Does T 0866/01 ("Euthanasia Compositions") of an Appeal Board of the EPO provide the Answers for the Enlarged Board of Appeal Case G 2/06 ("Primate Embryonic Stem Cells")?

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This report deals with decision T 1374/04 of a Technical Board of Appeal of the European Patent Office, which forwarded several questions concerning the patentability of claims directed to embryonic stem cells to the Enlarged Board of Appeal (EBA). The case before the EBA is still pending as G 2/06.

Moral aspects of stem cell technology are the subject of great controversy in the European public. Whereas a detailed consideration of all moral aspects of stem cell technology may turn out to be fairly complex, the EBA will have to make their decision on the sole basis of the EPC and the relevant articles and rules laid down therein, in particular Article 53(a) EPC and Rule 23d(c) EPC[1]. Here we show how, within the legal framework of the EPC, the Technical Board in charge dealt with issues of morality in the recent Decision T 0866/01 ("Euthanasia compositions"). This case might provide some hints as to how the EBA might find a way to provide the answers in the case G 2/06 pending before it.

[1] *Article 53(a) EPC stipulates 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.

Rule 23d(c) EPC stipulates that

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

The questions referred to the EBA in pending G 2/06

In the case underlying decision **T 1374/04** the Examining Division refused European patent application No. 96 903 521.1 ("Primate embryonic stem cells") comprising ten claims. Claim 1 reads:

1. 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 feeded layer.

The Patentee lodged an Appeal against this decision. The Board of Appeal considered the question of patentability of human embryonic stem cells as being an exceptionally important point of law in the meaning of Article 112(a) EPC, for which a decision by the Enlarged Board of Appeal is required. According to the Appeal Board's reasoning the patentability of

human embryonic stem cells is a highly critical matter, which is passionately debated in Europe. The Board also referred to the implementation of Directive 98/44/EC of the European Parliament and the Counsel of 6 July 1998 on the legal protection of biotechnological inventions ("the EU Biotech Directive"), which resulted in the implementation of Rule 23d(c) EPC as a supplementary means for the interpretation of Article 53(a) EPC.

Rule 23d(c) EPC concerns the exclusion from patentability of inventions using human embryos for industrial or commercial purposes.

The legal and technical background of the case may be summarized as follows:

(a) The term "primate embryonic stem cells" as used in the claims covers **human** embryonic stem cells;
(b) at the filing date, the skilled person willing to repeat the invention, i.e. to prepare a cell culture of **human** embryonic stem cells, necessarily had to start from spare pre-implantation embryos, as indicated in the application, and thus destroy them in the process;
(c) the said pre-implantation embryos from which human embryonic stem cells are to be derived are "embryos" within the meaning of Rule 23d(c) EPC;
(d) Rule 23d EPC applies when assessing whether the presently claimed invention meets the requirements of the EPC, although it entered into force after the filing date of the application;
(e) the legal situation as regards the interpretation of Rule 23d(c) EPC is not yet clear;
(f) the patentability of human embryonic stem cells is a highly debated matter.

Against this background the following questions were referred to the EBA:

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

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?

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

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

Comments by the Board of Appeal in Decision **T 1374/04**

When referring these four questions to the EBA, the Board of Appeal made the following comments:

As regards the first question, the Board was of the Opinion that there were two preceding decisions, i.e. **T 272/95** and **T 315/03**, which both held that Rule 23 b to e EPC (and consequently also Rule 23d(c) EPC) applied to cases filed before said rules entered into force. Whereas in decision **T 272/95** the Board concluded that the Rules at issue are applicable insofar as they relate to the interpretation of Article 53 (a) EPC, **T 315/03** found that the "package" of these Rules was applicable without any further conditions. As this question, however, had not been

decided by the EBA, the Board found in **T 1374/04,** discussed herein, that this issue had to be referred as a specific question to the EBA.

As regards the second question, the Board at first commented on Appellant's argument that Rule 23d(c) and Article 53(a) EPC have to be interpreted narrowly, as both refer to exceptions from patentability. The Board found that this principle does not apply without exceptions as was shown in EBA decision **G 1/04,** referring to exclusions from patentability under Article 52(4) EPC (methods of treatment). The Board expects a complex analysis to be necessary to decide how to interpret Rule 23d(c) and Article 53(a) EPC.

The Board also commented on the meaning of the term "use" in Rule 23d(c) EPC. The Appellant had submitted arguments in view of the word "use" of said Rule which led him to the conclusion that only **use** claims directed to uses of human embryos for industrial or commercial purposes fall under the exclusion from patentability laid down in Rule 23d(c) EPC. The Board, however, observed that the category of a claim is not relevant *per se.* On the contrary, it tended to the position that the term "use" in Rule 23d(c) EPC is not to be construed as referring to the category of the claim in question. The wording of said Rule was merely thought by the European legislature as a definition of the essence of the inventions, which should not be patentable. This was all the more true in view of the history of the implementation of Rule 23d(c) EPC.

As regards the third question, the Board emphasized that it would not add more on this matter than just raising its doubts that the "balancing test" as applied in decision **T 19/90** (Oncomouse Case) should also be applied in a decision regarding human life. According to the Board's view, the critical issue would be whether it would be ethically acceptable to make a decision by weighing the interest of human beings who could potentially benefit from the exploitation of the technology against a right - if any - of human embryos to live and not be destroyed for the benefit of others.

As regards the fourth question, the Board commented that there was one decision, namely **T 315/03**, which applied Rule 23d and Article 53(a) EPC based on morality standards as existing at the filing or priority date; evidence arising after that date may be taken into account provided it is useful for demonstrating the morality standards as of the priority or filing date. If this issue turns out to be relevant in view of questions 1 to 3, the EBA will have to answer whether or not this approach is correct.

Summary:

The basic question underlying **T 1374/04** and to be answered by the EBA is whether activities during the stage of arriving at the claimed invention and which are not mentioned in the claim may nevertheless exclude an invention under Article 53(a) EPC from being patented. In other words, the EBA will have to decide on what kind of activities may form part of "exploitation of the invention" as mentioned in Article 53(a) EPC.

In the meantime, another Appeal Board of the EPO had to decide on a case which required an extensive analysis and interpretation of Article 53(a) EPC, in particular an interpretation of the term "exploitation" of the invention. This case is **T 0886/01** ("Euthanasia Compositions") and provides very detailed guidance on how to interpret and apply Article 53(a) EPC.

In the case underlying **T 0866/01**, claims 1 and 14 read as follows:

1. A composition which comprises an aqueous solution comprising
   (a) a cardiotoxic compound selected from the group consisting of a quinacrine salt

and a chloroquine salt in a cardiotoxic amount; and

(b) embutramide in a lethally anesthetic amount.

14. Use of the composition according to any of claims 1 to 13 for preparing a medicament for providing euthanasia in a lower mammal.

This composition was disclosed as suitable for euthanasia in a lower mammal. The Opponents argued that the composition was also suitable for killing humans and therefore the claims would be inadmissible under Article 53(a) EPC.

The Board found that the claimed invention was not excluded from patent protection by Article 53(a) EPC and argued as follows.

First of all, the Board found that exceptions to patentability have been narrowly construed in the jurisprudence of the Boards of Appeal, in particular in decisions made with respect to plant and animal varieties on the basis of Article 53(b) EPC (e.g. in decisions **T 320/87** and **T 19/90**). The Board found that a narrow interpretation is also applicable with respect to the provisions of Article 53(a) EPC.

This reasoning deviates from the position of the Board in decision **T 1374/04**, which also mentioned these two decisions, but also emphasized decision **G 1/04** (see above) in which the Board took a broader approach regarding the interpretation of exclusion provisions (in said case "the exclusion of methods of treatment" under Article 52(4) EPC[2]).

Secondly, the Board in **T 0866/01** held that the exception to patentability according to Article 53(a) EPC applies only if the **publication and/or exploitation** of the invention would contribute causally to the infringement of the fundamental principle of "ordre public" and/or morality.

In the Board's conclusion, it was not a question of Article 53(a) EPC whether or not the **invention *per se***, i.e. the claimed subject matter, in the case at issue the lethal composition or its preparation, may be regarded as a breach of the principles of "ordre public" or morality. Moreover, it was also no question of Article 53(a) EPC whether and under what conditions the **act of granting** the patent either for the claimed composition *per se*, its preparation or its use might be regarded as an infringement of ethical principles, nor was it relevant whether or not **making the invention** as such or the inventor's activity during making or development of the invention were to be regarded as a breach of the principles of "ordre public" or morality.

These findings are particularly interesting when compared to the legal and technical situation of the stem cell case **T 1374/04** as summarized by the respective Board when referring their questions to the EBA for decision **G 2/06** (see above). If one follows **T 0866/01**, the way of making the invention or providing the claimed subject matter *per se* is not an issue under Article 53(a) EPC as long as this does not lead automatically to a publication and/or exploitation of the invention which is to be seen as contrary to the "ordre public" or morality. It will be interesting to see how the EBA will assess the relevance of the process of making the claimed cell culture in **T 1374/04** for the patentability of the claimed cell cultures as such.

Thirdly, the Board in **T 0866/01** explained how the **exploitation** of the invention within the meaning of Article 53(a) EPC is to be construed. According to an earlier Enlarged Board of Appeal decision, **G 1/98,** "exploitation" is to be construed as the normal **avowed use** indicated in the patent. Moreover, patent protection is only to be denied under Article 53(a) EPC, if

[2] For the details of this decision **G 1/04** see Zimmer and Wang, Patentability of diagnostic methods, under the most recent decision of the Enlarged Board of Appeal G 1/04, 25, Biotechnology Law Report, 384, 4 (2006)

the exploitation as suggested by the patent, i.e. the avowed use of the invention, **would** infringe "ordre public" or morality. It is not sufficient for a rejection under Article 53(a) EPC that the invention **could** be exploited in a way that might violate Article 53(a) EPC. Therefore, if the intended use of the invention as taught by the patent does not infringe the principle of "ordre public" or morality, an exclusion from patentability under Article 53(a) EPC is not justified, even if there are one or more conceivable uses of the invention which could be regarded as a breach of the principle of "ordre public" or morality. In other words, the possibility of abuse of the invention in a way that would be in conflict with Article 53(a) EPC is not sufficient to deny patent protection under Article 53(a) EPC.

Consequently, the disclosure of animal experiments reported in the case underlying **T 0866/01**, in which animals were killed with the compositions falling under claim 1, was also not sufficient to justify an objection under Article 53(a) EPC. The Board argued it was evident from the disclosure of the invention that it addressed only euthanasia in veterinary practice, which was generally accepted under ethical concepts rooted in the culture inherent in European society and civilization. Accordingly, there was at least one exploitation or avowed use of the patent teaching, which does not infringe "ordre public" or morality.

The interpretation of Article 53(a) EPC as given in **T 0866/01** and its potential impact on the answers of questions 2, 3 and 4 of **G 2/06**

Following **T 0866/01** patent protection could only be denied under Article 53(a) EPC, if virtually any exploitation or use of the claimed invention which might be reasonably considered would infringe "ordre public" or morality. Moreover, the process of preparing the claimed subject matter *per se* or making the invention *per se*, were not to be regarded as sufficient for breaching the principles of "ordre public" or morality. Furthermore, **T 0866/01** held that the exceptions from patentability such as those laid down in Article 53(a) EPC have to be interpreted narrowly.

It will be interesting to see how the exploitation or avowed use in the case underlying **T 1374/04** as referred to the EBA in **G 2/06** will be determined by the EBA. Will the exploitation of the claimed invention, e.g. the application of human embryonic stem cells for therapeutic purposes, be determined to be independent of the stem cell preparation process and will this application of the stem cells in therapy be regarded as at least one exploitation or avowed use of the patent teaching that does not infringe "ordre public" or morality? Or will the exploitation of the claimed invention be regarded as a process comprising, besides the therapeutic application, also the stem cell preparation process? If so, a further question would then have to address an exploitation of the invention comprising one or more steps that may be in conflict with Article 53(a) EPC (e.g. the destruction of embryos) and further steps that are not in conflict with the EPC (e.g. the application in therapy) and whether such an exploitation might be in conflict with Article 53(a) EPC.

Following **T 0866/01,** the fact that during the making of the inventions the principle of "ordre public" or morality may have been violated would be irrelevant for the question of whether the claimed cell culture might be in conflict with Article 53(a) EPC.

Further, applying the standards of **T 0866/01**, the process of preparing human embryonic stem cells, even if it were found by the EBA to be a process contrary to "ordre public" or morality according to Article 53(a) EPC or Rule 23d(c) EPC, would not be sufficient to answer questions 2 to 4 with "yes".

In summary, the crucial question for the stem cell case **G 2/06** appears to be

whether the EBA shares the view of the Board in **T 0866/01** and regards the exploitation of the claimed invention as merely comprising the application of the stem cells in therapy or whether they regard said exploitation of human embryonic stem cells as a combination of both the preparation process and, for example, the therapeutic application.

Last but not least, one should keep in mind that a patent gives the owner only the right to exclude third parties form practicing the claimed invention, but is not a positive right (or allowance) for the owner to perform what he claimed. This is very evident in the field of pharmaceuticals, where having a patent on a medicament is one thing but being allowed to exploit such a patent is another thing. If a medicament fails in clinical trials for having shown side effects which are too severe, and its application is therefore in conflict with morality, this is not a reason for rejecting a patent application.

Therefore, there are good arguments available for a very narrow interpretation and restrictive application of Article 53(a) EPC and, consequently, for answering questions 2 to 4 with “no”.

Note added: In the meantime the German Federal Patent Court partially invalidated German Patent DE 19756864 to the extent that the claims covered human embryonic stem cells (see Az.: C 12N 5/006).