MYRIAD GENETICS: In the Eye of the Policy Storm

Myriad Genetics, a small Utah-based biotechnology company, walked into a policy storm in 1996 when it launched a new genetic test to identify women at high risk of breast and ovarian cancer. What ensued was a series of strategic errors, institutional dysfunction and a breakdown of trust and communication. The result was one of the first genetic tests put to market becoming a cause celebre for critics of Old IP and its misuse of patents and other intellectual property rights.

The Ingredients of a Perfect Storm

In the late 1990s, after a controversial race to chart the human genome, Myriad obtained patents for two genes linked to breast and ovarian cancer as well as for tests used to identify those genes. Armed with these patents, Myriad introduced the test in the US in 1996 and in much of the rest of the world around 2000. Controversy quickly ensued:

1. Other research teams suggested there was something suspicious about Myriad patenting one of the genes the day before another team published its results in the preeminent science journal, Nature.

2. Many scientists, ethicists and religious groups opposed the idea of patenting human genes as they considered these to be non-patentable discoveries as opposed to a person's invention.

3. After Myriad threatened, in 1998, to sue a UPenn laboratory for patent infringement, clinical researchers feared that the company would also seek to shut down their ongoing research into the two genes.

4. Those who managed public health care systems in Canada and Europe were afraid that Myriad had too much influence over how the new test was to be administered and that this would set a very poor precedent for the proliferation of genetic tests expected in the 2000s.

5. Physicians and ethicists were worried that Myriad was aggressively pushing the public, in part through TV ads, to take its tests without considering potential psychological implications of the tests.

Today, mere mention of the name Myriad elicits strong negative reactions among many scientists, policy-makers and ethicists. The impact of this has been missed research collaborations, the failure to share knowledge and lack of trust towards any company proposing a genetic test.

Anatomy of Old IP Gone Wrong

The International Expert Group on Biotechnology, Innovation and Intellectual Property dug beneath the surface of the controversy to uncover the motivations and actions of not only Myriad, but of governments, researchers, physicians and patients. It conducted the most extensive research of the Myriad story to date: a search of Myriad's patents worldwide; an analysis of academic, policy and business articles on Myriad; a review of previously unpublished documents and letters; interviews with key players; and, most notably, a workshop during which the principal actors in the controversy – including Myriad itself – discussed what they did and why they did it.

In view of all human gene patents, the question arises as to why Myriad attracted so much attention – including a mention in Michael Crichton's thriller, Next. A primary explanation is that Myriad employed an old model of how to license its patents. It employed what can be called Fortress IP – a model that is increasingly ill-adapted to the needs of biomedicine today.

Findings

Contrary to popular accounts, the Myriad controversy cannot be explained simply in terms of cavalier actions on the part of the company. Instead, an account of the story must also include the missed opportunities that arose from key stakeholders failing to display trust and a proper understanding of interests. This was exacerbated by fundamental failure on the part of government institutions to effectively respond to the situation. Together, these missteps impeded the successful introduction of a potentially life-saving technology. In particular, the International Expert Group on Biotechnology, Innovation and Intellectual Property discovered the following:

1. Myriad appears to have proceeded on a sincere but misguided belief that simply holding patent rights would allow it to determine how the genetic test should be used. This led it to take aggressive action against Canadian provincial governments when they refused to comply with its terms for providing the test. Myriad even went so far as to surprise the Minister of Health in Ontario with letters threatening trade sanctions written by the US ambassador to Canada and a US Senator. As a result of this approach, Myriad lost the Canadian and European market.

2. Contrary to popular belief, Myriad had an open attitude to research. It was willing – and said so to the press and in agreement with the National Cancer Institute in the US – to allow researchers conducting their own research to either use the genes without permission and without payment or to have Myriad do so at a deeply discounted rate. Myriad only threatened to sue those such as UPenn who provided the test as an outside service, and not those who were using it as part of their own research. Nevertheless, Myriad failed to disseminate this policy, leaving many researchers with the fear that Myriad might sue them.

3. Myriad did not understand the needs of public health care systems. Not only did its senior management make negative comments about public health care systems, but the company failed to try to understand the needs of government to both limit total health expenditures and to make services available to the largest population possible.

4. Government institutions, such as patent offices, departments of industry and departments of health, failed to promptly and efficiently address the concerns raised by the introduction of a patented genetic test. These institutions could not overcome the limitations of their mandates to find a solution that was acceptable to all.

5. While physicians and ethicists criticized Myriad's direct-to-consumer advertising, the company actually targeted only high risk women, according to a study by Kaiser Permanente, a large health provider in the US. Further, the advertising was only a test and revealed a lack of trained physicians and genetic counselors. It did not push, the study found, women at low risk to take the test as has sometimes been claimed.

Recommendations

1. Decision-makers in government and industry as well as the public at large need to better understand the social context in which innovation occurs and in which inventions are introduced. Rather than demonizing or sanctifying intellectual property, the media must take on the task of educating the public about the longer-term policy implications of scientific research, particularly on the health care sector and the role for intellectual property. More training needs to be given to senior policy-makers on intellectual property and industry needs to better understand the needs of public health care systems. Independent organisations are best placed to provide this training.

2. Too often, institutional constraints within government cause, rather than resolve, problems of a cross-cutting nature. Governments need to work better at removing blinders from individual departments so that government policy-makers take a broader, whole-of-government approach to decision-making. Better communication between departments would assist in this.

3. Underlying both poor communication and institutional failures is a lack of trust among industry, government and researchers and within these communities. In order to regain trust, industry, government and researchers must work through independent brokers who can assist in resolving disputes, in structuring licences and in building relationships to allow for efficient use of intellectual property.

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For further information please contact:

The Innovation Partnership
3800A St-Hubert, Montreal, Quebec H2L 4A5 Canada
www.theinnovationpartnership.org

Centre for Intellectual Property Policy
Faculty of Law - McGill University
3644 Peel Street, Montreal, Quebec H3A 1W9 Canada
www.cipp.mcgill.ca