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Taming intellectual property in biotechnology

The genealogy of a gene: Patents, HIV/AIDS, and race, Myles W. Jackson. The MIT Press, Cambridge, MA (2015). 352 pp., Price $37.00 cloth, ISBN 9780262028660

Patent politics: Life forms, markets, and the public interest in the United States and Europe, Shobita Parthasarathy. University of Chicago Press, Chicago & London (2017). 304 pp., Price $25.00 cloth, ISBN 9780226437859

Charles Lawson, Berris Charnley. (Eds.), Intellectual property and genetically modified organisms: A convergence in laws, Routledge, New York & London (2015). 258 pp., Price £83. 99 hardback, ISBN 9781472443458

1. Introduction

In 2009, the American Civil Liberties Union (ACLU) filed a lawsuit against the Myriad Genetics, a biotech company specializing in genetic diagnostics. The ACLU claimed that the Myriad's patents on two human genes associated with a high risk of breast and ovarian cancer, the BRCA1 and BRCA2, should be invalidated. The ACLU's charge was not merely directed against the validity of human gene patenting. It argued that the product-of-nature doctrine in the U.S. patent law rendered human genes, as a nature's product, non-patentable. Along with patient activist groups and biomedical researchers, the ACLU further claimed that the patents on the BRCA genes constituted a violation of the U.S. Constitution, especially of its First Amendment, which guarantees a right to free and academic inquiry. They felt that the patenting of a human gene would give an individual or institution unfettered control of the gene, which could hinder the subsequent biological and medical research involving the patented gene.

One may wonder why and how a civil rights group came to be involved in such an arcane, technical issue as gene patenting. The lawsuit marked a key moment in the U.S and Europe when issues of the ownership of life forms in biotechnology emerged not merely as a technical question but also as a matter of key public policy issues in science. Civil society groups like the ACLU has begun to ask poignant questions about whether biotechnology could be a key tool to secure health and promote prosperity. In many ways the moment exhibits a stark contrast to what early promoters of biotechnology proclaimed—that the development of genetic engineering would promise innovations in the broad ranges of pharmaceutical drugs and medical therapy, biomedical diagnostics, and agricultural products. Moreover, they had also claimed that the private control of key molecular technologies would not only promote the public interest and alleviate public concerns about risks associated with genetic engineering. Thus, academic patenting was initially envisioned as a new optimal solution to economic prosperity, public health regulation, and biomedical innovations.[1] Biotechnologists tried to expand the scope of private ownership in the life sciences by challenging traditional legal regimes of intellectual property, blurring the fine line between basic research and corporate development. Early gene hunters developed gene-modification and gene sequencing technologies and relentlessly pursued the commercialization of research technologies and materials. Biotech companies favored the patenting of key technologies and materials at the earliest stage possible, as huge changes in the company's value occurred with each step of the infusion of venture capital. The business model of biotechnology in the age of venture capitalism thus made deep inroads into academic science, and biotech firms pushed new biological forms, ranging from single genes and modified cells to new strains of bacteria and genetically-engineered plants and animals, to be included under the purview of intellectual property.[2]

It was only in the 1990s, with the surge in gene sequencing and cloning technologies, that gene hunters were finally equipped to claim an ownership stake in their material possession. Alongside the burgeoning Human Genome Project, several biotech and agricultural companies developed more proprietary approaches to their scientific ventures. Gene sequencing and diagnostic companies, such as Human Genome Sciences (HGS) and Myriad Genetics, made the controversial decision to pursue human gene patenting. Agricultural biotech companies attempted? to commercialize their genetically modified products; Monsanto for example, began to market its so-called “Round-Up Ready” seeds and crops that were resistant to its own Round-up pesticides. It also filed patents for genes conferring pesticide-resistance to plants, and even extended its ownership claim to such genetically modified organisms (GMOs) of the pesticide-resistance gene as canola and soybean. The expanding scope of intellectual property in basic research material such as genes and cell-lines, reflects a shift in the political economy of science that has encouraged the commercialization of biomedical research.

Myles Jackson's *The Genealogy of a Gene*, Shobita Parthasarathy's *Gene Politics*, and Charles Lawson and Berris Charnley's edited volume, *Intellectual Property and Genetically Modified Organisms*, raise timely and important questions about the social and political implications of the biotech industry's expansive redefinition of intellectual property in the biomedical and agricultural sciences. Each in its own way undermines a certain picture of the role of intellectual property in science, politics,

[1] See Juma (1988); Hall (1987); Hughes (2011); Rasmussen (2014); and Yi (2015).
[2] For the proliferation of biotechnological forms of life, see Landecker (2007).

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and business. Reformed and fortified legal regimes for intellectual property were praised by early promoters of biotechnology as a powerful means for liberate biomedical discoveries for public benefit. Now, however, all three books challenge the benevolent role of intellectual property in biotechnology at a moment when biotechnology was still exuberantly promoted as an engine for economic growth and food and public health security at the global level. They advance the ongoing discussion about the place of intellectual property in the US and Europe, and in the global economy.[3] Technical complexity and the arcane vocabulary adopted by the patent systems and the biotech industry around the world have made it a daunting task to examine how shifting regimes of intellectual property had instigated the role of biotechnology for securing health and prosperity. Part of the challenge comes from the intangible nature of intellectual property, and part from its elusiveness in historical terms. The three books reviewed here represent some of the best efforts to broaden the analytic framework for the examination of the intersection between science, business, and politics.

First, all three books analyze the way in which patenting in biotechnology has become a key site through which a civil society—in an age of dazzlingly developments in genomics, stem cell research, and agriculture biotechnology—addresses central issues of science, innovation, and the public interest. How has the inclusion of new biotechnological forms of life under the purview of intellectual property been beneficial to the public in large? Have the promoters of biotechnology brought prosperity and health through patenting? Do they strike the right balance between private profit and public benefit? Has this balance resolved such potential patent-related problems as economic inefficiency, monopoly, and their stifling effects on innovation? Has patenting, by giving over the control of biotechnology to the private sector, enhanced security in food and environmental risk, fulfilling both profit-motives and regulatory needs?[4] With billions of public funds invested in biomedical sciences and technologies, how has the field of biomedicine contributed to furthering distributive justice, especially with its focus on capitalizing patents and the private control of materials and data?

2. Genomics: commodifying inalienable human properties and identities?

Jackson's *The Genealogy of a Gene* focuses on one important human gene, CCR5, in order to examine the recent historical nexus of genomics, biocapitalism, and racial politics. Jackson sets out to examine how “the definition and emergence of the CCR5 gene were predicated on capital, laboratory practices, computer algorithms, statistical analyses, population genetics and biomedical studies, and historical and sociological studies” (p.23). The first part of the book deals with the patenting of the CCR5 gene by HGS, the biotech firm co-founded by gene-sequencing maverick, Craig Venter of the U.S. National Institutes of Health. Right from the time of its founding in the 1990s, HGS aimed to revolutionize pharmaceutical development by mobilizing an immense amount of capital toward advancing gene sequencing and computing technologies. The company began to stake aggressive proprietary claims on genes presumed to be linked to certain diseases, with an intention to own these genes, for their potential future use as therapeutic targets. HGS scientists discovered the CCR5 gene in the 1990s and the company filed a patent for it soon thereafter.[5] By the time the U.S. Patent and Trademark Office (PTO) issued the patent for the CCR5 gene to HGS in 2000, it had become clear that CCR5 would serve a critical therapeutic target for treating HIV infection, as a specific mutation in the gene could confer HIV resistance.

The Genealogy of a Gene shines in its detailed examination of HGS's concerted efforts to solidify its claim of ownership of the CCR5 gene, despite many salient legal and technical instabilities surrounding gene patenting. The book analyzes some of the key technical issues in the status of gene patenting within the context of shifting interpretations in intellectual property: the patentability of gene sequence; the product-of-nature doctrine, and the distinction between discovery and enablement in the life sciences. In what ways could a gene be regarded as a product of human ingenuity rather than a product of nature? How could an act of isolating a gene be construed as an invention, not a discovery? What distinguished possession from enablement in the case of gene patenting? And could a mere description of a physical gene sequence be presented as a case for enablement in broad-utility patents? Jackson is judicious enough to claim that these unsettled technical questions surrounding gene patenting caused patent leniency, rather than the converse. He illuminates, in detail, the pains taken by the biotech industry to stabilize the status of gene patenting and personalized medicine. On the patenting front, the CCR5 gene was constituted by scientists at HGS and other academic and commercial institutions that not only named, sequenced, and deposited it, but also traced its cellular function, indicated its various correlations with other gene sequences, and finally, filed an application to patent it. HGS was able, through its efforts, to articulate the chemical ontology of gene patenting, whereby the CCR5 gene was presented as a sequence of chemical bonds rather than as a container of biological information.[6]

The story of the CCR5 patenting, as Jackson tells it, is far from one of scientific ingenuity or business innovation. HGS's initial application contained an error in the gene's sequence, and besides, did not disclose the CCR5's biomedical function. The grant of utility claims on the gene had a potential to block subsequent research, as a particular gene “cannot be invented around” like other chemicals. In addition, the US PTO issued a patent for the CCR5 gene to two other biotech companies, Euroscreen and ICOS. Critics of the CCR5 gene patenting, along with other scientists who independently illuminated CCR5's function in HIV infection, insisted that HGS was rewarded for something they neither discovered nor invented. Despite criticisms against “the robber barons of the genetic age,” the stock market rewarded HGS, increasing its stock value by 50% within a few days of the announcement of the US PTO's grant of the CCR5 gene patent. HGS defended its ownership of CCR5, insisting that it was “rewarded for speculation,” namely, for taking a scientific venture and business risk (p.31).

As an engaged history of the present in biomedicine, *The Genealogy of a Gene* painstakingly details how the regimes of U.S. and European intellectual property made it possible for taking such risky venture, and how we can envision an alternative form of biomedical enterprise. The CCR5 gene patenting case shows how the speculative pursuit of profit by HGS undermined the public trust in science and business as the center for innovation, and how the expansion of the scope of intellectual property in biotechnology could hamper scientific research and the public interest. Biocapitalism, through the interplay of competing interests, shaped the contemporary form that the gene as an object of scientific and business interest had taken. More interestingly, some of the scientists and biotech companies who criticized HGS drew on some of the powerful cultural forces in biomedicine that has argued for open access and sharing. It would be interesting to see how this call for open access can help us to envision an alternative form of work in genomics.[7]

The final third of *The Genealogy of a Gene* is dedicated to discussing

[3] See Biagioli, Jaszi, & Woodmansee (2011).

[4] For an early attempt to envision patenting as a means for quality control in pharmaceuticals and for ensuring national security in nuclear technologies, see Creager (1999); and Wellerstein (2008).

[5] Li & Ruben (2000). U.S. Patent 6,025,154 (Filed: June 6, 1995/Date of Patent, Feb. 15, 2000).

[6] For a history of the chemical ontology of patents, see Gaudillière (2008).

[7] For an analysis of the significance of the moral economy of science in biomedicine in terms of property and priority, see Creager and Morgan (2008); Strasser (2011); García-Sancho (2012); Stevens (2013); and Leonelli (2016).