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Certain inventions relating to human embryos can be patentable under the EPC

The Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) has recently considered the patentability of human embryonic stem (ES) cells and in particular the scope of Rule 23d(c) EPC (Rule 28 EPC 2000) which prevents patents being granted for inventions which involve commercial or industrial use of human embryos.

The EBA has decided the questions put to it in Decision G2/06. The EBA say that it is not possible to grant a patent for an invention which exclusively and necessarily involves the use and destruction of human embryos, regardless of whether these steps are actually claimed or not. The EBA decision did not however address the direct question of whether human stem cells are themselves patentable.

Background to Decision G2/06

Key background to the Decision is summarised below:

Relevant EPC Law

Article 53 EPC states that:

European patents shall not be granted in respect of: (a) invention the commercial exploitation of which would be considered contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States"

Rule 23d(c) EPC (Rule 28 EPC 2000) lists exclusions to patentability, including "use of human embryos for industrial or commercial purposes".

Wisconsin Alumni Research Foundation ("WARF") Patent Application

The claims of the patent application in question recited a cell culture which comprised primate embryonic stem cells which had a number of defined characteristics.

The application as originally filed disclosed generating the claimed cell cultures exclusively using methods which necessarily required the use and subsequent destruction of human pre-implantation embryos. No alternative starting material was disclosed. The EPO Examining Division (ED) ruled that the claims fell foul of Rule 23d(c) EPC because the use of the embryo starter material was seen as being industrial use of an embryo, despite the fact that the method itself was not part of the invention as claimed. In particular, the average skilled person following the steps of the methods specifically disclosed in the application inevitably used and destroyed an embryo. The ED refused the patent at oral proceedings.

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An appeal (Decision T1374/04) against the decision of the ED gave rise to G2/06 in which a number of questions of law were referred up to the EBA concerning Rule 23d(c) EPC.

EBA Decision G2/06

From amongst the referred questions, the EBA ruled that the legislative intention behind both Art. 53(a) EPC and Art. 27(2) of TRIPS - on which the interpretation of Rule 23d(c) EPC depends - was to outlaw protection for inventions of the sort disclosed in the WARF application where human embryos are destroyed.

The EBA acknowledged that the term “embryo” had not been defined by the legislator and no definition of the term was given by the EBA. What an embryo is remains a question of fact to be decided in the context of a patent application on a case-by-case basis.

The term “commercial or industrial use of a human embryo” was considered by the EBA not to include inventions for therapeutic or diagnostic purposes applied to the human embryo and useful to it.

Rule 23d(c) EPC has its origin in EU Biotechnology Directive and so a request was made of the EBA to seek a preliminary ruling on interpretation from the European Court of Justice (ECJ). The EBA declined on the basis that there is no legal and institutional link between the EPO Boards of Appeal and the EU.

Conclusion

The EBA Decision appears to clear a path for patenting of certain inventions involving human embryos, or inventions which directly concern human embryos and which amount to non-commercial and non-industrial uses of such embryos. Particular care will need to be given as to the extent of the supporting description and enabled disclosure of how to make the claimed invention, whilst avoiding description of procedures involving destruction of human embryos.

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