

## [biblio.ugent.be](http://biblio.ugent.be)

The UGent Institutional Repository is the electronic archiving and dissemination platform for all UGent research publications. Ghent University has implemented a mandate stipulating that all academic publications of UGent researchers should be deposited and archived in this repository. Except for items where current copyright restrictions apply, these papers are available in Open Access.

### **This item is the archived peer-reviewed author-version of:**

Title: Assessing the morality of the commercial exploitation of inventions concerning uses of human embryos and the relevance of moral complicity: Comments on the EPO's WARF decision

Authors: Sigrid Sterckx & Julian Cockbain

In: SCRIPTed – A Journal of Law, Technology & Society 7(1), pp. 83-103, 2010.

### **To refer to or to cite this work, please use the citation to the published version:**

Sterckx, Sigrid & Cockbain, Julian (2010). Assessing the morality of the commercial exploitation of inventions concerning uses of human embryos and the relevance of moral complicity: Comments on the EPO's WARF decision. *SCRIPTed - A Journal of Law, Technology & Society* 7(1), 83-103. DOI: 10.2966/scrip.070110.83

*Volume 7, Issue 1, April 2010*

**ASSESSING THE MORALITY OF THE COMMERCIAL  
EXPLOITATION OF INVENTIONS CONCERNING USES OF  
HUMAN EMBRYOS AND THE RELEVANCE OF MORAL  
COMPLICITY: COMMENTS ON THE EPO'S WARF DECISION**

*Sigrid Sterckx\* and Julian Cockbain†*

**Abstract**

In late 2008, the Enlarged Board of Appeal of the European Patent Office (EPO) reached a decision supporting the rejection of a patent application on human embryonic stem cells filed by the Wisconsin Alumni Research Foundation (WARF). This article comments on some of the shortcomings of the decision. The key legal provisions at issue in this case were Rule 28(c) EPC, which forbids the granting of patents in respect of biotechnological inventions which concern uses of human embryos for industrial or commercial purposes, and Article 53(a) EPC, the morality provision of the European Patent Convention. The Board rightly found the Rule to exclude WARF's claims (but, we argue, left a "deposit loophole"). However, one of the issues the Board had to address was whether the Rule might not apply because it extended the scope of prohibited subject matter beyond that prohibited by the Article. We argue that, unless the Article had been found to exclude patentability, the applicability of the Rule could not be determined. Even though at the oral hearing before the Board, both WARF and the EPO President identified the question whether the Article (the morality provision) constituted a barrier to patentability as the core issue in this case, the Board astonishingly decided that this question did not need answering (even though the Board did hint at the basis for the answer). We argue that this is a major shortcoming of the decision. Finally, we comment on the relevance of moral complicity to the question of patentability.

DOI: 10.2966/scrip. 070110.83



© Sigrid Sterckx and Julian Cockbain 2010. This work is licensed under a [Creative Commons Licence](#). Please click on the link to read the terms and conditions.

---

\* Professor of Ethics, Vrije Universiteit Brussel and Universiteit Gent, Belgium

† European Patent Attorney, Dehns, Oxford, United Kingdom. The views expressed herein are those of the author alone.

## 1. Introduction

On 25 November 2008, the Enlarged Board of Appeal of the European Patent Office handed down its decision in relation to European Patent Application No 96903521.1 of Wisconsin Alumni Research Foundation, Decision G-2/06.<sup>1</sup>

The Enlarged Board of Appeal, in our view correctly, decided that it was necessary to reject the WARF claims to compositions containing human embryonic stem cells (hES cells). The reasoning underlying Decision G-2/06 is however insufficient. This article comments on some of the shortcomings of the Decision and issues arising from it.

## 2. Background

The WARF patent application<sup>2</sup> related to an invention by James Thomson and included claims<sup>3</sup> covering compositions containing pluripotent hES cells.<sup>4</sup> At the time the WARF application was filed in 1996, such compositions could only be made by a process that involved the destruction of human embryos. The Examining Division of the EPO argued that the rejection of the claims was required by Rule 23d(c) [meanwhile renumbered as Rule 28(c)] and Article 53(a) of the European Patent Convention (EPC), the law governing the grant of European Patents by the EPO. Rule 28(c) and Article 53(a) EPC (see below) will, for the sake of convenience, simply be referred to as “the Rule” and “the Article” throughout much of this article.

Article 53(a) EPC reads as follows:

European patents shall not be granted in respect of ... inventions the commercial exploitation of which would be contrary to “ordre public” or morality; such exploitation shall not be deemed to be so

---

<sup>1</sup> European Patent Office, “G-2/06: Use of embryos/WARF”, (2009) *Official Journal of the European Patent Office* 306. A comment on this decision is made by P Treichel, “G2/06 and the verdict of immorality” (2009) 40 *IIC* 450-471. It is to be noted that, while Treichel quotes extensively from submissions made by the President of the EPO, he does not draw attention to his involvement as a member of the EPO legal team representing the President of the EPO at the oral hearing before the Enlarged Board of Appeal in the WARF case.

<sup>2</sup> J Thomson, *Primate Embryonic Stem Cells*, International Patent Application Publication Number WO96/22362 (Geneva: World Intellectual Property Organization, 1996).

<sup>3</sup> Claim 1 of the WARF application, at the time of the hearing before the EPO Technical Board of Appeal, read “[a] cell culture comprising 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”: European Patent Office, (2009), see note 1 above, at 309.

<sup>4</sup> By ‘pluripotent’ it is meant that the cells may differentiate to form many different cell types, but not all possible cell types. Cells capable of differentiating to form all possible cell types, such as fertilised egg cells, are referred to as ‘totipotent’. Pluripotent cells, such as those claimed by WARF, do not have the potential to develop into a human being. Any consideration of the potentiality argument thus resides in the potential of the starting material (i.e. human embryos) for obtaining the pluripotent cells (i.e. human embryos) rather than in the potential of the pluripotent hES cells themselves.

contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.<sup>5</sup>

Rule 28(c) EPC reads as follows: “[u]nder 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.”<sup>6</sup>

WARF appealed the rejection of their application and the Technical Board of Appeal of the EPO hearing their appeal referred four questions (see below) relating to the interpretation of the Rule and the Article to the Enlarged Board of Appeal.<sup>7</sup> The Enlarged Board of Appeal invited interested parties to comment, and, after many hundreds had done so, held a hearing in June 2008 at which WARF and the President of the EPO presented their arguments. Besides the four questions referred by the Technical Board of Appeal, the Enlarged Board of Appeal also had to respond to a request by WARF that the interpretation of wording in the Rule be referred to the European Court of Justice.

We have discussed elsewhere the points at issue in the WARF case, as well as the points raised at the oral hearing in June 2008.<sup>8</sup> This article is concerned primarily with the approach of the Enlarged Board of Appeal to the morality question posed by the Rule and the Article. We can therefore dispose of the question of the reference to the European Court of Justice by simply mentioning that the Enlarged Board of Appeal, to our minds correctly, found no basis for complying with WARF's request.<sup>9</sup>

---

<sup>5</sup> European Patent Office, *Convention on the Grant of European Patents (European Patent Convention)*, 13<sup>th</sup> ed (Munich: European Patent Office, 2007), at 80.

<sup>6</sup> *Ibid.*, at 256-258.

<sup>7</sup> European Patent Office, “T-1374/04: Stem cells/WARF” (2007) *Official Journal of the European Patent Office* 313.

<sup>8</sup> S Sterckx, “The European Patent Convention and the (non)patentability of Human Embryonic Stem Cells: the WARF Case” (2008) *Intellectual Property Quarterly* 478-495; S Sterckx, “The WARF/Stem Cells Case Before the EPO Enlarged Board of Appeal” (2008) 30 *European Intellectual Property Review* 535-537.

<sup>9</sup> The reference to the European Court of Justice (ECJ) is dealt with in paragraphs 2 to 11 of the Reasons of the Enlarged Board of Appeal (EBA) decision (see note 1 above, at 317-321). In paragraph 8, the EBA commented that it “had not been made aware of any precedent for [the Board for] asking the ECJ for a consultative opinion and it must be questionable whether the ECJ would entertain such a request in a situation where it would be unclear as to who would be entitled to make submissions to the ECJ on any questions submitted”. Nonetheless, a referral to the ECJ in a similar matter has been made by the Bundesgerichtshof (BGH) in the Brüstle case (German Patent No 19756864). Thus the BGH in late 2009 asked the ECJ to interpret Article 6 of EU Directive 98/44/EC, which corresponds to Rule 28(c) EPC, in three respects: firstly what is meant by “human embryos”; secondly whether “use of embryos” is fulfilled if obtaining the stem cells to be used according to an invention necessarily involves the destruction of blastocysts (the multi-cell stage in the progression from a zygote to a foetus at which pluripotent hES cells are harvested); and thirdly whether *all* exploitation, including for research or therapeutic purposes, should be considered to be “commercial” use within the meaning of Art 6 of the Directive. Unlike the EPO, the BGH is entitled to refer points to the ECJ for interpretation; however, the answers given by the ECJ may not be fully relevant to the EPC, not least since the German patent law expressly refers to the German Embryo Protection Act (*Embryonenschutzgesetz*).

The four questions put to the Enlarged Board of Appeal may be paraphrased briefly as follows:<sup>10</sup>

1. Since the Rule was not enacted until after the WARF application was filed, did it apply to the application?
2. If the Rule did apply, did it deny patentability to compositions of pluripotent hES cells, the production of which necessarily involved destruction of a human embryo?
3. If the answer to Question (1) or (2) was no, did the Article deny patentability to compositions of hES cells?
4. Would the answer to Question (2) or (3) have been different if, after the WARF application was filed, it had become possible to produce the claimed hES cell compositions without having to destroy human embryos?

Again, given the focus of this article, we can dispose of Question (4) by simply confirming that the Enlarged Board of Appeal's answer, rightly in our view, was “no”. So in the remainder of this article we will comment on the treatment by the Enlarged Board of Appeal of Questions (1), (2) and (3).

### 3. Does the Rule Apply?

Since the WARF patent application predated the enactment of the Rule, it was necessary to address the question as to whether the Rule applied to this application at all. Not surprisingly, the Enlarged Board of Appeal answered “yes” to this question, commenting that “[a]s the Appellant [WARF] itself agrees with this answer, as does the President of the EPO and the vast majority of the *amicus curiae* briefs, nothing more need be said”.<sup>11</sup>

This disposal of Question (1) is not however as innocent as it seems. Had the answer been “no”, it would have been a direct criticism by the Enlarged Board of Appeal of the actions of the President of the EPO in enacting the Rule.<sup>12</sup> Thus, it was

---

<sup>10</sup> The four questions set to the EBA read as follows: (1) Does Rule [28(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 [28(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)?

<sup>11</sup> European Patent Office (2009), see note 1 above, at 322.

<sup>12</sup> Rule 28 EPC lists instances of inventions contrary to Art 53(a) EPC. However, at the time the Rule was introduced at the behest of the EPO President, in September 1999, Art 53(a) EPC excluded inventions “the exploitation [i.e. not limited to commercial exploitation] of which would be contrary to ‘ordre public’ or morality” and it is arguable that an invention whose commercial exploitation was so contrary might not, if it had non-commercial applications which were not so contrary, have been excluded under that wording of the Article. If that were to be the case then the Rule would have excluded more than the Article, so limiting the scope of inventions patentable under the EPC without the approval of all EPC member states. Nonetheless, in T-315/03, the EPO Technical Board of Appeal had commented in relation to the Rule that “since it is unimaginable that cases within those four

foreseeable that the President would take the position that a “yes” answer was correct. Likewise, since the Rule *prima facie* provides a clearer basis than the Article for rejecting the claims of WARF, the vast majority of the *amicus curiae* briefs which were opposed to the patenting of hES cells obviously also supported a “yes” answer. WARF's support for a “yes” answer to Question (1) was inherently qualified by its allegation that the Rule did not in fact require a rejection of its claims - i.e. that the answer to Question (2) should be “no”.

One must therefore turn to the Enlarged Board of Appeal's justification for its “yes” answer to Question (1). This is set out in the Decision as follows:

The introduction of this new chapter [i.e. of the Rule] without any transitional provisions, can only be taken as meaning that this detailed guidance [i.e. that provided by the Rule] on what was patentable and un-patentable was to be applied as a whole to all then pending applications.<sup>13</sup>

This seems indisputable - the Rule *was* intended to apply. However, it is a separate question as to whether it may *legitimately* apply since Article 164(2) EPC provides that where a Rule and an Article conflict, the Article must prevail, i.e. that if the Rule excludes something from patentability that is not excluded by the Article then the Rule cannot be applied.

The Enlarged Board of Appeal continued: “[i]t has not been argued that Rule 28 ... EPC took away the possibility to patent anything which had previously been regarded as patentable under Article 53(a) EPC.”<sup>14</sup>

This position was supported by the Enlarged Board of Appeal's statement that:

*Already by 1984* (see Dolder),<sup>15</sup> instrumentalization of the human body (as opposed to parts of it), thus degrading it to an object of technology, had been considered as a barrier to patentability. There is no indication that the commercial exploitation of human embryos was ever regarded as patentable.<sup>16</sup>

This quote in effect contains the *entire* reasoning of the Enlarged Board of Appeal in relation to the morality aspect of this case. We will come back to it, and to the Dolder article, but it is worth first identifying four points the Enlarged Board of Appeal is relying on here:

---

categories [i.e. of Rule 28 EPC] would not always have been considered under Article 53(a) EPC, it would be incorrect to say that the new Rule broadens the law as regards the exclusion of such cases”: European Patent Office, “T-315/03: Transgenic animals/HARVARD” (2006) *Official Journal of the European Patent Office* 15, at 42-43.

<sup>13</sup> European Patent Office (2009), see note 1 above, at 321-322.

<sup>14</sup> *Ibid.*

<sup>15</sup> F Dolder, “Schranken der Patentierbarkeit biotechnologischer Erfindungen nach dem Europäischen Patentübereinkommen” 1984 *Mitteilungen der deutschen Patentanwälte* 1-7. The title translates as “Barriers to patentability of biotechnological inventions under the EPC”.

<sup>16</sup> European Patent Office (2009), see note 1 above, at 322 (emphasis added).

- i) That instrumentalisation of the human body is sufficiently wrong as to constitute a bar to patentability;
- ii) That commercial exploitation of human embryos has never been regarded as patentable;
- iii) That Article 53(a) of the EPC, which dates from 1973, is adequately explained by an article from 1984 which focuses on law and legal writings, in particular relating to the position in Germany and Switzerland, rather than on the *travaux préparatoires* relating to the EPC; and
- iv) That the state of European legal opinion *in 1984* is relevant to the interpretation of a law dating from 1973.

The question as to whether the Rule could not apply because it extended the scope of prohibited subject matter beyond that prohibited by the Article was reverted to by the Enlarged Board of Appeal when it stated that:

Addressing the relationship of Rule 28(c) ... EPC to Article 53(a) EPC, the Appellant [WARF] argues that, if the Rule is read to exclude inventions such as the one underlying this case, the Rule would go beyond Article 53(a) EPC and thus be *ultra vires* (Article 164(2) EPC)...The Enlarged Board of Appeal does not share the opinion that such a reading makes Rule 28(c) ... EPC *ultra vires*. ... [I]t is important to point out that it is not the fact of the patenting itself that is considered to be against *ordre public* or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of a human embryo) that has to be considered to contravene these concepts.<sup>17</sup>

It will be appreciated that such comments add nothing to any analysis as to whether or not the Rule extends beyond the Article, as that can *only* be determined by a *separate* analysis as to whether the Rule and the Article, respectively, each constitutes a barrier to patentability of the subject matter claimed by WARF. Unless such an analysis is done and the Article is found to exclude patentability, the applicability of the Rule quite simply *cannot* be determined, for, as noted above, Article 164(2) EPC states that where Rules and Articles conflict the Articles prevail. To decide whether Rule 28(c) conflicts with Article 53(a) by excluding more than the Article, the WARF subject matter *must* be assessed under the Article. Moreover, this position was indirectly acknowledged at the hearing in June 2008, when both WARF and the President of the EPO identified Question (3) (i.e. Does the Article constitute a barrier?) as the core issue in this case.

Thus, to summarise this section, the Enlarged Board of Appeal concluded that the Rule did apply to the WARF application but it did so without a full analysis and comparison of the scope of the Rule and of the Article. Whether the Rule excludes the WARF claims will be addressed in the next section. The topic of the subsequent section is whether the Article precludes patentability.

---

<sup>17</sup> *Ibid*, at 328-329.

#### 4. Does the Rule Preclude Patentability?

Given that the WARF claims were not directed to the process of producing the cells, the next question for the Enlarged Board of Appeal was whether the Rule denied patentability to compositions of pluripotent hES cells, the production of which necessarily involved destruction of a human embryo. The Rule reads as follows: “[u]nder Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern ... uses of human embryos for industrial or commercial purposes.”<sup>18</sup>

This Rule corresponds to former Rule 23d(c) EPC which was introduced into the EPC in September 1999 by a decision of the Administrative Council of the EPO and which corresponds with Article 6(2)(c) of the EU *Directive on the legal protection of biotechnological inventions* (1998).

The Enlarged Board of Appeal looked to the *travaux préparatoires* relating to the abovementioned EU Directive and concluded that:

On its face, the provision of Article 6(2)(c) of the Directive and thus also of Rule 28(c) ... EPC is straightforward and prohibits the patenting if a human embryo is used for industrial or commercial purposes. Such a reading is also in line with the concern of the legislator to prevent a misuse in the sense of a co-modification of human embryos ... and with one of the essential objectives of the whole Directive to protect human dignity.<sup>19</sup>

Here it must be emphasised that it is the legislators responsible for the EU Directive who are being referred to, and not those responsible for Article 53(a) EPC. The EU Directive essentially represented a compromise in that it confirmed as patentable certain subject matter that had been recognised by the EPO to be patentable (despite the concerns of many that it was excluded from patentability by Articles 52 and 53 EPC). Other subject matter was specifically deemed by the EU (the membership of which is not coextensive with the set of countries party to the EPC), to be unpatentable. The provisions of the EU Directive on patentability and un-patentability were incorporated into the EPC Rules – the implementing regulations of the EPC - by action of the EPO President in 1999 without ratification by EPO Member States. Any effect that they may have on the scope of the subject matter that may be legitimately patented under the Articles of the EPC is therefore unenforceable.<sup>20</sup>

WARF argued that its invention would only fall under the Rule’s prohibition on patentability if a use of human embryos was *claimed*, and that the claims in its patent application did not recite any such use. In reply, the Enlarged Board of Appeal stated that:

What needs to be looked at is not just the explicit wording of the claims but the technical teaching of the application as a whole as to

---

<sup>18</sup> European Patent Office (2007), see note 5 above, at 257-258.

<sup>19</sup> European Patent Office (2009), see note 1 above, at 324.

<sup>20</sup> Amendments to the Articles of the EPC require ratification by all the member states of the EPC - amendments to the Rules do not.



how the invention is to be performed. ... Since in the [WARF] case ... the only teaching of how to perform the invention to make human embryonic stem cell cultures is the use (involving their destruction) of human embryos, this invention clearly falls under the prohibition of Rule 28(c) ... EPC.<sup>21</sup>

In its welcome acknowledgement that the *intent* of the law should be taken into account when law is interpreted, the Enlarged Board of Appeal went on to state that:

To restrict the application of Rule 28(c) ... EPC to what an applicant chooses explicitly to put in his claim would have the undesirable consequence of making avoidance of the patenting prohibition merely a matter of clever and skilful drafting of such claim.<sup>22</sup>

As an aside, however, we might draw the reader's attention in this regard to two earlier decisions of the Enlarged Board of Appeal, G-5/83 *Eisai*<sup>23</sup> and G-1/04 *Diagnostic methods*,<sup>24</sup> which suggest that a more standard response of the EPO might be to look favourably on the avoidance of patenting prohibitions by clever and skilful claim drafting. These two cases demonstrate that the prohibitions on patenting of methods of therapy and diagnosis set out in Article 53(c) EPC may be evaded: in the first case, by claiming the use of a known drug for the manufacture of a known composition for use in the new method of therapy; and, in the second case, by claiming all steps in a diagnostic procedure except the step of diagnosis itself. The possibility that the intent of the legislators may be circumvented by clever and skilful actions is currently the subject of another case pending before the Enlarged Board of Appeal, case G-3/08 *Computer programs*,<sup>25</sup> in which the President of the EPO has referred questions relating to the exclusion from patentability of computer programs under Article 52(2)(c) EPC.<sup>26</sup>

In order to answer Question (2), the Enlarged Board of Appeal had to investigate whether the WARF invention concerned a use of human embryos for industrial or commercial purposes. Even though at the time of filing of the WARF application Thomson had not yet prepared any hES cell cultures of the type claimed, it was apparent to the reader of the application - because a patent application is required to

---

<sup>21</sup> European Patent Office (2009), see note 1 above, at 326.

<sup>22</sup> *Ibid.* See also F Dolder, see note 15 above, at 3.

<sup>23</sup> European Patent Office, "G-5/83: Second medical indication/EISAI" (1985) *Official Journal of the European Patent Office* 64.

<sup>24</sup> European Patent Office, "G-1/84: Diagnostic methods" (2006) *Official Journal of the European Patent Office* 334.

<sup>25</sup> European Patent Office, "G-3/08: Letter of 22 October 2008 from Alison Brimelow, President of the European Patent Office, to Peter Messerli, Chairman of the EPO Enlarged Board of Appeal" (2008), available at [http://documents.epo.org/projects/babylon/eponet.nsf/0/B89D95BB305AAA8DC12574EC002C7CF6/\\$File/G308\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/B89D95BB305AAA8DC12574EC002C7CF6/$File/G308_en.pdf) (last accessed on 19 Jan 2010).

<sup>26</sup> See S Sterckx and J Cockbain, "The Patentability of Computer Programs in Europe: An Improved Interpretation of Art 52(2) and (3) EPC" (2010) *The Journal of World Intellectual Property*, forthcoming (published online 9 Dec 2009, DOI: 10.1111/j.1747-1796.2009.00390.x).

describe how the claimed invention may be put into effect - that to make and commercially exploit an hES cell culture using the teachings of the WARF application would require the destruction of human embryos.

Since the destruction of human embryos was required in order to derive the claimed hES cell cultures, and since destroying embryos is clearly an example of *using* embryos, it could not reasonably be denied that the WARF invention concerned a “use of human embryos” – regardless of the wording of the claims. Neither could it be said that the use was not “for industrial or commercial purposes”, the additional criteria for exclusion by the Rule, since “the intention of commercialization ... is necessarily linked to a patent application” – as rightly noted by the now EPO Board of Appeal member Rainer Moufang.<sup>27</sup> Once the Rule had been deemed to apply, therefore, the answer to Question (2) was clearly affirmative.<sup>28</sup>

It should come as no surprise, therefore, that the Enlarged Board of Appeal found the Rule to exclude the WARF claims:

A claimed new and inventive product must first be made before it is used. Such making is the ordinary way commercially to exploit the invention and falls within the monopoly granted, as someone having a patent application with a claim to this product has on the grant of the patent the right to exclude others from making or using such product. Making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research. On the facts which this Board must assume in answering the referred question 2, making the claimed product involves the destruction of human embryos. This use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the

---

<sup>27</sup> R Moufang, “Patenting of Human Genes, Cells and Parts of the Body: the Ethical Dimensions of Patent Law” (1994) 25 *IIC* 487-515, at 504.

<sup>28</sup> Torremans however has argued “whilst patents that directly claim *repetitive* use of the human embryo in a technical process would be excluded from patentability, patents that claim products which derive from a human embryo would not contravene the morality clause [of the Rule]”: P Torremans, “The construction of the Directive’s moral exclusions under the EPC” in A Plomer and P Torremans (eds) *Embryonic stem cell patents: European law and ethics* (Oxford: Oxford University Press, 2009), 141-171, at 163 (emphasis added). This analysis, under which the WARF claims would have been acceptable, seems to be based on arguments in A Plomer, “Towards systemic legal conflict: Article 6(2)(c) of the EU Directive on biotechnological inventions” in *ibid*, 173-202, at 189-193, and A Plomer et al, *Stem Cell Patents: European Patent Law and Ethics Report* (Brussels: European Commission, 2006), at 74. Thus Plomer et al equate “uses ... for industrial and commercial purposes” in Art. 6(2)(c) of Directive 98/44/EC with the acts from which a patentee may use a patent to exclude others according to Recital 14 of Directive 98/44/EC and conclude that “uses ... for industrial and commercial purposes” must be given a construction at variance with the “industrial” of “industrial application” in Art 57 EPC (*ibid*). The authors therefore suggest that “the terms ‘industrial and commercial purposes’ ... should thus be read as precluding the granting of a patent on inventions which as such involve either the direct, repetitive use of a human embryo as a raw material in a mechanical, chemical or technical process and/or any uses involving a trade in human embryos *per se*” (*ibid*). This analysis however ignores the effect of the words “the invention concerns” which, as the Enlarged Board of Appeal has found, mean that one must look beyond the definition of the invention in the claims of the patent application. Moreover, simply because an industrial process may involve performance of one step (e.g. genetic modification of an organism which is to be cultured to produce a desired end product) a *single* time does not mean that that step is not part of the industrial process.

claimed invention, and thus violates the prohibition of Rule 28(c) ... EPC.<sup>29</sup>

For the “reasons” quoted above, the Enlarged Board of Appeal concluded that the prohibition of the Rule remained within the scope of the Article and that in view of that result it was:

... not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of *ordre public* or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain stem cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess *ordre public* or morality under Article 53a EPC. The legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre.<sup>30</sup>

Once again, it should be emphasised that the Enlarged Board of Appeal *did not analyse the scope of the Article* in order to confirm that the legislators of the EU Directive and hence of the Rule remained within the ambit of the Article. The Board had thereby manoeuvred itself into a position where there was “no room for manoeuvre” and indeed no need to discuss in any detail the implications of the Article.

Before turning to the questions of morality at issue in the WARF case, i.e. to Question (3), we must quote the precise words used by the Enlarged Board of Appeal in answering Question (2):

Rule 28(c) ... EPC forbids the patenting of claims directed to products 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, even if the said method is not part of the claims.<sup>31</sup>

On the face of it, it was a hearteningly moral decision. Closer inspection however is needed. Patent attorneys will read these words carefully. If a product, for example an hES cell culture, is produced by a production method which *initially* involves the destruction of a human embryo, then if *further* production (e.g. by incubation of the derived hES cell culture) need not involve further destruction of human embryos after the patent application filing date, it could be argued that patentability is *not* excluded by the wording quoted above. A patent applicant may readily ensure that such further production without destruction is possible by depositing a sample of the culture at a recognised depository no later than the filing date of the patent application. Our

---

<sup>29</sup> European Patent Office (2009), see note 1 above, at 327.

<sup>30</sup> *Ibid*, at 329-330.

<sup>31</sup> *Ibid*, at 331-332.

conclusion is that the Enlarged Board of Appeal may again have pointed out to patent applicants how they may circumvent a patenting prohibition of the EPC, viz. by what we term the “deposit loophole”.

Whether such a deposit circumvents the exclusion depends upon whether and to what extent *actions in the history of the making of an invention* must be considered to be part of the commercial exploitation of the invention. Our suspicion is that acts which do not have to be repeated following the filing of the patent application would *not* be considered relevant by the EPO. The basis for this suspicion is the following passage from the Enlarged Board of Appeal Decision:

In a case like the present one, where the teaching to obtain the embryonic human stem cells claimed is confined to the use (involving their destruction) of human embryos, the argument raised by the Appellant [WARF], namely that the exclusion from patentability would go much too far if one would consider all the steps preceding an invention for the purposes of Rule 28(c) ... EPC, *is not relevant*.<sup>32</sup>

However, this issue *is* relevant. The way in which an invention is made or put into effect must be taken into consideration when determining whether the Article applies. As Moufang has argued:

... the exclusion clause [Article 53(a) EPC] may also apply with respect to inventions, the development of which was decisively characterized by an ethically dubious procedure. ... [T]he invention should be examined as regards its possibly unethical content according to its dynamics, i.e. in its different stages. Despite the far-reaching consequences of such an argumentation, there are indeed good reasons to take into account the development of an invention.<sup>33</sup>

It is obvious why WARF wanted the EPO to consider the destruction of the embryos as a step *preceding* the invention rather than as one of the stages *in the commercial exploitation* of the invention. By the *form* of its *claim* to the subject matter of its patent application, WARF sought to divert the attention of the EPO away from the core moral issue. As the Enlarged Board of Appeal has confirmed, however, whether or not an application results in exclusion from patentability should not be determined merely on the basis of the words used by the patent applicant to claim the subject matter.

Nor should exclusions from patentability be avoidable merely by the strategic decision-making of the applicant as to the *time of filing*. Let us consider two patent applications for an invention which can only be brought into concrete form by performing a morally dubious step. In the first case, the applicant has filed the patent application *after* performing that step (e.g. destroying human embryos to derive an hES cell culture). In the second case, that step has not yet been performed at the time of filing and the applicant may have no need or intention of doing it (e.g. the intention

---

<sup>32</sup> *Ibid*, at 326-327 (emphasis added).

<sup>33</sup> R Moufang, see note 27 above, at 504 (footnote omitted).

might be to leave the derivation of the culture to a licensee, if one can be found). In the second case, which corresponds to the WARF case, the decision of the Enlarged Board of Appeal would result in the rejection of the patent application, on the basis that any commercial exploitation of the invention would necessarily involve performance of a prohibited step.

If the successful performance of the morally dubious step means that that step need not be repeated, then the perverse result of the decision of the Enlarged Board of Appeal in the WARF case could be that patentability is determined solely by the time of filing. We say “perverse” since the decision might “reward” the applicant who has already performed the morally dubious step and deposited a sample in a culture collection, but “penalise” the one who has not. Given that the overall set of actions required for the commercial exploitation of the invention is in both cases the same, we consider that the decision on patentability should also be the same.

If the “deposit loophole” were to be accepted in principle by the EPO Examiners, they should give careful consideration to whether commercial exploitation of the claimed invention would generally involve use of the deposited sample or whether fresh destruction of human embryos would normally occur after the filing date of the patent application. Any use of the loophole should perhaps be restricted to claims requiring the use of the deposited material rather than of any material “having similar characteristics to those of the deposit”. The morality of the use of hES cell cultures prepared specifically by or for the end user is discussed by Green in connection with the concept of moral encouragement or complicity.<sup>34</sup>

Indeed, where the history of the making of an invention involves a morally dubious step, we would submit that one of the key questions to be addressed is *the extent of any complicity* between the performer of that step and the patent applicant. Complicity is relevant in the determination of the actions that fall within the ambit of

---

<sup>34</sup> Green has made an interesting analysis of different forms of complicity or “moral encouragement”, as he terms it, which he discusses with regard to human embryonic stem cell research. He distinguishes between three forms of moral encouragement. First, “direct encouragement through agency”, where one person asks someone else to commit a wrongful deed and benefits from her agent’s wrongdoing, although she is not directly involved in the performance of the wrongdoing. In these cases, moral responsibility obviously cannot be escaped by the first person. The second form is “direct encouragement through the acceptance of benefit”, where one person performs a wrongful deed and, for some reason, another (unconnected) person experiences a benefit as a result of that deed, and decides to enjoy the benefit rather than to forego it. Such toleration of the wrongdoing then encourages the first person to repeat the wrongful act. In this second type of cases, the wrongdoer may receive rewards from those he has benefited. As Green notes, “this kind of benefiting from others’ wrongful deeds is morally objectionable and inadmissible. Although less pernicious than wrongdoing through agency, it provides a powerful incentive for misconduct”: R Green, “Benefiting from ‘evil’: An incipient moral problem in human stem cell research” (2002) 16 *Bioethics* 544-556, at 549-550. The third kind of moral encouragement Green identifies is “indirect encouragement through the legitimization of a practice”. Like in the second case, no agency need be involved. However, it differs from the second form of moral encouragement in that it “does not require the existence of an identifiable wrongdoer or wrongdoers who are encouraged to repeat their wrongful deeds as a result of one’s acceptance of the benefits of their misconduct. It is not the immediate impact of one’s acceptance [of benefits] on identifiable wrongdoers that concerns us in this case, but the future impact on people generally of the public rule of conduct that is created by one’s acceptance of the benefits of wrongdoing. ... [S]ome benefits may be wrong to accept even in cases where we do not (or cannot) directly encourage the wrongdoers who created them, for in doing so we implicitly legitimize a morally repellent practice”. (*Ibid*, at 550-551) In the present context, the first and second kinds of moral encouragement seem to be those of particular concern.

the “commercial exploitation” of an invention mentioned in the EPC. Moreover, if the grant of a patent may be seen as official encouragement (i.e. by or on behalf of the state) to exploit an invention and thereby derive benefit, then the prospect of a grant of patent in the absence of any consideration of complicity may serve as official encouragement of morally dubious behaviour which might be hoped to lead to patentable and profitable inventions. The field of human embryo research had a recent very high profile example of morally dubious behaviour in the example of Dr Hwang Woo-suk.<sup>35</sup> We will come back to the question of complicity below.

To conclude this section, we would submit that the Enlarged Board of Appeal rightly argued that the subject matter claimed by WARF concerned a use of human embryos for industrial or commercial purposes. Nonetheless, the Board also stated that the scope of the Rule did not extend beyond that of the Article, without however having analysed this issue — an analysis requiring investigation of the Article.

The interpretation of the Rule by the Enlarged Board of Appeal supported the rejection of the WARF application, on grounds that the invention for consideration was the invention *as a whole* as described in the patent application and not simply that defined by the applicant in the *claims*. The application of the Rule thus required a consideration of the *full* range of acts required to make or perform the claimed invention. The position adopted by the Enlarged Board however opened the “deposit loophole”, raising the question as to the extent of the freedom from complicity in a morally dubious action that is necessary before patentability can be acknowledged.

We must now turn to the issue of the implications of the Article for the WARF patent claims.

## 5. Does the Article Preclude Patentability?

Article 53(a) EPC sets out the basis for the refusal of European patent applications relating to ethically dubious subject matter. More specifically it states that:

European patents shall not be granted in respect of ... inventions the *commercial exploitation* of which would be 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.<sup>36</sup>

It is important to note that Article 53(a) EPC is *not* concerned with the morality of *patenting* the invention or even with the morality of *performing* the invention - the point at issue is the morality of *commercially exploiting* the invention. Many acts, for example organ “donation”, are widely deemed to be morally acceptable when no financial exchange is involved but morally unacceptable when performed for financial gain. Likewise, the commercial exploitation of an invention may be contrary to morality even if the research underlying the invention and the performance of the invention outside a commercial context are not. This is a crucial point, which is clearly explained by Moufang:

---

<sup>35</sup> For a series of detailed reports on this case in the scientific journal *Nature*, see: <http://www.nature.com/news/specials/hwang/index.html> (last accessed on 1 March 2010).

<sup>36</sup> European Patent Office (2007), see note 5 above, at 80 (emphasis added).

[I]t is conceivable that the elementary conflict with the legal system derives from the intention of commercialization that is necessarily linked to a patent application. In such a case the legal system would disapprove not of the innovation itself or of its working in practice, but specifically of the economic exclusionary position afforded by the patent with regard to the particular innovation at issue.<sup>37</sup>

... a broad interpretation of the term “exploitation” in Art. 53(a) EPC must be applied: Even if the concrete use of the invention may possibly be justified from an ethical point of view, the sole circumstance that an exclusive right will be granted for it for the purpose of commercialization may violate fundamental ethical principles.<sup>38</sup>

Question (3) for the Enlarged Board of Appeal was whether the WARF claims would be excluded by the Article. Astonishingly, and in spite of the fact that both WARF and the President of the EPO had emphasised that Question (3) addressed the core of the issue, the Enlarged Board of Appeal simply decided that “Question 3 does not need answering”.<sup>39</sup>

In fact the Enlarged Board of Appeal *did* comment on the scope of the Article as far as it is relevant to the WARF case. Its comments only appear in the passage quoted above referring to Dolder:<sup>40</sup>

Already by 1984 (see Dolder<sup>41</sup> ...), instrumentalization of the human body (as opposed to parts of it), thus degrading it to an object of technology, had been considered as a barrier to patentability. There is no indication that the commercial exploitation of human embryos was ever regarded as patentable.<sup>42</sup>

The other comments of the Enlarged Board of Appeal regarding morality relate to the Rule or simply confirm that, in the opinion of the Board, the prohibition of the Rule falls within the ambit of the Article. As we noted earlier, there was no separate analysis as to whether the WARF application contravenes the Article. This is the most serious shortcoming of the Decision of the Enlarged Board of Appeal, for several reasons. For one, as we mentioned earlier, unless such a separate analysis is done *and* the Article is found to exclude patentability, even the *applicability* of the Rule – cf. Question (1) – cannot be determined. In the absence of such an analysis it remains unknown whether a conflict exists between the Rule and the Article – a conflict which would invalidate the Rule.

---

<sup>37</sup> R Moufang, see note 27 above, at 504.

<sup>38</sup> *Ibid*, at 507 (footnotes omitted).

<sup>39</sup> European Patent Office (2009), see note 1 above, at 330.

<sup>40</sup> F Dolder, see note 15 above.

<sup>41</sup> *Ibid*, at 1.

<sup>42</sup> European Patent Office 2009, see note 1 above, at 322.

The Dolder article,<sup>43</sup> despite its interesting contributions to the question of exclusions from patentability as regards the field of biotechnology, *only provides a legal – rather than an ethical– analysis* of patentability with respect to the human body (dead and alive) and parts of it. This is insufficient, as Article 53(a) EPC explicitly states that whether an invention should be excluded from patentability on grounds of morality or ‘ordre public’ must *not* be decided merely on the basis of law or regulation. Law and regulation in EPC member states may be instructive in the context of assessing patent applications under Article 53(a) EPC, but they are certainly not decisive.

Dolder rightly points out that, in continental law, from a perspective of private law, instrumentalisation of the human body with a view to generating economic goods degrades the human body to an *object* (of technology), whereas the legal order accords the position of a *subject* to the human person. He provides detailed references to Swiss and German law when mentioning that, for this reason, the national patent laws of several EPC member states forbade the granting of exclusive rights for instrumental uses of the human body:

The objectified use of the human body as a biological category for the purposes of commercial production of goods degrades it to an object of technology and is thus in profound conflict with the central position as a subject that is accorded to a human being by the civil law. The idea that inventions that contain or presume an objectified use of the human body for the purposes of commercial production of goods cannot be the subject of private exclusive rights has therefore been part of the established state of knowledge of many national patent law systems for many decades.<sup>44</sup>

He argues that the abovementioned central prescription in private law must be transposed to the context of patent law, leading to the non-patentability of *the human body as a structured whole* of cells, tissues and organs and the non-patentability of instrumental uses of the human body, while allowing the patentability of *isolated parts* of the human body.<sup>45</sup>

Where inventions relate to the use of parts of the human body *after death*, Dolder argues that it is decisive to patentability whether the performance of the invention has an impact on the timing of death.<sup>46</sup> He provides no basis for this being the crucial divide between inventions which must be excluded on morality grounds and inventions which are not so excluded.

Dolder also argues that the goal of an ethically motivated exclusion from patentability is to prevent the commercialisation, i.e. the commercial monopolisation, of particular technical teachings. He emphasises this point both in the 1984 article and in the

---

<sup>43</sup> We gratefully acknowledge Kristof Van Assche for his help in analysing this article.

<sup>44</sup> F Dolder, see note 15 above, at 1 (translated from German, footnotes omitted). Translations of extracts from Dolder are kindly supplied by Jane Mann.

<sup>45</sup> *Ibid*, at 3.

<sup>46</sup> *Ibid*, at 6.



*amicus* brief he submitted to the Enlarged Board of Appeal in context of the WARF case:<sup>47</sup>

It is not the actual process of the objectified use of the human body in carrying out a technical teaching that infringes the legal interests protected in Art. 53(a) in the field in question, but the legal process of exercising an exclusive right to this teaching.<sup>48</sup>

The goal of an ethically motivated ban on patenting ... is to prevent the commercialisation, i.e. the commercial monopolisation, of certain technical teachings.<sup>49</sup>

In our view, this interpretation of the Article is incorrect and too narrow. The prohibition laid down in the Article excludes patenting where *commercial exploitation* of the invention, *whether monopolistic or not*, would be contrary to morality. To *limit* the operation of the exclusion to circumstances where commercial monopolisation would be wrong is to say that what is at issue is whether the *patenting* of the invention is wrong. This is not the assessment the Article prescribes. As Moufang<sup>50</sup> indicates, the act of applying for a patent places exploitation of the invention within a commercial context, but the question to be addressed remains whether *commercial exploitation* rather than monopolisation is contrary to morality.

Returning to the “analysis” by the Enlarged Board of Appeal, the Board mentions “instrumentalization of the human body (as opposed to parts of it)” as being considered a “barrier to patentability” already by 1984 (when the Dolder article was published).<sup>51</sup> While there is probably general agreement that instrumentalisation of a conscious human being is wrong, there is no such agreement in relation to “the human body” as such. The widespread acceptability of *post mortem* transfer of human organs, i.e. the use of cadavers as organ sources and hence the instrumentalisation of cadavers, clearly supports this point.

The position that “instrumentalization of the human body (as opposed to parts of it)” might constitute a bar to patentability derives unambiguously from the abovementioned EU *Directive on the legal protection of biotechnological inventions* (1998),<sup>52</sup> an instrument that postdates the Article and that was enacted by a different set of legislators than the member states of the EPC. While we consider that this Directive gives an authoritative insight as to what might and might not be considered morally acceptable within Europe, we must emphasise the fact that it can provide no binding basis for interpreting the Article.

---

<sup>47</sup> F Dolder, “Amicus Curiae Brief Submitted to the Enlarged Board of Appeal of the European Patent Office” (31 Oct 2006), available at <https://register.epoline.org/espacenet/regviewer> (publication number EP0770125) (accessed 19 January 2010).

<sup>48</sup> F Dolder, see note 15 above, at 3 (translated from German).

<sup>49</sup> F Dolder, see note 47 above, at 6 (translated from German).

<sup>50</sup> R Moufang, see note 27 above, at 504.

<sup>51</sup> European Patent Office (2009), see note 1 above, at 322.

<sup>52</sup> See, in particular, Recitals 16, 17, 20 and 21 as well as Article 5(1) and (2) of this Directive.

That “[t]here is no indication that the commercial exploitation of human embryos was ever regarded as patentable”,<sup>53</sup> is clearly not the case. First, WARF *has* been granted equivalent patents in the United States. Second, *Dolder* himself identifies a British patent granted to the National Research Development Corporation (a state institution) with claims to a “human embryo liver cell line”.<sup>54</sup> The derivation of that human embryo liver cell line involved destruction of a human embryo, as is abundantly clear from the statement in this British patent that the “cell line is produced by disaggregating human embryo liver”.<sup>55</sup> Third, we might point out that in 1999 the EPO itself issued European Patent No. 695351 B1<sup>56</sup> which raised issues virtually identical to those raised in the WARF case. This European Patent, often referred to as the ‘Edinburgh patent’, was opposed and in due course maintained in amended form in October 2008, but the fact that the EPO *granted* this patent clearly disproves the statement by the Enlarged Board of Appeal that “[t]here is no indication that the commercial exploitation of human embryos was ever regarded as patentable”.

Thus, the Board’s “analysis” of the applicability of the Article is seriously incomplete. In our view, the Board should have commented on the ethical basis for determining whether an action is contrary to morality, before dismissing the need to answer Question (3). We have indicated elsewhere how such an analysis can be undertaken with regard to the present case and what the outcome might be.<sup>57</sup> As we have argued, the key ethical concept here is human dignity. This is also recognised by the Enlarged Board of Appeal in its discussion of the EU Directive.<sup>58</sup> Moreover, the Enlarged Board has identified the purpose of the Rule as being “to prevent a misuse in the sense of a commodification of human embryos” and “to protect human dignity”<sup>59</sup> as well as to “prevent the commercialization of embryos”.<sup>60</sup> The concept of human dignity is acknowledged by the overwhelming majority of the member states of the EPC and, unlike the concept of human rights, can be argued to apply to human beings at all stages of development and whether dead or alive.<sup>61</sup>

---

<sup>53</sup> European Patent Office (2009), see note 1 above, at 322.

<sup>54</sup> F Dolder, see note 15 above, at 6-7. Incidentally, it might be noted that Professor Dolder himself in his *amicus curiae* brief to the Enlarged Board of Appeal (see note 47 above) argued that the answers to Questions (1) to (4) should be yes, yes, and no, respectively.

<sup>55</sup> A Zuckermann, “Cell Lines and Virus Culture” (1972), British Patent No 1300391, at 1.

<sup>56</sup> A Smith and P Mountford, “Isolation, Selection and Propagation of Animal Transgenic Stem Cells” (1999), European Patent No 0695351 B1, Munich: European Patent Office.

<sup>57</sup> See S Sterckx, “The European Patent Convention and the (non)patentability of Human Embryonic Stem Cells: the WARF Case” (2008) *Intellectual Property Quarterly* 478-495, at 486-493 and the references cited there.

<sup>58</sup> European Patent Office (2009), see note 1 above, at 324-325.

<sup>59</sup> *Ibid.*

<sup>60</sup> *Ibid.*, at 325-326.

<sup>61</sup> See S Sterckx, see note 57 above, at 489-493 and the references cited there. Other interesting sources on issues regarding propertisation, commodification and commercialisation of the human body are: D Beylveled and R Brownsword, *Human Dignity in Bioethics and Bio-law* (Oxford: Oxford University Press, 2001); B Björkman and S Hansson, “Bodily Rights and Property Rights” (2006) 32 *Journal of Medical Ethics* 209-214; S Holland, “Contested Commodities at Both Ends of Life: Buying and Selling Gametes, Embryos and Body Tissues” (2001) 11 *Kennedy Institute of Ethics Journal*, 263-284; B Parry, “Entangled Exchange: Reconceptualising the Characterisation and Practice of Bodily

To summarise this section, while stating that since the WARF claims could be rejected under the Rule it was not necessary to consider the Article, the Enlarged Board of Appeal nonetheless hinted that the basis for rejecting the WARF claims under the Article would be that commercial exploitation of the claimed subject matter would involve commercialisation and commodification of human embryos, which would be a violation of human dignity. Indeed, given that the principles of non-commercialisation and non-commodification are key dimensions of human dignity, and that human dignity applies to the embryo,<sup>62</sup> the subject matter of the WARF patent application clearly contravenes the Article, since obtaining the patent would have allowed WARF to reap financial reward from the use of human embryos.

When discussing Question 1 above (Does the Rule apply?), we explained that no answer could be given to this question until both Questions 2 and 3 had been answered. Since the subject matter claimed by WARF is excluded by *both* the Rule and the Article, the answer to Question (1) appears to be yes.

## 6. The Relevance of Complicity to the Question of Patentability

The possible existence of a deposit loophole, as mentioned above, highlights the relevance to patentability of the effect and the extent of any complicity between the person destroying the human embryo and the patent applicant, which may or may not be the same person. In the case of WARF, anyone seeking to commercially exploit the hES cell culture following the instructions in the WARF application, would have to *be* the embryo-destroyer, to *commission* embryo-destruction, or to otherwise *obtain* cultures from someone who had carried out the destruction. Where a deposit of a hES cell culture has been made by the time a patent application is filed, this act of deposit could be by a party acting alone and independently from the patent applicant, by the applicant herself, or by an agent or commercial collaborator of the applicant.

As we indicated above, we see no difference between the WARF position of no prior deposit and the situation in which the applicant both derives and deposits the hES cell culture, or has the culture made and deposited by an agent, or even where the culture is derived and deposited by a current or future commercial collaborator of the applicant. However, if the deposit is not to invalidate a patent application for the culture (by depriving the subject matter of novelty), there must be collaboration or identity between the embryo-destroyer, the culture depositor and the patent applicant, as the culture must be deposited by, but not publicly available before, the patent application filing date.

Complicity *might* be avoided if the culture were to be derived and a deposit to be made independently of the applicant and if the deposited culture were to be publicly available *before* the applicant filed the patent application. In this case, however, any claims in the patent application to the deposited culture itself would lack novelty, although the applicant *might* successfully obtain claims to novel and inventive

---

Commodification" (2008) 39 *Geoforum*, 1133-1144; President's Council on Bioethics, *Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics* (Washington DC: President's Council on Bioethics, 2008); S Wilkinson, *Bodies for Sale: Ethics and Exploitation in the Human Body Trade* (London: Routledge, 2003).

<sup>62</sup> S Sterckx, see note 57 above, at 491.

products derived (only) from the publicly available deposited culture. Nonetheless, even here the question remains as to whether sufficient complicity, in terms of benefiting from wrongdoing,<sup>63</sup> still exists that the commercial exploitation of the invention remains contrary to morality and its patentability remains excluded by the Article.

Some of our actions may be morally right in one context but wrong in another. Patent law gives others, patentees, the right to invoke civil law to prevent us from taking certain actions. On the whole, such actions are generally performed in a commercial context, i.e. they are actions taken for a reward which may include a profit. Patent law does not however restrict the patent holder from invoking civil law to prevent actions taken *only* for profit.

Since some actions may be wrong within a commercial context, but tolerable (probably with other constraints) outside a commercial context, European patent law rightly prevents patent holders from invoking civil law to prevent actions in this “grey” area and leaves control in this zone to the state. This is done by excluding certain subject matter from being patentable. The most obvious area where this takes place is in the field of medical treatment, an area where criminal law serves to provide those constraints and to prevent others from taking actions which may adversely affect the public.

This “grey” zone, where actions may be acceptable, but only with consistently enforced restrictions, is one where we rely upon law to regulate our behaviour. Besides medicine, it most obviously includes aspects of finance, public safety, and education.

Article 53(a) EPC addresses this “grey” zone generally, by saying in effect that patent holders must not have the right to invoke the law to prevent actions which, in carefully, legally controlled areas outside the commercial arena, our society may deem acceptable but which, without that control and within the commercial arena, are deemed to be immoral.

The exclusion of the Article is limited – the requirement is the absolute that *commercial* exploitation be “contrary to morality”, not that it be merely morally dubious or contrary to some theories of morality or even that it must also be immoral outside the commercial arena.

In its original form, i.e. from 1973 to 2007, Article 53(a) EPC *also* excluded from patentability inventions the publication or *non-commercial* exploitation of which were contrary to morality. Since the EPO clearly could not prevent a patent applicant from publishing details of the invention, the “publication” exclusion had no real effect in terms of preventing others from performing immoral acts by civil or private law. The Article, however, and improperly in our mind, allowed a patentee to invoke civil law to prevent others from performing actions that, while immoral within the commercial context, might be deemed to be desirable by the state when performed outside the commercial context, i.e. without charge or on a cost-only basis. By way of example of such actions, we might point to *post mortem* organ donation (as opposed to organ sales).

---

<sup>63</sup> R Green, see note 34 above.

In view of (the current version of) Article 53(a) EPC, it seems to us that the Enlarged Board of Appeal in the WARF case ought to have considered at least the following questions:

- a) Is the use of an entity to generate something that only benefits others, an “instrumentalisation” of that entity?
- b) Can an instrumentalisation of *the human body* be contrary to morality?
- c) Can a *self-aware human being* “morally neutralize” the instrumentalisation of herself by giving consent to the instrumentalisation after being fully informed as to what may result therefrom?
- d) Can the instrumentalisation of a *human embryo* be of moral concern or, even, “contrary to morality”?
- e) If the answer to (d) is yes, what is the *property* of the human embryo, either as an individual or in general, that can raise the concern referred to in (d) above?
- f) Can instrumentalisation of a human embryo be, in a particular context, merely a matter of concern (i.e. in need of being *regulated*), while in another context it is contrary to morality (i.e. in need of being *forbidden*)? An example of this is the use of human embryos for the purpose of fertility treatments versus the use of human embryos in the manufacturing of a commercial product.
- g) Does the context of *commercialisation* make instrumentalisation of the human embryo contrary to morality?
- h) If commercial exploitation of an invention is to escape being labelled as “contrary to morality” as a result of an earlier use of a human embryo, what disjunct or barrier is required between the commercial activity and that earlier use?

Question (c) is not relevant here since human embryos cannot give consent. Questions (a), (b) and (d), to our mind, demand the answer “yes”, while perhaps the most important answer to question (e) is “human dignity”, which is not solely a property of the individual embryo but of embryos as a class. Our answers to questions (f) and (g) are likewise “yes”.<sup>64</sup>

The interesting question is thus question (h). Any action is characterised by its nature (what is done), its location (where it is done), its timing (when it is done), its performer (who it is done by), and its object (what it is performed on). Any pair of related acts is likewise characterised by these five parameters, but also by the *connection* between the acts, which may be material (e.g. some common identity between the objects of the acts) or informational (e.g. information derived from the first act is used to determine parameters for the second act). If the two acts are characterised by the nature of the first being (at least in some context) immoral and the nature of the second, viewed in isolation, being morally acceptable, we would posit that complicity is *not* avoided by a disjunct in timing or location or where there is identity or collaboration between the performers.

---

<sup>64</sup> We cannot elaborate on the arguments underlying these answers here. It may be noted that our answers to (f) and (g) do not appear to diverge essentially from those of the Enlarged Board of Appeal.

This brings us to the *nature of the connection* between the acts. Here, the question at issue is whether complicity can be avoided by the nature of this connection. To our mind, a *material* connection is enough to establish complicity. A stolen object used by someone other than the thief remains a stolen object. Where the connection is only *informational*, then we would argue that the extent of complicity may not be sufficient to cause the second act also to be contrary to morality. If a researcher, reading a publication describing an immoral experiment, can recognise that that information can be deployed to the benefit of humanity, then an invention he makes on the basis of that information should perhaps not be excluded from patentability under Article 53(a) EPC. Consider the example of a researcher designing life jackets for air crew, taking into account the survival times of humans in cold water determined by experimentation on concentration camp inmates. It can be argued that allowing the researcher to use this information sends the signal to other researchers that even information generated by atrocities will be used as long as it can generate a benefit to society. This could lead future researchers to ignore ethical rules in order to promote their research, which would clearly be undesirable. Yet, as Green argues,<sup>65</sup> in exceptional cases, such undesirable effects may be outweighed by some degrees of benefit to society.

Thus, to conclude this section, considering the question of complicity shows that the “deposit loophole” left by the Enlarged Board is highly problematic — in other words, provision of a deposit is clearly not enough to avoid exclusion, under the Article at least.

## 7. Conclusion

The Enlarged Board of Appeal correctly decided to reject the WARF claims. As we have attempted to show, however, the reasoning underlying Decision G-2/06 is insufficient. Moreover, the decision raises two major problems: firstly whether patentability can be achieved by the simple expedient of depositing a cell culture (derived directly or indirectly from human embryos); and secondly to what extent an upstream morally dubious act taints a downstream invention to such an extent as to deny it patentability.

Clearly, achieving clarity on the meaning and the implications of the EPC’s exclusion from patentability of inventions the commercial exploitation of which would be contrary to morality requires further reflection, not only on the meaning of the concept of “morality” but also on what should be understood by “commercial exploitation” of an invention, as well as on questions regarding complicity.

---

<sup>65</sup> R Green, see note 34 above, at 551.