

## Genomics & Patents: Human Heritage and the Cost of Innovation

In 1980, the Supreme Court ruled in *Diamond v. Chakrabarty* that “anything under the sun made by man” is patentable (Candlish, 165). This ruling, before the advent of breakthroughs in genomic research, set the standard for what is presently a contentious and highly philosophical debate concerning the future of genetic sequencing. The field of genomics is not what it used to be. Confused methods, uncertainty and frenzied research are relics of the past. Progress in genomics is highly commercialized; and this brings its own set of legal issues. Many scientists, of course, continue to innovate, but behind their strides lay the ambitions of the biotech industry. At the heart of the biotech presence is the patenting of genetic information or processes. Genetic patents specifically are the focus of this composition. As Louise Bernier puts it, “some important issues arising from genetic patents relate to human dignity; access to research, products and service; and to the suitability of granting exclusive property rights over material embodying essential information for building our common knowledge of human genetics and genomics” (*Justice in Genetics*, 93). In response to these issues, both lawmakers and scientists advocate the partial or complete prohibition of gene patents. Through this essay, I attempt to illuminate some of the bioethical dilemmas surrounding genetic patents. To end, I offer insight on solutions proposed by notable figures and on bioethical dilemmas.

Let us first consider the requirements for getting a patent. Why might researchers and biomedical companies find genetic patents so useful? In order to be patented a concept or product must be novel (new and not presented before), inventive (taking mere natural knowledge a step further in a creative process), useful (can be applied in society) and fully disclosed (its features must be fully explained in the patent application). According to Rimmer, patent examiners, the judiciary and legislatures usually distinguished between mere discoveries and new applications of existing

knowledge (110). This notion of “existing knowledge” extends to anything that *at some point* can be observed in natural phenomena. Therefore, discoveries, which are just an observation of natural phenomena, did not usually receive patents.

With a patent, one can essentially regulate the usage of their patented subject matter. This aspect makes genetic patents tempting. Imagine the nascent biotech company striving to earn enough funds for an ambitious genetic (or protein) sequencing project. Should the company succeed, it will not only look for public recognition but also a means of profit. Copyright and infringement laws that protect intellectual property are the perfect means for generating such revenue. Despite the risks in such an economic model (e.g. failing to sequence DNA and file a genetic patent quickly enough), many biotech companies have shown they are willing to gamble. Bernier affirms the appeal of gene patenting: “In the field of genetics, translating scientific discoveries into useful therapeutic products and services can be a long, complex and expensive process. Additionally, the economic value of patents is very high” (91). Interestingly, Candlish also points out that commercialization compels researchers to protect their own intellect (162-163), an instance where one seeks a patent to prevent a theoretical loss of profit and not to necessarily gain profits.

As noted in *Patenting Lives*, copyright and infringement laws reap colossal profits for patentees because they, in affect, create artificial scarcity (Palomi, 75-76). In this case, regulating genes is like regulating a certain good or product. At their discretion, patentees therefore control how their “intellectual” good can be used, which in turn affects their profit margin. Patents are so useful because they incur specificity. Losing specificity (i.e. when biotech company’s good becomes less scarce) means losing an economic advantage. Because a lack of patents reduces the marketability of genetic goods (a form of intellectual property), the patentee’s economic success is undermined (87-92). At this point, I am not condemning the want for monetary compensation. It would be

foolish to argue that economic success for the patentees is irrelevant. Although genetic innovations help society, their cost can often cripple biotech companies.

For now, we should review more closely how these companies or other patentees argue for their genetic patents. “Since September 2008, over three million genome-related applications have been filed,” (Bernier, 92). Consider the infamous case of the patented *BRC A1* & 2 genes. (Marshall, “Gene Patents Ruled Invalid”). How did genetic patent seekers acquire full reign over these valuable sections of DNA? Current bioethical literature points overwhelmingly the rhetoric. The arguments involve economic competition, biotechnological innovation and the nature-product isolation. The first two, for genetic patentees go hand-in-hand and stick to the tried and true notions of Western capitalism. Perhaps this is why the logic is so effective in the US. Genetic patenting causes scarcity of intellectual goods and prevents all companies from using identical patented material. Therefore, in order to succeed economically, the companies that have been shut off from one biological fortune, must find an alternative route to profit (Bernier 102, 104). This alternative route increases the diversity of options for consumers and would not be possible if every company had equal access to the patented information. While this theory justifies the use of patents in the context of the national population, it does not address whether the genetic patents are warranted. It is here that nature-product rhetoric comes in.

The most common objection to the patenting of the human genome is that it [the genome] belongs to the public domain; more specifically, genetic patent opponents deem the genome as part of the storehouse of natural phenomena or “the heritage of mankind.” This implies that genomes do not meet the requirements of intellectual property patents (Rimmer, 139). Genetic patent opponents offer that because the human genome is part of nature, any patent derived from it reveals no new information at all. Though, biotech companies evade this problem by simply separating the context of their genetic patents and the source of their DNA patents (Palomi, 78). Gene patentees seek to

protect either a DNA sequence or the process through which the sequence is procured. To do this, they offer that the process itself is an invention and that the DNA procured is done outside of nature and therefore cannot be considered a part of natural phenomena. Since it is not part of natural phenomena, these intellectual goods do not break the novelty requirement for patenting (Candlish, 181). Furthermore, because “the subject from whom a substance in a patent comes from cannot be granted ownership of the said patent,” biotech industry would argue it is impossible for any entity other than the patentee to own the patented substance (Kuppuswamy, 12). As such, one cannot give ownership of *BRCA 1* to the human from whom the gene was originally taken.

Though it is possible that genetic patents improve economic competition, the system of acquiring and justifying genetic patents shows conflict. This portion of the essay explicates the murky areas in the patent system and the debate over its so-called utilitarian nature. An ambiguous area in gene patenting is the extent to which DNA is private or can be privatized. According to Kuppuswamy, the right to own property (in any physical sense) is not the same as the right to intellectual property. The prior is a fundamental right for the basic needs of society and the latter can be disposed of in the interest of society (*The International Legal Governance of the Human Genome*, 142). Furthermore, because subjects from whom a patented substance is acquired cannot own that substance, it becomes even more difficult for gene patentee opponents to argue (convincingly) that genetic patents infringe on personal property.

But, the “common heritage of mankind” objection still remains. This objection makes patentability of genetic information questionable. Consider for a moment the dilemma of an entity having intellectual property rights to *any* portion of DNA shared by all humans. Now the isolated DNA is patented and therefore deemed free from nature. But even if I, for example, am not the subject from whom the DNA was acquired, does the fact that I also share the gene and do not consent to its preferential use create a problem? That particular isolated sequence may not be mine,

but it is identical (Palomi 78), to a sequence I have within my own body. Will my consent for the commercialization of something over which I have quasi-ownership be necessary? If I were to sequence a portion of my DNA identical to that of the genetic patent, could I hope for free reign of my new product? Such considerations are often put aside.

Palomi, additionally, isolates this problem in his distinction between *absolute* and *conditional* claims in genetic patents (78-80). An absolute property right claim such as the one for HCV in an Australian Patent for Chiron Corp, gives the patentee exclusive control over genetic information. In this case, Chiron was awarded ownership of any protein with “at least 40% homology to the 859 amino acids” of a particular region of the HCV virus genome. This claim effectively limit *any* related use of this gene outside of Chiron (80). It is thus impossible for other entities to sequence or make use of this genome without the consent of Chiron. Notice that genetic patenting only encourages innovation by forcing interested parties to look *elsewhere* when trying to solve societal problems or earn profits. Because of their exclusionary nature, however, patents prevent innovation regarding the patented material itself.

Companies seeking to use this material may request permission; but as means of revenue, this is both uneconomical and tiring. Unlike absolute claims, conditional property right claims involve the process or means through which genetic material is procured. In some ways, these right claims are even more dangerous than absolute claims because they prevent the use of specific gene-involved processes by other entities. This puts the underfunded scientists in quite a quagmire. Unable to gain direct access to genetic information they must turn to innovative methods of gene isolation, but what happens when either these methods have been patented already or the genes themselves are patented even if the sequencing method is novel?

In *Intellectual Property & Biotechnology*, Rimmer warns of the falling standard in patent policy. He condemns the accepting of theoretical and not physically justifiable evidence (140). Truly,

conditions 3 (utility) and 4 (explication) are the most shoddily fulfilled requirements in the patent system. Rather than possessing a full understanding of the complex and biological mechanisms underlying the so-called “isolated” genes, genetic patentees blindly request exclusive usage rights. Romantic words and pedantic, tangential product descriptions make patentees very successful. As Bernier suggests, the biotechnology industry relies too heavily on anecdotal and theoretical evidence (109). Such testimonials contradict scientific inquiry. Moreover, how can one adequately illustrate the usefulness of one’s “invention” without a complete understanding of how the product functions or any other significant proof of utility? The patenting of genes is nothing more than the patenting of a transcript within the natural world whose *meaning* changes but whose *essence* does not.<sup>1</sup> The meaning changes inasmuch as the nature of the genome becomes more illuminated.

For a moment, think about this about this point: *The field of biotechnology is constantly evolving*. It appears that unlike other fields in which patents continue to be filed, biotechnology involves an unclear line between the licensing of natural products and the interpretation required to justify these patents. It is perhaps a field transforming in ways the patent system is not fully capable of handling. Perhaps then, the theoretical use of utility in patent application is even more inappropriate simply because the biotech field is relatively unstable and even impressive findings have some relative uncertainty. Notice the difference with mere discoveries. In regards to discoveries, uncertainty is irrelevant. No legal worries arise from a scientist failing to fully comprehend the nature of something he or she has discovered. Unfortunately, this is not the case with patents, in which a good understanding of subject matter is necessary. Rimmer furthermore suggests that the use “potential utility” as basis for acquiring patents is unacceptable. I would like to this statement a step further

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<sup>1</sup> . The patenting of processes related to genes, though still ambiguous, does not definitively jeopardize material in the natural world. In general, it seems absolute patents cause more problems in the use of DNA and conditional patents cause more problems in the acquiring of said DNA. In general, I find conditional patents more in line with the requirements of patents. This is not to say that conditional property claims are not subject to the same form of bioethical controversy as absolute property right claims.

and offer that it is unacceptable because it allows the patent system to accommodate biotechnological needs and fails to rectify the loose language of patenting in general (140).

Evidence is also emerging that such loose language has actually damaged the progress in the biomedical field (Rimmer, 145). Because theoretical utility has allowed questionable wholesale patents of certain areas of the genome, crucial genomic regions cannot be studied or analyzed. It is disheartening that this problem arose because patentees were not required to specify and methodologically prove the nature and utility of their products. Their short but influential free reign effectively prevents large portions of DNA from being used, even if the research in question would use only a small subset a patented DNA sequence. While, I would hope that legislation could ameliorate this issue, I realize that changes to patent law would have very little affect on patents awarded in the past. Rimmer states that although a law could make DNA patenting illegal, this law would not implicate the illegality of past patents, since those patents were legal at the time they were awarded (147).

Lastly, the utilitarian conception of gene patenting is flawed. Bernier presents a series of compelling arguments against the utilitarian justification of gene patenting. For the most part, these objections contend that blind faith in utility undermines the ability of companies to actually provide the most good for society.<sup>2</sup> According to Bernier, biotechnological genetic innovations are patented to preserve discoveries and achievements. Patentees maintain that this preservation ensures competition and diversity in the biotech industry; more importantly, this competition promises maximal societal benefit. One worrying flaw is that in striving to maximize efficiency and creativity, entities seeking genetic patents sacrifice equality. The utilitarian outlook does consider the greatest amount of good results, but not the equal distribution of these results (108-111). It does not take

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<sup>2</sup> Also related to the philosophical justification of genetic patents are consequentialist theories, which advocate acting in such a way as to maximize the total societal benefit, and deontological theories, adhering to established moral principles (*Justice in Genetics*, 108-111).

into account possibility of smaller but no less groundbreaking efforts in the genomic field that would affect a less significant amount of the general population. For example, consider Lesch-Nyhan Syndrome, a neurodegenerative disease that impairs physical motion and results in self-mutilation. The locus of the gene is found on chromosome X. Imagine that this portion of chromosome X is already patented by a biotech company that does not intend to use this specific locus for anything, but still wishes to have control of the gene that is part of a larger genomic region. Although, Lesch-Nyhan is a fairly uncommon disease, genomics presents the opportunity to find innovative solutions to this genetic disorder. However, the fact that LNS is not common and that research concerning its locus might not affect a significant amount of the general population would preclude any innovative discoveries concerning the disease.

Another interesting point made by Kuppuswamy, Bernier, and Palomi is that there is no guarantee that the information protected by genetic patents *will* improve society. Many patentees not only fail to understand the mechanism underlying the genes they patent, but also fail to recognize the synergy within the genetic field and that discoveries in one area of the genome directly influences discoveries in other areas of the genome. Given the anecdotal utility of genetic patents, it is quite possible that, as the understanding of genomic phenomena evolves, certain sequestered portions of DNA will not be able to produce the results promised by the patentees (142; 140; 78). Thus there is danger in the genetic patenting process. The uncertainty itself is not bad, but when held together with a series of superficial promises that legalize exclusionary rights over natural phenomena, it becomes a frightening impasse for genomic research.

Recent bioethical literature offers two solutions to genetic patents. The first is bill proposed by Representative Becerra. The *Genomics Research and Accessibility Act* would effectively eliminate the patenting of genomes; however, it would allow soundly verifiable innovations to be patented as means of “rewarding inventors” (Rimmer, 142-145). In *Patenting Lives*, Palomi sets forth the second

proposed solution, the *Genetic Sequence Right Project* (GSR).<sup>3</sup> This effort seeks to create a pseudo-patent registration in which one has the right to claim status as the originator of genetic information that would otherwise be patented. As the originator, one receives a GSR commission each time one's discovery is used in a commercial manner (i.e. educational endeavors are exempt). But the originator does not have the freedom to discriminate on how the knowledge is applied. Palomi cites the GSR as compelling because it allows innovators to maintain ownership of their inventions (however precarious they may be) but prevents the exclusionary use of these inventions that haunts the current patenting system (93).

Though these solutions show promise, I remain a bit skeptical about how well they can be incorporated into biotech industries and legislature. Judicial support will be absolutely necessary for either proposal to pick up speed and be effective. As we have seen with cases (even those not related to bioethics), the courts are reluctant to rule in such a way that contradicts precedence set in prior cases (Candlish, 142). This reluctance could quickly jettison either solution were it passed as law. Additionally, if the GSR fails to make more exact distinctions between what constitutes an invention and what does not, it will be very difficult to prevent a series of redundancy in the application process and complications from multiple GSR fee requirements. Moreover, this solution appears to solve the problem of strict discretionary fees with loose indiscriminate ones; but it is not clear where the underfunded entities fall into play in this regard. Nonetheless, these remedies affirm even more clearly that in order for biotechnology to coexist with ethical norms, strides will need to be made to target the dysfunctional relationship between genetic patents and the standards of intellectual property. According to Palomi, it is perhaps for this reason that the patent system may be unsuited for the emerging field of biotechnology (91).

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<sup>3</sup> The *Genetic Sequence Right Project* is far beyond the scope of this paper, but the following link contains more information about the initiative. <http://cgkd.anu.edu.au/menus/projects.php#genetic>

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