

# WHAT, IF ANY, ARE THE ETHICAL OBLIGATIONS OF THE U.S. PATENT OFFICE?

## A CLOSER LOOK AT THE BIOLOGICAL SAMPLING OF INDIGENOUS GROUPS

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### ABSTRACT

*The patenting of biological resources collected from indigenous groups has become a controversial trend. Two U.S. patents in particular, one claiming a cell-line from a 26-year old Guayami woman and one claiming a leukemia virus from a Hagahai man in Papua New Guinea, demonstrate just how volatile this issue has become. This iBrief examines how, in light of such “ethically questionable” patents, the U.S. Patent Office has failed to implement any procedures to identify or curb patent applications involving indigenous peoples.*

### INTRODUCTION

¶1 The ethical debate surrounding the patenting of biological material has reached new levels now that scientists and researchers have been gathering and patenting DNA samples from indigenous populations around the world. The debate raises numerous issues. For instance, will the data, which to date has revealed information on diseases such as leukemia and AIDS, stigmatize or create outsider prejudice towards indigenous populations? Have these isolated groups, which may speak different languages than researchers and scientists, given informed consent to the researchers and scientists? Should indigenous populations receive compensation for use of their genetic material? To what extent do these groups control or own their genetic material, which to many groups holds very sacred and religious significance? Finally, what are the collective rights of the tribe, which often defiantly oppose the testing, versus the rights of individual tribe members who wish to partake in the biological research?

¶2 Part I of this iBrief addresses the various aspects of the debate concerning the biological testing of indigenous peoples and subsequent

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patenting of test results. Part II of the iBrief will then discuss the Guayami and Hagahai patents, which have largely fueled this debate. Finally, the last part of the paper will focus on a much narrower and often overlooked issue. That is, what are the responsibilities of the U.S. Patent and Trademark Office (USPTO) to monitor these ethically questionable patent applications?

## I. THE DEBATE

¶3 The rush to patent genome sequences<sup>2</sup> did not start with the DNA testing of indigenous peoples. Nor is the public unease with this sort of intellectual property new. In fact, as early as 1980, the U.S. Supreme Court declared that the patenting of living micro-organisms was permissible under U.S. patent laws.<sup>3</sup> There has been a surge in what some scholars have referred to as “hyperownership,” a term that refers to the international movement to “own or control access to the subcellular genetic sequences that direct the structure and characteristics of all living things, or, in popular usage, nature’s or God’s blueprints for life.”<sup>4</sup> The U.S. has been the leader in this trend, “extending patent protection to a wide and increasing array of genetic material.”<sup>5</sup> By the middle of the year 2000, “the [USPTO] had issued over six thousand patents on full-length genes isolated from living organisms and were considering over twenty thousand gene-related patent applications.”<sup>6</sup>

¶4 The legal world has recently addressed *human* genome sequences as a source of intellectual property. Debate has arisen regarding whether doctors have a right to the research and subsequent patenting of a patient’s

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<sup>2</sup> See, e.g., Brian Gargano, *The Quagmire of DNA Patents: Are DNA Sequences More than Chemical Compositions of Matter?*, 2005 SYRACUSE SCI. & TECH. L. REP. 3, 5 (2005) (“With the advent of recombinant DNA technology and advanced techniques in DNA sequencing, it became possible to identify and isolate individual genes. . . . A ‘genome’ is the set of all DNA and DNA sequences in an organism, including its genes.”), available at <http://www.law.syr.edu/students/publications/sstlr/framesets/archive/arcset.htm>.

<sup>3</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (allowing Ananda Chakrabarty to patent his creation of a genetically engineered bacterium capable of breaking down crude oil).

<sup>4</sup> Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 AM. J. INT’L L. 641, 641 (2004) (addressing how the U.S. and various members of the international community have approached the “ownership” of biological material in different ways, with some countries, such as the U.S., utilizing a patent-based “privatization” system and others maintaining sovereign-based systems of ownership).

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

“discarded” biological tissue.<sup>7</sup> Also, a huge uproar ensued when it was discovered that research physicians patented and commercialized a test for Canavan’s disease from the bequeathed biological material of patients who donated their biological tissue under the belief that it would be used solely to help diseased patients.<sup>8</sup> Critics have noted that “[p]atient lawsuits seeking recovery of a researcher’s patent profits, from patents involving the patient’s genetic material . . . will likely recur.”<sup>9</sup> Furthermore, “[a]bsent legislative intervention to compensate patients, they have reduced incentives to donate their genetic material to further scientific research.”<sup>10</sup> The DNA collection from indigenous groups, however, has created a new, much more ethically-charged, dialogue to this decade-old debate.

### *A. The Human Genome Diversity Project*

¶5 The Human Genome Diversity Project (HGDP) served as the catalyst behind the biological testing of indigenous groups. Founded by Luigi Luca Cavalli-Sforza, a population geneticist at Stanford University, and other U.S. scientists, the HGDP “aims to collect blood, skin, and hair samples from hundreds of ethnic groups around the world and use new techniques to preserve genetic information indefinitely.”<sup>11</sup> The HGDP is part of an international movement that wishes to “analyz[e] the structure of human DNA and ascertain[] the location of all human genes by mapping and sequencing the human genome.”<sup>12</sup> Collection of this information is of utmost importance to scientists for the following reasons:

First, thus far the vast majority of detailed research into human genetics has been done with Europeans or North Americans of European descent, and thus omits the eighty percent of the world’s population that is not of European ancestry. It is fundamentally unfair to the majority of humanity to describe the human genome without

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<sup>7</sup> See, e.g., *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

<sup>8</sup> *Greenberg v. Miami Children’s Hospital*, 264 F. Supp. 2d 1064, 1067-68 (S.D. Fla. 2003).

<sup>9</sup> Eric Chen, *Who Owns the Property Rights to Your Genetic Material*, 13 U. BALT. INTELL. PROP. L.J. 1, 2 (2004) (discussing recent state and federal judicial patterns concerning the granting of property rights in human tissue).

<sup>10</sup> *Id.*

<sup>11</sup> DARRELL A. POSEY & GRAHAM DUTFIELD, BEYOND INTELLECTUAL PROPERTY: TOWARD TRADITIONAL RESOURCE RIGHTS FOR INDIGENOUS PEOPLES AND LOCAL COMMUNITIES APP. 1 at 161 (International Development Research Centre 1996), available at [http://www.idrc.ca/openebooks/799-x/#page\\_16](http://www.idrc.ca/openebooks/799-x/#page_16).

<sup>12</sup> Gargano, *supra* note 2, at 5 (critiquing the U.S. patent system because it “does not treat patent applications on human genome sequences any differently than it treats patent applications claiming chemical compositions of matter”).

including a representative sample of all humans. Second, studying human genetic diversity will help us understand better the workings of evolution in humans, including the ways in which culture influences evolution. Third, greater knowledge of human genetic diversity will improve medicine, both because it will advance the study of those genetic diseases found largely in non-European populations, and because genetic variation is basic to better understanding a host of diseases found in all peoples. Finally, studying human diversity will help us uncover our shared human history. Genetic results, when interpreted along with evidence from anthropology, archaeology, history, linguistics, and other fields, will help map human migrations and expansions in prehistoric times.<sup>13</sup>

¶6 HGDP advocates also point out that ethnic groups that in the past have been subjects of genetic testing have welcomed the research. In particular, the Old Order Amish were very concerned about mental health issues within their ethnic group and were thus very cooperative with genetic researchers.<sup>14</sup> Like indigenous populations, “this group is located within a small geographic location” and “is both genetically and culturally homogenous.”<sup>15</sup> The HGDP advocates that participation from *all* groups is essential because “[r]esearch in human genetics is by its nature collective research. One person’s genome is only revealing in the context of the genomes of others.”<sup>16</sup> The individual, the group, and the world all benefit from this information. For instance:

Research into a family or a group of families with a high incidence of a disease may reveal that those families are more likely than average to carry a “flawed” allele of a gene. That information necessarily has implications for every family member, whether she took part in the research or not. She knows that she, her parents, her children, and her other relatives are at a higher risk for this genetic disorder. She will often learn that she can be tested for the disease allele—and so will everyone else, including her potential employers and insurers. The same dynamic is at work in ethnic groups. The fact that sickle cell anemia, for example, is much more common among African-Americans than among European-Americans necessarily provides some probabilistic information about African-Americans who did not

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<sup>13</sup> Henry T. Greely, Symposium: International Health Law, *The Control of Genetic Research: Involving the “Groups Between,”* 33 HOUS. L. REV. 1397, 1414–15 (1997).

<sup>14</sup> *Id.* at 1409.

<sup>15</sup> *Id.*

<sup>16</sup> *Id.* at 1409-10.

take part in the genetic tests. Information about groups has implications for all the members of those groups.<sup>17</sup>

### B. Indigenous Peoples

¶7 Indigenous populations have seen the seemingly commendable goals of the HGDP in a different light. Although the project's goals suggest that "hundreds of ethnic groups" will be tested, the result has been that "peoples to be investigated are very small indigenous groups chosen in part because of their endangered situation."<sup>18</sup> Many groups view the project as a new type of "biocolonialism."<sup>19</sup> Isolated indigenous groups have become an ever-limited and rare "source" for the research community.<sup>20</sup> Members of indigenous groups loathe this characterization and feel exploited for their biological resources, recognizing that "the presence of company scientists on medical teams—drawing blood as they provided services—represented the growing corporate interest in their genes."<sup>21</sup>

¶8 Indigenous groups also resent that their tribes have yet to reap any benefit for such invasive testing and have begun to "demand equitable compensation."<sup>22</sup> Equitable compensation could be given in the simplest form, such as money, or it could just mean that the results of the testing benefit the community from which samples were taken. However, neither of these forms of compensation is being used. This is largely due to the fact that the original goals of the HGDP were indifferent to benefiting the subjects of the test. The HGDP began its research with a purely scientific focus, stating that "[t]he purpose of the research is ultimately to add to the body of scientific knowledge without focusing on the needs of a specific community."<sup>23</sup> The subjects of the tests are only considered "necessary to provide data, and [are] rarely involved in the research development."<sup>24</sup> Biomedical results were not meant to be used for, or returned to, the

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<sup>17</sup> *Id.* at 1411.

<sup>18</sup> POSEY & DUTFIELD, *supra* note 11, at 161.

<sup>19</sup> Dorothy Nelkin, Symposium: Legal and Ethical Issues in Genetic Research on Indigenous Populations, *A Brief History of the Political Work of Genetics*, 42 JURIMETRICS J. 121, 127 (2002).

<sup>20</sup> Laura S. Underkuffler, *Human Genetic Studies: The Case for Group Rights*, J.L. MED. & ETHICS (forthcoming Spring 2006) (manuscript at 11, on file with author).

<sup>21</sup> Nelkin, *supra* note 19, at 127.

<sup>22</sup> *Id.*

<sup>23</sup> Laura Arbour & Doris Cook, *DNA on Loan: Issues to Consider when Carrying out Genetic Research with Aboriginal Families and Communities*, COMMUNITY GENETICS 3 Vol. 319, (2006), available at <https://courses.washington.edu/phg580/readings/CMG319%252Epdf.pdf>.

<sup>24</sup> *Id.*

participants.<sup>25</sup> In fact, the individual subjects who participated in the research were kept anonymous.<sup>26</sup>

¶9 Finally, there is concern as to whether indigenous populations, as groups, have any rights or liberties at all to stand against the biological testing being conducted. Under American jurisprudence, group rights “are generally ignored.”<sup>27</sup> The genetic testing of indigenous groups, however, raises many group issues because the results of the tests often present very specific information about the “ill health” of the entire tribe, which can cause panic and fear within the group, as well as bestow upon the entire group a certain “stigmatization” that can lead to “discrimination by third parties, who act on the prejudices and predictions that this information may arouse.”<sup>28</sup> Also, many of these groups believe that their genetic materials “hold traditional and spiritual significance.”<sup>29</sup> A Native American geneticist, Dr. Frank Dukupoo, has stated that “[f]or an Indian, it’s not just DNA, it’s part of a person, it is sacred, with deep religious significance. It is part of the essence of a person.”<sup>30</sup>

¶10 This opposition was not anticipated by HGDP scientists.<sup>31</sup> Researchers never foresaw that their work, which they believed would benefit everyone in the world in some sense, would raise such ethical issues. Although researchers stated that the HGDP would be carried out in the general “interests” of indigenous peoples (i.e. it would “immortalize vanishing peoples”), it appears as though those “interests” had nothing to do with the actual desires of the research subjects.<sup>32</sup> Furthermore, “[t]he research became a lightning rod for broader concerns about the exploitation of developing countries and their resources.”<sup>33</sup> The scientific goals of the HGDP have been muddled with ethically-loaded questions such as whether “the blood taken for this research [was] intended for the purpose of improving health or for the purpose of patents and profits.”<sup>34</sup> HGDP scientists have lost sight of the deeper implications of their work, and

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<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> Underkuffler, *supra* note 20, at 6 (noting that “whether we are speaking of private wrongs or wrongs by the government, it is generally assumed...that it is the individual who is the focus of concern”).

<sup>28</sup> Underkuffler, *supra* note 20, at 19.

<sup>29</sup> Arbour & Cook, *supra* note 23, at 3.

<sup>30</sup> *Id.* at 3 (quoting *Indigenous People, Genes and Genetics: What Indigenous People Should Know about Biocolonialism*. A Primer and Resource Guide. Nevada, Indigenous Peoples Council on Biocolonialism (2000), available at <http://www.ipcb.org/publications/primers/index.html>).

<sup>31</sup> Nelkin, *supra* note 19, at 128.

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

“critics believe the research [is] only exploiting indigenous people, intervening in their heritage, families, communities, and nations.”<sup>35</sup>

## II. INTELLECTUAL PROPERTY OVER DATA COLLECTED

¶11 The USPTO, despite the erupting public controversy, has actually encouraged “patents on newly discovered, naturally occurring genes, DNA fragments, proteins, and other biochemicals in contravention of long established principles of patent law.”<sup>36</sup> The USPTO’s Director of Biotechnology Examination, John Doll, declared that genetic and DNA sequencing should be patented for the following reasons:

Without the incentive of patents, there would be less investment in DNA research, and scientists might not disclose their new DNA products to the public. Issuance of patents to such products not only results in the dissemination of technological information to the scientific community for use as a basis for further research, but also stimulates investment in the research, development, and commercialization of new biologics. It is only with the patenting of DNA technology that some companies, particularly small ones, can raise sufficient venture capital to bring beneficial products to the marketplace or fund further research. A strong U.S. patent system is critical for the continued development and dissemination to the public of information on DNA sequence elements.<sup>37</sup>

¶12 Critics of this approach, however, demand “an explanation as to how chemicals found in the human body can be ‘inventions’ under the positive law of patents.”<sup>38</sup> Clearly a patent application involving the human body varies greatly from, say, patent applications involving software or an electronic device. Currently, however, the USPTO does not demand separate patent application requirements.

¶13 Two U.S. patents, in particular, shed light on the need for government involvement in curbing patent applications. The first effort to patent the genetic sequences revealed from the testing of indigenous groups was the Guayami patent. A Guayami woman, who belongs to an indigenous group in Panama, was said to have been “illiterate and unschooled” yet

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<sup>35</sup> *Id.*

<sup>36</sup> Linda J. Demaine & Aaron X. Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 304-05 (2002) (critiquing how the USPTO has started a spreading trend in “acclaiming the patentability of naturally occurring biochemicals after ‘isolation and purification’”).

<sup>37</sup> *Id.* at 304-05 (citing John J. Doll, *The Patenting of DNA*, 280 SCIENCE 689 (1998)).

<sup>38</sup> *Id.* at 305.

allegedly gave “‘informed oral consent’ to the research, even though neither the tribe nor the woman knew anything about the development of the cell line or the patent application.”<sup>39</sup> This patent application was “filed on behalf of the Department of Commerce, published as PCT application WO92/08784 on May 29, 1992 and directed to ‘Human T-Lymphotropic Virus Type II from Guayami Indians in Panama.’”<sup>40</sup>

¶14 As a result of the patent application, the President of the Guayami General Congress wrote a letter to the U.S. Secretary of Commerce.<sup>41</sup> First, the letter “demand[ed] that the application be withdrawn because it had been made without consultation with the Guayami community or its traditional organizations.”<sup>42</sup> Second, the letter asserted that “this is not an invention but rather a discovery of an antibody which is part of the blood of a Guayami woman.”<sup>43</sup> The letter also queried what, if any, benefits the Guayami people would gain from the proposed patent application.<sup>44</sup> As a result of this protest from the Guayami leadership as well as from the Rural Advancement Foundation International (RAFI) and numerous public interest groups, the patent was withdrawn.<sup>45</sup>

¶15 The United Nations (UN) also responded to the Guayami patent with a “Draft Declaration on the Rights of Indigenous Peoples . . . including human genetic materials as cultural property that indigenous populations are entitled to control.”<sup>46</sup> The UN supported a view, as taken up by many protestors, that individuals should have property rights in their biological material and should not be forced to comply with the whims of researchers when it comes to the human body.<sup>47</sup>

¶16 In response to, and slightly rejecting, the UN’s stance that indigenous people should have control over their genetic material, Henry

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<sup>39</sup> David E. Winickoff, *Governing Population Genomics: Law, Bioethics, and Biopolitics in Three Case Studies*, 43 JURIMETRICS J. 187, 200 (2003). (examining three case studies as exemplary of changes in population genomics, including “the Human Genome Diversity Project, Iceland’s Health Sector Database, and ‘Clinical Genomics’ as defined by the Beth Israel-Ardais collaboration”).

<sup>40</sup> Kate H. Murashige, *Patent Protection for Biotechnology*, 382 PLI/PAT 473, 476 (1994) (commenting on the environmental and socioeconomic impact of biotechnology “inventions”/patents).

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> *Id.* (quoting the actual letter).

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* See also Alternative Law Forum—TRIPS, Indigenous Knowledge and the Bio-rush, <http://altlawforum.org/PUBLICATIONS/document.2004-12-18.1352831511> (last visited May 11, 2006).

<sup>46</sup> Demaine & Fellmeth, *supra* note 36, at 438.

<sup>47</sup> *Id.*

Greely, a Stanford Law professor as well as chair of an ethics subcommittee for HGDP, protested that “the idea that the U.S. government owns the person or his genetic material is absolute rubbish . . . . [T]he donors involved can continue, obviously, to use their own DNA to run their bodies.”<sup>48</sup> Greely believes that once separated from the body, the genetic material of indigenous people no longer shares a relationship with the body that it was taken from. This view does not assuage concerns regarding the “prevalent popular belief that ownership of another person’s genetic material invades that person’s privacy; violates his or her bodily integrity, often for purposes of economic exploitation; and offends his or her human dignity.”<sup>49</sup>

¶17 The second controversial claim for intellectual property over an indigenous person’s biological material concerns the Hagahai<sup>50</sup> patent. Here, biomedical researchers successfully “patented the T-lymphotropic virus found in blood of the Hagahai people in Papua New Guinea, believing that it could be developed into a diagnostic tool or vaccine for certain types of leukemia.”<sup>51</sup> The scientists who filed the Hagahai patent claimed to have “negotiated a profit-sharing agreement with the Hagahai, a tribe that had had no contact with outsiders until 1984, when some tribe members sought help for an illness that afflicted the group.”<sup>52</sup> Public interest groups were outraged. RAFI described the incident as an egregious act of “biopiracy” and human “bioprospecting.”<sup>53</sup>

¶18 Despite the public outcry, the USPTO granted the application for the Hagahai patent to the National Institute of Health (NIH). The patent application apparently met the congressionally established “invention” requirement.<sup>54</sup> The patent application read as follows:

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<sup>48</sup> *Id.*

<sup>49</sup> *Id.*

<sup>50</sup> Patricia A. Lacy, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 794–95 (1998) (“The Hagahai are a 260-member, hunter-horticulturist group which first made sustained contact with government and missionary workers in 1984. The Hagahai are of particular interest to the NIH because tribe members carry the gene that predisposes humans to leukemia, yet they do not manifest symptoms of the illness.”)

<sup>51</sup> Winickoff, *supra* note 39, at 201.

<sup>52</sup> *Id.*

<sup>53</sup> *Id.*

<sup>54</sup> Lacy, *supra* note 50, at 796 (“The U.S. Constitution establishes the basis for protecting invention in the United States: ‘To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ Patent law has interpreted the framers’ use of ‘Discoveries’ to refer to ‘invention,’ as in discoveries requiring human innovation. More recently, biotechnology has blurred the distinction between ‘discovery’ and ‘invention.’”)

[T]he present invention relates to a vaccine for humans against infection with and diseases caused by HTLV-I (Human T-Lymphotropic Virus) and related viruses comprising a non-infectious antigenic portion of the PNG-1 variant, in an amount sufficient to induce immunity against said infection and disease, and a pharmaceutically acceptable carrier.<sup>55</sup>

¶19 It appears as though biological material taken from human beings can, in fact, constitute a patentable invention. In fact, the Supreme Court laid out the lax test for patenting biological material in *Diamond v. Chakrabarty*<sup>56</sup> where the majority supported the notion that “anything under the sun that is made by man” constitutes patentable subject matter as long as there is a “human-made aspect” to it.<sup>57</sup> In the end, the Hagahai patent produced little financial award for its owners, and the rights to the patent were abandoned.<sup>58</sup>

### III. THE RESPONSIBILITIES OF THE U.S. PATENT OFFICE

¶20 Although the patenting of biological resources has existed for the last ten years, the USPTO has failed to modify how it reviews patents involving genetic resources. Scholars currently believe there is virtually *no review at all*.<sup>59</sup> U.S. Senator Mark O. Hatfield has voiced his concern for such inaction, noting that “the underlying ethical decisions related to the developments in biomedicine transcend our . . . patent laws,” and not only do they transcend our patent laws, but “they transcend our national borders,” as is the case with the biological research of indigenous peoples.<sup>60</sup> Researchers are rushing to patent human genome sequences. Consider the fact that on just one day “the National Institute of Health (NIH) filed patent applications on 2300 gene fragments,” which is surprising considering that “the Patent and Trademark Office (PTO), aided only by centuries old patent law, could offer such protection.”<sup>61</sup> One would think that the patenting of genetic material extracted from human beings “is more than a technical or legal question of patentability.”<sup>62</sup> To date, it looks like the USPTO has failed to implement any type of formal ethical review process of patent applications. The floodgates remain open for patent application regarding

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<sup>55</sup> Lacy, *supra* note 50, at 794 (quoting U.S. Patent No. 5,397,696 (filed Aug. 12, 1991)).

<sup>56</sup> 447 U.S. 303.

<sup>57</sup> *Id.* at 309 n.3.

<sup>58</sup> Winickoff, *supra* note 39, at 200.

<sup>59</sup> Email from Arti Rai, Professor of Law, Duke University School of Law (Feb. 7, 2006) (on file with author).

<sup>60</sup> Mark O. Hatfield, *From Microbe to Man*, 1 ANIMAL L. 5, 6 (1995).

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

genes from the human body. As a result of this failure, Senator Hatfield advocated the following to Congress:

The USPTO has no way of dealing with the various moral, international, economic and environmental questions which arise from the patenting of human genes, cells, and organs, or the patenting of genetically engineered animals. Careful consideration and examination has not taken place in the case of the genetic alteration and patenting of human genes and body parts, or in the case of the creation and patenting of transgenic animals. In each session of Congress since 1987, I have introduced legislation to place a moratorium on allowing the Patent and Trademark Office to issue patents on living organisms.<sup>63</sup>

¶21 Some groups, however, are taking action, including the HGDP. In response to the public dismay at the Hagahai and Guayami patent applications, the North American Regional Committee of the Diversity Project of the HGDP developed a “Proposed Model Ethical Protocol (MEP) For Collecting DNA Samples.”<sup>64</sup> Although nothing like this has been implemented by the USPTO, the HGDP’s own efforts have helped to curb patent applications in the U.S. and address *some* of the ethical issues at stake. The MEP has inserted a new ideology into their work, stating that “the research must ‘not only [do] no harm to the participating communities, but, where possible, bring them benefits.’”<sup>65</sup> This has been a shift from what much of the public considered as a dispassionate view on research subjects. Further, the MEP states that the HGDP itself “‘will not profit from any commercial uses of samples it gathers or knowledge derived from those samples’ and that the HGDP ‘has vowed to ensure that, should commercial products be developed as a result of the HGDP’s collections, a fair share of the financial rewards shall return to the sampled populations.’”<sup>66</sup> Dr. David E. Winickoff suggests three possible ways in which these requirements can be satisfied as set out by the Protocol:

- (1) researchers could not “make use of the HGDP’s samples or data in a patent application or a commercial product without the express written permission of the sampled populations involved, . . . subject to whatever conditions they impose for that permission;”
- (2) “anyone making commercial use of the HGDP’s samples would pay a set percentage royalty . . . for the benefit of the sampled populations;” and
- (3) “anyone making commercial use of the HGDP’s samples or data

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<sup>63</sup> *Id.*

<sup>64</sup> Winickoff, *supra* note 39, at 197.

<sup>65</sup> *Id.* at 200 (quoting Symposium, *Proposed Model Ethical Protocol for Collecting DNA Samples*, 33 HOUS. L. REV. 1431, 1436 (1997)).

<sup>66</sup> *Id.* at 200-01 (quoting Symposium, *Proposed Model Ethical Protocol for Collecting DNA Samples*, 33 HOUS. L. REV. 1431, 1466-67 (1997)).

would have to negotiate a reasonable financial payment with a trustee for the sampled populations, with the proceeds for the population's benefit."<sup>67</sup>

¶22 Although the HGDP has not vowed to stop its research altogether, it does aim to “stick to science”—that is, it is making it clear that it is not in it for its profit potential. However, this MEP does not rule out commercial uses of the research. In essence, the HGDP is trying to rid *itself* of the moral implications of profiting from collected biological material. This act essentially places an even greater responsibility on the USPTO. With the HGDP's MEP washing its hands clean of the possible uses of its research, the USPTO now stands even more alone as a potential barrier to patents involving the genetic materials of indigenous peoples. In its MEP, the HGDP also agrees that if profits do result from the research that it will attempt to return some of those financial gains to indigenous groups. This MEP, however, does not come close to addressing some of the “property” issues at stake (i.e. is there a property interest either individually or collectively in human genetic material at all?). Nor does it consider the sacred value that many indigenous groups place on the biological matter which is being taken from them.

¶23 The USPTO has yet to implement its own Model Ethical Protocol or any procedure of “ethical review.”<sup>68</sup> One scholar, Nuno Pires de Carvalho, proposed a rather novel “re-engineering” of the law concerning biotechnology patents.<sup>69</sup> In particular, he suggests that the government should implement, as a requisite for patentability, the “requirement that applicants for patents in the field of biotechnology disclose the source of the genetic resources eventually used as raw materials or tools in the inventive activity”<sup>70</sup> (“Carvalho Requirement”). He also suggests that evidence, if any, of informed consent from the research subjects be included in the application.<sup>71</sup> However, what should constitute proper informed consent and how scientists should go about getting it is still very controversial.<sup>72</sup>

¶24 The Carvalho Requirement has already been integrated into two foreign statutes: “Andean Decision No. 391 of August 16, 1996, which

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<sup>67</sup> *Id.*

<sup>68</sup> Rai, *supra* note 59.

<sup>69</sup> 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).

<sup>70</sup> *Id.* at 374.

<sup>71</sup> *Id.*

<sup>72</sup> Winickoff, *supra* note 39, at 197 (discussing recent “innovations in informed consent” such as the use of “group consent” and accompanying criticism of such novel uses).

establishes a Common Regime on Access to Genetic Resources; and the Biodiversity Law (No. 7788) of Costa Rica enacted May 27, 1998.”<sup>73</sup> Both of these laws require patent applicants to describe, in detail, the following: “information concerning the origin of the genetic resource in question and some proof of prior informed consent from government authorities as well as traditional knowledge holders, whenever the resource will be obtained through their technical knowledge.”<sup>74</sup> Furthermore, the Carvalho Requirement is expected to be proposed to the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO), and there has already been a proposed amendment to Article 29 of the TRIPS Agreement.<sup>75</sup>

¶25 It appears as though the international community has started to recognize the lack of oversight in biological patents. For instance, when the WIPO Standing Committee on the Law of Patents convened in 1999, Colombia proposed some very ethically-conscious language to be included in the proposed Patent Law Treaty:

1. All industrial property protection shall guarantee the protection of the country’s biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof where the goods or services for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.<sup>76</sup>

¶26 Carvalho considers the Colombian proposal to be a more “substantive” requirement than his proposal in that the Carvalho Requirement “concerns information that does not relate directly to the activity of inventing” and it “does not characterize the invention itself.”<sup>77</sup> Rather, he refers to the Carvalho Requirement as an “accessory” not unlike other requirements found within a patent application such as “where the invention was invented as part of the work performed under a contract with the government” and the applicant must provide “any document containing a statement which indicates any government licensing rights in the

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<sup>73</sup> Carvalho, *supra* note 69, at 375-76 (citing Common Regime on Access to Genetic Resources, Andean Decision No. 391, Andean Community of Nations (July 2, 1996); Article 81 of the Biodiversity Law of Costa Rica).

<sup>74</sup> Carvalho, *supra* note 69, at 376.

<sup>75</sup> *Id.* at 376-77.

<sup>76</sup> *Id.* at 377.

<sup>77</sup> *Id.* at 377-78.

invention and identifies the government contract.”<sup>78</sup> What both the Carvalho Requirement and the Colombian proposal share in common, however, is that each impose a “condition on patentability.”<sup>79</sup> And as with any imposed condition, both of these proposals would make it more challenging for researchers to assert intellectual property rights over biological material collected from indigenous populations.

#### IV. CONCLUSION

¶27 With the advent of a heightened international consciousness concerning the ethical implications of collecting the DNA of indigenous peoples, it would seem as though the USPTO would have taken some sort of step by now to modify the patent application process. Unfortunately, no changes have been made. Rather, the USPTO has approved of what some see as a “patent on a foreign citizen.”<sup>80</sup> This iBrief, by outlining the multifaceted debate on this issue as well as by demonstrating how other countries have chosen to revise their patent application process, hopes to increase public awareness and contribute to the patent reform movement concerning human biological material.

¶28 The above proposals offer some guidance as to how the U.S. might finally implement a procedure of ethical review when faced with biological patents. Even minimal “accessory” changes to the U.S. patent application would create a heightened system of awareness as to the activities being conducted behind the veil of the patent application. Also, they put a burden on the patent applicant herself. Hopefully, the USPTO can start to move towards a more active role in curbing ethically-questionable patent applications, so that not “anything under the sun that is made by man”<sup>81</sup> is patentable, especially when it involves the sacred genetic elements that many indigenous groups believe make up the essence of who they are as people.

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<sup>78</sup> *Id.* at 378.

<sup>79</sup> *Id.*

<sup>80</sup> *Indigenous Person from Papua New Guinea claimed in US Government Patent*, Oct. 4, 1995, <http://www.spunk.org/texts/colon/sp001144.txt>.

<sup>81</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).