

Patentability of Stem Cells

The European Patent Office has recently given a historic ruling on the patentability of human embryonic stem cells. In arriving at their decision, the EPO had to consider not only the usual patentability criteria - novelty and inventive step - but also issues relating to the patentability of living matter and the morality of such inventions.

Introduction

When assessing the patentability of inventions based on genes, proteins and micro-organisms, the European Patent Office (EPO) applies the standard criteria that it has developed for the patentability of chemical inventions. In particular, is the claimed subject-matter novel, inventive, adequately described and capable of commercial use?

Claim format

With biological inventions, however, the form of the patent claim is particularly important. Although human genes and proteins are present in the human body, if these genes/proteins are claimed in "isolated" or "purified" form, the latter forms will be novel over the form present in the body, and hence the first patentability hurdle will be overcome. Similarly, if human cells (or indeed any new micro-organisms) are isolated and purified for the first time, and a commercial use can be identified, such cells are technically patentable and a claim to such cells (not just their uses) might be obtainable. In this way, many patents have already been granted covering genes and proteins, and also various animal and human cells.

Immoral inventions

There are special issues, however, regarding the patentability of human embryonic stem cells (in Europe, at least). The European Patent Convention (EPC) has a provision that prevents patents for inventions "the commercial exploitation of which would be contrary to ... morality".

WARF patent application

During the examination of a European patent application filed by the Wisconsin Alumni Research Foundation (WARF), claiming "primate embryonic stem cells", the EPO Examiner asserted that such an invention was immoral. The Examiner refused the patent application and hence WARF filed an Appeal. The Appeal ultimately came to be heard by the Enlarged Board of Appeal of the EPO, the EPO's highest ruling body. The Enlarged Board sought comments from WARF, the President of the EPO and from the public on the patentability issues, and particularly on the morality of the invention since the EPO does not have experts on such moral matters.

Decision of the Enlarged Board of Appeal

In the end, the Enlarged Board avoided having to look at the morality of the invention itself because it ruled that the invention fell squarely within one of the existing immoral exclusions from patentability, i.e. "uses of human embryos for industrial or commercial purposes". The Enlarged Board did comment, however, that all inventions which require the destruction of human embryos in order to put the invention into practice are immoral.



Practical impact of the decision

In practice, this decision is unlikely to have a significant impact on the patenting of stem cells because it does not relate to animal (i.e. non-human) stem cells or to adult human stem cells. Furthermore, there are now a number of deposited human embryonic stem cell lines upon which new inventions can be based without the need to destroy additional human embryos.

Further advice

If you would like any further advice please contact us at Dehns using the details below.

United Kingdom

Dehns
St Bride's House
10 Salisbury Square
London
EC4Y 8JD

T: +44 (0)20 7632 7200
F: +44 (0)20 7353 8895
E: london@dehns.com

Dehns
Aspect House
84-87 Queens Road
Brighton
BN1 3XE

T: +44 (0)1273 244200
F: +44 (0)20 7353 8895
E: brighton@dehns.com

Dehns
Willow Court
West Way
Oxford
OX2 OJB

T: +44 (0)1865 305100
F: +44 (0)20 7353 8895
E: oxford@dehns.com

Germany

Dehns
Singlspielerhaus
Sendlinger Str. 29
80331 Munich

T: +49 89 2422 8130
F: +49 89 2422 8140
E: munich@dehns.com

www.dehns.com