

**Scottish Council on Human Bioethics**

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**Briefing (amicus curiae letter) to the Enlarged Board of Appeal of the European Patent Office concerning case G 2/06****Patenting human embryonic stem cell cultures**

By interlocutory decision T 1374/04 dated 7 April 2006, Technical Board of Appeal 3.3.08 has referred the following points of law to the Enlarged Board of Appeal following Article 112(1)(a) EPC: (language of the proceedings)

The text of the referral in the English language is available on the Website of the European Patent Office under <http://legal.european-patent-office.org/dg3/pdf/t041374eu1.pdf>

The case is pending under Ref. No. **G 2/06**.

The Enlarged Board of Appeal considering the referral will be composed as follows: P. Messerli (Chairman), S. Perryman, U. Kinkeldey, A. Nuss, J.-P. Seitz, M. Scuffi, O. Spineanu-Matei.

It is expected that third parties will wish to use the opportunity to file written statements in accordance with Article 11b of the Rules of Procedure of the Enlarged Board of Appeal (OJ EPO 2003, 59). To ensure that any such statements can be given due consideration without holding up the proceedings more than necessary, they should be filed by the end of October 2006 at the Registry of the Enlarged Board of Appeal, quoting case number G 2/06.

**Questions:****1. Does Rule 23d(c) EPC apply to an application filed before the entry into force of the rule?**

Rule 23d (c) (Exceptions to patentability) indicates that:

*Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: uses of human embryos for industrial or commercial purposes;*

**SCHB Response:**

The SCHB agrees that Rule 23d(c) EPC does apply to an application filed before the entry into force of the rule. This is because the rule is based on ethical principles which are widely held by society both before and after the entry into force of the provision. The rule, therefore, was implemented to represent and substantiate the long-held ethical position of society which goes beyond the time in which the rule entered into force. In other words it is because the spirit of Rule 23 d (c) extended before the rule was implemented that it should not be considered as only setting a specific regulation in time.

In addition, since the application to the European Patent Office concerning the use of human embryonic stem cell cultures was made after the rule came into force, it is only to be expected that it should follow the provisions of the rule without exception.

**2. If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?****SCHB Response:**

The SCHB is of the opinion that Rule 23d(c) EPC forbids the patenting of claims directed to products which could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.

This is because, it is at present impossible to derive human embryonic stem cell cultures and seek to patent them without the use of human embryos for industrial or commercial purposes as described in Rule 23d(c) EPC.

Moreover, any derivation of embryonic stem cell cultures for industrial or commercial purposes necessarily entails the destruction and use of human embryos for industrial or commercial purposes.

**3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?**

Article 53 (a) (Exceptions to patentability) indicates that:

*European patents shall not be granted in respect of: inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the 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;*

**SCHB Response:**

The SCHB concurs that Article 53 (a) forbids the patenting of human embryonic stem cell cultures because it is an invention, the publication or exploitation of which, would be contrary to "ordre public" or morality,

This is because:

- the concept of "ordre public" has its origins in revolutionary France and reflects the fact that a proposal should not be accepted if it may give rise to deep and widespread public disquiet, alarm or even unrest.
- the concept of morality is based on a set number of beliefs in ethical principles and their general acceptance by society.

Thus, since the patenting of human embryonic stem cell cultures would undermine the "ordre public" of society and be contrary to its morality, Article 53 (a) does apply.

**4. In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: eg derivation from available human embryonic cell lines)?****SCHB Response:**

The SCHB agrees that the spirit of Rule 23 d (c) extends before the rule was implemented. Therefore, it is of no relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos.

Moreover, any derivation of embryonic stem cell cultures for industrial or commercial purposes necessarily entails, at present, the destruction and use of human embryos for industrial or commercial purposes.