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*Confronting the Abolition of Man*

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PATENTS ENCROACH UPON THE BODY

Andrew Kimbrell

To justify patenting living organisms, those who seek such patents must argue that life has no "vital" or sacred property. . . . But once this is accomplished, all living material will be reduced to an arrangement of chemicals, or "mere compositions of matter."

—Ted Howard, *amicus* brief before the Supreme Court in the *Chakrabarty* Case (1979)

We've known for years that we are a bag of chemicals, mind you a very special bag of chemicals.

—Jeffrey Powell, *associate professor of biology, Yale University, at the Sixteenth International Congress of Genetics* (1988)

OVER 200 YEARS AGO, Thomas Jefferson introduced America's first Patent Act. An amateur scientist himself, Jefferson was determined to ensure that "ingenuity should receive a liberal encouragement." In 1793, Congress enacted into law a proposal allowing inventors to patent "any new and useful art, machine, manufacture or composition of matter, or any new useful improvement [thereof]." As established by the 1793 law, a patent is a grant issued by the U.S. government giving the patent owner the sole right to make, use, or sell an invention within the United States during the term of the patent—generally 17 years. Whatever "machine, manufacture or composition of matter" invented—be it an airplane, computer, pesticide, or toaster—the patent provides a government-sanctioned monopoly to the inventor of the product. This is a financial reward for the inventor's ingenuity, designed to help the inventor recoup the time and expense spent in creating the new and "useful" invention.

For better or worse, the U.S. economy has been built on innovation rewarded by the patent system. Since 1793, over five million patents have been issued. Patents pro-

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ANDREW KIMBRELL is attorney and policy director for the Foundation on Economic Trends in Washington D.C. His book, *The Human Body Shop*, has just been published by Harper San Francisco.

vided the profit trigger for the machine age in America. It's an American truism that behind each great discovery lies a patent.

But on October 29, 1991, the United States Patent and Trademark Office (PTO) issued a patent of a type never imagined by Jefferson and more startling than any of the millions that preceded it—a patent which represented a bold expansion of commerce into what can only be described as the "human body shop," and a major development in the industrialization of life. On that day, for the first time, the patent office granted patent rights to a naturally occurring part of the human body. Patent number 5,061,620 grants to Systemix Inc., of Palo Alto, California, corporate control of human bone marrow "stem cells" (stem cells being the progenitors of all types of cells in the blood). What makes the patent remarkable, and legally suspect, is that the patented cells were not any form of product or cell line. They had not been manipulated,

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engineered, or altered in any way. The PTO had never before allowed a patent on an unaltered part of the human body.

Stem cells, which are key to bone marrow transplants and other treatments designed to help a patient produce healthy blood, are difficult to isolate. Researchers at Systemix claim to have discovered a process that yields an unusually pure strain of stem cells. The Systemix process could represent a significant breakthrough in improving

bone marrow transplants and in the developing of new genetic therapies for leukemia and a variety of other blood disorders—even for AIDS patients. What stunned

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and outraged the scientific community was that the Systemix patent not only covers the process by which Systemix isolates human stem cells, but the stem cells themselves. "It really is outlandish to believe you can patent a stem cell," asserted Peter Quesenberry, medical affairs vice chairman of the Leukemia Society of America. "Where do you draw the line? Can you patent a hand?"

If the stem cell patent survives an inevitable series of court challenges, every individual or institution which wishes to use stem cells for a commercial cure for diseases or disorders would have to come to a licensing agreement with Systemix. Systemix now has its own privately controlled monopoly on human stem cells. As ethicist Thomas Murray says, "they've invaded the commons of the body and claimed a piece of it for themselves."

The cell patent granted to Systemix has been accompanied by patent applications even more astounding. On June 20, 1991, National Institutes of Health (NIH) researcher Craig Venter filed a 400-page patent application that would result in patent protection and ownership for 337 genes found in the human brain. This controversial application is seen by many in the scientific community as the first step in the patenting all of the 100,000 or more human genes. A few months after the first application, Venter applied for patents on 2,000 more brain genes fragments. This would represent patent ownership of roughly five percent of all human genes.

VENTER IS one of dozens of scientists around the world involved in gene sequencing and mapping. Like many others taking part in the various human genome research projects, Venter's work is somewhat mechanical. His job is to locate the chemical sequences which make up genes. He and the other researchers have no idea what function the genes they are "tagging" actually perform in the human body. In fact, it may take years after various genes are identified before their func-

tions in human biology or psychology are even partially understood. Yet no matter how deep their current ignorance about the function of the brain genes they have tagged, Venter and others at the NIH want to patent them all. Any one of the genes could turn out to be extremely valuable—perhaps a key gene for brain cancer research or future therapies to increase I.Q. The researcher and NIH could then form lucrative licensing agreements with biotechnology companies for exclusive commercial exploitation of the genes. As such, Venter's patent claim has been aptly compared to a "quick and dirty land grab"—equivalent to attempting to claim large tracts of land in the hope that some of the acres contain oil or gold. Dr. James Watson, co-discoverer of the structure of DNA and former head of the \$3 billion U.S. Human Genome Project, which is committed to mapping and sequencing each and every human gene, called the patent applications "sheer lunacy." Many believe Watson's strong stance against the patents led to his resignation from the Genome Project in April 1992. Then in July of 1992, Venter announced that he was leaving the NIH so as to establish his own gene-mapping institute with the help of \$70 million from a venture capital fund. Locating and patenting genes has become big business.

### Genetic Monopoly

Venter's patent application, and similar applications by other governmental and private corporations, create a unique and profoundly disturbing scenario. The entire human genome—the tens of thousands of genes that are our most intimate common heritage—will be owned by a handful of companies and governments. While the pro up to now has not accepted Venter's applications, if his (and others) are accepted, a few government bureaucracies and powerful corporations will have a monopoly to make use of, or sell, all human genes. We will see the privatization of the genes that make up the human body—the corporate enclosure of our genetic commons.

Not surprisingly, the patenting of human cells and genes has led to massive legal and moral confusion. For example, one patient, John Moore, is suing the University of California for a share of the millions of dollars of profits being made on a cell line created from his spleen cells. The California Supreme Court denied his claim. Kevin O'Connor, a senior analyst at the U.S. Office of Technology Assessment (OTA), confesses that few have even begun to think through all the arguments on whether the human genome or combinations of genes and cells can be patented. Others are concerned about the potential patenting of human body parts including ultimately the entire human body. Derek Wood, head of the biotechnology patent office in London, comments:

This is clearly an area that is going to prove a pretty horrendous problem in the future. The difficulty is in deciding where to draw the line between [patenting] genetic material

and human beings per se. Until we have a specific case in front of us we have to make some pretty delicate judgements.

Those delicate judgments will have to come sooner rather than later. According to published reports, the European Patent Office (EPO) has received patent applications which would cover women who would be genetically engineered to produce valuable human proteins in their mammary glands. The genetic engineering of mammals (such as mice, cows, and sheep) to produce various

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valuable human proteins in their milk is underway and has shown some success. The EPO patent applications demonstrate that researchers want patent protection that would include any women who would be genetically altered in a similar manner. In one reported instance, Grenada Biosciences of Texas has applied to the EPO to patent genetically altered mammals created by Baylor College of Medicine in Houston, and wants the patent to include both genetically altered animals and humans. Brian Lu-

cas, a British patent attorney who represented Baylor College, has stated that the American patent attorneys who wrote the Grenada/Baylor application that was submitted to the EPO carefully crafted the application to include the coverage of women because "Someone, somewhere may decide that humans are patentable." The attempt to patent a "pharm-woman" who would produce valuable pharmaceutical products in her breasts has stirred considerable controversy in Europe. Paul Lamoye, the Belgian president of the European Green Party, called the reports of the patent applications "chilling news." He noted that "The fact that medical researchers and biotech companies have the audacity to even apply for it is clear evidence of the frightening direction this technology is taking."

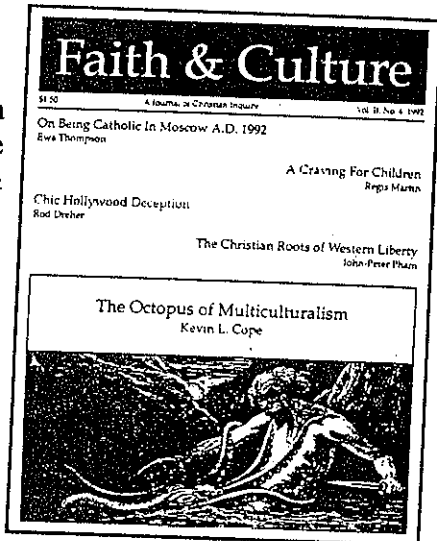
**H**OW COULD this be? How did our cells, genes, embryos, and body parts become assignable commodities? How could living things or parts of living things, including the human body, be seen as patentable products indistinguishable from mechanical or chemical products? When was it determined that the building blocks of life belonged not to God, humanity, or nature, but to patent holders? And perhaps most perplexing, when and how was it determined that the historic question of the legal meaning of life was to be decided not by the people, but by the U.S. Patent Office? The answers to these questions draw us back two decades and to the very definition of a "slippery slope."

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## Of Men in Mice

Working for General Electric in Schenectady, New York, in 1971, Indian microbiologist Ananda Mohan Chakrabarty set out to develop a special kind of "bug" that would eat crude oil. Its central use would be to devour oil slicks created by tanker spills or similar disasters. Nature already had produced several strains of bacteria that had the propensity to digest different types of hydrocarbons in oil. All of these bacteria were from a family of bacteria known as *Pseudomonas*. Each of these bacteria had plasmids (auxiliary parcels of genes) which break up or "eat" oil. The trick was to somehow put them all together to get a "super," oil-eating bacteria. Chakrabarty performed this feat of genetic manipulation by fusing the genetic material from four types of *Pseudomonas*. Taking plasmids from three of the oil-eating bacteria, Chakrabarty transplanted them into the fourth, thereby creating a crossbred version with an enhanced appetite for oil.

In 1971, G.E. and Chakrabarty applied to the U.S. Patent and Trademark Office (PTO) for a patent on their genetically engineered microbe. After several years of review, the PTO declined the request. The agency rejected the Chakrabarty application on the premise that animate life forms are not patentable. PTO noted that, if either Jefferson or Congress had intended life to be patentable under the 1793 Act, they would say so in the law. The PTO also noted that, in the few instances in which life forms had been patented—certain asexually reproducing plants—it was not the Patent Office which authorized the patenting, but, rather, specially designed legislation passed by Congress.

G.E. and Chakrabarty appealed the Patent Office rejection to the Court of Customs and Patent Appeals (CCPA). To the shock of many, they won. In an historic opinion, the CCPA, in a three-to-two decision, reversed the decision by the Patent Office and held that Chakrabarty could patent the oil-eating microbe. For the first time in patent law history, a court had allowed the patenting of a life form. The opinion was direct: "the fact that microorganisms . . . are alive . . . [is] without legal significance." The legal distinction between living and non-living matter had been rejected. The court attempted to minimize its historic legal melding of animate with inanimate by noting that microorganisms were patentable because they are "more akin to inanimate chemical compositions such as reactants, reagents, and catalysts, than they are to horses and honeybees or raspberries and roses."

THE PTO was not impressed by the CCPA's legal decision to patent life, even lowly life forms. It held to its original rejection of the G.E. patent, and appealed the CCPA decision to the Supreme Court. Many supported the PTO's rejection of life patents. One amicus brief submitted

by a public interest group powerfully posited the importance of the Chakrabarty case:

The case before the court may not appear to involve the life and death issues and passions of abortion, euthanasia or brain death rulings. Nonetheless, appearances aside, this case actually eclipses the import of these others because, in reaching a decision, a precedent-setting determination of the very nature of life will have to be decided upon. Whether such a definition is explicitly stated by the Court or not, hardly matters. If a ruling in favor of patenting genetically engineered living organisms is forthcoming, then manufactured life—high and low—will have been categorized as less than life, as nothing but common chemicals.

Several legal analysts also warned that, though the *Chakrabarty* case concerned a mere microbe, it could be used as a precedent for patenting decisions on all other life forms including plants, animals, and perhaps—eventually—humans.

Oral argument before the court was held on March 17, 1980. Three months later, the Court handed down its decision. By a five-to-four margin the Court upheld the patenting of life. Chakrabarty was to be granted his patent. The Court stated that "the relevant distinction was not between living and inanimate things," but whether living products could be seen as "human-made inventions." The four dissenters issued a terse and understated five-paragraph opinion written by Justice William Brennan. It concluded:

It is the role of Congress, not this court, to broaden or narrow the reach of patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

All nine justices deciding the *Chakrabarty* case did agree on one thing. They specifically noted that this was a "narrow" case—one which did not affect the "future of scientific research." Chief Justice Warren Burger went out of his way to note that his decision in no way implicated "the gruesome parade of horrors," including the engineering and patenting of animals and man, cited in various amicus briefs. The complete failure by the Court to correctly assess the impacts of the *Chakrabarty* decision may go down as one of the most important judicial miscalculations in United States history.

The biotechnology industry heralded the Court's decision as "enlightened" and a "breakthrough." Others were not so sure. Ethicist and author Leon Kass summarized the concern of many:

What is the principled limit to this beginning extension of the domain of private ownership and dominion over living nature? Is it not clear, if life is a continuum, there are no visible or clear limits, once we admit living species under the principle of ownership? The principle used in *Chakrabarty* says that there is nothing *in the nature of a being*, no, not even in the human patentor himself, that makes him immune to being patented. . . . To be sure, in general it makes sense to allow people to own what they have made, because they art-

fully made it. But to respect art without respect for life is finally contradictory.

The next decade was to prove correct both patenting proponents and opponents. Patenting *did* provide the trigger for a lucrative biotechnology industry. It also created the slippery slope feared by Kass and other ethicists.

In 1985, five years after the Court's historic decision, the PTO ruled that the *Chakrabarty* holding allowing the patenting of microbes could be extended to include the patenting of genetically engineered plants, seeds, and plant tissue. By 1987, the Reagan Administration's patent "slippery slope" had turned into an icy precipice. On April 7 of that year, the Patent Office issued a ruling specifically extending the *Chakrabarty* ruling to include all "multicellular living organisms, including animals." The radical new patenting policy suddenly transformed a decision about patenting microbes into one allowing the patenting of all life forms on earth, including animals. The ruling meant that, if a researcher implants foreign cells or genes into an animal—for example, cancer cells into a mouse, or human growth genes into a pig—the genetically altered animal is considered a human invention under Jefferson's two-century-old definition of patentable "manufactures." The patented animal's legal status is no different from other manufactures such as automobiles or tennis balls.

For those concerned about the ethics of patenting life,

the revolutionary 1987 ruling on the patentability of animals, signed by Donald J Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, did have a silver lining. The PTO ruling excluded human beings from patentability. The restriction on patenting human beings was based on the Patent Office's interpretation of the

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Thirteenth Amendment of the Constitution, the anti-slavery amendment, which prohibits ownership of a human being. Unfortunately, there were several problems with the exemption of humans. For one, under the PTO's 1987 ruling, embryos and fetuses—human life forms not presently covered under Constitutional Thirteenth Amendment protection—are patentable, and so are genetically

## THE ASSUMPTIONISTS

### Augustinians of the Assumption



The crisis of our time reaches back to the last century. The Assumptionists were founded to meet that crisis.

Emmanuel d'Alzon, a man of energy and vision, gathered others to work with him to rescue God's human family wherever it was threatened. Not a man for the quick fix or stop gap

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engineered human tissues, cells, and genes. In fact, a genetically engineered "human" kidney, cornea, arm or leg, or any other body part might well be patentable. As we have seen, even a genetically engineered woman who has been altered to produce a certain valuable pharmaceutical in her mammary glands may be patentable.

On April 12, 1988, the U.S. Patent Office issued the first patent on a living animal. The patent was issued to Harvard Professor Philip Leder and to Timothy A. Stewart of San Francisco for their creation of a transgenic mouse containing a variety of genes found in other species, including chickens and man. These foreign genes were engineered into the mouse's permanent germline in order to predispose it to developing cancer. The mouse was genetically engineered and designed to be a better research animal in which to test the virulence of various carcinogens.

In December 1992, and again in February 1993, five more animals were patented. There are now over 190 animal patents pending at the PTO. Many are for fish, cows, and pigs which have had human genes engineered into their permanent genetic codes in order to change size, skin consistency, reproduction, or other traits.

### Life or Machine?

Now, as human cells are patented, and thousands of human brain genes are patent-pending, and almost 200 animals—many containing human genes—are lined up for patenting, we have an important perspective from which to survey the influence of the Supreme Court's ill-advised decision in *Chakrabarty*. The *Chakrabarty* decision has

*In coming weeks, Congress will hold hearings on these issues, and the Office of Technology Assessment will issue a report. As Congress seeks to legislate on the question, it will have to decide between two very different definitions of life.*

continued to extend up the chain of life. The patenting of microbes inexorably led to the patenting of plants, then animals, and, finally, human body elements. Most of the "gruesome parade of horrors" predicted by those opposing the 1980 patent decision have become, in dizzying rapidity, realities.

The distance traveled since the *Chakrabarty* decision in furthering the patenting of life can be highlighted by considering whether the Court, in 1980, would have ruled that life forms were patentable had the organism in question not been a lowly, ineffective, oil-eating bacteria, but a human embryo, or a genetically engineered chimpanzee, or the entire set of over 100,000 human genes. The an-

swer, clearly, is *no*. The Supreme Court never would have ruled for the patenting of these other living organisms or human subparts. Any such decision would have led to an immediate uproar in the legal and ethical community. Yet, down the slippery slope of the last decade, just such an expansion of patenting has occurred. History has born out bio-ethicist Robert Nelson's assessment of *Chakrabarty*: "It's a staggering decision. It removes one more barrier to the protection of human life. Good God, once you start patenting life, is there no stopping it?"

Now, as government agencies refine the legal and technical means to patent numerous life forms and untold thousands of humanity's genes and cells, we can only look with extreme trepidation at the future with regard to the patenting of life. There is little question that, unless stopped, the patenting juggernaut will continue to transgress into life in all its forms. As research continues in cell analysis and in the deciphering of the human genome, corporations and researchers will fight for patent ownership of commercially valuable genes and cells held to be the key to health, intelligence, or youth. As there are advances in reproductive technology, human embryos will be up for patent grabs. Animals with increasing numbers of human genes will be patented. Genetically engineered human body parts almost certainly will be patented. And, looking into the more distant future, perhaps a genetically altered human body itself may be patentable. As patenting continues, the legal distinction between life and machine, life and commodity will begin to vanish.

In coming weeks, Congress will be holding hearings on these patenting of life issues, and the Office of Technology Assessment will be issuing a report. As Congress seeks to legislate on the patenting of life question, ultimately it will have to decide between two very different definitions of life. Senator Mark Hatfield, Republican of Oregon, and a leader in the Congressional fight against life patenting, sums up the dilemma:

The patenting of life forms brings up the central ethical issue of reverence for life. Will future generations follow the ethic of this patent policy and view life as mere chemical manufacture and invention with no greater value or meaning than industrial products? Or will a reverence for life ethic prevail over the temptation to turn God-created life into reduced objects of commerce?

Others, however, are eager for the new definition of life to become a reality. The *New York Times* has repeatedly supported the patenting of life. In a lead editorial, "Life, Industrialized," the *Times* succinctly stated a view of life consistent with patenting:

Life is special, and humans even more so, but biological machines are still machines that now can be altered, cloned and patented. The consequences will be profound, but taken a step at a time, they can be managed. ❖