

# The limits of “*ordre public*” and “morality” for the patentability of human embryonic stem cell inventions

## Abstract

Inventions involving human embryonic stem cells (hESC) have unprecedented potential to improve human life through discovery of new drugs and treatment of incurable neurodegenerative diseases, but at the same time, the use of human embryos in research gives rise to contrasting ethical, moral, and religious views on the patentability of such inventions. Whether and to what extent patent offices should take these views into account is an open question. Although the “*ordre public*” and “morality” clause in patent law may help us find an answer, neither the legislator nor courts have clarified the meaning of these vague terms. Judicial interpretation has sometimes increased their ambiguity and raised legal uncertainty for the patentability of hESC inventions. This situation may be desirable in some cases, but not in others where the principles of the legal system as a whole come into play. This paper will shed light on the meaning of “*ordre public*” and “morality” for hESC inventions by examining patent law in the broader legal framework and emphasizing the interconnectedness of national legal systems in a global market as well as the common interest in healthcare innovations.

## Introduction

We are living in an era where Frankenstein’s inventions have become a reality. Dolly the sheep, human-pig chimeras,<sup>1</sup> and human genome editing for therapeutic purposes<sup>2</sup> are all inventions driven by scientific reasons, but they unavoidably spur a debate on the ethics, morality, public acceptance and philosophical foundations of such inventions. When these inventions are patented, the discussion on different interests and values underlying “Frankenstein’s inventions” transposes into patent law. Among these inventions, human embryonic stem cell (hESC) inventions may be considered the most controversial because they have the potential to introduce inheritable changes to the human genome. This may occur, for example, when the CRISPR-Cas9 technique is applied to modify the DNA of human embryos in order to cure genetic diseases. The main clash of values and interests in this case is between those that seek to improve human health with those that fear the creation of designer babies or humans with superlative skills as depicted in the movie *Gattaca*.<sup>3</sup> Although these inventions and related patents have not yet materialized, it is interesting to note that the USPTO has awarded a patent on “gamete donor selection” that enables prospective parents to handpick a sperm or egg donor with whom they would be likely to produce a child born with desirable traits<sup>4</sup> and the Japan Patent Office now allows patents on CRISPR-Cas9 applied to hESC as long as the invention does not aim at creating a human being. These patents encourage research with hESC in order to improve human life through

---

<sup>1</sup> Wu et al., ‘Interspecies Chimerism with Mammalian Pluripotent Stem Cells’ (2017) 168 (3) *Cell*, pp. 473- 486, available at [http://www.cell.com/cell/fulltext/S0092-8674\(16\)31752-4](http://www.cell.com/cell/fulltext/S0092-8674(16)31752-4). Accessed 14 February 2018.

<sup>2</sup> Since 2015, Chinese doctors have conducted 11 trials on humans using CRISPR-Cas9, a gene-editing tool, to treat cancer. See *The Washington Post*, *Unhampered by Rules, Races Ahead in Gene-Editing Trials*, 24 January 2018, available at <https://www.wsj.com/articles/china-unhampered-by-rules-races-ahead-in-gene-editing-trials-1516562360>, accessed 24 January 2018.

<sup>3</sup> This is a science fiction representing a future society driven by eugenics.

<sup>4</sup> The patent has been granted to [23andMe](https://www.23andme.com), the genetic testing company that sells at-home DNA kits directly to consumers. For more on this invention, see <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm551185.htm>, accessed 15 February 2018.

discovery of new drugs, treatment of incurable neurodegenerative diseases, drug toxicity arrays, organ transplantation and through understanding of the origin of health problems,<sup>5</sup> but they may also represent a step towards human genome modification.<sup>6</sup>

The current debate on the patentability of hESC inventions, however, focusses on the destruction of the embryo.<sup>7</sup> The generation of human embryos implies the destruction of the blastocyst, a structure in early development that contains a cluster of cells from which the embryo arises.<sup>8</sup> Some deem the destruction of the blastocyst equivalent to the destruction of an unborn child, while others sustain that the blastocyst will never develop into a child unless implanted in the uterus wall.<sup>9</sup> This ethical dilemma on the status of the embryo<sup>10</sup> and related social concerns enter into patent law through the public policy clause. This clause, which excludes some types of inventions from patentability, is found in art. 27. 2 of the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS Agreement). The provision gives an option to World Trade Organization (WTO) countries to exempt subject matter from patentability for reasons of “*ordre public*” and “morality”:

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, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

This provision recognizes the differences between different jurisdictions.<sup>11</sup> Prior to the TRIPS agreement, the EU, Japan, New Zealand, and other WTO members had a public

---

<sup>5</sup> This has been affirmed by scientific researchers in the field both in Europe and Japan. See the bibliography section for the interviews with scientists in Europe and Japan. For a comprehensive understanding of regenerative medicine see Anthony Atala (ed), *Foundations of Regenerative Medicine. Clinical and Therapeutic Applications*, Elsevier, Academic Press, 2009.

<sup>6</sup> It is worth noting here that there exists a market for human genome modification. See better Fox D., ‘Paying for Particulars in People-to-Be: commercialisation, commodification and commensurability in human reproduction’ (2008) 34 *Journal of Medical Ethics*, pp. 162-166.

<sup>7</sup> The importance of hESC in research remains even after the invention of induced pluripotent stem cells (iPSC) from Prof. Yamanaka. Although iPSC circumvent the problem of embryo destruction, hESC are still relevant for conducting similarity tests (to evaluate their similarity with iPSC) and for studying diseases. As confirmed during interviews with scientists (Friederike Matheus and Micha Drukker of Helmholtz Centrum in Munich, December 2016 ) the performance of iPSC and hESC varies in base of the object and purpose of research.

<sup>8</sup> Final Report of the Expert Group on the development and implications of patent law in the field of biotechnology and genetic engineering (E02973) of 17 May 2016, p. 133. The report is available on the European Commission’s website: <http://ec.europa.eu/DocsRoom/documents/18604/attachments/1/translations/>. Accessed 8 January 2018.

<sup>9</sup> Embryonic Stem Cell Research: an Ethical Dilemma, available at <https://www.eurostemcell.org/embryonic-stem-cell-research-ethical-dilemma>. Accessed 8 January 2018.

<sup>10</sup> Please, note that the blastocyst is a distinctive stage of the embryo. For a scientific definition of “blastocyst” see Encyclopaedia Britannica, available at <https://www.britannica.com/science/blastocyst>. Accessed 8 January 2018.

<sup>11</sup> Prior to the TRIPS Agreement, the clause was originally inserted in national patent laws and in the text of the EPC. For more see S. Sterckx and J. Cockbain, *Exclusions from Patentability. How Far Has the European Patent Office Eroded Boundaries?*, Cambridge University Press, Cambridge, 2012, pp. 23-24, p. 289. For the clause in the TRIPS Agreement see D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, Thomson Reuters, 3<sup>rd</sup> ed., North Yorkshire, 2008, pp. 334-350.

policy clause into their patent systems, contrary to Australia,<sup>12</sup> Canada,<sup>13</sup> or the United States.<sup>14</sup> The implementation of the TRIPS Agreement did not affect their provisions on “*ordre public*” and “morality” or public policy. However, art. 27.2 gives poor guidance on the type of inventions that should be excluded from patentability. The vagueness of its terms can be clarified by courts and national legislations. But the interpretation of these legal terms in different jurisdictions may result in different types of permissible hESC inventions under national patent laws. This situation creates legal uncertainty, it may hinder the competitiveness of research institutions and business firms that operate internationally,<sup>15</sup> and thus run counter to the objectives of the TRIPS Agreement.<sup>16</sup> In order to shed light on the matter, this paper will clarify the limits of “*ordre public*” and “morality” for hESC inventions. It will first explain the rationale of these limits and their significance for hESC inventions. Then it will try to elucidate the meaning of the terms through an analysis of courts’ decisions and suggest some criteria for assessing “*ordre public*” and “morality” for hESC inventions. The legal considerations will build upon elaborations on the concept of ethics as a set of values that guides judicial and legislative decisions. The paper will seek to offer an answer to two questions formulated in the Call for Papers: how are morality and *ordre public* relevant considerations in determining the scope and application of intellectual property rights? ; and can and should morality and *ordre public* be defined or assessed as global norms?

### **The rationale of the “*ordre public*” and “morality” clause in patent law**

The public policy clause in patent law restricts the scope of patent rights *ex ante*. This means that patents cannot be granted for the subject matter that falls under the patent clause. This type of limitation to patent rights is known with the term “exclusion to patent rights”.<sup>17</sup> Exclusions to patent rights are not new. They have their origin in national laws. European countries excluded some type of inventions from patentability for reasons of public health, morals, or safety, or as being contrary to the general interest of the state since the 19<sup>th</sup> century.<sup>18</sup> Other countries such as Japan and China refer to inventions liable to contravene public order, morality, or public health and to creations that violate the law or social ethics, or harm public interests, respectively.<sup>19</sup> The United States also considered morally controversial inventions under the requirements of utility and subject matter as delineated in section 101 of the Patent

---

<sup>12</sup> C. Monger and J. Clark, IP Australia. Patentable Subject Matter, The Walter and Eliza Hall Institute of Medical Research, Response to the IP Australia Consultation Paper (2013), 27 September 2013, available at: [https://www.ipaustralia.gov.au/sites/g/files/net856/f/walter\\_eliza\\_hall\\_institute\\_-\\_submission\\_patentable\\_subject\\_matter.pdf](https://www.ipaustralia.gov.au/sites/g/files/net856/f/walter_eliza_hall_institute_-_submission_patentable_subject_matter.pdf). Accessed 13 November 2017.

<sup>13</sup> To be noted that the Canada Patent Act exempted inventions with an illicit object from patentability prior to its 1993 amendment.

<sup>14</sup> For the morality doctrine in the US patent system see M.A. Bagley, Patents First, Ask Questions Later: Morality and Biotechnology in Patent Law (2003) 45 (2) William Mary Law Review, pp. 469-547.

<sup>15</sup> For an understanding of legal hurdles see Eric Furman, ‘The Dynamic State of Patents in Regenerative Medicine’ (2013) 10 (5) Tissue Engineering and Regenerative Medicine, pp. 230-233.

<sup>16</sup> This may happen because less competition in the market might reduce the transfer and dissemination of technology as required in art. 7 of the TRIPS Agreement.

<sup>17</sup> For more on the conceptual understanding of the term see Christie, A. F. (2011). Maximising permissible exceptions to intellectual property rights. In A. Kur & V. Mizaras (Eds.), The structure of intellectual property law: Can one size fit all? (pp. 121–135). Cheltenham: Edward Elgar.

<sup>18</sup> For specific examples on Austria, France, and Italy see Bently, L. (2010) (2010). Exclusions from patentability and exceptions and limitations to patentee’s rights. WIPO Standing Committee on the Law of Patents, SCP/15/3, Annex 1.

<sup>19</sup> Art. 32 of the Japan Patent Act and art. 5 of the Patent Law of the People’s Republic of China.

Act.<sup>20</sup> Justice Story is repeatedly quoted for explaining that a ‘useful’ invention is one “which may be applied to a beneficial use in society, in *contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous or insignificant.*”<sup>21</sup> Although the Supreme Court later declared that the power to impose limits to patentability of subject matter belongs only to Congress,<sup>22</sup> the USPTO “inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.”<sup>23</sup>

A WIPO study identifies six public policy justifications for exclusions from patentability<sup>24</sup> and it notes that these justifications are subject to change.<sup>25</sup> For the purpose of this paper, two rationales are relevant. Those that aim at excluding undesirable subject matter from patent protection and those that recognise countervailing policy considerations. The first type of rationale can be understood in relation to the role of patent law in signaling the kind of desirable activity under the patent system.<sup>26</sup> In this respect, the Board of Appeal of the EPO has argued that the *ordre public* and morality clause is a question of principle to safeguard the public trust in the patent system as a whole.<sup>27</sup> This rationale can be further explained based on economic reasoning. Neoclassical economic theory suggests that patents act as incentives to invest in R&D. The absence of patents in a technological field will discourage research in that particular field. Since patents guide “the investment of capital in the use and development of pre-existing developments”,<sup>28</sup> they can be a means to direct the flow of capital towards improvements of current research. In absence of patents, the capital may be directed towards more profitable research.<sup>29</sup> This is how patent offices signal desirable types of inventions and indirectly influence the inventive activity.

The exclusion based on countervailing policy considerations takes account of values or rights that deserve protection. In terms of the issue at hand, it may be envisaged that patents on hESC may be counterbalanced against the right to health. For example, patents may increase prices

---

<sup>20</sup> Bagley, M (2007) A global controversy: the role of morality in biotechnology patent law, The University of Virginia Law School, Public Law and Legal Theory Working Paper Series, no. 57, p. 317, 319-320. See also Bently et al., *supra* note, p. 53

<sup>21</sup> Notes on the Patent Laws, 3 Wheat App 13, 24. Cited in Brenner (1966) 383 US 519, 533. *Lowell v Lewis* 15 Fed Cas 1018 (No 8568) (CCDMass); *Bedford v Hunt*, 3 Fed Cas 37 (No 1217) (CCDMass).

<sup>22</sup> Bagley, *supra* note, p. 320 citing *Chakrabarty*, 447 U.S. at 318. The grant of exclusive property rights in a human being is deemed to be prohibited by the Thirteenth Amendment.

<sup>23</sup> Bagley, p. 321 citing USPTO, *Media Advisory: Facts on Patenting Life Forms Having a Relationship to Humans*, <http://www.uspto.gov/web/offices/com/speeches/98-06.htm> (last modified Apr. 1, 1998).

<sup>24</sup> Bently et al., *supra* note, pp. 44-55.

<sup>25</sup> In particular, it refers to the Board of Appeal of the European Patent Office (EPO) reasoning in T 315/03, *Oncomouse*, para 4.4. See p. 44 of the WIPO report.

<sup>26</sup> Prof. Schneider, in particular, explains the Parliaments role in reframing patent law as regulatory law, I. Schneider, (2009) *Can Patent Legislation Make a Difference? Bringing Parliaments and Civil Society into Patent Governance* in S. Haunss and K.C. Shadlen, *Politics of Intellectual Property, contestation over Ownership, Use, and Control of Knowledge and Information*, Edward Elgar, Cheltenham.

<sup>27</sup> D. Stauder, ‘Artikel 53 Ausnahmen von der Patentierbarkeit’ in D. Stauder and S. Luginbühl, *Europäisches Patentübereinkommen Kommentar*, Carl Heymanns Verlag, 7<sup>th</sup> ed., Munich 2016, pp. 200-201.

<sup>28</sup> Arthur Twining Hadley (1986) *Economics. An Account of the Relations between Private Property and Public Welfare*. G.P. Putnam’s Son. New York, London, p. 134.

<sup>29</sup> Patents remain a business tool for companies to capture their investment although Burk argues that other types of IP rights or regulatory mechanisms may play a more important role than patents in personalized medicine, Dan L. Burk, ‘Patents as Data Aggregators in Personalized Medicine’ (2015) 21 *Boston University Journal of Science and Technology Law*, pp.232-255; W. Nicholson Price II, ‘Big Data, Patents, and the Future of Medicine’ (2016) 37 *Cardozo Law Review*, pp.1401-1452.

for hESC-based inventions and impair the right to receive healthcare for patients who cannot afford high prices. In this case, competition law can be a more appropriate mechanism to address the monopoly effects of patents. Indeed, several authors propose to leave the public policy clause outside the patent realm<sup>30</sup> since patent examiners are not well-equipped to decide on matters beyond patent law.<sup>31</sup> Moreover, the interpretation of art. 27.2 is quite complex.<sup>32</sup> The irrelevance of national laws in defining “*ordre public*” and “morality” may, in particular, seem difficult to conceive because if a country prohibits the commercial exploitation of an invention, there may be no interest to grant a patent. Similarly, if a country allows the commercial exploitation of the invention, there may be no interest to disallow the patent.

Since the TRIPS Agreement was negotiated with the aim to foster trade, the author of this paper believes that the wording “exclusion is not made merely because the exploitation is prohibited by their law” can be better understood in relation to the international system. This may be the case of a company that has protected the invention in countries where patentability is allowed but intends to obtain a patent in a country that prohibits research or has no regulations on the patented invention in order to have market power when laws change in the future. Even if the provision is applied in the national context, it can have a significance when the legislator plans to change the regulation. Legislative procedures may be long and complicated compared to patent processes. In this case, it may be quicker and easier to grant a patent while waiting for the regulatory change. Indirectly, patent offices play a regulatory role<sup>33</sup> but their position cannot depart from governmental objectives. Patent grants are often political decisions that indicate the types of inventions can be deemed beneficial for the public. This may occur when a patent is granted on an invention for which no regulation is in place yet. Indeed, this is the case of hESC inventions. Different countries have different regulations for hESC research<sup>34</sup> but new scientific discoveries in the field create legal loopholes. Until the legislative body takes a decision on the ethical aspects of patentability, patent offices will bear the burden. This is especially the case of those countries that have an “*ordre public*” and “morality” clause into their patent laws.

### **The meaning of “*ordre public*” and “morality” in patent law for hESC inventions**

Although exclusions aim at providing clarity for patentability, they are a “constant source of contention”.<sup>35</sup> The vagueness of the terms “*ordre public*” and “morality” is a significant example of interpretative difficulty. Their meaning can be clarified through definitions offered by dictionaries, literature, and court cases. The terms “*ordre public*” and “morality” have their origin in French law.<sup>36</sup> While a definition of “morality” as “a set of social standards for good

---

<sup>30</sup> J. Strauss. Kommerzielle und Patentrechtliche Aspekte der Genomforschung in G. Orth (ed) *Forschen und tun was möglich ist?* Edition “ethic kontrovers”, pp. 45-62. Bagley, *supra note*, suggests that the same.

<sup>31</sup> P. Treichel, “G2/06 and the Verdict of Immorality” (2009) IIC 450. However, the UK patent barrister, Daniel Alexander, notes that the patent system is the only legal arena where technologies are investigated on a case-by-case basis and institutions such as the EPO might be particularly to making decisions of this kind and ought to do so. See better Sigrid Sterckx and Julian Cobain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?*, Cambridge, Cambridge University Press, 2012, p. 300.

<sup>32</sup> For example, the exclusion concerns the commercial exploitation of the patent, not the patent *per se*. For a better understanding of the restrictions set in art. 27.2 see Carlos Correa, ‘Patent Rights’, in Carlos Correa and Abdulqawi Yusuf, *Intellectual Property and International Trade. The TRIPS Agreement*, pp. 267-268.

<sup>33</sup> It has been stated by the EPO that “The EPO being at the crossroads between science and public policy, was qualified to make value judgements about a given technology.” T 0356/93 (Plant cells) of 21.2.1995.

<sup>34</sup> For an understanding see “Richtlinien & Vorschriften” available on the EuroStemCell website, <https://www.eurostemcell.org/theme/policy-regulation>. Accessed 15 February 2018.

<sup>35</sup> Bently et al, *supra note*, p. 67, referring to several decisions of the US Supreme Court.

<sup>36</sup> Gervais, *supra note*, pp. 334-350.

behavior”<sup>37</sup> or “principles concerning the distinction between right and wrong or good and bad behavior”<sup>38</sup> offered by dictionaries may correspond to the French concept of *bonnes mœurs*<sup>39</sup> understood as “the degree of conformity to moral principles (especially good)”,<sup>40</sup> it is not possible to find a definition of “*ordre public*” in English. In French law, the term is an evolutionary concept that expresses concerns about “matters threatening the social structures of civil society as such”.<sup>41</sup> The EPO guidelines explain that the purpose of this public policy clause is to “deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour”.<sup>42</sup> According to the guidelines, the provision will be invoked in rare and extreme cases, when the public would “regard the invention as so abhorrent that the grant of patent rights would be inconceivable”.<sup>43</sup> On the other hand, the concept of morality has been related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture.<sup>44</sup> Obviously, this explanation offers poor guidance for hESC inventions, which need a case-by-case evaluation.

It is worth focusing our attention on EPO case law since the EPO boards of appeal have decided on twenty-six cases on “*ordre public*” and “morality”, of which 10 concern human embryonic stem cell inventions.<sup>45</sup> While it is not possible to infer a general rule on the interpretation of the public policy clause,<sup>46</sup> we can refer to art. 53 (a) of the European Patent Convention (EPC)<sup>47</sup> as the legislative basis for EPO decisions. This provision establishes that European patents shall not be granted in respect of:

---

<sup>37</sup> Cambridge online dictionary, available at <https://dictionary.cambridge.org/dictionary/english/morality>. Accessed 6 December 2017.

<sup>38</sup> The Oxford online dictionary, available at <https://en.oxforddictionaries.com/definition/morality>. Accessed 6 December 2017.

<sup>39</sup> The foundations of the concept can be found in the “boni mores” in Roman law. For an understanding of the concept see Reinhard Zimmermann, *The Law of Obligations: Roman Foundations of the Civilian Tradition*, Clarendon Press, Oxford University Press, Oxford, pp. 706 – 715.

<sup>40</sup> This definition is often found in literature. See UNCTAD-ICTSD. *Resource Book on TRIPS and Development*. Cambridge: Cambridge University Press, 2005, p. 375; D. Gervais, *supra note*, p. 345 with further references.

<sup>41</sup> Gervais, *supra note*, pp.343-344; UNCTAD-ICTSD, *supra note*, p. 375.

<sup>42</sup> EPO Guidelines for Examination, Part G- Chapter II-12, November 2017. Available at <https://www.epo.org/law-practice/legal-texts/guidelines.html>, accessed 7 December 2017.

<sup>43</sup> EPO Guidelines for Examination, Part G – Chapter II-12, 13.

<sup>44</sup> For more explanations see The Case Law of the Boards of Appeal of the European Patent Office, 8<sup>th</sup> ed, /July 2016, available at [https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clar\\_i\\_b\\_2\\_2\\_2\\_b.htm](https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clar_i_b_2_2_2_b.htm). Accessed 14 February 2018.

<sup>45</sup> The results are based on a search performed on the Boards of Appeal database, <http://www.epo.org/law-practice/case-law-appeals/advanced-search.html>, last accessed 27 January 2018. The search terms were “52(a)” in the box “EPC article” for the period 1989-2018. Please, note that although the results page displays 36 cases, some concern cases published in different languages.

<sup>46</sup> This is because the EPO judges have elaborated different tests for assessing “*ordre public*” and “morality” depending on the subject matter. For example, in the Oncomouse case, T 0315/03 (Transgenic animals/HARVARD) of 6.7.2004, the judges adopted a utilitarian understanding of the clause and allowed the patentability of the transgenic mouse. In another case, they used the test to reject an application claiming a transgenic mouse for screening hair growth stimulants.

<sup>47</sup> Convention on the Grant of European Patents of 5 October 1973 as amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005 and its Implementing Regulations as last amended by the Administrative Council on 9 December 2004. The text of the convention is available on the EPO website: <http://www.epo.org/law-practice/legal-texts/epc.html>. Accessed 31 January 2018. The EPC incorporates the provisions of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of biotechnological inventions. Although their provisions apply to different jurisdictions, they are highly harmonized.

inventions the commercial exploitation of which would be contrary to "*ordre public*" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.

R. 28 of the Implementing Regulations to the EPC further explains that under art. 53 (a), patents should not be granted on the following inventions:

- a) processes for cloning human beings;
- b) processes for modifying the germline genetic identity of human beings;
- c) uses of human embryos for industrial or commercial purposes;

Since R. 28 is a special provision compared to the general provision of art. 53 (a), this means that patentability decisions on hESC inventions should first be examined under this rule. If a decision cannot be reached, the provisions on "*ordre public*" and "morality" should be assessed. The application of R. 28, however, requires an interpretation of terms such as "cloning", "human being", "germline genetic identity", "use of human embryos" and "industrial or commercial purposes". Courts have not yet exhaustively clarified these terms, but there is common understanding that the terms "cloning process" refer to the process of creating a cell or organism with the same nuclear genome as another cell or organism.<sup>48</sup> It should be noted here that patent law is not concerned with the morality of the invention, but with the morality of the commercial exploitation of the invention. This means that if a human being were cloned, patent law would deem its "commercial exploitation" as immoral, not the cloned human being. There are two different types of cloning, reproductive and therapeutic cloning. The first aims at making an entire cloned human, while the second clones human cells for transplants and other medical uses. Two common methods of therapeutic cloning are somatic cell nuclear transfer (SCNT) and pluripotent stem cell induction. Cells obtained by the SCNT method are not currently patentable in Europe<sup>49</sup> but induced pluripotent stem cells (iPSC) can be patented. The interpretation of this provision is yet uncertain because there is no legal definition of the status of "human being" and it is not clear whether the human embryo can be deemed a human being.<sup>50</sup>

The terms "human being" are also relevant for interpreting the ban on "processes for modifying the germline genetic identity of human beings". This provision refers to processes that introduce heritable changes into the human genome. For example, the CRISPR-Cas9 technique could potentially be used to correct DNA sequences responsible for causing genetic diseases. The genetic modifications introduced by CRISPR-Cas9 are transmissible over generations. This is considered to be against "*ordre public*" and "morality". Likewise, "uses of human embryos for industrial or commercial purposes" are deemed immoral under R. 28. Although the meaning of these terms may appear quite straightforward, they have been subject to interpretation. For instance, the Expert Group on patent law<sup>51</sup> elaborates on three meanings of the term "use": strict; middle; and widest. The "strict meaning" refers to the direct use of human embryos in the inventive process, the "middle meaning" involves an invention obtained by destroying the human embryo, whereas the "widest meaning" implies a "process or substance which depends on a prior, "upstream" non-destructive use of a human embryo". The majority of the members of the Expert Group conclude that only those inventions that require the direct use of human embryos and of processes that destroy human embryos are excluded from

---

<sup>48</sup> Please, refer to Part G, Chapter II, 5.3 of the EPO Guidelines for Examination, available at [https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g\\_ii\\_5\\_3.htm](https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_3.htm). Accessed 31 January 2018.

<sup>49</sup> SCNT cells are patentable in other jurisdictions. For instance, Japan grants patent rights on SCNT for therapeutic purposes.

<sup>50</sup> A landmark case on this point is *Vo v. France* [GC], no. 53924/00, ECHR 2004-VIII.

<sup>51</sup> Please, refer to fn. 3. See page 146 of the Expert report.

patentability, while two dissenting members argue that any use of human embryos should be excluded from patentability. With respect to the purpose of embryo use, the Court of Justice of the European Union (CJEU)<sup>52</sup> has clarified that any use of the of human embryo is excluded from patentability unless the use of the invention is “for therapeutic and diagnostic purposes which are applied to the human embryo and are useful to it”.<sup>53</sup> This definition may add to legal uncertainty since it does not clarify the meaning of “useful”. It would be important to explain if the utility of the invention contributes to the embryo per se and/or to the development of the embryo in order to understand the type of inventions that may be deemed patentable.

There is also no agreement on the scientific understanding of “embryo”. In this case, lack of clarity does not necessarily have negative effects. The provisions on patent law are closely linked to scientific developments. Since the field of hESC inventions is in rapid progress, it may be desirable to avoid a static definition of “human embryo”. Indeed, the CJEU changed the definition of human embryo from a wide concept in the *Brüstle* case to a narrower one in the *International Stem Cell Corporation* case.<sup>54</sup> The understanding of “human embryo” in *Brüstle* was coined as:

any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive;

In the *International Stem Cell Corporation* case, the CJEU judges excluded a non-fertilized human ovum whose division and further development have been stimulated by parthenogenesis from the concept of human embryo. The exclusion was justified on the fact that, in light of the current scientific knowledge, a human parthenote as such is not “capable of commencing the process of development which leads to a human being”. The reference to “current scientific understanding” is important because it highlights how law is influenced by scientific developments. When science is in continuous evolution, legal interpretation navigates uncertain waters. In both cases, the CJEU argued that it is upon national courts to decide “whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive”. It appears that the judges took account of the different understandings of “human embryo” under national European laws. In addition to defining the concept of “human embryo”, the CJEU judges reiterated the reasoning of EPO decisions on morally acceptable hESC inventions. In Europe, only hESC inventions that are obtained by not destroying the blastocyst are patentable.

The rationale of this exclusion is strongly linked to the supremacy of human dignity as clarified in *Use of embryos/WARF*.<sup>55</sup> The Wisconsin Alumni Research Foundation (WARF) claimed products “prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, even if the said method is not part of the claims.” The EPO explained that the intended purpose of the rules on biotechnological

---

<sup>52</sup> To be noted that the decisions of the CJEU apply only to EU countries, but the EPO follows CJEU’s decision for the sake of substantive harmonization in patent law. For more see Pila J. and Torremans P., *European Intellectual Property Law*, Oxford University Press 2016, Oxford, p. 129.

<sup>53</sup> Case-34/10, *Oliver Brüstle v Greenpeace eV*.

<sup>54</sup> Case-364/13, *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* Request for a preliminary ruling from the High Court of Justice (England & Wales), Chancery Division (Patents Court).

<sup>55</sup> G 0002/06 (*Use of embryos/WARF*) of 25.11.2008.



inventions is to preserve human dignity<sup>56</sup> and the rationale of R. 28, in specific, is to prohibit misuse or commodification of the embryo. The EPO ruled that the invention violates the prohibition of Rule 28(c) since the destruction of the human embryo is an integral and essential part of the industrial or commercial exploitation of the claimed invention. Although the Enlarged Boards of Appeal in the WARF case offered no definition of “human dignity”<sup>57</sup>, it confirmed the respect for human dignity as one of the primary objectives of EU law. The safeguard of human dignity was previously explained by the Court of Justice of the European Union in case 377/98.<sup>58</sup> The Advocate General observed the following:

The right to human dignity is recognised by nearly all Contracting States and also the ECJ as a fundamental right. The human body is the vehicle for human dignity. *Making living human matter an instrument is not acceptable from the point of view of human dignity.* The right to human dignity is perhaps the most fundamental right of all, and is now expressed in Article 1 of the Charter of Fundamental Rights of the European Union, which states that human dignity is inviolable and must be respected and protected (emphasis added).

Some authors argue that the wording in the “Use of embryos/WARF” decision, “implies that if a product is produced by a production method which initially involves the destruction of hESC then if further production (incubation of the cell culture) does not require further destruction of human embryonic stem cells after the patent application filing date, patentability would not be precluded”,<sup>59</sup> and therefore, human dignity would not be violated. At present, the EPO does not deem immoral patents on hESC filed after 5 June 2003. This is the date when a protocol to derive human parthenogenetic embryonic stem (hpES) cells from activated oocytes (parthenotes) was disclosed in the PCT application WO 03/046141 (Advanced Cell Technology). After this date, patent filings on “inventions relating to human pluripotent stem cells including hES cells, to their uses and to products derived from them are patentable (subject to fulfilling all patentability criteria) on the basis that these may be produced and put into practice using a method which does not involve destroying a human embryo”.<sup>60</sup> Based on statutory prohibitions and legal decisions, the following table gives an overview of the current state of patentability in Europe.<sup>61</sup>

Table 1. Patentability of hESC inventions in Europe

Non-patentable inventions	Patentable inventions
Destruction of hESCs	iPSC

<sup>56</sup> For a better explanation see Sigrd Sterckx and Julian Cobain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?*, Cambridge, Cambridge University Press, 2012, p. 286.

<sup>57</sup> For a study on the meaning of the concept see Beyleveld D, and Brownsword R, *Human Dignity in Bioethics and Law*, Oxford University Press, Oxford, 2001.

<sup>58</sup> C-377/98, Kingdom of the Netherlands v European Parliament and Council of the European Union.

<sup>59</sup> “The use involving destruction of a human embryo is an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28c.” Sterckx and Cobain, p. 287.

<sup>60</sup> Expert Group, fn 3, p. 145. In addition, the EPO clarified that patent claims should be examined in combination with the “technical teaching of the application as a whole as to how the invention is to be performed”. This reasoning appeared necessary in order to avoid patent prohibitions by clever and skillful drafting.

<sup>61</sup> The US and Japan patent laws allow for more types of patentable hESC inventions.

Human cloning	hESCs obtained through a non-destructive process
hESC for modifying human germline	Use of hESC for therapeutic or diagnostic purposes which is applied to the human embryo and is <i>useful</i> to it (emphasis added)
hESC to create chimeras	
Uses of human embryos for commercial or industrial purposes, including scientific research	
Human ovum after fertilization	
hESC obtained through SCNT	

Nevertheless, patentability of hESC research is far from certain for two main reasons. The first reason pertains to the continuous evolution of science, while the second to judicial interpretation which is often influenced by several actors. In Europe, for example, third parties<sup>62</sup> have often advanced many arguments against patents on human embryonic stem cells concerning mainly the monopoly effects of patent rights and informed consent of genetic material extracted from the human body. These arguments have not been substantiated<sup>63</sup> and have rarely been considered by the Boards of Appeal. In this regard, the EPO has clarified that it has not been vested with the “task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject-matter accordingly”.<sup>64</sup> Similarly, the EPO has declared its incompetence to decide on informed consent since the EPC does not provide for such provisions.<sup>65</sup> If third parties’ arguments were sufficiently substantiated, their arguments may further limit the patentability of hESC inventions. This will depend on the type of invention. One reason that may justify this interpretation is the necessity to interpret exclusions from patentability in order to give effect to their purpose.<sup>66</sup> A narrow or a broad interpretation can be adopted depending on the interests

<sup>62</sup> Patents granted by the EPO may be opposed before the EPO within nine months of the publication of the mention that the patent has been granted.

<sup>63</sup> Christopher Rennie-Smith, “Life Form Patents: Proceedings in the European Patent Office and the Role of Non-Commercial Parties”, in [Title TBC: Volume emerging from the conference ‘Patents on Life: Through the Lenses of Law, Religious Faith, and Social Justice’], edited by Thomas C. Berg, Roman Chelij, and Simon Ravenscroft (Cambridge: Cambridge University Press, forthcoming 2018/19).

<sup>64</sup> See, for instance, G 1/98 Reasons 3.9 and T 1213/05. In T-666/05, the EPO adopted skilful legal drafting to distinguish between “exploitation of the patent” and “exploitation of the invention”. Since art. 53 (a) refers to “exploitation of the invention”, the judges argued that the negative effects of the patent could not fall under the wording of the provision.

<sup>65</sup> See, in particular, T-272/95 and T -666/05.

<sup>66</sup> Para. 3.1 of the G 0001/07 (Treatment by surgery/MEDI-PHYSICS) of 15.2.2010.

at stake. For example, if the purpose of the exclusion is deemed to be the safeguard of human dignity, no inventions that destroy human embryos should be allowed. If the purpose of the exclusion is the protection of human life (and the embryo is not considered to be “human life”), inventions that imply the destruction of human embryos could be patentable.

This suggestion on the interpretation of “ordre public” and “morality” may add to legal uncertainty. In the area of patent law, “it is especially important that the law remain stable and clear.”<sup>67</sup> This is because vagueness of law creates incentives to overcome legal hurdles through skilful drafting. This raises transaction costs and as mentioned in the introductory part, it may damage the competitiveness of firms in the market. Different interpretations of the public policy clause may also facilitate the lack of public’s trust in the patent system. Therefore, it is imperative to explore options that offer legal certainty.

### **Exploring options for assessing “ordre public” and “morality” in patent law for hESC inventions**

A suggestion to offer legal certainty for hESC inventions may appear more as a brave proposal rather than a pragmatic solution. This is because the concepts of “ordre public” and “morality” are subject to change over time and it is not possible to have a common understanding of the terms even in a particular point in time. Patents on life forms are an example of significant divergence with respect to the morality criterion. While most of the European society strongly opposes patents on life forms and the modification of human germline,<sup>68</sup> there have been no similar reactions in other jurisdictions. The reasons for these views may be founded on various religious and philosophical concepts,<sup>69</sup> but it may be worth drawing our attention to the dichotomy between those that contrast patents on any life form based on the belief that life is sacred and those that accept the patentability of biological material driven by the intention to realize social goals. Depending on the interests at stake, the last category may be composed of a plurality of actors with different views on the type of subject matter to be excluded from patentability. Some may deem hESC inventions obtained through the destruction of human embryos non-patentable, others may not see the destruction of human embryos as a limit to patentability and may further opt to extend patentability to human genome modification.

The idea of value pluralism considers all these views valid and incommensurable.<sup>70</sup> Indeed, they are all important given that societal wellbeing is determined by the welfare of its individuals. However, when legislative and judicial bodies are asked to decide on the matter, they need to compare different values. A common denominator for hESC inventions may be found on the objective to improve healthcare. Given that ethics permeates all body of law<sup>71</sup> and it is present in the concepts of “ordre public” and “morality”,<sup>72</sup> it appears reasonable to propose

---

<sup>67</sup> Bently et al., supra note, p. 61 citing the reasoning of the US Supreme Court in *Bilski*, Stevens J.

<sup>68</sup> In the *Oncomouse* case, polls showed the contrariety of Europeans to animal patents. The initiative “Kein Patent auf Leben!” or “No Patents on Seeds” represent an umbrella of organizations in Europe against life forms and the opposition to patents on modification of human germline is related to eugenics fears.

<sup>69</sup> To be noted here the humanist inheritance of the European Union as stated in the preamble of the Consolidated version of the Treaty on the European Union, *OJ C 326*, 26.10.2012, p. 15–16.

<sup>70</sup>For a discussion of value pluralism see “Isaiah Berlin” available at <https://plato.stanford.edu/entries/berlin/#BerlDefiValuPlur>. Accessed 14 February 2018.

<sup>71</sup> R. Moufang, ‘Patenting of Human Genes, Cells and Parts of the Body – the Ethical Dimensions of Patent Law’ (1994) 25 IIC, pp.487-515.

<sup>72</sup> Sterckx and Cobain, p. 297 referring to Ullrich Schatz’s comments on “ordre public”.

that ethics as a ‘a set of concepts and principles that guide us in determining what behavior helps or harms sentient creatures’<sup>73</sup> serves as a yardstick for assessing hESC inventions against “ordre public” and “morality”. Ethics is as a means to distinguish between bad and good laws and helps determine morality, *les bonnes mœurs*, what is especially good. Since the primary aim of hESC inventions is to improve healthcare, in terms of the issue at hand, ethics can be found in human rights and in universally accepted principles. The human right to health, often coined also as the right to receive healthcare<sup>74</sup> has been enumerated in several international instruments such as the preamble of the Constitution of the World Health Organization, art. 25 of the Universal Declaration of Human Rights, art. 12 of the International Covenant on Economic, Social, and Cultural Rights, art. 24 of the Rights of the Child, art. 5 of the Convention on the Elimination of All Forms of Discrimination, art. 12 and 14 of the Convention on the Elimination of All Forms of Discrimination against Women, and art. 25 of the Convention on the Rights of Persons with Disabilities. Countries may refer to the potential of hESC inventions to realize the right to health as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”<sup>75</sup> in order to justify the patentability of controversial research. This may be the case of human genome modification experiments in China conducted with the aim to find a cure for cancer. The patentability of germline therapy is another example. Some countries allow it, others prohibit it *a priori*,<sup>76</sup> whereas “others consider it ethically unacceptable at current levels of understanding, not per se”.<sup>77</sup> This raises the question of to what extent should the right to health prevail.

Human dignity may represent a limit. For example,<sup>78</sup> a life-saving invention obtained by destroying human embryos would be prohibited. Human dignity is reiterated in EPO and CJEU decisions on hESC inventions. The Japan Patent Office has also affirmed the protection of human dignity as a public policy objective.<sup>79</sup> The protection of human dignity of unborn embryos may appear unreasonable when compared with the potential of hESC inventions to save lives. In this regard, it is worth noting that the legal status of the embryo is determinant for deciding on the matter. There is no doubt that in addition to law, science and national public policies influence the interpretation of the public policy clause. Whereas it is upon governments to direct scientific developments to the benefit of society, the types of advantages that hESC inventions bring to the society will depend on the interests at stake. The vagueness of the terms “ordre public” and “morality” accommodate all of the interests involved and it may be unreasonable to provide a static definition of the terms. However, health is a global concern

---

<sup>73</sup> Paul, R., & Elder, L. (2013). *The thinkers guide to ethical reasoning*. Tomales, CA: The Foundation for Critical Thinking.

<sup>74</sup> See better Office of the United Nations High Commissioner for Human Rights and World Health Organization, The Right to Health, Factsheet no. 31, available at <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>. Accessed 14 February 2018.

<sup>75</sup> Art. 12 of the International Covenant on Economic, Social, and Cultural Rights

<sup>76</sup> Germany prohibits it under embryo protection laws, while Switzerland has a constitutional ban.

<sup>77</sup> Ulrich Schatz, ‘Patentability of Genetic Engineering Inventions in European Patent Office Practice’ 1998 IIC

<sup>78</sup> This is a hypothetical case. If hESC inventions were filed after 5 June 2003, patent offices would deem the inventions patentable.

<sup>79</sup> Trial against Examiner's Decision of Refusal 2008-7386 on Japanese Patent Application No. 2003-523634 “Isolation of inner cell mass for establishment of human embryonic stem cell (hESC) strain” Case of appeal against rejection appeal, WO 03/18783, Heisei 17 2005. The case is available at the following link: <http://tokkyo.shinketsu.jp/originaltext/pt/1218942.html>, accessed 29 January 2018. An English translation is available here: <https://translate.google.com/translate?hl=ja&sl=ja&tl=en&u=http%3A%2F%2Ftokkyo.shinketsu.jp%2Foriginaltext%2Fpt%2F1218942.html>.

because of its importance in personalized, precision, and regenerative medicine. Investments both from the public and the private sector are on the rise and studies show that the global market for hESC research will reach 2 billion USD by 2020.<sup>80</sup> If an invention happens in one country, it will undoubtedly be distributed in other countries. Therefore, it is not unreasonable to propose some principles that provide guidance in understanding the public policy clause. Common accepted values as a guide on the patentability of hESC inventions can be found in soft law international instruments such as the UNESCO Universal Declaration on the Human Genome and Human Rights, and the UNESCO Universal Declaration on Bioethics and Human Rights.

These international legal instruments set the limits for the evolution of science in line with a concept of ethics that helps humanity advance. In specific, art. 11 of the UNESCO Universal Declaration on the Human Genome and Human Rights prohibits reproductive cloning of human beings as a practice contrary to human dignity. Current patent laws comply with this provision. Art. 3 of the UNESCO Universal Declaration on Bioethics and Human Rights further explains that “human dignity, human rights and fundamental freedoms are to be fully respected” and “the interests and welfare of the individual should have priority over the sole interest of science or society”. The primacy of the human being and prohibitions on the intervention on the human genome are also affirmed in the Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.<sup>81</sup> Art. 12 and art. 14 of this Convention establishes that predictive genetic tests should be performed only for health purposes and the use of techniques of medically assisted procreation shall be allowed only if “serious hereditary sex-related disease is to be avoided”. It appears thus that relevant limits for hESC inventions in international law are the ban on human genome modification and the welfare of the individual over the interest of science or society.

Another option for an evaluation of “*ordre public*” and “morality” may be the examination of scientific guidelines developed by national science foundations and guidelines on human embryonic stem cell research elaborated by public bodies. This route was followed by the Japan Patent Office in Trial against Examiner's Decision of Refusal 2008-7386, where several scientific national and international documents were cited.<sup>82</sup> The Asilomar Conference and its recommendations on experiments with recombinant DNA and ban on cloning have been followed by the scientific community for a long time.<sup>83</sup> Therefore, it appears reasonable that patent judges include scientific evaluations in their decisions.

Given different levels of socio-economic development between WTO countries, it is not wise to recommend a uniform understanding of the public policy clause at present. But the above

---

<sup>80</sup>Global Industry Analysts, Inc., *Human Embryonic Stem Cell Research: A Research Brief*, February 2017, available at <http://www.strategyr.com/MCP-6831.asp#sthash.RqEW7WUG.dpbs>. Accessed 31 January 2018.

<sup>81</sup> This Convention is binding for EU member states and it is available at <https://www.coe.int/en/web/conventions/full-list/-/conventions/rms/090000168007cf98>. Accessed 15 February 2018.

<sup>82</sup>Reproductive Supplementary Medicine by Providing Sperm/Ovum/Embryo etc” The report is published by the Technical Committee on Reproductive Supplementary Medical Technology on 28 December 2000 by the Health Science Council Advanced Medical Technology Evaluation Subcommittee and it is available at [http://www1.mhlw.go.jp/shingi/s0012/s1228-1\\_18.htm](http://www1.mhlw.go.jp/shingi/s0012/s1228-1_18.htm). Accessed 29 January 2018; the 9<sup>th</sup> Annual Report published by the UK Human Fertilization and Embryology Research Authority Bureau; “Guidelines on the use of human ES cells”, Notification no. 157 of the Ministry of Education, Culture, Sports, Science and Technology.

<sup>83</sup> Fredrickson. D.S., *Asilomar and Recombinant DNA: The End of the Beginning*, Institute of Medicine (US) Committee to Study Decision Making; Hanna KE, editor. Washington (DC): National Academies Press (US); 1991. Available at <https://www.ncbi.nlm.nih.gov/books/NBK234217/>. Accessed 15 February 2018

analysis allows us to give some general recommendations for conducting a test of “*ordre public*” and “morality” based on art. 27.2. The test may involve two steps. The first step should reply to the following question: Is the patent rejection necessary<sup>84</sup> to end the offence? If there are alternative measures to stop the offence against “*ordre public*” and “morality”, a ban on patentability will be of no use. If there are no alternatives to stop the offence, patent judges should assess whether the commercial exploitation of the invention is against “*ordre public*” and “morality”. The investigation of this question should first examine laws, regulations and scientific guidelines of national public authorities, then consider international soft or hard law instruments, and finally examine the purpose and use of human embryonic stem cells in relation with domestic public policy. If the purpose and use of human embryonic stem cells promotes the public policy objective for healthcare and does not harm the individual, the invention should be considered patentable.

## Conclusions

The inclusion of the “*ordre public*” and “morality” clause in patent law serves as a means to guide scientific developments to the benefit of society. As explained in this paper, patent offices have important regulatory functions and the inclusion of a public policy clause in patent law is not a surprise.<sup>85</sup> The interpretative difficulty linked with value judgments enclosed in the terms of “*ordre public*” and “morality”, however, encumbers the work of patent offices. The current interpretation of the public policy clause for hESC inventions is filled with legal uncertainty on the definition of scientific terms. Indeed, it is not easy to hem scientific developments in a legal definition. This paper argued that in some cases it may be preferable to adopt flexible definitions but a global interest in healthcare innovations may require a common understanding of “*ordre public*” and “morality” in the long run. To this purpose, it was suggested that ethics as a set of values should determine the *bonnes mœurs*, what is good for society. The set of common values was found in international legal instruments and scientific guidelines that prohibit human cloning and put the welfare of the individual over the interest of science or society. At present, the concept of human dignity appears to set important limits for the patentability of hESC inventions. But these limits are subject to interpretation. Science is in continuous evolution and the question is not whether society or law will follow, but at what pace.

---

<sup>84</sup> For an interpretation of art. 27.2 in light of the necessity test developed under the GATT Agreement, see Harper M. B., TRIPS Article 27.2: An Argument for Caution, 21 Wm. & Mary Env'tl. L. & Pol'y Rev. 381 (1997), <http://scholarship.law.wm.edu/wmelpr/vol21/iss2/4>. For an analysis of GATT decisions on general exceptions see the Repertory of the Appellate Body Reports, available at [https://www.wto.org/english/tratop\\_e/dispu\\_e/repertory\\_e/g3\\_e.htm](https://www.wto.org/english/tratop_e/dispu_e/repertory_e/g3_e.htm). Accessed 14 February 2018.

<sup>85</sup> As Professor Peter Drahos explains: “Patent law is located within and not outside a public ethic of community values and shared economic and social interests. There is nothing surprising about this.” Drahos, P. “Biotechnology Patents, Markets and Morality (1998) 21 Eur. Intell. Prop. Rev., 441.