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# Stem cell patents and morality: The European Patent Office's emerging policy

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*Introduction*

There are important developments at the European Patent Office (EPO) regarding the patentability of stem cells. In a patent application filed by the Wisconsin Alumni Research Foundation (WARF), a Board of Appeal of the EPO has referred several questions to the EPO's highest 'court', the Enlarged Board of Appeal. The Enlarged Board's decision will have far-reaching consequences as regards the EPO's ability to exclude inventions from patentability on moral grounds.

*Background*

The patent application (no 96903521)[1], which identifies James Thomson as the inventor, relates to cultures of primate – including human – embryonic stem cells. In July 2004, the EPO Examining Division refused the application on morality grounds. WARF appealed and a Board of Appeal referred four questions to the Enlarged Board.

The Examining Division referred to Rule 23d(c) of the European Patent Convention (EPC) which states 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.[2]

The Article 53(a) referred to in this Rule is the 'morality provision' of the EPC, which provides that:

> European patents shall not be granted in respect of: (a) inventions the publication or exploitation of which would be contrary to 'ordre public' or morality, provided that the

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[1] For documents regarding this case: go to <http://ofi.epoline.org/view/GetDossier> and enter application no 96903521.

[2] This corresponds to Art. 6(2)(c) of the EU Directive on the legal protection of biotechnological inventions (Directive 98/44/EC). This Directive requires that Art. 6(2)(c) "does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it". However, this exception does not apply here: since obtaining stem cells from an embryo involves the destruction of the embryo, the intervention cannot be said to be useful to it.

> 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.

*WARF's main arguments*

In its *Grounds of Appeal*, WARF mainly raises two arguments.

One is that the EPO should not act as a moral censor. A broad interpretation of the 'morality provision' should not be adopted, according to WARF, in two circumstances. Firstly, where there is no consensus among the EPC member states as to the ethical acceptability of the invention. "This is particularly important", WARF adds, "where exploitation of the invention is permitted under national legislation in certain (albeit not necessarily all) Contracting States".

Admittedly, the exploitation of hES cells is legally allowed in some European countries. But this is irrelevant for the purposes of the moral assessment of the application, as Art. 53(a) explicitly decouples the determination of morality from legality.

Secondly, according to WARF, a broad interpretation of the morality provision is precluded:

> Where there is an ongoing moral debate in relation to the ethics of the invention, *a fortiori* where it is apparent that moral attitudes are changing. In such circumstances, it would be presumptuous for the EPO to interfere in the public debate or in any way pre-empt its outcome.

This too is unconvincing since *granting* the patent would also 'pre-empt' the outcome of the public debate.

Moreover, WARF's general line that the EPO should not act as a 'moral censor' is flawed, as the EPO is *obliged,* under Art. 53(a) EPC, to assess the morality aspect. This might lead to the rejection of some patent applications — even if, in practice, the EPO has a history of interpreting the law, and in particular the morality provision, in an 'applicant-friendly' fashion.

WARF's second argument is that whether a patent application violates Rule 23d(c) must be decided by reference to the exact subject matter of the patent claims. According to WARF:

> Patent applications whose claimed subject matter comprises a product which derives from a human embryo do not contravene Rule 23d(c), even in circumstances where the isolation of the product necessitated the direct and unavoidable use of a human embryo.

This argument goes to the heart of the matter. Hence, unsurprisingly, the issue posed here is also the subject of three of the questions that have been referred to the Enlarged Board, viz. questions 2, 3 and 4.[3]

*Questions referred to the Enlarged Board*

In the second question, the Board of Appeal asks whether Rule 23d(c) forbids the patenting of claims directed to *products* which, at the date the patent application was filed, could only be obtained by a method which necessarily involved the destruction of human embryos, even though the method *itself* is not claimed.

The third question asks whether the claims should in any event be refused under the general 'morality provision'.

The fourth question to the Enlarged Board asks whether it matters if, after the date of filing of the patent application, the stem cells could be obtained without having to recur to a method which necessarily involves the destruction of human embryos.

The answers to these questions are unlikely to come soon. However, various outcomes are possible; some would be more convincing and desirable than others. Some of the potential approaches to the second and third questions are discussed below.[4]

*The implications of Rule 23d(c)*

The second question pertains to the soundness of WARF's argument that Rule 23d(c) does not apply because the patent claims relate only to stem cell cultures and not to methods for obtaining them, whereas the Rule talks about inventions which "concern … *uses* of human embryos for industrial or commercial purposes".

It seems to us that the Enlarged Board can only rationally conclude that the fact that this application contains no claims to methods for obtaining hES cells is irrelevant. The word "concern" in the Rule is crucial: if the invention *concerns* use of human embryos for commercial purposes, then the Rule applies, even though the claims may be carefully worded to exclude the actual steps of handling the embryos. Making hES cell cultures clearly *concerns* such use of human embryos: hES cells are obtained by dismantling a human embryo. Hence, the stem cell cultures should not be patentable under the Rule.

An EPO Opposition Division has recently indicated that, in its view, the morality assessment should not depend on the type of claim presented.[5]

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[3] The first question asks whether the Rule applies when, as here, the patent application was filed before the Rule entered into force.

[4] One answer to the fourth question will most likely be that the morality provision, like any other provision of the EPC, should be decided as of the filing date.

[5] European Patent No. 0 695 351 (Edinburgh University), currently under appeal.

*The implications of Art. 53(a)*

Although an answer to the third question is only being sought if the Enlarged Board's reply to the second question is no (i.e. if grant is not precluded by the Rule), we think the Enlarged Board must address this important question in any case.

The dilemma facing the Enlarged Board is whether to follow previous practice and construe exceptions to patentability narrowly, or whether to decide that some exceptions should be construed sufficiently broadly as to have real effect.

In an opinion handed down in December 2005, the Enlarged Board indicated that not all exclusions must be construed narrowly, i.e. that EPO practice might change. In the decision on WARF, issued after December 2005, the Board of Appeal argues that a narrow construction is incorrect in the case of the morality provision.

A narrow construction would allow the patent applicant, by careful choice of claim format and language, readily to circumvent the morality provision, thus rendering it essentially toothless and thereby going against the public interest and the wishes of the legislators.

Here the words requiring construction are "*invention which concerns commercial use*" of Rule 23d(c) and "*exploitation of the invention*" of Art. 53(a). A narrow construction of "invention" is "that which is claimed"; a narrow construction of "concerns commercial use" is "commercial, rather than research, performance of the invention as it is claimed"; and a narrow construction of "exploitation of the invention" is "commercial performance of the invention as it is claimed". Since WARF claims stem cell compositions that could be reproduced by culturing without sacrificing further embryos, a narrow construction would not exclude such compositions.

However, if a broader construction is given which would prevent the circumvention of the morality provision, it seems to us that this can only be by construing "concerns use" and "exploitation" to include elements of the *past* and *future* of the subject matter claimed. Hence, an object would be contrary to morality if the procedure involved in its creation included a step that was contrary to morality (e.g. destruction of human embryos) or if its intended use is contrary to morality (e.g. a letter bomb). In other words, an invention may be 'tainted' by its history.

Broad interpretation, while giving effect to the morality provision, opens the door to the question as to how far the taint persists from the immoral act through subsequent development stages, perhaps carried out by independent actors over a broad span of time.

This appears to be the essence of the fourth question, which is effectively: if the invention can be put into effect from the filing date without a further immoral act, is exploitation then not contrary to morality?

A 'yes' answer would close the door on speculation as to how much any medical advance has involved murky deeds in its distant past. hES cell cultures, moreover, would not then be excluded from patentability as long as a viable culture was deposited before patent filing.

However, it seems to us that any decision that would allow patent applicants to circumvent the morality provision would be inappropriate; this would go against the public interest and the wishes of the legislators. As in other cases, the moral issues arising in the context of hES cell research are complex. The main question is obviously whether destroying human embryos is contrary to morality and, if so, to what extent this 'taints' downstream products (in this case hES cell cultures).

"Exploitation" of hES cell cultures should be interpreted as including the actions necessary to reach, and not just reproduce, hES cell cultures — in this case the destruction of human embryos. If (1) destroying human embryos for purposes leading to a commercial product is contrary to morality, and if (2) something that results from an act that is contrary to morality is itself contrary to morality, then this patent application should be refused under Art. 53(a).

As to (1): since destruction is one example of 'use', this is contrary to morality under the Rule. But obviously part of the task of the Enlarged Board will have to be to think about the *soundness* of the Rule (as there is no necessary parallel between law and morality). Although we cannot elaborate on this here,[6] this is one of the key issues.

As to (2), it seems that arguments, aimed at morally 'neutralizing' the use of hES cells, based on a distinction between the 'stages' of *deriving* and *using* stem cells, even if different actors are involved, are unconvincing since such a distinction is hardly justifiable. Research involving the use of hES cells and research involving the derivation of hES cells are inextricably linked. This link implies a *moral complicity*.[7] Those who derive the cells and those who use the cells share the *intention* that the cells are used to reach the same goals. Both *know* that using the cells necessarily required, at some stage, destroying embryos. For these reasons, those who use hES cells are morally complicit in the process of deriving the cells. If the act of destruction raises moral concerns, then exploitation is at least morally problematic.

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[6] See e.g. Holland, S et al. (eds) *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*. US, Mass: MIT Press; 2000.

[7] Bratman, M E, Ethics **104**:97-113(1993).