

The Patent Is Political: The Consequences of Patenting the BRCA Genes in Britain

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Key Words

Breast cancer · Genetic testing · Technology transfer · BRCA

Abstract

Objectives: The paper explores the attempt by an American biotechnology company, Myriad Genetics, to use its patent rights over the BRCA genes to transfer its technology of genetic testing for breast and ovarian cancer to Britain. It also investigates the responses of British scientists, health care professionals and patient advocates to this attempted technology transfer. **Methods:** This paper is based on approximately 100 in-depth interviews, document analysis and ethnographic observation conducted in the United States and Britain from 1998 to 2001. **Results:** The BRCA gene patents inspired political resistance and mobilized opposition to the patenting of genes in general. They also provided an opportunity for the British to assert their national identity as they argued that a British BRCA testing service needed to be available within the context of the National Health Service to all citizens equally. **Conclusions:** Patents are not only legal documents and technical descriptions, but political tools as well. As they are increasingly deemed vital to economic globalization, patents have become mobilizing

tools for anti-globalization activists and non-governmental organizations from less developed countries, and for asserting local and national identities.

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Introduction

We usually think of patents as written documents that describe technologies. However, they are technologies themselves. They are tools that facilitate the transfer of knowledge, allowing, for example, engineers in Indonesia to build farming technologies originally devised in the United States or Europe. They are legal devices, used to articulate and defend the details and extent of one's intellectual property. They are also increasingly becoming political technologies, used to exert control over territories and consumers, legitimize particular actions and mobilize opposition. Consider, for example, recent debates over access to HIV/AIDS medications in South Africa. In response to multinational corporations who sued manufacturers of generic anti-HIV drugs on the grounds of patent infringement, activists used these same patents as a device to launch an international debate about whether or not there is a global right to public health and specifically to lifesaving drugs. In this paper, I will demonstrate

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how patents become political technologies, using as a case study another controversy in contemporary biomedicine – the attempt by an American company to transfer to Britain its technology to test for mutations in genes linked to breast and ovarian cancer incidence.

As soon as the two genes linked to breast and ovarian cancer (known as the BRCA genes) were discovered in the mid-1990s, groups in both the United States and Britain began to develop technologies to test for BRCA gene mutations that predicted an inherited susceptibility to breast or ovarian cancer [1]. By 1998, very different BRCA testing systems dominated the biomedical landscapes of the two countries. In the United States, Myriad Genetics (Myriad), a start-up biotechnology company that had been credited with finding the first BRCA gene, used its relative financial strength and legal power, gained through acquisition of patents and licenses covering both BRCA genes, to become the sole provider of BRCA testing. Unlike most other genetic tests which were only offered through specialized genetics clinics, Myriad's BRCAAnalysis™ service was available through any physician. By allowing access to any individual who received a referral from any physician, Myriad ensured that the potential market for its service was quite large – it was available to anyone who could afford it. In Britain, BRCA testing services were provided on a regional basis through the state-run National Health Service (NHS). Its shape was reminiscent of other specialist services offered by NHS, involving both risk assessment and triage. Individuals interested in testing would first provide their family history of breast and ovarian cancer to a primary or secondary care physician in their region. Then, using a standard that had been developed in consultation with geneticists across the country, these physicians would classify individuals into low, moderate and high risk categories and offer services accordingly. Only individuals classified as high risk would be allowed to visit a regional genetics clinic and access both counseling and laboratory analysis of the BRCA genes [2].

Although approaches to providing genetic testing for breast cancer were quite different in the two countries, Myriad soon sought to expand its American testing service to Britain. The company argued that its pending US and European patent rights that covered both genes made it the only legitimate provider of BRCA testing services on either side of the Atlantic. British scientists, health care professionals and patients did not respond positively to Myriad's claim, and instead began to organize resistance to both the patenting of genes and the testing service itself.

In this paper, I describe Myriad's attempt to control the provision of BRCA testing in Britain through its patent rights as well as the British response in order to demonstrate how the BRCA gene patents operated not only technically and legally but politically as well. It begins by describing how Myriad attempted to expand its testing service to Britain. Then, it explores how British scientists, health care professionals and patients used the BRCA patents to organize themselves, question the patents' designations of authorship and inventorship, and assert national identity. Next, the paper describes the negotiations between Myriad and the NHS and the eventual resolution of Myriad's attempted technology transfer. Finally, the paper concludes with a discussion of the implications of this story for our understanding of current controversies over the patenting of biotechnology.

Myriad Tries to Transfer Its Technology

Expecting that the European Patent Office (EPO) would soon grant its patent applications covering both BRCA genes, Myriad turned its attention to the European market soon after it had established itself in the United States. Its first strategy was to market its BRCA testing regime directly to European health care professionals, emphasizing that it could provide them with an accurate laboratory service that would be widely available.

It invited representatives from the European Familial Breast Cancer Demonstration Project, an initiative designed to investigate methods of management of women at high risk for breast cancer, to tour its laboratories and facilities. It hoped to convince Project members, which included delegates from the United Kingdom, France, Italy, Germany, Norway and the Netherlands, that it could provide services that were more technically accurate than those that were already available in those countries. Myriad's BRCA testing services involved full sequencing of both BRCA genes, which was considered 99% sensitive, while most European services used a variety of methods that ranged in sensitivity from 80 to 95% [UK geneticist No. 1, personal interview, 1999]. Company officials argued that cooperation between Myriad and the European Project would allow for an expansion of the 'currently limited availability of breast cancer genetic testing in Europe', placing emphasis on the technical superiority of the DNA sequencing services that they could provide [3]. However, few European health care professionals seemed interested in using Myriad's ser-

vices. Most seemed to prefer to continue with their existing national systems of BRCA testing.

By the end of 1998, Myriad had focused its efforts on Britain and taken an aggressive approach, not only explaining the benefits of the testing services of the company but also threatening legal action on the grounds of patent infringement if British regional genetics clinics did not begin sending their samples to Myriad's US laboratories [UK genetics nurse No. 1, personal interview, 1999]. The Chief Executive Officer and lawyers of the company presented their case to a biennial meeting of the UK Cancer Family Study Group, which included medical geneticists, molecular geneticists, oncologists, genetic nurses and genetic counselors involved in providing services or conducting research in the area of inherited cancer risk. Myriad argued that by continuing to provide BRCA testing, the British NHS would be in violation of its European patents as soon as they were issued, just as US testing providers had been found in violation of Myriad's American patents. However, British health care professionals were unmoved either by Myriad's promise of a better testing service or its threats to file suit and shut down NHS BRCA testing services.

Myriad then tried another approach and directly contacted the UK Department of Health (DoH), which was in charge of NHS services. It demanded that the UK DoH pay a licensing fee to continue testing or that samples be sent to Myriad's US laboratories, or it would risk suits for patent infringement [DoH official No. 1, personal interview, 1999]. Meanwhile, the company also explored other options; for example, it contacted private laboratories in Britain to see if they were willing to serve as satellite laboratories that would send mutation information back to Myriad's BRCA gene databases in Salt Lake City. However, such arrangements were still unacceptable to many in the British genetics community because they felt it would damage their indigenous approaches to testing. As the company devised strategies to use its impending patent position to gain control of BRCA testing in Britain, resistance to the company began to build across the country.

Responding to Myriad

Myriad's concerted effort to use its BRCA gene patents to pressure the DoH led British scientists, patients, health care professionals and government officials to begin to organize targeted responses to the company. Most major scientific and professional organizations, such as the Brit-

ish Society of Human Genetics (BSHG) and the Clinical Molecular Genetics Society (CMGS), a branch of the BSHG devoted to molecular genetics, wrote position papers and official statements questioning the patentability of genes and predicting negative consequences for the ownership of human gene sequences. Wendy Watson, a patient activist who had been diagnosed with a BRCA gene mutation, gave interviews to the media expressing her concern over gene patenting and the commercialization of genetic testing and helped to mobilize opposition to Myriad among patient groups. Meanwhile, the UK DoH developed a consultation committee to help it in its discussions with the genetic testing company, which included, along with Watson, Rob Elles, chairperson of the CMGS, physicians, counselors and nurses from regional genetics clinics and NHS officials involved in purchasing regional services [DoH official No. 1, personal interview, 1999].

As we shall see below, Myriad's opponents not only tried to delegitimize the reliance of the firm on its patent position, but also used the BRCA gene patents of the company as a tool to ask larger questions about the ethical, scientific and public health consequences of patenting disease genes. They adopted two lines of attack. First, they argued that the patenting of genes was unethical and inappropriate. Second, they suggested that acceptance of gene patents such as Myriad's would be detrimental to the British scientific and medical communities, and also possibly violate NHS goals of equal access to health care.

The Legitimacy of Patent Rights

Questioning the Patentability of the BRCA Genes

In response to Myriad's assertion of its impending BRCA patent rights, the BSHG, which represents the human genetics community of the country, issued multiple press releases asserting that genes should not be patentable. It stated: 'A natural human gene sequence is part of the human body ... The suggestion that such a sequence might be patentable if it is "isolated in a pure form" or "isolated outside of the body" seems to us a sophistry, and should not be allowed' [4]. The BSHG also specifically suggested that Myriad's attempts at European expansion exemplified the dangers of patenting. 'If the sequence as such is patentable, it will not be possible for anyone at any time to devise a better or different way of genetic diagnosis; this is inequitable' [4]. The patenting of the BRCA genes, the organizations argued, would interfere

with downstream innovation – patents on disease genes might prevent scientists from doing research that might eventually lead to new drugs or other technologies.

Collective Inventorship

A number of British scientists, health care professionals and patients asserted that even if genes were inventions that could be patented and owned, it was impossible to assign sole inventorship to one party [5]. The discovery of the BRCA genes were the result of collective efforts, they argued, involving researchers, women and funding bodies in both Britain and the US. Many British researchers noted that if authorship of the BRCA genes could be claimed, they deserved some ownership because they, too, had contributed to the gene discoveries. Sir Walter Bodmer, one scientist involved in early research on the BRCA1 gene, said: 'Myriad is claiming it contributed far more than it actually achieved. As a result ... there is a lot of feeling of unfairness among British scientists' [6]. Other scientists simply argued that the BRCA gene discoveries were the result of a protracted collective effort, and the final mapping and sequencing was more a matter of luck than inventiveness. Andrew Read, chairman of the BSHG, explained that 'the whole area of gene patenting is controversial because it gives the prize to the person who put the last brick in the wall ...' [6]. Scientists frequently used this type of metaphor to explain their opposition to gene patenting, tapping into an age-old image of science as both disinterested and collective [7]. Oncologist Bruce Ponder noted: 'We are uneasy about the principle of patenting genes. Finding a gene is just the final step in a pyramid of knowledge and the question is whether it is justifiable for one company to own the patent ...' [8]. Many of these geneticists argued that because the genes were the result of considerable research done by multiple investigators across the world, the attribution of sole inventorship to Myriad simply did not make sense. Patient activists agreed. Wendy Watson noted: 'I do know that when it got to this stage, it was pure spade work, there was nothing inventive about it, it was pure spade work' [W. Watson, personal interview, 1999]. Of course, this outrage contrasted starkly with the silence of American geneticists and activists with regard to Myriad's claims to inventorship and rightful ownership of BRCA testing in the US.

Other geneticists pointed out that Myriad's claims to sole ownership were particularly offensive because most Britons (as well as most other Europeans and Americans) credited Mike Stratton, a geneticist at the Institute for Cancer Research in London, not Myriad, with finding the

BRCA2 gene. Establishing priority in the BRCA gene discoveries had been very controversial. The public excitement and potential scientific, medical and industrial rewards had led a number of scientists to search for both genes and many even referred to research to find the breast cancer genes as a 'race' [1]. Researchers throughout the world participated in this 'race', but Myriad was able to complete the mapping and sequencing of the BRCA1 gene first. However, the race continued as researchers looked for the BRCA2 gene, another major cause of hereditary breast and ovarian cancer. This time, however, the 'winner' was much more difficult to determine [9]. The day before Mike Stratton's group published the BRCA2 gene sequence in *Nature* magazine, Myriad announced that it had found the gene and submitted its sequence to GenBank, an international depository of gene sequence information. Both Myriad and Mike Stratton's group filed for US and European patents on the BRCA2 gene, each claiming that they had first mapped and sequenced the gene. (Both American and British groups were eventually awarded separate US patents covering different aspects of the BRCA2 gene, which led both groups to argue that they were legitimate in controlling ownership of both the gene and the test.) This BRCA2 controversy led many of the British scientists and health care professionals who were part of Britain's small cancer genetics community to feel personally aggrieved by Myriad's proposed expansion. One scientist said that she would rather continue testing and go to jail on the grounds of patent infringement than accept Myriad's patent claims over the breast cancer genes. 'At the end of the day, I hope I am locked up, because I'll make such a big deal about it. I mean they say they'll try and enforce this patent but I just hope the NHS doesn't just cave in and pay them money. The other thing is that my mate found BRCA2 at Sutton. So you can imagine how galling that is' [UK geneticist No. 1, personal interview, 1999].

Many questioned the ethics of forcing women to pay for tests that had been developed with their money (through charities) and blood. One geneticist expressed sadness at the prospect that women who helped to find the BRCA genes by donating blood samples might later have to pay Myriad to receive access to testing [UK geneticist No. 1, personal interview, 1999]. Unlike in the US, where both scientists, other testing providers and patient groups accepted that Myriad's patent rights gave it control over the provision of testing, scientists in Britain saw BRCA testing as the result of multiple contributions from a variety of sources and felt that Myriad had no right to claim sole ownership or control. Patient activists also

questioned the attribution of sole inventorship to Myriad. Wendy Watson noted: 'Nobody has the right to patent this kind of information, which was only found with the help of the many families who had suffered a case of hereditary cancer ... It is morally wrong that any company should benefit commercially from that kind of research' [10]. Watson also took this position further as she argued that it was not simply Myriad's money that contributed to finding the BRCA genes, but money from UK medical charities as well. 'It was charity money that was looking for the gene', she said, 'academic money, not private enterprise money that was looking for the gene' [W. Watson, personal interview, 1999]. Watson's argument was similar to those being concurrently made by the patient-led National Tay-Sachs and Allied Diseases Association in the United States, which had contributed both money and DNA samples to find the gene linked to Canavan's disease, only to find the gene patented and access to testing limited because of restrictive licensing practices [11].

Finally, some scientists argued more broadly that not only was the BRCA gene discovery itself the product of multiple inventors, but also that the process of actually finding the gene was identical to the way hundreds of other genes had been found. From their perspective, there was not even anything novel about the process of finding the BRCA genes as the process of gene discovery was a well-understood, widely used and fairly uniform process. Scientists engaged in the process of looking for any gene would have followed a process similar to Myriad's. The BSHG simply noted that 'the discovery of gene sequence has for some little time been a well understood process. There is nothing novel or inventive about this in principle, and as such new gene sequences should not be patentable, even where a straightforward utility, e.g., diagnostic testing, has been specified, unless there has been real progress towards the design of a specific commercial product' [12]. Myriad's attempt to exert its patent rights in Britain led British scientists, health care professionals and patients to make broad statements not only about the patentability of genes but also about how inventors and inventions should and should not be defined.

What explains this passionate opposition in Britain to the BRCA gene patents and the patenting of genes more generally? In the United States, assignment and acquisition of patent rights over the BRCA1 and BRCA2 genes to Myriad had not only clearly identified the company as an inventor of the isolated and purified genes but also helped justify Myriad's efforts to become the sole provider of BRCA testing and control how the testing system

would be built. While scientists, health care professionals and patients in the US had questioned the architecture of Myriad's testing system and the roles it prescribed for health care professionals and individuals, they largely did not challenge the assignment of inventorship of the BRCA genes to Myriad or the ownership that these patents represented [13, 14]. This lack of organized opposition within the scientific community might be better understood by considering the regulatory and industrial environment in the US; not only were linkages between the university and industrial sectors not uncommon, but technology transfer offices at American universities actively encouraged scientists to patent their inventions, and some scientists even left academia to start companies and commercialize their own research findings [15]. But patents, and the BRCA gene patents in particular, did not have the same meaning in Britain. In contrast to their American counterparts, European universities did not actively encourage their scientists to patent their work and had not had such a historically close relationship with the industrial sector. Moreover, very few European scientists left academia to 'start up' their own companies.

Consequences for Health Care

British critics also responded to Myriad's exertion of its patent rights by arguing that such tactics would negatively affect the authority of public health and scientific professionals as well as the health care received by patients. As they made this argument, they also articulated a British national identity that was tied to particular approaches to the provision of BRCA testing and genetic medicine more generally.

The Authority of the Health Care Professional

In particular, British health care professionals argued that Myriad's system might remove the gatekeeping power of health care professionals and possibly jeopardize the future of genetic medicine in Britain. The national BRCA testing system devised by the NHS provided genetics clinics with the authority to direct care while demonstrating to administrators that the NHS could provide genetics services for common diseases within the existing NHS culture. By relinquishing control to an outside group that claimed patent rights, health care professionals worried that Myriad would diminish their authority and encourage patients to circumvent the risk assessment and triage system and demand BRCA testing services that were un-

necessary. One molecular geneticist stated: 'We need to ... develop a system that gives equitable access to these services, but gives also some kind of gateway function. And the gateway can operate both ways, really, it can operate as a funnel into access to something, but it's also a controlling function. And I do think that if you had completely open access, it wouldn't be a good use of either public or private resources' [UK geneticist No. 5, personal interview, 1999]. Scientists and health care professionals argued that if such genetic testing services were provided on demand, costs would spiral out of control and NHS administrators would be less likely to fund genetic medicine services in the future.

Opponents also argued that acquiescing to the demands of gene patent holders could hurt the expertise of practitioners of genetic medicine in the NHS. In a detailed paper on 'Gene Patents and Clinical Molecular Genetic Testing in the UK' that was published in 1999, the CMGS, which was usually concerned with laboratory quality standards, predicted that allowing private concerns to provide genetic testing services would jeopardize clinical and laboratory expertise in the NHS. It stated: 'At best, UK centres would be deskilled to the level of subcontractors of Myriad Genetics for routine work ... A feature of Clinical Molecular Genetics in the last 10 years has been the rapidity of transferring research funding to tests of clear benefit to patients. Unless Regional Centres and the research groups with whom they collaborate are exposed to the problems of applying leading edge technologies to diagnostics, development will be increasingly confined to commercial companies' [16]. They argued that if the development of most genetic testing services began to take place outside the NHS, clinicians and laboratory researchers and technicians would become less competent in providing any services at all. This might eventually have dire consequences within the NHS. 'Removal of significant income streams, removal of key elements of the analytical process and exclusion from experience with developing technologies will impoverish Regional Genetics Centres and cause a stagnation and loss of morale that is hard to reverse'. It also predicted that both molecular and clinical geneticists were likely to be rapidly deskilled as they were prevented in engaging in their own laboratory analysis [16]. Not only might health care professionals and researchers leave to join a likely more lucrative career in private genetic medicine, but those personnel that stayed might not have the expertise, infrastructure or funding to provide many services at all.

Access and Equity

British critics also worried that succumbing to Myriad's patent claims would set a precedent that would interfere with the British commitment to provide all individuals equal access to health care. Some argued that if genetic testing became available on demand like Myriad's services were, it would be provided in an uneven manner across the country. The CMGS report stated that such a demand-based system could have very damaging consequences for the overall NHS. 'On the one hand it threatens ... spiralling costs and on the other hand geographic inequalities of access to diagnosis' [16]. Access would be based on initiative and financial opportunity, they worried, rather than demonstrated need.

Many health care professionals also felt that paying private companies for tests (or even licenses to be able to continue to test themselves) would devastate the NHS's mission to provide individuals with the health care that they needed by drastically limiting the number of individuals who could be tested. If the NHS had to pay a company (Myriad charged approximately USD 2,500 for testing the full sequences of both BRCA genes) within its limited and relatively stable budget, it would be able to offer genetic testing to far fewer individuals than the current system allowed. One oncologist noted that 'in a way I'd rather offer a 70% service to the whole of the UK rather than a 100% service to a tenth of the country' [8]. One geneticist stated that Myriad's test was simply too expensive to fulfill the NHS's commitment to effectively allocate resources to maintain the health of the public. 'Because we've got a month's delay to send the DNA abroad, we are paying [Myriad far more than the test costs], and the whole principle of the NHS is that it should be cost-neutral' [UK oncologist No. 1, personal interview, 1999]. Rationing schemes would have to become more strict, and many individuals with extensive family histories of breast and/or ovarian cancer might not qualify for BRCA testing services. Wendy Watson questioned: 'Will genetic testing become more rationed than it should be because of the extra expense? If that happens, I shall fight it. That's where I am coming from. I'm not particularly bothered if somebody's patented a part of my gene or whatever. That's not the issue. The issue is that it might reduce the number of people who are able to have genetic testing, who may well die because they haven't had genetic testing. And that is wrong' [W. Watson, personal interview, 1998]. While this statement seems to contradict Watson's strong opposition to gene patenting quoted earlier in this paper, it actually points us to the main concern of Myriad's critics. Scientists, health care profession-

als and even Watson were less concerned with the patenting of genes themselves than with the implications that such a practice would have on the British approach to providing health care.

As these critics articulated their opposition to Myriad's testing system, they also reinforced their commitment to specific public health goals. Rather than providing health care on demand, they felt that it should be allocated as needed, with care being determined by health care professionals. In addition, they also advocated the provision of genetic testing services that combined laboratory analysis and specialized counseling, rather than technologies based solely on DNA sequencing. They emphasized that the NHS was responsible for both present and future public health, maintaining the health of the current population while ensuring the expertise of researchers and health care professionals to benefit generations to come.

Resolution

The UK DoH, British scientists, health care professionals and patient advocates negotiated with Myriad for over a year, trying to reach an agreement that would be acceptable to all parties involved. However, by late 1999, it had become clear that opposition to Myriad was nationwide – neither British health care professionals nor patients would be likely to welcome the company. Some health care professionals even threatened to bring Myriad to court if the company tried to enforce its patents. In addition, there were indications that Mike Stratton might sue Myriad for illegally acquiring a license to his patent.

Still, Myriad remained persistent. It negotiated with private laboratories to offer BRCA testing to the UK population, and in March 2000, the company announced that it had issued a license to Rosgen Ltd., an Edinburgh-based private genetics laboratory, which would provide BRCA testing on a fee-for-service basis [17]. Patients with private health insurance or who could afford to pay out of pocket could utilize the faster and arguably more technically sensitive services of Rosgen/Myriad. However, at the time, this agreement did not affect Myriad's ongoing negotiations with the NHS.

Rosgen's testing system did not preclude individuals from using the NHS system. Moreover, the Rosgen system required individuals to undergo genetic counseling. Dr. Pete Kitchin, Managing Director of Rosgen, noted: 'Our aim is to ensure that such NHS patients [who used Rosgen's BRCA testing services] in the UK are able to

gain the widest possible access to the best possible testing. However, we must stress that Rosgen will offer the test only if appropriate pre-test and post-test counseling services are in place' [18]. Although Rosgen planned to follow Myriad's example and widely offer BRCA testing, it seemed to accept the British approach to counseling.

Despite Rosgen's counseling requirement, many British health care professionals were still reluctant to use its laboratory service, choosing instead to continue to use the NHS BRCA testing system. For example, when Rosgen sent letters to General Practitioners across Britain announcing its service in June 2000, the staff of one of the regional genetics clinics issued a vehement response: 'Much of the original work in mapping the genes for BRCA1 and BRCA2 was done on families in the South West London and Surrey area as part of the charitably funded work by the Cancer Research Campaign at the Institute of Cancer Research and The Royal Marsden Hospital. This work was put in the public domain and Myriad Genetics has claimed a patent for BRCA2 on the basis of sequencing the remainder of the gene. It seems ironic therefore that relatives of these individuals who gave samples to improve medical science for all should potentially have testing prejudiced by this commercial interest' [19]. The clinic was reluctant to use Myriad's system because it seemed to doubly exploit those who had given blood samples used in isolating the gene.

Finally, in November 2000, Myriad and Rosgen reached an agreement with the UK DoH. The settlement allowed the NHS to continue testing without paying royalties or licensing fees to Myriad. In what was hailed as an 'unprecedented deal', Myriad and Rosgen agreed to waive royalties on all breast cancer genetic tests that had or would be provided by the NHS while Rosgen agreed to provide the NHS with data about the mutations it collected in order to improve the NHS's clinical services. Rosgen would continue to provide testing privately in the UK to those individuals who could afford the GBP 179–2,600 fee (depending on which test was performed).

However, the fate of the deal was threatened in January 2001 when Rosgen filed for voluntary liquidation for reasons unrelated to its agreement with the NHS. Rosgen's collapse meant that Myriad no longer had a presence in Britain, because its deal with the NHS had been based on its license with Rosgen. Myriad could choose to renegotiate, but it had not done so as of spring 2005.

It is unlikely that Myriad will again try to transfer its testing service to Britain. While the company has successfully expanded its testing service in South America and Asia, efforts to expand its system to the rest of Europe

have led to resistance very similar to what it faced in Britain [20]. In fact, a diverse group of European geneticists, health care professionals, patient advocates and national governments challenged the legitimacy of Myriad's patents at the EPO which were granted in 2001, after the Myriad/Rosgen/NHS deal had been struck. In early 2005, the EPO considerably narrowed the scope of Myriad's BRCA1 patents [21]. These revised parameters will no longer allow Myriad to broadly claim ownership over the BRCA1 gene in Europe, which will surely affect the plans of the company for international expansion.

Conclusion

This paper demonstrates how the BRCA gene patents were used as political technologies by Myriad and British scientists, health care professionals and patients. They were used as tools to assert control over BRCA testing as well as mobilize opposition to the expansion of Myriad's BRCA testing service and the patentability of genes in general. They also provided an opportunity for British critics to assert their national identity in terms of their approach to health care, as they argued that British genetic testing services needed to be available within the context of clinical care and to all citizens equally.

The use of patents as political technologies is increasing, as the biotechnology and pharmaceutical industries have grown and extended their international reach and anti-globalization movements have emerged. In Europe, where a patent granted by the EPO is subject to challenge by any party within 9 months of its issue, patents over genes and novel biotechnological products such as stem cells have not only been challenged as part of transnational battles over globalization and the future of public health, but inspired the formation of specially dedicated advocacy groups. For example, the German group *Kein Patent auf Leben* (No Patents on Life) was formed in 1992 to fight patenting of a genetically altered mouse and has been active in fighting the patenting of biotechnological inventions ever since. Meanwhile, as noted above, opposition to the BRCA patents in Britain has grown into Europe-wide resistance to the patenting of the BRCA genes and gene patenting in general. Untraditional activists such as scientists and health care professionals, who already occupy influential positions in their respective countries, have organized transnational networks to fight Myriad through national governments and the EU Parliament, as well as at the EPO. Now, more than ever, biotechnology patents have become political technologies to assert control, inspire mobilization, focus resistance and articulate identity.

References

- 1 Davies K, White M: Breakthrough: The Race to Find the Breast Cancer Gene. New York, Wiley, 1995.
- ▶ 2 Parthasarathy S: Architectures of genetic medicine: comparing genetic testing for breast cancer in the USA and UK. *Soc Stud Sci* 2005;35: 5-40.
- 3 Myriad Genetics, Inc: Myriad Genetics hosting conference of European experts on breast cancer genetic testing. Salt Lake City, press release, 1998.
- 4 British Society for Human Genetics: BSHG statement on patenting and clinical genetics. 1998. <http://www.bham.ac.uk/BSHG/patent2.htm>.
- 5 Meek J: Money and the meaning of life; business and science in race to crack the genetic code. *The Guardian*, January 17, 2000.
- 6 Ross E: Scientists object to gene patent. *Associated Press*, January 18, 2000.
- ▶ 7 Mulkay MJ: Norms and ideology in science. *Soc Sci Inf* 1976;15:637-656.
- 8 Connor S: Concern over cancer gene patent. *The Independent*, September 15, 1994.
- 9 Dalpé R, Bouchard L, Houle A, Bédard L: Watching the race to find the breast cancer genes. *Sci Technol Human Values* 2003;28: 187-216.
- 10 Dobson R: Women fight patent on cancer test. *The Sunday Times*, April 20, 1997.
- 11 Merz JF: Are there limits on what may be patented? In Magnus D, Caplan A, McGee G (eds): *Who Owns Life?* New York, Prometheus, 2002.
- 12 British Society for Human Genetics: Patenting of human gene sequences and the EU Draft Directive. 1997.
- 13 Lewin T: Move to patent gene is called obstacle to research. *The New York Times*, May 21, 1996, A14.
- 14 National Breast Cancer Coalition: Gene patenting: yes or no? Call to action! *The Quarterly Newsletter of the National Breast Cancer Coalition and the National Breast Cancer Coalition Fund*, Fall/Winter 1997.
- 15 Kenney M: *Biotechnology and the Creation of a New Economic Space. Private Science: Biotechnology and the Rise of the Molecular Sciences.* Philadelphia, University of Pennsylvania Press, 1998.
- 16 Clinical Molecular Genetics Society: Gene patents and clinical molecular genetic testing in the UK. Report 1999.
- 17 Myriad Genetics: Myriad Genetics launches genetic testing in the United Kingdom and Ireland. Press release, March 2000.
- 18 Rosgen Ltd: UK company announces licensing agreement for breast cancer genetic testing. Press release, March 2000.
- 19 Southwest Thames Regional Genetics Service: Stop press: Myriad Genetics attempt to monopolize breast cancer testing. 2000. <http://www.genetics-swt.org/oldnews.htm>.
- ▶ 20 Matthijs G, Halley D: European-wide opposition against the breast cancer gene patents. *Eur J Hum Genet* 2002;10:783-785.
- 21 Institut Curie: Breast and ovarian cancer susceptibility gene BRCA: another victory for opponents of patents held by Myriad Genetics: European Patent Office rejects the essential points of BRCA1 gene patents. Press release, January 2005.