Genetic technologies, health care policy and the patent bargain


The idea of granting patents on human genetic material continues to cause controversy. The debate is largely focussed on the moral acceptability of human gene patents, the impact of gene patents on the research environment and the value of patents to stimulate innovation and the commercialization and dissemination of genetic discoveries. As highlighted by a recent controversy in Canada, patents can also have a profound effect on health policy and access to genetic services. Creative and bold patent reform initiatives are necessary to ensure that society will, to the highest degree possible, reap the health care benefits of the genetic revolution.

Since the inception of the Human Genome Project, the idea of granting patents on human genetic material has caused controversy. To date, much of the debate has focussed on the moral acceptability of human gene patents (1–3), the impact of gene patents on the research agenda and the research environment (4, 5) and the value of patents to stimulate innovation and the commercialization and dissemination of genetic discoveries (6).

However, as highlighted by a recent controversy in Canada, patents can also have a profound effect on health policy and access to genetic services. In the summer of 2001, Myriad Genetics decided to take steps to enforce their patents over the BRCA1/2 genes. Provincial agencies throughout Canada received a letter stating that all genetic testing that utilizes the BRCA1/2 genes must now be done through Myriad’s laboratories. Because of the cost associated with doing the tests out of country, more than $3800 CND, a number of Canadian provinces have gone so far as to formally state that they will either ignore or fight the patent (7). Across Europe, Myriad’s actions to enforce a related patent have elicited a similar response (8).

But is Myriad really to blame? Isn’t Myriad using its patent rights in a completely legal and logical fashion – to fully commercialize one of its products? In a world where gene patenting is viewed by a variety of stakeholders as an important part of the innovation process and is encouraged by governments and universities alike, this scenario illustrates the importance of understanding and creating strategies to address the long-term health policy implications of the thousands of patents that have been issued or remain pending on human genes. In this brief article we discuss the issues that flow from the conflict between gene patents and health policy. The paper is not meant to be a comprehensive analysis of all the ethical, legal and social issues associated with gene patents or the patent system.
Impact

By granting a limited term monopoly over an ‘invention’, patents are meant to encourage innovation and the rapid dissemination of new technologies. Although the economic data are ambiguous (9–11), conventional wisdom maintains that this monopoly is required to ensure the growth and commercialization of useful technologies. Naturally, this monopoly gives the patent holder a great deal of power to control how the new technology will be used, the price to be charged and, to some degree, who will provide the service. In exchange for this monopoly, the invention is fully disclosed to the public. This is one of the trade-offs that is built into the patent system.

The downside of this loss of state control is most readily apparent in countries, such as Canada, that have a publicly funded health care system where global budgets may not be able to accommodate the demanded monopoly price. In such situations, the patent may result in a loss of public access to a necessary health care service. This can happen because either the administrators of the public system decide that they will not pay for the patented test or the patent holder simply refuses to allow access. Currently, unless there are formal price control schemes in place, patent holders are well within their rights to charge whatever they deem appropriate. In fact, one could argue that one of the justifications for the patent system is to give patent holders the ability to charge a premium price, without the threat of competition, in order to reward the innovation process and allow a recouping of research expenses.

Interestingly, recent survey research done in Canada found that few of those surveyed had ‘moral or religious objections’ to the patenting of human genes and a majority (63%) saw more benefits than risks associated with the patenting process (12). However, in focus groups, it was found that there were major concerns based on issues of access and equity. In the context of health care, at least in Canada, access seems to be the dominant public consideration.

Limited term monopolies are associated with several other health policy concerns, including a possible loss of quality control and the erosion of service delivery efficiency. For example, a laboratory that has developed a cheaper, more efficient way of delivering a given genetic service may be prohibited from doing so by the patent holder. Additionally, if overbroad patents are granted, the effect can be that further research in the field is blocked (13, 14).

Harmonizing health care and innovation policy

The great irony of the Myriad controversy is that the patentee is doing precisely that which is encouraged by governments around the world. Both publicly and privately funded researchers are under increasing pressure to secure patent rights over their genetic ‘inventions’. Indeed, in the university setting, the number of patents a researcher holds is often one of the factors considered in the academic promotion process. The hope, of course, is that some of these patents will lead to a commercialized product and thus facilitate the growth of the biotechnology sector for a given region.

From a health policy perspective, governments throughout the world are concerned with the containment of the health care budgets. The introduction of new, and often expensive, health care procedures and technologies has been identified as an important factor in the rise of health care costs (15). Although genetic technologies may one day help to reduce health care expenditures by facilitating effective preventative health care strategies, at the current time genetic tests are largely viewed as another added expense (7). As such, it is understandable that governments would seek to find the least expensive alternative.

So, can governments have it both ways? Can they have policies that are designed to promote the patenting process and, at the same time, actively fight the logical implications of those same patents? We suggest that a more realistic balance must be struck between innovation policy and long-term health care policy. We need to develop strategies that allow governments to both reap the benefits of the intellectual property system and maintain a degree of control over how the new technologies are used.

Possible responses

There are several ways the issues associated with gene patents could be addressed. The most radical policy move would be to ban all human gene patents. In fact, this was recently recommended by the Canadian House of Commons Standing Committee on Health (16). However, the momentum of the biotech industry, the long history of patentability of gene sequences and the impact and complexity of existing international trade agreements make this, at present, an impractical and unrealistic option. In addition, there are economic and ethical arguments for retaining patents in this context (17).

Another approach would be to address the problems associated with the gene patents on a case-by-case basis. That is, we could wait for court de-
decisions to refine and clarify the existing patent criteria. But because patent jurisprudence will always lag behind the application of the science, such an approach is destined to fail as a means of producing timely patent reform. A case-by-case approach could never supply a comprehensive, and forward-looking, patent policy. Existing patent law has no means of incorporating health policy considerations into decisions about the appropriateness, scope or possible infringement of a given patent, the three usual subjects of patent litigation. Thus, patent litigation can provide important refinements to the current system, but it seems unlikely to provide the broad-based policy reform needed.

A more promising policy option would be to develop a system that allows governments to override the patent holder’s complete control over price and access. For instance, we could modify patent law such that the price to be charged for a given genetic service will be determined by an independent entity and a ‘reasonable’ fee would be guaranteed to flow to the patent holder. Such an approach provides policy makers with an explicit tool to balance the goal of stimulating innovation and controlling the impact of patents on health care policy. Patent holders would still retain a right to profit and a limited monopoly control over the ‘genetic invention’ but the government could ensure that the needed genetic service was accessible within the health care system at a reasonable price. Although untested, it is arguable that such a licensing scheme would be permissible under existing international agreements. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) allows compulsory licensing under certain circumstances. Although this agreement was not aimed at the issues associated with gene patents, it is an important recognition by TRIPS Agreement members that policy concerns may override economic and trade-related interests. Indeed, a recent Ministerial Declaration on the Trips Agreement and Public Health states unequivocally that:

“We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all” (18).

It could be argued that such an approach has the potential to introduce market uncertainty and, thus, remove a portion of the financial reward that allows patents to work as an incentive for innovation. This is a valid concern. However, as highlighted by the Myriad controversy, without some form of policy compromise, public access may be inappropriately compromised. In addition, it should not be forgotten that more radical options have been proposed – such as the outright ban on gene patents recommended by the Standing Committee on Health. In many respects, our more nuanced approach can be viewed as a fair compromise between two increasingly polarized positions.

Conclusion

We recognize that any reform to the patent system that could be viewed as weakening the economic value of patents will be met with a degree of resistance from both industry and those within government seeking to promote the innovation agenda. We also recognize that there are numerous valid and conflicting social values at play in this context that will make patent reform a tremendously challenging endeavour. Nevertheless, as more and more gene-related technologies move from the laboratory into clinical use, the relevance of gene patents to health care policy seems likely to increase substantially. Indeed, emerging technologies such as multiplex testing and pharmacogenetics have the potential to involve dozens, if not hundreds, of different gene patents at each clinical application (19, 20). Creative and bold patent reform initiatives are necessary to ensure that society can reap the health care benefits of the genetic revolution.

Acknowledgements

We would like to acknowledge Genome Prairie, Genome Québec, the Social Sciences and Humanities Research Council, the Stem Cell Network and FCAR as sources of funding that contributed to this work.

References

7. Benzie R. Ontario to defy U.S. patents on cancer genes: province will pay for $800 test, not $3,850 version by Myr-
Caulfield et al.
