ICR The Institute of Cancer Research

Patenting genetic information

Position Statement from The Institute of Cancer Research, London

Summary

Patenting and licensing policies at The Institute of Cancer Research (ICR) are driven by our ambition to achieve the maximum patient benefit from research findings.

Research carried out at the ICR and at other institutions into cancer susceptibility genes has transformed our understanding of the inheritance of cancer risk. It has also opened up new avenues for treatment, allowing us to use gene products as drug targets or as biomarkers to predict response to therapies. It's our ambition that genetic information should be routinely used to help people with cancer and their families by informing them about their risk and guiding decisions over personalised cancer treatment. We believe that isolated DNA, as a product of nature, should not be eligible for patenting and worry that current practice on gene patenting can allow companies to gain a market monopoly in areas such as gene testing or predictive biomarkers, limiting access to healthcare.

Where the ICR holds patents that include DNA sequences, we ensure that rights are made available on a non-exclusive basis to maximise patient benefit.

September 2013

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Background information

For 30 years, both Europe and the US have allowed patenting of isolated human genes, and it is estimated that around 20% of human genes have been patented. Companies can hold patents in different regions with varying degrees of protection, with patents awarded by national offices such as the UK Intellectual Property Office or the United States Patent and Trademark Office (USPTO). Similar criteria apply in both the US and Europe when assessing patents:

- novelty
- inventiveness or non-obviousness
- utility or industrial applicability

In the UK, the legal protection of biotechnological innovations such as DNA sequences is governed by the 1998 EU Biotechnology Directive on the legal protection of biotechnological inventions. This states that '*biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'*, meaning that isolated human DNA sequences can be patented as an invention.

In the US, a Supreme Court ruling in June 2013 altered the patent eligibility of human genes in the US. In a lawsuit originally filed in 2009 against Myriad Genetics Inc., the Supreme Court ruled that in the US, DNA that has been isolated from the human body is no longer eligible for patenting. It ruled that '*a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated'* but that complementary DNA [cDNA] is eligible for patenting.

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Key ICR positions on patenting genetic information

- The ICR believes research findings on all DNA sequences should be published and developed in ways that achieve the maximum patient benefit – including enabling multiple parties to research, develop and perform genetic tests or to discover and develop new drugs using genes as targets. Current practice enabling genes to be patented and a single organisation to hold exclusive rights allows companies to gain a monopoly on their use. This can limit access to healthcare for those who are unable to pay for it, and restrict the ability of competitor companies to develop alternative and potentially superior genetic tests, or to exploit potential new drug targets.

- We understand a careful balance needs to be struck between on the one hand offering exclusivity to promote commercial interest in therapeutics and diagnostics, and on the other hand dissemination of scientific knowledge to open up commercial competition. Where the greatest patient benefit can be achieved through non-exclusive rights, as in the case of DNA sequences or other research tools, we feel that exclusive rights are detrimental to public health. We believe market exclusivity should be limited to patents on technologies where large investment is needed from companies to take the product to patients, such as patenting of new drugs, which would not be developed without a market incentive.

- The ICR believes that isolated DNA should not be classed as an invention and therefore should not be eligible for patenting. Isolated DNA is native DNA which has been extracted from the body, and should be classed as a product of nature, even if it has been isolated by a technical process. We welcomed the review of this topic by the Supreme Court of the United States, and its June 2013 decision that isolated DNA was not eligible for patenting. We recommend that this subject is readdressed in other parts of the world, including Europe.

- The ICR believes that cDNA should not be eligible for patenting as it contains the same genetic information as in the exons of genomic DNA within the body. If the information in cDNA did not match the information in the genomic DNA, it would no longer be useful in applications such as gene testing. While many applications such as gene sequencing and testing will generally use genomic DNA, some applications of DNA sequences may rely on cDNA, and their use could be restricted by the US ruling.

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- Genetic tests could still be deemed eligible for patenting even if genes were not, where companies were able to show they met the three patenting criteria - novelty, inventiveness or non-obviousness, and utility or industrial applicability. This would allow and encourage healthy competition within the sector, rewarding innovation and driving up standards, while giving healthcare providers a choice of the tests they used.

- We would like every cancer patient to have access to genetic testing. We, and others, are focusing on improving capacity within the NHS to offer gene testing so that many more people can benefit from it. If patenting of genes and genetic tests continues to be allowed, we would like to see the proprietors of the genetic tests working with the NHS Commissioning Authority to ensure availability of these tests for NHS patients at a reasonable price. If current gene patents in the UK were enforced, it could hinder clinical use of genetic tests in the NHS.

- We believe that personalised medicines will be key in our mission to defeat cancer. Designing drugs to target cancer-causing gene products, and the use of predictive biomarkers to determine the most appropriate treatments, are vital to achieve this. Gene patenting could prohibit multiple organisations from developing drugs against a particular gene target or gene product or from using biomarkers to predict response to treatments. This area of research should be considered pre-competitive to allow for the development of the highest standard of treatments.

- While commercial bodies are able to patent DNA sequences of genes and hold exclusive rights to their use, the ICR (and many other not-for-profit organisations) will need to file patents to protect our interests and help ensure freedom to operate in the field for the ICR and others. Where the ICR does this, rights under such patents are made available for licensing on a non-exclusive basis to as many organisations as possible, with the aim of providing the maximum patient benefit.