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The Patenting of Human Genetic Material

ISSUE: In the 1980s US court decisions set international precedent for the patenting of human genetic material. As a result, exclusive monopolies over human genetic materials are becoming commonplace in the industrialized world, without discussion of the social, ethical and political implications. Perhaps most disturbing is the degree to which ordinary citizens, both South and North, have been marginalized from discussion and debate on the patenting of human genetic material. In the absence of public awareness and debate, issues of equity and ethics have been eclipsed by the interests of the biotechnology industry. Most recently, the US government has laid claim to "immortalized" human cell lines extracted from citizens of Panama, New Guinea and the Solomon Islands.

IMPACT: Private ownership of human biological materials raises many profound social, ethical and political issues. Industrialized nations are lobbying vigorously for "harmonization" of intellectual property laws worldwide with the ultimate goal of imposing life patenting laws worldwide. In the South, issues of development and national sovereignty are at stake. Fundamental human rights are jeopardized everywhere.

ACTIONS: The US government's recent patent applications on the cell lines of indigenous peoples highlight the need for international debate on the patenting of human genetic material, particularly in the context of multilateral trade agreements (GATT) and the Convention on Biological Diversity, which both cover biotechnology and intellectual property standards. National governments and intergovernmental organizations must address the issue of life patenting on the basis of ethics and equity. The US government should drop all claims to the human cell lines of foreign nationals and repatriate the materials to the indigenous communities or national governments involved. International protocols must be developed by the appropriate United Nations bodies for protecting the rights of human subjects from patent claims and unjust commercial exploitation.

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Introduction

This issue of RAFI Communiqué provides a brief introduction to human genetic patenting in a broad context, with a special focus on the international controversy arising from claims of monopoly control over the cell lines of indigenous peoples.

History of Human Genetic Patenting

> *"Since 1980 it can no longer be said that something is not patentable just because it is living...biotechnology has advanced so rapidly in recent years that there is now virtually no life form which does not have the potential as the subject of a patent application."* -- Sally I. Hirst[1]

The short history of biotechnology patents for human genetic material began just 14 years ago when the U.S. Supreme Court made its landmark decision in *Diamond v. Chakrabarty* that U.S. patent law applies to new life forms created by genetic engineering. The court's 1980 ruling established that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability, as long as the invention is the result of human intervention.[2] *Diamond v. Chakrabarty* opened the door for the patenting of human biological materials, and set a clear precedent for the patenting of life worldwide.[3]

Commercial interest in human biological materials was propelled further in 1980 when the US Congress amended its patent laws to encourage patenting and licensing of inventions resulting from government-sponsored research. The result was dramatic. From 1980 through 1984, patent applications by publicly-funded universities and hospitals for inventions containing human biological material increased more than 300 percent.[4]

Aren't Human Biological Materials and other Living Organisms Considered "Products of Nature"?

Traditionally, industrial patent regimes do not permit the patenting of naturally-occurring materials. In addition to meeting basic criteria for patenting: novelty, utility, and non obviousness, there is a well-established doctrine in patent law that "products of nature" are not patentable. In reference to biotechnology products and processes, however, the US judicial system has interpreted this doctrine in such a way that promotes biopatenting and exclusive ownership of genes, plants, animals and human genetic material. Bioethicist Ned Hettinger explains:

"The product of nature doctrine has been rendered vacuous by allowing that the isolation, purification, or alteration of an entity or substance from its natural state turns it into something not "found in nature." Thus genes are patentable when they are isolated from their "impure form" (mixed in with other DNA in an organism's cells). By placing foreign genes into organisms, these organisms also become "substantially altered" and hence patentable "works of man."[5]

Biotechnicians who newly alter, isolate, purify, modify, assist, and manipulate naturally occurring microorganisms are thus eligible to apply for biopatents under US and European patent laws.

What are Human Biological Materials?

Human biological material is a very broad term that covers replenishing substances from the human body (blood, skin, bone marrow, hair, urine, perspiration, semen, etc.) as well as non replenishing parts such as organs (heart, kidney, etc.)

The human biological materials that are most frequently used in biotechnology are tissues and cells.[6] It is important to understand the distinction that is made

between "un-developed" human biological materials and the biological "inventions" or commercial products developed from them. So-called "un-developed" biological materials (human tissues and cells) may be considered biological "inventions" and hence patentable subject matter when they are used to produce **cell lines**, **hybridomas**, and **cloned genes**. The following are basic definitions for three of the most common "inventions" based on human genetic material:

Human Cell Line: A sample of cells removed from the human body that are capable of sustaining continuous, long-term growth in cultures. Cell lines are said to be "immortal" because they can continue to live indefinitely under artificial conditions (with strict control of temperature, nutrient requirements, and sterile conditions). Human cell lines provide an inexhaustible supply of DNA (the complete genetic code) of the individual from whom they are taken.

Cloned Genes: Using genetic engineering, scientists can isolate a human gene or fragment of human DNA and make many copies of it by inserting it into cells (which can be from a non-human species) and letting it multiply. Cloned material can be used to examine how a biological process is regulated, identify and isolate scarce compounds, or produce commercial quantities of important substances. Many patents are being granted for DNA sequences coding for the production of human proteins for biomedicine. Examples of genetically engineered products created through gene cloning are: human growth hormone, human insulin, and human alpha interferon.

Hybridomas: A hybrid cell that is capable of multiplying continuously in culture and supplying a specific type of antibody. The hybridoma cell results from the fusion of a particular type of immortal tumor cell line (a myeloma) with an antibody-producing white blood cell (B lymphocyte). The antibodies secreted by hybridomas, known as monoclonal antibodies, have revolutionized the way that human illnesses are diagnosed and treated.

Since the early 1980s, biotechnology and pharmaceutical corporations have applied for patents on thousands of "inventions" based on human-derived materials. In fact, the patenting of human biological materials is considered so routine that one patent analyst observes it "is now commonplace and raises no moral issue."[7]

Patent Depositories for Biological Materials

Patent applications in biotechnology usually involve the deposit of biological material in "culture collections"--institutions designed to preserve living biological materials (microorganisms, cell lines and special gene and cellular products) "in perpetuity." The patent laws of the US and most countries require an inventor to give a full disclosure of their invention to the Patent Office. In cases where novel microorganisms are involved, patent law usually requires the deposit of a sample with a recognized patent culture depository. Patent culture depositories are regulated internationally by the Budapest Treaty administered by the World Intellectual Property Organization in Geneva. Since 1981, 26 institutions in 15 states have been officially recognized as culture depositories for the purpose of patent procedure. These institutions contain the living materials (microorganisms, genes, seeds, animal embryos, human and animal cell lines, etc.) that are the basis for virtually all biopatents. Patent depositories contain biological samples collected worldwide.

But not surprisingly, the overwhelming majority of the institutions that preserve these genetic resources are located in industrialized countries of the North. (See table below.) It should be noted that all of the patent depositories listed below vary according to the type of

microorganisms that they preserve, and the size of their collections. The United Kingdom, for instance, maintains 7 separate facilities to store food bacteria, yeast cultures, animal cultures, algae and protozoa, marine bacteria, etc. The world's largest patent culture depository is the American Type Culture Collection (ATCC) based in Rockville, Maryland (USA). Founded in 1925, the ATCC became the first approved international patent depository in 1981.

According to the ATCC, the patent office in every country (except China) recognizes deposits made in the ATCC to satisfy deposit requirements for patent purposes. As of December, 1991 the ATCC held 41 percent (17,724 deposits) of all microorganisms on deposit worldwide for purposes of patent procedure.[8]

Samples of genetic materials deposited in culture collections (for which patents are pending), are not made freely available to individuals and/or institutions that request them.

According to ATCC officials, written authorization must first be obtained from the depositor, or the European Patent Office. Once a patent is issued, the restrictions are lifted.

PATENTING HUMAN LIFE: Who Draws the Line?

The 13th Amendment of the U.S. Constitution forbids any grant of property rights in a human being. That much is clear. But science and technology are moving far faster than legal systems, blurring traditional boundaries and definitions. Bioengineers have inserted foreign genes, including human genes, into the chromosomes of many animals, including pigs, sheep, goats and chickens. In the future, genetic engineering will enable scientists to intermingle the genetic material of humans and animals to produce human-animal hybrids. "It may be possible," writes one commentator, "to patent and to enslave human-animal hybrids who think and feel like humans but who lack constitutional protection under the 13th Amendment."[9] Given that animals containing human genes are already patentable, will it be possible to patent human-animal hybrids? Some are calling on US courts to begin developing a legal theory of "constitutional personhood" that can be applied to genetically engineered species, and afford them protection under the US Constitution.

On October 24, 1992, the *New York Times* reported that Dr. Robert Stillman of George Washington University had successfully cloned human embryos. The article pointed out that Stillman's work was "not a technical breakthrough," simply the application of widely known animal cloning techniques to human embryos. Livestock embryos are, in fact, routinely cloned by bioengineers. In 1988, the first frozen animal embryo was accepted for patent purposes at the American Type Culture Collection. What's next? Dr. George Annas of Boston University asks: "Since cloned human embryos are not persons protected by the constitution and theoretically at least could be as 'immortal' as cloned cell lines, could a ?"particularly 'novel' and 'useful' human embryo be patented, cloned and sold?"[10]

International Patent Culture Depositories

Institution	Country	Date Status Acquired
ARS Culture Collection	USA	1981
American Type Culture Collection	USA	1981
All-Union Institute of Genetics and Industrial Cultivation...((VKPM)	Russian Federation	1987
All-Union Centre of Antibiotics (VNIIA)	Russian Federation	1987
Aust. Govt. Analytical Laboratories	Australia	1988
Belgian Coordinated Collections (BCCM)	Belgium	1992
Centraalbureau voor Schimmelcultures	Netherlands	1981
Coleccion Espanola de Cultivos Tipo	Spain	1992
Collection Nat. de Cultures...(CNCM)	France	1984
Culture Coll. of Algae & Protozoa	UK	1982
Culture Coll. of Yeasts	Slovakia	1992
Czech Coll. of Microorganisms	Czech Rep.	1992
Deutsche Sammlung... (DSM)	Germany	1981
European Coll. of Animal Cultures	UK	1984
Institute of Biochemistry...(IBFM-VKM)	Russian Federation	1987
Intl. Mycological Institute	UK	1983
Korean Cell Line Research Found.	Rep. of Korea	1993
Korean Collection for Type Cultures	Rep. of Korea	1990
Korean Culture Centre for Micro.	Rep. of Korea	1990
Natl. Bank for Ind. Microorganisms...	Bulgaria	1987
Natl. Coll. of Ag. and Ind. Micro.	Hungary	1986
Natl. Coll. of Food Bacteria	UK	1990
Natl. Coll. of Type Cultures	UK	1982
Natl. Coll. of Yeast Cultures	UK	1982
Natl. Coll. of Ind. & Marine Bacteria Ltd.	UK	1982
Natl. Inst. of Bioscience & Human Tech.	Japan	1981

Who Owns the Human Genome?

In 1992, National Institutes of Health (USA) researcher Craig Venter ignited worldwide protest when he filed for US patents on thousands of gene sequences from the human brain. Venter, a US government employee, was involved in the international collaborative effort to decode the entire collection of human genes called the Human Genome Organization.[11] Nobel laureate Dr. James Watson described NIH's decision to apply for patents on human gene sequences as "sheer lunacy." Other scientists expressed fears that the rush to patent and commercialize pieces of the genome project would hinder greater advances that should be the "prized possession of all humanity."[12]

The uproar over the NIH patent applications did not focus entirely on the ethical impropriety of patenting human genes. After all, hundreds of human genes were already "owned" by private companies, universities and governments. Previous patents, however, were usually granted in conjunction with a specific process and/or product. By contrast, Venter and the NIH were attempting to patent human gene fragments without knowing what they were, or what role they played in the human body. Some scientists also argued that the use of automated gene sequencers to decode anonymous human genes represented practically nothing in the way of innovation. One biotechnology

industry representative observed: "Venter has sequenced them [human genes] by rote in a process that is easier to do than operate a sewing machine."[13]

The US Patent Office ultimately denied the NIH claims on human gene sequences because they failed to meet standard patent criteria--they were not useful, not new and were too obvious, in that they could be derived from existing data banks.[14] The issue, however, sparked debate on the patenting of human genes and prompted some governments to take action against exclusive ownership of human genetic materials.

In December, 1993 French scientists working on the Human Genome Project unveiled a first-generation physical map that covers about 90% of the human genome. In stark contrast to the US government's approach, the French researchers stressed repeatedly that they will make all of their information freely available. Daniel Cohen, director of the Centre d'Etude du Polymorphisme Humaine (CEPH, Paris) also announced that the Centre is establishing the Africa Foundation to assure that results of the genome technology will be available to research centres in Africa. "Our goal has been to deliver this map as quickly as possible, even if it needs refinement, so that it can begin to benefit geneticists and ultimately humanity," stated Dr. Cohen.[15]

The French government is also considering a bill that would establish a strong precedent in regulating human gene therapies and ownership of the human body. The bill would prohibit patenting of human genomes, human genes, or partial DNA sequences. Intellectual property would be available only when a gene sequence is used in an industrial process.[16]

In November, 1993 the UK's Medical Research Council announced that it will no longer apply for patents on segments of genes discovered as part of the international human genome project.[17]

It should be noted, however, that private efforts to commercialize research stemming from the Human Genome Project are advancing at a frantic pace in the United States. Dr. Craig Venter, formerly of NIH, is one of many scientists who have left federally-funded positions to start private companies that are hoping to profit from technologies related to the Human Genome Project. Venter, now a multi-millionaire, owns 766,612 shares of Human Genome Sciences, Inc. worth $13.4 million. The company (which has yet to market a single product) is only one of a dozen human genome companies that have been set up with venture-capital funding in the US in the past few years.[18]

From Whom do Biotechnology Companies and Medical Researchers Obtain Human Biological Materials for Research?

According to the US Office of Technology Assessment (OTA), there are three major sources of human tissues and cells: patients, healthy research subjects (volunteer or paid), and cadavers. Tens of thousands of samples of human tissue are routinely used in research, but information on the amount and type of materials used, or their source, is not available.[19] Biotechnology companies often cite information about the source or use of human biological materials as confidential business information. In its 1987 report on the ownership of human tissues and cells, the OTA found that the vast majority of human biological materials are relatively common and easy to obtain, concluding that "it is difficult to ascertain the contributions of any one individual's sample to a final commercial product."[20] Nevertheless, there are many important and notable exceptions.

In some cases, for example, unique individuals or populations can naturally produce greater than normal amounts of a valuable substance, or some might

overproduce it because of an illness. Novel human tissue or cells can become valuable research tools, and in some cases, can be developed to produce valuable commercial products. The following are just two examples:

Selling Human Cells for Profit: The Case of John Moore

In 1976 surgeons removed cancerous spleen cells from a leukemia patient, John Moore of California (USA), and later developed a cell line (designated "Mo") from the cell sample. In 1979, Moore's doctors applied for a patent on the Mo cell line, which was found to produce high levels of useful (and profitable) proteins. (The patent was granted in 1984.) In 1984, John Moore filed a lawsuit claiming that his blood cells were misappropriated, and that he was entitled to share in the profits derived from commercial uses of these cells.

The potential value of the pharmaceuticals derived from the Mo cell line could reach several billion dollars--but the California Supreme Court ruled in 1990 that John Moore has rights to none of it.[21] A clear victory for the biotechnology industry, the court ruled that although John Moore had the right to sue his doctors for failing to inform him of the potential commercial value of his cell line, he did *not* have rights of ownership over his cells after they had been removed from his body. [22]

The AI-Milano Gene

In the 1970s, Dr. Cesare Sirtori of Italy's University of Milan discovered that some residents of a small Italian village were carriers of a mutant gene that makes them produce low levels of high density lipoprotein (HDL), and thus protects them from heart disease. The discovery led to the isolation, cloning and patenting of the mutant gene with the promise of developing a genetically engineered product to treat heart disease. Dr. Sirtori now works for Kabi Pharmacia of Sweden, which holds US and European patents on the AI-Milano gene and plans to commercialize it in Europe.

Patenting the Human Cell Lines of Indigenous Peoples

In May 1993, RAFI's *Communiqué* "Patents, Indigenous People and Human Genetic Diversity" sounded an alarm, based on trends in life patenting, about potential abuses and commercialization of human genetic material. It described the Human Genome Diversity Project's (HGDP) proposal to collect and "immortalize" human tissue from 722 human populations, including many indigenous peoples from around the world. RAFI immediately notified the World Council of Indigenous Peoples (WCIP), the First International Conference on the Intellectual and Cultural Property Rights of Indigenous Peoples, and other indigenous organizations about these concerns.

In June 1993, the WCIP and RAFI raised questions about the HGDP at the United Nations Human Rights Conference in Vienna, and called for its halt until concerns about human patenting and other ethical considerations had been satisfactorily addressed by indigenous people.

As if to confirm our worst fears, RAFI discovered in August, while researching data from the American Type Culture Collection (ATCC), that the US Government had applied for US and world patents on the cell line of a 26-year old Guaymi Indian woman from Panama (W0 9208784).

We contacted the Guaymi General Congress in Panama City to inform them of these claims, and met with them in September. In letters to relevant authorities, the Guaymi demanded that the US government withdraw its patent claims, and that the ATCC return the woman's cell line to Panama. RAFI

worked with the Guaymi General Congress, the WCIP, the World Council of Churches, and a growing list of organizations worldwide, to oppose the Guaymi patent claim and all human patenting.

In early October, RAFI accompanied the Guaymi president and a colleague to Geneva, to protest the US Guaymi patent claim at the inter-governmental meeting on the Biodiversity Convention, and at the GATT Secretariat. Press statements were made in North America and Europe. The President of the Guaymi General Congress, Isidro Acosta, and Jean Christie of RAFI met with the GATT TRIPS Secretariat and determined that human genetic material is not excluded from the GATT agreement.

Later in October, the European Greens introduced an emergency resolution into the European Parliament. It opposed the world and US patent claims, requested data on human patenting in Europe, called for a common European position against human patenting, and urged a halt to the Human Genome Diversity Project. Under mounting pressure, the U.S. government withdrew its claim in early November.

> *"I never imagined people would patent plants and animals. It's fundamentally immoral, contrary to the Guaymi view of nature, and our place in it. To patent human material...to take human DNA and patent its products...that violates the integrity of life itself, and our deepest sense of morality."* [23] - Isidro Acosta, President, Guaymi General Congress

But the case is not closed, and the issue is far from being resolved. The Guaymi General Congress continues to call for the repatriation of the cell line, since there is no guarantee that it will not be used and subsequently patented by others, if it remains in the ATCC.

In December, the World Council of Indigenous Peoples invited Henry Greely, Law Professor at Stanford University, member of the North American Human Genome Diversity committee, and chair of its ethics sub-committee, to discuss the HGDP at their Annual Assembly in Guatemala. After four hours of heated discussion, the WCIP unanimously adopted a resolution to "categorically reject and condemn the HGDP as it applies to our rights, lives, and dignity", and to oppose, monitor, and publicize its progress.

In early January, Miges Baumann of the European NGO, SWISSAID, unearthed two more patent claims by the US government

on the human cell lines of indigenous peoples. Both applications are world patent claims pending in Europe.

The first patent application (Publication Number WO93/03759), filed in the name of the US Department of Health and Human Services and the National Institutes of Health, stakes claim to the human T-cell line of a Papua New Guinean. According to the patent application, blood samples were taken from 24 people who belong to the Hagahai people of Madang Province, New Guinea, in May, 1989. The cell line, the first of its kind from an individual from Papua New Guinea, is potentially useful in treating or diagnosing individuals infected with an HTLV-1 variant virus.[24] Human T-lymphotropic virus type I (HTLV-I) is associated with adult leukemia and with a chronic degenerative neurologic disease. The novel cell line is of potential value in understanding the enhancement or suppression of an immune response to this virus.

The second patent claim (WØ-9215325-A), filed in the name of the US Department of Commerce, is for the human T-cell line of a 40-year old woman from Marovo Lagoon in Western Province and a 58-year old man from Guadacanal Province, both of the Solomon Islands. Blood samples were taken in March and August 1990. Similar to the patent claim mentioned above, the cell line may be useful in producing vaccines and/or diagnosing human T-lymphotropic virus type I.

The human cell lines derived from blood samples taken from Papua New Guineans and Solomon Islanders are now on deposit at the American Type Culture Collection in Washington, DC. As noted above, access to these materials is generally restricted while patent claims are pending, even to the governments of Papua New Guinea and the Solomon Islands, without special authorization from the depositor or the European Patent Office.

As with the Guaymi patent claim, RAFI has begun to make information available about these patent claims to contacts in both Papua New Guinea and the Solomon Islands, with the goal of beginning a process to denounce, and hopefully stop the patent claims. In late January, RAFI met with embassy officials from both Papua New Guinea and the Solomon Islands in New York. Each government is considering taking action in defense of their national sovereignty.

> "*Over the last 200 years, non-Aboriginal people have taken our land, language, culture, health--even our children. Now they want to take the genetic material which makes us Aboriginal people as well.*" - John Liddle, Director of the Central Australian Aboriginal Congress[25]

RAFI continues to call for a complete halt to the Human Genome Diversity Project and similar efforts being undertaken by independent scientists, institutions, and/or governments to collect DNA samples from indigenous peoples. All such efforts must be carried out with the full approval and participation of indigenous peoples' organizations, under the auspices of the United Nations.

Do US Patent Applications on the Cell Lines of Indigenous Peoples Violate US Laws Governing "Informed Consent?"

As a means of protecting human subjects, the US government requires that US government researchers (or others who receive federal funding) obtain "informed consent" from human subjects prior to and during research. (Protection of Human Subjects, Title 45, Code of Federal Regulations, Part 46). Blood samples, for example, may not be taken by government researchers without first obtaining the "legally effective informed consent of the subject or the subject's legally authorized representative."

Informed consent requires, among other things, that the investigator provide an explanation of the purposes of the research, a description of reasonable risks involved, a disclosure of appropriate alternative procedures or treatment, etc. The information must be given in a language understandable to the subject or representative.

Informed consent regulations do not contain specific language requiring that the investigator disclose his/her intention to apply for patents on products/processes derived from human genetic material. Nor is there language requiring disclosure of the prospect of commercial gain resulting from the research. However, informed consent guidelines do require researchers to provide "a description of any benefits to the subject or to others which may reasonably be expected from the research," (CFR46.116a3) and,

"significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation." (CFR46.116b5)

A strong argument can be made that US government researchers are in violation of federal informed consent regulations if they do not disclose to research subjects: 1) their intention to patent products and/or processes derived from human genetic material; 2) the prospect for commercial gain derived from the same.

As noted above in the case of John Moore, the California Supreme Court upheld the right of an American citizen to sue on this basis.[26]

Conclusion

In the industrialized world new biotechnologies are being developed at a rate far faster than responsible social policies can be devised to guide them, or legal systems can evolve to adequately address them. In the 1980s, the US and other industrialized nations took giant steps to accommodate the biotechnology industry's desire to patent life, with public debate lagging far behind.

In the mid-1990s the biotechnology industry is lobbying vigorously to see minimum standards of intellectual property enforced worldwide. Will the US precedent for commodification of human biological materials be imposed on developing nations? Both national governments and intergovernmental organizations must now address the issue of life patenting on the basis of ethics and equity, with the full and informed participation of civil society.

The General Agreement on Tariffs and Trade (GATT), and the Convention on Biological Diversity came to a head in the closing weeks of 1993. These multilateral agreements offer two important arenas for action and debate on the patenting of human genetic materials.

The GATT trade related intellectual property agreement (TRIPS) requires that signatory states adopt intellectual property laws covering both microbial materials and plant varieties. Human genetic material is not specifically excluded from the deal.

Meanwhile, the Biodiversity Convention obliges signatory states to recognize the ownership of genetic materials by countries or companies. Germplasm collected in one country prior to the Convention coming into force must be regarded as the property of the country that now stores the material. Thus, the human cell lines of people in Panama, Papua New Guinea, and the Solomon Islands stored in the United States and under patent claim by the U.S. government are their legal property and, according to corporate interpretations of the Convention, the people and countries involved will have to pay for access to their donated human materials and any medical products derived from them. Specific actions and decisions include:

- GATT's 118 participating states (the majority from the developing world) must determine whether or not human genetic materials are included in its definition of microbial materials.
- Similarly, contracting parties to the Biodiversity Convention must come to a clear decision on the role of intellectual property with respect to biological materials and especially whether or not human genetic materials are part of the Convention.
- The Biodiversity Convention should respond to the request of indigenous peoples for protection from patent claims.
- The US Government should drop all claims to the human cell lines of foreign nationals and repatriate the materials to the indigenous communities or national governments involved.

- International protocols should be developed by the appropriate United Nations bodies for protecting and broadening the rights of human subjects from commercial exploiation and patent claims. The International Bioethics Committee of the UN Education, Scientific and Cultural Organization (UNESCO) is one such body.

A Note on Recent US Action: In October 1993 the Board of the Council for Responsible Genetics (CRG) in Cambridge, Massachusetts adopted a sweeping statement opposing patenting of the human genome. The policy states:

> *"The Human Genome is the common heritage of the human species. No individual, corporation, institution or national entity shall have patent rights to the genome and/or its parts thereof, which are properly outside the realm of patent laws. We therefore call upon the Congress of the United States to pass legislation amending the patent laws to specifically exclude from patenting living organisms and their organs and cells."*

The CRG is a US-based NGO dedicated to public education on the social impacts of genetic engineering.

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[1]Hirst, Sally I, "Biopatents: A Sense of Order," in *Trends in Biotechnology*, August, 1992, (Vol. 10).

[2]U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells--Special Report*, OTA-BA-337 (Washington, DC: US Govt. Printing Office, March, 1987, p. 49.

[3]In Diamond v. Chakrabarty the Supreme Court stated that U.S. patent law allows patenting of "anything under the sun that is made by man."

[4]U.S. Congress, OTA, March, 1987, p. 50.

[5]Hettinger, Ned, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, July 14, 1993, p. 17-18, unpublished paper. Hettinger is a professor of philosophy at College of Charleston, Charleston, SC.

[6]U.S. Congress, OTA, March, 1987, p. 5.

[7]Crespi, R.S., "The Patenting of Genetic Resources," in *Impact of Science on Society*, No. 158, p. 183.

[8]Information provided by Bobbie A. Brandon, Head, Patent Depository, ATCC, personal communication, 31 January 1994.

[9]Michael D. Rivard, "A Theory of Constitutional Personhood for Transgenic Humanoid Species," *UCLA Law Review*, Vol. 39, Issue 5, June, 1992.

[10]Annas, George J., "Of Monkeys, Man and Oysters," *Hastings Center Report* 17 (August, 1987), p. 22.

[11]Launched in 1988, the goal of the international Human Genome Organization is to locate and define the chemical sequences of all 100,000+ human genes. Gene mapping determines the relative location of different genes on chromosomes.

[12]"Declaration on Patenting of Human DNA Sequences," issued by scientists attending an international Human Genome Conference in Brazil, May, 1992. The declaration was quoted in "The Great Gene Gold Rush," by Robin Herman, *Washington Post Magazine*, June 16, 1992, p. 14.

[13]Lisa Raines, government relations official for the Industrial Biotechnology Association was quoted in "The Great Gene Gold Rush," cited above, p. 13.

[14]Charles, Dan, "First Round Lost in Battle to Patent Genes," *New Scientist*, 3 October 1992, p. 7.

[15]Dr. Cohen is quoted in *Genetic Engineering News*, "French Team Completes Physical Map of Human Genome," by Ricki Lewis, January 1, 1994, p. 35.

[16]*Bio/Technology*, Vol. 11, December, 1993.

[17]*New Scientist*, 6 November 1993

[18]Fisher, Lawrence M., "Profits and Ethics Collide in a Study of Genetic Coding," *New York Times*, January 30, 1994, p. 16.

[19]U.S. Congress, 1987, p. 52.

[20]Ibid.

[21]Hettinger, Ned, p. 2.

[22]Annas, George J., "Outrageous Fortune: Selling Other People's Cells," *Hastings Center Report*, November/December, 1990,p. 36.

[23]Isidro Acosta, translated from Spanish. Quoted in RAFI Press Release, "Indigenous People Protest US Secretary of Commerce Patent Claim on Guaymi Indian Cell Line," October 26, 1993.

[24]Information on these patent applications comes from Miges Baumann, SWISSAID, a development NGO based in Bern. January 14, 1994, received via e-mail.

[25]Mr. Liddle was quoted in *The Australian*, "Tickner warns over Aboriginal Gene Sampling," by David Nason, 25 January 1994, p. 3.

[26]*Moore v. Regents of the University of California*. For discussion see, Annas, George J., "Outrageous Fortune: Selling Other People's Cells, *Hastings Center Report*, November/December, 1990, pp. 36-39.

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