in accordance with complex U.S.P.T.O. guidelines under what is known as "TEK*PAD," the Traditional Ecological Knowledge Prior Art Database.[124] Projects such as this help to establish valid, proscriptive prior art by translating oral history and tradition into written words.[125]

Unfortunately, these prophylactic measures may not last long. Because these self-preservation tactics have only been initiated within the last few years, attempts to document information as prior art are futile in the face of proposed legislation such as H.R. 242.[126] H.R. 242, for example, strove to narrow the prior art base with which plant patent applications may be invalidated by dis-

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[120] Shiva, *supra* note 117.

[121] *Id.*

[122] VanFleet, *supra* note 3.

[123] *Id.*

[124] *About T.E.K.*P.A.D.*, A.A.A.S. SCIENCE AND HUMAN RIGHTS PROGRAM, *at* http://ip.aaas.org/tekindex.nsf/About?OpenPageofAutoFramedofBaseTarget=body (last visited Feb. 14, 005).

[125] *Traditional Ecological Knowledge Prior Art Database*, A.A.A.S. SCIENCE AND HUMAN RIGHTS PROGRAM, *at* http://ip.aaas.org/tekindex.nsf (last updated Oct. 9, 2003) [hereinafter T.E.K.*P.A.D.].

[126] VanFleet, *supra* note 3.

counting the last ten years of prior art.[127] This would have eliminated virtually all documentation efforts by international organizations in the very recent years to establish proper, prohibitive prior art. "[I]f an indigenous community would like to document a discovered plant, the documentation would not serve as prior art for 10 years."[128] Therefore, H.R. 242 was a legislative smokescreen that, if enacted, would have enabled biopirates to continue to violate human rights.

C. Fighting Back—The Battle Against Biopiracy and Legislation Such As H.R. 242

"Do you think this wise, boy? Crossing blades with a pirate?"
-Jack Sparrow, Pirates of the Caribbean

In the battle against biopiracy, the victims are clearly at a disadvantage. Superpower corporations versus third world countries—corporations that everyday settle litigious claims for millions of dollars, still making a profit and coming out on top, versus impoverished rural communities whose daily battles are focused on where their next meal will come from—is an unfair fight. When legislation such as H.R. 242 threatens to undermine prophylactic prior art documentation efforts such as TEK*PAD, the future seems bleak. Yet, like David and Goliath, these communities are beginning to battle back in other ways, with the help of the ETC Group and other NGOs.

One of the first successes involved the quinoa plant. Quinoa is known to be a highly nutritious food, with the highest protein content of any grain.[129] This "mother grain," as it was referred to by the Incas, contains all the essential amino acids, vitamins, and minerals necessary for a healthy diet.[130] Due to its richly nutritious profile, scientists at Colorado State University filed for and obtained a patent on quinoa.[131] However, Bolivia's National Association of Quinoa Producers and RAFI decried such biopiracy, and the University, in response, surprisingly did not pay the patent

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[127] *Id.*; *see also* Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. (2003).

[128] T.E.K.*P.A.D., *supra* note 125.

[129] *Super Seed (Beyond Fiber) by Garden of Life*, 911 HEALTH SHOP, *at* http://www.911healthshop.com/superseed.html (last visited Feb. 14, 2005).

[130] *Id.*

[131] *Biopiracy Threat to Traditional Crops*, NEW AGRICULTURIST ON-LINE, *at* http://www.new-agri.co.uk/02-5/develop/dev03.html (last visited Feb. 14, 2005).

office fee, thereby letting the patent lapse.[132] The Andean people had won their first battle.

A second success story involves the Indian plant turmeric, which has medicinal value including anti-oxidant and anti-inflammatory properties.[133] Two students at the University of Mississippi Medical Center applied for and received a patent for the indigenous Indian plant.[134] The Council for Agriculture Research in New Delhi, India, however, refused to meekly accept this and filed a challenge to the patent with the U.S.P.T.O.[135] The U.S.P.T.O. sustained the challenge based on the absence of novelty and effectively cancelled the patent.[136]

An on-going battle concerns the Enola bean patent discussed earlier in Part III(A). In December 2000, the International Center for Tropical Agriculture ("CIAT") in Columbia decided to fight back for the Enola bean and filed paperwork with the U.S.P.T.O. for re-examination of the Enola bean patent.[137] The basis for re-examination was the lack of novelty and the obviousness of the patent. As Dr. Daniel Debouck, Belgian genetic resources specialist at the CIAT noted, "[t]here has been no breeding or improvement in this bean, and newness is the first feature for claiming an invention under U.S. patent law."[138] The CIAT gene bank houses "the world's largest" bean collection, with over 28,000 beans, of which 260 are yellow and several are similar to the Enola bean.[139] The CIAT argues that because the basis of the claim in the patent was the yellow color of the bean, "it will make a mockery of the patent system to allow statutory protection of a color per se,"[140] implying that any of the 260 yellow beans in the CIAT's gene bank could be considered infringing upon this patent.[141] In addition, Dr. Joachim Voss, director of the CIAT, "calls the Enola patent both legally and morally wrong . . . [due to] solid scientific evidence that Andean peasant farmers developed this bean first,

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[132] *Id.*

[133] *Spices: Exotic Flavors & Medicines: Tumeric,* UCLA HISTORY & SPECIAL COLLECTIONS, LOUISE M. DARLING BIOMEDICAL LIBRARY, *at* http://unitproj.library.ucla.edu/biomed/spice/index.cfm?displayID=26 (last visited Jan. 30, 2005).

[134] Shiva, *supra* note 117.

[135] *See id.*

[136] *Id.*

[137] CIAT, *supra* note 104.

[138] Pratt, *supra* note 100.

[139] *Id.*

[140] CIAT, *supra* note 104.

[141] Pratt, *supra* note 100.

together with Mexico."[142] This is further supported by "genetic fingerprinting," which illustrates that the Enola bean is identical to a bean registered in 1978 in Sinaloa, Mexico.[143] To date, the U.S.P.T.O. has yet to formally rule on this matter, but hopefully the outcome will continue the victorious trend set by the quinoa and turmeric battles.[144]

While these victories provide positive reinforcement for continuing the battle against biopiracy, the above examples encompass only fights initiated once the patent has been obtained or only in the litigious forum. Oftentimes, these processes involve more cost in terms of the monies already lost to the indigenous communities through enforcement of the patent during the battle, as well as the increased costs of litigation for these impoverished regions.[145] In addition, the implementation of pretextual legislation such as H.R. 242 will only strengthen the patent claims, thereby weakening the indigenous communities' position in the battle against biopiracy.

D. Battles Ahead—H.R. 121 and its Analogous Impact on Biopiracy

"You may have to fight a battle more than once to win it."
-Margaret Thatcher

As discussed in Part I of this Note, Congressman Issa initially introduced H.R. 5119 in 2002.[146] Hearings on this bill were never held in that congressional session, so Issa reintroduced the content of the bill via H.R. 242 in the 108th Congress of 2003.[147] While the AIPLA and others expressed their dissatisfaction with this bill in its ability to address the horticultural problems and in the manner it exacerbated the biopiracy issues,[148] H.R. 242 was never directly addressed in Congress. It was last referred to the Subcommittee on Courts, the Internet, and Intellectual Property,[149] but then allowed to simply die, as hearings were never held on this bill either. In the 109th Congress, Congressman Issa

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[142] *Id.*
[143] *Id.*
[144] Telephone Interview with Spokesperson, ETC Group (Feb. 15, 2005).
[145] *See Peruvian Farmers and Indigenous People Denounce Maca Patent*, ETC GROUP, July 3, 2002, *at* http://www.etcgroup.org/text/txt article.asp?newsid=353 (last visited Feb. 14, 2005).
[146] Plant Breeders Equity Act of 2002, H.R. 5119, 107th Cong. (2002).
[147] Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. (2003).
[148] *See supra* Part II.
[149] VanFleet, *supra* note 3.

introduced H.R. 121 on January 4, 2005.[150] Unlike past years, however, the content of this Plant Breeders Equity Act did not remain exactly the same. Amongst other provisions of the bill, such as explicitly stating the horticultural reasons for its introduction, the essence of H.R. 121 is to amend the definition of novelty under 35 U.S.C. § 162:

> (c) Novelty—
>
> (1) IN GENERAL—Except as provided in paragraph (2), no plant patent application shall be denied, nor shall any issued plant patent be invalidated, on the grounds that the invention was sold or otherwise disposed of.
>
> (2) EXCEPTIONS—Paragraph (1) shall not apply if—
>
> (A) more than 1 year prior to the date of the application for patent in the United States, the invention was sold or otherwise disposed of to other persons in the United States, by or with the consent of the inventor or discoverer, or the successor in interest of the inventor or discoverer, for purposes of exploitation of the invention;
>
> (B) except as provided in subparagraph (C), more than 4 years prior to the date of the application for patent in the United States, the invention was sold or otherwise disposed of to other persons in a foreign country, by or with the consent of the inventor or discoverer, or the successor in interest of the inventor or discoverer, for purposes of exploitation of the invention; or
>
> (C) more than 6 years prior to the date of the application for patent in the United States, in the case of a tree or vine, the invention was sold or otherwise disposed of to other persons in a foreign country, by or with the consent of the inventor or discoverer, or the successor in interest of the inventor or discoverer, for the purposes of exploitation of the invention.[151]

Because H.R. 121 was introduced so recently, formal commentary has not yet begun in response. At first glance, the content appears to have changed considerably from H.R. 242; however, a closer look would suggest otherwise. While H.R. 242 would have altered the definition of novelty through printed publications, H.R. 121 now more complexly proposes altering the definition of novelty through sales and use of the invention in question.[152]

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[150] Plant Breeders Equity Act of 2005, H.R. 121, 109th Cong. (2005), *at* http://thomas.loc.gov/bss/d109/d109laws.html.

[151] *Id.*

[152] *Id.*; *see also* Plant Breeders Equity Act of 2003, H.R. 242, 108th Cong. (2003).

Regardless of the motivations behind the introduction of H.R. 121, it too should not be passed. The enactment of H.R. 121 would have a devastating impact on biopiracy, just as its predecessors did. Under 35 U.S.C. § 102, an invention is rendered unpatentable when the invention has already been patented or discussed in a printed publication anywhere in the world.[153] Thus, third world countries may, at the moment, document the use of their medicinal plants to preclude patenting in the United States. H.R. 242 attempted to redefine the boundaries of novelty by narrowing the prior art base by which a patent application could be rejected.[154] Under § 102, the invention is additionally rendered unpatentable if it has been made, used, sold, or offered for sale in the United States within the year prior to application.[155] H.R. 121 proposes to expand the requirement such that inventions would be unpatentable if proof exists that foreign sales or uses occurred up to four or six years ago, depending on the type of plant.[156] This requires third world countries to prove that they either "sold or otherwise disposed of" the plant more than four years ago, or six years ago "in the case of a tree or vine," in order to preclude patenting by another party in the United States.[157] This destroys the potential for prophylactic measures of documenting uses now because of the change in the prior art base to four or six years. Even if third world countries began documenting uses immediately, U.S. pharmaceutical companies would nevertheless be able to obtain a patent because of the four and six year windows of novelty. Not only do third world countries not have proof that they sold or used their herbal medicines more than four or six years ago, but more importantly their use more than four or six years ago precludes those very countries from patenting those plants.

As stated, H.R. 121 would prevent third world countries from patenting the plants themselves. Presently, they still could patent these plants in the United States because the prior sales and uses preclusion is domestically limited.[158] If H.R. 121 were passed however, and it could be proven that a third world country has sold or used its plants more than four or six years ago, then that country would not be able to obtain a patent in the United

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[153] 35 U.S.C. § 102 (2003).

[154] Plant Breeders Equity Act, H.R. 242, 108th Cong. (2003).

[155] 35 U.S.C. § 102.

[156] Plant Breeders Equity Act of 2005, H.R. 121, 109th Cong. (2005), *at* http://thomas.loc.gov/bss/d109/d109laws.html.

[157] *Id.*

[158] 35 U.S.C. § 102.

States.[159] That country would remain exposed to biopirates in the United States.

Although the very recently introduced H.R. 121 seems to have changed in its content, its impact on biopiracy and the concept of novelty in patent law remains unchanged as compared to its predecessors. Legislation such as H.R. 121 simply represents the fact that the battle against biopiracy must be fought more than once. As long as no comprehensive scheme exists to protect the victims of biopiracy, these battles must be fought again and again in order to prevail.

E. Stepping Back—Diplomatic Weapons of International Licensing and ICBGs

"All war represents a failure of diplomacy."

-Tony Benn

While warring against patents that have been applied for, or granted, has resulted in some victories, as noted in Part III(C), this process involves costly litigation and hostility amongst superpowers that poor nations cannot afford in the defense of their human rights. Stepping back from the initial instinct to fight with weapons and voices raised, alternative preemptive methods are more diplomatic, and perhaps more advantageous to all parties involved, including the pharmaceutical companies and research scientists. At this point, the author wishes to "step back" herself and provide the caveat that, while this Note has been highly critical of the pharmaceutical companies, biopiracy can quickly become a pejorative term if one is not cautious. While studies indicate that the value of drugs extracted from traditional sources is estimated in the billions of dollars, these communities are too impoverished to efficiently exploit the rich treasure trove of knowledge in their backyard.[160] Therefore, "many countries are currently making unsustainable use of their natural resources, and it has been estimated that up to 10% of the world's species will be extinct within 25 years."[161] Compromise in the form of international licensing agreements and the International Cooper-

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[159] Plant Breeders Equity Act of 2005, H.R. 121, 109th Cong. (2005), *at* http://thomas.loc.gov/bss/d109/d109laws.html.

[160] Walter H. Lewis & Veena Ramani, *Ethics and Practice in Ethnobiology: Analysis of the International Cooperative Biodiversity Group Project in Peru* (2003), *at* http://law.wustl.edu/centeris/Confpapers/lewisramani.html (last visited Feb. 14, 2005).

[161] *Id.*

ative Biodiversity Group ("ICBG") programs funded by the National Institute of Health would optimize efficient use of natural resources. Furthermore, cooperation would also provide a more effective defense against potentially devastating legislation such as H.R. 242 and H.R. 121 by pre-empting the need to battle against stronger patents with a more limited prior art database.

Researchers at the University of Illinois at Chicago ("UIC") are attempting to patent a plant native to the Palawan region of the Philippines, called dichapalin I, for its anti-cancer properties.[162] The Philippine watchdog organization, Palawan NGO Network, Inc. ("PNNI"), endeavors to ensure that consent of the Palawan indigenous communities is obtained, in accordance with the Philippine government Executive Order 247, which was enacted to curb biopiracy.[163] Further, Philippine legislation against biopiracy, which is thought to be the most comprehensive in the world, has mandated "a 'benefit sharing' agreement laying out how royalties arising from the licensing of the compound to a pharmaceutical company would be shared."[164] However, while this would seem to provide the Palawan communities with "substantial benefits, the numbers represent the percentage of royalties negotiated by UIC from the pharmaceutical company, not the percentage of royalties overall."[165] In addition, administrative costs contribute to lowering these royalties.[166] While this may seem like at least a step in the right direction, the status of royalties in reality is bleak:

> [F]or the most part, these royalties only exist on paper and may never materialize or may only materialize in the far distant future. Typically source countries receive less then three percent of net royalties and often receive less than one percent. RAFI knows of no local community that has ever actually received any royalty benefits.[167]

When contemplating RAFI's hopeless outlook of the royalties in the Philippine Palawan situation, however, one must scrutinize RAFI itself as an organization. Stepping back once more, while RAFI has been pivotal in calling attention to and gathering public

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[162] Someshwar Singh, *Rampant Biopiracy of South's Diversity*, THIRD WORLD NETWORK (TWN) ONLINE, *at* http://www.twnside.org.sg/title/rampant.htm (last visited Feb. 14, 2005).

[163] *Id.*

[164] *Id.*

[165] *Id.*

[166] *Id.*

[167] *Id.*

outcry against the injustices of biopiracy, it has at times overstated situations or intervened to the detriment of all parties concerned.[168] One prominent example of this is the ICBG-Maya project initiated in 1998.[169] O. Brent Berlin, a world-renowned ethnobiologist and anthropologist, had worked in close proximity with the Tzeltal and Tzotzil-speaking Indians of Chiapas, Mexico.[170] No one could have asked for better qualifications for the lead investigator, especially with his team members from the University of Georgia, the Mexican organization El Colegio de la Frontera Sur ("ECOSUR"), and the Welsh biotech firm Molecular Nature, Ltd.[171] Unfortunately, factors beyond Berlin's control destroyed what had the potential to be a successful research endeavor.

In Chiapas, the political climate was rife with tensions when the armed Zapatista Army of National Liberation ("EZLN"), consisting of mostly "Maya-speaking Indians," engaged in a violent rebel war with the Mexican Army in 1994, eventually leading to the use of a threatening containment tactic by the Mexican Army.[172] Facing this risk, Berlin and his team detailed economic

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[168] BROWN, *supra* note 88, at 126–36. For example, in the early 1990s, Shaman Pharmaceuticals took an innovative approach to R&D by consulting closely with traditional communities and working to extract essential medical knowledge, while at the same time working to preserve the natural resources and adequately compensate the indigenous populations. By 1994, the company had hopes for an anti-viral drug using sangre de drago, a plant native to Peru, Bolivia, Ecuador, and Colombia. Unfortunately, Shaman's financial situation struggled, and the project had to be scrapped, with Shaman eventually entering the less risky dietary supplement industry. Before the switch, RAFI harshly criticized Shaman in 2000 for only paying a few thousand dollars to the indigenous communities that provided the sangre de drago, neglecting to mention the very pertinent fact that Shaman and its investors lost millions in the process. The complex R&D process for pharmaceuticals, and its risks to companies, is often overlooked by quick-to-judge organizations such as RAFI. *Id.*; *see also* E-mail from Charles McManis, Thomas & Karole Green Professor of Law, Washington University School of Law, to Author of this Note, Law Student, University of Illinois at Urbana-Champaign (Nov. 10, 2003, 18:29:00 CST) (on file with author). The author of this Note would like to acknowledge Professor Charles McManis and thank him for his expertise and insight into biodiversity issues.

[169] BROWN, *supra* note 88 at 114.

[170] *Id.* at 114–15.

[171] *Id.* at 115.

[172] *Id.* at 115–18. As the author Michael Brown was writing this book, the cease-fire between the Chiapas peasants and right-wing paramilitary groups was still tense, with continued terrorizing of local villages. *Id.* at 115. The origin for such violence began in the 1980s when the Mexican government increased privatization of social programs, thereby worsening the situation for the poverty-stricken populations in Mexico, mostly consisting of Chiapan Maya-speaking

and moral rights for the Maya, while ensuring that prior informed consent ("PIC") was first obtained from all the villages.[173] Concerted efforts included translating negotiation and contractual details in the native Tzeltal and Tzotzil languages, and writing a play to explain biodiversity and patent laws in simpler terms to the local farmers.[174] Economically, twenty-four trained Maya field assistants would be paid from 12% of the project's budget and, more importantly, the Maya communities, even those that refused to cooperate, would be paid one-quarter of all royalties from a nonprofit organization, PROMAYA, if the project was a success.[175] At this point in 1999, ICBG-Maya was proceeding rather smoothly, especially considering the political tensions in the area—then, RAFI stepped in.[176] RAFI and the Council of Indigenous Traditional Midwives and Healers of Chiapas ("COMPITCH") publicly denounced ICBG-Maya, criticizing it for excluding the Maya communities that would not consent to collaboration and alleging that this unwittingly exploited their knowledge as well.[177] RAFI's insistence on consent by every Maya community, however, would have required consent from the Maya residing outside Chiapas, such as in Guatemala and Belize, since RAFI adopted a rather broad view of the definition and boundaries of what comprises a community.[178] RAFI also assumed that COM-

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Indians. *Id.* at 116–17. The implementation of the North American Free Trade Agreement increased their precarious economic position by placing small Maya farmers in competition with large U.S. corn producers. *Id.* The Zapatistas responded to the social and economic threat against collective identities by engaging in the "rhetoric of indigenous nationalism" and opposing "globalization." *Id.* at 117. Ironically, globalization became one of the EZLN's primary driving forces in its cause, using the Internet and the media to gain public recognition, not necessarily positive but recognition nonetheless, from the United States and Europe. *Id.*

[173] *Id.* at 119.

[174] *Id.*

[175] BROWN, *supra* note 88, at 119–20.

[176] *Id.* at 120.

[177] *Id.* at 120–21.

[178] *Id.* at 121; *see also* JOSHUA ROSENTHAL, POLITICS, CULTURE AND GOVERNANCE IN THE DEVELOPMENT OF PRIOR INFORMED CONSENT AND NEGOTIATED AGREEMENTS WITH INDIGENOUS COMMUNITIES, NATIONAL INSTITUTES OF HEALTH: FOGARTY INTERNATIONAL CENTER (final draft for Chuck McManis) (Sept. 4, 2003), *at* http://law.wustl.edu/centeris/Confpapers/PDFWrdDoc/PICFinal.html (last visited Feb. 14, 2005). The definition or boundaries of what comprises a community is still in debate—e.g., whether it comprises the local village where the plant species was originally found, all villages where the plant species can be found, only those villages from which the plant species will be extracted for R&D purposes, or every village where the indigenous peoples are found, regardless of geographic proximity. *See* ROSENTHAL, *supra* note 178, at 162.

PITCH was a valid representative of the entire Maya people; in reality, it was simply another "professional guild" with special interests.[179] The positions asserted by RAFI in the ICBG-Maya situation were contradictory, insisting on individualized PIC from each Maya community, while at the same time insisting on national standards to be imposed by the Mexican government for uniform treatment and generalizing all bioprospecting agreements as biopiracy.[180] Berlin claimed that "he was a victim of his own honesty. While he and his colleagues communicated the goals and methods of their project in public forums and applied for all necessary government permits, less scrupulous researchers continued to collect plants and ship them off to distant laboratories for analysis."[181]

Eventually, under the sustained pressure and opposition in an atmosphere already brimming with suspicion and violence, the ICBG-Maya project crumbled in November 2001.[182] RAFI's joy in its claimed Chiapas victory is confusing, rooted perhaps in its private "war against capitalism and the world intellectual property system."[183] RAFI's impulsive actions in the ICBG-Maya case meant the loss of income to the impoverished Tzeltal and Tzotzil trainees, and the loss of opportunities for further mutual education and industrialization, all of which could have stimulated the flagging economic situation, to say nothing of the loss of traditional knowledge that may have been used in R&D to develop important pharmaceuticals.[184]

Despite similar intervention by RAFI in 1994, ICBG-Peru managed to prevail. In a significant move toward international licensing, the Aguaruna people of Peru, in collaboration with "ethnobotanists from Washington University in St. Louis," engaged in negotiations with the U.S. company Searle Pharmaceuticals, which is currently a subsidiary of Monsanto.[185] RAFI, however, almost destroyed the ICBG-Peru project, as it had later done with the ICBG-Maya project. In working with the

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[179] BROWN, *supra* note 88, at 121.

[180] *Id.* at 122–23.

[181] *Id.* at 124.

[182] *Id.* at 125. As Berlin told the press, "[t]he goals of the Maya ICBG were noble goals—the real losers are the Highland Maya themselves." *Id.*

[183] *Id.*

[184] *Id.*

[185] Janet Bell, *Biopiracy's Latest Disguises*, GENETIC RESOURCES ACTION INTERNATIONAL (GRAIN) (June 1997), *at* http://www.grain.org/seedling/?id=90 (last visited Feb. 14, 2005); BROWN, *supra* note 88, at 112.

Aguaruna people, the ICBG-Peru team was working with the Aguaruna-Huambisa Council ("Council"), promising to train the Aguaruna and hire them for related work.[186] Eventually, however, RAFI's interference led to a dismantling of relations between the Aguaruna and the researchers.[187] Unlike the clearly exploitative situation involving the ayahuasca,[188] where RAFI's aid proved to be invaluable in preventing human rights violations, their interference simply proved destructive in a less defined situation such as this one.[189] As with ICBG-Maya and COMPITCH, RAFI once again "assumed that the . . . Council was the true representative of the Aguaruna people."[190] Again, this assumption was debatable, as not all local communities of the Aguaruna supported the Council.[191] Negotiations with the Council having been destroyed by RAFI, the ICBG-Peru team turned to an agreement with the Confederation of Amazonian Nationalities of Peru ("CONAP"), a multi-ethnic group that had the backing of several "local Aguaruna organizations."[192]

The agreement with CONAP involved negotiating a "know-how license" to protect the Aguarunas' property rights.[193] "Since Peru's genetic resources are patrimony of the state, the 'know-how' license tied the rights to use the plants to the need for a license to use the knowledge provided by the Aguaruna."[194] In addition to paying $20,000 a year to obtain the know-how license, royalty rates were negotiated such that Searle would pay a minimum annual collection fee of $10,000 during the four years of collection activities.[195] The license fee itself would be paid over the course of the R&D phase, approximately ten to fifteen years.[196]

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[186] BROWN, *supra* note 88, at 112–13.

[187] *Id.* at 113.

[188] *See id.* at 107 (discussing the outcry that arose due to the patenting of ayahuasca by an American); *see also supra* notes 88–97 and accompanying text.

[189] BROWN, *supra* note 88, at 113.

[190] *Id.*

[191] *Id.*; *see also* ROSENTHAL, *supra* note 178. In addition to criticizing ICBG-Peru's choice of Council as a quasi-representative group of the Aguaruna, RAFI asserted that the Consejo Aguaruna y Huambisa ("CAH") was the only group capable of representing all the Aguaruna people, simply because they were a larger organization. *See* ROSENTHAL, *supra* note 178. As mentioned in footnote 162, RAFI has no more authority or expertise in defining a representative group for the fluid boundaries of indigenous communities than the ICBG teams. *Id.*

[192] BROWN, *supra* note 88, at 113–14.

[193] *Id.* at 114.

[194] Bell, *supra* note 185.

[195] *Id.*

[196] *Id.*

Having negotiated and established this know-how license with Searle, the Aguaruna retained some control in that if Searle terminated the agreement, its right to use the plant and its derivatives terminates as well.[197] The attorney to the Aguaruna people, Brendan Tobin, noted that "this agreement is significant because it is the first of its kind in which indigenous people have been able to maintain an element of control over the use of the resources passed to a third party."[198] Unlike other situations where the people were paid a fixed monetary award,[199] the Aguaruna will be receiving compensation for collection of the plant resources and for the use of their traditional knowledge.[200] This provides the advantage of advance royalties, or milestone payments, which provide indigenous communities with compensation for their resources earlier in the R&D process, perhaps better ensuring that they will actually be paid, and thus alleviating RAFI's concerns that corporations will not pay regardless of the existence of an agreement.[201] Furthermore, the Aguaruna were named as joint owners in any patents involved, providing them with concrete IP rights in their resources.[202]

While Searle Pharmaceuticals eventually withdrew from the ICBG-Peru project, this was forced only because of its parent company's acquisition by Pharmacia, Inc., and its withdrawal was completed only after fulfilling its contractual obligations to CONAP by paying the royalty and know-how license fees in full to the Aguaruna people.[203] Thus, while ICBG-Maya was unable to withstand political pressure and criticism by RAFI, the ICBG-Peru project was rather successful, providing creative potential solutions for biopiracy. As Cesar Sarasara, president of CONAP, said "CONAP . . . is working to find new formulas for collaborating with industry so that we're [indigenous communities] not looking

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197 *Id.*

198 *Id.*

199 *See, e.g., Bushmen Will Share Royalties on TK-based Anti-obesity Drug*, TRADITIONAL ECOLOGICAL KNOWLEDGE PRIOR ART DATABASE, RECENT NEWS AND EVENTS (Mar. 31, 2003), *at* http://ip.aaas.org/tekindex.nsf (last visited Feb. 14, 2005) (detailing the interests of pharmaceutical companies in a type of cactus called Hoodia, which has been a traditional source of food and water for the Kung tribesmen in Africa).

200 ROSENTHAL, *supra* note 178.

201 *Id.*

202 Lewis & Ramani, *supra* note 160.

203 Charles R. McManis, *Intellectual Property, Genetic Resources and Traditional Knowledge Protection: Thinking Globally, Acting Locally*, 11 CARDOZO J. INT'L & COMP. L. 547, 570 (2003).

in from the outside. We're not waiting for NGOs or the Catholic Church to help us. We're looking for opportunities to exploit the economic value of our resources."[204] In essence, the ICBG projects allow the indigenous communities to take matters into their own hands, precluding potential problems with legislation such as H.R. 242 and H.R. 121 by simply negotiating around it—this proves that diplomacy is perhaps more profitable than war for all parties involved.

IV. RECOMMENDATIONS

> "Thieves respect property; they merely wish the property to become their property that they may more perfectly respect it."
>
> -G.K. Chesterton

In attempting to provide homogeneity in international IP laws, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") fails to alleviate the biopiracy dilemma. Developing nations opposed TRIPs because it requires all World Trade Organization ("WTO") members to accord IP rights to plants—"the basis of food security and health care."[205] Before TRIPs, Asian countries for example, which were victims of biopiracy regarding plants such as basmati and jasmine rice, "prohibited patents on life forms because corporate monopolies touching peoples' basic needs are dangerous. Also, many Asian cultures are based on a holistic view of and respect for life, which Western technologies and property systems fundamentally disregard."[206] After TRIPs, however, these Asian countries are bound to legalize IP titles on seeds, easing the way for transnational corporations wanting to obtain patents on rice, a staple crop.[207] In this regard, TRIPs undermines, or at least is at odds with, the UN Convention on Biological Diversity ("CBD").[208] The CBD is an especially significant treaty, as it was "[t]he first international treaty to recognise state sovereignty over genetic resources," and it "include[s] access and benefit sharing obligations."[209] In addition,

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[204] BROWN, *supra* note 88, at 114.

[205] *Biopiracy, TRIPs and the Patenting of Asia's Rice Bowl*, GENETIC RESOURCES ACTION INT'L (GRAIN) (May 1998), *at* http://www.grain.org/briefings/?id=29&print=yest (last visited Feb. 14, 2005).

[206] *Id.*

[207] *Id.*

[208] Kristy Hall, *Bioprospecting: New Zealand's International Commitments*, *at* http://www.med.govt.nz/ers/natres/bioprospecting/review/seminar20030221/-hall/ (last visited Feb. 14, 2005).

[209] *Id.*

the United States has, not surprisingly, failed to ratify the CBD.[210] Thus TRIPs, rather than alleviating biopiracy, actually tends to exacerbate it by contravening the protectionist ideology of the CBD and requiring that the international community recognize the legality of certain plant patents.

The future may seem bleak, but some recommendations may alleviate the suffering caused by biopiracy. First, smokescreen legislation such as H.R. 242 and H.R. 121 should be defeated. It is far too tempting to couch such biopiracy aids within alternative topics of legislation such as agriculture, not to mention that it is also far too broad a remedy for the horticultural problem at hand.[211] Regardless of whether these bill were intended to adversely impact biopiracy, incidental effects of legislation must be considered with great caution.

Second, international IP regimes need to be solidified and harmonized. Deficiencies in combating biopiracy exist in all systems. Section 102 of the U.S. Patent Act, for example, provides that:

> Prior foreign activity anticipates a US patent only when the foreign activity is in a tangible, accessible form such as a published document or a patent. However, prior foreign knowledge, use and invention are all excluded when . . . prior art is considered in relation to a US patent application.[212]

The European Patent Office, on the other hand, has perhaps a slightly improved policy in that it accepts "oral descriptions" and traditional knowledge as prior art, seeming to contradict the essence of the U.S. novelty requirement to allow known uses of plants to be patented simply because they have not been documented in a written form.[213] In consideration of the spectrum of policies of other countries, the Philippines has one of the strongest IP regimes fighting biopiracy,[214] while New Zealand, where the Maori have been targeted for their rich, biodiverse knowledge, has

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[210] THE CONVENTION ON BIOLOGICAL DIVERSITY AROUND THE WORLD, *at* http://www.biodiv.org/world/map.asp?ctr=US (last visited Feb. 14, 2005).

[211] *See* Statement of Vincent E. Garlock, *supra* note 16, at 2. Remedies more narrowly tailored to the situation would include perhaps amending the quarantine process such that it does not entail ten years to pass foreign plants through testing, or perhaps negotiating with the U.S. PTO to return to the traditional view on § 102(b) by inquiring into their motives for the sudden policy shift.

[212] Shiva, *supra* note 117.

[213] Report on Science and Human Rights, *supra* note 72.

[214] *See supra* Part III(E) (detailing the Palawan example of comprehensive Philippine legislation on IP regulations).

no regulations in place to defend itself from biopirates.[215] In addition to strengthening the IP regimes of other countries, IP laws must also be able to co-exist in harmony to be effective, or else they simply contravene each other, allowing the nation with the stronger IP laws, typically the biopirate, to be victorious. Therefore, when implementing new IP legislation, countries must look to other nations' IP regimes to see if their regulations against biopiracy will survive other countries' policies.

Third, while harmonizing IP laws and attempting to gain public support to challenge biopirates and their respective patent claims are positive first steps in battling biopiracy, harmonization and public support are perhaps not the most effective methods. Although H.R. 242 was defeated in Congress,[216] that does not preclude the possibility of future legislation either directly or incidentally affecting biopiracy—known as the "Law of Unintended Consequences."[217] As discussed in Part III(D), Congressman Issa has now introduced H.R. 121 in 2005 in the face of the failure to pass H.R. 242.[218] While the content of H.R. 121 has technically changed from previous years, its impact on biopiracy remains analogous. Rather than attempting the impossible by predicting the type of impact future legislation may have on biopiracy and determining how to effectively prevent such adverse effects, it would be more effective to simply work around such possible legislation. For example, one tool discussed above was the ICBG project, which, while not foolproof, shows great promise in satisfying all parties concerned. In formulating future ICBG projects, several structural aspects must be taken into consideration. ICBG projects are aided by access to independent counsel for the indigenous communities and are useful in precluding pharmaceutical companies from obtaining an advantageous bargaining power too large to overcome.[219] Allowing the representative group of the community to negotiate with pharmaceutical companies and

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[215] Hall, *supra* note 208.

[216] H.R. 242 was allowed to quietly die in Congress as H.R. 5119 in the 107th Congress; *see* E-mail from Charles McManis, Thomas & Karole Green Professor of Law, Washington University School of Law, to Author of this Note, Law Student, University of Illinois at Urbana-Champaign (Nov. 10, 2003, 18:29:00 CST) (on file with author). Congress and its committees typically accord AIPLA and its Executive Director Mike Kirk, a former U.S. PTO official, a good deal of discretion.

[217] *See* BROWN, *supra* note 88, at 213.

[218] Plant Breeders Equity Act of 2005, H.R. 121, 109th Cong. (2005), *at* http://thomas.loc.gov/bss/d109/d109laws.html.

[219] ROSENTHAL, *supra* note 178.

researchers directly rather than through third-party NGOs can lead to more satisfied parties by avoiding miscommunication and engaging in a more direct understanding of each party's needs and desires.[220] Moreover, the use of a know-how license seems to alleviate concerns that any of the parties will be economically exploited.[221] In general, all parties involved in the ICBG projects must be open to making concessions and respecting mutual cultural quirks.

In addition, ICBG projects must be prepared to cope with the unpredictable. Comparing the failure of the ICBG-Maya project with the relative success of the ICBG-Peru project, it is evident that a country rife with political dissonance will prove to be a challenge, though not necessarily an impossible one, to appease.[222] Furthermore, pre-existing reputable and representative governance bodies provide greater stability, authority, and legitimacy to the negotiations.[223] Finally, "geographically contiguous communities" ease discussions regarding the extent of compensation among local groups, and avoid discord among remote communities.[224] While these factors reach beyond the control of ICBG projects, ICBG may alleviate the potentially devastating impact of non-coordination and political instability through measures such as incorporating a larger budget or enlisting the aid of the media and other public channels. Therefore, pre-emptive negotiation and diplomacy, as opposed to contentious litigation and hostility, appear to be the more peaceful, effective, and realistic methods of overcoming biopiracy and the potentially devastating impact of legislation such as H.R. 242 and H.R. 121.

V. CONCLUSION

> "The true civilization is where every man gives to every other every right that he claims for himself."
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> -Robert Ingersoll (1833–1899)

Biopiracy is a burgeoning exploitation of the traditional knowledge of indigenous third world communities. Impoverished rural farmers are no match for the sophistication of Western corporate powerhouses in the fight against biopiracy. While biopiracy victims have initiated prophylactic measures to document their

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220 *Id.*
221 *Id.*
222 *Id.*
223 *Id.*
224 *Id.*

traditional knowledge in order to establish proscriptive prior art, smokescreen legislation such as H.R. 242 and H.R. 121 will undermine such efforts. In the effort to salvage the human rights of the indigenous peoples in developing countries, a more comprehensive remedial scheme in the form of globally harmonized IP regimes must be developed. While this would be ideal, it would also require a great deal of time to efficiently implement, thereby requiring an intermediary substitute solution. Although not perfect, countries which have engaged in international licensing schemes and ICBG projects have met with some success in pleasing scientists and pharmaceutical companies, as well as indigenous communities. Convincing more skeptical, yet powerful and potentially damaging, groups such as the well-intentioned RAFI of the efficacy of theories such as the ICBG projects will be more difficult. As a French diplomat once told former U.S. Secretary of State Madeleine Albright when discussing bureaucracy: "It will work in practice, yes. But will it work in theory?"[225] The harsh, but very tangible, reality of biopiracy as a human rights violation is that not everyone can be saved in the face of new legislative measures such as H.R. 242 and H.R. 121—it is a Darwinian world in which the strongest will survive. It is the hope, however, that this brutal reality may be alleviated with more diplomatic weapons in the ongoing battle of bills, beans, and biopiracy.

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[225] BROWN, *supra* note 88, at 247.

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