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PRESS RELEASE

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PATENTLY PROBLEMATIC: THE EUROPEAN PATENT LAWS MAY DISSUADE STEM CELL RESEARCH

The European patent law on biotechnological inventions is deeply flawed in principle and highly problematic in practice, an expert in patent law warned today (Tuesday 20 July) at a conference in Glasgow. Dr Graeme Laurie from Edinburgh University believes that it could prevent patents resulting from research on human and animal embryos and may discourage the development of stem cell technologies in Europe.

Since 2000 the European Union directive on biotechnology has included new provisions to allow patents to be denied on grounds of moral concerns. Although the provisions do not mention stem cell research, two independent guidelines provided by the European Group on Ethics and the UK Patent Office, and a ruling by the European Patent Office cast a heavy shadow over the prospect of patenting stem cell technologies.

The guideline provided by the European Group on Ethics indicates that technologies involving early embryos (three to four days old) are not patentable whereas those developed using older embryonic cells may be protected. The decision by the European Patent Office denied patent protection for inventions involving embryonic cells, and would only allow protection for adult stem cells.

“The overall message is that embryonic work is morally problematic and so are patents of any invention in this area,” said Dr Laurie, speaking at BioScience 2004. “The irony, however, is that this will not stop research on embryonic stem cells in Europe. It just means that stem cell technologies developed here are not patentable. The result is that such research is likely to move outside Europe – either to the US or elsewhere,” he continued.

Research on embryonic stem cells has provoked global ethical debates about whether such research should take place at all and, if so, how it should be governed. “There are moral concerns about the science, which is already dealt with by regulatory laws,” argued Dr Laurie. In the UK, the Human Fertilisation and Embryology Authority is responsible for implementing the regulatory laws regarding human stem cell research. “On the other hand, patent laws deal with moral concerns about patents, that is, whether the technologies should be granted monopoly in the market,” he continued.

“The directive confuses ethical concerns about the science with those about patents,” Dr Laurie said. “It fails to understand that its remit is in the field of patents and not in the regulation of science more generally. This distorts the patent system and may dissuade technologies for not very good reasons.”

The European Commission’s first report on the implementation of the directive showed that all is not well. The majority of the member states had failed to implement the provision and 8 members were referred to the European Court of Justice. Many concerns relate to the bioethical aspects of the law.

“It took 10 years of marathon debate and discussion before the European Union finally adopted the directive. Yet many consider it to be a failure. Lessons must be drawn.” Dr Laurie remarked.

According to Dr Laurie, innovative, highly promising research, such as stem cell technologies, simply will not occur in the absence of patent protection. It is estimated, for example, that it costs in excess of £300 million pounds to bring a single drug to market.

“Patent protection is the best means to recoup these outlays. It allows the patentee to prevent unauthorised uses or copying of his technology,” Dr Laurie said. “In the precarious world of stem cells, where there is much promise but so far little is proven, the costs of the first successful therapies will be many times the figures for pharmaceutical developments.”

“If Europe removes the incentive to invent within its boundaries, the promise and the potential profit of stem cell technologies may end up on other shores,” Dr Laurie concluded.

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