Biotechnology patents: strategies for meeting economic and ethical concerns

With new challenges to Myriad Genetics's patents on *BRCA1* in Europe and in Canada and the effort made by the National Institutes of Health to gain access to patented stem-cell lines in the US, the long anticipated clash between biotechnology patents and social and ethical concerns has materialized[1–5].

It is therefore worthwhile and timely to consider the tools that patent law offers to address some of the ethical and social issues arising from biotechnology patenting. Although not all ethical and social concerns can be addressed within patent regimes, patent law can have an important role in addressing some of them.

One of the more obvious ways to address concerns relating to the overabundance of patents in the biotechnology field is to make patents more difficult to obtain. Patent offices can achieve this by toughening the patent standards of novelty, non-obviousness and industrial application (or utility)[6].

Unfortunately, the development of patent standards takes time. It is only with the accumulation of experience that patent offices and courts can adapt existing law to reflect the realities of biotechnology. Given the ever-changing nature of biotechnology, by the time courts and patent offices have adapted their standards to a particular technology, that technology has often become outdated. Moreover, patent offices will continue to issue what are later determined to be bad patents, costing in the range of $1 million to attack, once the standards have been established.

A second tool to address ethical and social concerns is the determination of the size or scope of a patent[7]. Essentially, a patent provides its holder the ability to prevent all others from making, using or selling the invention. Which activities constitute making, using, importing or selling the invention is thus important to establish.

Including too much activity within the patent scope risks undermining future research, for two reasons. First, if there are too many overlapping patents, it simply becomes too expensive to buy licenses to carry out further research[8]. Second, broad patents render more acute problems related to patient access to technology because the patent holder can dictate not only license terms, but also who has access to a gene and for what purposes. As there are no substitutes for a particular person's genes, this is an important consideration. In fact, it is one of the fundamental concerns raised in Europe and in Canada against the Myriad Genetics patents over *BRCA1*. Legislatures ought therefore to consider establishing laws that distinguish between the physical DNA molecule and the informational content of those molecules. Patent holders perhaps ought not be able to prevent individuals from having a laboratory reproduce or use one's DNA sequence so as to determine whether he or she faces an increased risk of disease.

A third tool is the use of an 'ordre public' or morality clause. Most nations (but not the US or Canada) include such a clause in their patent regimes, permitting them to withhold patents over inventions where commercialization would violate shared fundamental norms[9]. For example, the European Community considers certain processes to contravene these norms[9]: cloning human beings, modifying human germ lines, using human embryos for commercial purposes and altering the genetic identity of animals so as to cause suffering without a substantial medical benefit to humans.

An ordre public or morality clause could be fashioned to address a wide range of ethical and social issues connected to the commercialization of biotechnological inventions. To do so would require not only legislation but also the establishment of an administrative body, to apply the clause in a fair and consistent manner. This body would need to be separate from the patent office and have flexible powers to suspend the operation of a patent where the commercialization of the invention presents ethical problems.

A fourth tool to consider is the establishment of a collective society to administer certain biotechnology patents, such as those over DNA sequences. These societies would be similar in form and function to those organizations that currently provide radio stations with the right to play music on-air. Researchers and others would pay a fee to the society, in an amount that depends on the nature of the use they wish to make, for the right to use the invention. These societies could be created by either the private or public sector.

Biotechnology patents are here to stay. This does not mean, however, that the application of patent law to biotechnology inventions will remain static. As social and ethical issues rise in importance, courts and legislatures will be forced to grapple with balancing the commercial needs of industry with the social and ethical costs of patents in biological materials. The good news is that there are tools available, both within patent law and external to it, that permit us to reduce the negative social and ethical impact of patents while preserving their benefits. The only question that remains is whether we will use them.

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