The Battle to Patent Your Genes

The Meaning of the Myriad Case

Marcy Darnovsky & Jesse Reynolds

April 12, 1955 was a day of celebration. Across the United States, church bells rang, sirens blew, and people poured into the streets singing and dancing. The rejoicing was a spontaneous response to news that field trials of Jonas Salk's vaccine against the dread polio virus had been successful. The public had avidly followed the search for a vaccine for years. Hundreds of thousands of volunteers had participated in the trials, and tens of millions contributed dimes, quarters and dollars to the effort. According to a 1954 Gallup poll, more Americans knew about the polio field trials than knew the full name of their President, Dwight David Eisenhower.

On the day the field tests were pronounced a success, Edward R. Murrow interviewed Salk live on his television show *See It Now*. "Who owns the patent on this vaccine?" Murrow asked. "Well, the people, I would say", Salk replied. "There is no patent. Could you patent the sun?"[1]

What a difference a half-century makes. Today, patent applications are a part of the research routine, especially in the life sciences. Pharmaceutical and biotechnology companies, universities and governments hold patents not just on vaccines and other drugs and devices critical to human health, but also on things once considered beyond the reach of property law. For example, in recent decades, patents have been granted on a menagerie of laboratory-created life forms, from microbes like the oil-eating bacterium at issue in a 1980 Supreme Court case to mammals like Harvard's OncoMouse, genetically modified to be cancer-prone.

Human bodies have also become sources of materials that can be privately claimed and commercially exploited. A wide variety of human tissues and molecules have been ruled patentable. Most troubling to many are the patents that now bedeck the human genome. The U.S. Patent and Trademark Office (USPTO) has granted somewhere between 3,000 and 5,000 patents on human genes themselves, including those associated with Alzheimer's disease, muscular dystrophy, colon cancer, asthma, and many other illnesses. A 2005 study published in *Science* estimated that some 20 percent of all human genes had

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[1]Sources for all quotations and case law referred to in this essay are available from the editors upon request.

already been patented, 63 percent of them by private firms.[2]

Though patents on human genes are strongly supported by the biotechnology industry and its financial backers, they make many basic researchers uneasy. For example, the Human Genome Project website points out that because U.S. patent applications must remain confidential for 18 months after filing, researchers who use genetic sequences "risk facing a future injunction if those sequences turn out to be patented by a private company."

Patents confer a great deal of power. For 20 years (after which the protected inventions are supposed to enter the public domain), they give their holders the right to prevent anyone—including doctors, patients and other researchers—from studying or testing "their" genes. They control what research can be done on the genetic sequences themselves or any mutations of them, whether for commercial or other purposes. They can decide who can do diagnostic tests involving those genes, and—through royalties—determine how much the tests cost.

In contrast to the keen public interest in Dr. Salk's pronouncement about the ownership of the polio vaccine, few Americans outside the biotechnology industry and specialized legal and business circles are aware of what the subtitle of a recent book by attorney and philosopher David Koepsell terms *The Corporate Gold Rush to Patent Your Genes* (2009). Many people are shocked to learn that exclusive rights to human genes can be assigned patents at all. There has been surprisingly little public discussion of the broad social and ethical concerns raised by gene patents, or of their concrete implications for health care and biomedical research. But that may be about to change.

In May, the half-million-member American Civil Liberties Union and the Public Patent Foundation of the Benjamin Cardozo School of Law at Yeshiva University filed a lawsuit that could turn gene patents into a public controversy and change the way many biotechnology companies do business. Most previous gene patent cases have involved a battle over ownership of a particular gene in which neither side has any incentive to question the gene's patentability. However, this lawsuit challenges the validity and constitutionality of human gene patents in general, and specifically of two genes associated with a greatly increased risk of breast and ovarian cancer. Observers are already predicting that the case will eventually wind up before the Supreme Court, which has never directly ruled on the patentability of human genes.

In addition to the USPTO, the lawsuit names Myriad Genetics, a private corporation, and the University of Utah Research Foundation, which together hold the patents on the breast cancer genes known as BRCA1 and BRCA2. Its twenty plaintiffs include four scientific organizations representing more than 150,000 researchers and laboratory professionals; two influential women's health organizations, Breast Cancer Action and Our Bodies Ourselves; and individual researchers, genetic counselors and breast cancer patients.

The plaintiffs give several reasons for their challenge. Genetic scientists state that Myriad has directly prevented some of their work with cease-and-desist letters, and indirectly hindered other research because of the chilling effects of its aggressive patent patrolling. And because Myriad has exclusive control over the data it collects from its tests, it has the sole power to use—or to withhold from other researchers—a large set of data with significant implications for breast cancer research.

Several women's health organizations say that Myriad has kept the cost of the test for BRAC1 and BRAC2 unreasonably high; priced at more than $3,000, some women who need it can't afford it. Myriad's monopoly also means that no one can develop additional tests on the genes. Breast Cancer Action says that some women get ambiguous results from Myriad's test, but there is no alternative to it. Breast cancer patients and their female relatives point out that they can't get second opinions about their particular genetic variants or the interpretation of them and are thus forced to make decisions about their health care with inadequate information.

These are some of the immediately tangible consequences of Myriad's patents and the way the company has chosen to protect them. A

[2]Kyle Jensen and Fiona Murray, "Intellectual Property Landscape of the Human Genome", *Science* (October 14, 2005).

lawsuit, of course, also turns on precedent and technical legal issues. The ACLU and Public Patent Foundation make three core legal claims in this regard. First, they argue that gene patents violate the Federal patent statute, which—as interpreted by the courts—says that products of nature and laws of nature are not patentable subject matter. Defenders of gene patents contend they are valid because they apply to genes in their "isolated and purified" state, but the ACLU and Public Patent Foundation argue that "[h]uman genes, even when removed from the body, are still products of nature, and their associations with diseases are laws of nature."[3]

Second, the lawsuit claims that gene patents violate the Constitution's patent clause, which gives Congress the authority to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." But awarding patents on human genes fails to promote the progress of science, the lawsuit says; in fact, it "slow[s] scientific advancement, because there is no way to invent around a gene—the gene is the basis for all subsequent research."[4] However, backers of gene patents highlight their utility, claiming they provide important incentives for socially beneficial discoveries.

Third, the lawsuit makes the novel argument that, because the BRCA patents and most gene patents cover the actual variation among individuals' genes and the relationship between the genes and biology, they violate the First Amendment. The plaintiffs hold that while a particular gene test is a patentable invention, a claim to all of a particular gene's tests, variants and biological roles is not. A gene, argues the lawsuit and many scientists, is both a basic research tool and an idea, and thus patents on them amount to prohibitions on thinking about the genes' roles. Patents are meant to provide an incentive to build a better mousetrap, but human gene patents, in effect, claim the entire concept of catching mice.

Summarizing the legal and political arguments, ACLU Executive Director Anthony Romero said in a May press statement,

> Knowledge about our own bodies and the ability to make decisions about our health care are some of our most personal and fundamental rights. The government should not be granting private entities control over something as personal and basic to who we are as our genes. Moreover, granting patents that limit scientific research, learning and the free flow of information violates the First Amendment.

The ACLU/Public Patent Foundation suit is the first with a chance of getting the Supreme Court to consider how the "product of nature" and the "isolated and purified" doctrines should be applied to human gene patents, and the first patent challenge to invoke the First Amendment. It's also the first challenge supported by a large number of prestigious scientists who explicitly counter the argument that gene patents are needed for scientific progress.

To date, U.S. courts have had far more to say about human gene patents than has Congress or the Executive Branch. The focus has thus been on technical legal issues rather than on social consequences and the broader public welfare. Although granting intellectual property rights on human genes strikes many people as odd if not morally wrong, and certainly as a new development that ought to be debated, the broader concerns and questions have not been much considered even by policymakers or elected officials, and certainly not by the public.

There has been at least one recent exception, however. In 2007, a bipartisan bill crafted by Representatives Xavier Becerra (D-CA) and Dave Weldon (R-FL) proposed to disallow future human gene patents. Their Genomic Research and Accessibility Act was a model of simplicity. Its 180 words would have added a "prohibition on patent of human genetic material" to the U.S. Code. In a statement on his website, Becerra argued in 2007 that "Congress has the constitutional right to proliferate and reward the advancement of invention, but it also has the responsibility to intervene should

[3]ACLU Fact Sheet: Genes and Patents on "BRCA: Genes and Patents", available at www.aclu.org/brca.

[4]ACLU Fact Sheet.

that advancement be misdirected or incorrect."

The Becerra-Weldon bill received high-profile support from the late Michael Crichton, the best-selling author of science-based thrillers like *Next* (2006), whose plot centers on a greedy corporation bent on protecting its gene patents at all costs. A *Wall Street Journal* review said that Crichton "makes five eminently sensible policy suggestions" about human gene patents that "might chafe some biotech companies, but are essentially pro-market and pro-research." In a February 2007 *New York Times* op-ed applauding the bill, Crichton wrote, "Genes aren't human inventions, they are features of the natural world. You can't patent snow, eagles or gravity, and you shouldn't be able to patent genes, either."[5] The bill died in committee, but Becerra plans to reintroduce it soon in very similar form. Supporters of the bill are careful to make clear that they do not oppose patents in general, and that they strongly support medical research.

The legal basis for patents derives from interpretations of the Constitution, in which the Federal government's authority to oversee intellectual property is among its few enumerated powers. By the mid-19th century, the foundation of modern intellectual property law had been set: Patents may be granted on a "process, machine, manufacture, or composition of matter" that is novel, useful and non-obvious (the last characteristic was added by an 1850 court case).

Claims on natural substances and processes have been particularly controversial from the outset. In 1853, the Supreme Court rejected one of Robert Morse's patent claims to the telegraph, declaring that electromagnetism itself is "a principle of nature" and thus outside the purview of patents. In subsequent cases, American courts walked a fine and sometimes seemingly contradictory line in judging the patentability of natural substances. In 1884, the Supreme Court declared that a synthesized chemical with the same structure as one found in nature cannot be patented. Then in 1912, a Federal circuit court held that "isolated and purified" adrenaline, which is found in nature but only in a more dilute form, *can* be subjected to patent claims. Soon after World War II, the Supreme Court ruled that a proprietary mixture of bacteria, each kind of which occurs naturally but not collectively, cannot be patented.

A case often cited as a turning point in the history of patents on biological entities is *Diamond v. Chakrabarty* (1980), in which the Supreme Court held in a five to four ruling that life forms created in the laboratory are patentable. The "invention" in question in this ruling was a modified bacterium that a patent examiner had originally found to be outside the legal definition of patentable "subject matter" on the grounds that it was a living organism. Others observed that the microbe was merely a mixture of genes found in nature. But the Court majority said that it is a product of manufacture, not of nature, and that "anything under the sun that is made by man" is subject to patent claims. Despite citations of *Chakrabarty* in many accounts of gene patents, the ruling did not address the patentability of genes. In fact, the Supreme Court in its ruling specifically said:

> The laws of nature, physical phenomena, and abstract ideas have been held not patentable. Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. . . . Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'

Two years later, the USPTO granted the first patent for a human gene sequence to the University of California for the "isolated and purified" form of a gene that encodes the insulin protein. Myriad Genetics filed for its patents on the BRCA genes in 1994 and 1995. After several years of legal skirmishes, it established complete control over them by 1999.

But the gene patent gold rush really began in earnest when the private biotech company Celera, led by publicity-seeking scientist-entrepreneur Craig Venter, initiated a race with the publicly funded Human Genome Project. Celera used newly developed techniques to identify short sections of DNA that can be used to identify genes, though their function may be unknown. Its business model was to patent these DNA fragments quickly, and then to sort out

[5] "Patenting Life", *New York Times,* February 13, 2007.

their usefulness later. These patents on DNA fragments alarmed many scientists, who feared that they would interfere with subsequent research. In 2001, the USPTO tightened its regulations to exclude some DNA sequences, but it continues to grant patents on human genes and some DNA fragments.

If the United States has pushed the envelope on patenting human genes, its permissive policy has pulled the rest of the world in its direction. The primary international agreement governing intellectual property, the Trade-Related Intellectual Property Rights Agreement (TRIPS) of the World Trade Organization, requires nations to make patents available for inventions that are "new, involve an inventive step, and are capable of industrial application." This standard is similar to the traditional U.S. approach, although TRIPS permits denials for reasons of public health, or if a patent would be contrary to "public order or morality."

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European Union policies are not far from those of the United States, despite its generally stronger resistance to the "commodification of life." Unlike the United States but like TRIPS, the European Patent Office (EPO) permits public health and morality exceptions, although in practice they are almost never exercised. Its 1998 Directive on human gene patents also explicitly removes some practices, such as human cloning and genetic modification, from the purview of patent claims.

Myriad's BRCA gene patents, in particular, have not fared well internationally. After years of challenges, the EPO only recently reached a compromise that partially allows them. Ontario, Canada's most populous province, is simply ignoring the patent, and conducting its own BRCA tests at publicly funded labs at a far lower cost.

Public concerns about patents on genes and other biological products are often couched as opposition to "owning life." The phrase bespeaks disquiet about the very idea of treating human tissues and genes as private property to be exploited for profit rather than managed in the public interest. Various international bodies have declared the human genome to be part of a "commons." The Universal Declaration on the Human Genome and Human Rights, ratified by the United Nations General Assembly in 1998, states that the "human genome . . . is the heritage of humanity" and "in its natural state shall not give rise to financial gains." In 1999, the Parliamentary Assembly of the Council of Europe, a 47-member intergovernmental human rights body, declared "that neither plant, animal nor human derived genes, cells, tissue or organs can be considered as inventions nor be subject to monopolies granted by patents." The World Medical Association, an umbrella for 84 national medical associations, states that "human genes must be seen as mankind's common heritage."

Defenders of gene patents scoff at such notions. They point out (correctly, in a narrow sense) that the genes residing in your body are not "owned" any more than your computer is owned by those who hold the patents for its components. They argue that without patent protection, biotech companies would be unable to fund the research and development of new drugs and treatments—processes that may be privately profitable but also publicly beneficial. They claim, in short, that without patents, there will be no cures. A response from the American Enterprise Institute to the gene patent challenge by the ACLU and Public Patent Foundation is typical. AEI resident scholar John Chalfee argued that high prices are the expectable and legitimate consequence of patents, and that gene patents haven't really hindered research. He concludes that "gene patents are turning out to work more or less the way patents are supposed to work and have been working for a couple of centuries and more. The research

process, and ultimately patients, are the beneficiaries."[6]

That many financial backers of the biotechnology industry believe patents are necessary to protect their investments was starkly illustrated by an episode in the competition between Celera and the Human Genome Project. In March 2000, in anticipation of an announcement that a "rough draft" of the genome had been completed, President Bill Clinton and British Prime Minister Tony Blair issued a 200-word joint statement, apparently aimed at Celera, applauding the Human Genome Project's decision to "release raw fundamental information about the human DNA sequence and its variants rapidly into the public domain" and called on "other scientists around the world to adopt this policy." Though the statement explicitly supported "intellectual property protection for gene-based inventions", the stock prices of Celera, as well as Incyte and Human Genome Sciences, immediately plunged. The White House and National Institutes of Health quickly backpedaled.

Public interest opposition to "patents on life" has been stronger in other countries, but there have been U.S. challenges as well. In the 1980 *Chakrabarty* case, a public interest group led by Jeremy Rifkin filed an *amicus curiae* brief in support of the USPTO's original rejection of the patent claim on the genetically modified oil-eating bacterium, on the grounds that it was a living organism. It raised social and moral concerns about "manufactured life" and contended that Congress, not the courts, was the appropriate venue for consideration of how this fundamentally new technology should be governed. Writing for the four-justice minority, William Brennan agreed that "it is the role of Congress, not this court, to broaden or narrow the reach of patent laws", and said that Congressional guidance is crucial because "the composition sought to be patented uniquely implicated matters of public concern."

In 1994, more than thirty organizations representing indigenous peoples formally announced their opposition to patenting genes and biological tissues taken from members of their groups. In 1995, a coalition of some 180 religious leaders issued a "Joint Appeal against Human and Animal Patenting." The same year, Congress considered but rejected a bill that would have disallowed many kinds of gene patents. In 1996, Rifkin's Foundation on Economic Trends put together a coalition of more than 400 women's organizations in more than forty nations to challenge Myriad's breast cancer gene patents. In 2000, the Council for Responsible Genetics issued its ten-point "Genetic Bill of Rights", one of which read, "All people have the right to a world in which living organisms cannot be patented, including human beings, animals, plants, microorganisms and all their parts."

Less frequently, debates about human gene patents have reached into the Federal legislative and executive branches. In 2002, a bipartisan bill was introduced into Congress to institute a research and diagnostic testing exemption for gene patents, of the sort provided by many other countries' intellectual property laws. At the same time, the Federal Trade Commission and Department of Justice were studying whether patents were stifling rather than encouraging innovation. A government panel heard from the biotech company Affymetrix, one of the dissenters from most of the industry's support for human gene patents. The company's general counsel, Barbara Caulfield, said bluntly, "There should be no patenting of gene sequences, period. They were invented by nature."

A number of non-commercial scientific organizations are critical of at least certain aspects of U.S. patent policy. The American Society of Human Genetics and the international Human Genome Organisation, while generally supportive of gene patents, oppose claims to sequences whose functions are unknown. Similarly, the American Association of Medical Colleges argues that patents with medical uses should be widely licensed without excessive royalties. In contrast, the Association for Molecular Pathology, the American College of Medical Genetics, the American Society for Clinical Pathology and the College of American Pathologists are plaintiffs in the ACLU's and Public Patent Foundation's challenge to Myriad's claims. As this sketch suggests, the legal issues are

[6]Chalfee, "Decoding the Uses of Gene Patents", *The American* online (May 15, 2009).

enormously complex, and various actors see their interests in many different ways.

Human gene patents raise three kinds of basic questions, and the fate of the current challenges to them—both the lawsuit against the breast cancer gene "owners" and the Congressional bill to halt human gene patents—will be determined by how they are answered. First, are human gene patents legal? The present policy evolved in incremental steps at the USPTO and in court rulings. Does the USPTO actually have the legal authority to grant these patents, or has it exceeded its authority? Although the Supreme Court has heard related cases, neither it nor Congress has ever directly addressed this question.

Second, what are the practical consequences of patents on human genes? Do they effectively balance incentives for innovation with the promotion of science? As scientists increasingly learn that segments of DNA perform multiple functions, they are concluding that the potential for complicated, overlapping intellectual property claims is significant. Myriad has become a prime target of gene patent critics for its aggressive patent enforcement, but the general problem of "patent thickets" that interfere with research and development is growing.

Third, what are the social and ethical implications of human gene patents? While the public as well as policymakers strongly support biomedical research, the extension of property claims deep into areas formerly considered outside the commercial realm has stirred great unease across the political spectrum. Patents on human genes, along with other novel biotechnology practices, introduce profound questions about our relationships to each other and the natural world. These matters overflow the boundaries of evaluative criteria based on legal precedents and economic expediency. They go to the very core of who we think we are and how we view each other.

Too often, discussions of biotech practices and products gloss over these deeper concerns. The tendency is to narrow the conversation to technical issues (for example, the legal status of patents on life, the environmental impacts of synthetic biology experiments, the health risks of efforts to clone human beings) and to procedural considerations (for example, informed consent, disclosing conflicts of interest, bio-containment precautions). All of these are important. But in grappling with emerging biotechnological innovations, public discussion must also tackle the goals and purposes of our techno-scientific enterprises; their consequences for social justice, human rights and democracy; and the ways they shape us as individuals, as members of communities, and as upholders of a shared humanity. Today's debate over patents on human genes has the potential to set social, cultural and political precedents, as well as legal ones, for addressing some of the most profound questions we currently confront.