

# Time to Revoke Invalid Gene Patents?

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Gene patenting is big business, with nearly 20% of all our genes explicitly patented in the United States (and a similar proportion in the EU) (1). This should not be worrying except that gene patents detrimentally affect healthcare, allowing companies such as Myriad Genetics to charge large royalties on any diagnostic tests that screen their patented genes (2). Faults in two of Myriad Genetics' patented genes increase the risk of breast cancer (and occur in about 5% of the population), and these royalties made the tests too expensive to be offered to everyone. It then transpired that these two patents were invalid and had to be revoked in 2004 by the European Patent Office.

So what makes a gene patent valid? According to the UK Patents Act 1977, an invention qualifies for a patent (giving 20 years of exclusive ownership rights) if "a) the invention is new, b) involves an inventive step, c) it is capable of industrial application" (3). Some would argue that genes are a natural product and therefore cannot qualify for patents. However, genes become an invention once they have been extracted, isolated and sequenced, and after their biological function has been determined or suggested (4).

There has been some concern that many gene patents may be invalid. In 2005, a study published in *Science* found that 38% of US gene patents studied did not comply with legal requirements (5). The main problem it seemed was that patents were too broad, claiming rights to much more than had been 'invented'. Another common problem is that modern genetic analysis techniques allow the automation

of research. Computers can search a gene for similarities with the sequences of known proteins or enzymes, which once found can indicate a correspondence in structure or function (homology), allowing a computerised guess at the gene's function (6). The resulting patent applications based on the computerised guess can be dismissed by patent examiners as lacking the necessary 'inventive step', but efforts must also be made to revoke patents previously granted on these grounds.

It is important for invalid patents to be revoked because the opportunity to impose fees on any commercial use of a patented gene has been unjustly exploited by owners of some invalid patents, to the detriment of medical research. In 2000, Human Genome Sciences, a US company, was granted a patent on a gene whose product helps the AIDS virus enter cells (7). However, when they filed for a patent in 1995, they could only roughly predict the gene's function using a computer program (taking away the inventive step). The vital research showing the connection with AIDS was done subsequently by other scientists. Since the patent has not been revoked, Human Genome Sciences are still profiting from this and can charge royalties for any research that use this gene to look for potential HIV drugs. In this way, an invalid patent has created a strong disincentive both for research into gene function after a patent has been filed, and for research into treatments based on patented genes.

Whilst valid patents can have similar negative effects on healthcare and research, they can also be justified as making genetic research commercially viable and by enabling future advances in healthcare by putting genetic information in the public domain; without patents, companies are secretive until they can recoup costs. Invalid patents, however, cannot be tolerated as they are exploiting the system and, through broad and imprecise claims, they allow patent holders to profit from other scientists' research. There need to be more cases like Myriad Genetics, so that healthcare and research are not restricted and harmed by unjustified profit-making. Gene patenting may be big business, but it is time it was better policed.

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