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**Citation:** Bonadio, E. (2012). Stem Cells Industry and Beyond: What is the Aftermath of Brüstle?. *European Journal of Risk Regulation*, 3(1), pp. 93-97. doi: 10.1017/s1867299x00001860

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13 December 2016<sup>11</sup> while it is currently only mandatory when a nutrition claim is made.<sup>12</sup> Articles 29 to 35 of Regulation (EU) No. 1169/2011 establish detailed requirements for nutrition declarations, and also address issues like the eventual expression on a per portion basis or per consumption unit. Food business operators should analyse in detail the new EU rules on nutrition labelling and the possibilities which Regulation (EU) No. 1169/2011 provide to promote the nutritional properties of foodstuffs. The respective labels on food products should, however, be carefully assessed so as to ensure compliance with these detailed and not always straightforward rules.

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## Intellectual Property

*This section is devoted to giving readers an inside view of the crossing point between intellectual property (IP) law and risk regulation. In addition to updating readers on the latest developments in IP law and policies in technological fields (including chemicals, pharmaceuticals, biotechnology, agriculture and foodstuffs), the section aims at verifying whether such laws and policies really stimulate scientific and technical progress and are capable of minimising the risks posed by on-going industrial developments to individuals' health and safety, inter alia.*

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## Stem Cells Industry and Beyond: What is the Aftermath of Brüstle?

Enrico Bonadio\*

### I. Introduction

On 18 October 2011 the Court of Justice of the European Union (CJEU) released its decision 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.

This report aims to verify whether the *Brüstle* ruling may expose the EU and some of its Member States to a WTO challenge for failing to comply with Article 27(2) of the TRIPS Agreement as well as whether the decision 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.

### II. The decision

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 from HESCs.<sup>2</sup> By growing specific tissue from these cells, this invention is intended to treat damaged organs in patients suffering from various diseases including 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 CJEU was asked to interpret Article 6(2)(c) of Directive 98/44 on the patentability of biotechnological inventions (Biotech Directive<sup>3</sup>), according to which, "uses of human embryos for industrial or commercial purposes" are not patentable. Article 6(2) lists some examples of non-patentable inventions<sup>4</sup>, which

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

2 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?", 29 *Loyola of Los Angeles International and Comparative Law Review* (2007), pp. 505 *et seq.*

3 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. In its ruling of 9 October 2001 the Court dismissed the application brought by the Netherlands and confirmed the validity of the directive.

4 The list also includes the following non-patentable inventions: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) 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.

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11 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ 2011 L 304/18.

12 Article 2(2) of Council Directive 90/496/EEC on nutrition labelling, OJ 1990 L 276/40.

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>5</sup>

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 a “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>6</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 an 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>7</sup>

The final issue decided by the CJEU 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>8</sup> Indeed, not excluding them from patentability would allow patent attorneys to skilfully draft claims to gain patentability on an otherwise non-patentable invention under Article 6(2) of the Biotech Directive. The CJEU thus held that an invention is not 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>9</sup> As noted by the Advocate General, if that were not the case, the prohibition under Article 6(2) of the Biotech Directive would be easy to get around, as the applicant would simply 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>10</sup>

The biotech industry has obviously criticised the ruling. One 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 inventions on moral and *ordre public* grounds.<sup>11</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 in the CJEU’s ruling), several scientists expressed their “profound concerns” about the possibility of a lack of patent protection in a highly R&D intensive industry such as the HESCs field.<sup>12</sup>

5 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 and 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 in extreme cases only, e.g. when the invention applied for is so abhorrent that the grant of the patent would be inconceivable.

6 See paragraphs 35-36 of the decision.

7 See paragraphs 42-43 of the decision.

8 The European Parliament’s “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).

9 It is clear from the way the third question was formulated that the said prior use of human embryos is a destructive one.

10 See paragraph 108 AG’s opinion.

11 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.

12 Yet, the patenting of HESCs inventions has also been blamed for paving the way towards 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 and Paul Torremans (eds.), *Embryonic Stem Cell Patents* (Oxford: Oxford University Press, 2009), p. 372.

### III. A possible WTO implication of the ruling

The CJEU's decision may expose the EU and some of its Member States to litigation before the WTO adjudicatory bodies for allegedly violating Article 27(2) of the TRIPS Agreement.<sup>13</sup> 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>14</sup> This provision was lobbied for by industrialised countries during the Uruguay Round negotiations and mainly directed at developing and least developed nations. Indeed, absent this provision, 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) of the TRIPS Agreement 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 there is a mere necessity to prevent the commercial exploitation of the invention<sup>15</sup>. Such interpretation seems to be 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 it simultaneously allows said commercial exploitation?<sup>16</sup> It seems thus reasonable

to affirm that, in order to comply 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>17</sup> This was also 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>18</sup>

Having said that, the Brüstle decision – which has affirmed the non-patentability of HESCs inventions that involve the destruction of human embryos – may expose the EU to a challenge under Article 27(2) of the TRIPS Agreement. Indeed, research and commercial activities which involve the use of human embryos, including destructive uses, are not specifically prohibited by EU legislation.<sup>19</sup> Some Member countries that have adopted quite liberal legislation in this specific regard (such as the United Kingdom) might also be involved in 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 symmetrical correspondence between ethical norms built inside patent law (as is known, EU Member States must respect and follow CJEU rulings, including therefore the Brüstle decision) and moral provisions applied outside patent law.

In addition to a possible violation of the TRIPS Agreement, such a "systemic incoherence"<sup>20</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 of legitimising a paradoxical 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.

13 The TRIPS Agreement was signed by all WTO member countries in 1994 and covers all types of intellectual property including patents, copyright and trademarks. It requires intellectual property rights to be protected in all WTO member countries.

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

15 See Dan Leskien and 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 on the Internet at <ftp://ftp.cgiar.org/ipgri/Publications/pdf/497.pdf> (last accessed on 4 January 2012).

16 See Gerard Porter, "Human Embryos, Patents and Global Trade: Assessing the Scope and Contents of the TRIPS Morality Excep-

tion", in Plomer and Torremans (eds.), *Embryonic Stem Cell Patents*, *supra* note 12, pp. 359–360.

17 See Aurora Plomer, "Towards Systemic Legal Conflict: Article 6(2) (c) of the EU Directive on Biotechnological Inventions", in Plomer and Torremans (eds.), *Embryonic Stem Cell Patents*, *supra* note 12, p. 178.

18 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.

19 See Plomer, "Towards Systemic Legal Conflict", *supra* note 17, p. 180.

20 *Ibid.*, p. 186.

#### IV. Extending the effect of the ruling

One might also wonder 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 can be learned from the ruling is that the full history of the invention is to be taken into account when applying morality and *ordre public* clauses. In other words, patent officers and judges should inquire whether the invention is built on immoral foundations, and not only whether the invention can be described in a moral manner when filing the patent application.

Two considerations stem from the above-finding of the Court.

First, the decision seems to contradict 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 to activities before and after the grant, whether they involve research or the use of the patented products”.<sup>21</sup>

Second, 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 must 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 decisions of the International Criminal Tribunal for the former Yugoslavia found that several prisoners had been murdered with the intention to extract 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 seemed to believe that these hypothetical inventions would be considered non-patentable based on morality grounds.<sup>22</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, footballs and sporting shoes made by Pakistani children, 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* favors an affirmative response.

If an affirmative answer is eventually given to the above question, it is proposed to exclude from patentability on morality grounds the (many) biotech patents obtained as a result of the misappropriation of genetic resources. Indeed, as is well-known, 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, but the relevant inventions use germplasm gathered in biodiversity-rich developing states, e.g. DNA sequences or genes extracted by plants which have particular and commercially valuable properties. This often occurs without requiring and obtaining 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 that have provided the raw materials and maintained their valuable properties throughout many years and sometimes even centuries.<sup>23</sup> These activities may also turn out to be contrary to key principles established by the Rio de Janeiro Convention on Biodiversity.<sup>24</sup>

The point is thus the following. If the Advocate General in *Brüstle* believed that a hypothetical invention reached through experiments on the organs

21 See paragraph 79 of the decision (Case C-377/98).

22 See paragraphs 106–108 AG’s opinion.

23 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 of the WTO talks (WTO document IP/C/W/447, p. 6).

24 The Biodiversity Convention was signed in 1992 and entered into force in 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.



of murdered prisoners could not be patented based on morality grounds, why could not we deem non-patentable, on the same grounds, patents obtained through the misappropriation of genetic resources? It seems indeed that the distance between such acts of misappropriation and the subsequent inventions is no greater than the distance between the experiments on the organs of murdered prisoners and the downstream inventions.<sup>25</sup>

## V. Conclusion

The Brüstle ruling has already been the object of hot debates and will continue to spur discussion in the months to come.

It is difficult to foresee whether a WTO action under Article 27(2) of the TRIPS Agreement will be eventually taken against the EU and/or some of its Member States. Indeed, the stem cell industry is still in its infancy and countries such as the United States may not be interested in running the risk associated with WTO litigation, especially considering that the provision in question – as we have seen – might be interpreted in different ways.

The ruling might also be open to extensive interpretation, and in particular it could be relied on in fields other than HESCs, for example in order to oppose the issuance, or challenge the validity, of patents covering any inventions obtained through illegal activities, including biotech inventions reached through the misappropriation of genetic resources. Indeed, one might argue that patent applicants should not be able to avoid 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.

<sup>25</sup> In the context of WTO talks some states have adopted similar views. See 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).

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## Lifestyle Risks

*This section discusses the regulation of “lifestyle risks”, a term that can apply to both substances and behaviours. Lifestyle risks take place along the line of “abstinence – consumption – abuse – addiction”. This can concern substances such as food, alcohol or drugs, as well as behaviours such as gambling or sports. The section also addresses the question of the appropriate point of equilibrium between free choice and state intervention (regulation), as well as the question of when risks can be considered to be acceptable or tolerable. In line with the interdisciplinary scope of the journal, the section aims at updating readers on both the regulatory and the scientific developments in the field. It analyses legislative initiatives and judicial decisions and at the same time it provides insight into recent empirical studies on lifestyle risks.*

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## Lifestyle Risk: The Challenging Marriage of Two Thorny Concepts

Liana Giorgi\*

*The terms lifestyle and risk are so commonplace today that we tend to take their meaning (and social history) for granted. This is unfortunate, since neither of them is either value-free or unequivocal. Linking them – in an abstract sense as well as with regard to policy – is therefore bound to raise multiple questions regarding the definition of boundaries. If we recognise that lifestyle is not a matter of individual agency alone but also a question of structure and, similarly, if risk assessment is not just determining objects or incidences of risk but also about establishing the societal and environmental contexts within which specific negative outcomes are more likely to happen, then we are confronted with the challenge of how to approach the subject of lifestyle risk without falling prey to the temptation to impose normative expectations. This paper takes issue with some of the ideas advanced in the article by Planzer and Alemanno published in EJRR 4/2010 “Lifestyle Risks: Conceptualization of an Emerging Category of Research” by considering the framing of the concept of lifestyle risk. The emergence of this concept is symptomatic of a general trend from both the right and the left of the*

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