

EPO Enlarged Board of Appeal decides on patentability of embryonic cells

By Benjamin Quest and Dr. Josef Zimmer

The present decision of the Enlarged Board of Appeal (EBoA) defines criteria when stem cell inventions are not patentable.

Claim 1 of the underlying European patent application No. 96903521.1 reads as follows:

"A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer."

The Enlarged Board considered the following questions:

Q1. Does Rule 23d(c) EPC[1973] [now Rule 28(c) EPC¹] apply to an application filed before the entry into force of the rule?

¹ *Rule 28:* Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- (a) processes for cloning human beings;
- (b) processes for modifying the germ line genetic identity of human beings;
- (c) **uses of human embryos for industrial or commercial purposes;**
- (d) processes for modifying the genetic identity of animals which are likely to cause

Q2. If the answer to question 1 is yes, does Rule 23d(c) EPC[1973] 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?

Q3. If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims?

Q4. 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: e.g. derivation from available human embryonic cell lines)?

The EBoA decided as follows:

A1: The answer to Q1 is yes.

The EBoA stated that Rule 23b(1) EPC1973 (now Rule 26(1)EPC) provides that the relevant provisions are to be applied to all European patent applications and patents including those filed before the coming into force of the Rule. No transitional provisions were set. Furthermore, the EBoA could not identify

them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

any indication that the introduction of Rule 23d EPC1973 took away the possibility to patent anything which had previously regarded patentable. (Reasons 12-14)

A2: The answer to Q2 is yes.

In light of the "travaux préparatoire" and Rule 23b(1) EPC1973 (now Rule 26(1)EPC) the EBoA refers to the Directive 98/44/EC for an interpretation of Rule 23d EPC1973 (now Rule 28 EPC). First, the term "embryo" is to be construed as not having a restrictive meaning, i.e. may pertain to any definition of what an embryo is in the factual context of a patent application. Second, Rule 23d(c) EPC1973 does not mention claims, it mentions "inventions" in the context of its exploitation. If the exploitation of the invention necessarily involves the destruction of human embryos, it falls under the exemption of Rule 23d(c) EPC1973. Third, the making of the product (with the right to exclude others from making the product) is a commercial exploitation of the product, even if the product is intended for use in further research. If said making of the product involves the destruction of human embryos said destruction is consequently part of the commercial exploitation and is therefore prohibited under Rule 23d EPC1973. The use of embryos in inventions for therapeutic or diagnostic purposes applied to the embryo and useful to it (which is not the case here) is not prohibited. Rule 23d EPC1973 was held to not go beyond Article 53(a) EPC. (Reasons 15-31)

A3: Q3 is not needed to be answered as the answer to Q1 and Q2 is yes. (Reasons 32)

A4: The answer to Q4 is no.

At the time of filing there was no way to put the claimed invention into practice in a way not contravening Article 53(a) and Rule 23d EPC 1973. As a matter of legal certainty, the EBoA held that the technical progress in the field has to be disregarded; what counts is the technology available at the filing date.

Remarkably, the Enlarged Board closes its reasoning with the statement that the decision is not concerned with the *general* patentability of inventions relating to human stem cells or human stem cell cultures. However, inventions concerning products that can only be obtained by the use of human embryos which use involves the destruction of the human embryo are held unpatentable. (Reasons 33-35)

This should be considered when amending claims in order to overcome objections under Article 53a and Rule 28 EPC.