

BODY AND SOUL: The Price of Biotech

By [Philip L. Bereano](#)
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(first of two parts)

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In December of 1994, Seattle businessman John Moore traveled to Europe. He went to Brussels to visit the European Parliament; he visited Munich and took in the European patent office; and in Geneva, by the shores of the lake, he spent several hours at the World Intellectual Property Organization. These are not usual stops for a traveler's itinerary, and indeed, John Moore was not on vacation. He was in Europe because of what happened to him in 1976 when UCLA doctors removed rare "hairy cell leukemia" cells from his spleen and then developed a line of cells which produced valuable antibacterial and cancer-fighting proteins.

Of course, Moore had signed a surgery consent form which included fairly standard language allowing research to be done on his discarded tissues. But after the doctors received a patent on the so-called "Mo cell line" in 1984, Moore sued, alleging at the very least he should receive a share of the profits (potentially several billion dollars) on the grounds that-if one wanted to view it in such a light-every individual has a property right in their own body parts. In July of 1990 the California Supreme Court denied the existence of such a right of control over our own bodies (although it allowed John Moore to sue his doctors for a breach of fiduciary duty in failing to inform him of the potential commercial value of his cells). John Moore, as the only human known to have been patented in whole or in part, went to Europe last winter to lobby. The European Parliament was

considering whether or not to accept a Directive from the Executive branch of that multi-nation political entity which would have allowed the patenting of life forms, including human parts. And, in an historic vote, on March the 1st of this year, the Parliament rejected such patentability by 240 to 188. At the same time that the biotech industry is rushing ahead with myriad patent applications, the vote in Europe is yet another example of widespread concern among the general public regarding the commodification of life forms. Patenting, formerly a sleepy preserve of corporate engineers, individualistic sole inventors, and exceptionally high paid lawyers, is becoming a subject of general political discourse.

Background

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Despite the fact that Thomas Jefferson was the master of a large plantation and thus a breeder of plants and animals (as well as being a scientist and inventor himself), there's no reason to believe that when he drafted America's first Patent Act in 1793 that he intended it to cover life forms. ***Jefferson*** was quite clear, however, that he ***viewed the concept of patent monopolies as a necessary evil which could be tolerated in order to insure that "ingenuity should receive a liberal encouragement."*** ***Patents were also intended to foster the widespread dissemination of technical information which is "new" and "useful" and "not obvious" to practitioners in the field.***

Jefferson was not one to confuse means and ends, and there is no doubt that the patent system was envisioned only as a means to increase the knowledge available to the public and secure good fortune to the Commonwealth. Among the over five million patents which have been issued under Jefferson's system, there have obviously been a number which have significantly spurred the American economy.

But ***for almost 200 years the idea that general patents could cover life forms was viewed as ridiculous***; indeed, Congress refused to include coverage for plant varieties under these statutes and enacted specific (and much more limited) protection schemes for new plant varieties in mid-20th-century. In 1971, the General Electric Corporation and one of its scientists, Anand Chakrabarty, filed a patent application for bacteria which had an enhanced propensity to digest oil hydrocarbons. Although getting bugs to eat oil seems like a neat trick, the Patent Office initially rejected the application. The case was appealed to the courts. ***The Supreme Court*** had recently issued an opinion noting that "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress." However, it ***ruled in 1980, in a 5 to 4 opinion by Chief Justice Warren Burger, that the oil-eating microbe was not a product of nature but a "human-made invention."*** ***Whether it was alive or inanimate was not seen as the major criterion.*** The dissent by Justice Brennan, urged judicial restraint and noted that it was up to Congress, not the courts, to decide whether the scope of patentable matter should be extended.

All nine of the justices agreed that this was a narrow ruling, and the commentators were also essentially unanimous in the view that patentability of microbes might be one thing but monopolizing plants and animals (no one was even thinking of humans at that time) was beyond the pale. With no further guidance from Congress or the courts, the US Patent Office has run off on its own expanding the Chakrabarty ruling in many directions. ***In 1985, it decided that plants, seeds, and plant tissues could be patentable, and in 1987 all "multi cellular living organisms, including***

animals'' were held patentable (this last ruling by the Patent Commissioner, by specifically excluding human beings from patentability, did acknowledge that there was an ethical issue involved in the patenting of life). The Thirteenth Amendment (outlawing slavery) may be seen as a bar to the patenting of humans; nonetheless embryos and fetuses and human body parts all appear capable of being monopolized under these Patent Office rulings. And *now there are even attempts to patent whole human beings and their genomes.*

The Geneticization of Society

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Although there has always been a recognized public policy exemption to patentability (for example, nuclear devices are not patentable, under the Atomic Energy Act of 1954), one has to ask what ideological currents are gaining strength in America to permit such an unusual notion as the ability to have exclusive ownership of life forms. Genetics is increasingly being presented to the American public as a mysterious realm of knowledge which is now coming under human control, presumably for our economic and social betterment. "We used to think our fate was in the stars. Now we know, in large measure, our fate is in our genes," is the way this ideology has been formulated by James Watson, the Nobel laureate who participated in the discovery of the DNA double helix. This world view-which magnifies the claims to power by scientists and is trumpeted in the media-ignores the complex interactions within an organism and between an organism and its environment, as well as the social and political and economic factors that contribute to shaping life patterns.

But the biotechnology industry has succeeded in presenting itself as the next shining hope for America's economic development (along with infomatics--the computer/information industry). Together with other high tech industries, it has succeeded in making some substantial alterations in public consciousness, laws, and programs which directly benefit its own interest. These include such elements as: the enactment of the Technology Transfer Act enabling private entities to apply for patents on research which was largely funded by the government; trade negotiations such as GATT (the main purpose of the last set of negotiations-called the "Uruguay round"-was to bring global harmonization to specific areas of trade including "intellectual property rights"); tax write-offs and other governmental subsidies; and the Biodiversity Convention, which is concerned with the international legal aspects of genetic resources (the raw base of power over these important resources can be seen in the definition of the owner of genetic material-for example, a tropical medicinal-as either the country in which the species grows naturally or the country which houses a germ bank to which the germ plasm was taken and stored artificially).

Other societies have more explicit public policy examination of the patentability of life forms and products. For example, *the patent laws in Brazil, India, and Argentina forbid the patenting of pharmaceuticals on the grounds that drugs are of such great importance that no one should have the right to monopolize them.* Columbian researcher Dr. Manuel Patarroyo recently gave the World Health Organization exclusive royalty-free rights on an antimalaria vaccine he developed; "We wanted to do this for the benefit of humanity," he explained. *The European viewpoint is greatly influenced by the Napoleonic concept that denies patentability to subject matter which is contrary to ordre public, (fundamental moral precepts essentially acknowledged universally).* In Europe, too, the more explicit acknowledgment of a colonialist past may play a role in shaping public consciousness; according to a Dutch member of the European Parliament from the Green Party

"Ninety percent of the genetic resources which are used in our agricultural production come from the Third World. We have never asked if we ought to pay anything for them. And now for the biotechnology industry to demand monopoly property rights over them is utterly unjustifiable. Whether wild species or crop plants, genetic resources are the common heritage of humankind. All farmers must be guaranteed free access to them."

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Why Say No

According to GRAIN (Genetics Resources Action International), a European nonprofit organization promoting sustainable agriculture throughout the world, there are "12 reasons to say no to life patents." With patenting:

- Farmers would be obliged to pay royalties on every generation of plants and livestock they buy and reproduce for production purposes;
- Breeders will no longer have free access to germ plasm for developing new varieties of plants and animals;
- Consumers are likely to end up paying higher prices for food, medicine, and other products and biotechnology;
- Public research which is paid for by all of us will be privatized by a few;
- Market structures will undergo increased concentration;
- Genetic diversity will be diminished, as monopoly control over genetic resources severely restricts their circulation;
- The food supply will be threatened by monopoly control over genetic resources, farmers' harvests, and processed foodstuffs;
- The Third World will increasingly lose access to scientific information and technology transfer, and will see their freely donated biological resources privatized by the societies of the developed world;
- The concept of human rights will be eroded as human beings, and parts of their bodies, become the exclusive property of patent holders;
- Animal welfare will become a nostalgic notion of the past, as patenting stimulates the genetic engineering of animals to serve as industrial systems for the production of food and medicine no matter how they suffer;
- Society's relationship to nature will be reduced to a commercial enterprise based on exploitation and profit; and
- Ethical and religious values based on respect for life, creation, and reproduction will be subverted by a reductionistic and materialistic concept.

John Moore's journey successfully limited the heedless patenting of life forms in Europe. On this side of the Atlantic, however, ***more people need to insist that our policy makers address the social and ethical issues raised by the biotech industry's inappropriate attempts to monopolize life.***

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policy issues. He wishes to acknowledge colleagues around the world whose work has contributed to the ideas in this Op Ed. This is one essay in an occasional series of articles on technology policy.

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Patent Pending: THE RACE TO OWN DNA

Guaymi tribe was surprised to discover they were invented

By [Philip L. Bereano](#)

Special to The Times
(Second of two parts)

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Two years ago, for the first time in history, an applicant for a U.S. patent tried to establish monopoly ownership over the genome of a living person.

It was in August 1993 that Pat Mooney of the Rural Advancement Foundation International (RAFI) was examining a patent database primarily for agricultural information when he came across an application filed by the U.S. Secretary of Commerce on the cell line of a 26-year-old Guaymi Indian woman from Panama. A cell line is a group of cells taken from a human body that is capable of being sustained and grown in laboratory culture media, and is therefore said to be "immortal;" a line of cells contains the complete genetic code, the genome, of an individual.

These cells were believed to contain special anti-viral qualities. Although two American men were listed in the application as "inventors," it is not at all clear that their actions in taking this women's blood when she went to the hospital for treatment and isolating these cells amounts in any sense to what the ordinary American (no less Thomas Jefferson, creator of the Patent Office) would consider an "invention."

Mooney immediately contacted the Guaymi -- who, of course, had no idea they were candidates for monopolization -- and also alerted a group of international activists who had gathered in Geneva that September under the auspices of the U.S. Biotechnology Working Group.

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The Guaymi demanded that the U.S. withdraw its patent claim and return the cell line to the tribe.

RAFI and other activist groups supported the Guaymi, including bringing their president to Geneva to protest the patent claim at a number of venues -- the World Intellectual Property Organization, an intergovernmental meeting of the parties to the Biodiversity Convention, and at the secretariat of the GAT trade organization. European Greens spearheaded opposition in the European Parliament, and in early November of that year, the U.S. government withdrew its claims.

The Guaymi tribal president reflected, "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."

Subsequently, however, the U.S. government has filed two other patent applications on human cell lines of indigenous peoples -- from the Solomon Islands and from Papua New Guinea. Brushing off a letter of protest from the ambassador of the Solomon Islands, *U.S. Commerce Secretary Ron Brown stated, "Under our laws, as well as those of many countries, subject matter relating to human cells is patentable and there is no provision for considerations relating to the source of the cells that may be the subject of a patent application."*

Brown's department houses the U.S. Patent Office, which has been creating its own "law" on this subject, providing sufficient cover for Brown to dismiss such concerns.

Genetic engineering has enabled scientists to turn some barnyard animals, such as cows and sheep, into miniature chemical factories, producing valuable human proteins in their milk. *Some ethical objections have been raised to the insertion of human genes into animals, both by the animal welfare movement as well as by ethicists and religious leaders.*

Amazingly enough, on Feb. 10, 1988, a European patent application was filed by Baylor University of Texas, which would include the genetic alteration of a human female so that she could be similarly used as a drug factory, facetiously labeled by European activists as the "pharm-woman."

The British attorney who represented Baylor said the application was specifically drafted broadly because "someone, somewhere may decide humans are patentable" and therefore he wanted to make sure that they had monopoly rights to the production of important pharmaceuticals in human female breasts.

As the Guaymi situation indicates, human communities do have small, and sometimes significant, variations among the estimated 100,000 genes in our body cells. For example, it is well known that the residents of the village of Limone in the Italian Alps have significantly lower incidence of heart disease than villagers in adjacent valleys. Inbreeding of relatively isolated biological populations (plant or animal or human) can produce and maintain such variations .

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On this basis, U.S. scientists are seeking funding for a grandiose plan called the Human Genome Diversity Project, which would sample approximately 10,000 to 15,000 human beings living in 722 indigenous or isolated communities. At an overall cost of approximately \$35 million, the project will spend more money gathering each individual blood sample than the per capital gross national product in any of the world's 110 poorest countries.

Although the scientists claim to be driven by purely intellectual curiosity, it doesn't take a lot of smarts to realize that if substances like the Limone heart disease preventative were isolated the pressures to make them commercially available to other people would be intense. Presumably the patenting and marketing of such portions of the human genome would be inevitable, no matter what the current scientists, naively or disingenuously, state.

This proposal has elicited much opposition from indigenous peoples and their supporters in developed countries. Scientists in the project are anxious to start collecting these "Isolates of Historic Interest" because "they represent groups that should be sampled before they disappear as integral units so that their role in human history can be preserved."

To put this project in perspective, note that a First World society which does not provide indigenous communities with even the rudiments of public sanitation, preventative medicine or curative treatments (allowing preventable diseases such as cholera and polio to be endemic) is going to ask these communities to give us something which may be beneficial for our health care.

After having dominated most of the mineral and vegetative resources of indigenous peoples, we are now talking about turning on their very bodies as the ultimate resource to exploit.

Indigenous peoples around the world have been united in their condemnation of the Human Genome Diversity Project. Tadodaho, chief Leon Shenandoah of the Council of Chiefs of the Onandaga Nation, wrote the National Science Foundation, "Your process is unethical, invasive, and may even be criminal. It violates the group rights and human rights of our peoples and indigenous peoples around the world. Your project involves the very genetic structures of our beings."

Planning for the Human Genome Diversity Project is still going forward despite such opposition.

Genetically engineering slight variations in a species genome has given rise to numerous plant applications. Many people who think patent protection is justifiable in such situations, both over the altered genome and its new products, are still shocked by the bold step of a number of corporations trying to expand the monopoly by claiming patentability over the genome in totality.

Such "species patents" include claiming exclusive rights over the 90-plus percent of the genome that nature evolved, the myriad birds and insects produced by cross fertilization, and which reflect millennia of cultivation and alteration by indigenous peoples.

Although such patents have been issued (for example, to Agracetus Corp. for cotton and soy), the U.S. and some foreign patent offices are reconsidering them in light of concerns raised by citizens and scientists. In this context, a recent study estimates that the annual profit to developed countries from the use of agricultural genetic resources from the Third World ("indigenous intellectual property") is between \$4 billion and \$5 billion.

Another attempt to extend the notion of a patent monopoly is the application for patents on specific human genes and on human gene fragments whose function is not even known. This situation, going well beyond the facts in the Moore case (involving a Seattle medical patient whose cells were patented for research without his knowledge), is sufficiently controversial even among scientists that the primary applicant (a researcher at the National Institutes of Health) was forced to leave the government; he is now continuing these patenting efforts under corporate auspices.

Scientists in the international Human Genome Organization, however, have recently issued a statement supporting the patenting of human DNA. They only oppose the patenting of partial genes or where the biological function of the gene sequence is unknown; they categorize this work as "mechanical" and "routine," certainly not rising to the level of innovation which should be associated with a patent.

On Oct. 24, 1992, newspapers reported that a researcher had successfully cloned human embryos. this was really not a technical breakthrough because it was simply the application of widely used animal cloning techniques to different mammalian embryos -- human. Dr. George Annas of Boston University observed:

"Since cloned human embryos are persons protected by the Constitution and theoretically at least could be 'immortal' as cloned cell lines, could a particularly 'novel' and 'useful' human being be patented, cloned and sold?"

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"Bioprospecting" is a modern-day gold rush in which ethno-botanists and other scientists are combing the farms, rain forests and jungles of the Third World looking for species that might lead to improved Northern Hemisphere agriculture or produce valuable pharmaceuticals. A World Bank official gave as an example the traditional medicines utilized within the Ethiopian Coptic Church. "Let's screen that knowledge stock," he suggested, "and explore how it might be commercialized." The U.S. government is funding five major industry-university consortia which have planted their stakes in developing countries. Although some talk is heard about giving a portion of the patent royalties to the indigenous people whose community wisdom is being expropriated, such a viewpoint is yet another form of imperialism. In indigenous societies, this biological knowledge is owned collectively rather than being an individual monopoly (although it may be preserved for the community by individual shamans). Should we insist that these communities overthrow their communitarian cultural/legal systems of millennia and adopt a privatistic Northern Atlantic one instead?

Strong responses to such arrogance and insensitivity are beginning to be evident. on March 1 of this year, the European Parliament voted to ban the patenting of life forms. On Ghandi's birthday in October 1993, a half-million Indian farmers demonstrated at the offices of multinational giant Cargill, protesting the patenting of seeds which had been used in their communities for thousands of years, and objecting to the agricultural and intellectual property provisions of the GATT. And a recent meeting of indigenous peoples in Fiji called for establishing a Life Forms Patent-Free Zone in the Pacific covering bioprospecting and human genetic research; a treaty to achieve these ends is currently being drafted.

Patenting Arguments [top](#)

The bio-tech industry's arguments in favor of patenting life forms falls into two main categories, both varieties of *a claim that the patent monopoly provides fiscal incentives necessary for "progress."* These are:

- Business is risky and without the promise of patentability the industry will not be able to attract the necessary capital for research, development and production;

- Without patents, society would have to forgo new drugs and lives would be lost and unnecessary pain prolonged.

Given these plausible claims, why did the American Medical Association conclude last month that "There is no empirical evidence to support the claim that the patent system is necessary to stimulate innovation"?

First, we have to understand that the bio-technology industry has been enormously subsidized by government on all levels, even without considering the existence of the patent monopoly as an additional form of support. Almost all of the basic genetic engineering research has been supported by the federal government, either directly (for example through grants from the National Institutes of Health) or indirectly (by allowing tax writeoffs for private donations for this purpose, such as the \$12 million gift by Microsoft founder Bill Gates which hired geneticist Dr. Leroy Hood to the University of Washington.)

Most of the laboratories on university campuses (where almost all the original work was done) were built with federal funds. Most of the younger researchers were supported on scholarships and fellowships by the NIH. Since citizens have made the investment which produced this new technology, why aren't the results considered public property available to anyone?

Even the Agricultural Biotechnology Council (an industry-government-university consortium) has noted that a public ownership mechanism -- which has been used occasionally by the government -- "has the advantage of stimulating the innovative activity without granting anyone the right to restrict its diffusion to others, as do grants of monopoly rights like patents."

Of course, in an era when the notion of privatization is running amok, advancing this argument may seem foolhardy; nonetheless, it is eminently sensible and just.

A second consideration is that *a great deal of the work occurring in the private sector consists of relatively small modifications to the enormous body of knowledge created by public funding or developed communally over the millennia.* Shortly after the Supreme Court decision granting a patent on genetically engineered oil-eating bacteria, Dr. Anand Chakrabarty told *People* magazine, "I simply shuffled genes, changing bacteria that already existed. It's like teaching your pet cat a few new tricks." And the grand Jeffersonian scheme that knowledge would be widely shared and made available to all (to provide the basis of yet additional inventions) has in fact been thwarted by the modern patent system in which the talents of the good patent attorney are enlisted in order to disclose as little as possible in the body of the patent document, Why let your competitors know exactly what you are doing if you can get away with not telling them?

The free exchange of scientific information in biology departments and scientific meetings has been substantially affected by a reluctance to talk about one's work and by delays in publications and lectures, until the patent application is filed; academic colleagues have been transformed into industrial competitors.

In the words of the NABC, "The openness and free flow of ideas so important to the development of knowledge is slowed by this atmosphere of safeguarding information in the hopes of making it proprietary."

The patenting of a drug may, in fact, restrict the ability of ordinary people to gain access to medication because the price may be artificially inflated due to the monopoly. this was clearly the case with AZT, the first anti-HI drug put on the market (developed with federal funds by National Cancer Institute but marketed under a special statute giving patent rights to private distributors.)

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Finally, much of the discussion collapses into fundamental questions of ethics. *Is a gene part of "life" or merely a bit of chemical?* Do we care whether the natural world is being desacralized by transformations of intricate organic interrelationships within ecosystems into isolatable commodities which can be exclusively fenced off and exchanged to the highest bidder?

This spring, American leaders of many religious denominations -- Protestant, Catholic, Jewish, Muslim and Buddhist -- gave voice to the sentiment which most of their congregants knew intuitively: It is unethical to patent life forms. ([To read an article on this statement, click here.](#)) Life patenting is not an issue which pits liberals against conservatives. Rather, elements of both the left and the right are raising concerns about the directions which technocrats (in the Patent Office, among venture capitalists, and on campuses) are taking society. Many voices are increasingly suggesting that it is time to step back and evaluate what is happening. A recent essay in The New York Times marking the passing of Dr. Jonas Salk discussed the conquest of polio and noted that the March of Dimes prohibited patenting or receipt of royalties on the results of its research projects. The late TV commentator Edward R. Murrow, in an interview occasioned by the immense public excitement created by the trials of the vaccine, asked Salk who would control the new pharmaceutical. Salk replied, "Well, the people, I would say. There is no patent. Could you patent the sun?"

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