THE SHOCKING CORPORATE TAKEOVER OF LIFE ITSELF - AND THE CONSEQUENCES FOR YOUR HEALTH AND OUR MEDICAL FUTURE

DEADLY MONOPOLIES

HARRIET A. WASHINGTON

AUTHOR OF *MEDICAL APARTHEID*,

Winner of the National Book Critics Circle Award for Nonfiction

The High Cost of Living: Questioning Life-Related Patents

"How does it feel to be patented? There was a sense of betrayal. I mean, they owned a part of me that I could never recover. I certainly have no objection to scientific research ... but it was like a rape. In a sense, you've been violated, for dollars. My genetic essence is held captive."

—John Moore, the subject of US Patent No. 4,438,032

Predictably, Myriad Genetics recently appealed a federal district court's recent decision rendering seven of its lucrative BRCA1 and BRCA2 gene patents invalid. The battle will probably run long, ending only when it reaches the Supreme Court, so the appeal raised hardly a ripple. This stands in contrast to the semantic mayhem triggered by the original ruling.

"Pigs fly!" a headline of the Genomics Law Report had wondered, going on to clarify, "Federal Court Invalidates Myriad's Patent Claims." In a ruling the *GLR* described as "jaw-dropping," "radical," and "astonishing," Judge Sweet United States District Court invalidated the patents on the breast- and ovarian-cancer genes, declaring that they are not made by man and thus patent-ineligible.

Genae Girard had been astonished, too, when she learned that women like herself who need genetic testing to quantify their risks and to define the best treatment for their cancer could obtain it only by paying Myriad's $3400 fee, enabled by the monopoly that the BRCA patents bestow. She resorted to wide-angle legal buckshot, suing not only Myriad and the United States Patent and Trademark Office, and other companies who hold patents on human genes.

Sweet's ruling will resound far beyond the BRCA genes. Biogen Corporation controls your kidney's essential KIM gene; the University of California holds patents on the TCP-1, -2 and -3 genes that enable your tongue to sense taste; and patents have been granted for genes that control the functions human bones, heart, teeth, tongue, colon, skin, brain, bone, ear, lung, liver, kidney, sperm, blood and immune system. 40,000 gene patents have been granted in the US alone. [1]

Spurred by the breadth of the issue, the American Civil Liberties Union rallied to Girard's side, organizing a lawsuit joined by a mammoth coalition of civil libertarians, cancer patients, activists, 100,000 pathologists, and many genetic researchers. All call for an end to gene patents.

The paradigm-shattering agenda of this breathtakingly broad coalition made me question whether its ambitions might be far too …. narrow.

Why? It's true that the USPTO has granted patents on more than 500,000 genes that control the most basic processes of human life. But as I detail in my forthcoming book *Deadly Monopolies: The Shocking Corporate Take-Over of Life Itself* (Doubleday 2011) what's true of gene patents is doubly true of many other types of life-related patents as well. The $60 billion pharmaceutical industry became the most profitable industry on the planet by exploiting its plethora of patents on not only genes, but also bacteria, viruses, biologicals such as "artificial blood", cell lines, tissues, pharmaceuticals, and even on medically important plants and animals such as Harvard's patented cancer-prone "oncomouse," which are indispensable to medical research. At least 20 human pathogens are privately owned, including , haemophilus, influenza and Hepatitis C.

This gold rush in life-related patents was promoted to the American public in the 1980s as a means of spurring the development of sorely needed new medications and treatments by fostering closer university-corporation relationships. Tax-supported research at US universities had long been generating medical discoveries when the Supreme Court's 1980 landmark *Diamond v Chakrabarty*[2] decision came down. Ananda Chakrabarty had tried to patent bacteria that he claimed could address pollution issues by "eating" errant oil spills, but the US Patent Office denied his application on the basis that the bacteria were living entities and only manufactured products were eligible for patents. (This despite the fact that plant patents on hybrids had long been allowed and Louis Pasteur had won a patent for yeast in 1873.) The *Chakrabarty* ruling permitted patents on a wide variety of living things, including bacteria, viruses, biologicals, and, yes, genes. In the wake of *Chakrabarty* , many universities took out patents on their tax-supported biomedical discoveries, but, as legislator Birch Bayh lamented, 28,000 patented discoveries developed with $30 billion in taxpayers' dollars were "lying there, collecting dust." Only 5 percent of patented items were being developed into medications, devices or other useful products. According to the US Comptroller General, innovation was being stifled because universities and corporations did not want to invest in developing technology that they did not own. A series of laws rapidly addressed this development vacuum by vigorously catalyzing the transfer of control over medical research from the university to private pharmaceutical and biotechnology corporations such as Myriad. For instance, Bayh partnered with Bob Dole via the "Bayh-Dole Act",[3] that allowed universities to own the resulting tax-supported patents. Subsequent laws such as the Stevenson-Wydler Technology Innovation Act[4] encouraged the sale of these patents to industry. [5]

Colleges and universities obtained only about 260 patents a year before 1980's Bayh-Dole Act : Today, universities secure 3,000 patents annually, according to the Association of University Technology Managers, and by 1991 they had gleaned $218 million in royalties.

Now, universities receive funds for the patents they assign to private companies and corporate support for the research and development necessary to realize their full value. The corporations receive valuable, ready-made patents on medications, biologicals, genes, devices, plants and animal hybrids that have been underwritten by the federal government and produced by university brainpower. These patents give companies twenty-year monopolies for unfettered profitability as they exploit the patents as they see fit.

And we, the American public, receive promises of a medical bounty in the form of newer, better medications for scourges such as HIV disease, hepatitis C , cancers, drug-resistant tuberculosis, and on a global scale, against killers such as malaria, tuberculosis and sleeping sickness.

The union of the university and industry to spin the dross of neglected patents into the gold of medical innovation is an alchemy that has worked only too well— but not in the direction we had expected.

Nearly 2800 patents and licenses were granted to North American universities and research institutes by 1991, and hospitals gleaned $218 million in royalties. By 2003, North American university researchers had started 374 companies and academic institutions had completed 4,516 licensing arrangements earning them more than $1.3 billion.[6] By 2006, university technology transfer offices had generated at least $45 billion, largely from licensing fees.[7]

But in place of the promised bounty of new lifesaving medications we have been left with a dangerous asymmetry in which industry has assumed control of medical research and the university more often resembles a corporation's satellite than an independent entity. The arrangement has eclipsed what Sheldon Krimsky called the "public-interest model" of the university, dedicated to public welfare in a wider sense, and one we could depend upon to place national interests above its own and that of its faculty members.

Industry, on the other hand, has focused on maximizing its fiscal return from patents and tends to choose profitability over medical need.

Thus industry controls access to its patents *via* expensive licensing fees, by discouraging rivals from working on diseases covered by its patents, by developing tests that can be widely administered rather than treatments and by developing many medications for minor but very common disorders.

For example, Hepatitis C which affects 170 million people[8] is the single largest cause of liver transplants in the US . The sole effective medication, interferon b, is rife with side effects and cures only 1 in 5 who take it. Chiron holds the patent on the HCV virus, but has produced no better treatment. Instead, the price of the hepatitis C virus (HCV) test in the UK leapt sixfold in 1994, making it too expensive for England's National Health Service because Chiron had stepped in to aggressively protect its patent. It did so by suing the UK firm Murex for patent infringement and preventing Murex from selling its cheaper HCV blood tests. The suit exerted a chilling effect on researchers who wish to work on better HCV treatments. Roger Williams, director of the Institute of Liver Studies at King's College School of Medicine and Dentistry in London warned ''A situation where one company — Chiron — can limit the number of companies carrying out research into hepatitis C must inhibit our knowledge of the disease and our efforts to reduce its spread.''

In 1998, the USPTO granted patents on both mutations of the hereditary hemochromatosis (HFE) gene and SmithKline Beecham Clinical Laboratories obtained an exclusive license that caused other researchers to abandon work on HFE due to the prohibitive costs and the specter of a similar suit.

Multi-drug resistant tuberculosis infects approximately 9 million people every year, including people in affluent Western nations. If none of the four drugs in its treatment regimen works for you, you die and vaccines are in still "in development". The global scourge of malaria killed 247 million people worldwide in 2006 and some of the eight drugs we deploy against it, such as quinine, have been in use since the 17th century.

By contrast, "erectile dysfunction," coined by Big Pharma to define a quasimedical market for its amorous wares, kills no one, although more than 570 men have died after using one of the more than 14 medications developed since

1996 to treat it. (Big Pharma assures women that "pink Viagra" is *en route* to them.) By the measure of drugs developed, erection on demand seems a higher drug-development priority than surviving malaria and tuberculosis.

Trypanosomiasis or "sleeping sickness" epidemics roil Africa regularly, and the fatal ailment infects 66 million people a year. It is treated with Melarsoprol which was discovered in 1949 and is derived from arsenic. It is as toxic as is sounds and kills 1 in 10 people who take it. In 1990 Sanofi-Aventis developed the drug Ornidyl (eflornithine) which is safe and effective against trypanosomiasis but it was withdrawn from the market in 1995 because few poor subSaharan sufferers could afford it. Ornidyl can no longer be bought for love or money but Aventis, and later, Bristol-Myers Squibb, began to market eflornithine to the West as Vaniqa, a prescription-only facial depilatory. Why? Because more Western women can part with $50 a tube to keep their faces hair-free than can subSaharan Africans even save their lives.

Liver cancer is the most common cancer in the world with a life expectancy of three years and few treatment options beyond surgery. Immunologist Chris Parish of Australian National University spent twenty years developing the promising anti-cancer drug known as "PI-88," a double-action drug that slows both the growth and the metastasis of tumors.

In a classic arrangement, Progen Pharmaceuticals Limited, contracted with ANU to pay for the research and development of PI-88 in exchange for ownership of the patent. By late 2008, clinical trials had demonstrated that the drug reduced recurrence rates in liver cancer patients by 35 to 40 per cent and it was ready for Phase III clinical trials, the last stage before approval and availability to the public.

A week before Christmas, however, Progen shut down the trials, voicing concerns about factors "that impacted the commercial return," of PI-88, including the imminent joint launch of Nexavar, a competing drug, by Bayer and Onyx pharmaceutical companies. PI-88 would likely face too much marketplace competition to become the next $1 billion blockbuster, and Progen simply pulled the plug. Because Progen holds the patent on PI-88, Parish cannot go elsewhere to conduct the Phase III trial and pursue its approval.

Industry, which holds the purse strings and the patents, has largely abandoned the quest for cures to pursue cheaper avenues to maximizing profits on virus, medication and tissue patents. Still worse, our very bodies are being mined for corporate profits, with or without our consent. Legal and ethical conflicts with patient interests are inevitable because the tissues in question reside within or emanate from our bodies, but biotech and pharmaceutical companies control them, becoming, in effect, our biological landlords. In 1984, John Moore became the subject of Patent No. 4,438,032 when his physicians David Golde and UCLA surreptitiously patented a cell line from his cancerous spleen. In 1984 Golde struck a $3 billion deal with Sandoz[9] to produce and refine nine valuable cancer-fighting pharmaceuticals produced by Moore's spleen.[10] The organ had been removed as part of Moore's treatment for hairy cell leukemia but Golde had withheld its true value from Moore and misled Moore about the real reason why he was periodically extracting Moore's blood,

tissue, bone marrow and semen, not as part of his therapy for the research laboratory. When Moore sued for rights to his own tissues he lost consistently in the courts, culminating in a Supreme Court decision for Golde and UCLA that noted its trepidation that a victory for Moore would have a chilling effect on medical research.

Parents of children with Canavan's disease sued the University of Miami when they discovered that it had also covertly patented the defective ASPA gene isolated from the donated tissues of their doomed children. A plethora of patents have been granted on HeLa cells, taken despite the express refusal of her husband from a Henrietta Lacks a Baltimore housewife who died in 1951.

But today, tissue volume trumps biomedical rarity, which is why anyone who undergoes surgery at hospitals such as Boston's Beth Israel Deaconess is first asked to sign away the ownership rights to his excised tissues to Ardais, a for-profit corporation. "Access to quality human disease tissue is becoming increasingly important to the drug discovery process," declared AstraZeneca vice-president Jeff Hanke, PhD. The resulting medication patents rest on the fruits of our own bodies.[11]

In the same manner in which European colonialists "discovered" continents that were filled with people, US corporations are not above "discovering," patenting and selling the traditional medical remedies, intellectual property and even the gene pools of poor people in the developing world. On March 14, 1995 the US National Institutes of Health (NIH) patented the T-cell line of a Hagahai man from Papua New Guinea.

The Indian government objected after the European Patent Office issued the patent on the medically and culturally important traditional *neem* tree to the US company W R Grace in 1994 . In 2005 the Havasupai tribe sued Arizona State University researchers for stigmatizing schizophrenia research the ASU conducted without consent on 400 blood samples from the tribe's members. In mid 1990s asthma-prone residents of the isolated Tristan da Cunha a island in the South Atlantic lost the battle for control of their own genetic material after it was collected and patented and provided to Sequana Therapeutics Incorporated and Boehringer Ingelheim by Canadian researchers who hoped to locate a gene that predisposing people to asthma. Estimated its cost at $70 million. The gene pools of not only Tristan de Cunha but even Western nations such as Iceland have been patented for profit under questionable models of consent.

Why is industry permitted to pursue profits unchecked by considerations of health or affordability? Because desultory FDA oversight and revolving-door lobbyists have midwifed loose regulation that allows pharmaceutical and biotech companies to set their own prices without government restraint. Fully half of health-care lobbyists are former government officials, cutting deals with their erstwhile colleagues for the industry's benefits and special protections.

The pharmaceutical industry, for example was the largest beneficiary of healthcare reform legislation. Companies such as Johnson & Johnson, Pfizer, and Merck enjoy profits that averaged between $2 to 10 billion in 2008, making Pharma the nation's third most profitable industry, while the health insurance industry ranks a distant 28th. Yet the latter is heavily controlled by reform while the former emerges unscathed for the 2010 Patient Protection and Affordable Care Act failed to

tighten federal regulation of medical products, to regulate pharmaceutical drugs, and utterly avoided price controls.

Some argue that gene patents are necessary to generate the profits essential to funding the medical cures. But as the cases of breast cancer, hepatitis C and hemochromatosis illustrate, genes are more commonly used for faster, easier routes to profit, such as marketing tests, selling licenses and suing those patent-infringers who step on the corporation's biomedical toes. As Sheldon Krimsky has observed, "The public ethos of science slowly disappears, to the detriment of the communitarian interests of society."[12]

---

[1] Begley, Sharon In Surprise Ruling, Court Declares Two Gene Patents Invalid *Newsweek*, Monday, March 29, 2010

[2] Diamond v. Chakrabarty, 447 U.S. 303 (1980), United States Supreme Court

[3] The text of the Bayh-Dole Act is at www.cptech.org/ip/health/bd Last accessed May, 2009

[4] Stevenson-Wydler Technology Innovation Act of 1980 Public Law 96-480, October 21, 1980, 96th Congress, 94 Stat. 2311, 15 U.S.C. 3701

[5] Leaf, Clifton The Law of Unintended Consequences - September 19, 2005 money.cnn.com/magazines/fortune/fortune_archive/2005 Last accessed September 3, 2008

[6] Leaf, Clifton "The Law of Unintended Consequences" September 19, 2005 money.cnn.com/magazines/fortune/fortune_archive/2005 Last accessed September 3, 2008

[7] Samantha Stainburn "Who Owns Your Great Idea?" *The New York Times* January 4, 2009

[8] Mukherjee, Sandeep (2008-06-30). "Hepatitis C". *eMedicine*. http://www.emedicine.com/MED/topic993.htm. Retrieved 2008-09-06.

[9] Murphy Timothy F *Case studies in biomedical research ethics* 4.1

[10] *Moore v. Regents of the University of California* (51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479)

[11] PRNewswire "Ardais Corporation Announces Agreement with AstraZeneca For Access To Clinical Samples" Lexington, Mass., Feb. 4

[12] Krimsky, Sheldon "Perils of university-industry collaboration," *Issues in Science and Technology* September 22, 1999 National Academy of Sciences 16:1 p. 14