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ICSU Statement on Gene Patenting[i]

In light of significant recent developments in science and law (see below), ICSU specifies its position on gene patenting as follows:

1. Efforts to patent genetic information should not jeopardise either progress in the basic science or access to the information which is necessary for such progress to continue (ICSU Statement, 1992);
2. ICSU opposes attempts to patent complementary DNA (cDNA) sequences corresponding to portions of unknown messenger RNAs (mRNA) by stimulating important investments and developments;
3. ICSU urges the relevant authorities to take due account of the possible implications (for science and society) when considering (gene patenting) applications and to ensure a strict application of long-established patenting principles (ICSU, 2002).

In 2000, relevant agencies in Europe and the USA revised their positions on gene patenting:

- the European Biotechnology Directive 98/44/EC,[ii] which contains provisions on patenting of DNA Sequences, came into force. Article 5(2) states that: "An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element";
- the United States Patent and Trademark Office (USPTO) responded to concerns, in particular from the National Institutes of Health (NIH) on its patent granting policy for fragments of gene sequences known as Expressed Sequence Tags. USPTO adopted more stringent examination guidelines concerning the requirements of written description and utility.

Over the past decade, the principle laid out in the EC directive has been broadly interpreted and applied, and a fifth of human genes now have patents granted or pending. While beneficial in securing investment for product development, the ruling has been criticised on the grounds of being anticompetitive (since a gene cannot be reinvented) and of being illogical (since the information content of a gene is identical whether it is inside or outside the human body). Practical concerns are that monopolistic pricing can disproportionately restrict access to benefits, and that the proliferation of human gene patents will create a 'thicket' that inhibits development of multifactorial genetic testing.[iii]

Recent events in US law-courts and developments in science are now raising serious questions about this principle and its interpretation by patent granting agencies:

- in 2010, a lawsuit was brought by a consortium of US researchers, genetic counsellors, scientific associations, women's health groups and the American Civil Liberties Union[iv] against the US Patent and Trademark Office, Myriad Genetics,

and the University of Utah Research Foundation.[v] Myriad had patented sequences for genes associated with breast cancer susceptibility and thus effectively established a monopoly on their use. The lawsuit claimed that such patents violate the First Amendment and patent law because genes are "products of Nature". A judge of the US District Court for the Southern District of New York ruled on 29 March 2010 that seven of Myriad's patents are invalid, emphasising the identity of sequence information of an isolated gene with that existing within the body. The case is going through a series of appeals;

- the US Department of Justice has filed an Amicus Curiae brief to the Appeal Court,[vi] supporting the opinion that isolated but unmodified human genes are products of nature and cannot be patented. The brief acknowledges that this conclusion reverses practices of government agencies that have in the past sought and obtained such patents;
- the acceleration of DNA sequencing, leading to large numbers of genomes being freely available, is undermining the concept of 'prior art' in naturally occurring gene sequences. As the field matures, inventive steps will increasingly reside downstream and lead to precisely defined process and product patents. Debate will continue over the patent status of modified and *de novo* gene sequences, but the arguments will be about utility and scope of claims rather than inventiveness.

As the science of genetics continues to develop, opening up new and exciting opportunities for commercial development and medicine, it is important that the lessons of the last decade are taken on board. An optimal balance needs to be maintained between the use of patents to protect and encourage genuine invention and the value of genetic information being openly available such that it can be widely exploited in research and innovation for the benefit of humanity as a whole.[vii]

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[i] This statement was prepared by the ICSU Committee on Freedom and Responsibility in the conduct of Science (CFRS) following consultation with the Biological Unions. It was approved at the 105th meeting of the ICSU Executive Board in September 2011. It replaces the version of June 2002.

[ii] OJ L213/13, 30 July 1998; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:213:0013:0021:EN:PDF

[iii] Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests: Report of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS, NIH, Bethesda, MD, April 2010); http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_patents_report_2010.pdf.

[iv] Association for Molecular Pathology v. U.S. Patent and Trademark Office, Southern District of New York (29 March 2010); http://www.aclu.org/files/assets/2010-3-29-AMPvUSPTO-Opinion.pdf

[v] This followed a variety of court challenges around the world to gene patents, particularly those of Myriad.

[vi] Brief for the United States as Amicus Curiae in Support of Neither Party submitted to the U.S. Court of Appeals for the Federal Circuit, re (1) (29 October 2010); http://patentdocs.typepad.com/files/croplife-international-amicus-brief.pdf.

[vii] Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications, Venice, Italy, 17 July 2009, http://unesdoc.unesco.org/images/0018/001855/185558e.pdf.