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SURPASSING THE MATERIAL:¹ THE HUMAN RIGHTS IMPLICATIONS OF INFORMED CONSENT IN BIOPROSPECTING CELLS DERIVED FROM INDIGENOUS PEOPLE GROUPS

INTRODUCTION

From the time man and woman first walked in the Garden of Eden, the world's resources have lain at their feet.² Although they soon erected city walls and drew country borders, human beings used natural resources with generous liberality, considering all flora³ and fauna⁴ their rightful inheritance. Using this principle, called the Common Heritage of Humankind,⁵ biological diversity prospectors,⁶ or bioprospectors, plunder the genetic wealth of the world's resources. With the rapid development and far-reaching effects of technology, biological diversity⁷ has suffered

1. Ovid described the transformative effect of fantastical artwork on simple walls with the words “[m]aterialiam superbat opus” (the workmanship surpassed the material). THOMAS BULFINCH, BULFINCH’S MYTHOLOGY 41, 333 (The Modern Library 1998) (1855). Considering how human cell research invariably provokes questions about the human condition, the description is an apt one in this context.

2. God said:

I give you every seed-bearing plant on the face of the whole earth and every tree that has fruit with seed in it . . . And to all the beasts of the earth and all the birds of the air and all the creatures that move on the ground—everything that has the breath of life in it—I give every green plant for food.

Genesis 1:29-30 (New International Version).

3. Flora denotes “[p]lants as a whole, [especially] those of a specific region or season.” WEBSTER’S II NEW RIVERSIDE DICTIONARY 269 (2d ed. 1984).

4. Fauna denotes “[a]nimals as a group, [especially] of a given time or region.” *Id.* at 254.

5. See *infra* note 26 and accompanying text (describing the Common Heritage of Humankind and its role in an international context). See *infra* note 27 and accompanying text (arguing that humankind has an inherent interest in the world’s genetic resources).

6. Biodiversity prospectors are scientists who extract valuable cells from the biodiverse flora and fauna of developing countries to further scientific research and manufacture commercially viable products. Biodiversity prospecting, or bioprospecting, is the collection of biologically diverse resources. See Christopher J. Hunter, *Sustainable Bioprospecting: Using Private Contracts and International Legal Principles and Policies to Conserve Raw Medicinal Materials*, 25 B.C. ENVTL. AFF. L. REV. 129, 131 (1997).

7. Biological diversity, or biodiversity, is the “variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part . . . includ[ing] diversity within species, between species and of ecosystems.” United Nations Conference on Environment and Development: Convention on Biological Diversity, June 5, 1992, 31 I.L.M. 818, 823 [hereinafter Biodiversity Convention]. See PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW VOL. 1, at 368 (1995) (describing three kinds of biodiversity: genetic diversity, species diversity, and ecosystem diversity); Hunter, *supra* note 6, at 133. See also BIODIVERSITY AND THE LAW xix (William J. Snape III ed.,

from this philosophy.⁸

When it became evident that private companies from developed countries were earning massive profits by exploiting natural resources from developing countries with little or no positive return for the source countries,⁹ the adequate compensation of indigenous people and the preservation of the biodiverse resources of developing countries through sustainable development became an international concern. In response to this concern, the Biodiversity Convention, an agreement that included provisions for the compensation of source countries for the use of their natural resources, entered into force in 1993.¹⁰ A year later, the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), a part of the General Agreement on Tariffs and Trade (GATT) Multilateral Trade Negotiations known as the Uruguay Round,¹¹ provided significant measures to encourage world trade through progressive intellectual property protection.¹²

This Note addresses the role of informed consent and adequate compensation in the problematic practice of patenting cell-lines derived

1996) (stating simply that “biodiversity is life”).

8. See discussion *infra* Part I.A (giving examples of U.S. biotechnology companies which extracted the genetic resources of developing countries and indigenous people groups without adequate compensation).

9. See Hunter, *supra* note 6, at 139. The exploitation of indigenous people groups includes the uncompensated use of indigenous knowledge as well as the extraction of plant, animal, and human cells for scientific research purposes. *Id.* See also Laurie Anne Whitt, *Indigenous Peoples, Intellectual Property & the New Imperial Science*, 23 OKLA. CITY U. L. REV. 211 (1998) (characterizing the commodification of cell-lines derived from indigenous peoples as biocolonialism, a “means of extending empire” through the privatization of genetic property). This Note focuses on the uncompensated use of human cells derived from indigenous people groups.

10. Biodiversity Convention, *supra* note 7. See discussion *infra* Part III (regarding inability of the Biodiversity Convention to adequately address the informed consent issue of U.S. biotech companies who extract cells from indigenous people groups).

11. General Agreement on Tariffs and Trade—Multilateral Trade Negotiations (The Uruguay Round): Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Dec. 15, 1993, 33 I.L.M. 81 [hereinafter TRIPS Agreement]. See discussion *infra* Part III (addressing the utility of international intellectual property rights protection versus that of human rights legal instruments with regard to safeguarding bioprospecting activities on indigenous people groups).

12. See Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255 (1998) (discussing the fundamental conflict between the Biodiversity Convention and the TRIPS Agreement in protecting the world’s resources). The TRIPS Agreement sets minimum procedural standards of intellectual property enforcement and prescribes national treatment. Under the TRIPS Agreement, nations have the obligation to extend the same kind of intellectual property protection to foreigners as is given to their own nationals. INTERNATIONAL INTELLECTUAL PROPERTY ANTHOLOGY 9 (Anthony D’Amato & Doris Estelle Long eds., 1996). See also TRIPS Agreement, *supra* note 11, at art. 3 (providing for national treatment, the requirement that a state party extend the same intellectual property protection to members of other state parties that it extends to its own nationals).

from indigenous people groups of developing countries. In its discussion, this Note maintains that the international intellectual property protection afforded by the Biodiversity Convention and the TRIPS Agreement are not sufficient to protect indigenous people groups from bioprospectors who fail to obtain informed consent. These bioprospectors subject the members of indigenous people groups to the indignities of involuntary commodification, thereby infringing fundamental human rights.¹³ Consequently, this Note proposes that the United States enact domestic legislation in order to implement its human rights obligations under various international law instruments to which it is a party.¹⁴ Instead of sacrificing the dignity of human beings for economic gain, the United States would make a valuable contribution toward establishing a *jus cogens* norm¹⁵ safeguarding the rights of indigenous people groups subjected to bioprospecting activities.¹⁶

Part I of this Note addresses the background and history of bioprospecting, including the development of property rights in human genetic resources, the utility of cell-lines derived from human cells, and the mechanics of the patenting process. This section also includes a historical treatment of the growing implications of bioprospecting. Part II discusses the Biodiversity Convention and the TRIPS Agreement. Part III

13. See discussion *infra* Part V (addressing how a lack of informed consent violates the fundamental human rights contained in various international legal instruments). See also text accompanying note 113.

14. See Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. GAOR, 3d Sess., pt. 1, at 71, U.N. Doc. A/810 (1948) [hereinafter Universal Declaration]; Charter of the Organization of American States, Apr. 30, 1948, 2 U.S.T. 2394, 119 U.N.T.S. 3 [hereinafter OAS Charter]; American Declaration of the Rights and Duties of Man, O.A.S. Res. XXX, OEA/Ser.L/V/I.4 Rev. (1965) [hereinafter American Declaration]; International Covenant on Civil and Political Rights, Dec. 19, 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 (entered into force for the United States Sept. 8, 1992) [hereinafter ICCPR]; International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3, 6 I.L.M. 360 [hereinafter ICESCR]; U.N. CHARTER. See discussion *infra* Part V.

15. A *jus cogens* norm is a peremptory, nonderogative norm that has the force of supreme law. Also known as customary international law, *jus cogens* status arises from (1) state practice, and (2) the fact that states practice this norm because they believe it is the law. See RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 102 (1987) (describing the sources of international law, which include customary international law, international agreements, and general principles). Customary international law cannot be derogated by treaty, and states are automatically bound without state practice or consent. See LOUIS HENKIN ET AL., HUMAN RIGHTS 355 n.4 (1999).

16. But see Lt. Martin A. Harry, *The Common Heritage of Mankind or Arena for Unilateral Exploitation?*, 40 NAVAL L. REV. 207, 207-08 (1992) (noting that the Common Heritage of Humankind has a *jus cogens* status in a number of developing countries). However, given the strenuous objections of indigenous people groups to the practice of bioprospecting human cells, it is likely that the Common Heritage of Humankind *jus cogens* norm in certain developing countries does not encompass human genetic resources. See discussion *infra* Part IV.B (addressing concerns of indigenous people groups that bioprospecting activities threaten cultural values and concepts of individual sovereignty).

explores *Moore v. Regents of the University of California*¹⁷ and its implications for property rights of human genetic resources. Part IV addresses the Human Genome Diversity Project (HGDP) and the surrounding controversy. This section includes the background of the HGDP, as well as its Model Ethical Protocol, the instrument that the HGDP uses to obtain informed consent from indigenous people groups before extracting their cells. Part V discusses the United States' obligation to adhere to various human rights instruments in order to safeguard fundamental human rights. This section will include descriptions of the Universal Declaration of Human Rights,¹⁸ the Charter of the Organization of American States,¹⁹ the American Declaration of the Rights and Duties of Man,²⁰ the International Covenant of Civil and Political Rights,²¹ the International Covenant of Economic, Social and Cultural Rights,²² and the Charter of the United Nations.²³ Finally, Part VI of this Note proposes that the United States enact legislation patterned after the HGDP Model Ethical Protocol in compliance with its human rights obligations under various international instruments in order to safeguard the fundamental human rights contained therein.

I. BACKGROUND AND HISTORY

A. *The Development of Property Rights in Human Genetic Resources*

The expansion of the biotechnology²⁴ industry escalated research in the biotech field, thereby increasing the measure of bioprospecting activities.²⁵ Under the principle of the Common Heritage of Humankind,²⁶

17. 793 P.2d 479 (Cal. 1990).

18. Universal Declaration, *supra* note 14.

19. OAS Charter, *supra* note 14.

20. American Declaration, *supra* note 14.

21. ICCPR, *supra* note 14.

22. ICESCR, *supra* note 14.

23. U.N. CHARTER.

24. Biotechnology encompasses "any process in which organisms, tissues, cells, organelles, or isolated enzymes are used to convert biological or other raw materials to products of greater values, as well as the design and use of reactors, fermenters, downstream processing, analytical and control equipment associated with biological manufacturing processes." J. COOMBS, *DICTIONARY OF BIOTECHNOLOGY* 45 (1989).

25. See Daniel L. McKay, *Patent Law and Human Genome Research at the Crossroads: The Need for Congressional Action*, 10 SANTA CLARA COMPUTER & HIGH TECH. L.J. 465 (1994).

26. The Common Heritage of Humankind is a principle that has been applied to "deep seabeds, Antarctica, and the Moon and other celestial bodies and certain worldwide historical sites" that gives all of humanity the benefit of use through the recognition that the "genome is integral to every human being." Melissa L. Sturges, *Who Should Hold Property Rights to the Human Genome? An Application*

bioprospectors are free to exploit natural resources because, in the end, their actions benefit the whole world.²⁷ The practice of bioprospecting is not limited to plant and animal resources; researchers have also patented cell-lines derived from excised human cells of indigenous people groups.²⁸ An example of cell extraction from indigenous people occurred in 1989 when scientists removed cells from twenty-four members of the Hahawai tribe, located in Papua New Guinea, and discovered that a cell-line derivation could have potential value in “diagnosing adult leukemia and chronic degenerative neurologic disease.”²⁹ The scientists submitted a patent application for the blood samples they derived from the tribe members.³⁰

Indigenous people groups are communities who “share customs and local knowledge of specific geographic territory and are relatively independent of, or have little contact with, the dominant national society of the country in which they live.”³¹ They are often the targets of scientific

of the Common Heritage of Humankind, 13 AM. U. INT'L L. REV. 219, 223, 247-48 (1997). The United Nations has applied this principle under the rationalization that such “environmentally vulnerable sites” are not the sole subject of domestic sovereignty. *Id.* at 248. See also Lt. Martin A. Harry, *The Deep Seabed: The Common Heritage of Mankind or Arena for Unilateral Exploitation?*, 40 NAVAL L. REV. 207, 207-08 (1992) (stating that the Common Heritage of Humankind has a *jus cogens* status in a number of developing countries).

27. Sturges argues that because the Common Heritage of Humankind confers a property right to all of humankind with regard to the genome of natural resources, the principle must also apply with regard to the human genome. See Sturges, *supra* note 26, at 223-24. See also Jeremy Rifkin, *The Biotech Century: Human Life as Intellectual Property*, THE NATION, Apr. 13, 1998, at 11 (describing the argument by nongovernmental organizations and countries that the “gene pool ought not to be for sale at any price—that it should remain an open commons and continue to be used freely by present and future generations”).

28. The exploitation of ethnobiological knowledge is an additional concern. Ethnobiological knowledge is the painstaking culmination of information about indigenous plants and animals passed down from generation to generation. It has been suggested that the use of ethnobiological knowledge on the part of bioprospectors should fall under trade secret laws in order to safeguard the rights of the indigenous people in this matter. See McManis, *supra* note 12.

29. Hunter, *supra* note 6, at 139.

30. *Id.*

31. Edith Brown Weiss, IN FAIRNESS TO FUTURE GENERATIONS: INTERNATIONAL LAW, COMMON PATRIMONY, AND INTERGENERATIONAL EQUITY 264 (1990). See also Naomi Roht-Ariaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH. J. INT'L L. 919, 921 (1996) (suggesting three frameworks to end “appropriation of indigenous and local communities’ knowledge and resources,” including “broadened and redefined intellectual property regimes, private contracts between communities or States and ‘bioprospectors,’ and expansion of the concept of ‘farmers’ rights’ to provide both compensation and control to indigenous and local communities”). See generally Russel Lawrence Barsh, *Indigenous Peoples: An Emerging Object of International Law*, 80 AM. J. INT'L L. 369 (1986) (describing the difficulty of the members of The Working Group on Indigenous Populations, “an organ of the United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities,” to define “indigenous populations”).

research because the relative isolation of the communities ensures minimal gene flow.³² In another case, a San Diego biotech company collected cells from an island population on Tristan da Cunha, where over half of the people were asthmatics.³³ Boehringer Ingelheim, a German company, funded the research and purchased the resulting patent for \$70 million.³⁴ Here, the inhabitants of the island of Tristan da Cunha were not considered indigenous, but the relative isolation of the population conferred the same kind of cell value from the perspective of the San Diego biotech company.³⁵

In *Diamond v. Chakrabarty*,³⁶ the United States Supreme Court made its first decision regarding patenting living organisms and held that a live human-made microorganism is patentable subject matter.³⁷ A decade later, the California Supreme Court faced the weightier issue of property rights in human cells in the landmark case, *Moore v. Regents of the University of California*.³⁸ Fully conscious of the implications of the issue, the court did

32. Genetic drift is a phenomenon composed of “irregular (random) fluctuations in gene frequency in a population from generation to generation due to finite population size (in ‘effectively’ small populations whose effective breeding size either remains small or periodically becomes small) or randomly fluctuating selection intensities.” R. RIGER ET AL., GLOSSARY OF GENETICS: CLASSICAL AND MOLECULAR 209 (5th ed. 1991). Gene flow is the movement of genes among populations, caused by movement of individuals prior to reproduction. *Id.* at 195. Therefore, gene flow can increase genetic variability in the population. Recombination, the phenomenon that occurs when differing genomes combine, results in ambiguous genetic markers, thereby making it difficult to track evolutionary lines. *See id.* at 411-12. Therefore, scientists value the relative isolation of indigenous people groups, where the minimal gene flow preserves a certain genetic marker. *See generally* Kara H. Ching, Note, *Indigenous Self-Determination In an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm*, 66 FORDHAM L. REV. 687 (1997).

33. *Asthma-Related Gene Found in Study on Small Island, Firm Says*, L.A. TIMES, May 21, 1997, at A18.

34. *Id.* *See also* Paul Salopek, *Genes Offer Sampling of Hope and Fear*, CHI. TRIB., Apr. 28, 1997, at 8.

35. Ching, *supra* note 32, at 687 n.1.

36. 447 U.S. 303 (1980). A microbiologist filed a patent claim on human-made, genetically engineered bacteria capable of breaking down multiple components of crude oil, a capability possessed by no naturally occurring bacteria. *Id.* at 303. The United States Supreme Court held that the bacteria was patentable subject matter because it constituted a “manufacture” or “composition of matter” within the meaning of 35 U.S.C. § 101 (1994), 447 U.S. at 309-10.

37. 447 U.S. 303. The United States Patent and Trademark Office Board of Appeals affirmed the decision of a patent examiner who found that bacteria were living things and therefore not patentable. The United States Court of Customs and Patent Appeals reversed, holding that the fact that microorganisms are alive is not relevant to the characterization of patentable subject matter. The United States Supreme Court affirmed. Justice Brennan was joined by Justices White, Marshall and Powell in his dissent, arguing that Congress had indicated its belief that prior statutes regulating the patenting of plants does not encompass living organisms. *Id.* *See generally* I. Jane Churchill, *Patenting Humanity: The Development of Property Rights in the Human Body and the Subsequent Evolution of Patentability of Living Things*, 8 INTELL. PROP. J. 249 (1994).

38. 793 P.2d 479 (Cal. 1990).

not assign the plaintiff property rights in the patented cell-line derived from his excised cells.³⁹ The court rendered an uneasy decision, finding that the plaintiff's complaint stated "a cause of action for breach of fiduciary duty, or lack of informed consent," but not conversion.⁴⁰

Controversy began anew in 1991 when the Human Genome Diversity Project (HGDP) began to map the cell-lines of the 5,000 linguistically distinguishable people groups in the world.⁴¹ The HGDP's goal to use the collected data for the benefit of all people by "preserv[ing] the record of our genetic heritage"⁴² has been met with hostile reaction by indigenous people groups who fear that the so-called "vampire project"⁴³ will continue the pattern of developed countries feeding off unprotected developing countries.⁴⁴ Several incidents further fueled the controversy, including the United States government's applications for U.S. and international patents on viruses from cell-lines extracted from tribal members.⁴⁵ When foreign governments lodged angry protests against what they perceived to be an invasion of "genetic privacy,"⁴⁶ the United States withdrew its patent applications.

In 1993, a researcher from the National Institute of Health (NIH) extracted a blood sample from a Guaymi Indian woman from Panama.⁴⁷ Upon developing a cell-line, the NIH found that the blood of Guaymi Indians contained a gene that conferred natural resistance to leukemia.⁴⁸

39. *Id.*

40. *Id.* at 485. The Court limited Moore's cause of action for a breach of fiduciary duty to the duty owed by the physician who extracted his cells. Moore had no cause of action against the researchers who developed the cell-line from his extracted cells because there was no contact between Moore and his physicians. *Id.* at 486. *See also* Ching, *supra* note 32, at 702, 704 (stating that "the doctrine of informed consent stems from a doctor's duty to a patient and recognizes the patient's right to self-determination and autonomy").

41. *See* Rifkin, *supra* note 27. *See also* Morrison Institute for Population and Resource Studies, *The Human Genome Diversity Project*, available at <http://www.stanford.edu/group/morrinst/hgdp/summary93.html> (last visited Aug. 29, 2000).

42. *See* Whitt, *supra* note 9, at 221. The scientists involved in HGDP are also anxious to collect data on indigenous people groups in danger of disappearing. *Id.* at 222.

43. *Id.*

44. *Id.* *See also* Debra Harry, *The Human Genome Diversity Project: Implications for Indigenous Peoples*, (March 14, 1995) available at <http://www.hartford-hwp.com/archives/41/024.html> (last visited Aug. 29, 2000) (stating that indigenous groups should "call for a world-wide moratorium on the collection, databasing, transformation, and commercialization of cell lines and genetic materials of Indigenous peoples until international standards and regulation [sic] are put into place which fully protect the environment and the interests of Indigenous peoples").

45. *See* Rifkin, *supra* note 27. *See generally* Roht-Arriaza, *supra* note 31, at 919 (describing examples of biotech corporations from developed countries whose patents of resources indigenous to developing countries brought great economic gain).

46. Rifkin, *supra* note 27.

47. *Id.*

48. *Id.*

When representatives of the Guaymi General Congress in Panama discovered that the United States had filed for both U.S. and international patents on the virus developed from the cell-line, they publicly expressed their opinion against what they considered an invasion of their “genetic privacy.”⁴⁹ The ensuing controversy caused the United States to withdraw its patent applications.⁵⁰

Nevertheless, “gene prospecting” continues, and technological developments have increased the rate of genome mapping greatly.⁵¹ U.S. companies have received broad patents granting ownership rights over human cells, including umbilical cord blood and bone-marrow stem cells.⁵²

B. Utility of Cell-Lines Derived from Human Cells

The utility in developing cell-lines lies in the replicative ability of excised cells.⁵³ Primary cells extracted directly from the body typically

49. *Id.*

50. *Id.*

51. *See id.* On April 6, 2000, Celera Genomics announced that it successfully completed the human genome sequencing phase and was ready to “assemble the sequenced fragments of the genome into their proper order based on new computational advances.” Celera Genomics Completes Sequencing Phase of the Genome from One Human Being, available at <http://www.pecorporation.com/press/prccorp040600.html> (last visited Oct. 31, 2000). *See infra* note 99 and accompanying text (regarding the Human Genome Project (HGP) and the Human Genome Diversity Project (HGDP)). *See also* Kathryn Brown, *The Human Genome Business Today*, SCI. AM., July 2000, at 50; Ken Howard, *The Bioinformatics Gold Rush*, SCI. AM., July 2000, at 58; Sharon Begley, *Decoding the Human Body*, NEWSWEEK, Apr. 10, 2000, at 50.

52. Rifkin, *supra* note 27. *See also* Jennifer Kulynych, *Blood As A Biological “Drug”: Scientific, Legal, and Policy Issues in the Regulation of Placental and Umbilical Cord Stem Cell Transplantation*, 32 U. RICH. L. REV. 407, 410-411 (1998) (recommending that the Food and Drug Administration (FDA) should treat umbilical cord blood as an “investigatory new drug subject to a period of clinical development,” because passing regulatory requirements would not adequately address the “ethical and scientific issues involved in cord blood transplantation”). In 1972, the FDA gained jurisdiction over biologics, or “products derived from living materials—humans, plants, animals, or microorganisms—when such products are used in the treatment or prevention of disease.” *Id.* at 421-22. *See* 37 Fed. Reg. 12,865 (June 23, 1972). After determining that biologics were subject to the same regulatory provisions as applied to drugs or medical devices (Investigational New Drug process), the FDA could require a showing of “clinical effectiveness prior to marketing.” 32 U. RICH. L. REV. at 422-23. However, such an investigation could prove needless if cord blood stem cells are “well-characterized blood products” and not “investigational” drugs. *Id.* at 426. Kulynych states that the unresolved “safety and efficacy” issues necessitate an investigation approach to cord blood products, as protected by the IND process, which includes “qualified investigators, informed consent, institutional review board approval of protocols, and detailed tracking and reporting of clinical outcomes.” *Id.* at 430 (emphasis added). *See also* Stephen R. Munzer, *The Special Case of Property Rights in Umbilical Cord Blood for Transplantation*, 51 RUTGERS L. REV. 493 (1999) (arguing that there should be limited property rights in umbilical cord blood).

53. The human body is composed of cells that contain chromosomes. Every person normally has a total of twenty-three pairs of chromosomes in each cell. Chromosomes contain thousands of genes,

replicate a few times before dying. However, when developed into a culture, cells may replicate indefinitely, thus creating an immortal cell-line.⁵⁴ Therefore, a cell-line allows scientists to continue their research efforts without immediately depleting their supply of genetic material.⁵⁵ Cell-lines also enable scientists to conduct their experiments under controlled circumstances.⁵⁶

C. Mechanics of the Patenting Process

In order to apply successfully for a United States patent, the applicant must fulfill five general requirements: that the invention “[1] falls within the broad category of patentable subject matter, (2) is novel, (3) is non-obvious, (4) has utility, and (5) is adequately disclosed.”⁵⁷

The United States Supreme Court extended patent protection to living microorganisms for the first time in *Diamond v. Chakrabarty*.⁵⁸ Subsequent to that decision, the United States continued to expand the category of patentable subject matter to include DNA sequences of proteins.⁵⁹ The United States Patent and Trademark Office has also issued life patents, which have been upheld by the Supreme Court.⁶⁰

which are the functional units that code hereditary traits. Genes store information in tightly compressed strands of deoxyribonucleic acid (DNA), which is a paired linear sequence of four distinct molecular bases: adenine, thymine, cytosine, and guanine. The human genome is the genetic information in each cell and contains approximately six billion base pairs of DNA. Because humans have approximately six billion base pairs of DNA, decoding the human genome is an ambitious task. Symposium, *Probing the Human Genome: Who Owns Genetic Information?*, 4 B.U. J. SCI. & TECH. L. 2 (1998). See generally Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV. 1037 (1993) (discussing the increasing interest in the human genome). For a more technically descriptive explanation of genetics, see ANTHONY J.F. GRIFFITHS ET AL., AN INTRODUCTION TO GENETIC ANALYSIS (6th ed. 1996); BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL (3d ed. 1994).

54. Moore v. Regents of the University of California, 793 P.2d 479, 481 n.2 (Cal. 1990).

55. See Jean de Vellis, *Ownership of Cell Lines*, 65 S. CAL. L. REV. 697 (1991) (discussing the development and use of cell-lines).

56. See Ching, *supra* note 32, at 690. Goals for genetic research include the detection of genetic defects, the production of proteins for those afflicted with a genetic defect that causes protein production inhibition, and the discovery of cures for general medical diseases. *Id.* at 690-91. See also Geoffrey Cowley & Anne Underwood, *A Revolution in Medicine*, NEWSWEEK, Apr. 10, 2000, at 58 (describing how genetic knowledge could impact medical treatment).

57. McKay, *supra* note 25 at 479. 35 U.S.C. § 101 provides the requirements for patentable subject matter, novelty, and utility. 35 U.S.C. § 102 provides the non-obviousness requirement. 35 U.S.C. § 112 provides the disclosure requirement. *Id.*

58. 447 U.S. 303 (1980).

59. See Ching, *supra* note 32, at 696.

60. See *id.* Life patents include patents on cell-lines derived from humans. *Id.* See McKay, *supra* note 25, at 495 (suggesting that a moratorium on patenting life forms would “create a bright-line rule that would be easy for courts to apply, [but] a ban on such patents might destroy the United States biotechnology industry, which is projected to have world-wide sales in excess of \$100 billion by the

The novelty requirement, the claim that the product has never been made accessible to the general public, necessarily excludes those products that are naturally occurring in the public domain, for example, certain chemical processes in the human body.⁶¹ The product must be non-obvious, that is, it must demonstrate an “inventive step” that makes the product distinguishable from all others.⁶² Additionally, the product must have a useful function,⁶³ a somewhat vague and subjective requirement. Lastly, the inventor must give complete disclosure on how to manufacture the product in order to be granted the right to exclude others from manufacturing the product.⁶⁴

On its face, cell-lines are subject to the United States patent process: the researcher claiming inventorship of the product may disclose the method by which the excised cells were developed into a cell-line, a method that calls for some amount of scientific ingenuity; the uniqueness of the cell-line can be easily proven by its very nature; and functionality can be proven by the resulting scientific data.⁶⁵

D. The Growing Implications of Bioprospecting

The granting of ownership interest in human cells, albeit limited to the twenty-year span of a U.S. patent,⁶⁶ has caused great concern for those who unwittingly donate their cells without fully understanding the implications of their actions.⁶⁷ As bioprospecting activities escalated, it became evident that private companies were gaining massive profits with little or no positive return for the source countries.⁶⁸ The discovery that bioprospectors were extracting cells in order to patent the resulting cell-lines without first obtaining informed consent from the indigenous people promulgated an ideological shift away from the Common Heritage of Humankind philosophy⁶⁹ to a more protective concern for the rights of the

year 2000”).

61. See Symposium, *Probing the Human Genome: Who Owns Genetic Information?*, 4B.U.J. SCI. & TECH. L. 2, ¶ 14 (1998).

62. *Id.* at ¶ 15.

63. See *id.* at ¶ 16.

64. See *id.* at ¶ 12.

65. See JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY, 21-24, 97-107 (Harvard University Press 1996).

66. TRIPS Agreement, *supra* note 11, art. 33.

67. Boyle, *supra* note 65, at 21-24.

68. See *supra* note 9 and accompanying text.

69. See *supra* notes 26-27 and accompanying text (describing the Common Heritage of Humankind principle).

indigenous people groups.⁷⁰

II. THE BIODIVERSITY CONVENTION AND THE TRIPS AGREEMENT

In response to this growing concern over the wanton exploitation of natural resources of developing countries, the United Nations formulated the Convention on Biological Diversity (Biodiversity Convention). Entering into force in 1993, the Biodiversity Convention includes provisions compensating source countries for the use of their natural resources. Constructed out of a concern for the conservation of natural resources, the Biodiversity Convention primarily addresses bioprospecting activities involving plants, animals, and microorganisms.⁷¹ A year later, the United Nations formulated the Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The TRIPS Agreement seeks to promote world trade by regulating international intellectual property rights⁷² and nation-to-nation agreements to protect the rights of indigenous people groups.

Under Article 1 of the Biodiversity Convention, the Convention's three objectives are: (1) the conservation of biological diversity, (2) the sustainable use of its components, and (3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.⁷³ The third objective includes "appropriate access to genetic resources and . . . appropriate transfer of relevant technologies."⁷⁴ The Bush Administration interpreted this to mean that nations are required to make a technology transfer in order to access the genetic resources of the developing countries.⁷⁵ However, because the phrase "genetic resources" is defined as "genetic material," which in turn "means any material of plant, animal, microbial, or other origin containing functional units of heredity,"⁷⁶ the Biodiversity Convention fails to apply clearly to the cell-lines patented by biotech companies. A vague reference to indigenous people occurs in Article 8(j), in which contracting parties must, among other things, "encourage the equitable sharing of the benefits arising from the utilization of . . . [the] knowledge, innovations and practices [of indigenous and local

70. See, e.g., Hunter, *supra* note 6, at 138-41.

71. Biodiversity Convention, *supra* note 7.

72. TRIPS Agreement, *supra* note 11. See also McManis, *supra* note 12.

73. Biodiversity Convention, *supra* note 7.

74. Boyle, *supra* note 65, at 21.

75. Curtis M. Horton, *Protecting Biodiversity and Cultural Diversity Under Intellectual Property Law: Toward a New International System*, 10 J. ENVTL. L. & LITIG. 1 (1995).

76. Biodiversity Convention, *supra* note 7.

communities].”⁷⁷ Although this language could be interpreted to mandate adequate compensation for the indigenous people subjected to bioprospecting activities, the Biodiversity Convention has been severely criticized for its general and vague provisions, which fail to bring about effective regulation.⁷⁸

In contrast, the TRIPS Agreement has a more definite influence on intellectual property rights through the establishment of international minimum standards to bring about “adequate and effective patent protection”⁷⁹ as well as “minimum standards for civil and criminal penalties and associated judicial procedures.”⁸⁰ Article 27 of the TRIPS Agreement concerns patentable subject matter, and provides that members may exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” as well as “plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.”⁸¹ Criminal procedures, outlined in Article 61, are applicable “at least in cases of willful trademark, counterfeiting or copyright piracy on a commercial scale.”⁸²

III. THE IMPLICATIONS OF *MOORE V. REGENTS OF THE UNIVERSITY OF CALIFORNIA*

The United States Patent and Trademark Office (USPTO) announced in April 1987 that “nonnaturally occurring non-human multicellular living organisms, including animals,”⁸³ were now considered to be patentable subject matter. It stopped short of including humans, however, because doing so would violate the United States Constitution by granting a “limited, but exclusive property right in a human being.”⁸⁴ Even so, the resulting criticism caused the USPTO to impose a moratorium on animal patents, in effect until September 30, 1987. Congress then held hearings

77. Biodiversity Convention, *supra* note 7, at art. 8(j).

78. *See* Horton, *supra* note 75, at 23-24.

79. McManis, *supra* note 12, at 267.

80. Horton, *supra* note 75, at 25.

81. TRIPS Agreement, *supra* note 11, art. 27.

82. *Id.* at art. 61. *See also* Horton, *supra* note 75, at 26.

83. Commissioner of Patents, *Nonnaturally Occurring Non-Human Animals are Patentable Under Section 101*, 33 PAT. TRADEMARK & COPYRIGHT J. (BNA) 664 (1987). This policy change stemmed from the United States Supreme Court’s groundbreaking holding in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), that recognized non-human organisms as patentable subject matter.

84. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice*, 100th Cong., 1st Sess. 22 (1987) (statement of Commissioner Donald Quigg).

during which the House Agricultural Committee proposed that the USPTO be prevented from “issuing animal patents until the moral, ethical and economic implications were thoroughly explored by Congress.”⁸⁵

The immediate alarm occasioned by the prospect of patenting animals is rooted in a deeper concern that it might lead to the patenting of human traits.⁸⁶ However, the relatively recent exercise and ultimate rejection of the practice of slavery,⁸⁷ a definitive example of the commodification of humans as commercial entities, negates this slippery slope argument.⁸⁸

Nevertheless, the basic question of property rights over the human genome remains unresolved. Little case law exists on the issue, and even less legislative activity. In the landmark case, *Moore v. Regents of the University of California*,⁸⁹ John Moore was diagnosed with hairy-cell leukemia, and underwent treatment at the University of California Los Angeles. During the course of treatment, Moore’s physicians discovered that Moore’s blood contained components that presented “competitive, commercial, and scientific advantages.”⁹⁰ Although it remained unclear as to whether it was medically necessary to do so, Moore’s physicians extracted samples of Moore’s blood, sperm, and other bodily fluids.⁹¹ They also removed his spleen and arranged for portions of it to be sent to a laboratory for research purposes.⁹² When Moore discovered that a cell-line extracted from his excised cells had been patented—its worth in 1990 estimated to be upwards of three billion dollars—he sued the Regents of California, his physicians, and the researchers involved in the cell-line development for, *inter alia*, the tort of conversion.⁹³ The California Supreme Court evaluated the conversion charge by examining the sensitive area of property rights to one’s own cells.⁹⁴ In the end, the court did not assign any property rights to the plaintiff regarding the patented cell-line and the conversion cause of action failed. However, the court held

85. Keith Schneider, *Agency and Congress Face Clash Over Patenting of Animals*, N.Y. TIMES, July 23, 1987, at A17. See also Hoffmaster, *infra* note 86, at 2.

86. See Barry Hoffmaster, *The Ethics of Patenting Higher Life Forms*, 4 INTELL. PROP. J. 1, 11 (1988).

87. See, e.g., ICCPR, *supra* note 14, art. 8(1) (providing that “[n]o one shall be held in slavery; slavery and the slave trade in all their forms shall be prohibited”); RESTATEMENT (THIRD) OF THE FOREIGN RELATIONS LAW OF THE UNITED STATES § 702 (1987) (“A state violates international law if, as a matter of state policy, it practices, encourages, or condones . . . (b) slavery or slave trade.”).

88. *Id.*

89. 793 P.2d 479 (Cal. 1990).

90. *Id.* at 481.

91. *Id.*

92. *Id.*

93. *Id.* at 482.

94. *Id.* at 487-88.

that the physicians owed a fiduciary duty to Moore, which they had breached by not advising him of their research interest in his cells.⁹⁵ Moore's small victory, then, was based on the strength of an informed consent argument rather than a bright-line resolution of the question of property rights to human cells.⁹⁶ The court agreed with the argument that assigning property rights would severely hamper the important progress of medical research.⁹⁷

IV. THE HUMAN GENOME DIVERSITY PROJECT (HGDP) AND THE SURROUNDING CONTROVERSY

A. Background of the HGDP

The California Supreme Court's treatment of the question of property rights in one's own genetic resources resonated in 1991 when Dr. Luigi Luca Cavalli-Sforza, emeritus professor of genetics at Stanford University, proposed what is now known as the Human Genome Diversity Project (HGDP).⁹⁸ The HGDP is an offshoot of the Human Genome Project (HGP).⁹⁹ The HGP is a \$3 billion, international effort to map and sequence every gene in the human body—a total of approximately one hundred thousand genes—within a fifteen-year period ending in the year 2003. In contrast, the HGDP is a \$25 million to \$30 million dollar project, which attempts to map and sequence a smaller number of genes from indigenous people groups in order to study human migration across cultural boundaries within a five-year period.¹⁰⁰ This is a crucial difference

95. See *supra* note 40 and accompanying text (describing the California Supreme Court's decision regarding Moore's cause of action for a breach of fiduciary duty).

96. See *Moore*, 793 P.2d at 497.

97. See *id.* at 497.

98. Morrison Institute for Population and Resource Studies, *The Human Genome Diversity Project*, available at <http://www.stanford.edu/group/morrinst/hgdp/summary93.html> (last visited Aug. 29, 2000).

99. The Human Genome Project (HGP) is not to be confused with the Human Genome Diversity Project (HGDP). The HGP is supported by the Human Genome Organization (HUGO), though private corporations have largely taken over. The HGDP is a nongovernmental organization that is made up of researchers around the world. See Barrad, *supra* note 53; Sturges, *supra* note 26; Mitchell Leslie, *The History of Everyone and Everything*, STANFORD MAGAZINE (May/June 1999), available at http://www.stanfordalumni.org/jg/mig/news_magazine/magazine/mayjun99/articles/cavalli_sforza.html (last visited Aug. 31, 2000); Rifkin, *supra* note 27.

100. The fact that indigenous people groups tend to intermarry facilitates the gene tracking, but the HGDP is not limited to small, disappearing tribes. Instead, it spans the 85% of the world population that has a non-European origin, which includes large people groups that account for millions of people (e.g., Han Chinese, the Yoruba and Fulani in Nigeria). See, e.g., David Perlman, *A Search Among Vanishing Peoples: Genetic Sleuths Race Against Time*, S.F. CHRONICLE, Apr. 21, 1993, at A1 (noting that "Cavalli-Sforza's project hopes to trace the paths our ancestors have taken

between the HGDP and the HGP, because the latter project collects and maps cells from primarily European subjects.¹⁰¹ In 1993, conscious of the concern for the rights of the indigenous people groups, HGDP representatives met in a planning workshop to discuss major issues, including informed consent.¹⁰² The representatives agreed that informed consent was a crucial component of the project, privacy would be protected, and the project would not have commercial ties.¹⁰³

B. *The HGDP Model Ethical Protocol*

Despite these promises, the HGDP has been inundated with protests accusing the project of fostering biocolonialism from indigenous people groups and organizations that safeguard the rights of indigenous people.¹⁰⁴

since they first radiated outward from mankind's birth place"). See also Leslie, *supra* note 99; Dorothy C. Wertz, *The DNA Ancestry* (Sept. 1, 2000), available at http://www.geneletter.com/09-01-00/features/prn_ancestry.html (last visited Oct. 30, 2000). See also Nathaniel Pearson, *My Blood Brother in Samarkand*, STANFORD MAGAZINE (May/June 1999) (describing a Stanford student's visit to a Samarkand man's home upon discovering that they shared a recent male-line ancestor), available at http://www.stanfordalumni.org/jg/m...jun99/articles/dna_detectives.html (last visited Aug. 30, 2000). Researchers involved in the HGDP hope that this comprehensive look at the human genome will reveal valuable information about the human body and further biomedical research. See *infra* note 101 and accompanying text (arguing that the HGP may result in erroneous conclusions about what is "normal," given that at least 70% of the world's population is omitted from project consideration).

101. An example of how it is significant that the HGP uses European subjects, whereas the HGDP uses subjects from a variety of ethnic groups, may be found in the fact that most people of European origin are lactose tolerant, whereas 70% of the world population is lactose intolerant. LACTOSE INTOLERANCE, available at http://healthcastle.com/herb_lact.shtml (last visited Oct. 30, 2000). See also NATIONAL DIGESTIVE DISEASES INFORMATION CLEARINGHOUSE, WHAT IS LACTOSE INTOLERANCE? ("As many as 75% of all African-Americans and Native Americans and 90% of Asian-Americans are lactose intolerant. The condition is least common among persons of northern European descent."), available at <http://nidk.nih.gov/health/digest/pubs/lactose/lactose.htm#whatis> (last visited Oct. 30, 2000). This cultural and genetic predisposition may be one of many that the HGP fails to address. Such omissions may significantly affect the "normal standard" scientists hope to derive from the mapping and sequencing of the entire human genome. Therefore, there is a risk that the HGP may arrive at erroneous conclusions. Wertz, *supra* note 100.

102. HENRY T. GREELY, *Informed Consent, Stored Tissue Samples, and the Human Genome Diversity Project: Protecting the Rights of Research Participants*, in STORED TISSUE SAMPLES: ETHICAL, LEGAL AND PUBLIC POLICY IMPLICATIONS 89, 93 (Robert F. Weir ed., 1998). Greely is a Stanford Law School ethicist who chairs the HGDP's ethics subcommittee. See Leslie, *supra* note 99. See generally *Net Resources Relating to the Human Genome Diversity Project*, available at <http://www.ratical.org/co-globalize/HumanGenomeP.html> (last visited Oct. 30, 2000).

103. Greely, *supra* note 102, at 93.

104. See Leslie, *supra* note 99. Anthropologist Jon Marks described a 1992 meeting "where anthropologists, linguists, geneticists and archaeologists selected roughly 500 populations [to study]" without inviting any representatives of these populations in order to "try to get blood out of natives' veins and into Palo Alto as expeditiously as possible." *Id.* But see Morrison Institute for Population and Resource Studies, *supra* note 98. The HGDP prompted an Australian aboriginal group to call it a "vampire project." See Leslie, *supra* note 99. See Paul Salopek, *Basically, We Are All the Same: Controversial Genetic Quest is Unlocking Secrets of the Human Rainbow*, CHL TRIB., Apr. 27, 1997,

There were concerns that the project would result in patented commercial products derived from their cells, which would then be sold back to the developing countries for a great profit.¹⁰⁵ Such an arrangement was all too common when biotechnology companies from developed countries extracted plant and animal cells to manufacture products, which they in turn sold for a profit to developing countries.

In order to preserve cultural sensitivity, the HGDP representatives formulated a protocol for ethical principles that delineated procedures for contacting source populations, including: obtaining informed consent,¹⁰⁶ providing medical services, maintaining privacy and confidentiality, and resolving questions of ownership and control.¹⁰⁷ The protocol specified that prior to extracting new samples, the informed consent of the individual donor—as well as, in some cases, the informed consent of the group—must be obtained. Groups would be able to limit the use of the

at C1 (describing the indignant reaction of Nilo Cayugueo, a Mapuche Indian from Argentina and the director of the Abya Yala Fund: “Imagine the arrogance of coming in and giving tribal people a machete or 15 bucks for their blood, then telling them, “well, you’re from so-and-so place 1,000 years ago” Who are they to tell us where we came from? Don’t they understand that’s sacrilegious?”). See generally Rifkin, *supra* note 27. There are also general concerns that “knowledge of an individual’s genetic makeup can lead to insurance and employment discrimination.” Sturges, *supra* note 26, at 226.

105. See generally Victoria Tauli-Corpuz, *Biotechnology and Indigenous People*, THIRD WORLD NETWORK (arguing that the Human Genome Diversity Project “is still the appropriation of what [indigenous peoples] have and even of what [they] are, not just for the sake of science but for more profits”), available at <http://twinside.org.sg/title/tokar.htm> (last visited Aug 31, 2000). *Patents, Indigenous Peoples, and Human Genetic Diversity* (May 30, 1993), available at <http://64.4.69.14/web/allpub-display.shtml?pf1=com-list-en.param> (last visited Oct. 30, 2000). Other concerns include the suggestion by the Rural Advancement Foundation International (RAFI), a non-governmental international organization based in Canada that “promotes sustainable agriculture and works to protect intellectual property rights of indigenous people,” that the data on “population-specific traits” could be developed into biological weapons used to commit genocide. Leslie, *supra* note 99. See generally RAFI: RURAL ADVANCEMENT FOUNDATION INTERNATIONAL, available at <http://www.rafi.org/> (last visited Aug. 30, 2000). Cavalli-Sforza counters these concerns by stating that the HGDP has no intention to patent DNA and that population groups aren’t vulnerable to custom-made biological weapons since “most genetic differences are between individuals, not groups.” Leslie, *supra* note 99. See also Morrison Institute for Population and Resource Studies, *HGDP Frequently Asked Questions*, (stating that “[g]enocidal use of genetics is not possible with any currently known technology” and that the HGDP would deplore the use of its data for such purposes), available at <http://www.stanford.edugroup/morrinst/hgdp/faq.html> (last visited Aug. 30, 2000). See generally U.N. CHARTER, arts. 55-56; Universal Declaration of Human Rights at 71.

106. But see Victoria Tauli-Corpuz, *Biotechnology and Indigenous Peoples*, THIRD WORLD NETWORK (expressing doubt that the “process of informed consent” will be thoroughly followed, “considering the time constraints imposed by the proponents on themselves For such a controversial project there is a strong possibility that informed consent will not be applied as it should be”), available at <http://www.twinside.org.sg/title/tokar.htm> (last visited Oct. 31, 2000).

107. See *Proposed Model Ethical Protocol for Collecting DNA Samples*, 33 Hous. L. Rev. 1431 (1997).

samples¹⁰⁸ and confidentiality would be carefully controlled. The protocol also outlined a culturally-sensitive approach to the form of consent by acknowledging, for example, that some cultures are averse to signing contract documents.¹⁰⁹

V. U.S. OBLIGATIONS TO SAFEGUARD HUMAN RIGHTS UNDER INTERNATIONAL LEGAL INSTRUMENTS

The issue of informed consent in bioprospecting practices invariably raises intellectual property concerns.¹¹⁰ Although amendments to the Biodiversity Convention or the TRIPS Agreement regarding informed consent could solve many problems related to bioprospecting,¹¹¹ the human element invokes fundamental implications outside of mere possession. The assigned rights within the “principal postwar human rights instruments are framed in terms of individual rights.”¹¹² A survey of these individual rights causes serious concern regarding the ethics of bioprospecting activities without obtaining informed consent.¹¹³

108. See Greely, *supra* note 102, at 101.

109. *Proposed Model Ethical Protocol for Collecting DNA Samples*, *supra* note 107.

110. See, e.g., McManis, *supra* note 12 (exploring the interface between international intellectual property and environmental protection in order to reconcile the conflicts within the Biodiversity Convention and the TRIPS Agreement); McKay, *supra* note 25; Roht-Arriaza, *supra* note 31, (suggesting three frameworks for ending “appropriation of indigenous and local communities’ knowledge and resources,” including “broadened and redefined intellectual property regimes”).

111. See McManis, *supra* note 12; 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) (suggesting that a “requirement that the origin of genetic resources and prior informed consent be disclosed in patent applications, as proposed by different countries in at least two different international fora” can be “adopted by [World Trade Organization] Members at the national, regional or international levels without infringing the TRIPS Agreement”).

112. LOUIS HENKIN ET AL., HUMAN RIGHTS 426 (1999). Although the principal human rights instruments in existence today arose out of the atrocities of World War II and the “Nazi persecution of victims targeted because of their membership in such minority groups as Jews, homosexuals, and Roma and Sinti communities,” the human rights instruments were drafted out of a desire to affirm the fundamental rights of every individual human being rather than concentrate on the rights of minority groups. *Id.* at 427. Therefore, although this Note focuses on indigenous people groups of developing countries as the primary targets of bioprospecting activities, the principle behind the proposal to enact legislation to protect their human rights should be attributed to an overall concern for the rights of all people.

113. This Note does not postulate whether or not the United States is in violation of the various international legal instruments of which it is a party. Rather, this Note suggests that bioprospecting activities without the benefit of informed consent invokes serious human rights questions that should be answered by domestic legislation.

A. *The Universal Declaration of Human Rights*

The Universal Declaration of Human Rights provides, “All human beings are born free and equal in dignity and rights.”¹¹⁴ In addition, “Everyone is entitled to all the rights and freedoms set forth in [The Universal Declaration of Human Rights], without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.”¹¹⁵ Article 22 provides that every person, “as a member of society . . . is entitled to realization, through national effort and international co-operation . . . of the economic, social and cultural rights indispensable for his dignity and the free development of his personality.”¹¹⁶

B. *The American Declaration of the Rights and Duties of Man*

As a member of the Organization of American States,¹¹⁷ the United States is obliged to follow the American Declaration of the Rights and Duties of Man,¹¹⁸ which recognizes that “[a]ll men are born free and equal, in dignity and in rights, and, being endowed by nature with reason and conscience, they should conduct themselves as brothers one to another.”¹¹⁹ In addition to the right to life, liberty, and personal security,¹²⁰ the United States is required to recognize and protect the right to protection of honor, personal reputation, private and family life,¹²¹ the right to work and to fair remuneration,¹²² and the right to recognition of juridical personality and of

114. Universal Declaration, *supra* note 14, art. 1.

115. *Id.* at art. 2.

116. *See id.* at art. 22; Horton, *supra* note 75, at 29-30.

117. Every sovereign state of the Americas, including the United States, is a party to the Organization of the American States (OAS). However, although all OAS parties are parties to the American Declaration of the Rights and Duties of Man, not all OAS parties are parties to the American Convention on Human Rights, Nov. 22, 9 I.L.M. 673. *See generally* LOUIS HENKIN ET AL., HUMAN RIGHTS 342-43, 523, 784 (1999). As of 1999, the United States is not a party to the American Convention. However, “[i]t may no longer be accurate to conclude that American states not party to the American Convention . . . are not subject to any human rights obligations in the American system.” *Id.* at 343 n.1.

118. The American Declaration of the Rights and Duties of Man is considered an “authoritative interpretation” of the Charter of the Organization of American States and “may also have contributed to customary law.” *See* HENKIN, *supra* note 117, at 343 n.1. However, “[i]t is generally accepted that the American Declaration was not intended to have legally binding character.” *Id.* at 342.

119. American Declaration, *supra* note 14, pmbl.

120. “Every human being has the right to life, liberty and the security of his person.” American Declaration, *supra* note 14, at art. I.

121. “Every person has the right to the protection of the law against abusive attacks upon his honor, his reputation, and his private and family life.” American Declaration, *supra* note 14, at art. V.

122. “Every person has the right to work, under proper conditions, and to follow his vocation

civil rights.¹²³ These rights recognize the inherent value of a person by endowing each individual with protection over his or her person, and validate a person's actions, whether it is establishing a family or following a vocation. Significantly, the United States must recognize an individual's identity as a "person having rights and obligations,"¹²⁴ independent of geography. The primary qualification is personhood.¹²⁵

C. *The International Covenant on Civil and Political Rights*

Under the International Covenant on Civil and Political Rights (ICCPR), the United States must "respect and . . . ensure to all individuals within its territory and subject to its jurisdiction the rights recognized"¹²⁶ in the ICCPR. Once the United States ratifies the ICCPR, relevant provisions in the treaty include a right of self-determination,¹²⁷ a right to not be subjected to medical or scientific experimentation without consent,¹²⁸ and the right to the "inherent dignity of the human person."¹²⁹

freely, insofar as existing conditions of employment permit." American Declaration, *supra* note 14, at art. XIV.

123. "Every person has the right to be recognized everywhere as a person having rights and obligations, and to enjoy the basic civil rights." American Declaration, *supra* note 14, at art. XVII.

124. *See id.* at art. XVII (giving every person a right "to be recognized everywhere as a person having rights and obligations").

125. The American states have . . . recognized that the essential rights of man are not derived from the fact that he is a national of a certain state, but are based upon attributes of the human personality; [t]he international protection of the rights of man should be the principal guides of an evolving American law." American Declaration, *supra* note 14, pmb1.

126. ICCPR, *supra* note 14, at art. 2(1). The United States became a party to the ICCPR in 1992 under the significant declaration that the treaty was not self-executing. This means that U.S. courts will not accept the treaty if Congress has not passed complementing legislation. *See generally* HENKIN, *supra* note 117, at 323.

It is commonly accepted that "within its territory and subject to its jurisdiction" was intended to mean "those within its territory and *those otherwise* subject to its jurisdiction." . . . The State is obligated to respect the rights of persons not within its territory but nevertheless subject to the State's jurisdiction, whether because they are national of the State, or residents temporarily outside the territory, or even generally, perhaps because the State Party reaches out beyond its territory to exercise jurisdiction over them.

Id. In the case of researchers from U.S. biotech companies who visit developing countries and extract cells from individuals belonging to indigenous people groups, the United States may be obliged to follow the ICCPR provisions if: (1) the United States exercises jurisdiction over the individual, and (2) the United States ratifies the ICCPR.

127. "All peoples have the right of self-determination. By virtue of that right, they freely determine their political status and freely pursue their economic, social and cultural development." ICCPR, *supra* note 14, at art. 1(1).

128. "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, no one shall be subjected without his free consent to medical or scientific experimentation." ICCPR, *supra* note 14, at art. 7.

129. *Id.* at art. 10. "All persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person." *Id.* Although the context of this provision is loss

D. The International Covenant on Economic, Social and Cultural Rights

The International Covenant on Economic, Social and Cultural Rights (ICESCR)¹³⁰ mimics the ICCPR in guaranteeing a right to self-determination.¹³¹ A significant provision states that “[n]othing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources.”¹³² Although the United States has historically assigned property rights to genetic resources, it is worth noting that an individual cannot take the genetic resources of another individual—blood, cells, or tissue—without violating the right to self-determination and every other right that defines an individual as an autonomous human being.¹³³

E. The United Nations Charter

According to the United Nations Charter, all member-nations should collectively promote “universal respect for, and observance of, human rights and fundamental freedoms for all,” which “all Members pledge themselves to take joint and separate action” to achieve.¹³⁴ Therefore, noting the human rights obligations of the United States under the international law instruments previously discussed,¹³⁵ the United States is bound, if not merely by law, then by conscience, to safeguard the rights of indigenous people groups it exploits through its bioprospecting activities.

of liberty, it is important to note that the preservation of human dignity remains an underlying value.

130. Although the language of the ICESCR is “softer” in obligating state parties “to the maximum of its available resources,” the ICESCR nonetheless establishes legally binding obligations. *See* ICESCR, *supra* note 14, at art. 2 (“Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.”). *See also* HENKIN, *supra* note 117, at 329.

131. “All peoples have the right of self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development.” ICESCR, *supra* note 14, at art. 1(1).

132. *Id.* at art. 25.

133. *See* HENKIN, *supra* note 117, at 88 (describing the inclusion of self-determination provisions in the ICCPR and ICESCR, thereby characterizing self-determination as a human right, despite arguments that it was merely a political right).

134. *See* U.N. CHARTER, arts. 55-56; Horton, *supra* note 75, at 29.

135. *See* discussion *supra* Part V.A.-V.D.

VI. PROPOSAL

A. *The Utility of Informed Consent and Adequate Compensation*

The *Moore*¹³⁶ decision and a technical application of U.S. patent regulations treat the human body as a “naturally occurring raw material”¹³⁷ that possesses no property rights to excised cells. But informed consent becomes the saving grace; it transforms the human from a mere repository of genetic material, subject to the big-picture importance of scientific research,¹³⁸ into a “sovereign individual with an unchallengeable entitlement to the facts necessary to make informed decisions.”¹³⁹

The Biodiversity Convention fails to speak directly to the indigenous people groups whose cells are excised without compensation, and the phrase “at least” in Article 61 of the TRIPS Agreement¹⁴⁰ is too weak to support the weighty human rights implications of patenting human cells without informed consent. Therefore, both the Biodiversity Convention and the TRIPS Agreement afford inadequate protection to the matter at hand because they lack any serious treatment of the patenting of cell-lines derived from extracted cells of indigenous people groups.

Given the United Nations mandate to safeguard the fundamental freedom of human dignity, the United States should adhere to the United Nations Charter and its other international treaties¹⁴¹ by implementing domestic legislation to protect the fundamental human rights of self-determination¹⁴² and “the inherent dignity of the human person.”¹⁴³

136. 793 P.2d 479 (Cal. 1990).

137. See Boyle, *supra* note 65, at 106.

138. An argument against the patenting of human cells posits that it hampers medical research by requiring scientists to pay the holder of the patent fees in order to utilize the patented matter. See Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, SCI. MAG., May 1, 1998, at 698 (discussing how intellectual property rights increases have led to an “anticommons,” where scarce resources are underused because “too many owners can block each other”). See also Thomas P. Dillon, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why A Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628 (1989) (stating that public policy considerations argue against unlimited property rights in human tissues and cells because the resulting competitive bidding will increase the costs of developing the product); Robert Heidt, *Maintaining Incentives for Bioprospecting: The Occasional Need for a Right to Lie*, 13 BERKELEY TECH. L.J. 667 (1998) (arguing that lying to a patient about the value of his cells will allow a researcher to obtain the patient's consent to collect valuable cells more easily).

139. See Boyle, *supra* note 65, at 107.

140. See discussion *supra* Part III.

141. The International Covenant of Civil and Political Rights and the International Covenant of Economic, Social and Cultural Rights are two such treaties to consider.

142. ICCPR, *supra* note 14, at art. 1.1; ICESCR, *supra* note 14, at art. 1.1.

143. ICCPR, *supra* note 14, at art. 10.1.

Informed consent is the primary exercise of sovereignty that humans have over their own bodies; a failure to regulate the patenting of human cells by way of procuring informed consent relegates the human body to a mere natural resource, robbed of a soul. Congress should implement legislation to safeguard the rights of indigenous people by mandating informed consent. Such a provision would cure the flaws of both the Biodiversity Convention and the TRIPS Agreement and prevent the patenting of human cells. Necessity obviates the need for such regulation¹⁴⁴ because, historically, the United States has abandoned such patents only after a public outcry by foreign governments.¹⁴⁵

Although some critics deem a protocol for delineating the issue of obtaining informed consent an unrealistic undertaking,¹⁴⁶ the need for the construction of such regulation supersedes the cultural morass. The Human Genome Diversity Project, for example, drafted a thirty-five page ethical protocol not to prevent the exploitation of the indigenous people groups specifically, but to benefit all humans generally.¹⁴⁷ Therefore, the HGDP's "Proposed Model Ethical Protocol for Collecting DNA Samples" (HGDP Ethical Protocol) is a useful model for the proposed international agreement.¹⁴⁸

The HGDP Ethical Protocol purports to use a culturally sensitive approach to all aspects of collecting cell samples from indigenous people groups. This approach includes preparation before contact as well as during contact with the population, and the details of obtaining informed consent. These details include identifying the person from whom consent

144. See Dorothy C. Wertz, *The Human Genome Diversity Project (HGDP)*, THE GENE LETTER (Nov. 1996) (stating that "[o]utside the United States, Canada, the United Kingdom, and Western Europe, there are few procedures for ethical review, and researchers can proceed without informed consent and may use genetic material for commercial purposes"), available at <http://www.geneletter.org/1196/hgdp.html> (last visited July 25, 2000) (on file with the author). Since the HGDP purports to elicit international adherence to ethical protocols from researchers all over the world, opponents to the HGDP may "inadvertently increase the very exploitation they are trying to prevent." *Id.*

145. Symposium, *Probing the Human Genome: Who Owns Genetic Information?*, 4 B.U. J. SCI. & TECH. L. 2 (1998); Rifkin, *supra* note 27.

146. Symposium, *supra* note 53. But see Dorothy C. Wertz, *The Human Genome Diversity Project (HGDP)*, THE GENE LETTER (Nov. 1996) (stating that individual researchers unrelated to the HGDP who have patented human genes without consent are examples of "what can happen in the absence of international agreement to an ethical protocol"), available at <http://www.geneletter.org/1196/hgdp.html> (last visited July 25, 2000) (on file with the author).

147. See Symposium, *supra* note 53, at ¶ 74 (noting that the "NIH's official agenda is to promote public health, not exploit indigenous people"). See Sturges, *supra* notes 26-27 and accompanying text (arguing that the Common Heritage of Humankind principle should be applied to the international regulation of genome use).

148. Symposium, *International Health Law Model Protocol*, 33 HOUS. L. REV. 1431 (1997).

should be obtained, the timing of obtaining consent, the characterization of what constitutes “informed consent,” and the manifest form of the consent. Concerns regarding the ability to relate to a culturally foreign group are rooted in what could be perceived as legal niceties that lack cultural counterparts due to untranslatable concepts and values. The HGDP Ethical Protocol mandates honesty and seeks an amenable understanding of what is culturally appropriate as a solution to such a difficulty. Human nature is the common ground by which all international agreements operate successfully, not language or national custom.

So too should the proposed legislation of this Note operate from the premise of shared humanity. It should urge the eventual acceptance as a fundamental norm both informed consent and adequate compensation of indigenous people groups by developed countries and developing countries alike. The objective of the legislation is to safeguard the rights of the indigenous people while preserving the integrity of scientific research. The economic benefits of bioprospecting are not worth the violation of the fundamental human right to self-determination and inherent dignity.

In order to facilitate a practical relationship with the indigenous people groups, bioprospectors must be thoroughly familiar with the language and customs of the people. It is not cultural sensitivity that will stifle scientific progress, but the alienating and dehumanizing effects of an invasion of genetic privacy.

An informed consent should be obtained from every individual from whom cells are extracted through hair samples, blood, and other bodily fluids. If the individual is still viewed as a child by the indigenous society, bioprospectors must obtain permission from the child’s caretakers. Family units must be respected. In addition to an individual informed consent, bioprospectors must obtain the informed consent of the governing body of the indigenous group. The governing body may be made up of a single leader or a small number of select individuals.

Informed consent must be obtained prior to any extraction of cells. This may be done before entering the territory of the indigenous people group, so as to build up a mutual trust, or it may be done after entering the territory. Should consent be requested and refused after the extraction, both parties have suffered needlessly: the bioprospector from effort and expense, and the indigenous individual from an invasion of privacy. Therefore, clear consent must be secured to prevent useless transactions.

Informed consent should be made up of three essential parts: (1) the nature and risks of the indigenous individual’s participation (the pledge that the extraction process will be performed in a safe, sanitary manner with little risk to the indigenous individual is necessary to the contract

between bioprospector and the indigenous individual); (2) the nature of the extraction and of the scientific study, including the expected utility of the study; and (3) expected actions with regard to the extracted cells (*e.g.*, developing a cell-line, mere storage for research purposes).

The way informed consent is to be transmitted may have varying levels of difficulty. The transaction must be recorded in a way that is legally recognized by the governments of both parties. Any mode of record allowable by the indigenous people (*e.g.*, video recorders, tape recorders) may be used.

Similar to Article 61 of the TRIPS Agreement, which provides for criminal procedures applicable in “cases of willful trademark counterfeiting or copyright piracy on a commercial scale,”¹⁴⁹ the proposed international agreement for patenting cell-lines of indigenous people groups would include criminal procedures for cases of willful extraction without obtaining informed consent. The crime would necessitate an *actus reus* finding—the extraction of human cells—and a *mens rea* element—the intentional failure to obtain informed consent. Remedies for such cases may range from civil penalties to imprisonment, in addition to the seizure and destruction of the “infringing goods and of any materials and implements the predominant use of which has been in the commission of the offense.”¹⁵⁰

CONCLUSION

The oddity of patenting human cells has aggravated and fueled much hysterical controversy, not without good cause. It is ironic that the painstaking research and backbreaking innovation involved in revealing the secrets of human history and the mysteries of human futurity are often met with the fear that this quasi-philanthropy dehumanizes its proposed beneficiary. Whether or not that is true is left unresolved; however, the struggle to safeguard the fundamental human rights of indigenous people groups through, *inter alia*, adequate compensation, begs the question: what is the basis of the transaction? A sense of fairness obviates the need to pay for what we buy; that is, the genetic resources we have extracted and utilized in the name of medical research. If the compensation is based on property right, then the Pandora’s Box of biological, philosophical, ethical, and spiritual chaos is opened and may never be closed again. However, if the compensation is based upon a simpler idea, namely the

149. TRIPS Agreement, *supra* note 11.

150. *Id.*

preservation of human sovereignty over personal dignity and individual freedoms, then so too should every human action be regulated. Far better than the so-called Golden Rule,¹⁵¹ the motivation to pursue our nobler objectives without compromising that which makes us human only lengthens the reaches we may go.

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151. "So in everything, do to others what you would have them do to you, for this sums up the Law and the Prophets." *Matthew 7:12* (New International Version).

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