HUMAN STEM CELL RESEARCH IN EUROPE AND THE U.S.A.: POST *BRÜSTLE* AND *SHERLEY*, ETHICS ISSUES AND PATENT QUAGMIRE

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ABSTRACT

Patent protection of human stem cell inventions (HSCI) has substantial challenges ahead in Europe. Regarding human embryonic stem cell (hESC) research recent European Court's decision narrows down the scope of the research and patent. This paper addresses the existing areas of lack of uniformity for the intellectual property right (IPR) protection of HSCI. A comparative picture between Europe and the U.S.A. regarding the recent legal and policy environment of human stem cell research (HSCR) and patent scope is drawn and the future complications which may arise is focused. One repercussion of present move of the European Court will be denial of patent protection in hESC inventions and rejection of patents obtained from other continents. However, in the national level, European States have perceived and implemented the patent laws relating to HSCI in a diverse manner. National patent remains in the hands of the countries. Recent 'Unitary Patent' is an added layer over the European Patent which would create lack of coordination and more divergence. One effect of diversity in protection tool of HSCI between the countries could be enforcement failure. The U.S.A. does not have uniform State level laws and policies for HSCR and patent, but there are fewer complexities than in Europe. The paper measures the appropriateness of patenting HSCI and encounters many ethical debates. This article calls for a balanced IPR protection framework unique to invention that uses human biological

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material while finding that patent as a protection tool is not the most appropriate one for the HSCI.

Keywords: Human stem cell research (HSCR), human stem cell invention (HSCI), patent, ethics

I. Introduction

Patent system was framed to define and ensure the rights of the "inventors."[1] But as the time passes by, now we have both "inventor" and "patent owner" or the "assignee." Both can be same person or can be different persons or entities. Patent, at this time of the history, is an exclusive property right that works in favor of the owner of the right. Behind a patent protection there are scientific, economic and ideological issues. The noble objective of patent protection was to set a mechanism to provide incentive for innovation. Patent is granted in all fields of technologies. Life science as patentable technology and living things as inventions, enabling a patent protection was identified and recognized first by the Court.[2] The judiciary both in Europe and U.S.A. have played substantial role in shaping the patent system for the life science. Legislators have framed laws around the societal, economic and technological goals of the patent system and patent offices have tested the compatibility between the legal provisions and the inventions. However, some authors have identified that other stakeholders, like "lobbyist, trade groups, patent lawyers" have also played a role to shape the patent system as it exist today.[3] Life science is different from other fields of technology for the reason that it is fast changing and raises ethical concern. Patent involving living human biological material such as stem cells faces challenge not only to rationalize the appropriateness of patent's commercial aspect but also embarks into serious ideological debates. Research and invention in human stem cells have quite a good number of varieties. Stem cells differ in their potencies and means of collection. While some of the researches and inventions relating to human stem cell are accepted, some has stuck in ethics debate. Opinions of scientists and ethicist have been different. These differences have been reflected in the judicial decisions.

The paper articulates possible repercussions of the judgment of the Court of Justice of the European Union (hereinafter, CJEU) in patent scope involving human stem cell inventions (hereinafter, HSCI) in Europe, outlines the recent changes made in the U.S.A. and predicts implications of following different directions by two major competing continents. The objective of this paper is to revisit the current patent policies of Europe and U.S.A. for HSCI,[4] identify the differences in attitude of patent protection by the

[1] *See* Steven W. Usselman & Richard R. John, *Patent Politics: Intellectual Property, the Railroad Industry, and the Problem of Monopoly*, 18(1) J. POL'Y. HISTORY 96, 99 (2006), *available at* http://muse.jhu.edu/journals/journal_of_policy_history/v018/18.1usselman.pdf.

[2] *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980) (the first case where living things got recognition to be protected under the umbrella of patent system).

[3] *See* Usselman & John, *supra* note 1, at 121.

[4] Patent protection typically sought for in the case of HSCI is both for the stem cell itself and the process of isolation or differentiation.

countries and what are the shortcomings of the patent system for protecting HSCI. This paper revisits some of the contemporary judicial and administrative decisions regarding human stem cell research (hereinafter, HSCR). The paper attempts to find out why the current patent law framework is inappropriate for the HSCI. It is worth mentioning that the paper recognizes the need for the protection of HSCI and advocates for the intellectual property right through a commercial but humane and functional mechanism.

The paper is organized in the following way. Part I is the introduction. Part II revisits the latest state of the art in HSCR in Europe and the U.S.A.. It explores the prevailing ambiguities in the judicial, legislative and administrative fora of Europe. It outlines that despite there is divergence in State level laws of the U.S.A., an environment more conducive to HSCR exists than in the Europe. *Brüstle* case [5] has been reviewed from the economic and scientific point of view and has been compared with *Costa and Pavan* case and *Sherley* case. The efficiency of present and future of patent as a tool of IPR protection in Europe for HSCI is eloquently discussed. Part III formulates a ground taking some of the prevailing legislation as example, that why patent is inappropriate for HSCI. The interplay between ethical issues and patenting HSCI are highlighted. While discussing the latest conditions of European patent system, this part stresses that the recent patent framework is inappropriate for the HSCI. Part IV is conclusion by way of recommendation. For the completion of the paper, large number of contemporary literature i.e., books, journals, newspapers, magazines, cases, legal texts, policy documents and relevant web sites on the subject are consulted.

II. Human Stem Cell Research and Patent in Europe and U.S.A.: Recent Legal and Policy Environment

European Union, in one hand funding and lending support for stem cell research, on the other hand it excludes from funding the projects that are believed by the European Parliament to be contrary to the EU legislation.[6] Views of European Parliament and of the Court of Justice for the European Union (hereinafter, CJEU) with respect to HSCR and HSCI are different

[5] Case C-34/10, Oliver Brüstle v. Greenpeace e.V., Judgment of the Court (Grand Chamber) of Oct. 18, 2011, *available at* http://curia.europa.eu/juris/liste.jsf?language=en&num=C-34/10 (last visited Nov. 21, 2012).

[6] *See* CATHERINE GANZLEBEN ET AL., PROCEEDINGS OF THE WORKSHOP ON STEM CELL RESEARCH AND PATENTING (Brussels, Mar. 19, 2012) 7 (Brussels, European Union 2012), *available at* http://www.europarl.europa.eu/document/activities/cont/201205/20120524ATT45764/20120524ATT45764EN.pdf (last visited Nov. 16, 2012).

from each other. The differences can be well observed from difference of the language of Biotech Directive and its interpretation of CJEU in the *Brüstle* case.[7] The approach of the European Court of Human Rights (hereinafter referred to as ECHR) and the CJEU are completely opposite. I would like to refer to the *Costa and Pavan* case[8] in this context. The European Court of Human Rights referring Art. 8 of the European Convention on Human Rights of 1950 has found that the Italian Law No. 40 of 2004 has resulted to discrimination to the carrier of sexually transmitted diseases and unjustifiably deprived them from selecting healthy embryos by conducting Preimplantation Genetic Diagnosis (PGD) in order to prevent the virus to be transmitted to the offspring.[9] The Court granted PGD for the applicant. This judgment came few months after the *Brüstle* case. The two judgments represent complete different ideologies. The *Costa and Pavan* decision is a very pragmatic one. It shows that there is necessity of application of technology to ensure human rights. This decision came when Italy took a conservative approach to the use of PGD as technique for the people who intend to screen the embryos and select the healthy ones to prevent disease transmission. It seems like the CJEU in the *Bruslte* case, which would be discussed afterwards, has probably chosen the same Italian law as role model which is one of the most conservative one amongst all the European national laws regarding HSCI. In Italy, Art. 13(3) of the Rules on Medically Assisted Procreation prohibits "production of human embryo for research," and Art. 13(2) says, "The clinical and experimental research on each human embryo is permitted provided that they pursue diagnostic and therapeutic purposes which are exclusively associated with it for the protection of health and development of the embryo itself."[10] This provision has been ideologically imitated in the decision of the *Brüstle* case to ban patentability of HSCI and

[7] The interpretation that could normally be drawn from the Art. 6(2)(c) of the Directive 98/44/EC has been made wider in favor of exclusion from patent protection by the Court. This provision of the Directive has been interpreted by States like U.K., Belgium and Sweden to allow broader scope of HSCR. But now CJEU has given direction that only invention that can be patentable is the therapeutic gain over the defected embryo, and therefore, the scope of research and patent has narrowed down. So the legislators' perception behind framing the Directive and CJEU's interpretations of the exclusion provision seems to be different.

[8] Costa and Pavan v. Italy, application no. 54270/10, Judgment of the European Court of Human Rights (Second Section) of Aug. 28, 2012, *available at* http://hudoc.echr.coe.int/sites/eng/pages/search.aspx?i=001-112993 (last visited Nov. 18, 2013).

[9] *See id*.

[10] Art. 13(2) of the Rules on Medically Assisted Procreation, Act No. 40 of Feb. 19, 2004, http://www.ieb-eib.org/en/pdf/loi-pma-italie-english.pdf.

keeping only one exception of patenting "for the benefit of embryo itself."[11] CJEU's decision seems to have been influenced by this Italian law and the ECHR rejects this same law's conservative approaches. Therefore, the ECHR and CJEU have chosen very different legal and moral standing regarding uses and research of human embryos.

However, the Proposal for a Regulation of the European Parliament and of the Council establishing Horizon 2020-the Framework Programme for Research and Innovation (2014-2020) embodies the ambition of Europe, its desire to lead in science, technology and business, to encourage industrial and entrepreneurial activities, to maintain standard of ethics, to create a healthy life and society contains an article on "ethical principles" which is worth giving attention.[12] Article 16, paragraph 3(c) mentions one of the research fields that shall not be funded which would "intend to create human embryos solely for the purpose of research."[13] It does not talk about 'embryo research' from other sources e.g., if the embryos were created for reproductive purposes and no more required and donated voluntarily for research would that be also the area outside of the purview of funding. Then Article 16, Paragraph 4 contains contrary directions which says that "[r]esearch on human stem cells, both adult and embryonic, may be financed" subject to some conditions and then it says that if the activity is forbidden in the Member State, it would not be funded.[14] This drafting came after the *Brüstle* case and seems like has deliberately leaves certain gray spaces of interpretation. Making the funding subject to national prohibition is a clear acknowledgement of existing differences in the national legal frameworks by the European policy making forum. However, on Feb. 19, 2013, 24 EU Member States signed an Agreement on a Unified Patent Court (hereinafter, UPCt Agreement).[15] Before that on Dec. 11, 2012 the European Parliament approved patent package for the 25 EU Member States which is

[11] Case C-34/10, Oliver Brüstle v. Greenpeace e.V., Judgment of the Court (Grand Chamber) of Oct. 18, 2011, recital 44 (quoting clause 42 of the preamble to the Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13-21).

[12] *See Commission Proposal for a Regulation of the European Parliament and of the Council to Establish Horizon 2020-The Framework Programme for Research and Innovation (2014-2020)*, at 19, COM (2011) 809 final (Nov. 30, 2011) (Article 16), *available at* http://ec.europa.eu/research/horizon2020/pdf/proposals/proposal_for_a_regulation_of_the_european_parliament_and_of_the_council_establishing_horizon_2020_-_the_framework_programme_for_research_and_innovation_(2014-2020).pdf#view=fit&pagemode=none (last visited Nov. 18, 2013).

[13] *See id.*

[14] *See id.*

[15] *See* Council Doc. 16351/12 (Jan. 11, 2013).

called "Unitary Patent" to be enforced by the Patent Court established under the abovementioned agreement. Moreover, Regulation 1257/2012 of the European Parliament and of the Council of Dec. 17, 2012 for enhancing cooperation for the unitary patent protection gives some instructions about how the unitary patent system would function.[16] None of these documents make any express reference to human stem cell (hereinafter, HSC) patent or even biotechnology patent. I shall discuss on the viability and functionally of unitary patent package for HSCI in chapter III. However, as I have indicated in the beginning of this chapter that in Europe between legislator and judiciary and between CJEU and ECHR there is no real uniformity of ideology exercised regarding the practice of embryo research and ascribing it legitimacy. Keeping in mind that the priorities of different European States are diverse, it is remains a difficult goal to achieve a uniform patent system, particularly for HSCI.

There is an environment more conducive to HSCR and patent in the United Sates than in Europe at this moment. At the Federal level, there exists good research and funding opportunities. There is no federal law that completely bans or prohibits HSCR but the Dickey-Wicker Amendment, 1995 had put restriction on availability of Federal Funding for research encompassing destruction of embryo, which is recently interpreted by the Court in *Sherley v. Sebelius* to be not an embargo for granting Federal Funding for stem cell research that "utilize already derived" embryonic stem cells.[17] The NIH Grants Policy Statement asserts supports for "responsible, scientifically worthy human stem cell research."[18] HSCR using donated embryos can be conducted with NIH Grants provided that they have been approved by the NIH according to its guidelines.[19] According to the guideline some of the experiments are prohibited that includes introduction of human embryonic stem cell (hereinafter, hESC) "into non- human primate blastocysts."[20] Therefore, despite the plain reading of the text of the guidelines gives vague picture, taking into account the practice at the state level and the decision of the Court in the *Sherley* case, it is clear that HSCR in the U.S. is now more open than it was in recent past and more liberal than Europe in general.[21] Moreover, aborted fetus properly donated can be used

[16] *See* Regulation (EU) No. 1257/2012, O.J.E.U. Vol. 55 (Dec. 31, 2012).

[17] *See* Sherly v. Sebelius, No. 11-5241, Slip op. at 8 (D.C. Cir. Aug. 24, 2012).

[18] NATIONAL INSTITUTES OF HEALTH, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES [NIH], NIH GRANTS POLICY STATEMENT IIA-22 (Oct. 1, 2012) (Part II, Subpart A, Chapter 4.1.13).

[19] *See id.* at IIA-22-IIA-23.

[20] *Id.* at IIA-23 (Chapter 4.1.13.1).

[21] Some of the countries in Europe have ample scope of HSCR which are UK, Sweden and Belgium. Creation of embryo for research is allowed in those countries, despite creation

for conducting "research on transplantation of human fetal tissues."[22] However, there are some thin lines drawn in many countries of Europe including U.S. between "supernumerary embryos donated from the IVF[23] process" and "embryos created for research" for the purpose of justifying the legitimacy from the ethical point of view. While ascribing the status of "legal" HSCR, some countries have allowed the use of the "redundant donated embryo" from the IVF process.[24] U.S.A. is not exception when it comes to frame an overall policy guideline. The NIH Grants Policy Statement prohibits the funding for research that uses hESC derived from "IVF embryos created for research purposes."[25] But as I have already indicated that the ethical and legal framework in U.S. varies in the state level, fifty U.S. states have different laws for the HSCR, but most of them are liberal and many of them are open to HSCR by using supernumerary embryos donated from the IVF process and some are permissive to Somatic Cell Nuclear Transplantation (hereinafter referred to as SCNT). Some of the States would allow HSCR quite openly. As for example, the New Jersey Senate Bill No. 1909 says that "[i]t is the public policy of this State that research involving the derivation and use of human embryonic stem cells, human embryonic germ cells and human adult stem cells [from any source], including somatic cell nuclear transplantation, shall [] be permitted in this State."[26] Some of the states like California,[27] New Jersey,[28] and Illinois[29]

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of embryo for research faces large scale prohibition in many countries. *See* LISELOTTE HØJGAARD & MARJA MAKAROW, HUMAN STEM CELL RESEARCH AND REGENERATIVE MEDICINE: A EUROPEAN PERSPECTIVE ON SCIENTIFIC, ETHICAL AND LEGAL ISSUES, Science Policy Briefing 38 (May 2010) (European Science Foundation 2010) (Annex 1), *available at* http://www.esf.org/fileadmin/Public_documents/Publications/SPB38_HumanStemCellResearch.pdf (last visited Feb. 27, 2013).

[22] NIH, *supra* note 18, at IIA-24 (Chapter 4.1.14.1).

[23] IVF stands for "In Vitro Fertilization."

[24] The redundant embryos from IVF process are meant to embrace the destiny called "destruction." If they are not utilized for the fertilization purpose and the donors retreat themselves to care about the material, they would not be preserved by the fertility clinics forever. One day those embryos would inevitably be destroyed, if not used for alternative purpose such as "embryo research." There is not much ethics debate around this destruction. The destruction issue comes to the forefront of the debate when those embryos are manipulated or used and destroyed for other inventions. *See generally* EVE HEROLD, STEM CELL WARS: INSIDE STORIES FROM THE FRONTLINES 128 (Palgrave Macmillan 2006).

[25] *See* HØJGAARD & MAKAROW, *supra* note 21.

[26] *See* New Jersey Senate Bill No. 1909 (Sep. 30, 2002), http://www.njleg.state.nj.us/2002/Bills/S2000/1909_R1.PDF (last visited Nov. 18, 2013).

[27] *See* Article 35 of the California Constitution, http://www.leginfo.ca.gov/.const/.article_35 (last visited Nov. 18, 2013).

[28] *See* New Jersey Senate Bill No. 1909 (Sep. 30, 2002).

have very open and supportive HSCR environment.[30] States like Arkansas[31] and Virginia[32] prohibit human cloning but do not make express prohibition on HSCR. However, in most of those states, reproductive cloning is expressly prohibited.[33] Okalahoma is one of the rare states that have restrictive policy, but it would also allow research on embryonic stem cell lines created before August of 2001.[34]

A. Europe: Aftermath of the *Brüstle* Case

Though it is too early to measure the impacts of the judgment of *Oliver Brüstle v. Greenpeace e.V.*,[35] the following implications one might anticipate:

(a) Legal purview of HSCR involving use and destruction of human embryo might have to be restrained;
(b) Some of the existing human embryonic stem cell lines shall not remain valid within the legal parameter;
(c) Policies of patenting HSCI in some European countries might have to be changed;
(d) The legislators have to rethink about the policy goals they should determine;
(e) EU States have to formulate national laws compatible with the judgment;

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[29] *See* Section 5 of the Stem Cell Research and Human Cloning Prohibition Act of 2007, http://www.ilga.gov/legislation/fulltext.asp?DocName=&SessionId=51&GA=95&DocTypeId=SB&DocNum=4&GAID=9&LegID=26958&SpecSess=&Session= (last visited Nov. 18, 2013).

[30] *See, e.g.*, Article 35 of the California Constitution; New Jersey Senate Bill No. 1909**;** Section 5 of the Stem Cell Research and Human Cloning Prohibition Act of 2007.

[31] *See* Arkansas Senate Bill 185 (Mar. 24, 2003), http://www.arkleg.state.ar.us/assembly/2003/R/Acts/Act607.pdf (last visited Nov. 18, 2013).

[32] *See* § 32.1-162.22, Chapter 5.2, Title 32.1, Code of Virginia, http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+32.1-162.22 (last visited Nov. 18, 2013).

[33] Prohibition of reproductive cloning finds support in many international legal instruments, e.g., UNESCO Universal Declaration on the Human Genome and Human Rights, 1997; Art. 1 of the Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, 1998; Art 3(2) of the Charter of Fundamental Rights of the European Union, 2000. Therefore, there is no much debate, rather a consensus in favor of complete ban on reproductive cloning exist in both the Europe and U.S.A.

[34] *See* § 2B(2) of the Advancement in Stem Cell Cures and Therapies Act of the State of Okalahoma, ENR. H. B. NO. 3126 (2008), http://ssl.csg.org/dockets/2011cycle/31Abills/2130b11okstemcellresearch.pdf (last visited Nov. 18, 2013).

[35] *See* the Brüstle case, *supra* note 5.

(f) There might be decrease in research and invention, which could be economic disadvantage for the Europe;
(g) Future health care services that will have therapeutic application of HSCI will be hindered; and
(h) Position of Europe in the global race of HSCR could be after U.S.A. and may be after some of the Asian countries.

If the judgment is considered as adequate instruction model and guideline for the HSCR, European countries shall enjoy very limited opportunity of diverse interpretation. Where the judgment has defined "embryo" in clear words and pointed out when the human life beings, countries shall have little choice to interpret the same notion otherwise. If that presumption is conceived as correctly drawn then countries that have provided hESC patents are supposed to revoke and nullify the patents that already have been granted.[36] It is a natural hypothesis that if the German Patent DE197586864 of Prof. Dr. Oliver Brüstle[37] is nullified, then other patents embracing same grounds of disqualification should follow the same consequences. Therefore, it is worth watching the actions of the U.K. patent office who has already granted many patents of stem cell lines that use hESC. However, it seems that U.K. has a different goal of research than most other European countries when it comes to patenting stem cell product. Being in the European Union and EPO member state it had interpreted many of the stem cell research guidelines differently from the other EU countries. U.K. has "provided about 100 patents on hESC based invention"[38] by now.

The approach of the European Patent Office and the interpretation of the CJEU regarding the patentability of stem cell inventions are seem to be similar to each other. The decision of the Enlarged Board of Appeal in WARF[39] excluded from patenting products that encompasses the destruction of human embryo which in principle seems to be identical to the decision in *Brüstle* case. The *Brüstle* case just went further into details of moral issues. EPO and CJEU do not appear to be going to take a contradictory position. Therefore, EPO does not seem to be granting patent on hESC inventions that would involve destruction human embryo or even when it is used as base material. Heil Pihlajamaa, Director of Patent law, European Patent Office in her presentation at a workshop mentioned that practice of EPO and approach

[36] *See* Clara Sattler de Sousa e Brito, Stem Cell Patents: Legal Aspects (June 18, 2012), http://www.eurostemcell.org/commentanalysis/stem-cell-patents-legal-aspects (last visited Nov. 22, 2012).

[37] Professor of Reconstructive Neurobiology, University of Bonn, http://www.uni-ulm.de/en/home2/alumni/interesting-alumni/seperate-portraits/medicine/prof-dr-oliver-bruestle.html (last visited Nov. 21, 2012).

[38] *See* GANZLEBEN ET AL., *supra* note 6, at 8.

[39] G 0002/06, Decision of Nov. 25, 2008.

of CJEU are in line with each other.[40] It may be presumed that since EPO is not bound by the decision of CJEU it might grant a patent on hESC invention, which I find unlikely to happen.[41]

Professor Aurora Plomer has identified this judgment as "flawed" from the legal perspective.[42] The *Brüstle* case does not define or outline the conditions for patentability or patentable subject matter is depth but gives a definition of embryo which could be one of many definitions of embryo that exist in different jurisdictions. A perfect definition of "human embryo," "human body" and "human life" acceptable both from scientific and ethical perspective has not been formulated for lack of scientific clarification and disagreement on ethical grounds. But the CJEU chooses a definition which is very strict and curtails the scope of embryo research. The court does not expressly define the term like "morality" and did not give a list of non-patentable subject matter by which specific scientific research works could have been declared illegal *ab initio*.[43] The Judgment also does not explain why destruction of human embryo or their commercial application or embryo research is a threat to *ordre public*. Destruction of embryo is considered by some ethicists as against human dignity and also the embryo is considered to have life the termination of which is perceived as morally wrong no matter how early it is. In a typical "ethics vs. science" debate, ascribing the status of "human life" to an embryo invokes arguments and counter arguments and does not produce a result. There is no universally applicable conclusive definition of "morality" and there is no defining moment of "beginning of human life." Therefore, a conclusion saying that "destruction of embryo is destruction of human life" and so "destruction of embryo is unethical" would not be well accepted from all quarters and stakeholders.

1. Absence of Economic Considerations

Until now, patent system has been offering a protection tool for the HCSI. The patentees are not concerned about 'patent' they are rather concerned

[40] *See* GANZLEBEN ET AL., *supra* note 6.

[41] *But see* Brian A. Donahue & Terri Shieh-Newton, *Legal Implications and Business Considerations for Technologies Involving Human Embryonic Stem Cells in Europe and U.S.*, 2012(Summer) MORRISON AND FOERSTER QUARTERLY NEWS 1, 4 (2012), *available at* http://www.mofo.com/files/Uploads/Images/120627-Intellectual-Property-Quarterly-Newsletter-Summer-2012.pdf.

[42] *See* Aurora Plomer, *EU Ban on Stem Cell Patents is a Threat Both to Science and the Rule of Law*, THE GUARDIAN, Dec 12, 2011, *available at* http://www.guardian.co.uk/science/blog/2011/dec/12/eu-ban-stem-cell-patents (last visited 22 Nov. 2012).

[43] *See generally* Aurora Plomer, *After Brüstle: EU Accession to the ECHR and the Future of European Patent Law*, 2(2) Q.M.J.I.P. 110, 110-35 (2012).

about a protection mechanism that would ensure their return of investment. The beneficiaries of inventions are concerned about availing the blessings of science at a reasonable means. Commercial incentives encourage investment and invention. Private sector investment would depend on how secure the return is. Patent rejection would be a kind of disincentive and curtailed research freedom is an added impediment. So after the *Brüstle* case, the two major areas of concerns are-(1) legitimacy and scope of the HSCR and (2) appropriate protection tool for HSCI.

Economic considerations are very important issue for the assignee. Most of the people who advocate for facilitating the scientific progress find their rationale in economic and social realities. Enrico Bonadio shows in his paper that "cost benefit analysis" plays a visible role for one section of the advocates in the HSCR debate.[44] The recent European trend in HSCR, if the *Brüstle* case is considered as the protagonist of the story, seems like a moral styling of science which ignored the economic realities. There still can be public funded research and university inventions but private biotech and pharmaceutical companies are major players that cannot be totally ignored.

If a ban on patentability becomes barrier to IPR protection on HSCI then many privately funded research projects and scientists may move from Europe to other continents where these researches could be validly undertaken and inventions would get intellectual property protection. The attractive alternative can be anywhere who is pursuing the same research with different interpretation to the ethical aspects in collection of stem cell lines, their destruction, utilization, preservation and commercialization than in Europe at present. Therefore, the scientists and the academic community in Europe have posed the most resistant reactions in these circumstances. Many scientists, academics and patient advocates have been expressing their opinion in favor of facilitating the research and emphasizing on intellectual property protection, and also for increasing the research budget in "Horizon 2020."[45] The legal quandary might have delayed many of the invention to reach the market or may make the treatment available in specific countries

[44] *See* Enrico Bonadio, *Biotech Patents and Morality After Brüstle*, 34(7) E.I.P.R. 433, 436-374 (2012).

[45] "Horizon 2020" is a programme that would put in place a visionary goal for Europe in scientific research, investment, creating more job opportunities, securing Europe's competitive advantage and a healthy life in a good society. For more information, please see http://ec.europa.eu/research/horizon2020/index_en.cfm (last visited Dec. 1, 2012). ALL European Academics (ALLEA) and Academia Europaea and European Academies Science Advisory Council (EASAC) in a joint note dated Nov. 13, 2012 wrote, while giving support for raising funds for research, "It is not only the creation of new knowledge that is at stake but benefits for citizens and their environment in this and future generations." *See* http://www.allea.org/Pages/ALL/33/507.bGFuZz1FTkc.html (last visited Dec. 1, 2012).

not all. Therefore, medical tourism is likely to rise in the next few years. And cost of the treatment seems to depend on its mode of IPR protection.

2. Implications in Progress of Science

The divergent practices adopted by the member countries within the Biotech Directive's purview shall have to be unified, at least at one point that by destruction of human embryos, there cannot be patent. However, after *Brüstle* case, conducting the research that involves destruction of human embryo is also not allowed, but research from the laboratories cannot be practically wiped out although patent protection may be denied. Steve Connor writes, "Scientists expressed their dismay at the decision [of the *Brüstle* case], saying the ban will act as a huge disincentive for investment in a critical area of research that promises to revolutionize medicine in the coming decades."[46] However, according to the judgment of CJEU in the *Brüstle* case, one use of hESC can be patented that is inventions for "therapeutic and diagnostic purposes which are applied to the human embryo and are useful to it", subject to non destruction of human embryos.[47] There are alternative means being explored by scientists to derive hESC without destruction of embryo which can be implanted soundly.[48] Using induced pluripotent stem cells (iPS) as substitute of hESC to avoid ethical objections could be an idea but they are not exact substitute of each other for the purpose of potency. The application of alternative techniques might be a bypass to mitigate the ethical crisis to some extent but the appropriate protection tool for the HSCI remains an issue. However, other stem cell inventions e.g., from adult stem cell and iPS are patentable.

It is a fact that there is no plenty of examples of successful application in humans of hESC inventions and most of them are at the trial stage now.[49] Some of them had been successfully tested over animals in laboratories. However, despite debates and hurdles, fast progress is taking place in the

[46] Steve Connor, *Medicine Thrown into Crisis by Stem Cell Ruling*, THE INDEPENDENT (London), Oct. 19, 2011, *available at* http://www.independent.co.uk/news/science/medicine-thrown-into-crisis-by-stem-cell-ruling-2372562.html (last visited Nov. 28, 2012).

[47] *See Commission Proposal for a Regulation of the European Parliament and of the Council to Establish Horizon 2020-The Framework Programme for Research and Innovation (2014-2020)*, at 19, COM (2011) 809 final (Nov. 30, 2011) (Article 16).

[48] The biotech company, Advanced Cell Technology, Inc., has pioneered a technology called "Blastomere Technology" which uses single-cell biopsy technique for derivation of hESC where the process does not require the destruction of embryo but is similar to the cell lines collected by destruction of the embryos. *See* Advanced Cell Technology, ACT's Blastomere Technology, http://www.advancedcell.com/patients/act-technology/ (last visited Dec. 6, 2012).

[49] For safe application of stem cell therapy transparency, accountability and strict application of safety guidelines should be followed.

application of hESC in human. Advanced Cell Technology on Oct. 22, 2012 announced that it has successfully experimented a hESC treatment over a patient of a genetic eye disease called "Stargardt's Macular Dystrophy" (SMD) which causes blindness and the results appear to be promising.[50] Neither the scientists nor the patients have lost hopes that hESC inventions will soon be able to cure many genetic and terminal diseases.

B. U.S.A.: After *Sherly v. Sebelius*

In 2009, President Obama, while acknowledging the potential benefits of HSCR, removed existing barrier from research activity by issuing an Executive Order for allowing the research and to make National Institutes of Health (NIH) funding available for the human stem cell projects.[51] There was growing frustration among the scientists' community during the previous regime of President Bush for restraining the federal funding for HSCR which has surfaced in many writings.[52] However, the Executive Order of President Obama categorically supported "responsible" and legally permissible research on hESC.[53] Accordingly, NIH issued "Guidelines for HSCR"[54] and as of now NIH has approved 184 stem cell lines eligible to be used for its funding.[55] But the NIH funding and its functioning had not been so smooth in the last few months. Its actions were challenged in a Court case by adult stem researchers and the litigation managed to get a preliminary injunction in 2010 putting halt on the Federal Funding on hESC research and the United States Court of Appeals for the D.C. Circuit then granted an emergency stay.[56] But interestingly enough, the NIH funding for hESC research was not challenged for ethical reasons, rather it was challenged by

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[50] *See* Advanced Cell Technology, ACT's European Clinical Trial Advances to First Patient Treatment with Higher Dosage of Embryonic Stem Cell-Derived Retinal Pigment Epithelial Cells, http://www.advancedcell.com/news-and-media/press-releases/actandrsquo-s-european-clinical-trial-advances-to-first-patient-treatment-with-higher-dosage-of-embryonic-stem-cell-derived-retinal-pigment-epithelial-cells/index.asp (last visited Nov. 18, 2013).

[51] *See* Exec. Order No. 13505, 74 Fed. Reg. 10667 (Mar. 11, 2009).

[52] *See, e.g.*, George Q. Daley, Foreward, *in* STEM CELL WARS: INSIDE STORIES FROM THE FRONTLINES xi-xviii (written by Eve Herold) (Palgrave Macmillan, 2006).

[53] *See id.* (Sec. 2).

[54] NIH, National Institutes of Health Guidelines for Human Stem Cell Research, 74 Fed. Reg. 32170-75 (July 7, 2009).

[55] http://grants.nih.gov/stem_cells/registry/current.htm (last visited Dec. 11, 2012).

[56] *See* Sherley v. Sebelius, 610 F.3d 69 (D.C. Cir. 2010). *See generally* Ryan P. O'Quinn, *Sherley v. Sebelius: Stem Cells and the Uneasy Interplay Between the Federal Bench and the Lab Bench*, 2011 DUKE L. & TECH. REV. 002 (2011), *available at* http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1216&context=dltr (last visited Dec. 11, 2012).

stem cell researchers who conduct research on adult stem cell over the ground of competitive disadvantage.[57] On August 2012, the preliminary injunction is vacated by the D.C. Circuit[58] which again made the functioning and funding of the NIH available for the hESC projects. As already mentioned before, this decision also made a way out to avoid the restrictions put by the Dickey-Wicker Amendment in 1995.

III. Europe and U.S.A.: Ambivalence, Ethics Debate and Patent Quagmire

Patent system as a tool for the protection of HSCI has many limitations and has embarked on endless complications. In this part I would like to draw attention to the fact that patent as a tool of protection for HSCI is not the most appropriate one at this moment. And some of my arguments shall follow taking the examples from the U.S.A. and Europe. I believe if HSCR is to be encouraged some more pragmatic and humane approach is needed. Patent is not an evil but it is evident that it is becoming gradually complex, multilayered and more of a commercial engine.

Human stem cell patent in Europe is an area were vagueness prevail due to interpretation differences of common European legislations. European Union States have diverse approach of implementing unified rules, regulations and judgments that they are all supposed to apply in their domestic laws in a coherent manner.[59] When it comes to implementation of a European legislation, e.g., any Directive, there is tendency to interpret the same provision in different manner which produces obvious different consequences.[60] This proposition can be suggested after witnessing the recent past that reveals sequence of actions of the European States when it came to interpretation of Article 6 of the Biotech Directive, the provision that excludes certain inventions from patentability on the grounds of *ordre public* or morality.[61] European States have interpreted the same provision as

[57] *See* Sherly v. Sebelius, No. 11-5241, Slip op. (D.C. Cir. Aug. 24, 2012).

[58] *See id*.

[59] *See generally* Rosario M Isasi & Bartha M Knoppers, *Towards Communality? Policy Approaches to Human Embryonic Stem Cell Research in Europe*, in EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 29-56 (Aurora Plomer and Paul Torremans eds., Oxford University Press 2009).

[60] *See generally* Josef Kure, *Human Embryonic Stem Cell Research in Central and Eastern Europe: A Comparative Analysis of Regulatory and Policy Approaches*, *in* EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 57-84 (Aurora Plomer and Paul Torremans eds., Oxford University Press 2009).

[61] According to Article 6(2)(c), human embryo used for commercial purposes shall not be considered for a patent on the ground of morality. *See* Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J.L. (213) 13-21 (July 30, 1998). However, a more

differently as they wanted to make it suitable to their scientific, economic and moral ambitions and ideologies and hence, the policies of UK are different from that of Germany.[62] Asa Hellstadius finds in a study that there is "plurality of views" existing in Europe regarding the interpretation of the exclusion from patentability on the ground of morality.[63]

Alternative to patent protection for HSCI are continuously explored and suggestions are made time and again. The European Group on Ethics in Science and New Technologies to the European Commission in 2002 explored feasibility of trade secret as alternative to patent protection for HSCI; but they finally opined to keep the patent protection with some changes.[64] Trade secret as protection tool is not affective for the invention in life science for two reasons, firstly, the trade secret continues without any specific term of protection and therefore, the invention does not enter into public domain; and secondly, reverse engineering is very likely in HSCI, therefore, there would be no protection once the product or process is in the market. For the commercial application of the inventions, trade secret is potentially failed tools at this age of technology.

A patent has aggravated some of the ethical concerns for its own characteristics. A patent is an exclusive right to commercially exploit the invention.[65] When the invention involves human biological material like stem cells and embryos, commercial application of patent system brings more ethical concerns than commercial application of human biological material through HSCI could normally have done. Industrial application is one of the universal preconditions of patent system and it commercializes inventions. Those who argue that embryo is human life, directly links the phases of actions and raises the ethical concern saying "HSC patent commercializes life." I would argue that HSCI does not commercialize human "life or body." The early stages of development of the cells following the immediate fertilization are so different from the human body that despite they contain the genetic information and exist at an early juncture of human

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general exclusion provision is contained in Article 53 of the 1973 European Patent Convention regarding morality which does not make reference to the HSCI though.

[62] *See generally* Asa Hellstadius, *A Comparative Analysis of the National Implementation of the Directive's Morality Clause*, *in* EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 117-139 (Aurora Plomer and Paul Torremans eds., Oxford University Press 2009).

[63] *See id.* at 119.

[64] *See* VAN OVERWALLE, STUDY ON THE PATENTING OF INVENTIONS RELATED TO HUMAN STEM CELL RESEARCH 81-82 (Luxembourg, European Communities 2002), *available at* http://ec.europa.eu/bepa/european-group-ethics/docs/publications/stud_vanoverw_en.pdf (last visited Nov. 18, 2013). The study was conducted at the request of the EGE.

[65] *See* Usselman & John, *supra* note 1, at 98.

body; an embryo itself is not a human body or human being.[66] Article 5(1) of the Directive 98/44/EC states, "The human body, at the various stages of its formation and development ... cannot constitute patentable inventions." "Human body" and "human body at various stages of development" are not same things. When it is used legitimately for fertility purposes it is not considered as human body, rather just a healthy embryo with potential to be human body. The Directive's language is also contributing to build the perception that those human biological materials are different stages of human body and, therefore, deserves the status of human body. This legal text also contributes to create the hypothesis that "destruction and commercial application of embryo is destruction and commercialization of life" for the purposes of HSCI. According to this provision many HSCI are not patentable invention as patent is a commercial engine. I believe that embryos used for research would have been considered just as sensitive human biological material, if they were protected under a less exclusive, less commercial and more humane mechanism and the benefits were easily accessible by the people at large at a cheaper price, and therefore, there would have been less ethical objection and more acceptances to HSCR. But patent system is completely incapable to offer those concessions. It is possible to secure the safe return of the investment through a commercial exploitation mechanism not as exclusive as patent. Therefore, patent being one of the factors that invokes "commercialization of life debate," it is not as appropriate tool for the protection of HSCI as it is for other types of inventions.

However, opinions against patent protection of HSCI does not always rely on the ethical[67] or religious grounds but sometimes lack of typical requirement of conditions of patentability and patentable subject matter is also argued to be a reason of exclusion.[68] The difference between the above two reasons against patent protection is that those who argue exclusion from patent protection for ethical reasons discourage the HSCR itself, particularly

[66] Much of the experiments are conducted on non human creatures. The available knowledge on the moment of conceptions and beginning of life is more philosophical than biological. *See generally* EVE HEROLD, STEM CELL WARS: INSIDE STORIES FROM THE FRONTLINES 131 (Palgrave Macmillan 2006); s*ee also* Maureen L. Condic, *Preimplantation Stages of Human Development: The Biological and Moral Status of Early Embryos, in* IS THIS CELL A HUMAN BEING? EXPLORING THE STATUS OF EMBRYOS, STEM CELLS AND HUMAN-ANIMAL HYBRIDS 30, n.8 (Antoine Suarez & Joachim Huarte eds., Springer-Verlag Berlin Heidelberg 2011).

[67] *See generally* Sina A. Muscati, *"Some More Human Than Others": Assessing the Scope of Patentability Related to Human Embryonic Stem Cell Research*, 44 JURIMETRICS J. 201, 201-27 (2004).

[68] *See* Leeron Morad, *Stemming the Tide: On the Patentability of Stem Cells and Differentiation Process*, 87 N.Y.U.L. REV. 551, 574-82 (2012).

hESC research. The other opinion that HSCI should not be protected under the patent law argues that it lacks the technical requirements of patent but does not necessarily deny the necessity of the research itself.[69]

Inside the United States, there exists different standard of research environment in the state level. Despite the federal policies are in recent months encouraging some forms of HSCR and making way for their patent protection, all the states in the U.S.A do not have same legal framework which I have discussed earlier. There are some differences in the patentability requirement between the U.S.A. and Europe. But the ethical issues also make differences between the two continents. For example the *Brüstle* case was challenged in Europe on ethical grounds and the *Sherley* case was contested in the U.S.A. on the grounds of competitive disadvantage. However, there are territoriality issues, issues of denial of recognition and enforcement of foreign judgments between Europe and the U.S.A. Respective States have authority to reject or grant a patent and it is a kind of discretion of the granting State.[70] This poses difficulties for commercialization of inventions and because the patent systems are not largely harmonized, the enforcement of right is a challenge. When the TRIPS Agreement was enacted it was believed to ensure effective mechanism for protection and enforcement of intellectual property rights. But, Article 27(2) could be a contrary example of this thought and rather indicates that signatories to TRIPS acknowledge that "you might have a patent in your country or several countries but I may deny to enforce your patent right because it is necessary to protect my *ordre public* or morality." Article 27(2) makes contradictory suggestions, such as, countries may exclude patentability if the commercial exploitation of the invention is against their concept of morality and it is not excluded only because the commercial exploitation is illegal according to their law.[71]

There are some differences in the national patent systems from country to country. As I have already mentioned in previous discussion that in order to bring uniformity in the patent system in general among the European States

[69] *See id*. at 551-89.

[70] Art. 4*bis*(1) of the Paris Convention for the Protection of Industrial Property of Mar. 20, 1883, as amended on Sept. 28, 1979 contains a provision that has established the notion that patents are independent of the one granted or denied in another country. According to this provision countries are not required to grant or reject a patent application by considering that it has been granted or rejected in another country. It is the law of each country that would evaluate the merit of the application and decide if the invention is patentable according to the law of that specific country.

[71] It can be interpreted that, under Art. 27(2) of the TRIPS Agreement, in order to be excluded from patent protection, something has to be grossly immoral, not just that the commercial exploitation is illegal for any discomfort that might be caused to the country.

the "unitary patent package" was declared. After the entry into force of the Agreement on a Unified Patent Court,[72] in Europe there shall be a multi layered patent protection system. It does not create a hierarchical system; rather there shall be parallel exercise of jurisdiction. 25 EU Member States shall be party to the unitary patent (hereinafter, UP), if they ratify, 38 Member States are party to the European Patent under the EPC and the national patent system remains in force. So the party to the UP shall approach to the UPCt. One can take UP and also European Patent. This patent package and the Regulation[73] has been critiqued by the Max Planck Institute for Intellectual Property and Competition Law as "hybrid" and 'imbalanced' which would have various problematic aspects, e.g., create fragmentation of internal market, making discriminatory effect by creating divergent standard amongst the applicants and lacking legal enforcement certainty.[74] This Regulation has made licensing as discretion of the patentee.[75] Compulsory licensing is absent; rather this issue is left to be dealt under the national jurisdiction. Article 7 of the Regulation[76] mentions unitary patent as an object of property and these wordings would bring more commercialization into the HSCR and make it look like more commodification of human biological material than it is perceived now. It does not attempt to create a uniform balanced patent system appropriate to all forms of technologies and inventions, rather it would help big enterprises to enforce a patent right in a bunch of country at a relatively reduced cost which would not ensure the goal of HSCI unless areas like compulsory licensing and overlapping of jurisdictions are addressed. Now Europe has more layers of a patent cake which is devoid of simplicity and uniformity as a protection tool. However, Spain has decided to remain outside of the UP patent package.

IV. Conclusion and Recommendation

This paper revisits the recent developments in patent law encompassing HSCI in Europe and the U.S.A. and finds that practice of patent protection is divergent both within Europe and U.S.A. and also between Europe and U.S.A. The tecent trend in U.S.A. is towards creating HSCR environment liberal and making patent protection available under certain circumstances.

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[72] *See* Council Doc. 16351/12 (Jan. 11, 2013).

[73] Regulation (EU) No. 1257/2012, O.J.E.U. Vol. 55 (Dec. 31, 2012).

[74] *See* RETO M. HILTY ET AL., THE UNITARY PATENT PACKAGE: TWELVE REASONS FOR CONCERN (The Max Planck Institute for Intellectual Property and Competition Law 2013), *available at* http://www.ip.mpg.de/files/pdf2/MPI-IP_Twelve-Reasons_2012-10-17_final3.pdf (last visited Nov. 18, 2013).

[75] *See id.* at 3.

[76] *See* HILTY ET AL., *supra* note 74.

European position regarding embryo research is a tug of war within and between its different fora. There is absence of uniform understanding of the concept of morality in Europe itself, though it is one continent.[77] The opinions of CJEU in *Brüstle* and the opinion of ECHR in *Costa and Pavan* are evidently contrary in embryo related matters. The most recent unitary patent package results creating a multilayered protection model that declares patent as 'property'.[78] It is complex and not a uniform system. Experts also identified that there is "incompatibility of the Unified Patent Court with EU law."[79] In recent months, Europe has banned hESC patents, defined embryo in most narrow sense, widened the scope of the exclusion from patentability whereas U.S.A. has recognized the need of hESC research, allowed use of donated embryo for hESC research which was created for reproductive reasons and defined embryo in a broader sense.[80] However, in the United States also all kinds of research using human embryo is not allowed[81] and NIH prohibits certain kinds of uses of hESC even if the embryos are donated following proper guidelines.[82] *Sherley* case also has directed a way to avoid previously existing restrictions. Therefore, the ethical framework in U.S.A. is different from Europe but not non-existent. There is always an apprehension of failure of recognition of rights and legal battles between European and non European States under the divergent conditions of patent protection.

Regarding HSCR, countries are divided and motivated by the political, religious, social and economic conditions prevailing in their own territory. Therefore, there is no uniformity in the ideology and practice of patent protection in the field of HSCI. How appropriate patent as a tool for protection of HSCI, is a timely question due to existing quandary in

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[77] *See* A M Viens, *Morality Provisions in Law Concerning the Commercialization of Human Embryos and Stem Cells*, *in* EMBRYONIC STEM CELL PATENTS: EUROPEAN LAW AND ETHICS 87-89 (Aurora Plomer and Paul Torremans eds., Oxford University Press 2009).

[78] Offering exclusive property right in favor of a patentee in life science many times gives rise to a debate around "treating life forms as property."

[79] HILTY ET AL., *supra* note 75, at 5.

[80] In the *Brüstle* case, the CJEU defines human embryo 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.'" *See* GANZLEBEN ET AL., *supra* note 6.On the other hand the NIH Grants Policy Statement mentions, that "[a]lthough hESCs are derived from embryos, such stem cells are not themselves human embryos." NIH, *supra* note 18, at IIA-22-IIA-23.

[81] NIH Grants Policy Statement says that "NIH funding for research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is […] prohibited." *See* HØJGAARD & MAKAROW, *supra* note 21.

[82] *See* HØJGAARD & MAKAROW, *supra* note 21.

patenting and research in HSC. The irreconcilable differences among philosophical interpretations regarding the legitimacy of HSCR and protection of the inventions among countries would be a driving factor for searching alternative to patent protection. There are various reason for which patent is not the most appropriate protection tool for the HSCI. Apart from ethical objections,[83] patent itself invokes certain feature into the issues relating to HSCR. Amongst them most noticeable is proprietary nature of the patented technology and commercialization of the invention without much considering the advantage the society should be able to materialize.[84] In this paper, I recommend for a protection model that would allow more inexpensive access to medication and therapies of future health care by the people in one hand, and ensure the return of the investment on the other hand. It should have a balanced approach to the protection of HSCI. If the protection tool makes less profit than the patent does for HSCI, there would be more acceptance and less rejection from the society. The compulsory licensing should be set in the protection model as a prerequisite of application for protection and the merits of the application should be judged on a case by case basis. I recommend a humane protection tool to be developed within IPR's framework for the inventions in life science that uses human biological material. My proposed protection tool would embody the idea of protection of the rights of the assignee and save the interest of the society by allowing less exclusive commercial exploitation for limited term of protection. I recommend that after the invention is put to the market for commercial exploitation, it would take into account the reactions of the health care receiver and shall bring changes in the means of exploitation according to the public reactions of that territory. Under the patent system, in a territory all the patentees enjoy same rights and obligations. Under this idea of protection tool each assignee shall be granted a protection license which would have certain common compulsory features and some additional unique rights and obligations applicable for the commercial exploitation of that particular invention. It would be universal in the sense that it would have same term of protection and provision for compulsory licenses in all jurisdictions. At the same time it would be a kind of 'personalized license' for the reason that certain rights and obligations would be imposed after revisiting the public response and public needs and that would be applicable for the exploitation of that invention in that territory only. However, public reactions can be received online. Public Office responsible for health care

[83] iPS cells and some of the reprogrammed stem cells are free from ethical objections although they are not exact substitute of the hESC.

[84] Some authors criticized patent protection in general for its ability to create monopoly. *See* Usselman & John, *supra* note 1, at 116.

services can monitor the impacts of the inventions over the patients from public reactions. Coordination between intellectual property office, health care department and assignee is needed for ensuring that maximum advantage of the invention is utilized. A system that takes into account of people's opinion would be more acceptable form of protection for HSCI from all perspectives; the opportunity typical patented inventions do not offer to the people.

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