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The BRCA Gene Patents: Arguments Over Patentability and Social Utility

Bonnie Chojnacki and Ronald F. White

Beginning in 2011, a series of contradictory U.S. court decisions cast doubt on the patentability of Myriad Genetics' BRCA1 and BRCA2, the primary genes responsible for breast and ovarian cancer. Similar legal and political opposition materialized within the European Union, Great Britain, Canada, and the rest of the modern world. Despite years of global debate, the long-term public policy implications for the BRCA gene patents—and indeed all gene patents—remain unclear. This essay will examine the two primary argument forms that have been presented in the BRCA gene patent debate: "patentability arguments" and "social utility arguments." Neither line of argument has yielded much in terms of national or international consensus. But both have generated increasingly complex, convoluted, and ultimately irreconcilable debate within and between nations. These endless cycles of legal, political, and scholarly debate cast serious doubt upon the long-term sustainability of the patent institution as a "one-size-fits-all" funding mechanism for genomic science, the genomic industry, and genomic medicine.

KEY WORDS: gene patents, genetic tests, BRCA1, BRCA2, Myriad Genetics

Introduction

By 2005, the U.S. Patent and Trademark Office (USPTO) had granted between 3,000 and 5,000 patents on human genes. About 63 percent of the patents were held by private firms and 28 percent by universities. The top assignee was the California-based drug company Incyte, which held about 2,000 genetic patents (Jensen & Murray, 2005). Today, four corporations hold the majority of gene patents: Incyte Corporation, Celera Genomics, Myriad Genetics, and Isis Pharmaceuticals. A growing number of those patented genes are now associated with *genetic diseases* that are diagnosed via patented *genetic tests*. Although gene patents have been codified in all modern nations, they continue to generate arguments over the *patentability* of specific genes, and over the *social utility* of the patent institution in the context of genomic science, the genomic industry, and genomic medicine.

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From the outset, let us acknowledge the obvious; namely that, worldwide, the legal, socioeconomic, and political dimensions of gene patents are dauntingly complex. Therefore it is not surprising that the scholarly research associated with the BReast CAncer (BRCA) gene patents is ponderous, multidisciplinary, and complex. But it is also often myopic and/or overly simplistic. For example, there is a distinct genre that approaches the BRCA1 and BRCA2 patents in the larger context of "intellectual property rights": patents, copyright, trademarks, and trade secrets (Gosseries, Strowel, & Marciano, 2008). Other works are primarily historical accounts of those gene patents and/or gene test patents (Williams-Jones, 2002). Other works propose alternative regulatory and funding mechanisms (Chahine, 2010; Dreyfuss, 2010; Van Overwalle, 2009). Although much of the scholarship is critical of gene patents (Gold & Carbone, 2010; Koepsell, 2009; Schacht, 2006; Soini, Aymé, & Matthijs, 2008; Williams-Jones, 2002), very few of these works really capture the "big picture."

This essay will, therefore, develop that "bird's-eye view" by focusing on the two main lines of argument within that BRCA debate: *patentability arguments* and *social utility arguments*. While this "bird's-eye view" will be primarily philosophical and theoretical, it will also shed much-needed light on some thorny public policy issues relating to the role that gene patents now play in funding genomic science, genomic industry, and genomic medicine. Although much of the analysis will emphasize the U.S. experience, other nations have been similarly trapped by these open-ended arguments.

Historically, the patent institution emerged as a "one-size-fits-all" solution to a cluster of problems associated with the economics of research. Today, scientific research requires a significant long-term investment of time, energy, and resources, including costs associated with hiring and training a highly skilled scientific workforce, purchasing and maintaining expensive equipment and technologies, and complying with governmental regulations. Historically, science often pays for itself in terms of the production of useful knowledge and/or inventions, but not always. Therefore sustainable research institutions (public and private), somehow, must recoup the costs, not only of their occasional successes, but also their more frequent failures. Modern nations view science as a "public good," and therefore directly and/or indirectly subsidize the cost of scientific research. Since the 1980s, the United States has subsidized scientific research, indirectly, via the patent institution; that is, by providing economic incentives for public and private universities, and private corporations to patent their inventions.

The social purpose of the modern patent is to promote research and innovation and to allow for the return of new benefits for society (Soini et al., 2008, p. S10). Since researchers must pay the costs of both their successes and their failures, they often pursue external (public and/or private) investment. In order to attract private investors, researchers must demonstrate the future potential for marketable applications of their research, most notably inventions. Defenders of patents in science argue that in the absence of patent protection, the incentive for private investment in scientific research would be undermined by

the invasion of opportunistic "free riders"; that is, competitors who would "copy" and "sell" the scientific inventions of others. Since "free-riders" do not pay the initial costs of research and development, they can (and will) copy and sell those inventions at a much lower price. Therefore, in the absence of governmental intervention, the potential invasion by free-riders provides a powerful disincentive for inventors and investors to expend their time, energy, and resources. Given the enormous costs associated with scientific research, the wedding of the age-old, patent institution with scientific research seems to be a logical, "one-size-fits-all" solution. But is it?

The patent institution is a legal mechanism originally designed to address the free-rider problem. It does so by employing the coercive power of government to reward inventors with a 20-year, legally enforced monopoly, which includes the legal right to *exclud*e others from making, using, or selling patented inventions; and, the legal right to charge users a *license fee.* In exchange for these benefits, inventors are legally required to disclose enough information for licensed users to copy and/or utilize their inventions. But does that "one-size" really "fit all?"

Worldwide, patent policies are implemented by "patent agencies" such as the United States Patent and Trademark Office (USPTO) or the European Patent Office (EPO) (Merz & Cho, 2005, p. 203). In the United States, there are two primary political bodies with the power to review the patentability of genes: Congress and the courts. Many scholars observe that Congress has attempted to take up the issue and the lack of significant impact (Andrews, 2002; Demaine & Fellmeth, 2002, p. 359). Therefore, for better or worse, the primary battleground for the gene patent debate in the United States has been within the courts.

Because patents are granted, monitored, and enforced by national governments, inventors interested in participating in the global market must apply for patents in multiple jurisdictions. The most potentially lucrative jurisdictions include: the United States, the European Union, Great Britain, and Japan. However, the application process of awarding patents in any jurisdiction is enormously complex, expensive, and can take many years to complete; thus, the familiar term "patent pending."

The most patent-savvy inventors seek to patent not only their individual inventions, but also the various components of their inventions. Therefore the most coveted patents tend to be multiple patents that are both "broad" and "interlocking." Genomic corporations often patent not only the multiple genes associated with a disease and the processes used to isolate those genes, but also partial sequences of DNA, expressed sequence tags (ESTs), and single nucleotide polymorphisms (SNPs). Ultimately they also seek patent protection for any genetic tests that they develop for identifying those genes.

Inventors that are price-sensitive to the cost of conducting scientific research, obviously prefer "monopolistic" patent licensing policies, characterized by unlimited exclusionary rights and unregulated license fees. However, patent agencies in most democratic nations are politically sensitive to the interests of competing stakeholders, and therefore tend to award narrower, less monopolistic patents. Since the 1980s, the United States has been noted for its extremely

"monopolistic" patent policies, which favor large genomic corporations; while European and Japanese policies tend to be much more "restrictive" and are more sensitive to competing interests (Soini et al., 2008, p. S11). Typical restrictions include statutory limits on the patent holder's right to "block" other stakeholders' access to their inventions, especially competing scientists and/or heath care providers. And most nations with highly "socialized" health care systems control the price that patent holders can charge licensees.

Beginning in the early 1990s, worldwide controversy over Myriad Genetics' gene patents for BRCA1 and BRCA2 raised complex arguments concerning the patentability of genomic material and the social utility of employing the patent institution as a funding mechanism for genomic science, the genomic industry, and genomic medicine.

The BRCA Gene Patents Controversy

Worldwide, breast cancer is the second most commonly diagnosed cancer for both sexes combined. In the United States, it is the most frequently diagnosed cancer across all racial and ethnic groups of women. In 2009, in the United States the most recent year for which statistics are available, 40,676 women diagnosed with the disease died (United States Centers for Disease Control and Prevention, 2013). In 2008 more than 332,000 new cases of breast cancer were diagnosed in the European Union (Cancer Research UK, 2008, 2011, p. 4). Hereditary breast cancer is responsible for 5–10 percent of breast cancers in women in the United States. Additional risk factors related to breast and ovarian cancers include: age, reproductive and surgical histories, oral contraceptives, and physical activity (National Cancer Institute, 2012). Those who have the genetic mutations have a 40–85 percent risk of developing breast cancer and 16–40 percent risk of developing ovarian cancer over their entire life span (Williams-Jones, 2002).

There are several scholarly books that critically explore the history of the BRCA controversy in the larger context of the gene patent controversy (Koepsell, 2009; Palombi, 2010), and many journal articles that provide historical background on the European context (Dreyfuss, 2010; Matthijs, 2006; Parthasarathy, 2005). As one peruses these works, the reader is struck by the complexity generated by the BRCA gene patents. The following is a brief account of the international origins of the BRCA controversy.

As early as 1988 seven major international groups were engaged in research to identify the location of the genes associated with breast cancer. The initiative was recognized as an international priority with research groups consisting of scientists from many countries in laboratories in the United Kingdom, France, Canada, and two groups from the United States. An awareness of the value of cooperation in identifying genetic mutations and its ability to promote future research led to formation of the Breast Cancer Linkage Consortium (BCLC), an international alliance of researchers from the United States, the United Kingdom, Canada, France, Belgium, and the Netherlands.

An initial breakthrough in the search for those breast cancer genes occurred in 1990, when one team from the United States led by Mary Claire King announced the discovery of a gene associated with breast cancer on chromosome 17 at a meeting of the American Society of Human Genetics. Collaborators included Francis Collins and other notable researchers. Following King's announcement, Gilbert Lenoir and Steven Narod published an article confirming those findings. In addition, Lenoir and Narod reported that a hereditary disposition for ovarian was identified at the same location (Gold & Carbone, 2010, p. S40).

The next step in furthering state-of-the-art molecular-level science was to identify the specific genes on chromosome 17 associated with the cancers. In order to assemble sufficient data for a statistically relevant analysis, the BCLC began collecting information from families with possible inherited predispositions to the cancers. From their analysis of 214 families BCLC scientists arrived at two conclusions. One, a gene located on chromosome 17, BRCA1, was associated with hereditary breast and ovarian cancers. Two other genes, as yet uncharacterized, were associated with the related breast and ovarian cancers. BCLC published a series of articles reporting these results in the *American Journal of Human Genetics* in 1993 (Gold & Carbone, 2010; Williams-Jones, 2002).

At the same time, Marc Skolnick, Adjunct Professor in the Department of Medical Informatics, University of Utah's Center for Genetic Epidemiology, was leading another research group from the United States in a search to identify the location of the genes for breast and ovarian cancers. Skolnick's group had an initial advantage through access to databases that were already populated. Skolnick's international team of scientists mined the Utah Population Database and cross-referenced it with the Utah Cancer Registry. Although the Population Database was previously developed as part of Skolnick's doctoral work, in the 1970s, it had become the property of the University of Utah, and was accessible for new research. By the time the database was mined for the new research it contained data from 200,000 Mormon families and 1.6 million decendents of the original 10,000 settlers of Utah. Linking the data to the 100,000 entries in the Utah Cancer Registry resulted in 40,000 cross-linked entries that formed the foundational data for future research.

In 1991, Skolnick became the Chief Scientific Officer of a business venture founded in conjunction with the University of Utah; Peter Meldrum (well-known venture capitalist) and Walter Gilbert (Nobel prizewinner, and faculty member in the Department of Molecular and Cellular Biology at Harvard University) joined the venture. Together they formed Myriad Genetics, Incorporated. But why would a public university join forces with a "venture capitalist?" Good question! The short answer is that the enormous costs of genomic research and the legal complexities associated with patents provided a powerful incentive for public and private universities to "spinoff" for-profit corporations.

The legal foundation for the use of gene patents as a funding mechanism for genomic research was firmly established in the early 1980s by a series of legislative, judicial, and regulatory decisions in the United States, most notably:

the *Human Genome Project* (which marked the first major effort by the United States to provide direct public funding for genomic research); the *Bayh–Dole Act* (which cleared existing legislative barriers that prevented publically funded colleges, universities, small businesses, and not-for-profits from holding intellectual property rights on "inventions" developed with federal funds); and the U.S. Supreme Court case, *Diamond v. Chakrabarty* (which ruled that an oil eating bacterium created in a laboratory fulfilled the legal criteria for patentability and that "anything under the sun that is made by man" can be patented"). Taken together, these three public policy decisions cleared the way for the patenting of living things, especially DNA (Koepsell, 2009, p. 140).

Myriad Genetics was the product of a new form of creative financing that merged public and private revenue streams. It included $10 million (U.S.) in private stock and $1 million (U.S.) in equity from the Eli Lilly pharmaceutical corporation. The U.S. National Institutes of Health (NIH) contributed $5 million (U.S.) to the Utah research group. Eli Lilly provided another $1.8 million (U.S.) over 3 years for the search for genes associated with breast cancer in exchange for licensing on diagnostic kits and therapeutics. At the time it was launched, Myriad Genetics held no patents as collateral for investment. Myriad filed its first patent application with the U.S. Patent and Trademark Office (USPTO) on BRCA1 in August 1994 with coassignee the University of Utah. The results of the research were published several months later in the October 7 issue of *Science*. In 1996, Myriad opened a $30 million (U.S.) laboratory and launched a gene discovery corporation. In December 1997, the USPTO granted the first patent to Myriad covering 47 separate mutations. By 1998 Myriad secured a patent covering all uses of the BRCA1 gene (Gold & Carbone, 2010, p. S41).

A second gene associated with breast and ovarian cancers was found on chromosome 13. The race to report the discovery of BRCA2 came down to competition between a group from the United Kingdom led by Michael Stratton and Myriad. Stratton's group published an article on the discovery BRCA2 co-authored by 31 scientists in *Nature* in 1995. Skolnick's research team at Myriad reported that they had already identified BRCA2 and had submitted their findings to GenBank, a public database for genetic information sponsored by the U.S. National Center for Biotechnology Information (NCBI). Myriad further claimed the information published by Stratton's team from the U.K. was less complete than the profile it had submitted to GenBank. The USPTO awarded patents on BRCA2 to Myriad in 1998 and 2000. Like the U.S. patents on BRCA1, the patents on BRCA2 were broad and interlocking, and covered "BRCA2 DNA, mutations, and diagnosis ... and for a patent over the method of detecting BRCA2 mutations and antibodies" (Gold & Carbone, 2010, pp. S41–S42).

By leveraging its patents and rigorously exercising its rights of exclusivity worldwide, Myriad Genetics has become a major biopharmaceutical corporation with a significant international market currently "specializing in the use of proteomic and genomic technologies to create break-through medical, diagnostic and therapeutic products" (Parthasarathy, in Williams-Jones, 2002, p. 129). Although, it has been a very "successful" from the standpoint of its investors,

Myriad's gene patents spawned worldwide controversy over the patentability of genes, social utility of gene patents, and the overall ethics of Myriad's behavior as a university-owned corporation.

Legal Arguments over the Patentability of the BRCA Genes

Worldwide, gene patents are complex legal entities steeped in arcane legal arguments embedded in ambiguous historical precedent. In the United States, Myriad's BRCA1 and BRCA2 patents led to a series of conflicting high court decisions over whether those genes fulfill the traditional legal criteria for patentability. While laws governing the patentability of specific objects and procedures vary between nations, it is widely agreed that the following legal criteria must be met:

C1: The object or procedure must be an *invention* and not a *discovery*. Therefore, you cannot patent a natural object or a natural process.
C2: The object or procedure must be *innovative* (or novel). Therefore you cannot patent something that already exists through the efforts of someone else.
C3: The object or procedure must be *non-obvious*. Therefore, you cannot patent something that has already been fully anticipated by a previous patent, publication, or other knowledge within the public domain. It must require substantial time, effort, and resources to create it.
C4: The object or procedure must be *useful*. Therefore, you cannot patent something that is useless in the hope that it might someday become useful (Schacht, 2006).

According to the U.S. Patent Act of 1952 (Title 35) an inventor may patent "... any new and useful process, machine, or any composition of matter, or any new and useful improvement thereof ... ." These criteria became obfuscated when the U.S. Supreme Court issued its decision on *Diamond v. Chakrabarty* (1980), which ruled on the patentability of a bacterium that, with the insertion of four plasmids, became an efficient way of managing oil spills. Initially patent examiners rejected the patent application for two reasons, (1) the bacteria are "products of nature" and (2) "they are living." A series of appeals brought the case to the Supreme Court which ruled: "the patentee has produced a new bacterium with markedly different characteristics than those found in nature, and one having significant utility ... ." The Court went on to rule that, "the relevant distinction was not between living and inanimate things, but between products of nature, living or not, and human-made inventions" (Brody, 2006, pp. 10–11). However, as Chahine points out, the "natural products doctrine" is itself vague and there has been "little consistency in the manner it has been applied" (Chahine, 2010, p. 1251). Nevertheless, this early decision opened the way for subsequent courts to rule that "usefulness" and "human made inventions" trump the other criteria of patentability, a decision that favored large corporations like Myriad whose products are pure biotechnology. Henceforth, the legal defense of gene patents consisted in the argument that genes encoding proteins are

analogous to chemicals (Eisenberg, 2006, p. 318). And the social utility of gene patenting became identified with the rapid discovery of naturally occurring, useful molecules (Demaine & Fellmeth, 2003, p. 5624).

Myriad and other defenders of gene patents also argued that the BRCA genes are patentable because, in order to be rendered "useful," they must be first "isolated" from the human genome, and that the process of isolating genes is complex and therefore "non-obvious." Critics like Palombi would later refer to this line of argument as the "isolation contrivance" (Palombi, 2010, pp. 205–223).

European critics also argued that the BRCA genes isolated by Myriad are not sufficiently *innovative*, because those genes had already been mapped to chromosome 17 by the international researchers and the BCLC and thus Myriad's gene patents simply added the "last brick in the wall" to a set of previous discoveries. Many also argue that most (if not all) patents in Science are inherently unfair because they arbitrarily and therefore unfairly reward one inventor at the expense of other deserving predecessors. So if Myriad merely put the "last brick in the wall" (Gold & Carbone, 2010, p. S64), then justice implies that the courts either require Myriad to share exclusionary rights and license fees with those previous bricklayers or completely disallow those patents and rule that the BRCA genes belong in the public domain.

On May 12, 2009, a challenge to Myriad's patents on the BRCA genes was brought in the Southern District of New York (SDNY) by more than 20 plaintiffs including the American Civil Liberties Union (ACLU), Association of Molecular Pathology, Public Patent Foundation (PubPat), medical professional organizations, patient advocacy groups, individuals, and physicians. The defendants included the United States Patent and Trademark Office (USPTO), Myriad and the University of Utah Research Foundation. On March 29, 2010, Justice Robert Sweet, in a 156 page opinion, invalidated 15 claims in 7 patents. He ruled that,

> [b]ecause the claimed isolated DNA is not markedly different from native DNA as it exists in nature, it constitutes unpatentable subject matter. ... The identification of the BRCA1 and BRCA2 gene sequences is unquestionably a valuable scientific achievement for which Myriad deserves recognition, but that is not the same as concluding that it is something for which they are entitled to a patent. (Sweet, 2010, p. 135)

Justice Sweet, basing his ruling on nineteenth century precedent, significantly departed from the convention of the USPTO and many lower courts decisions from the twentieth century and ruled in favor of the plaintiffs that mere isolation or purification as a product of human invention is insufficient:

> DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature. It is concluded that DNA's existence in an "isolated" form alters neither this fundamental quality as it exists in the body nor the information it encodes. (Sweet, 2010, p. 3–4)

On July 29, 2011, Judge Sweet's ruling was reversed by the United States Court of Appeals (CAFC) for the Federal Circuit. In a divided opinion the Appellate court affirmed that isolated DNA is patentable and ruled that only one of the plaintiffs had legal standing to bring charges against Myriad et al. The CAFC overturned Justice Sweet's opinion based on the twentieth century precedent that genes are equivalent to chemicals and, as such, both the genomic material and the process claims remain valid (Conley & Vorhaus, 2010). However, the Supreme Court "remanded" that decision back to the CAFC for reconsideration in light of the high-court's recent decision in *Mayo Collaborative Services versus Prometheus*, where they unanimously invalidated a patent on a medical test because it was tantamount to patenting "a law of nature." The CAFC reaffirmed their support for the patentability of gene patents but cast doubt on the patentability of Myriad's gene test.

Meanwhile in Australia (as was the case in the United States) members of the public rather than competing corporate interests challenged the BRCA patents. When Australian courts considered the impact of prohibitions on genomic patents, they also weighed the impact banning patents on DNA would have on biotechnology (Simmons & Wickham, 2012, p. 323). Their ruling affirming legitimacy on patents on DNA might be construed a nod to the argument Myriad has put forth. Myriad's case before the U.S. Supreme Court will strictly examine the law and legal precedent when it decides on the composition of matter issue put before it.

Cook-Deegan has argued that a ruling opposing claims on DNA molecules, now in front of the U.S. Supreme Court, is likely to have little impact on biotechnology industries except for a few who hold "service monopolies," like Myriad and Athena Diagnostics. Other biotechnology corporations whose genomic patents include narrow claims are unlikely to notice a significant difference (Cook-Deegan, 2012, p. 747). The challenge each country will need to grapple with is aligning law and policies with international trade agreements like the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and ethical considerations related to provision of health care especially those that have national health care systems (Simmons & Wickham, 2012, p. 323).

As the world anxiously awaits the U.S. Supreme Court's second decision on the Myriad case, again the primary question will be whether genes do or do not constitute patentable subject matter (Liptak, 2012). Indeed, as one peruses the various court cases, which are rife with dense scientific jargon, one might question the competence of legal experts, especially judges, to rule on technical matters of science, business, or medicine. Regardless of the outcome, legal scholars, philosophers, and scientists (and future courts) from all over the world will continue to argue over whether newly identified human genes are discoveries or inventions, and whether they are sufficiently innovative, non-obvious, and useful.

In sum, as Cho (2010) rightfully observed: "It is clear that the intellectual property model challenged by the Myriad decision will have to be replaced if new genetic technologies are to achieve their full potential in promoting the

"progress of science and useful arts" (Cho, 2010, p. 551). Therefore, at this point in time, it seems highly unlikely that patentability arguments will ever provide a stable legal foundation for global genomic science, the genomic industry, or genomic medicine.

Social Utility Arguments over the BRCA Gene Patents

Patentability arguments are, by their very nature, unlikely to generate stable, legal consensus within and/or between nations. However, the BRCA debate has also produced a variety of arguments over the *social utility* of gene patents. Unfortunately, those arguments are similarly destined to generate open-ended debate.

First, some basics. As Rachels (1986) observed, classical utilitarianism can be summarized in three propositions: "Actions are to be judged right or wrong solely in virtue of their consequences"; "in assessing consequences, the only thing that matters is the amount of happiness or unhappiness that is caused"; and "in calculating the happiness or unhappiness that will be caused, no one's happiness is to be counted as more important than anyone else's". Hence, any utilitarian analysis of gene patents is grounded in the meta-ethical proposition that the "social good" is manifest in future consequences. However, there is longstanding debate over the foundations of "classical utility" and interpretation the "social good" (Glover, 1990). One puzzle involves whether the "social good" lies in increased quantities of happiness (or measuring happiness) and/or increased numbers of happy persons (or "counting heads"). Regardless of the unit of measurement, if the estimated future *benefits* of a given policy outweigh the *costs*, then that policy is "justified" and conversely, if estimated costs outweigh the benefits, then it is "unjustified." Based on "head-counting," public policies that benefit at least 51 percent of stakeholders are deemed justified. However, in the real world, the anticipation of future consequences is enormously difficult and requires highly fallible social scientific calculations. Not surprisingly, there are hidden puzzles associated with accurately calculating cost and benefits of the BRCA gene patents.

The most obvious utilitarian criticism of the BRCA gene patents and (and gene patents in general) has been the subsequent emergence of "unanticipated costs" (and benefits) to various stakeholder groups. One of the most pernicious of the unanticipated costs has been their tendency to inspire organized political resistance. The primary source of political resistance to the BRCA gene patents has been that the would-be benefactors are often unwilling to pay the cost of advancing the interests of those would-be beneficiaries. Worldwide, the BRCA gene patents distribute benefits and costs unequally among a wide variety of competing stakeholder groups, most notably genomic scientists, research universities, genomic corporations, medical professionals, patent lawyers, breast cancer patients, and taxpayers. Thus, the political challenge for any utilitarian analysis of gene patents is that they require cooperation between patent-holding and non-patent holding genomic researchers and health care providers.

One time-tested strategy for fostering cooperation among stakeholders is to invoke feelings of sympathy among potential benefactors and argue that the primary beneficiaries of a given public policy are the "least advantaged," that is, women with breast cancer. However, unless the "least advantaged" turn out to be a majority, this is no longer a utilitarian argument. Moreover, gene patents benefit not only the "least advantaged" but also patent-holders (and patent lawyers) who are not among the "least advantaged." Hence, political resistance to the BRCA gene patents can be attributed to the perception that Myriad Genetics has benefitted more than breast cancer patients.

Another puzzle associated with justifying the BRCA gene patents based on classical utility is deciding whether utility ratios *ought* to be calculated based on a national or a global scale. *Nationalism* argues that utility ratios ought to be calculated within sovereign nation states. However, nation states are often composite entities comprised of political subentities with conflicting interests. For example, in the United States there are longstanding political conflicts between local, state, and federal levels of government; between upper, lower and middle classes; and between various racial and ethnic groups. Within the European Union there are frequent political conflicts between the individual member nation states, and in Canada the political conflicts occur between its various provinces. Compound political entities also harbor competing (and cooperating) universities, corporations, scientific organizations, health care providers, and patient advocacy groups. So while it may be true that the BRCA gene patents benefit Myriad Genetics, social utility requires that a majority of stakeholders within those national borders benefit. Here, the most common rhetorical device employed by the defenders of gene patents is to invoke the "trickle-down effect" and argue that lucrative benefits afforded gene patent holders, like Myriad, will produce benefits for the other stakeholders over the long run. However, these long run arguments are often tantamount to "kicking the can down the road."

Utilitarians, like Peter Singer, advocate "an abandonment of state sovereignty" in favor of universal principles (Singer, 2002, p. 5). *Globalism* (or universal utilitarianism) argues that utility ratios ought to be calculated with impartiality on a global level. Hence, a positive utility ratio for one nation may (or may not) generate negative utility ratios for other nations and/or the rest of the global community. Positive utility ratios for Europe and/or Canada may not yield positive ratios for the United States and, conversely, positive utility ratios for the United States may not be "good" for the rest of the world. At a global level, the BRCA gene patents are most likely to yield positive utility ratios within economically developed nations, especially those with national health care systems, such as the United States, Canada, Europe, and Australia. Under-developed nations, however, are not likely to immediately benefit. Therefore, globalists might argue that gene patents benefit, primarily, economically developed nations, a minority of global stakeholders. Defenders might respond that over the longer run under developed nations will also benefit, but are unable to specify how and/or when those benefits might flow their way.

The fact that utility can be estimated over both the long run and the short run gives rise to another notoriously vexing problem associated with classical utility—the "problem of future generations" (Rawls, 1999, pp. 251–262). Here is how that argument goes. Utility ratios calculated over the short run benefit the present generation; while projected long-run ratios aim to benefit future generations. This, inevitably, leads to conflict of interest between present and future generations. For example, a utilitarian might argue that future stakeholders are potentially more numerous and inherently "disadvantaged" in their power relationship with the present stakeholders. Therefore, negative ratios in the short term (for the present generation of stakeholders) might be acceptable if they produce positive long-term utility ratios (for future generations of stakeholders). Unfortunately, all of this raises a menagerie of problems, including the matter of "intergenerational justice" (Gosseries, 2012).

Perhaps the most problematic and puzzling is that knowledge of the long-term future consequences of any complex public policy is highly fallible and, therefore, long-term "one-size-fits-all" public policies, like gene patents, are likely to be undermined by unanticipated costs.

In sum, any utilitarian defense of gene patents as a "one-size-fits-all" public policy mechanism will have to address at least four notoriously thorny issues: unanticipated future costs and benefits, inequality in the distribution of costs and benefits, and the problem of future generations. One might add that the mind-boggling complexity of the BRCA patents and the ongoing legal controversy also generate unanticipated costs. Another dimension of the "one-size-fits-all" nature of gene patents is the assumption that they solve complex problems relating to genomic science, the genomic industry, and genomic medicine. Let's take a closer look at each of those arguments.

Genomic Science

Genomic science consists of the systematic search for the laws of nature governing biological inheritance; especially the human genome. Research is typically conducted by public and private research laboratories around the world, with a growing number of genomic researchers associated with private corporations that are owned by public and private universities.

Recall that the original impetus for employing gene patents was to solve a cluster of funding issues in genomic science. But what are the long-term and short-term costs and benefits of continuing to fund genomic science via the patent institution? Who are the primary stakeholders? And, in the final analysis is it a positive or negative utility ratio? Let us begin by acknowledging that there is a general consensus among developed nations that the anticipated social benefits of gene patents are associated with the provision of economic incentives that contribute to the future production of scientific knowledge and useful inventions. However, critics of gene patents argue that patent institution has already generated unanticipated costs for genomic science. So what is science and do the

BRCA gene patents advance or undermine its fundamental principles and institutions?

Philosophers of science often distinguish between genomic theory as "pure science" and the genomic applications as "applied science." Pure science seeks to discover the "laws of nature"; a collective human activity that is often "justified" based on the idea that knowledge of the Truth is "intrinsically good" or "good for its own sake." The most idealistic defenders of the pursuit of pure science argue that the primary incentive for scientists to expend their time, energy, and resources on pure science is (or ought to be) the worldwide honor bestowed upon successful scientists, and not financial gain. Moreover, "pure science" is a "public good," therefore there must be universal access to its findings via a "scientific commons" or "public domain." Therefore, unlike inventions, knowledge must remain universally open at its source (open-source). Hence, the most idealistic proponents of pure science often argue that the very idea of buying and selling scientific knowledge undermines the collectivist "ideals" of science, and argue that scientific patents and copyrights on scientific information are unjustifiable.

Another puzzle for the advancement of pure science is that it requires an extraordinary degree of impartiality and objectivity on the part of researchers. Since new discoveries build on previous knowledge, it is the nature of pure science to continually inquire and challenge old discoveries based on new research.

> Research works best when those engaged in scientific endeavors are dispassionate about the outcome and when scientific honors are bestowed based on merit alone. Scientific claims are expected to be original—to build on but extend beyond the work of others. And scientific research should be governed by an underlying skepticism, meaning that all claims are tentative, theory-dependent, subject to empirical verification and rigorous scrutiny by other scientists. (Angrist & Cook-Deegan, 2006, p. 88)

In short, the hallmark of scientific inquiry is that it is self-corrective; that is to say that, over time, Science replaces or modifies beliefs that are false. Any public policy that impedes this self-corrective function destroys the essence of science.

In contrast to pure science, *applied science* employs scientific methods and technologies in the production of useful products and services. So if pure science seeks "intrinsic value," then applied science pursues "extrinsic value," or utility. As for motivation, the most realistic proponents of applied science argue that the primary motivation for discovering the laws of nature is the production of useful inventions. However, other motivations, such as earning tenure and promotion, selling scientific books, journals, and video documentaries are perfectly acceptable. Idealistic critics, however, say that the pursuit of gene patents has already "crowded out" the cooperation and impartiality necessary for the discovery of objective Truth, universal access to the Truth, and the pursuit of science as a "social good." However, realistic defenders of gene patents observe that the traditional "ideals of science" can no longer sustain modern science and/or that national governments can no longer afford to pay the open-ended costs of both

successful and unsuccessful scientific research. Gene patents, they argue, provide the incentives necessary for the continued production of scientific knowledge and applications, especially genomic tests and genomic therapies.

The most frequently cited utilitarian argument offered against the BRCA gene patents, and all gene patents, is that those coveted, multiple, interlocking patents may produce a "patent thicket," which provides disincentives for the future development of genomic science, genomic industry and genomic medicine. Here is how the "patent thicket argument" works in the context of genomic science.

The human genome is comprised of millions of interacting genes. When Myriad patented BRCA1 and BRCA2, it created a legal obligation for other researchers to secure permission from Myriad to use that information. Myriad, however, aggressively exercised its exclusionary rights by "excluding" other researchers or charging multiple, prohibitively costly licensing fees. Thus, any scientists interested in either improving the BRCA1 and BRCA2 inventions, or hoping to "invent" (or isolate) other genes associated with breast cancer like BRCA3, BRCA5, and BRCA6, had to negotiate with Myriad from a position of legal disadvantage. Moreover, compound gene patents have generated so much complexity that is difficult for competitors to determine which patents might apply. The more patent licenses that are required, the costlier the research. So rather than risk litigation for patent infringement, rational researchers will choose not to compete in areas where patent thickets are present. However, it is important to note that the empirical question as to whether patent thickets do, in fact, stifle competition in genomic science, the genomic industry, and genomic medicine is open to debate (Merz & Cho, 2005).

Genomic science currently resides at the intersection of "pure science" and "applied science," and gene patents seem to straddle the ground between the "laws of nature" and "inventions." By legal precedent, the laws of nature fall beyond the bounds of patentability. In the 1854, the U.S. Supreme Court in *O'Reilly V. Morse* found that Morse's patent was "too broad" and argued that by granting a monopoly on electromagnetism, which it held to be a law of nature, rather than the invention of the telegraph "would be unjust to the public ... and defeat the manifest object of the law" (Andrews, Paradise, Holbrook, & Bochneak, 2006, p. 1394). However, inconsistencies in the decisions of the lower and intermediate courts in the U.S. courts have added to the confusion (Demaine & Fellmeth, 2002). Eisenberg has argued that this confusion is due, at least partially, to the fact that genomic science is relatively new and rapidly changing, which creates tension with time-honored stability expected of the courts. She explains that, "Strategic claim drafting (of patents) is itself an evolving art that advances in tandem with technology, subject to constraints of patent law" (Eisenberg, 2006, p. 317). However, one might question the social utility of constantly altering the rules of the game.

Critics of gene patents, therefore, conclude that because private research facilities lack the requisite incentives to pursue Truth for its own sake, governments must fill the void and finance that research. But again, all scientific research is costly and it does not always arrive at the Truth. And even when the Truth is

discovered, it may not "pay off" in terms of future discoveries or inventions. Moreover, the public investment in pure science, inevitably, competes for budgetary considerations with other more "practical" political priorities such as infrastructure, welfare, and/or national defense. Hence, the most attractive feature of the BRCA gene patents (and all gene patents) is that they offer an alternative to the direct funding of pure science by providing economic incentives for private investment, by resolving the free rider problem, and by rewarding inventors with legal monopolies. But then again, critics question whether the pursuit of research patents by colleges and universities undermines their mission to educate students.

In the final analysis, the BRCA gene patents inspired a much-needed debate over funding genomic science via gene patents. However, that debate has become increasing complex and difficult to evaluate. As Salzberg suggests, "Gene patents are antithetical to scientific progress."

> Patent lawyers have no business in the laboratory. But scientists have invited them in, and now we are finding that they are hard to chase out. Once a gene is patented, court cases drag on for years, taking up countless hours of scientists' time. Lawyers charge by the hour, and these are "productive" hours for them. Scientists measure progress by how many discoveries they make (and publish), and every hour spent on legal dispute is an hour taken away from real work. Thus, rather than being productive, gene patents are *destructive* of the scientific enterprise. (Salzberg, 2012, p. 970)

Genomic Industry

The genomic industry is comprised of private corporations that seek to earn a profit by investing in genomic science. One of consequences of funding genomic science via the patent institution has been the rise of a handful of highly profitable corporations such as Myriad Genetics. But how have gene patents affected the overall competitive structure of that industry, and what are its prospects for the future? In other words, what are the long-term and short-term costs and benefits of continuing to fund genomic science and the genomic industry via gene patents?

Again, let us begin with the basics. The purpose of any corporation is to serve the financial interests of its primary stakeholders: stockholders, employees, consumers, suppliers, financiers, and local communities. More specifically, corporations provide: investment opportunities for *stockholders*, employment opportunities for *employees*, products and services for *consumers*, lending opportunities for *financiers*, markets for *suppliers*, and a variety of benefits (including tax advantages) for *local communities* (Boatright, 2011). Predictably, the interests of these "stakeholder groups" often conflict. Therefore, the primary public policy question is to what extent governments ought to be engaged in resolving those conflicts of interest.

In business ethics there are two competing theoretical perspectives. Stockholder theory holds that the primary goal of an industry or corporation is to earn a profit for stockholders and that the free market (and not the government) ought to determine economic winners and losers. Stakeholder theorists argue that the primary goal of an industry or corporation is to advance the collective interests of all stakeholder groups (nationally or globally), and not just the stockholders and that government must play a major role in distributing costs and benefits among stakeholder groups. At a global level, European and Canadian economic policy leans toward stakeholder theory, while U.S. policy leans toward stockholder theory.

Stockholder theorists argue that in a free market corporations and industries that effectively serve the financial interests of their primary stakeholders are rewarded by earning a profit. Companies that do not earn a profit are "creatively destroyed" by competitive market forces. So, if the long-term goal of genomic science is to "creatively destroy" (modify or replace) "unfit" (false or inadequate) theories or suboptimal inventions, then the long-term goal of the genomic industry is to modify or replace "unfit" products, services, corporations, and perhaps even entire industries. So how do gene patents affect this process of creative destruction?

The most obvious problem is that gene patents provide patent holders with a 20-year legal (artificial) monopoly; that is, the right to exclude competitors from using their patented inventions, and the right to charge license fees. In short, gene patents by their very nature "protect" patent holding corporations like Myriad from economic competition, which means that patent holders earn monopolistic profits for 20 years. Again, these monopolies are traditionally justified based on social utility; that is, the claim that the long-term benefits of gene patents outweigh the short-term costs. But do those long-term economic benefits really outweigh the costs?

Critics of the BRCA gene patents insist that the long-term costs outweigh the alleged long-term benefits; and that the global industry would be better off without them. Although the genomic industry is comprised of competing corporations, that industry also competes with other industries for both public and private investors. Although, so far, the genomic industry has already benefitted greatly from both public and private investment, critics question the long-term sustainability of continuing to directly subsidize the genomic industry via the National Institutes of Health and the National Science Foundation. Hence, the attraction of gene patents as an alternative funding mechanism.

Anticipating the long-term and short-term costs and benefits of gene patents for the genomic industry is enormously complex and highly fallible. One of the unanticipated costs of gene patents has been the worldwide costs associated with monitoring and enforcing patent laws in multiple jurisdictions. Patent-holding corporations must invest a lot of time, energy, and resources protecting themselves from legal challenges to their patents. Competing researchers must expend time, energy, and resources determining the patent status of the genes they need to conduct their own research. This task is ongoing and complicated by

the fact that many gene patents are pending, and therefore, may be subject to license fees at a later date. If competing researchers are accused of failing to comply with patent law or if they discover that another company is infringing upon their patent rights, they will have to employ the services of any army of highly paid patent lawyers to represent them in long, drawn-out court proceedings. These kinds of legal "interferences" can cost somewhere between $100,000 and $500,000 to resolve (Merz & Henry, 2004, p. 154). Whether the overall costs of DNA-based patents outweigh their benefits requires much more empirical analysis (Mills & Tereskerz, 2008).

Another unanticipated cost for the genomic industry has been that gene patents tend to favor large genomic corporations that can afford to apply for patents around the world, can afford to defend their patents through litigation, and can defend themselves from claims of patent infringement. Therefore, gene patents protect, primarily, the interests of the largest and most powerful corporations, often at the expense of smaller (and often more innovative) corporations. However, that competitive advantage afforded large corporations does not necessarily correlate with the production of higher quality products and services at a lower cost. It is, however, a measure of their ability to effectively utilize legal systems. So, over the long run, will powerful genomic corporations, like Myriad, be able to manipulate gene patents in such a way as to limit competition from other smaller corporations? Will that industry end up being dominated by a few large, politically well-connected corporations like Celera and Myriad, or will there be room for start-up, individual entrepreneurs and small innovative corporations to enter the market?

Again, defenders of gene patents anticipate that if most gene patents are overturned by the Supreme Court, the genomic industry may suffer irreparable damage. Over the long run, would that be good or bad? Will the industry adapt to this new legal environment? How will the new legal environment affect future private investment in the genomic industry? Will future Supreme Courts, legislatures, and/or patent agencies revisit these issues and perhaps reverse these decisions? Will those decisions be based on credible patentability and social utility arguments, or will they merely advance the interests of the most powerful genomic corporations?

Indeed, a substantial portion of the genomic industry's income is based on acquiring patents and collecting licensing fees from other competing corporations. Is that a sustainable business model, or are there other alternatives? Recent stockholders of Myriad Genetics certainly are not complaining. The company reported earnings for the third quarter of 2012 of $129.8 million reflecting a 27 percent increase over the same quarter in 2011. Revenue from *BRCA Analysis* during this period represented 81 percent of the total revenue for the quarter. The President and Chief Executive Officer, Peter D. Meldrum, announced a commitment to continued growth in expansion of diagnostics in the United States and internationally (Myriad Genetics, 2012). From the perspective of the corporation and its stakeholders this outcome is impressive.

One idealistic alternative to funding the genomic industry via gene patents would be for either governments or nongovernmental organizations to directly fund genomic science; that is hire its own genomic researchers, and direct all discoveries and inventions into the public domain. Or, perhaps governments might regulate the genomic industry as a public utility. Without getting into the larger issue of the role of government in science-based industries, it is clear that given the current state of Western economies, increased public funding for scientific research and development may be a "hard sell." So if the genomic industry does in fact serve the public good, it will probably have to do so without an endless flow of direct government subsidies.

It is important to note that the Supreme Court will not take into account the impact that destroying longstanding gene patents will have upon the genomic industry (Demaine & Fellmeth, 2002, pp. 376–78). "Thousands of patents have been issued to hundreds of universities, companies, and others researchers on human DNA sequences" (Morgan & Haile, 2010, pp. 1172–73). If a myopic U.S. Supreme Court ultimately rules that BRCA1 and 2 genes, and all (or most) other genes are not patentable via U.S. law, then what will be the consequences for the industry? Will genomic corporations like Myriad adapt, diversify, and/or pursue other ways of funding scientific research, or simply go out of business?

Genomic Medicine

Finally, it is widely acknowledged that the "discoveries of the human genome are to be used to improve health" (U.S. National Human Research Institute, 2002). Therefore, the social utility of gene patents is contingent upon the future development of applications in health care, especially genetic tests and genetic therapies. So what exactly are the short-term and long-term costs and benefits of gene patents for genomic medicine?

First, genomic medicine is based on discoveries in genomic science. There would be no genomic medicine without genomic science. Moreover, in the United States, since the 1980s, corporations, in general, have made most discoveries and inventions in science and medicine with the assistance of research grants provided by the National Science Foundation and the National Institutes of Health. Gene patents were initially introduced to incentivize pure genomic science in the hope that they would "pay off" in terms of useful discoveries and inventions. Thus, genomic medicine is conditioned by advances in diagnosis and therapeutics. So far, that utility has been limited, primarily, to the area of diagnostic gene tests. However, Myriad's BRCA gene test has been challenged globally for its suboptimal utility and its monopolistic pricing, which critics directly attribute to the patent institution.

First, let us acknowledge that in the health care industry where price insensitivity and quality insensitivity are both common, it is difficult to discern "information" from "marketing." Therefore we can expect sellers to emphasize individual and social benefits while downplaying costs. The quality of the BRCA gene test as a diagnostic tool is proportionate to its ability to pre-symptomatically

predict the onset of a breast cancer. Therefore, reliability diminishes in proportion to interpretative ambiguity, and false positives, and false negatives. French physicians allege that Myriad's test can only assess 10–20 percent of potential BRCA1 mutations (Andrews, 2002, p. 804). Moreover, the overall benefit of Myriad's pre-symptomatic BRCA gene test is that the presence of the BRCA1 or BRCA2 genes indicates about a 40–85 percent probability that the patient will develop breast or ovarian cancer over the course of her lifetime. However, only a small percentage of all breast cancers involve the two known BRCA genes, which suggests that either there are either other unknown genetic causes (BRCA3, 4, 5, etc.), and/or unknown environmental causes. So the mere fact that a patient tests negative for BRCA1 and 2 does not necessarily indicate that she will not develop breast cancer during her lifetime.

Diagnostic tests for the BRCA genes do contribute to a growing baseline of information which may be helpful in deciding among the possible interventions including: undergoing immediate medical treatment (chemo and/or radiation), forgoing medical treatment, or delaying medical treatment. Many physicians respond to a positive BRCA test by increasing the level and frequency of screening to detect cancer in the early stages. However, those technologies are not only costly, but they also carry with them serious long-term side effects. However, the primary therapeutic strategy associated with BRCA testing has been that patients who test positive get prophylactic mastectomies and/or ovariectomies.

The overall social utility of Myriad's BRCA gene test is also counter balanced by the monopolistic pricing of the test and Myriad's insistence that its own U.S. laboratory conduct the test. Indeed, the BRCA tests are so expensive (around $3,000) that many private insurance companies (in the United States) and government programs (United States, Europe, Canada, and Australia) refuse to pay for those tests, and only a few private patients are willing or able to pay out-of-pocket. Indeed, 17 laboratories in Europe are still performing diagnostic tests in violation of Myriad's patents (Lecrubier, 2002, p. 1120).

In Great Britain, Myriad's patents inspired organized resistance from British scientists, health care professionals, and breast cancer patients (Parthasarathy, 2005, p. 236). In Canada, organized response to the BRCA patents was mounted at the provincial level. In Ontario, the response endorsed by the National Healthcare System was to ignore Myriad's patent claims. Diagnostic testing for breast and ovarian cancers in British Columbia and Quebec ceased while options were considered. Australia initially ignored Myriad's patent rights. However, in 2002 Myriad granted an Australian biotechnology company an exclusive right to conduct diagnostic testing for BRCA1 and BRCA2 for Australia and New Zealand (Paradise, 2004). In addition, as noted earlier in this article, Australian courts upheld patentability of BRCA1 in February 2013 ruling in opposition to a suit brought by a patient advocacy group and breast cancer survivor (Simmones & Wickham, 2012).

Critics argue that patents on genetic tests undermine the self-corrective function of medicine by inhibiting other researchers from modifying or replacing

Myriad's diagnostic tests. First, because Myriad also held patents on both the BRCA1 and BRCA2 genes, it was able to legally "block" other genomic scientists and corporations from improving upon those tests or developing other more reliable gene tests. Myriad aggressively enforced its patent rights when it began diagnostic testing in 1998 by sending "cease and desist" letters to many competing laboratories already performing diagnostic tests for breast cancer. In fact, Myriad was also the first corporation to sue a university to insure enforcement of its monopolistic control of testing (Gold & Carbone, 2010, p. S42). Myriad's patents made it difficult to negotiate mutually acceptable alternatives (Paradise, 2004). Once the BRCA gene test was patented, there was little incentive for Myriad to improve the quality of that test. There is also that lingering question of how the gene patents for BRCA1 and 2 will affect the future development of gene tests for BRCA3, 4, and 5 ... ? Would Myriad's gene and diagnostic test patents create a "patent thicket" that discourages rather than encourages the future development of gene therapies? However, some scholars acknowledge that the degree to which Myriad has been actively thwarting other researchers is itself complex and difficult to establish (Carbone et al., 2010, p. 785).

There is an overlapping consensus among health care policy analysts that a "good" health care system provides universal *access* to high *quality* health care at a reasonable *cost*. Given the enormous costs associated with applied genomic medicine, critics might doubt the future potential for positive utility ratios. Any beneficiaries of genomic medicine will be limited to patients residing in nations that have well-developed health care systems (United States, European Union, Canada, Japan, Australia, etc.). Within those nations, access will be greater in urban than rural areas. However, not all health care systems in the developed world will be willing to provide expensive, patent-protected genetic tests and therapies. Highly socialized health care systems in England and Canada routinely refuse to pay for expensive, high-tech health care.

If the long-term utility of genomic science and the genomic industry are, ultimately, contingent upon applications in genomic medicine, then one might question the long-term consequences of continuing to invest in an ever-growing number of expensive diagnostic tests for genetic diseases. So far, genetics tests have been of variable reliability and expensive. Gene tests that are protected by multiple compound gene patents are also immune from external scientific scrutiny, and prohibitively expensive. Critics doubt whether gene patents and/or gene test patents undermine the future development of more reliable tests. If and when more useful genomic tests and genomic therapies are developed, there is always the question of whether individual patients, private health insurance companies, and/or socialized health care systems will be willing and/or able to afford to pay monopolistic prices for those therapies? Finally, after the patents expire on genetic tests and therapies, one might question whether genomic corporations and/or governments will be willing to continue to provide those less lucrative "generic" tests and therapies?

If and when genomic scientists develop genomic therapies, genomic medicine will certainly have to employ an army of technically trained providers. Training

these providers will require the expenditure of large quantities of time, energy, and resources with no guarantee that these expenditures will "pay off" in terms of improved health care. How will governmentally enforced wage and/or price controls affect the availability of these downstream jobs?

Finally, it is important to acknowledge that since the 1980s there has been a substantial body of scholarly literature that questions the social utility of the growing number of diagnostic tests that have emerged out of the genomic revolution (Nelkin & Tancredi, 1989).

So although defenders of gene tests, especially corporate CEOs of genomic corporations, assure us that that a flood of new therapies are in the pipeline, those therapies remain (for the most part) elusive. If and when those therapies do arrive, scholars will no doubt debate the access, quality, and costs of those therapies. In sum, the questions of whether patents advance or impede the future development of genomic medicine and whether genomic medicine really advances national or global health care involves enormously complex utility ratios.

Conclusion

Since the 1980s, gene patents have served as the primary mechanism for financing genomic science, the genomic industry, and genomic medicine. One of the purposes of this essay has been to examine some of the arguments that have emerged for and against this "one-size-fits-all" mechanism. It is always tempting to follow the path of other scholars and argue that the BRCA gene patents are either "justified" or "not justified" based on either patentability or social utility arguments. However, based on this "bird's-eye view," it is not at all obvious whether (1) the BRCA gene patents are consistent with internationally recognized patentability criteria nor (2) the BRCA gene patents are worth the time, effort, and resources already expended.

Patentability arguments invariably invoke highly debatable metaphysical assumptions and arcane legal distinctions between genetic material versus genetic information and between natural objects (and processes) versus inventions. The impending U.S. Supreme Court decision will almost certainly gloss over subtle differences between the patentability of different genetic technologies. It may even destroy genomic science, the genomic industry, and genomic medicine. Indeed, the very fact that a relatively narrow U.S. Supreme Court decision concerning the patentability of genes has the potential to upend the entire genomic revolution suggests that there is something fundamentally amiss.

Social utility arguments for and against gene patents have also generated a lot of irreconcilable debate, with little consensus within or between nations. Some stakeholders (genomic researchers, genomic corporations, genomic health care providers, and patients) benefit from gene patents while some do not. Future stakeholders may or may not benefit from gene patents. Of course some nations no doubt benefit from gene patents, while most do not. All of this suggests that

the costs and benefits of gene patents involve infinite complexity and endless political activity.

Despite these mind-boggling complexities, many critics of gene patents agree with Lauer that the gene patent mechanism can be tweaked and that the "ultimate goal should be to narrowly tailor the law in order to counteract the disparate effects that gene patents have on different types of scientific research" (2011, p. 198). Others follow Johnston and Wasunna's nuanced, but nonetheless optimistic, conclusion that "patents are not always the optimal tool for encouraging biomedical innovation ..." (Johnston & Wasunna, 2007, p. S30) But, given the open-ended nature of *patentability* and *social utility* arguments, it is hard to be even modestly optimistic.

We really should not be surprised by the controversy raised by the BRCA gene patents and the BRCA gene tests. The laws governing "intellectual property" have always been controversial, and subject to global debate. Why would gene patents be any different? The social utility of all expensive, allopathic, high-tech diagnostic tools and therapies has also been subject to debate. How much biomedical research should be expended on expensive, high-tech allopathic treatments, versus preventative medicine? There are also the omnipresent questions of political philosophy. What role should national governments play in funding scientific research? How much should corporations be regulated by national governments? What role should governments play in providing health care?

The common denominator between arguments based on patentability and utility is an underlying quest for "one-size-fits-all" political solutions. However, as Lauer observes, "... a one-size-fits-all solution—all gene patents are allowed or no gene patents are allowed—is not the best way to resolve the current debate about gene patenting" (2011, p. 185). Let us take that one step further. Perhaps we ought to be skeptical of all "one-size-fits-all" public policy solutions.

Since the 1980s, this "one-size-fits-all" approach to public policy has also led to the widespread pursuit of scientific patents by colleges and universities and the merging of public and private research funds. As Myriad Genetics anxiously awaits a Supreme Court decision that will, most likely, undermine (if not destroy) its current business model, other colleges and universities (and private investors) might think twice about investing in scientific patents that are perpetually vulnerable to outside legal and political interference. Moreover, the myopic perpetuation of "one-size-fits-all" gene patents has also impeded the exploration of other less politically charged licensing models such as: patent pools, clearing-houses, open-source models, and liability regimes (Van Overwalle, 2009).

In the final analysis it is important to acknowledge that "patents are not only legal documents and technical descriptions, but political tools as well" (Parthasarathy, 2005, p. 235). Some nations, such as the United States, grant patent-holders, relatively unencumbered discretion in terms of exercising exclusionary rights and/or setting licensing fees, while European nations and Canada tend to limit both. Therefore, in response to internal and external political pressures, most nations place a variety of legal provisos and restrictions on gene

patents. The most common restrictions include restricting the right of gene patent-holders to exclude competing researchers, primary research scientists, and/or health care providers. Many nations also enforce price controls on licensing fees charged by gene patent holders. Consequently, there is a lot of international dispute over patents, as inventions patented in one nation may (or may not) be recognized by other nations. Most nations are not anxious to start a "trade war" with the United States over gene patents, as other patent-dependent industries might be put at risk.

Interminable global debates over the patentability of genes and the social utility of gene patents clearly indicate that it is time to explore alternative funding mechanisms for genomic science, the genomic industry, and genomic medicine. However, let us not merely replace one "one-size-fits-all" mechanism with another. Perhaps it is time to recognize a larger truism; namely, "one size *does not* fit all."

Bonnie Chojnacki, B.A. (philosophy), M.L.I.S., is an Assistant Professor of Bibliography at The University of Akron in Akron, Ohio.
Ronald F. White, Ph.D., is a Professor of Philosophy at the College of Mount St. Joseph in Cincinnati, Ohio.

Notes

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