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***Stem Cells, Patents and Morality in the EU after Brüstle***

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Abstract

The aim of the proposed presentation is to highlight the moral and ethical issues stemming from the patentability of human embryonic stem cells in the European Union. It will focus on the recent decision of the Court of Justice of the European Union (CJEU) in *Brüstle v Greenpeace* (Case C-34/10). This decision interpreted the provision of the EC Directive on the patentability of biotech inventions devoted to human embryos (Article 6(2)(c) EC Directive 98/44). The ruling clarifies that a process, which involves removal of stem cell from a human embryo at the blastocyst stage, entailing the destruction of that embryo, should be excluded from patentability. The author will argue that, in reaching this decision, the CJEU confirms that patent registration procedures regarding biotech inventions should constitute a “*social and moral filter*” and the patent system should be a “*servant of public policy*”. This ruling confirms, therefore, that patent offices should carefully examine the moral concerns (as well as the environmental and social issues) stemming from the production and exploitation of biotech products or processes, which are the subject of matter of a patent application and, on the basis of such analysis, grant or reject the patent application.

## Introduction

This paper aims at highlighting some thorny issues raised by the recent decision of the Court of Justice of European Union (CJEU) in *Brüstle v Greenpeace*<sup>1</sup>. This is a widely reported case on the exclusion from patentability of inventions related to human embryonic stem cells (HESCs) on morality grounds. The ruling offers the opportunity (i) to delve into an old debate surrounding patent law, i.e. whether moral aspects should be effectively dealt with by patent officers and judges when it comes to granting or invalidating a patent, (ii) to highlight the role of experts in the context of patent procedures concerning allegedly outrageous and/or harmful inventions, and (iii) to verify *whether there exists a common concept of morality in the field of biotechnology and in particular HESCs*. It is also interesting to verify whether the decision in *Brüstle* may trigger a WTO challenge against the EU and some of its Member states for failing to comply with Article 27(2) of the TRIPS Agreement as well as whether it may have an impact in fields other than HESCs and thus be invoked to oppose the issuance, or challenge the validity, of any patent obtained through immoral or unlawful activities.

The article limits its scope of analysis to the European experience. It will not address the US scenario. Indeed in the US, as opposed to the European patent system, there are no statutory limits on patent eligibility on moral and ordre public grounds<sup>2</sup>.

## The ruling

The facts of the case are well-known. Dr Olivier Brüstle from the University of Bonn obtained a German patent covering isolated and purified neural precursor cells produced

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<sup>1</sup> *Oliver Brüstle v Greenpeace e.V., Case C-34/10, decision of 18 October 2011.*

<sup>2</sup> For an overview of morality issues in the US patent system see Margo A. Bagley, "Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law", *William and Mary Law Review* (2003), pp. 469-547.

from HECs<sup>3</sup>. By growing specific tissue from these cells, this invention aims at treating damaged organs in patients suffering from diseases such as dementia, blindness and Parkinson's. Greenpeace successfully challenged the patent before the Federal Patent Court on morality grounds: it was basically argued that patenting an invention based on a human embryo which is later destroyed is unethical. Dr *Brüstle* appealed the decision before the German Supreme Court which eventually referred the case to the CJEU. The Court was asked to interpret Article 6(2)(c) of Directive 98/44 on the patentability of biotechnological inventions (Biotech Directive<sup>4</sup>), according to which "uses of human embryos for industrial or commercial purposes" are not patentable. Article 6(2) gives a list of unpatentable inventions<sup>5</sup>, which intends to guide the implementation and interpretation of the broader morality clause of Article 6(1), according to which inventions cannot be patented if their commercial exploitation is contrary to *ordre public* or morality<sup>6</sup>.

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<sup>3</sup> For a brief technical overview of HESCs and the associated ethical concerns see Kenneth C. Cheney, "Patentability of Stem Cell Research under TRIPS: Can Morality-Based Exclusions be Better Defined by Emerging Customary International Law?", *Loyola of Los Angeles International and Comparative Law Review* (2007), pp. 505 et seq.

<sup>4</sup> The directive was adopted on 6 July 1998. The Netherlands brought Case C-377/98 before the CJEU against the adoption of the directive with six different pleas and requested the annulment of the directive. With the ruling of 9 October 2001 the Court dismissed the application brought by the Netherlands and confirmed the validity of the directive.

<sup>5</sup> The list also includes: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

<sup>6</sup> Analogous provisions are contained in Article 27(2) of the TRIPS Agreement ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality") and Article 53(a) of the European Patent Convention (EPC) ("European patents shall not be granted in respect of: (a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality [...]". Rule 28 EPC reflects the contents of Article 6(2) of the Biotech Directive. The EPC Guidelines, Part C, C-IV, paragraph 4.1, confirm that the purpose of the patentability exclusion under Article 53(a) EPC is "to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behavior". The Guidelines mention anti-personnel mines as an obvious example and note that this exception is likely to be relied on just in extreme cases, e.g. when the invention applied for is so abhorrent that the grant of the patent would be inconceivable.

In its decision of 18 October 2011 the CJEU first gave a broad interpretation of “human embryos” under Article 6(2)(c) by clarifying that any human ovum, as soon as fertilized, should be considered as “human embryo” if the fertilization is such as to commence the process of development of a human being. The above term, added the Court, also covers cells that are artificially stimulated or manipulated but not fertilized and which are able to trigger the development of a human being (so called parthenogenesis)<sup>7</sup>.

The Court also interpreted the expression “uses of human embryos for industrial or commercial purposes” under Article 6(2)(c). The issue was basically whether the use of embryos for research purposes amounts to a use for a mere commercial aim. The CJEU admitted that in general the concept of scientific research must be distinguished from industrial or commercial purposes. Yet, held the Court, as patent rights are in principle connected with activities of industrial and commercial nature, the use of human embryos for the purposes of research which constitutes the subject matter of a patent application (as it was in *Brüstle*) cannot be separated from the patent itself and cannot therefore enjoy protection<sup>8</sup>.

The final issue was whether an invention involving the destruction of human embryos can be considered patentable even though the patent specification (as in *Brüstle*) does not mention said destructive use. The Court held that such invention is not patentable<sup>9</sup>. Indeed, not excluding them from patentability would allow patent attorneys to avoid the non-patentability by skillfully drafting the claims. The CJEU thus held that an invention is not

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<sup>7</sup> See paragraphs 35-36 of the decision.

<sup>8</sup> See paragraphs 42-43 of the decision.

<sup>9</sup> The European Parliament “Resolution on Patents for Biotechnological Inventions” of 26 October 2005 (P6\_TA(2005) 0407) had already endorsed this position: “The European Parliament insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2) of the Directive” (paragraph 14).

patentable if its implementation requires either the prior destruction of human embryos or their prior use as base material, even though the patent application does not mention such prior destruction or use<sup>10</sup>. As noted by the Advocate General, if that were not the case, the prohibition under Article 6(2) Biotech Directive would be easy to get around, as the applicant would just have to avoid mentioning in the application that human embryos were destroyed or used: in such a manner the provision would be deprived of its effectiveness<sup>11</sup>.

The ruling has obviously been criticised by the biotech industry. A possible negative consequence – noted the industry - could be a “brain drain” towards more biotech friendly countries such as the United States where there are no statutory limits on patent eligibility of HESCs inventions on moral and ordre public grounds<sup>12</sup>. In a letter published in the well known scientific journal *Nature* on 28 April 2011 (a few weeks after the opinion released by Advocate General Bot, which was almost entirely followed by the CJEU’s ruling), several scientists expressed their “profound concerns” about the possibility of lack of patent protection in a highly R&D intensive industry such as the HESCs field<sup>13</sup>.

### **Patent law and morality**

A sensitive issue stemming from the *Brüstle* decision relates to “morality”. Even though both the Court and the Advocate General took the pain to specify that their findings were not

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<sup>10</sup> It is clear from the way the third question was formulated that the said prior use of human embryos is a destructive one.

<sup>11</sup> See paragraph 108 AG’s opinion.

<sup>12</sup> It should however be noted that the *Brüstle* ruling does not affect future HESCs inventions which do not involve the destruction of human embryos. This is an interesting point as new approaches have recently been proposed for deriving HESCs lines without injuring embryos.

<sup>13</sup> Yet, the patenting of HESCs inventions has also been blamed for paving the way to anticompetitive behaviors. In particular, it has been argued that many HESCs patents rely on very broad claims, which might stifle follow-on innovation in the nascent stem cells industry. See Antonina Bakardjieva, “Stem Cells Patenting and Competition Law”, in Aurora Plomer – Paul Torremans (eds), *Embryonic Stem Cell Patents* (2009) OUP, p. 372.

dictated by moral beliefs<sup>14</sup>, it seems clear that they took, at least impliedly, a moral stance. Indeed by embracing a broad interpretation of “human embryo” (so as to include any human ovum as soon as fertilized as well as cells which are artificially stimulated or manipulated but not fertilized) and stating that the technical teachings which involve its destruction are not patentable, the Court chose to safeguard “life” in all its forms and therefore protect human dignity. The CJEU held in particular that “the context and aim of the [Biotech] Directive thus shows that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ within the meaning of Article 6(2) of the Directive must be understood in the wide sense”<sup>15</sup>. Analogous considerations were put forward by the Advocate General. He first recalled that Article 5(1) of the Biotech Directive prohibits the patentability of the human body at the various stages of its formation and development<sup>16</sup> and that “human dignity is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilization”<sup>17</sup>. He added that the creation of embryos just for the purposes of being destroyed would not “be consistent with the concept

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<sup>14</sup> See paragraph 30 CJEU’s decision: “The Court is not called upon [...] to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive”. See also paragraphs 39-40 AG’s opinion: “39. It is on the question of an embryo that the main points of different philosophies and religions and the continual questioning of science meet. 40. I do not intend to decide between beliefs or to impose them”.

<sup>15</sup> See paragraph 34 CJEU’s decision.

<sup>16</sup> An analysis of the travaux préparatoires of the Biotech Directive discloses that the intention of the EU legislator was to exclude patents on human embryos, as the said embryos amount to stages in the formation and development of the human body (on 11 July 1996, during the preparatory works to the Biotech Directive, the European Economic and Social Committee noted that “the human embryo, which is a special case, should be excluded from patentability”). Several commentators believe that the exclusion from patentability under Article 5(1) Biotech Directive covers the human embryo both in its natural state and *in vitro*: as a matter of fact the final text of the provision removed the earlier wording which had been introduced in a previous draft, according to which the exclusion covered the human body “in its natural state”. See the Report “Stem Cell Patents: European Patent Law and Ethics Report”, coordinated by Aurora Plomer, available at <http://www.nottingham.ac.uk/~llzwww/StemCellProject/reports.htm>, pp. 66-67 and 128 (last accessed on 3 January 2012: hereinafter “Report”).

<sup>17</sup> See paragraph 96 AG’s opinion.

of *ordre public*, and with an ethical conception which could be shared by all the Member States of the Union”<sup>18</sup>. The Advocate General moreover referred to specific EU provisions which protect human dignity, *i.e.* Articles 1 and 3(2) of the Charter of Fundamental Rights<sup>19</sup>: the former states that human dignity is inviolable and should be protected whereas the latter establishes a prohibition on making the human body and its parts as such a source of financial gain.

It seems evident that, by stressing the above, the Court and the Advocate General basically held that inventions involving the destruction of human embryos are immoral and therefore caught by the patentability prohibition under Article 6 of the Biotech Directive. They thus took a moral stance. Their finding appears to be even more traditionalist and conservative than customary international law, which only prohibits research activities on any embryo over fourteen days old, and not from fertilization<sup>20</sup>.

This decision confirms once again that patent law has incorporated ethical and *ordre public* principles which should be considered as overriding. In other terms, the *Brüstle ruling* impliedly confirms that patent law is not neutral but is subject to these principles<sup>21</sup>; and that patent officers and judges are effectively entrusted with the task of assessing the morality and *ordre public* compatibility of the inventions, and that depending on the outcome of such assessment they grant, refuse or invalidate the patent.

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<sup>18</sup> See paragraph 114 AG’s opinion.

<sup>19</sup> Charter of Fundamental Rights [2000] OJ C364/1. The Charter was signed in Nice in December 2000 and acquired legal status in the EU with the entry into force of the Lisbon Agreement in December 2009.

<sup>20</sup> See Cheney, above note 3, pp. 517-518 and 534.

<sup>21</sup> See Paul Torremans, “A Transnational Institution Confronted with a Single Jurisdiction Model, Guidance for the EPO’s Implementation of the Directive from a Private International Law Perspective”, in Plomer – Torremans, above note 13, p. 288.

It is appropriate and necessary to stress the above as in the past it has been submitted several times that patent law is a forum which should remain neutral *vis-à-vis* ethical aspects. For example, in the proceedings brought against the Biotech Directive the CJEU held that the latter concerns only the grant of patents and its aim is not to replace the restrictive provisions which guarantee, outside the scope of the Directive, compliance with certain moral rules<sup>22</sup>. Also the European Patent Office (EPO) have come to analogous conclusions on some occasions. For example, in the first decision of the *Oncomouse* saga the EPO Examining Division noted that the patent system was not the suitable forum for analysing moral and *ordre public* related issues<sup>23</sup>. In the *Plant Genetic Systems* case it was held that the “possibility of risks traditionally has no bearing on whether a patent is granted or not”<sup>24</sup> and in *Leland Stanford v Modified Animal* that it cannot be the role of the EPO to act as moral censor and to refuse patents on ethical grounds<sup>25</sup>. In other words, according to this school of thought patent registration procedure cannot represent the appropriate

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<sup>22</sup> Case C-377/98, decision of 9 October 2001, paragraphs 79-80.

<sup>23</sup> See the first decision of 14 July 1989, in which the Examining Division stated that “*patent law is not the right legislative tool*” to examine whether the invention is contrary to *ordre public* or morality. The *Oncomouse* is a type of laboratory mouse that was genetically modified by the Harvard University and the company DuPont to carry a specific gene. The activated oncogene significantly increased the mouse’s susceptibility to cancer, and thus made the mouse suitable for cancer research. The European patent application n. 85304490.7 – covering the said invention - was filed in June 1985 by the President and Fellows of Harvard College. It was initially refused on the grounds that the EPC excludes patentability of animals *per se* (thus not on morality or *ordre public* grounds). The decision was subsequently appealed and the Board of Appeal held that *animal varieties* were excluded from patentability by Article 53(b) EPC, while *animals* as such were not excluded (decision of 3 October 1990). The Examining Division then granted the patent on 3 April 1992. The European patent was then opposed by 17 parties on the grounds laid out in Article 53(a) EPC. After opposition proceedings took place in November 2001, the patent was maintained in amended form. This decision was then appealed and the appeal decision was taken on 6 July 2004 by the Technical Board of Appeal. The case was remitted to the Opposition Division, with the order to maintain the patent on a newly amended form.

<sup>24</sup> See paragraph 624 of the decision of 15 February 1993. The case dates back to 1990, when a European patent was granted to the company *Plant Genetic Systems* for processes and products relating to conferring resistance to an herbicide by genetic engineering. The patent contained claims to seeds, plants and plant cells that are herbicide-resistant due to having a foreign nucleotide sequence incorporated into its genome, as well as methods for making and using the transgenic plant. *Greenpeace* filed an opposition in 1992. After the Opposition Division upheld the patent, *Greenpeace* appealed the decision to the Technical Board of Appeal which confirmed the patent on 21 February 1995.

<sup>25</sup> See paragraph 51 of the decision (*Leland Stanford v Modified Animal* [2002] E.P.Q.R. 2 (Opp. Div.), 23). The invention regarded the modification of animals which were implanted with human red blood cells extracted from aborted fetuses or young children. The modified animal was considered useful for researching the effect and development of HIV.

forum wherein to assess the environmental, ethical and social issues mentioned in Article 53(a) EPC.

The argument often submitted in support of this thesis is that what a patent offers is not the “positive” right to work and commercially exploit the invention, but a mere *ius excludendi alios*, i.e. the “negative” right to prevent others from using the invention in question<sup>26</sup>; and that the grant of a patent does not amount to a licence to practice the invention<sup>27</sup>. The patent system – the argument goes – is not interested in whether the invention can be used in a morally deplorable manner. Indeed, the right to use the invention could be forbidden or anyhow limited on morality or *ordre public* grounds by national or supranational legislations on the production, sale and diffusion of the relevant products, regardless of the grant or refusal of a patent<sup>28</sup>. The patent system should not be bothered with these issues, but

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<sup>26</sup> See the first part of Recital 14: “*whereas a patent for invention does not authorise the holder to implement that invention, but merely entitles him to prohibit third parties from exploiting it for industrial and commercial purposes [...]*”.

<sup>27</sup> As has been noted, the inventor of a new and inventive rifle would be entitled to the patent, but the issuance of the latter would not give him the right to shoot innocent people (see Marco Ricolfi, *Biotechnology, Patents and Epistemic Approach*, *Journal of Biolaw and Business*, Special Supplement 2002, pp. 77 et sqq.). Also the inventor of a new and original copying machine (which, due to its high technical performances, would be capable of printing high-quality counterfeit banknotes) would be entitled to the patent, but the latter would not give him the right to produce and circulate counterfeit banknotes: this example was given by Advocate General Jacobs in Case C-377/98 (paragraph 26 of his opinion).

<sup>28</sup> See the second part of Recital 14 of the Biotech Directive “*whereas, consequently, substantive patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialisation of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards*”. See also Cynthia M. Ho, “Building a Better Mousetrap: Patenting Biotechnology in the European Community”, *Duke Journal of Comparative & International Law* (1992), p. 195 (noting that the issuance of a patent “is not an ethical event. Instead it is the regulatory system of a given nation that monitors social concerns as it implements general legislation – concerns which frequently encompass ethics and morality”); James R. Chiappetta, “Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute”, *William Mitchell Law Review* (1994), p. 178 (stressing that “*the proper venue for consideration of moral issues of biotechnology is within the regulatory agency entrusted with the product’s oversight, and not the patent office*”).

would be neutral *vis-à-vis* any anti-ethical or unlawful use or method of realisation of the invention<sup>29</sup>.

The author does believe that these thesis and arguments are weak and must be rejected<sup>30</sup>.

Trying to push the patent system out of the morality debate would amount to ignoring its very function, which is to stimulate and reward innovation useful to our society. It would also hand over the architecture of intangible property rights entirely in the hands of restricted elites (especially, patent applicants and their attorneys) that are more interested in maximizing monopolistic profits rather than in pursuing efficiency and morality<sup>31</sup>.

On the contrary, as impliedly confirmed by the CJEU's decision in *Brüstle*, patent registration procedures and in general patent law must address ethical and *ordre public* aspects. Article 6 of the Biotech Directive and 53(a) of the EPC are part of patent law and should not be ignored: they state that inventions contrary to *ordre public* and morality must not be patented and are clearly addressed to patent offices and courts, which have thus been entrusted with a specific task, *i.e.* to assess the *ordre public* and morality compatibility of the inventions applied for or which are object of invalidity proceedings<sup>32</sup>. This is also buttressed by Recitals 38 and 39 of the Biotech Directive: the former provides that "the operative part of this Directive should also include an illustrative list of inventions excluded from patentability [the list contained in Article 6(1)] **so as to provide referring courts and**

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<sup>29</sup> See also Graeme Laurie, "Patenting Stem Cells of Human Origin", *European Intellectual Property Review* (2004), p. 64 (noting that "it is not for patent law to address that concern [moral concern] if the objection is to the science rather than to the grant of a monopoly right. Not only is it a matter more appropriately tackled by regulatory authorities using their entire gamut of legal tools, but the deep irony is that patent law cannot address such a concern. The sole power that a patent examiner or court has is to deny or revoke a patent").

<sup>30</sup> See also Peter Drahos, "Biotechnology patents, Markets and Morality", *European Intellectual Property Review* (1999), p. 441.

<sup>31</sup> See Drahos, above note 30, p. 447.

<sup>32</sup> It should however be noted that the morality and *ordre public* clauses have almost always been applied narrowly (as also suggested by the EPC Guidelines). See Gerard Porter, "Human Embryos, Patents and Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception", in Plomer – Torremans, above note 13, p. 348.

patent offices with a general guide to interpreting the reference to *ordre public* and *morality* [...]” (emphasis added) whereas the latter recalls that ethical and moral principles integrate the standard legal examinations under patent law. The same rationale lies behind what affirmed by the Advocate General in *Brüstle*: “the argument put forward to the Court at the hearing, that the problem of patentability which hinges on the removed cell, the way in which it has been removed and the consequences of such removal do not have to be taken into account seems unacceptable, in my view, for reasons connected with *ordre public* and morality”<sup>33</sup>.

There is thus little doubt that the patent offices and courts and the patent law in general should deal with moral issues. The patent system should thus be considered as servant of public policy and patent officers and judges, far from being neutral and shut their eyes in front of immoral or harmful inventions, must act as social and moral filters and arbiters<sup>34</sup>. As has been noted, moral considerations and bio-ethical issues permeate the all legal structure of the patent system and play a relevant role for its development and success<sup>35</sup>.

### **EPO case law**

The case law of the EPO confirms that the Munich-based office has effectively dealt with ethical issues and acted as a moral arbiter.

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<sup>33</sup> See paragraph 105 AG’s opinion.

<sup>34</sup> See Daniel Alexander, “Some Themes in Intellectual Property and the Environment”, *Review of European Community and International Environmental Law* (1993), pp. 113-120; Angus J. Wells, “Patenting New Life Forms: An Ecological Perspective”, *European Intellectual Property Review* (1994), pp. 111-118; Sigrid Sterckx, “The European Patent Convention and the (non-) patentability of human embryonic stem cells – the WARF case”, *Intellectual Property Quarterly* (2008), p. 487; Amanda Warren-Jones, “Identifying European moral consensus: why are the patent courts reticent to accept empirical evidence in resolving biotechnological cases”, *European Intellectual Property Review* (2006), p. 37.

<sup>35</sup> See Rainer Moufang, “Patenting of Human Genes, Cells and Parts of the Body – The Ethical Dimensions of Patent Law”, *International Review of Intellectual Property and Competition Law* (1994), p. 514.

For example, in the *WARF* case the Enlarged Board of Appeal, even though it did not explicitly state that HESCs inventions which involve the destruction of human embryos are against morality, clearly found that such processes are caught by the prohibition of patentability under Article 53(a) EPC, which protects human dignity. The invention at issue related to a cell culture comprising primate embryonic stem cells, which – as in *Brüstle* - required the use and destruction of human embryos as starting material. And the Board held that the exclusion from patentability under Article 53(a) EPC relates to the immoral nature of the invention itself and that the rationale of the exclusion is to prevent the commodification of human embryos<sup>36</sup>.

In the *Edinburgh* case the invention concerned the isolation, selection and propagation of animal transgenic stem cells. The main issue focused on whether the patent extended to human embryos. The Opposition Division held that the exclusion from patentability on morality grounds has to be interpreted broadly as to include not only the commercial or industrial use of human embryos but also the HESC obtained by destroying human

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<sup>36</sup> Paragraphs 18 and 29 of the decision of the EPO Enlarged Board of Appeal (EBA) rendered on 25 November 2008 (case G 0002/06). Such decision upheld the July 2004 decision of the Examining Division which had rejected under Article 53(a) and Rule 28(c) EPC the European patent application filed by *Wisconsin Alumni Research Foundation (WARF)*. The Board in particular considered whether EPC Rule 28(c) “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”, even if the method in question is not part of the claims. Noting that the EPC Rule 28(c) prohibition refers to “invention” and not claims, the Board held that the use of the undefined “embryo” need not be claimed to violate the provision. Instead, in the context of the protection of human dignity upon which the rule is based, it was the performance of the invention that was at issue, since, to be used as claimed the stem cells must first be created, and the teaching of the application involved destruction of an embryo (as we have seen, the CJEU reached a similar conclusion in *Brüstle*). The Board clarified that its decision did not touch upon the patentability of human stem cells in general, but only those cellular inventions necessarily requiring the destruction of embryos for their creation. Since the EBA prohibited patents in connection with products produced exclusively by a method which involved destruction of an embryo, such finding – it is widely believed – has allowed the so-called “deposit loophole”, *i.e.* the possibility of avoiding the prohibition if the patent applicant, by depositing a sample of the culture at a competent centre at the time of the filing of the application, proves that further production without destruction is possible. This possibility was impliedly ruled out by both the Advocate General and the CJEU in *Brüstle*. It will be interesting to verify whether in this specific regard the EPO will disregard its finding in *WARF* and instead follow the CJEU. See also Mark Paton – Alex Denoon, “The Ramifications of the Advocate General’s Opinion in the Oliver Brüstle Case”, *European Intellectual Property Review* (2011), p. 595.

embryos<sup>37</sup>; and by also relying on the principle of human dignity and personal integrity and autonomy it amended the patent so as to exclude human or animal embryonic stem cells<sup>38</sup>.

Other leading biotech cases confirm that the EPO has dealt with moral issues.

For example, in the *Oncomouse* case the Technical Board of Appeal carried out a costs/benefits analysis. It examined on the one hand the advantages that the genetically modified mouse could produce for the treatment of cancer and, on the other hand, the relevant costs, *i.e.* animal suffering and environmental risks associated to the uncontrolled spread of unwanted genes. It finally held that the benefits overwhelmed the costs<sup>39</sup>. This is the so-called “utilitarian approach” of weighing up benefits and disadvantages of a given invention. It is believed that who takes a decision based on the costs/benefits analysis, even without specifically taking human dignity into account, should still be considered a moral arbiter<sup>40</sup>.

In the *Plant Genetic Systems* case the above Board also carried out a morality based assessment and eventually upheld the patent. In particular, it could see no moral distinction

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<sup>37</sup> Patent Application No 94913174.2; decision of the EPO Opposition Division of 21 July 2002. The patent was opposed on morality grounds by Germany, Italy, the Netherlands and other 11 parties including *Greenpeace*. In reaching its decision, the Opposition Division rejected the opinion released in 2002 by the European Group of Ethics (EGE) in Science and New Technologies, which had supported the patentability of human stem cell lines modified by an inventive process and capable of technical application. See also Penny Gilbert, “The Root of the Problem for Stem Cell Research”, *European Lawyer* (2004), pp. 32-34.

<sup>38</sup> See also Shawn H. E. Harmon, “The Rules of Re-Engagement: the Use of Patent Proceedings to Influence the Regulation of Science (“What the Salmon does when It Comes Back Downstream”)", *Intellectual Property Quarterly* (2006), pp. 397-398; Shawn H. E. Harmon, “From Engagement to Re-Engagement: the Expression of Moral Values in European Patent Proceedings, Past and Future”, *European Law Review*, pp. 656-658.

<sup>39</sup> See the decision of the Technical Board of Appeal of 6 July 2004, which concluded that the balancing exercise between medical benefits and costs favored the grant of the claim (paragraphs 9(1)-(7) and 13(2)(1)-13(2)(4).

<sup>40</sup> Other commentators prefer the so-called “deontological approach”, according to which inventions are to be considered contrary to accepted principles of morality even though they bring more benefits than disadvantages. In other words, the fact that an invention is against morality could not be “neutralized” by any real or potential benefits it may produce. According to this school of thought, therefore, the utilitarian approach could not be used when it comes to human embryos, as the latter enjoy human dignity and dignity cannot be outweighed in a balancing exercise. See Sterckx, above note 34, pp. 487-490 and 494.

between modifying plant characteristics by genetic engineering (the gist of the invention) and modifying them by traditional selective breeding. Genetic engineering – noted the Board - simply increased the number of possible modifications and made them punctual. The Board noted that “[...] plant biotechnology per se cannot be regarded as being more contrary to morality than the traditional selective breeding because both traditional breeders and molecular biologists are guided by the same motivation, namely to change the property of a plant by introducing novel genetic material into it in order to obtain a new and, possibly, improved plant [...]. [...] none of the claims of the patent in suit refer to subject-matter which relates to a misuse or destructive use of plant biotechnological techniques because they concern activities (production of plants and seeds, protection of plants from weeds or fungal diseases) and products (plant cells, plants, seeds) which cannot be considered to be wrong as such in the light of conventionally accepted standards of conduct of European culture”<sup>41</sup>.

The *Relaxin* case is also relevant as the EPO Opposition Division, while upholding the patent, explicitly delved into moral issues. The patent covered a DNA fragment encoding *Relaxin*, a human protein that is only produced by pregnant women. It was challenged under Article 53(a) EPC. The opponents raised three morally based arguments: a) patenting human genes would be similar to patenting life which is intrinsically unethical; b) the implementation of

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<sup>41</sup> See paragraph 17(1)-(3) of the decision of the Technical Board of Appeal of 21 February 1995. The Board added that the opponent had not provided sufficient scientific evidences about the environmental and social risks allegedly stemming from the genetically engineered plant. It noted in particular that “no conclusive evidence has been presented by the Appellants showing that the exploitation of the claimed subject-matter is likely to seriously prejudice the environment. In fact, most of the Appellant’s arguments are based on the possibility that some undesired, destructive events (e.g. the transformation of crops into weeds, spreading of the herbicide-resistance gene to other plants, damage to the ecosystem) might occur [...]” (paragraph 18(6)). That is why – the Board noted - it was not necessary to strike a balance between the costs (deemed not sufficiently proved) and the benefits: “it would be unjustified to deny a patent under Article 53(a) merely on the basis of possible, not yet conclusive-documented hazards [...]. [...] since no sufficient evidence of actual disadvantages has been adduced, the assessment of patentability with regard to Article 53(a) EPC may not be based on the so-called ‘balancing exercise’ of benefits and disadvantages” (paragraph 18(7)-(8)).

the invention would be immoral because it requires extracting tissue from a pregnant women, *i.e.* an act which violates the principle of human dignity; and c) patenting human genes would amount to a form of slavery, whereby humans are being sold piecemeal for commercial purposes. These arguments were all rejected. The Opposition Division held that in order for Article 53(a) EPC to be invoked an invention must be universally regarded as outrageous and in *Relaxin* it was not<sup>42</sup>. It held that a) DNA cannot be compared to “life”, DNA being only a chemical substance which incorporates a piece of genetic information and can be used for the production of medically-useful proteins; in this regard the Opposition Division stressed that there cannot be a distinction between patenting human proteins (which is widely accepted) and patenting human genes; b) the Opposition Division added that, as long as the subject from whom human tissue was taken consented to the taking of that tissue, there was nothing immoral in the mere act of taking tissue since this is a standard practice in medical procedures (other human substances, such as blood and bones, are often used for commercial purposes); c) moreover, no women would be reduced to slavery as a consequence of patenting the objected gene, being those women free to live their lives exactly in the same way as they would have lived before the patent was issued<sup>43</sup>.

This case law confirms that patent officers have often dealt with moral aspects stemming from the working of both HESCs inventions and other biotech processes or products. And they have done so exactly because the provisions which exclude inventions from patentability on morality grounds are addressed to them.

### **Integrating technical experts into patent related proceedings**

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<sup>42</sup> See the decision of the Opposition Division of 18 January 1995. This ruling was unsuccessfully appealed.

<sup>43</sup> See paragraphs 6(3)(1), 6(3)(3) and 6(3)(4) of the decision.

It could be argued that patent officers may find it difficult to deal with morality and *ordre public* issues stemming from HESCs and in general biotech inventions, and that therefore such complicated aspects should not be dealt with in the context of patent registration procedures. The same goes with reference to specialized patent judges who are requested to invalidate a biotech patent on the same grounds. One may note that such task exceeds the skills of patent offices and courts which do not have expertise in social values and lack crucial mechanisms that ensure the protection of ethical principles<sup>44</sup>.

This objection however could be overcome.

Indeed, patent officers and judges could be partnered with experts to be questioned about technical and moral issues. They might also be appropriately trained in moral thoughts. After all, it is Article 7 of the Biotech Directive that provides that the Commission's European Group on Ethics in Science and New Technologies (Group) "evaluates all ethical aspects of biotechnology" and Recital 44 adds that the Group may be consulted on patent law as well<sup>45</sup>. In 2002 in its opinion on the "Ethical aspects of patenting inventions involving human stem cells" the Group noted that "there may be the need to make ethical evaluations in the course of the examination of patent applications involving specific ethical dimensions. It would be desirable that such ethical evaluation becomes part of the review process of national patent offices or European institutions like EPO and that advisory panels of independent experts are set up for that purpose".

The Swedish and Norwegian experiences are here relevant. In Sweden a patent application covering inventions stemming from research already "cleared" by an ethical committee

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<sup>44</sup> See Antonina Bakardjieva Engelbrekt, "Institutional and Jurisdictional Aspects of Stem Cell Patenting in Europe (EC and EPO): Tensions and Prospects", in Plomer – Torremans, above note 13, p. 258.

<sup>45</sup> Yet the Group's advice can be requested – Recital 44 clarifies – only where biotechnology must be assessed "at the level of basic ethical principles".

makes it unnecessary another moral assessment by the patent office; and disapproved research is unlikely to be considered patentable. Moreover, both patent offices and judges must ask for expert reports when it is necessary for completing their ethical evaluation<sup>46</sup>. In Norway a government appointed Ethics Committee – including five members competent in philosophy, medicine, animal protection, morality and biotechnology - has been established by the national Parliament with advisory functions as to the exclusion from patentability on morality grounds. Patent officers and judges can ask the Committee an opinion whenever such issues arise. Yet the opinion is not binding<sup>47</sup>. The Committee itself can also file an opposition against a patent application by invoking morality or *ordre public* grounds<sup>48</sup>.

### **Are there common European principles of morality?**

When it comes to granting European patents covering morally controversial inventions such as HESCs processes and products, a delicate issue is whether the office should take into consideration a common European concept of morality or rather verify whether the invention raises ethical concerns in just one or several European states. In other words: is there a common European standard on morality, especially in the field of biotech and in particular HESCs patenting? Is there a shared consensus in Europe precluding research involving destruction of human embryos?

It has been argued that the concepts of morality and *ordre public* can only be interpreted as common European concepts. Otherwise, EPO patent procedures would be dependent on

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<sup>46</sup> See Asa Hellstadius, "A Comparative Analysis of the National Implementation of the Directive's Morality Clause", in Plomer – Torremans, above note 13, pp. 131-132.

<sup>47</sup> Proposing binding effect of these opinions, see Timothy Sampson, "Achieving Ethically Acceptable Biotechnology Patents: A Lesson from the Clinical Trials Directive", *European Intellectual Property Review* (2003), p. 424.

<sup>48</sup> See again Asa Hellstadius, "A Comparative Analysis of the National Implementation of the Directive's Morality Clause", in Plomer – Torremans, above note 13, p. 130. In general on the role of ethics committees in the context of patent registration procedures see Elodie Petit, "An Ethics Committee for Patent Offices?", in Plomer – Torremans, above note 13, pp. 305-322.

the decisions of each country designated in the application and accordingly the whole European patent system – which is based on a centralised registration procedure - would be jeopardised<sup>49</sup>.

This line of argument seems to find support in the European Convention on Human Rights (ECHR)<sup>50</sup>, which sets forth several fundamental and morality based principles that are considered common to all European people. And the need to respect the fundamental rights enshrined in the ECHR is also referred to in Recital 43 of the Biotech Directive<sup>51</sup>. Reference to common European concepts of morality has also been made in the EPO case law on biotech inventions. For example, in the *Oncomouse* case it was held that “the use of animals in medical and scientific research [...] is an established feature of European culture. The Board agrees and thus finds that not just animal welfare but also the use of animals for research and testing is established in European culture”; “there is nothing before the Board to suggest that such unease could be elevated to the status of moral disapproval in European culture of the use of animals for medical research”<sup>52</sup>. Similarly, in *Plant Genetic Systems* the moral assessment of the transgenic plant was carried out by the Board by taking into account “conventionally accepted standards of conduct of European culture”<sup>53</sup>, *i.e.* moral norms that are deeply rooted in European culture<sup>54</sup>. We have already seen that an

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<sup>49</sup> See Otto Bossung, “Erfindung und Patentierbarkeit im europäischen Patentrecht”, Mitteilung der deutschen Patentwalte (1974), p. 123.

<sup>50</sup> Convention for the Protection of Human Rights and Fundamental Freedoms, Nov. 4, 1950, Europ. T.S. No. 5; 213 U.N.T.S. 221.

<sup>51</sup> It has even been argued that the European Court of Human Rights, which monitors the application of the ECHR, should have a final say on any moral aspects arisen in the European patent system. See Deryck Beyleveld - Roger Brownsword, “Mice, Morality and Patents”, Common Law Institute of Intellectual Property (1993), p. 90.

<sup>52</sup> See paragraph 13(2)(18) and 13(2)(21) of the decision of the Technical Board of Appeal of 6 July 2004.

<sup>53</sup> See again paragraph 17(1)-(3) of the decision of the Technical Board of Appeal of 21 February 1995.

<sup>54</sup> In the *Plant Genetic Systems* case the relevance and usefulness of survey and polls was also debated. The opponents had argued that a morality based assessment can be supported and enhanced by opinion polls and

analogous position has been taken by the Advocate General in *Brüstle*, as he held that the creation of embryos just for the purposes of being destroyed would not “be consistent with the concept of *ordre public*, and with an ethical conception which could be shared by all the Member States of the Union”<sup>55</sup>.

According to several commentators, however, a single and unitary European concept of ethics does not exist<sup>56</sup> and the definition of morality is one of cultural normative relativism<sup>57</sup>, even more so in the specific field of human embryonic stem cell patenting<sup>58</sup>. This opinion seems to have its merits. After all it is widely accepted that *ordre public* and morality are open concepts, which each country can apply and interpret depending on their cultural, social, religious and political beliefs<sup>59</sup>. Recital 39 of the Biotech Directive is relevant here as it clarifies that these concepts correspond to “ethical or moral principles recognized **in a Member State**”. The added emphasis confirms that there can be approaches to morality different from country to country. Moreover, an *a contrario* interpretation of Recital 40 (which stresses that there is a consensus in the EU that research related to human

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survey, on the assumption that empirical analysis helps to identify common values and renders the evaluation free from subjective and personal opinions (in particular, the opponents had claimed that the result of a survey in Sweden and of an opinion poll in Switzerland showed that public opinion was contrary to the patenting of genetically modified herbicide-resistant plants). See also Drahos, above note 30, pp. 447-448. Yet, the Technical Board of Appeal eventually held that (i) survey and polls do not necessarily reflect *ordre public* concerns or moral norms deeply rooted in European culture; (ii) the results of said survey and polls can fluctuate in unforeseeable ways and can be swayed by the specific kind of question, choice and size of the representative sample; and (iii) surveys of particular groups tend to reflect specific beliefs and interests (paragraph 15 of the decision). This finding has been criticised by Peter Drahos in the above mentioned article (p. 444) as its effect would be to “rob the morality test of any empirical content”.

<sup>55</sup> See paragraph 114 AG’s opinion in *Brüstle*.

<sup>56</sup> See Paul Torremans, “The Construction of the Directive’s Moral Exclusions under the EPC”, in Plomer – Torremans, above note 13, p. 162.

<sup>57</sup> See A. M. Viens, “Morality Provisions in Law concerning the Commercialization of Human Embryos and Stem Cells”, in Plomer – Torremans, above note 13, p. 111.

<sup>58</sup> See Bakardjieva Engelbrekt, above note 44, p. 259.

<sup>59</sup> See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, London, 2003, p. 46; Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries*, Kluwer Law International, The Hague, London, Boston, 2001, p. 42; Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights*, Kluwer Law International, London, The Hague, New York, 2002, p. 171; Porter, above note 32, p. 366 (noting that concepts of morality may be greatly different amongst WTO countries).

germ line and the cloning of human beings is contrary to morality and *ordre public*) seems to reveal that on many other issues there is no unanimity amongst EU states as to how to fill the details of said concepts: and this is further buttressed by how differently European states have regulated research on HESCs<sup>60</sup>.

The not so high number of ratifications of the Convention on Human Rights and Biomedicine, signed in Oviedo in 1997 under the auspices of the Council of Europe, seems to confirm the absence of a common European concept of morality, with particular reference to bioethics. Article 18(2) of this treaty prohibits the creation of human embryos for research purposes. However, the convention has not been ratified yet by several countries, including Italy, Malta, the Netherlands, Poland, Russia and Sweden. Germany and United Kingdom have not even signed it. Further, Article 18(1) permits Member countries with laws allowing research on embryos *in vitro* to keep such laws by making a reservation pursuant to Article 36<sup>61</sup>. It is thus believed that the Bioethics Convention still lacks the required level of endorsement amongst the countries parties to the Council of Europe<sup>62</sup>.

Even the European Court of Human Rights (ECtHR), the watchdog of the ECHR, which sets forth fundamental principles common to all European peoples, held in the (non-intellectual-property-related) cases *Vo v France* and *Evans v UK* that there is no consensus at European level on the nature and status of the embryo or fetus and that therefore the issue of when

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<sup>60</sup> See Torremans, above note 21, pp. 290-291.

<sup>61</sup> In the United Kingdom destruction of supernumerary embryos created for *in vitro* fertilization purposes is even required by law. See Sigrid Sterckx, "The WARF/Stem cells case before the EPO Enlarged Board of Appeal", *European Intellectual Property Review* (2008), p. 536.

<sup>62</sup> As is known, the Council of Europe is not an EU body but it is an international organization promoting the protection of human rights and the rule of law. It has 47 member countries with some 800 million citizens. Another treaty which has been sponsored by the Council of Europe is the already mentioned European Convention on Human Rights.

the right to life begins is to be decided by each country<sup>63</sup>. The CJEU also found in three cases (two of which were non-intellectual-property-related) that Member states have the freedom to determine what morality amounts to in their own territory in accordance with their own values. It has done so in *Van Duyn v Home Office*<sup>64</sup>, *R v Henn and Derby*<sup>65</sup> and in the proceedings brought about against the Biotech Directive<sup>66</sup>.

That no common concept of morality exists in the field of biotech inventions has also been affirmed by the EPO on some occasions. In the already mentioned *Leyland Stanford* case, that concerned the modification of animals which were implanted with human red blood cells extracted from aborted fetuses or young children, the Opposition Division admitted that the difficulty with taking a moral decision in biotech matters is that “there is at present no consensus in European society about the desirability or otherwise of this technology”<sup>67</sup>.

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<sup>63</sup> See Case 53924/00 (paragraph 84) and Case 6339/05 (paragraph 54). See also Malene Rowlandson, “WARF/Stem cells (G2/06): the ordre public and morality exception and its impact on the patentability of human embryonic stem cells”, *European Intellectual Property Review* (2010), p. 74.

<sup>64</sup> See Case C-41/74: “the particular circumstances justifying the recourse to the concept of public policy may vary from one country to another and from one period to another, and it is therefore necessary in this matter to allow the competent national authority an area of discretion within the limits imposed by the treaty” (paragraph 18).

<sup>65</sup> See Case C-43/79: “in principle it is for each Member State to determine in accordance with its own scale of values and in the form selected by it the requirements of public morality in its territory” (paragraph 15). See also the analogous finding of the WTO Panel of 10 November 2004 in *United States — Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, according to which public morals and public order “can vary in time and space, depending upon a range of factors, including prevailing social, cultural, ethical and religious values. [...] Members should be given some scope to define and apply for themselves the concepts of “public morals” and “public order” in their respective territories, according to their own systems and scales of values” (paragraph 6.461).

<sup>66</sup> See Case C-377/98. Here the Court held that Article 6 of the Biotech Directive allows “the administrative authorities and courts of the Member State a wide scope for manoeuvre in applying this exclusion. However, that scope for manoeuvre is necessary to take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative and court authorities are better placed to understand than are the Community authorities [...]” (paragraphs 37 and 38).

<sup>67</sup> See paragraph 51 of the decision. See also Amanda Warren-Jones, “Finding a ‘common morality codex’ for biotech – a question of substance”, *International Review of Intellectual Property and Competition Law* (2008), p. 654.

And in the *Edinburgh* case the Opposition Division noted that there were no uniform moral standards in Europe on HESCs<sup>68</sup>.

In light of all the above, it seems difficult to affirm the existence of a single and unitary European concept of morality, especially when it comes to patenting biotech and HESCs inventions.

As no single concept of morality in these fields seems to exist at European level, it has been proposed that the EPO adopts a “maximalist” test. This means that the EPO should not grant the patent if the exploitation of the invention is morally deplorable in just one country. The contrariety to accepted principles of morality in just one state would therefore block the patenting of the invention before the EPO. As an alternative a “minimum” test has also been proposed, according to which the refusal of a patent would be allowed only if all the states designated in the application deem the invention morally unacceptable<sup>69</sup>. The author believes that this latter approach would be preferable. In this regard Paul Torremans is right in noting that it would be unfair if an EPO patent application designating several European countries were to be rejected just because one state deems the invention unpatentable on morality or *ordre public* grounds. And the solution he proposes is appropriate, *i.e.* that a revocation procedure in the countries where the inventions raises morality based objections should be made available<sup>70</sup>. Paul Torremans goes even further and proposes to go beyond the minimum test by transforming it into a “distributive application” approach. In short, this

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<sup>68</sup> See paragraph 2(5)(3) of the decision.

<sup>69</sup> See Torremans, above note 21, p. 298.

<sup>70</sup> See Torremans, above note 21, pp. 298-299. See also Josef Straus, “Ethische, rechtliche und wirtschaftliche Probleme des Patent- und Sortenschutzes für die biotechnologische Tierzucht und Tierproduktion”, *International Review of Industrial Property and Copyright* (1994), pp. 918 *et seq*; Ulrich Schatz, in Margarete Singer – Dieter Stauder, *The European Patent Convention. A Commentary*, Vol 1 (Cologne: Carl Heymans Verlag 2003) section 22, 91, quoted by Bakardjieva Engelbrekt, above note 44, p. 260 (noting that, in case an invention is morally unacceptable in just one or a few countries, the applicant could, on his own initiative or as a result of a decision of the EPO, cancel the designation of the states concerned).

proposal would entail that the EPO - when dealing with a patent application designating several countries - must assess the morality or *ordre public* acceptability of the invention by taking into account the ethical principles of each designated state; it would then issue the patent exclusively in those countries in which the invention is morally acceptable and/or complies with *ordre public*<sup>71</sup>. This proposal has been criticised as the EPO would lack the capacity to carry out said assessment: an assessment which implies that the body entrusted with this task must have a deep knowledge of domestic non-patent-related laws, case law and moral norms. It has moreover been noted that the EPO has not been authorized to apply national statutes<sup>72</sup>.

Thus far, we have wondered whether the EPO, when applying Article 53(a) EPC, should take into account a common European concept of morality or rather verify whether the invention raises ethical concerns in just one or several European states. What about a EU-wide patent title valid in all the Members States? As a matter of fact, it seems that the EU will soon create such unique title<sup>73</sup>. It has been argued that in this case the best solution would be the maximalist test<sup>74</sup>. This would imply that the patent should not be issued if the exploitation of the invention is morally unacceptable also in just one EU Member state. This option would however irritate other countries in which the invention in question would raise no morality or *ordre public* related concerns. This negative aspect could be alleviated by the fact that the applicants could nonetheless rely on alternative patent procedures, such as national, EPC or PCT based routes<sup>75</sup>.

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<sup>71</sup> See Torremans, above note 21, pp. 300-301.

<sup>72</sup> See Bakardjieva Engelbrekt, above note 44, p. 260.

<sup>73</sup> See Enrico Bonadio, "The EU Embraces Enhanced Cooperation in Patent Matters: Towards a Unitary Patent Protection System", *European Journal of Risk Regulation* (2011), pp. 416-420.

<sup>74</sup> See Torremans, above note 21, p. 300.

<sup>75</sup> See Torremans, above note 21, p. 300.

## **Back to *Brüstle*: what could be the aftermath of the decision?**

After analyzing the moral issues stemming from patent procedures involving biotech and HESCs inventions, it is now interesting to comment on the possible consequences of the CJEU's decision in *Brüstle*.

First of all, the ruling may expose the EU and some of its Member states to a possible litigation before the WTO adjudicatory bodies for allegedly violating Article 27(2) TRIPS Agreement. As already mentioned, this provision states that "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment". Thus far WTO courts have given no interpretation of this provision. Yet it is believed that it should be interpreted as allowing the exclusion from patentability of a given invention only if at the same time the distribution and sale of the relevant product is prohibited<sup>76</sup>. This provision was lobbied by industrialised countries during the Uruguay Round negotiations and mainly directed to developing and least developed nations. Indeed, absent this rule, the latter states could have pursued free-riding strategies by allowing the commercial exploitation of foreign inventions locally while maliciously prohibiting their patentability.

Another interpretation of Article 27(2) has been proposed according to which an actual ban on the sale of the relevant products would not be required as a condition for introducing an exclusion from patentability on the above grounds: a state would just need to prove that

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<sup>76</sup> See Van Den Bossche, *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, Cambridge University Press (2008), p. 785.

there is a mere necessity to prevent the commercial exploitation of the invention<sup>77</sup>. The author believes that such interpretation is flawed. As has been noted, how could a state realistically claim that the prevention of the commercial exploitation of an invention in its territory is necessary if at the same time it allows said commercial exploitation<sup>78</sup>? It seems thus reasonable to affirm that, in order to be compliant with this TRIPS provision, a country should guarantee that there is a symmetrical correspondence between ethical norms built inside patent law and moral provisions applied outside patent law<sup>79</sup>. After all, this was the position of the European Parliament Committee on Legal Affairs and Citizens' Rights of 25 June 1997 in the context of the discussions which eventually led to the enactment of the Biotech Directive<sup>80</sup>.

Having said that, the *Brüstle* decision – which has affirmed the non-patentability of HESCs inventions that involve destruction of human embryos - may expose the EU to a challenge under Article 27(2) TRIPS. Indeed, research and commercial activities which involve the use of human embryos, including destructive uses, are not specifically prohibited by EU legislation<sup>81</sup>. Some Member countries that have adopted quite liberal legislations in this specific regard (such as the United Kingdom) might also be involved in a WTO litigation on the same grounds. And both the EU and those Member states which are “permissive” in the field of HESCs research would probably be unable to prove that in such a field there is a

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<sup>77</sup> See Dan Leskien – Michael Flitner, “Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System”, IPGRI, Issues in Genetic Resources No 6, 1997, p. 15 (available at <ftp://ftp.cgiar.org/ipgri/Publications/pdf/497.pdf>: last accessed on 4 January 2012).

<sup>78</sup> See Porter, above note 32, pp. 359-360.

<sup>79</sup> See Aurora Plomer, “Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions”, in Plomer – Torremans, above note 13, p. 178.

<sup>80</sup> Committee on Legal Affairs and Citizens' Rights, 25 June 1997, A4-0222/97. Report on the Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions/COM/95/0661.

<sup>81</sup> See Plomer, above note 79, p. 180.

symmetrical correspondence between ethical norms built inside patent law and moral provisions applied outside patent law.

In addition to a possible violation of the TRIPS Agreement, such a “systemic incoherence”<sup>82</sup> between legislation applied outside patent law and patent related case law seems to violate the principle of legal certainty. The ruling in *Brüstle*, in particular, carries the risk to legitimise a paradoxical situation, a situation which has obviously been highlighted and criticised by the biotech industry: *i.e.* the fact that the CJEU has rendered unpatentable what is not deemed as morally unacceptable by EU legislation and in several EU countries.

The author also wonders whether the *Brüstle* decision might be invoked in other fields, for instance in order to oppose the issuance, or challenge the validity, of patents covering inventions reached through unlawful activities. Indeed, as we have seen, in the case at issue it was held that an invention cannot be patented on morality grounds if its implementation requires either the prior destruction of human embryos or their prior use as base material, even though no reference to said prior destruction or use is made in the application. What we learn from the ruling is that the full history of the invention is to be taken into account when it comes to applying morality and *ordre public* clauses. In other words, patent officers and judges should verify whether the invention is built on immoral foundations, and not only whether it can be worked in a moral manner at the time of the filing of the patent application.

Two considerations stem from the above finding of the Court.

First, the finding seems to be contrary to what the very CJEU held ten years earlier in the proceedings instituted against the Biotech Directive. On that occasion the Court noted that the directive in question regards only the issuance of patents and its “scope does not extend

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<sup>82</sup> See Plomer, above note 79, p. 186.

to activities before and after the grant, whether they involve research or the use of the patented products”<sup>83</sup>.

Secondly, the ruling leaves open a thorny question. How far must patent officers and judges dig to find an immoral act upon which an invention is based? In other words, what distance should there be between an immoral act and the patenting of the downstream product or process? The Advocate General in *Brüstle* dealt with this issue. He interestingly noted that one of the findings of the International Criminal Tribunal for the former Yugoslavia was that several prisoners had been murdered with a view to extracting their organs for trafficking. He then asked himself the following question: if instead of trafficking there were experiments leading to new and inventive products or processes, would such inventions have had to have been considered as patentable on the grounds that how they had been reached was not included in the application? The Advocate General believed that these hypothetical inventions would not be patentable on morality grounds<sup>84</sup>.

Many other examples could be given. For instance, does the use of slave or child labour in the manufacturing process of certain goods (*e.g.*, rubber for tires made by Liberian slaves; football balls and sporting shoes made by Pakistani kids; etc.) entail that said products could not be patented because they are morally unacceptable? Again there is no easy answer, even though the above observation by the Advocate General in *Brüstle* could militate in favor of an affirmative response.

If an affirmative answer is eventually given to the above question, the author also proposes the exclusion from patentability on morality grounds of the (many) biotech patents obtained as a result of the misappropriation of genetic resources. Indeed, as is well-known,

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<sup>83</sup> See paragraph 79 of the decision (Case C-377/98).

<sup>84</sup> See paragraphs 106-108 AG’s opinion.

many biotech-related patents in the last decades have been granted and are nowadays still being granted to companies or universities established in industrialised countries, the relevant inventions being reached using germplasm gathered in biodiversity-rich states, *e.g.* DNA sequences or genes extracted by plants which have particular and commercially valuable properties. All this often occurs without requiring and obtaining a prior informed consent from the country or local community which provides the germplasm in question, *i.e.* the raw material of the inventions. And it also often happens that the natural or legal persons that obtain these patents do not share the benefits stemming from the commercial exploitation of the invention with the local communities which have provided the raw materials and have maintained their valuable properties throughout the years and sometimes even centuries<sup>85</sup>. These activities may also turn out to be contrary to key principles established by the Rio de Janeiro Convention on Biodiversity<sup>86</sup>.

The point is thus the following. If the Advocate General in *Brüstle* believed that an hypothetical invention reached through experiments on the organs of murdered prisoners could not be patented on morality grounds, why could not we deem unpatentable on the same grounds patents obtained thanks to misappropriation of genetic resources? It seems indeed that the distance between such acts of misappropriation and the subsequent

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<sup>85</sup> The cases are many and have been widely reported. See for example the “enola”, “neem” and “ayahuasca” cases. See also the position of Peru in the context the WTO talks (WTO document IP/C/W/447, p. 6).

<sup>86</sup> The Biodiversity Convention was signed in 1992 and entered into force on December 1993. It establishes (i) that states enjoy sovereignty rights on the genetic resources found on their territories, (ii) a system which allows respect for “prior informed consent” of the country providing the resource and (iii) the fair and equitable sharing of the benefits arising out of the utilization of the resources with the above entity.

inventions is not greater than the distance between the experiments on the organs of killed prisoners and the downstream inventions<sup>87</sup>.

### **Concluding remarks**

Patentability of HESCs is a thorny topic which has already kept scholars busy in the recent past and will definitely do the same in the years to come.

One of the key issues is whether patent officers and courts should verify the moral implications of inventions in the biotech and in particular HESCs field. It is believed that they should. The clear wording of Recital 38 and 39 and Article 6 of the Biotech Directive and Article 53(a) EPC as well as the case law from EPO do not leave room for doubts. And the CJEU in *Brüstle*, at least in an implied way, took a moral stance, confirming once again that ethical and moral concerns have entered into the patent system. Patent law should not therefore be isolated from moral and *ordre public* issues, even more so if we look at the general purpose of the patent system, *i.e.* to incentivise (before) and reward (after) products and processes useful to our society. And the task of patent officers and judges, that may find it difficult to deal with ethical issues, could be facilitated by coupling them with technical experts.

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<sup>87</sup> In the context of WTO talks some states have adopted similar views. See again the position of Peru which has proposed to add an additional letter to Article 27(2) TRIPS, by specifying that WTO Member States may also exclude from patentability “(c) *products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use. Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity*” (see WTO document IP/C/W/447, p. 13).

The author also proposes that the EPO adopts a minimum test when it comes to patenting inventions which are contrary to accepted principles of morality in just one or some European countries. Indeed, as there does not seem to be a common concept of morality in Europe, especially in the field of biotechnology and HESCs, the above test seems the more appropriate. It would be unfair if an EPO patent application designating several European countries were to be rejected just because one state deems the invention unpatentable on morality or *ordre public* grounds. As suggested by Paul Torremans, an additional proposal could be to envisage a revocation procedure in the countries where the inventions raises moral objections.

The CJEU's ruling in *Brüstle* – which has affirmed the non-patentability of HESCs inventions that involve the destruction of human embryos - might also expose the EU and some of its Member states to a challenge under Article 27(2) TRIPS. This provision should be interpreted as allowing the exclusion from patentability of a given invention only if at the same time the distribution and sale of the relevant product is prohibited. Yet, we have seen that research activities which involve the use of human embryos, including destructive uses, are not prohibited by EU legislation and some of its Member states.

Finally, the author proposes to invoke the *Brüstle* ruling in the future in fields other than HESCs, for example in order to oppose the issuance, or challenge the validity, of patents covering biotech inventions obtained through misappropriation of genetic resources. Indeed, patent applicants should not be in a position of avoiding a refusal or an invalidation decision just because upstream unlawful activities, which have been necessary to reach the invention, are not mentioned in the application.