The "Ordre Public" and "Morality" Clause in EU and Japanese Patent Law. The Case of Human Embryonic Stem Cell Inventions (*)

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This research projects explores art. 32 of the Japanese Patent Act in a comparative perspective with art. 53 (a) of the European Patent Convention as applied to patentability of human stem cells. Whereas Japanese law exempts from patentability inventions that injure public order, morality, and human health, European law excludes from patentability inventions for reasons of "ordre public" and "morality". The reason for investigating this topic stems from the necessity to harmonize patent law in the controversial field of human embryonic stem cell inventions. While Japan is a world leader in stem cell research (the first patent on induced pluripotent stem cells (iPS) was granted to Prof. Yamanaka of Kyoto University), the competitivity of its research institutions and business firms in the global market will also depend on the patentability of Japanese innovations. This requires legal certainty both in Japanese and foreign legislation. To this purpose, this research will clarify the types of human stem cell inventions that can be patented under Japanese and European law. Through an analysis of case law and interviews with relevant stakeholders, a test for complying with "ordre public" and "morality" will be elaborated and it will be argued that a common understanding of the concept of "ordre public" and "morality" will bring benefit to the substantial harmonization of law in the field of biotechnological inventions.

I. Introduction

The new era of regenerative medicine has increased the importance of research with human embryonic stem cells (hESC).[1] Research with hESC has unprecedented potential for improving human life through discovery of new drugs, treatment of incurable neurodegenerative diseases, drug toxicity arrays, organ transplantation and through understanding of the origin of health problems.[2] Human embryonic stem cells are unique and important for advancing regenerative medicine because, unlike other types of stem cells, they can give rise to any type of cell in the body. This means that they have a broader application and can be used to study any kind of disease. Research with hESC, however, encounters ethical limits because the generation of embryos implies the destruction of the

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[1] For an overview of recent developments see Lea Lowthorp and Katie Hasson, 'What Just Happened? Looking Back at 2017's Human Germline Editing Developments', Centre for Genetics and Society, available at https://www.geneticsandsociety.org/biopolitical-times/what-just-happened-looking-back-2017s-human-germline-editing-developments. Accessed 15 January 2018.

[2] 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.

blastocyst, a structure in early development that contains a cluster of cells from which the embryo arises.[3] 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.[4] The ethical dilemma on the legal status of the embryo[5] has implications for the patentability of hESC inventions. Research with hESC remains important 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.[6]

Ethical concerns enter into patent law through the public policy clause. This clause, which excludes some types of inventions from patentability, is found in art. 32 of the Japanese Patent Act (JPA) and in art. 53 (a) of the European Patent Convention (EPC). Whereas Japanese law exempts from patentability inventions that "injure public *ordre*, morality, and human health", the EPC disallows patents for "*ordre* public" or "morality" reasons. The interpretation of these legal terms in different jurisdictions may result in different types of permissible hESC inventions under patent laws. This situation does not only create legal uncertainty, but it may also hinder the competitivity of research institutions and business firms that operate both in Europe and Japan.[7] In order to shed light on the issue, this report will clarify the type of patentable hESC inventions under the Japanese and the European law.

II. The link between patents and hESC research

Patents are necessary instruments to attract investments for developing biotech inventions and take basic research to the marketplace.[8] Although it has been argued that other types of IP rights or regulatory mechanisms may play a more important role than patents in personalized medicine,[9] patents remain a business tool for companies to capture their investment. This is especially important

[3] 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.

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

[5] 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.

[6] This was confirmed during an interview with Friederike Helmholtz in December 2016 of Helmholz Centrum in Munich.

[7] 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.

[8] Hadley, A. T. (1986). Economics. New York: G.P. Putnam's Sons.

[9] 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.

nowadays where the success of research projects remains uncertain[10] but investments both from the public and the private sector are on the rise. Studies show that the global market for hESC research will reach 2 billion USD by 2020.[11]

Since investments will incentivize more innovation in the field, a growth of patent filings, is to be expected. Data obtained in the period 2004 – 2015 show that patent applications have already increased both in Europe and Japan.[12] It is interesting to observe that although there have been more patents filed with the EPO, less patents have been granted in Europe. On the contrary, the JPO has received less patent filings but has granted more patents compared to the EPO. Another difference between the JPO and the EPO can be noticed in the opposition of hESC patents on "*ordre* public" and "morality" grounds. At present, there has been only one case decided by the JPO.[13] The EPO, on the other hand, has decided on 10 hESC patents opposed on "*ordre* public" and "morality" grounds.[14] The application of the public policy clause for excluding hESC inventions from patentability may reduce incentives to invest in some research projects or encourage smart legal drafting to overcome legal hurdles. This situation may increase transaction costs[15] and reduce legal certainty. Therefore, it may appear reasonable to shed some light on the meaning of the "*ordre* public" and "morality" clause in patent law.

III. The concept of "*ordre* public" and "morality" in patent law for hESC inventions in Europe

The legal texts that govern patents on biotechnological inventions in Europe are the European Patent Convention (EPC)[16] and the Directive 98/44/EC on the legal protection of biotechnological inventions. Art. 53 (a) of the EPC prohibits patents on inventions, the commercial exploitation of

[10] This is particularly true for biotech start-ups. For an understanding see Bruce Booth, The Successful Failure of a Biotech Start-Up, Forbes, 17 November 2017, available at https://www.forbes.com/sites/brucebooth/2017/11/17/painful-truth-successful-failure-of-a-biotech-startup/#5527a7a1d025. Accessed 10 January 2018.

[11] 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.

[12] As of 12 December 2017. The search terms used were *13 patent families "WORD = "hESC" AND (PUC = (JP))" for Japan and "WORD = "hESC" AND (PUC = (EP))" for EPO. I found 13 patents (of which, 7 were granted, 3 refused, 1 filed, and 2 under examination) for Japan and 17 (8 withdrawn, 4 granted, and 5 under examination) for EPO.*

[13] Trial against Examiner's Decision of Refusal 2008-7386.

[14] This is based on a search conducted on the EPO website on 11 December 2017.

[15] Transaction costs include the costs of search, negotiation, and enforcement. For an understanding see Robert Cooter and Thomas Ulen, Law and Economics, 6th edition, Berkley Law Scholarship Repository, p. 88, available at https://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?referer=https://www.google.co.uk/&httpsredir=1&article=1001&context=books. Accessed 31 January 2018.

[16] The 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.

which would be contrary to "*ordre* public" or morality. 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". 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.[17] Based on the interpretation of scientific terms and case law, patentable hESC inventions in Europe concern iPSC inventions, use of hESC for therapeutic or diagnostic purposes which is applied to the human embryo and is useful to it and hESC obtained through a process that does not destroy human embryos.

VI. The concept of "*ordre* public" and "morality" in patent law for hESC inventions in Japan

Art. 32 of Japan Patent Law establishes that "Notwithstanding Article 29, any invention that is liable to injure public order, morality or public health shall not be patented." The Japan Patent Office (JPO) has decided on inventions involving human embryonic stem cells in the Trial against Examiner's Decision of Refusal 2008-7386.[18] This case concerns the establishment of human embryonic stem cells by isolating the inner cell mass. The patent application was refused because the invention included a step involving the destruction of human embryonic stem cells. The applicant argued that the human blastocyst was obtained from surplus embryos created for *in vitro* fertilization treatments, which would have been discarded if not utilized in hESC research. The JPO clarified that human embryonic stem cells obtained from in vitro fertilization (IVF) should be treated in the same way as other types of human embryonic stem cells because they have the potential to become a human being.

[17] The results are based on a search performed in 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.

[18] 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.

To support the view that embryos obtained by IVF treatments give rise to a human being, the JPO examiners cited a report on "Reproductive Supplementary Medicine by Providing Sperm/Ovum/Embryo etc"[19] and the 9th Annual Report published by the Human Fertilization and Embryology Research Authority Bureau[20]. The JPO ruled that inventions involving a step where the human blastocyst is destroyed cannot be patented because they violate human dignity. Human dignity was, in particular, deemed to be violated by the commercialization of embryos. In this case, the public policy of human dignity prevailed over the interest to patent scientific inventions on human embryonic stem cells. It is also interesting to observe that the JPO mentioned policy documents in order to support its decision and show that laws are interconnected. For example, the "Guidelines on the use of human ES cells"[21] were cited to enhance the view that commercial use of hESC is not permitted. At present, iPSC, hESC obtained through SCNT for regenerative medicine purposes, hESC obtained through a process that does not destroy the embryo and CRISPR-Cas9 technology applied to hESC (unless it aims at creating a human being) are patentable under Japanese law.

V. Towards a harmonized understanding of "*ordre* public" and "morality" for hESC inventions

The terms "*ordre* public" and "morality" enclose value judgments that may encumber the work of patent offices. Although many argue that it is the duty of the legislator to decide on morality issues, patent offices are *de facto* entitled by patent law provisions to decide on the morality of inventions. This may not be an easy task, especially if it involves judgments on human life, but as explained by the EPO, patent offices are at the crossroads between science and public policy and are qualified to make value judgments about a given technology.[22] It is even more difficult to envisage a uniform understanding of "*ordre* public" and "morality" across different jurisdictions because the interpretation of these concepts varies among countries and even within the same country. The study of the European and Japanese patent clause is an example of how similar legal provisions can be interpreted differently and result in different patentable inventions. However, research on human embryonic stem cells is a common interest for all countries because of its importance in personalized, precision, and regenerative medicine. If a related invention happens in one country, it will

[19] 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.html. Accessed 29 January 2018.
[20] See table 4.11 of the report, which lists 42 births by IVF treatments.
[21] Notification no. 157 of the Ministry of Education, Culture, Sports, Science and Technology.
[22] "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.

undoubtedly be distributed in other countries. For this reason, it may be relevant to conceive common standards for defining the concepts of "*ordre* public" and "morality" as a global interest.

At present, there are different understandings of "*ordre* public" and "morality" and regulations on healthcare. One significant example can be found in the gene-editing trials on humans conducted by Chinese doctors. Since 2015, Chinese doctors have conducted 11 trials on humans using CRISPR-Cas9, a gene-editing tool, to treat cancer.[23] This puts European and US companies at a competitive disadvantage with respect to CRISPR-Cas9 inventions, but at the same time it questions the boundaries of scientific experiments and the related regulations. Some relevant questions in this context are: Will European and US patients be impeded from receiving effective cancer treatments because regulations do not allow research with CRISPR-Cas9 on humans or patent law discourages this type of research? Or should experiments in China be banned because they violate human dignity? These questions may have different answers depending on the objectives pursued by public policy. But if these controversial inventions reach the market, they will be patented. Biotechnological companies, especially start-ups, have an incentive to file patent applications because patents attract investments. If countries adopt different concepts of "*ordre* public" and "morality", there will be legal uncertainty for international patent filings. Since patent law is strictly related to business interests and international markets,[24] there may be an interest in the future to harmonize the public policy clause on "*ordre* public" and "morality".

Some guidance on a harmonized concept of "*ordre* public" and "morality" may be found in international instruments. For example, a WTO panel may offer clarity on the interpretation of "*ordre* public" and "morality" though this option may not appear feasible in the near future. It may seem more realistic to propose that patent judges refer at studies of international organizations such as the World Intellectual Property Organization (WIPO),[25] or soft law instruments such as the Universal Declaration on Human Rights, 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. Another option for an evaluation of "*ordre* public" and "morality" may be the examination of scientific guidelines developed by national science foundations

[23] These figures are found in the following article China, Unhampered by Rules, Races Ahead in Gene-Editing Trials, the Washington Post Journal, 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.

[24] Patent rights are territorial rights but international agreements on patent law (the TRIPS Agreement) and patent-related provisions in foreign trade agreements clearly indicate the role of patents in market expansion.

[25] See, for example, Shamnad Basheer *et al*., Patent Exclusions that Promote Public Health Objectives, SCP/15/3, available at http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf. Accessed 33 January 2018.

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.
A suggestion for conducting a test of "*ordre* public" and "morality" may involve two steps. The first step should reply to the following question: Is the patent rejection necessary 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 analyse laws, regulations and scientific guidelines of national public authorities, then consider the international soft law instruments, and finally examine the purpose and use of human embryonic stem cells. If the purpose and use of human embryonic stem cells promotes public policy objective for healthcare, the invention should be considered patentable.

VI. Conclusions

This report explored the meaning of "*ordre* public" and "morality" for hESC inventions in Europe and Japan and suggested an interpretation that helps harmonize the understanding of this public policy clause in patent law. The EPO and the JPO currently follow different policies for the patentability of hESC inventions. This means that biotech companies have to be informed about different laws and draft their claims based on the jurisdiction where they seek patent protection. The different perceptions of "*ordre* public" and "morality" in different countries and cultures may also affect the distribution of medicinal products and treatments. Since health is a global concern, it appeared reasonable to refer to international soft law instruments for finding limits for the patentability of human embryonic stem cells. These limits lie in the ban of human germline modification as a way of protecting human dignity. Both Japanese and European patent laws take this limit into consideration, but Japanese law seems to be more flexible for accommodating scientific developments because it allows the patentability of SCNT for regenerative medicine purposes and the application of CRISPR-Cas9 to human embryonic stem cells as long as the invention does not aim at creating a human being. These inventions are currently prohibited under European patent law and as shown in the report, European civil society has raised significant concerns on the patentability of life forms.
In spite of all these differences, there is a common interest in advancing inventions in the healthcare sector. For this reason, the report recommended adopting a test for assessing "*ordre* public" and "morality" that promotes healthcare innovations and at the same time takes account of different public policy objectives of countries. The challenge of the "*ordre* public" and "morality" tests lies in balancing fears of modifying human germline for creating superhumans with the promotion of healthcare inventions.