Gene patenting: what is implied for the future of R&D?

'It is vital for a patent system to maintain a balance between encouraging innovation and stifling research.'

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The announcement, in June 2000, that the international Human Genome Project and the private venture Celera Genomics (Rockville, MD, USA) had both completed a 'working draft' of the human genome has been hailed as confirming the start of a new era of genetic and molecular medicine. This remarkable achievement, years ahead of schedule, promises to accelerate the development of new methods of preventing, diagnosing, treating and curing diseases.

Turning genetic knowledge into useful and beneficial products does not come cheaply, however. Generally, the costs of developing a new drug and proving that it is safe and efficacious run into hundreds of millions of dollars, and no commercial entity is likely to invest such quantities of money to develop a product if it could be immediately and freely copied by someone else. It is therefore necessary to guarantee a period of exclusivity to the innovator to allow them to obtain a reasonable return on their investment and reward them for their ingenuity. Essentially, this is the objective of the patent system.

Is the gene patent debate over?

The Human Genome Organization has stated that it does not oppose the patenting of useful benefits derived from genetic information; however, it does oppose the patenting of genomic sequences with no known function. In 1998, the European Biotechnology Directive was passed, which confirmed that gene-based inventions could be patented in the EU provided the criteria of novelty, inventiveness and industrial applicability were met. In a joint announcement in March 2000, Bill Clinton and Tony Blair also endorsed the need to provide intellectual property protection for gene-based inventions.

Approximately 6,000 US patents have already been granted for full-length genes (>1,000 of these are directed specifically to human genes and genetic variations) and >20,000 patent applications relating to genes are currently pending in the USA. Similar numbers of genetic patents have been applied for at the European Patent Office (Munich, Germany). One might therefore be forgiven for thinking that the debate surrounding gene patenting was, to all intents and purposes, over.

The debate continues, however, at least in Europe. The Council of Europe's Parliamentary Assembly (a body of parliamentarians from Europe) in Summer 2000 called for a rethink of the ethical issues surrounding the patenting of genes. An influential and internationally respected UK organization, the Nuffield Council on Bioethics, is currently holding a series of round-table meetings to consider the ethics of patenting DNA and proteins. The validity of the Biotechnology Directive is being challenged by The Netherlands and Italy, and the Directive has still not been implemented in several other EU countries. Finally, confidence in the patent system was not helped when The European Patent Office announced in 2000 that it had granted, in error, a patent for animal transgenic stem cells that did not specifically exclude human beings from its claims.

A balance must be maintained

It is, of course, vital for the patent system to maintain a balance between encouraging innovation and stifling research, and also to recognize that certain inventions should not be patented on ethical grounds. However, this was precisely the objective of the European Biotechnology Directive, which, among other things, prevents the patenting of: (1) genes in their natural state, (2) DNA and genes having no known function or use, (3) the human being and (4) any element of the human body. In addition, the US Patent Office has stated that human beings cannot be patented and is implementing new rules to ensure that US patents will not be granted for DNA or genes with no identifiable 'real world' use.

Maintaining wide access by scientists to the huge amount of information generated by genome sequencing

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efforts is essential to harvest the fruits of the Human Genome Project. However, the possibility of obtaining gene patents, if anything, should help, rather than hinder, such access. If gene patents did not exist, then companies and commercially minded academics might be less willing to publish their sequences because they would lose their commercial value after secrecy was lost. It has also been argued that academic research will be inhibited on genes that have been patented. However, most academic researchers would find it difficult to point to one instance where a patent was used to prevent them doing their work for non-commercial purposes.

Unfortunately, much of the debate regarding gene patenting has been clouded by issues that, although important, are more appropriately debated in another context. A patent gives its owner the right to prevent use of the patented invention by others, but it does not constitute approval for the patent owner to use the invention. Thus, the patent owner must still comply with regulations concerning, for example, the protection of human and animal health and welfare. Patents are even less relevant to the debates over genetically modified foods and the use of genetic testing by employers and the insurance industry. Whether or not patents existed, these issues would still need to be resolved by legislation outside the ambit of patent law.

Despite challenges ahead, the outlook remains good

But what are the prospects for future R&D? A strong patent system, with appropriate checks and balances, is essential to encourage investment in novel technologies and products. Notwithstanding the Dutch and Italian challenge to the European Biotechnology Directive, it is established patent law in both the USA and Europe that genes and other DNA sequences can be patented. However, the possibility is now receding of patents being granted for DNA fragments and genes of no known use, and of broad patents being granted that stifle further research by others. At the same time, the promise of huge amounts of information being available about the human genome heralds a new era for the development of new diagnostic methods and treatments, the early diagnosis of patients at risk of disease, and the tailoring of treatment to match each patient's genetic make-up.

The outlook for R&D is, therefore, still good, although the industry must continue to act responsibly and sensitively in order to build public confidence and to allay genuine concerns about the use of gene-based technology.

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What do you think about gene patenting?

How do you think we should balance return on investments by companies with the ethical issues of gene patenting?

Do you think the law goes far enough by preventing the patenting of DNA fragments and genes of no known use?

Please send your comments to Dr Rebecca Lawrence, News & Features Editor, *Drug Discovery Today*
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