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Bioethics and the Patent Eligibility of Human Embryonic Stem Cells-Related Inventions in Europe

Nomos

MIPLC Munich Intellectual Property Law Center
Augsburg München Washington DC

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Foreword

This work corresponds to the thesis submitted to the Munich Intellectual Property Law Center in partial satisfaction of the requirements for the degree of Master of Laws in Intellectual Property (LL.M. IP) in September 2012.

The patent eligibility of hESC-related inventions creating a tempestuous nexus between patent law and stem cell technology is analyzed in this research with a special focus on the situation in Europe. Achievements in the biotechnology industry related to the stem cell technology are quite important. This is also recognized by the Nobel Prize Committee by awarding the Nobel Prize in Physiology or Medicine 2012 to John B. Gurdon and Shinya Yamanaka for the discovery that mature cells can be reprogrammed to become pluripotent. In line with the pace of development in the stem cell technology, awaited judiciary development at the submission date of the thesis has reached to a result and the update has been done accordingly for the publication purpose as of the situation in November 2013.

It is needless to say that the completion of this research is not the sole achievement of the author. I would like to express my deepest and sincere gratitude to Prof. Dr. Dr. h.c Joseph Straus for his valuable guidance and support for the completion of this thesis. It was an immense pleasure working under his supervision. I am thankful to Dr. Gintarė Surblytė and Seth I. Ericsson for keeping open their door to answer any question during the whole LL.M program. I thank to my tutors, Andrea Hüllmandel and Eugenio Hoss for their mentorship, assistance and encouragement during the coursework. I acknowledge the endless help of the MIPLC team to facilitate our stay at MIPLC. I would like to acknowledge the financial support of the Max Planck Institute for Intellectual Property and Competition Law for the publication of this work. Last but not least, I am thankful to my parents who supported and endorsed me during my stay in Munich. This book is dedicated to my grandmothers.

Munich, November 2013 *Ali Seyhan Uğurlu*

Table of Contents

Acronyms and Abbreviations

AG	Advocate General
Apr.	April
Art.	Article
Aug.	August
BGH	Bundesgerichtshof
Biotech Directive	Directive 98/44/EC of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions
BPatG	Bundespatentgericht
CJEU	Court of Justice of European Union
Dec.	December
DNA	Deoxyribonucleic Acid
EBA	Enlarged Board of Appeal
EC	European Council
ECHR	European Court of Human Rights
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Organisation
ESC	Embryonic Stem Cell
EU	European Union
Feb.	February
GPA	German Patent Act
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
hESC	Human Embryonic Stem Cell
IIC	International Review of Intellectual Property and Competition Law
iPSCs	Induced Pluripotent Stem Cells
Jan.	January
Mar.	March
Nov.	November
NGO	Non-Governmental Organisation
Oct.	October
OD	Opposition Division

SCNT	Somatic Cell Nuclear Transfer
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
WTO	World Trade Organisation
para	paragraph
R&D	Research and Development
StZG	Stammzellgesetz (German Stem Cell Act)
TBA	Technical Board of Appeal
TFEU	Treaty on the Functioning of the European Union
U.K.	The United Kingdom
UK IPO	United Kingdom Intellectual Property Office
WARF	Wisconsin Alumni Research Foundation
WTO	World Trade Organisation

I. Introduction

The biotechnology industry has shown an emerging and promising character since 1980[1] and the patent law plays an important role by incentivizing inventors to direct their intellectual efforts into this field.

Important and exciting achievements in the biotechnology industry have been observed in the area of stem cell technology which could offer a big promise in the treatment of serious disabilites and diseases such as organ disfunctions, Alzheimer, Parkinson, diabetes etc.[2] Therefore various results of stem cell research have been considered in the scientific environment as a human welfare increasing instrument.[3] The patent eligibility of hESC-related inventions generating a tempestuous nexus between patent law, ethics and biotechnology will be covered in this research with a special focus on the situation in Europe.

In this research, several questions have been raised: Through this research, we aim to determine first whether the patent law serves its incentivizing purpose for the inventors working in the stem cell technology field. Second, we want to adress the possible hindrances that the stem cell technology encounters in the current legal status quo which is especially determined by the judicial activity. Third, we provide a projection about the interrelation between the stem cell technology and the patent law.

Within this general context, to facilitate the general understanding of the science, a primer on related concepts of the stem cell technology has been created in Chapter II. In Chapter III, the statutory framework applicable to the hESC-related inventions is outlined. Chapter IV gives details about the moral inquiry by philosophical references to issues of human dignity, the beginning of life and the embryo with the intent to create a framework ap-

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1 Modern Biotechnology and the OECD, OECD Policy Brief at 1 (1999).

2 Bonnie Steinbock, *Moral Status, Moral Value, and Human Embryos: Implications for Stem Cell Research* in The Oxford Handbook of Bioethics 416,437 (Bonnie Steinbock ed., Oxford University Press 2007).; Steve Goldman, *Stem and Progenitor Cell-Based Therapy of the Human Central Nervous System*, 23 Nature Biotech. 862, 867 (2005); Sheng Ding&Peter G.Schultz, *A Role for Chemistry in Stem Cell Biology*, 22 Nature Biotech. 833,839 (2004.).

3 T.Hviid Nielsen, *What Happened to the Stem Cells?,* 34 J. Med. Ethics 852, 853 (2008).

plicable to the patent law practice. After analysing the background and the history affecting dynamics of the legislative action in the EPO and the EU, the patent eligibility status of hESC-related inventions and possible objections would be situated in Chapter V. The case-law, although low in number, attempts to clarify the blurred situation created by legal provisions; its crucial points are analytically discussed in Chapter VI. Chapter VII concludes with the analysis of the momentous judgment of the CJEU and the decision of the BGH which referred to the former about the validty of the so called *Brüstle* patent.

II. Background to the Science

A. What Are Stem Cells?

Stem cells are the "body's natural reservoir."[4] They have the capacity of self-renewal or differentiation. In other words, they can copy themselves or become other specialized cell types.**(Annex II)** For instance, blood and muscle cells as such are not able to make copy of themselves, then in that case stem cells fulfill this task. As regards their capacity to differentiate into specialized cells, stem cells could be categorized as totipotent, pluripotent and multipotent. Totipotent stem cells have the ability to form any cell types that make up the extraembryonic tissues such as placenta and have the potential to develop into the whole organism. Contrary to that, pluripotent stem cells have the potency to develop into any of 220 cell types in the human body but not to the whole organism. Having the least flexibility, multipotent stem cells have the ability to develop into more than one cell type of the body.[5]

B. Source of stem cells

There are three types of human stem cells known so far with regard to their sources. These are adult stem cells, ESCs and iPSCs.[6]

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4 Euro Stem Cell, *FAQ about Stem Cells and Regenerative Medicine*, *available at* http://www.eurostemcell.org/stem-cell-faq/introduction-stem-cells#t14n43 (last visited Aug 11, 2012); California Institute for Regenerative Medicine, Stem Cell Definitions, http://www.cirm.ca.gov/StemCellBasics_Definitions#2 (last visited Aug. 11, 2012); The Nat'l. Inst. of Health, *Stem Cells Basics, Resource for stem cell research*, www.stemcells.nih.gov (last visited Aug. 11, 2012).

5 Nirupama Shevde, *Flexible Friends*, 483 NATURE, S23 (2012).

6 *Id.*.

1. Adult Stem Cells

The first isolation of blood-forming adult stem cells was accomplished by Irving Weismann of Stanford University.[7] Adult stem cells should not be confused because of the use of the term 'adult' to create a false impression that they could be found only in the body of adults. For that reason, the tissue-specific stem cell would be a more accurate choice of terminology.[8] These specialized cells can be found in tissues of adults, children and fetuses. The problem encountered by scientists in the research on adult stem cells is related to their low quantity and to the difficulty to generate it because of their location in the tissue. In addition to that, at the current state of the art, there is no full understanding about their place of derivation and the manner of differentiation.[9] For now, known locations of adult stem cells are brain, liver, intestine and skin. Because these cells go out from their niche when there is a signal from the organism for the repair of the damaged cell.[10]

Adult stem cells are multipotent, they can become a cell related to their tissue of origin. **(Annex IV)** As to their functionality, in the case of heart attack for example, one could think to refer to adult stem cells found in the heart. However, heart cells could hardly be generated because scientists do not know yet the characteristics of the necessary signal of the body to derive the stem cell able to form the heart muscle cell. Another problem is that, adult stem cells from other tissues having usually the self-renewal capacity, would only differentiate into cells similar to their origin. Shevde draws attention in her article to the latest development in 2011 related to the discovery of a protein to make the adult stem cells of different origin to become the heart muscle cell. From these findings, it seems that there is a need to get over more ground for adult stem cells.[11]

2. ESCs

With regard to the history of the research in this field, ESCs were derived for the first time in 1970 by Leroy Stevens at the Jackson Laboratory. Also

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7 California Institute for Regenerative Medicine, *supra* note 4.
8 *Id*..
9 Shevde, *supra* note 5, at S25.
10 *Id*. at S23.
11 *Id*. at S25.

human embryos could be used to generate hESC lines. The growing of hESCs was achieved for the first time by James Thomson at the University of Madison.[12] Unlike adult stem cells, ESCs are generated from the inner cell mass of the embryo at the blastocyst stage which is a period of 5-6 days after fertilisation.**(Annex III**) Embryos that have been traditionally fertilised 'in vitro', in fertilisation clinics could be one source for ESCs.[13] Another source for ESCs could be the embryos created by the transfer of a nucleus of a somatic cell (any body cells different from egg or sperm) into an egg cell without nucleus. This technology is called SCNT.[14] **(Annex V)** Resulting ESCs have the same DNA as somatic cells and they can differentiate like ESCs derived from the traditionally fertilised embryos.[15]

The uniqueness of ESCs lies in their capacity to self-renew endlessly and to differentiate into any cell type in the body; in other terms, they are pluripotent.[16] For that reason, ESCs are quite important in the field of biotechnology and medicine research.

3. iPSCs

In a fervent research environment dealing with stem cells, some exciting developments continue to occur. In 2006, Dr. Yamanaka and Takahashi showed that a regular cell being with a particular purpose which is not pluripotent anymore, could become a stem cell having similar properties to ESCs.[17] This was done for the first time by the introduction of four genes into mouse fibroblasts. **(Annex VI)** A year later, the applicability of this method to humans was also reported by the same group of scientists.[18] At the time very close to this announcement, Dr. Thomson's group have reported the generation of human iPSCs using a different method from the one

12 Thomas F. Budinger&Miriam D. Budinger, Ethics of Emerging Technologies, 342 (John Wiley&Sons, 2006).
13 California Institute for Regenerative Medicine, *supra* note 4.
14 *Id.*.
15 Byrne J.A et al. *Producing Primate Embryonic Stem Cells by Somatic Cell Nuclear Transfer*, 450 Nature, 497, 497 (2007).
16 Budinger&Budingger, *supra* note 12, at 342.
17 Shinya Yamanaka, *Induced Pluripotent Stem Cells: Past, Present, and Future*, 10 Cell Stem Cell 678, 678 (2012).
18 *Id.*.

used by Yamanaka's group.[19] For the possible use of these cells in patient treatments, some concerns about their probability to develop tumours have been discussed. As we learn from Shevde, Dr. Yamanaka and his colleagues announced that they resolved this problem by the elimination of the tumour causing gene.[20] Although iPSCs have different origin, namely embryos are not required for their generation, they are 'remarkably similar' to ESCs according this field.[21]

19 Shevde, *supra* note 5, at S24.
20 *Id.*.
21 Yamanaka, *supra* note 17, at 681.

III. Legal Provisions Applicable to the Patent Eligibility of hESC-Related Inventions

A. EPC

The EPC[22] governs a centralized examination procedure which results in the grant of a bundle of national patents. At the very beginning, this procedure starts with the assessment whether an invention is patent eligible. This is the question preceeding the patentability of an invention, which requires the fulfillment of other conditions, namely novelty, inventive step and industrial applicability. The EPC has a negative approach by determining the exclusions from patent protection especially as provided in Art. 53. The first exclusion under literae (a) is based on the grounds of *ordre public* and morality, inventions the commercial exploitation of which would be contrary to *ordre public* or morality would not be patent eligible. Literae (b) sets forth exclusions for plant or animal varieties or essentially biological processes for the production of plants or animals. At the end, there is also the exclusion for methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body. However, these exclusionary provisions also contain exceptions: Art. 53(b) and 53(c) state respectively, that microbiological processes or the products thereof and products in particular substances or compositions for use in surgery, therapy and diagnostic methods could be patent eligible. So far, the exclusionary provision based on *ordre public* and morality grounds has proved to be the most oft encountered barrier to the patent eligibility of biotechnological inventions in the EPC.

22 Convention on the Grant of European Patents ratified, Oct. 5, 1973, revised Dec.13, 2007.

B. TRIPs

Art. 27 of TRIPs[23] draws the contours of the patentable subject-matter. This article is significant because its first paragraph points out that patents should be available for all inventions "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." As stated by Straus, this is a "historical event" for the international industrial property protection because "almost all" inventions would be treated similarly to other trade objects throughout borders.[24] However, this generous rule is followed by some allowed exclusions in the second and third paragraphs of the said article. The second paragraph of Art. 27 provides for the WTO Member States an option to exclude from patent protection, inventions, "the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality." As it might be seen, this provision is similar to the EPC Art. 53(a). This might be the evidence that the EPC influenced drafting specific provision of TRIPs.[25] The same inference is true for Art. 27(3) but one must be aware that EPC's exclusions have a narrower scope in comparison with the provisions of TRIPs. The latter allows also exclusions in other fields of technology or for other types of inventions.[26] It is suggested that the legislator of TRIPs needs to review its position with regard to exclusions from patentability depending on the technological and scientific developments.[27] The similar result could be true for the EPC as well. As pointed out by Straus[28], since TRIPs does not contain "negative catalogue of creations of the human intellect," the patentability issue of biological materials such as DNA, cell lines, etc. is not clearly guided by TRIPs. This result is also valid in regard to the focal point of our research, namely, hESC-related inventions. There-

23 Agreement on Trade Related Aspects of Intellectual Property, Apr. 15, 1994 (*hereinafter* TRIPs.).

24 Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in From GATT to TRIPs the Agreement on Trade Related Aspects of Intellectual Property Rights 160, 180 (Friedrich-Karl Beier&Gerhard Scricker eds., VCH, 1996).

25 United Nations Conference on Trade and Development-The Information and Communication Services Division, Resource Book on TRIPS and Development 376 (Cambridge University Press 2005).

26 Straus, *supra* note 24, at183.

27 *Id.,* at 185.

28 *Id.,* at 187.

after, the debate concerning hESC-related inventions would be mainly within the boundaries of ethical issues.

C. EC 98/44 Directive

Since the "biotechnology and genetic engineering are playing an increasingly important role in a broad range of industries, … the protection of biotechnological inventions … [is] of fundamental importance…"[29], the Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions has been adopted on July 6, 1998. (hereinafter the Biotech Directive). The essentiality for Member States of the effective and harmonized protection of biotechnological inventions throughout the EU Member States was an incentivising factor to draft the Biotech Directive.[30] The patent eligibility of hESC-related inventions is covered under the following provisions: Art. 5(1) provides for the exclusion from the patent protection of "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene." On the contrary, "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene" is the patent eligible subject matter under Art. 5(2). Additionally, similar to the language of TRIPs and the EPC, Art. 6(1) of the Biotech Directive draws an exclusion based on moral grounds. In the Art. 6(2), some examples of biotechnological inventions excluded from the patent protection based on the reasons related to the *ordre public* and morality are enumerated such as "processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes."

Although we already described the applicable provisions within the context of the EPC, it is necessary to draw attention to the link between the Biotech Directive and the EPC: After the adoption of the Biotech Directive, on June 16, 1999, the EPO implemented the rules laid down in the Directive into the EPC Implementing Regulations under a new chapter entitled

29 Council Directive 98/44 Directive, recital 1, 1998 O.J. (L 213) (EC) (*hereinafter* Biotech Directive.).

30 *Id.,* Recital 3.

'Biotechnological Inventions'.[31] In the Notice Concerning the Amendment of the Implementing Regulations, the EPO draws attention to the fact that this implementation has been done to create harmonisation and uniformity in the European patent law.[32] These new rules are intended be used to interpret EPC provisions in conformity with the Biotech Directive.[33] Thus, by virtue of Art. 164(1) of the EPC, Rule 26-29 constitute an integral part of the Convention. As a result, a link is generated between two legislative bodies and one could assert that the application of the Biotech Directive has to be closely followed by the EPO for a better functioning of the EPC for the purpose of consistency among Contracting States.

31 EPO Notice Concerning the Amendment of the Implementing Regulations to the European Patent Convention, 8-9/1999 O.J EPO, ¶1, at 573.
32 *Id.,* ¶3, at 573.
33 *Id.,* ¶9, at 575.

IV. Ethics and Stem Cell Related Patents

A. Ethics and Patent Law

The issue of morality based exclusion to the patent law is discussed under the term ethics as well. In the framework of this research, the interchangeable use of concepts 'morals' and 'ethics' would not create any ambiguity to understand the main issue. Ethics are defined as "the science of morals, the department of study concerned with the principles of human duty."[34] Although we did not encounter a salient difference between concepts of morality and ethics within the framework of statutory texts, a terminological distinction is made by Zimmerli.[35] As an attempt to interpret him, ethics constitute a subpart of morality and have practical implications for our behavior guided by our choice between the good and the bad, the right and the wrong in which the rationality also plays role in shaping our moral values. For that reason, the rules guiding human conduct could not be deemed as independent from the legal rules. Along the same lines, the patent law cannot avoid interaction with questions of ethics since its subject matter, namely, technological progress has discernible influence on the society.

In that respect, it is debated whether patent law should have provisions in regard to ethics and moral concerns. One group of arguments departs from the uncomplicated premise that the patent law as a branch of the judical system should take into account the moral principles established by the society.[36] According to this view, the patent law does not differ from other branches of the law dealing with moral principles determining the well-being

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34 The Oxford English Dictionary 421 (2nd ed. 1989).

35 *"The difference between moral and ethical is that ethics is that little bit, as my teacher Günther Patzig, would call it, that little bit of morality we can grasp by rationality and there are lots and lots of irrational but nonrational motivations included which are not capable of being grasped rationally".* Walther Christoph Zimmerli, *Discussion Session Comment* in Patenting of Human Genes and Living Organisms 148, 148 (F. Vogel & R.Grunwald, eds. Springer 1994).

36 Peter Egerer, *Who in Our Society Should Take on the Responsibility of Deciding What Is Ethically or Morally Just, and What Are the Criteria Upon Which Decisions Should Be Based*, in Eposium 1992 Genetic Engineering -The New Challenge 332 (Cookson et al.eds., European Patent Office, 1993).

of the society.[37] On the contrary, another set of arguments doubts whether legislation should be based on morality as this might cause negative effects on democratic values such as freedom of choice and belief.[38] Having stated these two lines of arguments, it is important to look at the factors that are likely to shape the legislator's decision whether to effectuate morality based provisions in the patent law.

1. Patent Law Isolated from Morality Based Provisions? A Look into the Legislative Discretion

First, let us take a brief look into the history. As we learn from Karet, the first patent legislation dealing with morality was the French Patent Law 1844.[39] According to its Article 30 para.4, all patents would be void if they are granted for inventions deemed to be against *ordre public*, public security or public decency.[40] Although these concepts sound familiar, their meaning in the 19th century differs from today. What seems to be stable, is the usual attitude not to counteract the belief of the general public. Such approach can be justified by democratic principles. The public opinion cannot be assessed independently from an individual's level of education and religious belief. The purpose of the science is to understand the universe; and its results can lift the veil over some facts deemed as sacred and mysterious by some religious people. For instance, Galileo Galilei[41] and Omar Khayyam[42] in different times and territories during the history, were the ones who came up

37 Margo Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 Wm. & Mary.L. Rev. 469, 534 (2003.).

38 *Id*..

39 Bryan Karet, *Moral Dilemmas in the History of Patent Legislation*, in Eposium 1992 Genetic Engineering -The New Challenge, *supra* note 36, at 316.

40 "…. *si la découverte, invention ou application est reconnue contraire à l'ordre public ou à la sûreté publique, aux bonnes mœurs ou aux lois, sans préjudice, dans ce cas et dans celui du paragraphe précédent, des peines qui pourraient être encourues pour la fabrication et le débit d'objets prohibés" Comores Loi sur les Brevets d' Invention* of July 5, 1844 [French Patent Act 1844], Art. 30. *available at* http://www.wipo.int/wipolex/en/text.jsp?file_id=214532&tab=2#LinkTarget_153 (last visited July 27, 2012).

41 Italian physicist, mathematician, astronomer and philosopher who lived between 1564-1642.

42 Persian philospher, mathematician and astronomer who lived between 1048-1131.

with seminal and novel scientific ideas. At the same time, their work faced some negative reaction from the religious community.

From another aspect, the patent system has its incentivizing role in the fulfillment of human endeavours in crucial technical areas. Therefore, what matters most, is the interest of the scientific community in the protection of their achievements. In my view, politicians should make the legislation according to the rules of democracy that requires the settlement of the conflict of interests of different parties in a consensus manner, where both sides are better off. The incentive theory is dominant for the patent law; it assumes that the social welfare and values would be increased if people get benefit after having invested money into inventions.[43] However, since not all inventions are believed to be a tool to optimize the social welfare, there exist exclusions from patent protection. Some of these exclusions are created not to hinder the further innovation by granting the exclusive right for a basic idea or theory and others are based on concerns about ethics and moral values.

These concerns increase as far as science and technology develop and the man is oftentimes "blamed for playing God". This is an apparent approach by some religious people towards the development in the biotechnology that even extends to works like genome mapping, artificial organ creation, cloning, etc. One could argue that since living organisms constitute the subject-matter of the related scientific field, the regulation of these areas cannot avoid intersection with the social values, beliefs and sensibilities that might differ extremely. As we do not have expertise in religious matters, this research will not focus on any religious doctrine. This attitude also shows our intent to think about the possible right approach of legislators in that regard in order to overcome one possible handicap in the legislative process, namely, imposing one truth about morality to different groups of people within the same society.[44] Especially, moral convictions about hESC-related inventions are mostly based on the sacred character of the early human life. If the legislator participates in this debate by standing on one side of arguments,

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43 Fritz Machlup, *An Economic Review of the Patent System*, 15 Study of the Subcomittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary United States Senate 23 (1958).

44 Justine Burley*, An Abstract Approach to the Regulation of Human Genetics: Law, Morality and Social Policy* in The Regulatory Challenge of Biotechnology, Biotechnology Regulation Series 86 (Han Somsen ed., Edward Elgar Publishing 2007).

the rules of the liberal democracy would be challenged. The legislator should make efforts to support the creation of a multiplicity of arguments[45] and follow a secularist view by not giving priority to one religious belief in the formation of morality based provisions but by taking into account all possible view of its citizens.[46]

Another hindrance faced by the legislator to make morality based provisions in the patent law, is its unability to make foresighted rules in accordance with the fast developing nature of the technology. A layman might lack understanding of possible advantages of the technology for the humanity, and only after some time, the technology which is not deemed in compliance with moral concerns of the society might receive approval after a certain period of time. A more reasonable strategy of the legislator is not to create rules targeting specifically existing technology but, rather, to make easily adaptable rules in regard to the dynamic character of the field. But one should admit that it is not a straightforward task.[47] In other words, the dilemma is whether the legal rules may shape the society based on new developments in the science and technology. In the patent law, to expect a foresighted legislative activity from the legislator would not be in accordance with the fact that the subject matter deserving a patent protection should be non-obvious. In that case, the patent law had to be made with an *ex post* approach in regard to scientific and technological developments. However, the challenge exists always because of the 'one size fits all' characteristic of patent law provisions.

So far, the legislators in many countries opted to implement the moral based exclusion into their laws. One could argue that the patent protection should not incentivize the technological progress that could be detrimental for the public and not cause unease due to the moral concerns. If this is the case, the legislator would be forced to react politically according to the requirement of the public majority, likewise the situation for rules banning child pornography and hate speech. Criminal sanctions against latter acts could effectively be dissuasive to prevent them.[48] On the contrary, exclusions from patent protection based on moral concerns would not have the same inhibiting effect, because the scientists have a big impulsion to reach

45 *Id*..
46 David Resnik, *Embryonic Stem Cell Patents and Human Dignity*, 15(3) Health Care Anal, 211, 215 (2007).
47 Bagley, *supra* note 37, at 540.
48 Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

to the unknown and to come up with new ideas. The fact that there is not patent protection for certain subject matter, for the reason that is not patent eligible does not mean that the practice of this invention would be terminated.[49] Since the patent law does not provide the right to use the invention, the inexistence of a patent would not disable the use of the subject matter.[50] On the contrary, there might be more people who practice such inventions since the exclusive right to exclude others from exploiting the invention does not exist.

Nevertheless, one cannot deny that patent exclusion would not be without effect on the scientific R&D. The economic incentive to effectuate the scientific work could be reduced and scientists would not be able to find venture capitalists to invest money into the development of the industry involving scientific achievements. Therefore, the patent law should not take the place of other regulatory laws and statutory bans when there are no other provisions restricting the use of immoral inventions. Especially for promising and improving technologies like those in the biotechnological field, as mentioned above the achievement motive of the researcher would not be dependent solely on the existence of the patent protection. Particularly, positive effects of biotechnological inventions for the treatment of severe diseases would be the driving force for scientific exploration in that field.

With the purpose to elaborate our explanation about the selection of the suitable patent law policy, it would be useful to take a further look at the European patent law system. Rules for patent eligibility exclusions on moral grounds could be found in the European patent law policy, particularly, in the EPC the relevant provisions of which were stated above. In the next section we would closely analyze EPC's provisions related to patent exclusion on *ordre public* and morality grounds and try to understand their rationales.

a) A Closer Look at the EPC

The main provision related to the morality is the Art. 53(a) of the EPC. According to it, the commercial exploitation of inventions which is in contro-

49 Bagley, *supra* note 37, at 535.

50 Joseph Straus, *Intellectual Property Rights: Ethical Aspects*, 11 International Encyclopedia of the Social&Behavioral Sciences, 7621 (Neil J.Smelser&Paul B.Baltes eds, Elsevier, 2001).

versy with the *ordre public* or morality would not get patent protection. The patent examiner at the EPO, who has been assigned the duty to make an assesment, should have a clear understanding of the meaning of two core terms, namely, *ordre public* and morality. In the decision of the TBA of the EPO[51], the intent of the legislator leaving these terms undefined is also stated based on the historical documents of the EPC and this task is given to the European institutions.[52] Therefore the TBA makes an attempt to interpret the meaning of these terms. In *Plant Genetic Systems* case, these concepts are construed by the TBA as having independent meaning from each other. In the decision it was stated that the term *ordre public* should be interpreted as referring to the "public security and the physical integrity of individuals as part of society." The protection of environment is also considered as an element of *ordre public*.[53] In its judgment the TBA defines also the morality as related to "the belief that some behaviour is right and acceptable whereas other behaviour is wrong" and adds that this belief is "founded on the totality of accepted norms which are deeply rooted in a particular culture."[54] This definition, especially, by adding the environment protection shows that the exclusion from patentability could have broad and slippery foundation and this interpretation might not be really what is meant by the legislator. Besides, with regard to *ordre public,* Warren-Jones underlines that the choice of the French notion instead of 'public order' was on purpose which shows the difference of meaning between these terms.[55] This distinction of meaning is also defined in the legal literature. For example, Moufang considers the *ordre public* as the fundamental principles of the legal system and the morality as ethically-established norm of vital significance, the binding force of which is generally accepted.[56] Also, Straus has a similar approach that *ordre public* signifies "basic foundations of our legal system."[57]

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51 T 0356/93, Plant Cells / PLANT GENETIC SYSTEMS, O.J.1995, 511, at 557.

52 Minutes of the Meeting on April 1961, Travaux Preparatoires EPC 1973, *available at* http://www.epo.org/law-practice/legal-texts/archive/epc-1973/traveaux.html (last visited Nov. 05, 2013.).

53 *Id.*.

54 *Id.*.

55 Amanda Warren-Jones, *Finding a "Common Morality Codex" for Biotech – A Question of Substance*, 6 International Review of Intellectual Property and Competition Law [IIC] 644 (2008).

56 Rainer Moufang, *Patenting of Human Genes, Cells and Parts of the Body? – The Ethical Dimensions of Patent Law,* 4 IIC 487, 503 (1994).

57 Joseph Straus, *Biotechnology and Patents*, 54 Chimia 294, (2000).

Once the borderline between these concepts is drawn, another issue open to debate is the clarification of *ordre public* and morality of the European culture. The task to define common European cultural principles and values is not easy. Take into account the diversity of member countries of the EPO, the disparity between various understanding and practice in the technological development seems to be unavoidable. There are some propositions[58] that European *ordre public* and morality should refer to the values enshrined in the ECHR[59]. Accordingly, any invention against the right to life (Art. 2 of the ECHR) or the prohibition of treatment in violation of human dignity (Art. 3 of the ECHR) would not be able to get patent protection based on Art. 53(a) of EPC.[60] In the same vein, despite all discrepancies of moral conceptions among the Contracting States of the EPC, the continuous desire to reach the common understanding of European morality and *ordre public* might not be an utopia. In this context, the EPO could seek for the common principle of *ordre public* and morality for Contracting States but should avoid creating artificial rules related to these issues.[61]

Considering these possible questions triggered by the morality based provisions, one could simply suggest the removal of morality based rules. This hypothesis is not seen in conformity with the general particularity that legal rules of European democracies are based on principal ethical values, namely, justice, equality and freedom.[62] In that, the legislator of the EPC opted for a morality provision phrased in broad terms, in a way that is applicable in different countries. From another perspective, the legislator's choice to make a broad provision brought the question to determine the threshold of *ordre public* and morality criteria i.e whether an invention would be considered immoral or against *ordre public* when it is unacceptable by the public or creates a serious objection which is, by no means, rebuttable.[63]

These foregoing standards referred by the case-law would be examined more in detail below in light of some landmark judgments. After having analyzed one example of how the legislator could regulate morality concerns

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58 Moufang, *supra* note 56 at 503.
59 European Convention of Human Rights [ECHR], Sep 3, 1953 (Council of Europe).
60 Moufang, *supra* note 56, at 503.
61 Joseph Straus, *Patenting Human Genes and Living Organisms – The Legal Situation in Europe*, in Patenting of Human Genes and Living Organisms, *supra* note 35, at 25.
62 Moufang, *supra* note 56, 497.
63 Amanda Warren-Jones, *Vital Parameters for Patent Morality- A Question of Form*, 2 J. Intell. Prop. L& Prac. 832, 835 (Oxford University Press, 2007).

in patent law, we should mention another piece of legislation dealing with morality based exclusions from patentability, namely, the Biotech Directive. In spite of its existing common points with the EPC, this body of rules indicates another path of resolving the issue by the European legislator and its provisions will be discussed in the next section.

b) Specific Examples of Immorality in the Biotech Directive

As mentioned earlier, the legislator in the Biotech Directive followed the path of the EPC by including morality based provisions. As evidenced from the discussion occurred in the European Commission and Parliament, the ethical and moral aspects of patenting the biotechnological inventions are of political necessity.[64] By doing so, the Biotech Directive introduces an article, going along with the EPC Art. 53(a), which bans the patenting of biotechnological inventions the commercial exploitation of which would be against the *ordre public* or morality.

Differently from the EPC, the legislator of the Biotech Directive adds to the general morality provision a non-exhaustive list of inventions being considered against *ordre public* and morality and, thus, excluded from the patent protection.[65] By doing so, the purpose of the legislator is "to provide national courts and patent offices with a general guide to interpret the reference to *ordre public* or morality."[66] Now these specific examples become the core subject of the current debate let alone establishing its guiding role.[67] This is mainly due to the inefficacy of provisions made by the legislator with a retrospective approach to the actual development of that time in the scientific field. This could be exemplified by referring to Art. 6(2)(d) of the Biotech Directive being included therein after the judgment of the EPO. The case before the EPO was related to a patent for a method of producing

64 Gerard Porter, *The Drafting History of The European Biotechnology Directive*, in Embryonic Stem Cell Patents 10 (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009).
65 Biotech Directive, *supra* note 29, Recital 38.
66 Biotech Directive, *supra* note 29, Article 6(2).
67 Porter, *supra* note 64, at 5.

transgenic mice capable to develop cancer cells.[68] The patent was discussed in different stages of the EPO before the grant. Eventually the result achieved was a balancing exercise applied by the Examining Division as instructed by the judgment of the TBA which specified the method as the careful 'weighing up' of the suffering of animals and possible risks to the environment, on the one hand, and the invention's usefulness to the mankind, on the other. At the end of the balancing exercise, the grant of the patent created unease among the public and this triggered the introduction of this provision.[69]

Another defect of the non-exhaustive list of guiding examples is the difficulty to make specific provisions in a field which continuously develops.[70] This could be exemplified by the Art. 6(2)(c) of the Biotech Directive excluding from patentability inventions using "human embryos for industrial and commercial purposes." The intent of the legislator in this provision is dependent on the current state of the technology at the time of the legislation. Therefore, while assessing the patentability of hESC-related inventions one should be very cautious about the scope of exclusionary provisions.

Having said that, we will discuss implications of these legal provisions in depth in the next chapter, but before that, since the main problem of our research necessitates the thorough analysis of the patentability of hESC-related inventions, a general philosophical background for the nexus between bioethics and hESC-related inventions should be established in the following subpart.

B. Bioethics and Patents for hESC-Related Inventions

We previously described the term 'ethics'.[71] Along the same lines, bioethics would constitute another aspect of the subject related to the patent law, especially, assessing the implication of biological research and its technolog-

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68 *Claim 1: A method for producing a transgenic non-human mammalian animal having an increased probability of developing neoplasms, said method comprising chromosomally incorporating an activated oncogene sequence into the genome of a non-human mammalian animal.,* Harvard Oncomouse EPO Patent EP 0169672, 13.5.1992, *available at* http://worldwide.espacenet.com (last visited July 31, 2012).

69 Porter, *supra* note 64, 12.

70 *Id.,* 24.

71 See *supra* Part IV. A.

ical application which would be subject to the patent eligibility, in particular, for the debate related to the human dignity, conception of the person and human being.

In our research, the current debate in the bioethics about the patentability of hESC-related inventions is important as well. For that purpose, we should discuss in the following section the relevant moral status of the human embryo since we are dealing with stem cells derived thereof.

1. Moral Status of Human Embryos and Its Implications for the hESC Research

The ardent discussion on the moral status of the human embryo could be summarised under two opposing approaches: the biological humanity view and the person view.[72] Under the former, human life begins at conception and even at the blastocyst stage an embryo is considered as a person having the right to be respected, whereas according to the latter view, the embryo is just a bunch of cells not having any human characteristics. Although these views are simply stated, the thorough assessment of two approaches would not help us come up with a clear-cut answer. The result of these views is closely related with the question whether an embryo might have dignity. In the biological humanity view, the matter is seen from a pure biological perspective and the human embryo is considered as a human being upon the completion of the fertilisation process. According to this view, an ovum having the genetic information capable to develop into a human being could be accepted as a human. Contrary to this approach, as it is the case in the 'person view' the moral status of a human being is closely related to human characteristics such as the sentience, consciousness, the reasoning, self-motivation and use of language.[73]

72 Bonnie Steinbock, *Moral Status, Moral Value, and Human Embryos: Implications for Stem Cell Research* in The Oxford Handbook of Bioethics 416,421 (Bonnie Steinbock ed., Oxford University Press 2007).

73 *Id.,* 427.

a) Debate on whether Human Embryo Has Human Dignity

As far as the idea of human dignity is concerned, the reference can be made to the German philosopher Immanuel Kant, who contributed to the development of the human dignity view in the western philosophy. By doing so, Kant drew the line between what is human and non-human. According to him, the humanity is embodied in rationality because he believes that only rational beings are able to follow universal rules that they develop themselves. In this view, rationality prevails over other human characteristics such as emotion and language.[74] The famous passage of Kant from his work *The Groundwork of the Metaphysics of Moral,* usually referred in academic works concerning bioethical debates, states that the humanity should not be treated only having a market price but always having the moral value, which is dignity.[75] This statement has become a springboard for the debate between people being against the hESC-related technology and their opponents.

Arguments against hESC-related technology, based on Kantian approach, are in line with the biological humanity view. According to Kant, any tentative of commodification and instrumentalisation of a human being is against the human dignity. In that respect, it is believed that the status of being a human is dependent on being a part of the Homo sapiens species.[76] As the beginning of human organism corresponds to the completion of fertilisation, human embryos are considered as human beings whose right to life should be respected and could not be made subject to any condition. Human being should be treated as an end in itself. Therefore, the destruction of a human embryo to obtain hESCs is considered as commodification of human being since it is used to satisfy others' ends. Following this argument, the removal of the inner cell mass even of a blastocyst resulting in its destruction is equated to a murder thus, it is an act against the human dignity. This view has a weakness as it does not make any difference for the moral status of different stages of human life, for instance, between a child and an embryo.[77]

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74 Resnik, *supra* note 46, at 215.

75 Susan M. Shell, *Kant's Concept of Human Dignity as a Resource for Bioethics*, in Human Dignity and Bioethics: Essays Commissioned by the President's Council on Bioethics,334 (The President's Council on Bioethics, 2008).

76 Fuat S. Oduncu, *Stem Cell Research in Germany: Ethics of Healing vs. Human Dignity*, Med., Health Care and Phil. 5, 12 (2003).

77 Resnik, *supra* note 46, 216.

From another perspective and contrary to arguments sketched out in the previous paragraph, it is stated that Kant's person conception is not used in relation to be members of Homo sapiens family, but rather to have the reasoning and self-consciousness.[78] Hence, deriving hESCs from human embryos is not seen immoral and against human dignity. In that view, human embryos are not considered as rational beings since they cannot be attributed moral status or human dignity characterized by intelligence, morality, emotion and aesthetic appreciation.[79] In our opinion, the unsatisfying part of this argument is that it could even exclude people having some mental disabilities from having the moral status.

b) Double-Edged Sword: A Need of Compromise Considering Different Methods of Obtaining hESCs

Before ardently defending any of the previously stated views, one must be aware of the fact that both sets of arguments make a double-edged sword, mainly, due to weaknesses they present. Neither of them would help reduce morality concerns related to the hESC-related inventions. This situation underscores the necessity of a compromise which is not an easy task to accomplish. Because there are even some divergence of ideas inside the group of people sharing the same moral position. These divergent views are worth considering in an attempt to reach a compromise.

(1) Research on Embryos Within 14 days After Fertilisation

In the biological conception itself, there is a slightly divergent view that the human organism appears after 14 days after fertilisation. We learn from the reference made to R.M Green by Steinbock[80] that the early embryo is not an expression of one individual since there is a likelihood of the formation of twins and triplets at the early stage of the embryo. Consequently, the moral

78 Bertha Alvarez Manninen, *Are Human Embryos Kantian Persons?: Kantian Considerations in favor of Embryonic Stem Cell Research*, 3 PHIL, ETHICS and HUMAN in MED 4 (BioMed Central, 2008), *available at* http://www.peh-med.com/content/3/1/4 (last visited July 18, 2012).

79 Resnik, *supra* note 46, 216.

80 Steinbock, *supra* note 2, at 422.

status of an individual's embryo deserves to be respected 14 days after fertilisation. A compromise could be reached by limiting the research only having blastocysts as their objects in other terms, human embryos which are earlier than 14 days old.

(2) Research with Supernumerous Embryos

According to another argument, an embryo deserves protection as it develops and becomes more human-like. Put in another way, a human being does not have the same moral status at all stages of its life. Unlike the restriction of 14 days view, the timeline is divided more broadly into many stages, whereby the moral status differs in a gradually increasing manner. Resnik elaborates this idea by making analogy to a child having the right to life but not to vote and marry.[81] This argument is important in the search of compromise, especially, to justify the use of spare or supernumerous embryos from the *in vitro* fertility treatment. (hereinafter, IVF). In this method many embryos are generated in order to decrease the physical burden of the woman in the treatment process and increase chances of success. Extra embryos generated should be frozen within first six days after fertilisation.[82] If they are not used within a certain period of time, they lose their suitability to be implemented in the uterus of a woman.[83] These embryos would be inevitably discarded as they are no longer needed for the purpose they are generated for.

The destruction of unviable embryos is approved as a part of the process in the IVF treatment. When it comes to the generation of ESCs from these embryos, their destruction could be justified on the basis that it is done for human treatment purpose of serious diseases like Alzheimer, Parkinson, diabetes, etc.[84] At this point, Kant can be mentioned for an additional justification. According to Kant, human beings should be treated as an end in themselves however, in light of the foregoing facts, we come to the result that non-implanted human embryos in the woman womb have neither a po-

81 Resnik, *supra* note 46, at 217.

82 *See* Reproductive Genetics Institute website for a short explanation of the treatment available at http://reproductivegenetics.com/frozen_embryo.html (last visited July 23, 2012).

83 Roberto Gambari&Alessia Finotti, *Bioethics and Freedom of Scientific Research in Gene Therapy and Stem Cell Biology*, in BIOTECH INNOVATION and FUNDAMENTAL RIGHTS 120. (Bin et al. eds, Springer 2012).

84 *See supra* note 3.

tential to life nor an end. To assure the success of this alternative of compromise there is another important aspect that should be taken into account, namely, the informed consent of the woman or the couple who take part in the IVF treatment process directed to further research on spare embryos.[85] At this point, the problem arises related to the scope of this consent, i.e whether it also covers the patent protection of the hESC research results. Therefore, the scope of the given consent should be clearly determined.

(3) Research with Embryos from SCNT

Ethical debate becomes more important in regard to the method used in the SCNT technology. This technique to create human embryos for the purpose of research and their subsequent destruction makes the compromise more difficult since embryos are generated to be destroyed in order to obtain hESCs. The destruction of these embryos to treat serious human diseases should not create a stir in the society considering that the destruction of spare embryos created in the process of the IVF treatment has already been in practice as mentioned above.[86] However, while defending this argument, one should bear in mind the existence of very strict requirements in many European countries regulating the human embryo destruction in research.[87]

So far we simply stated some ways of compromise to moderate some moral concerns which should be taken into account while one is thinking to oppose certain methods of hESC research. As a result, it could be said that these methods involving the use of human embryos could be construed in compliance with ethical concerns.

85 Gambari&Finotti, *supra* note 83, at 120.

86 Steinbock, *supra* note 2, at 438.

87 For example, policies of Finland and the UK differ as to the suitable period for the storage period of human embryos before their destruction. *See* for more information, Rosario M.Isasi&Bartha M. Knoppers, *Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe*, in Embryonic Stem Cell Patents, *supra* note 64, at 49.

V. The Panorama in Europe

There is no place for speculation in the law and one should defend her argument based on strong justification. The previous chapter represented the blurred situation constituted of a wide array of views regarding the patentability of hESC-related inventions based on different philosophical and scientific arguments. Under this chapter, we intend to be more concrete and specific in regard to the positive law. We start by examining the Biotech Directive to find out the right application for hESC-related inventions in the first part of this section. The Biotech Directive constitutes the basis of the applicable law in the territory of EU member states. Moreover, the interpretation of its provisions is important because of its essentiality for the application of the EPC rules to the same issues that would be subsequently dealt.

A. Determining the Right Interpretation of the Biotech Directive

1. The Patent Eligibility of the Human Embryo

Before we deal with the hESC-related inventions, Art. 5(1) of the Biotech Directive should be mentioned to clarify the difference among subject matters of the patent protection. The said article precludes the patentability of human body at various stages of its formation and development. According to that, the human embryo could refer to an early stage of the human body formation. This literary interpretation does not conflict with the intent of the legislator. As we learn from Porter about the preparatory works of the Directive, the legislator's intent was to avoid the availability of patent protection for human embryos *per se*.[88] One drawback of this provision is that the Biotech Directive does not provide for the definition of human embryo.Nevertheless, especially the definition of a scientific term should not be made in a legal text because of the possible inconsistency that might appear with the actual state of the science when the said rule is applied.

88 Porter, *supra* note 64, at 18.

Therefore there is a concern about the existence of a variety of the human embryo definition in national laws. In the German Embryo Protection Act the human embryo is defined as "*the human egg cell, fertilised and capable of developing from the time of fusion of the nuclei, and further, each totipotent cell removed from an embryo that is assured to be able to divide and to develop into an individual under the appropriate conditions for that.*"[89] In the law of the U.K., the embryo is "*a live human embryo and does not include a human admixed embryo (as defined by section 4A(6)), and references to an embryo include an egg that is the process of fertilisation or is undergoing any other process capable of resulting in an embryo*."[90] The German law has a broader definition of human embryo than the law of the U.K. in a sense that totipotent cells removed from an embryo are covered by the definition as well. As it might be seen, this difference between legal definitions of the human embryo is also important to make a decision whether the definition covers the hESCs and, thus, the hESC-related inventions are patent eligible.

2. The Patent Eligibility of hESC-related Inventions

The patent eligibility of hESC-related inventions is the most controversial issue. Since hESCs do not have the potential to develop into the human body, it is not possible to consider them within the framework related to embryos.[91] Nevertheless, there are two aspects of morality concerns related to the patent eligibility of hESCs. The first ethical aspect is related to the destruction of human embryos irrespective of the source of the human blastocyst for the collection of hESCs. Second perspective of ethical concern is related to the source of human embryos, especially when blastocysts are created specifically for the purpose to collect hESCs.

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89 Gesetz zum Schutz von Embryonen [ESchG] [Embryo Protection Act], Feb. 13, 1990, Sec.8 (F.R.G)*available at* http://www.auswaertiges-amt.de/cae/servlet/contentblob/480804/publicationFile/5162/EmbryoProtectionAct.pdf (last visited Aug. 01, 2012).

90 Human Fertilisation and Embryology Act, 2008, c.22, Part 1, (U.K.) http://www.legislation.gov.uk/ukpga/2008/22/pdfs/ukpga_20080022_en.pdf (last visited Aug, 01.2012).

91 *See supra* Part II. B.2.

a) The Destruction of Human Embryos for hESCs

The most relevant provision related to the patentability of hESCs obtained by the destruction of human embryos is possibly Art. 6(2)(c) of the Biotech Directive. This is an example of a provision that EU Member States have no discretion to interpret it in light of their national rules.[92] Therefore, it is important to identify cases which could fall within the scope of this Article. If one considers the patent eligibility of hESCs within this provision, the moral rationale for the exclusion from the patent protection would be the industrial and commercial use of human embryos for the extraction of hESCs. One could reach the result that the invention is immoral by looking at commercial and industrial purposes of the use of human embryos. So this is mostly related to the use of the embryo which results with its destruction. In this approach, there are two crucial points that should be considered. One problem is to determine the scope of the invention excluded from the patent protection: The question is whether the immoral element of the invention lies within the scope of the claims, or in the whole specification, or even beyond. One could say by reference to Art. 69 of the EPC that only claims matter to construe the scope of the patent protection and thus the same rule is valid for the exclusion. As a counter-argument, it is possible to say that the 'invention' covers the whole content including its teaching and other acts accomplished to reach the invention.[93] Therefore, even though the destruction of human embryos to generate hESCs is not claimed, it could be considered as an element of the patent teaching constituting immorality and, thus, precluding the patent eligibility.

The second problem is that according to the Biotech Directive, the existence of either commercial or industrial purpose would suffice for the exclusion and this requires a cautious approach when this legal provision is

92 C-456/03, Commission v. Italy, 2005 ECJ CURIA, ¶78 (June 16, 2005).

93 This argument is accepted by the Stem Cells Patent Report prepared for the European Commission that the scope of the invention must be determined with regard to the claim. To strengthen this argument the reference is made to the para.79 of ECJ's Netherlands v. Parliament and Council judgment of the date 9.10.2001 stating that "[T]he Directive concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products." *See* A.Plomer et al., *Stem Cell Patents: European Patent Law and Ethics Report,* 78 (European Commission, 2006), *available* at http://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf (last visited Aug. 01, 2012).

applied. The distinction between commercial and research purposes should be clearly made. It is also important to specify the point of time when the use of the invention could be closely attributed to the commercial purpose of the use of human embryo. Additionally, whether concepts 'commercial' and 'industrial' refer to the repetitive and multiple use of the embryo is an issue that should be clarified in order to make a decision under the Art. 6(2) (c).[94]

So far in light of explanations made above, one might reach to the argument that the patentability of hESCs would not be immoral under Art. 6(2) (c) as long as the invention is not related to the direct use of human embryos *per se* for commercial or industrial purposes. Nevertheless, it could be still argued that the invention is unpatentable based on Art. 6(1) of the Biotech Directive. This article, as mentioned earlier in this research, constitutes the general morality provision and therefore EU Member States have a right of manoeuvre based on their specific understanding of *ordre public* and morality.[95] At this point there is a possibility for applicants to establish the compliance of hESCs with the *ordre public* or morality by taking into account the Recital 39.[96] In that, the said recital makes clear that *ordre public* and morality principles would be derived from "principles recognised in a Member State." The plenitude of different approaches that we tried to show earlier in this research find their reflection in rules of different Member States. Unlike the consensus among Member States regarding the immorality of interventions into the human germ line and the cloning of human beings as stated in Recital 40 of the Biotech Directive, no similar common ground has been reached on the status of human embryo and on the issue when the life

94 Paul Torremans, *Legal Problems Raised by Patents on Human Stem Cell-Based Inventions,* in Translational Stem Cell Research, Stem Cell Biology and Regenerative Medicine 287, 305 (K.Hug&G. Hermerén, eds.,Humana Press, 2011).

95 C-377/98, Netherlands v. Parliament and Council 2001 ECJ CURIA, ¶38 (Oct. 10, 2001).

96 As a side remark, we must state that in the EU law, recitals of the Directive do not form the operative part of the rules. Hovewer, they are useful in providing the background of the legislative intent and, thus, contributing to a viable interpretation of the law.

begins.[97] Therefore the application throughout the EU Member States on the patent eligibility of hESCs could be diverse.

b) The Creation of Human Embryos for hESCs

As mentioned previously[98], the morality concern is tried to be overcome usually by the use of frozen blastocysts from the IVF treatment. These embryos are no more capable to develop into a human body. Here, the moral rationale for the exclusion of hESC related inventions from the patent protection could be the 'creation of embryos for destruction'. Some embryos could be created for the sole purpose to destroy them in order to obtain hESCs. In that perspective, we must especially analyze the status of hESCs derived from the SCNT according to the current legislation. The creation of an embryo by SCNT should be considered immoral if the reproduction of a human being from a cloned embryo is aimed. This method could be also called as reproductive cloning. If someone uses this method to extract hESCs from the embryo created, called as therapeutic cloning, there is also a possibility that this method falls within the scope of the Art. 6(2)(a), regardless whether the purpose of the cloning is reproductive or therapeutic, because in any case, the production of embryos is the unavoidable result. However, one should consider that this method is allowed in the U.K. under very strict conditions, e.g. the disease targeted with the stem cell research using supernumerary or cloned embryos should have particular seriousness and gravity.[99]

The assessment of *ordre public* or morality according to the rules briefly discussed of the Biotech Directive implemented in the national level, would not create a problem since this test of patent eligibility would be effectuated by national courts and patent offices of EU Member States based on different

97 *See also* the Report on the Protection of the Human Embryo in vitro, Steering Committee on Bioethics, CDBI-CO-GT3 (Council of Europe, June 19, 2003) at 37 *available at* http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3(2003)13E.pdf (Last visited Aug. 08, 2012).

98 *See supra* Part B.1.b.(2.).

99 Porter, *supra* note 64, at 24; Isasi&Knoppers, *supra* note 87, at 46. Even in the UK, some development within the method of SCNT for making ESCs is recently reported, *See* Human 'Cloning' makes embryonic stem cells, Oct. 5, 2011*, BBC News Health, available at* http://www.bbc.co.uk/news/health-15181015 (last visited Aug. 28, 2012).

ethical conceptions on the patent eligibility of hESCs. The lack of consensus on the concept of morality would create a more difficult situation when the EPO applies the EPC in a centralized patent grant procedure which will be discussed below in detail.

B. Application of the EPC

1. Lack of Uniform Moral Standard

The diversity and the relativity of the morality conception among different States are previously mentioned.[100] But when it comes to the EPC, the legislator's intent could possibly be the creation of a uniform European morality standard in light of some approaches we referred above.[101] The Rule 28(c) of the EPC is not different from Art. 6(2)(c) of the Biotech Directive and its application could create similar results like those encountered within the scope of the Biotech Directive. As stated before when the Art. 6(2)(c) of the Biotech Directive was analyzed, some hESCs-related inventions could not fall within the scope of the EPC Rule 28(c) depending on the interpretation of the said legal provision. In that situation, the problem might occur in the next step, where the assessment is done by the EPO according to the general morality clause under Art. 53(a) EPC. Additionally, the question which morality norm would be applicable for the patentability of hESCs-related inventions, arises at this point.

Alternative solutions have been developed in the literature, labeled by Torremans as 'extreme approaches'.[102] The first approach is that the finding of immorality for an invention in one EPC Contracting State should be taken into account by the EPO and this would suffice to refuse the grant of the patent protection. This, so called, 'maximalist test' requires the compliance of the invention to the morality in all Contracting States. The other, so called, 'minimum approach' underscores that the EPO would make a mistake by refusing the patent on moral grounds, once the patent eligibility of the invention is in line with morality norms of a single Contracting State. The second approach is more suitable while considering the complexity of morality issues of hESCs-related inventions in different Contracting

100 See supra Part IV.A.1) a.).
101 *Id.*.
102 Torremans, *supra* note 94, 298.

States.[103] In that context, the suitable approach to be taken by the EPO should be that inventions in conformity with the morality of, at least, one Contracting State get the patent protection.[104] It ia also possible to bring some variation of these extreme approaches. One variation is expressed by Schatz after having accepted that there could be an exception in regard to morality rules among Contracting States. He justifies his standing by stating that once the EPO is aware of contrariety of the invention to the morality in one Contracting State it should warn the applicant about the situation. In this case, the applicant could choose the path to withdraw its application for the designated states where there are morality concerns about the invention and get patent protection in the remaining designated States.[105]

All of these proposed approaches are not far from applicability. In my view, if the applicant does not comply with the warning of the EPO's Examining Division to withdraw the application for designated states where there could be morality concerns, the EPO must in any case, grant the patent as requested by the applicant. By doing so, the applicant takes a risk after the grant due to the buffer of Art. 138 of the EPC which provides for the start of national revocation proceedings where the patent eligibility of the subject matter on the morality ground could be the issue of discussion. As a result, the function of the EPO to assess an invention based on *ordre public* or morality could be pushed to the second plan. Nevertheless, there are attempts on the side of the EPO to create a uniform standard for the assessment of morality. This cannot be described as a morality rule setting initiative, but, rather the determination of a threshold to come up with viable consequences for all Contracting States. In the following subsection we would like to explain these two standards.

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103 This case is similar to the situation depicted in the EU. UK is one example having not restrictive provisions based on the morality of hESCs-related inventions.

104 Torremans, *supra note* 94, refers to Straus who defends this approach in his article, Joseph Straus, *Ethische, rechtliche und wirtschaftliche Probleme des Patent – und Sortenschutztes für die biotechnologische Tierschützung und Tierproduktion*, Gewerblicher Rechtsschutz und Urheberrecht [GRUR],913 (1990).

105 Ulrich Schatz, *Article 53*, *in* European Patent Convention- A Commentary, 91(Margarate Singer&Dieter Stauder, eds.,3rd edition, Carl Heymanns 2003).

2. Attempts to Create a Uniform Morality Standard

The EPO's Examining Division's practice to grant patent protection for inventions is mainly based on some internal rules without binding force. These instructions called 'Guidelines for Examination in the European Patent Office' are prepared to help EPO practitioners during the patent granting proceedings.[106] As regards the explanation of exceptions to patent eligibility, it is stated in the Examination Guidelines that the Art. 53(a) would be referred to in "rare and extreme cases."[107] This is followed by the depiction of the test to apply: "*To consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.*"[108] This is so called 'abhorrence test' or 'rebuttable presumption approach'.[109] In this approach, the patent eligibility of an invention would be only refused if there is no single evidence that the invention has the opportunity to comply with legal and ethical values. In other words, it should be highly unlikely that any counter-argument would be asserted.[110] In this approach, very strong evidence is required showing that the invention is against the *ordre public* and morality. Because this approach intends to assure that this invention has not a single chance to be granted patent protection in the future. The contrary result could create an unfair situation among competitors when one invention, which is deemed immoral today, could find a way around to get the patent protection in the future.[111]

Another test is the unacceptability test which suggests a lower threshold than the abhorrence test. According to this test, it is possible to discuss the patent eligibility of the invention in both ways. In other terms, arguments about the incompatibility of an invention with the *ordre public* and morality are not situated on the extreme points that there exist ways to balance them. Therefore it contains the balancing approach.[112]

We would like to develop our explanation about the balancing approach based on a concrete example although the subject-matter of the invention

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106 Guidelines for Examination, General Part ¶ 3.2, the European Patent Office (June 20, 2012) *available at* http://www.epo.org/law-practice/legal-texts/guidelines.html (last visited 20.8.2012) (hereinafter Examination Guidelines).
107 Examination Guidelines, *supra* note 99, Part G, Ch.II ¶.4.1.
108 *Id.*.
109 Warren-Jones, *supra* note 63, at 835.
110 *Id.,* at 835.
111 Warren-Jones, *supra* note 55, at 652.
112 Warren-Jones, *supra* note 63, at 835.

does not relate to stem cells. We had shortly mentioned the *Harvard Oncomouse* patent to explain Art. 6(2)(d) of the Biotech Directive.[113] In its judgment, the TBA required the Examining Division to use the balancing exercise of different interests, namely, suffering of animals and possible risks to the environment on the one hand and the benefit to the human health on the other hand, in order to make its assessment of patent eligibility.[114] Hence, the Examining Division decides by using this test that the invention is patent eligible.[115] After the grant, the opposition based on different grounds was raised against the patent application and the OD mainly focused on Article 53(a). At the time of the decision of the OD,[116] Article 6(2)(d) had already been transposed in the Implementing Rules, namely, Rule 23d(d) (which is now 28(d)). In the view of the OD, this Article reflects the balancing test postulated in the TBA decision *T 19/90*.[117] After having applied the balancing exercise the OD decided in the following way:

> *In the present case, it cannot be denied that the animals of the invention were made for a good cause, namely progress in cancer research. In view of the new approach the inventor took vis-à-vis the problem of medical cancer testing at the time, there were* ***bona fide reasons at the effective date to expect a substantial medical benefit****. Rule 23d(d) EPC is therefore no bar to patentability of those animals covered by the patent which were found to be allowable under Article 53(a) EPC above.*[118]

This decision was appealed again and it came before the TBA,[119] whichaffirmed the result of the balancing test.[120] However, it also made an important addition stating that the Implementing Rule 23d(d) reflects the balancing exercise only in regard to the suffering of animals *vis-à-vis* the medical benefit to man or animal. From this decision it could be understood that the scope of the balancing test scope might not be limited to the interests determined in the Rule 23d(d).

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113 *See supra* note 68.
114 T 19/90, Onco-mouse/HARVARD, O.J EPO 12/1990, Reasons of the Decision ¶5, at 490.
115 European Patent No: EP 0169672, May 13,1992.
116 Onco-mouse/HARVARD, Decision of the Opposition Division, Nov. 07, 2001, the O.J EPO, 10/2003, at 473.
117 *Id*. Reasons of the Decision, ¶9.3 at 502.
118 *Id.,* ¶9.5 at 504.
119 T 315/03, Decision of the Technical Board of Appeal, July 06, 2004, O.J EPO 1/2006, at 15.
120 *Id*., ¶10.5, at 53.

In light of the foregoing case we come to the opinion that the high number of references to this test could not bring satisfactory results for the patent eligibility assessment. The balancing of different interests based on *ordre public* and morality concerns mentioned in the *T 315/03* decision could lead us to the following result: if arguments based on morality and *ordre public* concepts are subject to the balancing exercise, it could be implied that they are weak and might be refutable at the end of the balancing exercise, thus, the invention should not be precluded from the patent protection This strengthens the conviction that the patent law should not be used as a platform to assess inventions on the morality constituted of contentious and vanquishable arguments when they are 'weighed up' with other interests.[121] Additionally, if the examination of inventions were done by evaluating their possible benefits and risks based on different parameters, a high proportion of inventions for chemical, pharmaceutical and military purposes would not have got patent protection.[122] For that reason, the refusal of the patent application based on morality grounds should take into account strong principles which could be put in no way under a contentious situation with possibly other prevailing interests. So we defend the position for the abhorrence test which targets the refusal of patent eligibility based on uncontroversial results departing from *ordre public* and morality principles.

As regards the morality assessment for hESCs-related inventions, the general public perception and different existing interests of the parties should be taken into account.[123] If we try to apply the balancing exercise for a moment, on the one hand, there is interest in human healing, the development of drugs and scientific knowledge for patients suffering from serious diseases like Parkinson, Alzheimer, diabetes and cancer. On the other hand, there is the ethical concern related to the commodification of the human being, violation of the right to life, and other. The act of balancing of these two arguments would differ depending on the prevailing interests of the

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121 "*The Opponent's first argument that the patenting of higher life forms in principle unethical is a philosophical argument that* WHICH CANNOT BE ACCEPTED IN THE ABSENCE OF ANY STANDARDS OF ABSOLUTE MORALITY.*"* Greenpeace UK v. Plant Genetic Systems N.V.,Opposition Division Decision EPO, (1992) 24 IIC 618, ¶3.16 at 624.

122 Straus, *supra* note 61, at 27.

123 Recitals of the Biotech Directive underscore these interests: In Recital 16, *"...fundemantal principles safeguarding the dignity and integrity of the person..." is mentioned followed by Recital 17 which states that the patent law system should incentivize the production of medicinal products "...derived from elements isolated from the human body...*".

person or group of persons involved and the result thereof would not be satisfactory for any of the parties.

Additionally, new developments in the stem cell research are reported on its unrevealed aspects. Moreover, the complexity of matters in the life sciences being subject to any judgment do not possess easy sides helping too much lay persons in the public to develop a convincing, reliable and uncontroversial position. Therefore, arguments which would be made by both parties would be neck and neck. Thereafter, the judgment to be made would not resolve discussions. For these reasons, opposing ideas in an emerging field should be strong and mature. Accordingly, for the hESCs-related inventions, if very convincing arguments are produced to justify the application of this technology, counter arguments should also come from the scientific environment. In the same vein, another implication could be made regarding the type of evidence that authorities in charge should devote their attention for the morality assessment. In *T 315/03* decision, the opinion polls were not seen as a reliable instrument to give evidence for the existence of morality principle.[124]

An example that would show the difficulty of the balancing test in regard to hESCs-related inventions is given by Annas in his article:[125] It is about the difficulty of making a choice between the rescue of seven embryos or one child from a fire in an IVF treatment laboratory. Even that difficulty shows the unsuitability of the balancing test for the patent eligibility assessment of hESCs-related inventions. Therefore, morality arguments should be very strong in this case in a way that leaves no justification for the healing purposes of the hESC technology and such arguments should be shared without any dissent by the Member States. This reflects especially the situation in the context of the EU, where a single European morality approach, particularly, for hESCs-related inventions is not easily achievable. So authorities should analyze each case in light of a diversity of evidence from legal rules to empirical data.[126] Hence, the test should be applied in a way that the decision to exclude hESCs-related inventions from the patent protection is reached when they are deemed abhorrent based on a wide array of evidence.

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124 T 315/03, *supra* note 119, Reasons for Decision ¶10.4 at 53.

125 George J. Annas, *A French Homunculus in a Tennessee Court*, 19 The Hastings Center Rep. 20, 22 (1989) *available at* http://www.jstor.org/stable/3561982 (Last visited Aug.11,2012).

126 Warren-Jones, *supra* note 55, at 660.

After having structured the guiding principles existing in the legislative tools, we must have a look to the practice in Europe in the following sections.

VI. EPO's Web of Precedents

A. University of Edinburgh Case

The University of Edinburgh filed a patent application on Apr.21, 1994 before the EPO. The patent claims refer to a method involving the *"use of a selectable marker to isolate and/or enrich and/or selectively propagate animal stem cells."*[127] The patent was granted by the EPO on Dec. 06, 1999. Thereafter,the patent was challenged several times. The main concern of the opponents was whether the term 'animal' could be considered in a manner including humans in regard to the source of selection of ESCs. Because even though the research subject to the patent was established by using the mice, claims of the patent were drafted in a way to cover also hESCs. As we learn from Porter, this was the first case of the patent eligibility of hESC-related inventions before the EPO.[128] The OD decided[129] to maintain the patent with amended claims, including claims to stem cells *per se*, but with a disclaimer to human or animal ESCs.[130]

In this case, the OD made an assumption about the possible situation of the patent without disclaimer. In that task, the OD opted for the broad interpretation of the Rule 23d(c) (now 28(c)). Because, according to the OD, the broad interpretation of the said rule would justify the rationale of the Rule 23e(1) (now Rule 29(1)). This reasoning of the OD could be rephrased as follows: inventions involving the use of human embryos for commercial and industrial purposes are not patentable. Therefore, the hESC-related inventions should not be patent eligible when they involve the destruction of human embryos. Since the rationale of Rule 23e(1) is to protect human embryos against commodification, then the elements extracted from human embryos for commercial and industrial purposes should not be patented.[131]

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127 For claims of the EP 0695351 B1 see EPO Patent Database Espacenet, *available at* http://worldwide.espacenet.com (last visited Aug. 05,.2012).

128 Porter, *supra* note 64, at 25.

129 EP 0695351 B1 Opposition Division Decision, Mar.21, 2003.

130 Porter, *supra* note 64, at 25.

131 Paul Torremans, *The Construction of The Directive's Moral Exclusions under the EPC*, Embryonic Stem Cell Patents *in supra* note 64, at 151.

Torremans does not agree with the reasoning of the OD stated above, because each of these provisions implemented from the Biotech Directive has specific and different purposes. According to him, Rule 23e(1) does not allow the patentability of human embryos *per se*, whereas the Rule 23d(c) prohibits inventions claiming *"the direct use of the embryo as a raw material in a repetitive (technical) process…"*[132] In other words, as long as the use of human embryos is not claimed in the application, it is not possible to make a broad interpretation which covers also the clause on the prohibition of the patentability of human embryos as such.

Before this decision was handed down, the 16th Opinion of the European Group on Ethics in Science and New Technologies to the European Commission (hereinafter, EGE) was published in May 2002 by virtue of Art. 7 of the Biotech Directive.[133] According to the 16th Opinion, *"…the patentability of processes involving human stem cells,* ***whatever their source****, there is no specific ethical obstacle, in so far as they fulfill the requirements of patentability."*[134] Therefore the statement of the OD decision does not go along with the 16th Opinion. In spite of its inconsistency with the EGE's opinion, the said decision got support from other instances of European institutions: European Parliament made reference to the decision of the OD accepting in its resolution that the patenting of hESCs is not possible.[135] Besides, the Parliament in the same Resolution stated: *"...for creation of embryonic stem cells embryos have to be destroyed and the patenting of technologies where human embryos are destroyed or used for commercial or industrial purposes is excluded according to Article 6(2)(c) of the Directive*". Nevertheless, these statements do not have any binding force for decisions of the EPO, however, it evidences the diversity of ideas and a lack of consensus on this issue.

It seems that the OD decision regarding *Edinburgh* patent had also some implication for future cases of the EPO. In the next subsection we will an-

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132 *Id.*.

133 Article 7:
The Commission's European Group on Ethics in Science and New Technologies evaluates all ethical aspects of biotechnology.

134 Opinion of the European Group on Ethics in Science and New Technologies to the European Commission 16, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, § 2.3, May 7, 2002 *available at* http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_complet_en.pdf (last visited Aug. 05, 2012).

135 European Parliament Resolution on *Patents for Biotechnological Inventions*, P6_TA(2005)0407, ¶I, Oct. 26, 2005.

alyze a related and very important case of the EPO determining the course of affairs.

B. The WARF Case

1. Background

The EBA of the EPO gave its judgment[136] on questions referred to it by the TBA[137] concerning the patent eligibility of inventions involving hESCs under the EPC. The subject-matter of the patent application filed by WARF was a cell culture comprising hESCs which do not lose their characteristics even after keeping them *in vitro* for one year.[138] In the claims there was no method claim pointing out the source or the generation of hESCs.

The Examining Division rejected the application based on the Rule 23d(c) (now 28(c)) and Art. 53(a) of EPC on the grounds that it would be contrary to *ordre public* or morality to grant a patent for an invention relying on the destruction of human embryos. WARF appealed this decision and by virtue of Art. 112 EPC, the TBA referred four questions to the EBA. The first question was whether Rule 23d(c) of the EPC is applied to patent applications filed before the entry into force of the said rule. The second question inquires the patentability of human embryonic cell cultures even if methods involving the destruction of human embryos to derive hESCs are not mentioned in the claim. In the third question it is asked whether there is the possibility of the sole application of Art 53(a) EPC. The last question was about the relevance of the existence of new techniques allowing the pro-

136 G 2/06, Use of embryos/WARF, Nov. 25, 2008, EPO OJ 5/2009, at 306-332 (hereinafter G 2/06).

137 T 1374/04, Stem cells/ WARF, Apr. 07, 2006, EPO OJ 5/2007, at 313-343 (*hereinafter* T 1374/04).

138 Claim 1 of European Patent Application 96903 521.1, EP Nr. 0770125 is taken from Prof. Joseph Straus, Protection of Biotechnological Inventions (June 5-6, 2012), (unpusblished slides used in summer term class of the Munich Intellectual Property Law Center).: A cell culture comprising primate embryonic stem cells which (i) are CAPABLE OF PROLIFERATION IN VITRO CULTURE FOR OVER ONE YEAR, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and ARE NOT NOTICEABLY ALTERED THROUGH CULTURE FOR OVER ONE YEAR, (iii) maintain the potential to derivates of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on fibroblast feeder layer.

duction of hESC cultures, which are generated without destroying human embryos after the filing date of the application at issue.

2. The Rationale

In regard to the first question, the EBA stated that the implementation of the new rule has not introduced a change as to the patentability criteria. Accordingly, EPC Rule 23d did not make unpatentable something which was considered as patentable before the entry into force of the Rule.[139] This was already the existing situation under Art. 53(a) EPC. Therefore the legal uncertainty as to the exceptions to the patentability is unlikely to arise for any potential inventor.

The core of the present discussion and which is more related to our research finds place in the second question. Claims of the patent application were not guiding the person skilled in the art to use human embryos. In that, WARF asserted that the subject-matter of claims was the cell culture comprising hESCs rather than a method necessarily involving the destruction of the human embryo to produce hESC cultures.[140] This argumentation is the result of a narrow interpretation of the Rule having the expression *"…inventions which, in particular, concern the use of embryos…"*. WARF based its argument on the Art. 84 EPC stating that the matter protected by the patent is in claims and claims are indicative of the invention. Then, as the invention does not have the use of human embryos as its object, the exception to the patentability should not apply here.[141]

The EBA had an opposite approach to WARF's opinion: It uses the method to find the object and purpose of legal provisions including preparatory documents according to the language of the Vienna Convention on the Law of Treaties.[142] By doing so, the EBA found that to remain undefined the term 'embryo' was the purpose of the legislator. The lack of the embryo's definition makes the situation more problematic.[143] Therefore, different approaches arise here again. According to WARF, an ovum could be called an embryo after being at least 14 days old. Hence, hESCs could be derived from

139 G 2/06, *supra* note 136, ¶13.
140 T 1374/04, *supra* note 137, ¶37.
141 G 2/06, *supra* note 136, ¶21.
142 Vienna Convention on the Law of Treaties, May 23, 1969.
143 Torremans, *supra* note 94, 302.

these organisms younger than 14 days old. Nevertheless, the EBA draws our attention, as we discussed earlier, to the diversity of approach to the term under national legislations and gives concrete examples from German Law and law of the U.K. It does not prefer a single definition and construction. This attitude might prove that with the exclusion of human embryos from patent eligibility it is aimed to extend its scope to cover all possible embryo definitions.[144] As a result, the EBA suggests a case-by-case analysis to determine whether an entity is an embryo by taking into account the particular facts of any patent application.[145]

The choice of the EBA for the broad interpretation, like in the Edinburgh patent case, could also be indicated in its approach to the term 'invention' which is deemed to cover not only the explicit wording of claims but also the technical teaching of the application as a whole and of the technology involved. The EBA strengthened its argument by referring to the decision of the German Federal Patent Court (BPatG)[146] on the revocation proceedings of Oliver Brüstle's patent. Brüstle case is not discussed here, as it will be analysed in detail in the following chapter. According to the EBA, when the patent eligibility of an invention is discussed on moral grounds, it is not possible to refer only to the claims of an application. It has been acknowledged that at the filing date, the skilled person willing to repeat the invention had necessarily to start from the spare pre-implantation embryos as indicated in the application followed by their destruction in the process, so that human embryos are 'used'.[147]

As to the another issue whether the use of human embryos is for commercial and industrial purposes, the EBA's finding was affirmative. In that, the product must be made first before it can be used and commercially exploited, and such making falls within the monopoly granted. Consequently, to make the claimed product is equated to commercial or industrial exploitation of the invention, even if there is an intention to use the product for further research. Accordingly, the use involving destruction of human embryos is

144 Pierre Treichel, *G 2/06 and the Verdict of Immorality*, 4 IIC 450, 459 (2009).

145 G 2/06, *supra* note 136, ¶20.

146 Bundespatentgericht [BPatG] [Federal Court for Patent Matters], Dec.5, 2006, 3 Ni 42/04 Entscheidungen des Bundespatentgerichts, *available at* http://juris.bundespatentgericht.de (last visited Aug. 05, 2012).

147 G 2/06, *supra* note 136, ¶20.

an integral part of the industrial or commercial exploitation of the claimed invention.[148]

I would tend to disagree with the EBA because of the erroneous determination of the scope of patent protection. The process of hESC generation to form hESC cultures does not exist in claims of the patent application. Therefore, it is not possible to agree with the existence of the monopoly on the method involving the destruction of human embryos. In addition to that, to make the product would not necessarily have a commercial purpose where there is an intent for research with that product. Moreover, Torremans does not accept the existence of commodification or, in other terms, the commercial and industrial purpose in this case, because the human embryo is not repetitively used every time when the invention is performed.[149]

Another important aspect of the case is analyzed by the EBA in answering the fourth question. The science is a dynamic field, therefore even after the application's filing date, the technology used to reach the end-product could change. In the case at issue, the technique used for the isolation of hESC involved at the time of filing the step of destruction of human embryos. whereas today, as mentioned earlier, alternative methods to procure stem cells have emerged such as iPSCs which are not of embryonic origin.[150] However, according to the EBA, these developments creating possibility to perform the invention without the need to destroy embryos are irrelevant to the patentability of the invention at issue. Thus, if the extraction of hESCs is possible exclusively by the destruction of human embryos at the filing date and the inventor is not aware of an alternative method, the hESCs-related invention would not get patent protection. In my opinion, this argumentation urges applicants to disclose the method used to obtain the base material either in the specification or in the claims. Although this might create certainty for the applicant, its lack should not be a barrier to get a patent for the invention. On the contrary, EBA makes the statement that the application in case is insufficiently described and has a lack of disclosure that the invention could be carried out by the skilled person in the art.[151] Unlike the EBA, I think that the application does not have a lack of disclosure to enable the skilled person in the art to perform the invention. Because even though the destruction of human embryos is not disclosed in the specifica-

148 *Id.,* ¶25.
149 Torremans, *supra* note 94, 301.
150 *See supra* Part II.B.3.
151 G 2/06, *supra* note 136, ¶33.

tion, there is always a certain possibility far from any uncertainty on the part of the skilled person to use derived hESCs found in cell banks as a research tool.[152] As a result, inventions, like the one at issue, concerning products obtained by techniques involving the destruction of human embryos are excluded from patentability according to the EBA.[153]

This decision of the EBA had important implications to the present debate. The findings in G 2/06 have played a role in the background of the revision made in the EPO's Guidelines for Examination which entered into force on June 20, 2012. In the section related to the patentability of the said Guidelines, there is an explicit reference to the G 2/06.[154] The Guidelines suggest that the examination should be targeted to 'the entire teaching' and 'the relevant disclosure in the description' to evaluate whether stem cell cultures are derived as a result of the destruction of human embryos. In the WARF's patent, the method of extracting hESCs by the destruction of embryos is not the invention. Rather, the gist of the invention is related to hESC cultures and how to keep the cell culture over one year in an undifferentiated state. Nevertheless, the assessment for patent eligibility is done in regard to the whole path leading to the invention. As stated by Torremans, the EPO should not look to the phase of gathering research tools and creation of other materials or methods pursued, for which the patent applicant does not require patent protection.[155] The reason for the inventor that one kind of technology is not expressed in the claims but in the description, might reflect his will to have flexibility towards the development in the technology. This is particularly the case for hESCs-related inventions: The first reason is that there is

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152 UK IPO, *Practice Notice, Inventions Involving Human Embryonic Stem Cells*, Feb. 3, 2009, http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm.; Kathleen Liddell, *Immmorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality in* New Frontiers in the Philosophy of Intellectual Property 140, 168 (Annabelle Lever, ed., Cambridge University Press, 2012.).

153 G 2/06, *supra* note 136, ¶35.

154 *"*Uses of human embryos for industrial or commercial purposes
A claim directed to a product, which at the filing date of the application could be ***exclusively*** *obtained by a method which* necessarily *involved the destruction of human embryos from which the said product is derived is excluded from patentability under Rule 28(c),* even if said method is not part of the claim *(see G 2/06).* The point in time at which such destruction takes place is irrelevant.*"*, Examination Guidelines *supra* note 98, Part G Ch.II at 15.

155 Paul Torremans, *The Construction of The Directive's Moral Exclusions under the EPC*, Embryonic Stem Cell Patents *in supra* note 64, at 166.

a continuous race to create new sources for hESCs. A second more concrete reason is the possibility to create hESCs with already existing hESC lines in laboratories.

Consequently in my opinion, the investigation of the whole genealogy of the invention is beyond the task of the EPO. If the aim is to preclude the incentive to use existing hESC lines obtained by human embryo destruction, the patent law is not the instrument to avoid it. There are other alternative administrative and regulatory tools.[156] To make this argument crystal clear an analogy could be made to the situation depicted in the novel 'Perfume',[157] in which the inventor was killing women and isolating pheromones to create the perfect scent. So according to the G 2/06 decision the scent would not be patentable. Given that analogy, the patent law would take the place of the criminal law and other rules regulating approval for sale of perfumes which could already sanction the inventor. Therefore, the EPO is not in good position to assess the acts indirectly related to the claimed invention.

156 Straus, *supra* note 61, 27.

157 Patrick Süskind, Das Parfum [The Perfume], This example is taken from the class of Biotechnology and IP by Professor Margo Bagley at Munich Intellectual Property Law Center on June 22, 2012.

VII. CJEU's Brüstle Judgment

A. Background

Dr. Oliver Brüstle, from University of Bonn, applied for a patent on Feb. 19, 1997. The German Patent Office issued the patent on Apr. 29, 1999. The application covered a product claim and a method claim, respectively, neural precursor cells and a method of obtaining them and the use of these neural precursor cells for therapy of neural defects.[158]

After the grant of the patent, Greenpeace, a NGO, commenced an action for nullification by asserting the violation of *ordre public* and morality. The BPatG revoked the patent to the extent that claim 1 of the patent application concerning precursor cells and claims 12 and 16 concerning the manufacture

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158 Claim 1: *Isolated, purified precursor cells with neuronal or glial properties from embryonic stem cells*, containing at most about 15% primitive embryonic and non-neutral cells obtainable by the following steps:
cultivate of E Cells into embryoid bodies,
cultivate of the neutral precursor cells to embryoid bodies,
……
Claim 5: Cells according to any one of claims 1 to 4, wherein *the embryonic stem cells were obtained from oocytes after nuclear transfer*
Claim 6: Cells according to any one of claims 1 to 4, wherein *the embryonic stem cells obtained from embryonic germ cells*
Claim 7: Cells according to any one of claim 1 to 6, wherein said cells are *mammalian cells*.
Claim 8: Cells according to claim 7, wherein the cells from the group *comprising mouse, rat, hamster, pig, are bovine, primate or human* been isolated.
….
Claim 12: *A method* for preparing *purified precursor cells with neuronal or glial properties*, comprising the steps of
cultivate of ES cells into embryoid bodies,
cultivate of the embryoid bodies to neural precursor cells,
……
Claim 22: *Use of the precursor cells* according to any one of claims 1 to 11 *for the therapy of neural defects.*
The translation of these claims are generated by using the Patent Translate tool powered by the EPO and Google. For more information about the patent DE 19756864 C1 http://worldwide.espacenet.com(follow out with the patent number above) (last visited Aug 07, 2012).

of precursor cells that are obtained from hESCs.[159] The BPatG based its decision on the Sec.2(2) first sentence No.3 of GPA which were implemented due to the Biotech Directive Art. 6(2)(c).[160] This decision was appealed by Dr. Brüstle in the BGH. The BGH has made a referral to the CJEU under Art. 234 of TFEU for a preliminary ruling related to the interpretation of the Biotech Directive.[161] The BGH asked three questions: The first question was dealing with the definition of the concept of the human embryo, whether its scope covered certain organism and whether stem cells obtained from human embryos at the blastocyst stage could be considered as a 'human embryo' under Article 6(2)(c) of the Biotech Directive. The second question was related to the meaning of 'use of human embryos for industrial or commercial purposes'. The last question was whether the invention would be patentable under Art. 6(2)(c) even if the use of human embryos is not part of the patented teaching but the claimed product requires the destruction of human embryos or such claimed product is needed as a starting material for the performance of the claimed method. The BGH made a gradual reasoning on the possible conditions for an invention which requires the use of 'human embryo'. The first step is to determine the scope of the definition of 'human embryo' and the second one is to decide whether hESCs used for precursor cells are 'human embryos'.[162] If the answer is negative to the first question then the categorization as 'human embryos' of blastocysts from which hESCs are derived should be analysed.[163] As the last step, in case the use of alternative methods such as SCNT and the development of an ovum stimulated by parthenogenesis are claimed, the question whether the cells derived therefrom would be classified as 'human embryos' needed a clarification.[164]

As it is seen, a comprehensive task was expected by the BGH from the CJEU who had to interpret the Art. 6(2)(c) of the Biotech Directive for the first time.

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159 Reference made by German Federal Supreme Court to the decision of Federal Patent Court in supra note 97, Bundesgerichtshof [BGH] [Federal Court of Justice] Dec. 17, 2009, Case No: X ZR 58/07, (Christopher Heath (trans.), 7 IIC at 853 (2010).

160 *Id.,* ¶12, at 853.

161 *Id.*.

162 *Id.,* ¶36, at 854.

163 *Id.,* ¶40, at 854.

164 *Id.,* ¶42, at 855.

B. The Rationale

The CJEU made its preliminary ruling regarding the questions referred by the BGH.[165] CJEU has followed substantially the legal solution offered by the AG Bot who delivered his opinion in that case.[166] In this section while revealing the rationale of the CJEU's judgment, we will also analyze the opinion of the AG.

The CJEU made an attempt to determine a common definition of 'human embryo' throughout the EU. According to the CJEU, a single definition of the term would be in line with the harmonization aim of the Biotech Directive.[167] It was admitted both by the CJEU and the AG that an ethical approach would not be followed in this exercise, mainly, because of the lack of consensus on this issue based on different moral, social and religious beliefs: so they both avoided the question of "medical and ethical nature".[168] The AG expressly determined that the single 'legal categorisation' of 'human embryo' should be based on "scientific objective information".[169] According to the CJEU, the lack of the definition of 'human embryo' would cause inconsistency among different results as to the patent eligibility of the same invention in different Member States. As a result, a situation against the purpose to create an internal market would appear.[170] Moreover, according to the AG in the same line with the CJEU, there is not any specific intent of the legislator revealed from the legislative history to leave the concept undefined. At this point we might think that some details of *travaux preparatoires* of the Biotech Directive are undermined by the CJEU. An evidence for the background of the diverse situation in different Member States guiding legislative intent related to the Art. 6(2)(c) is reported by Porter who

165 C-34/10, Oliver Brüstle v. Greenpeace e.V., Court of Justice of the European Union, [CJEU], 2011 CURIA (Oct. 18, 2011) (*hereinafter* C -34/10).

166 Op. of Adv. Gen. Bot, Case 34/10 Oliver Brüstle v. Greenpeace eV. CJEU Mar. 10, 2011 (*hereinafter* AG Opinion).

167 C-34/10, *supra* note 165, ¶26-27. Contrary to that argument it is stated that the Biotech Directive does not provide a suitable environment for such definition based on Recital 8 of the Biotech Directive setting forth "legal protection of biotechnological inventions does not necessitate the creation of a separate body of law in place of the rules of national patent law". For this argument *see* Aurora Plomer, *After Brüstle: EU Accession to the ECHR and the Future of European Patent Law*, 2 Queen Mary Journal of Intellectual Property 110, 125 (2012).

168 *Id.*,¶ 30., AG Opinion, *supra* note 166, ¶39.

169 *Id.,* ¶47.

170 C-34/10, *supra* note 165, ¶ 28.

makes a reference to the report of the rapporteur Rothley.[171] Nonetheless, in the CJEU's judgment we see the implication of the AG's view considering the diversity of the meaning given to 'human embryo' in different Member States' legislations. Hence, the CJEU came up with a very broad definition of 'human embryo' covering the range starting from "the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body".[172] The breadth of the definition is evidenced in the way that different points of biological development are included.

Contrary to the CJEU's findings and the AG's opinion, there is not a consensus on the meaning of 'human embryo' in the scientific environment.[173] The scope of the concept 'human embryo'is also construed by considering different technologies where traditional fertilisation does not take place, namely, in the SCNT and induced parthenogenesis. In that "unfertilised ova into which a cell nucleus from a mature cell has been transplanted and unfertilised ova whose division has been stimulated by parthenogenesis" are considered within the scope of the human embryo definition.[174] But this addition to the definition by the CJEU could be problematic, especially, in the context of the SCNT. Because the potential of a live birth of an entity which is created as a result of the SCNT is considered as a factor to define that the human embryo could not be analyzed in a clear-cut manner by the scientific community.[175] Nevertheless, in its definition, the CJEU focused on a cell's capacity of "commencing the process of development of a human being".[176] This yardstick could be insufficient, because the determination of the hESCs capability to differentiate into an individual would require *in vit-*

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171 Committee on Legal Affairs and Citizens' Rights, Report on the Proposal for the Directive, referred by Porter, *supra* note 60, at 20 n.61.

172 C-34/10, *supra* note 165, ¶35.

173 *"There has been a consensus within the scientific litterature that a human embryo is an entity in its earliest stages of development that is less than eight weeks gestation…However, there is a difference of opinion as to which points of biological development should be covered by the term 'embryo'."* Australian Government National Health and Medical Research Council*, Human Embryo, – A Biological Definition* (Discussion Paper) *available at* http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf (last visited Aug. 08, 2012).

174 C-34/10, *supra* note 165, ¶36.

175 *"... With the current state of the art it appears that a SCNT blastocyst is likely to have a significantly lower probability of successful development than one created by gamete fertilisation."* Australian Gov. Discussion Paper, *supra* note 173, at 21.

176 C-34/10, *supra* note 165, ¶35-37.

ro experiments or *in vivo* animal models. In some of these experiments hESCs have to be placed in primate blastocysts. This is a scientific exercise prohibited by guidelines at national and international levels.[177]

As regards the categorization of stem cells obtained from a human embryo at the blastocyst stage, the CJEU left this task to the BGH or, generally speaking to national courts. At this point, it seems that the Court was reluctant to make a distinction between totipotent and pluripotent hESCs depending on their capacity to develop into a human being. On the contrary, the AG concluded more precisely that the hESCs disclosed in the present case could not be considered as 'human embryo' because pluripotent hESCs do not have the capability to develop into a complete individual.[178] It would not be wrong to say that this is the only point where the CJEU's and the AG's opinion diverge.

The CJEU's answer to the second question should be analyzed as well. According to the CJEU, the use of human embryos for scientific research is also covered by their use for industrial and commercial purposes provided for by the Article 6(2)(c) of the Biotech Directive.[179] The CJEU held that if the use of human embryos for scientific research is a part of the subject-matter of the patent, then there is no possibility to distinguish between scientific research and industrial or commercial purposes.[180] To better understand this reasoning, one should refer again to the *travaux préparatoires* of the Art. 6(2)(c). The first version of this article was 'Methods in which human embryos are used…' but then it gained its actual state with amendments proposed.[181] The CJEU makes reference to the Recital 14 of the Biotech Directive to indicate that, in principle, a patent application implies the industrial or commercial use of an invention. This reasoning shows that the CJEU does not make a distinction between the 'industrial or commercial purposes' which indicates the rationale of moral exclusion and the 'industrial application' which is a patentability requirement. It is true that an invention should be 'susceptible to industrial application' according to the EPC

177 Katja Triller Vrtovec & Christopher Thomas Scott, *The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe*, 9 Cell Stem Cell 502, 503 (2011.).

178 AG Opinion, *supra* note 166, ¶100.

179 C-34/10, *supra* note 165, ¶.46.

180 *Id.,* ¶ 43.

181 *See* for the details of *travaux preparatoires*, Aurora Plomer et al. *supra* note 93, at 20-21.

Art. 51(1), but the aim of the Art. 6(2)(c) is to preclude a certain way of use of human embryos, namely, the use with industrial or commercial purpose.[182] In the case at issue, the mere fact that the patented invention (neural precursor cells) is used, for example, as an element of a disease treatment device, thus, proving its susceptibility for industrial application, should not be equivalent to the case where the patented invention still needs to be improved for a future use in the medicine. Scientific purpose could be pursued even if the inventor holds a patent. The important factor here should be whether human embryos *per se* are directly used each time the treatment device in our example is produced.[183] Otherwise, the same result of the Court could have been reached without the latter part of the sentence in Art. 6(2)(c), namely, 'industrial or commercial' purposes, because the Biotech Directive itself targets the patents related to the biotechnological inventions.

The most seminal part of the CJEU's judgment is related to the third question. Its focus is oriented to the process of hESCs' generation. The fact that hESCs are removed from the inner cell mass of a blastcosyst, which is defined as a human embryo by the AG,[184] deserves a closer look for the assessment made in light of '*ordre public*' and morality. The CJEU held that the invention should be excluded from patentability although the extraction of pluripotent hESCs from human embryos are neither claimed, nor described. The rationale behind this argument is the possible intention of the patent applicant to make an attempt to circumvent the exclusion under the Art. 6(2)(c) of the Biotech Directive.[185] Before commenting on this, we must underline the analogy made by the AG to reach the same result as the CJEU. AG made an assumption on the patent eligibility of some inventions based on the research on the organs of victims murdered in Yugoslavia. The choice of example is quite untenable by creating a link between the patent eligibility and an act which is described as 'humanity crime'. Probably, according to the CJEU with the same idea in mind, when a human embryo is a source for the biological material, regardless, whether it is claimed or described, the very end product is excluded from the patent protection, even though the

182 *Id.,* at 74.

183 AG does not bring a clear answer to the question but underlines that the 'industrial and commercial purposes' refer to a repetitive (each and every time) use of human embryos in the example he gave, namely the manufacture of medicines. AG Opinion, *supra* note 158, ¶114.

184 AG Opinion, *supra* note 166, ¶95.

185 *Id.,* ¶108.

inventor is unaware of the said act and does not perform it to come up with the invention.

In addition to our previous critics to the highly similar approach of the EBA in the WARF decision,[186] we must make further comments related to the CJEU's judgment. In the European patent system, the focus should be on the invention's claims to decide on its patentability and to determine its scope of protection. The specification should be used to understand and interpret the claim. Moreover, Art. 83 EPC requires the disclosure of the invention in a manner that makes the person skilled in the art capable to perform the invention. So to fulfill the sufficiency of disclosure requirement, the information how an invention is produced is not necessarily to be included in the claim.[187] If we come back to the case at issue, the generation of hESC used to obtain neural precursor cells does not have to be included in the claim as far as the person skilled in the art can produce the same invention by using hESCs in the stem cell banks.[188] Also according to the Rule 43(1) EPC, all technical features of the invention should be included in the claim. Therefore, there is no need to go beyond the claims when we make the patent eligibility assessment.

In my opinion, the origin of the flawed result belies under the one sided construction of the subject-matter related to the invention. We can try to find the source of this argument in AG's opinion in its discussion of the term 'industrial and commercial purposes'. He pointed out that for the performance of the invention many embryos would be destroyed.[189] That alone is a good evidence of the misconstruction of the invention. The inventor could perform this invention with already generated hESC lines, in other words without being involved in the destruction of human embryos. In my view, it is not a fair solution to preclude one invention for the reason that its base material has been obtained in immoral manner regardless the time it has occurred, the person who made it, its existence in the claim of the invention and even its procurement is in compliance with the regulatory provi-

186 *See supra* text accompanying note 143.

187 Rudolf Teschemacher, *in supra* note 105, ¶13, at 379.

188 W.Cornish et al., Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights ¶21-24 at 946 (Sweet&Maxvell,7.ed, 2010) (1981.).

189 AG Opinion, *supra* note 166, ¶ 114-115.

sions.[190] Also, there is no possibility for patent examiners to make this investigation throughout the whole life cycle of the invention. Contrary to the view of the CJEU, there could not be any intent to circumvent the law if there is no necessity for the inventor to put in the claim an act that he does not need to come up with the invention. This statement of the CJEU is not in line with general patent law principles and with the previous case of the ECJ we referred earlier in this research.[191]

C. Comparison of WARF and Brüstle Cases

Since the EU is not a contracting party to the EPC, the EBA and the CJEU are not bound with the decision of each other, but it is possible that one inspire the other. Although the CJEU has reached similar conclusion with the EBA, there are some points in which they differ.

In the *WARF* case, the patent application was made for hESCs, whereas in the *Brüstle* case, the neural precursor cells were claimed. When it comes directly to the patentability of hESCs *per se*, the WARF would struggle more before the CJEU. Because there is a possibility that national courts could categorize these hESCs as human embryos and non patent eligible.

Another point is related to acts, which occurred before the invention but not claimed in the application. In the WARF decision, if the invention is exclusively prepared by a method which necessarily involved the destruction of human embryos at the filing date and even if it is not in the claim, the invention could not be patentable.[192] Due to the use of the word 'exclusively', one could interpret this ruling that the EBA allows the patentability of inventions which could be performed with existing hESC lines from cell

190 Stammzellgesetz [StZG] [Stem Cell Act], Bundesgesetzblatt Jahrgang [BGBL] I, Jun. 29, 2002, Teil I, at.2277, last amended by Gesetz zur Änderung des Stammzellgesetzes (StZGAndG), Aug. 14, 2008, BGBL. I at 1708, *translated* in Oduncu, *supra* note 76, at 8.

191 *See* the case cited *supra* note 95.

192 G 2/06, *supra* note 136, ¶15.

banks.[193] In the same vein, one could find the CJEU's judgment as more restrictive, whereby a broad retrospective look encompasses the activities prior to the invention which could involve the destruction of human embryos. Judging solely based on this parameter, it could be possible to say that Dr. Brüstle's patent could be patentable under the EBA's approach because in this invention legally deposited hESC lines from stem cell banks in Israel were used. Nevertheless, our arguments could be criticised since they do not consider that the EBA sees also the definition of human embryo as decisive in each particular patent application.[194] It is true that unlike the CJEU, the EBA did not make any attempt to define the human embryo, however this was mainly because that the Board found it reasonable that the EU and EPC's legislators had chosen to not define the term but added that it would be against any restrictive interpretation of the term 'human embryo'.

D. The Devil is in Details, Unpatentable but Exploitable?

The expression in English 'the last but not least' is literally confirmed by the BGH. In the last paragraph of the referral judgment of the BGH, the attention is drawn to the controversial situation, in which hESCs-related inventions are excluded from patent protection but still can be commercially exploited in terms of sale, import, export, etc.[195] This last point made by the BGH deserves a closer look especially, in a legal environment, where there is a tendency to exclude the hESC-related inventions from patentability.

TRIPs does not force WTO member states to implement exclusion from patent protection based on *ordre public* and morality reasons. But the EU Member States and EPO Contracting States has bought this option. Hence, the Art. 1(2) of the Biotech Directive implies that any result generated by the application of the Biotech Directive rules should not contradict Member States obligations under TRIPs.

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193 This situation is called as 'deposit loophole' in the article written by Sigrid Sterckx& Julian Cockbain, *Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and The Relevance of Moral Complicity: Comments on the EPO's WARF Decision*, 7 SCRIPTed 83, 94 (2010) *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/sterckx.pdf (last visited Aug. 09, 2012).

194 G 2/06, *supra* note 136, ¶20, at 325.

195 *See* ¶ 62)cc) of the original version of the case cited *in supra* note 159 in GRUR Int 2010, at 243.

Nowadays, neither in Germany, nor in Europe, there is a prohibition of similar human treatments involving hESCs. As we learn from Plomer, an analysis of the EU legislation shows that there is no prohibition for the commercial and industrial exploitation of products derived from human embryonic tissues and cells derived products in the application of advanced therapy method.[196] As a result, there is no legal barrier to commercial exploitation of an invention whose patentability is precluded on moral grounds.

At this point, we should look whether this situation reflects the rationale of Art. 27(2). As a first step, the motivation of the legislator as reported by Bonadio could be found in the history. [197] Industrialized states were in favour for the implementation of this rule in order to avoid developing countries from freeriding on inventions which are not granted patents by these countries but commercialised in their territory. Bearing this in mind we should take a look at some commentators' approaches to the provision of TRIPs. Straus points out that a country could exclude one invention from patentability if that country prohibits the commercial exploitation of this invention.[198] Accordingly, a WTO Member State must bring a prohibition to the commercial exploitation of an invention, then it could preclude the patentability of an invention. In the same vein, Pires de Carvalho indicates that exclusion from patentability must follow the exclusion from commercial exploitation.[199] This argument is also stated in the Explanatory Statement to

196 Specific examples of legal provisions creating a free environment for the commercial explotation of hESC related inventions are: *EU Directive 2004/23 on Human Tissue and Cells* "setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells" and *EU Regulation 1394/2007 on Advanced Therapies for Medicinal Products* covering "advanced therapy medicinal products which are intended to be placed on the market in Member States and either prepared industrially or manufactured by a method involving an industrial process" Plomer&Torremans, *Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions*, *in* Embryonic Stem Cell Patents, *supra* note 64, at 180, 183, 186.

197 Enrico Bonadio, *Biotech Patents Morality After Brüstle*, 7 European Intellectual Property Review [E.I.P.R] 441 (2012).

198 Straus, *supra* note 24,at 182.

199 Nuno Pires de Carvalho, The Trips Regime of Patent Rights, 298 (Kluwer Law International, 2010.).

the Report on the Proposal for the Biotech Directive.[200] This interpretation of Art. 27(2) is made in light of prevailing principles in the TRIPs such as those laid down in Art. 27(1) and Art. 30. Therefore, when the commercial exploitation of an invention is precluded in a country, only then the exclusion from patentability based on *ordre public* and morality would be 'reasonable', justifiable and 'non discriminatory'.[201] Pires de Carvalho suggests a method of application called two-step necessity test.[202] In the first step, the exclusion of an invention from commercial exploitation should be necessary to protect *ordre public* or morality. Thereafter, the necessity of the patent exclusion should be assessed to implement the ban of commercial exploitation. As a result, the first step of prohibition of the commercial exploitation of an invention should be followed by its exclusion from the patent protection. Accordingly, States would be able to provide guidelines to patent examiners by prohibiting the commercial exploitation of inventions which are contrary to *ordre public* or morality. One could make a counter-arguement based on the second part of the Art. 27(2) which states that the mere prohibition by law does not suffice for exclusion from patentability. Our answer would be that only prohibitions by law having the purpose of protection of *ordre public* and morality should be determinative for the patent examiner when deciding for the exclusion. This situation would also require a harmony between rules reflecting moral concerns in other branches of law and those in the patent law.[203] Hence, the possible implication of this debate could be a possible start of the Dispute Settlement Mechanism for EU Member States excluding hESC-related inventions from patentability while they are not reacting to their commercial exploitation, in other terms diverging from the rationale of TRIPs Art. 27(2).

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200 Member of European Parliament (Rothley), Report on the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM/95/0661, June 25,1997 *available at* www.europarl.europa.eu (follow out reports).

201 Gerard Porter, *Human Embryos, Patents, And Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception*, Embryonic Stem Cell Patents, *supra* note 64, at 359.

202 Pires de Carvalho, *supra* note 199, at 298.

203 Plomer, *supra* note 93, at 178.

E. Implications of the CJEU's Judgment to the Future of hESC-Related Inventions

The CJEU's interpretation of the Biotech Directive is binding for the EU Member States. Below, we refer to the situation in different jurisdictions with the latest developments in Germany, in the U.K. and at the EPO.

1. Germany

Approximately one year after the CJEU's decision, the referring court, namely the BGH rendered its final decision about the validity of the Brüstle patent.[204] The Court in its judgment stated that in case the technical teaching of the invention requires the destruction of human embryos, the invention cannot get patent protection.[205] However, the hESCs which are extracted without necessitating the destruction of human embryos can be patentable.[206] For that reason, there is a necessity of an amendment to the claim expressing the non-use of human embryos.[207] Additionally, methods to extract hESCs without the destruction of human embryos should be already in existence in the state of the art at the time of filing of the patent application and it is sufficient that the applicant points out to the method that does not require the destruction of human embryos to get hESCs.[208] The existence of that kind of method has been adressed by a reference to a publication dated of 2009 in the decision of the Court.[209] Moreover, the BGH determined that the patent specification at issue sufficiently disclosed the invention to be applied by the person skilled in the art.[210] In addition to that, according to the Court, the fact that the extraction of hESCs from the embryonic germ cells is mentioned in the patent specification, shows that the invention can be carried out without the destruction of human embryos.[211]

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204 Bundesgerichtshof [BGH] [Federal Court of Justice] Nov. 27, 2012, Case No: X ZR 58/07, *available at* http://juris.bundesgerichtshof.de (last visited Nov. 11, 2013.).
205 *Id.,* ¶ 13.
206 *Id.,* ¶ 15.
207 *Id.,* ¶ 32.
208 *Id.,* ¶ 33.
209 *Id.,* ¶ 34.
210 *Id.,* ¶ 25.
211 *Id.,* ¶ 26.

The BGH made also some statements about the definition of the 'embryo'. The criteria that the BGH pointed out was the "commenc[ing] the process of development of a human being."[212]. If this development process of embryos is not completed, the extraction of hESCs thereof is not considered as the use of embryos within the context of Art. 2(2) of the GPA.[213] The CJEU left to the BGH the task to determine whether hESCs derived from human embryos at the blastocyst stage are within the scope of the definition of the 'embryo.[214] Given their inability to start to the process of development of a human being, BGH came to the conclusion that hESCs derived from human embryos at the blastocyst stage are not considered as 'embryo'.[215] Overall, the BGH decides for the partial invalidity of the patent in suit by some insertions into claims pointing out the non-destruction of human embryos.[216]

The BGH decision followed the general rationale of the CJEU but with a more moderate result as to the validity of the patent in suit possibly taking into account some criticisms to the CJEU's judgment and its potential implications in the scientific environment.

In light of this latest judiciary activity, the legal status quo in Germany should be shortly adressed. Main guidelines of the research in the stem cell field are set by the German Stem Cells Act.[217] According to the law, any use and importation of hESCs is forbidden in principle. However, in some circumstances, the use of imported hESC lines are allowed for research purposes if the user gets a license for import from the official authority. The condition for these imported hESC lines is that they should be generated from supernumerary embryos of IVF treatment and be produced before May 1, 2007.[218] Especially after the BGH judgment, end products such as neural precursor cells are not patented just because at an earlier stage of its generation it involves the destruction of human embryos, even if they are produced with hESCs legally obtained in compliance with the StZG like in Brüstle case.

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212 C-34/10, *supra* note 165, ¶35.
213 The decision of the BGH, supra note 208, ¶ 35.
214 C-34/10, supra note 165, ¶ 38.
215 *Id.,* ¶ 37.
216 *Id.,* ¶ 30.
217 *See supra* note 190.
218 Art. 4, § 2(1)a. of StZG, *supra* note 190; A. Elstner et al*., The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research*, 2 Stem Cell Research 101,104-105 (2009).

2. The U.K.

In the U.K, the research and technology development in the field of stem cell have enjoyed so far more freedom in comparison to other countries.[219] According to the UK IPO's Practice Notice, human totipotent cells could not be patentable due to their potential to develop into the entire human body, but hESCs lacking this potential are patentable.[220] However, this freedom is under attack of the case-law of different instances in Europe and as a result the change of practice for hESC-related inventions could be clearly seen. First of all, the U.K. had to react to the EBA's decision in the WARF case. In spite of the non-binding character of the EBA's decision for national patent offices, the UK IPO sets again its practice notice for the coherence with the EPO.[221] After the WARF decision, the UK IPO declared a new practice replacing the previous one. According to the new notice, the patentability of hESCs is conditioned to whether "at the filing or priority date, the invention could be obtained by means other than the destruction of human embryos."[222] At the very end, the UK IPO had to review its position after the CJEU has rendered its C-34/10 judgment. In its latest practice notice published on May 2012, the UK IPO affirms that the invention would be unpatentable if its implementation "requires the use of cells that originate from a process which requires the destruction of a human embryo."[223] Thus, only human stem cells not derived from human embryos for instance iPSCs and adult stem cells would be patentable. From the foregoing, we can see concretely the effect of the CJEU's judgment on the landscape of the patentability of hESC-related inventions: Therefore some patent applications are rejected by the UK IPO. These patent applications at issue were related to the extraction of hESCs by using parthenogenesis to activate

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219 GB2415781B2: Genes that are up-or down-regualed during differentiation of human embryonic stem cells GB2412379B2: Hematopoietic cells from human embryonic stem cells
See for more examples, Plomer, *supra* note 93, 198.

220 UK IPO, *Practice Notice on Inventions Involving Human Embryonic Stem Cells*, *supra* note 152.

221 Plomer, *supra* note 93, at 196.

222 UK IPO, *Practice Notice, Inventions Involving Human Embryonic Stem Cells*, Feb. 3, 2009, *supra* note 152.

223 UK IPO, *Practive Notice, Inventions Involving Human Embryonic Stem Cells*, May 17 2012, www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm (last visited Aug.10, 2012.).

oocytes.[224] Although the invention has fulfilled all the patentability requirements, the patent protection has not been granted because of "the use of embryos for industrial or commercial purposes".[225] This result is directly related to the findings of the CJEU in the Brüstle case. The opinion of the Comptroller of UK IPO has been appealed. The High Court of Justice Chancery Division Patents Court by its decision on 17.4.2013 has decided to refer some questions to the CJEU to clarify some issues that have already been discussed for the Brüstle case in order to reach a conclusion for the case at issue.[226] The reason for this referral is the fact that CJEU in its Brüstle decision while defining the scope of human embryo, included "any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis."[227] This classification of the CJEU generated the refusal of the patent application. According to the appellant, the observation done in the Brüstle case does not point out a consensus about the ability of parthenotes to develop into human body.[228] As mentioned above the meaning of CJEU's criteria of "commenc[ing] the process of development of a human being" is not clear as well. Therefore the need of a new referral to the CJEU has been arised. This referral's main point is related to the clarification of whether the process of developing into the human body should be completed or the start to this process is sufficient.

In the decision for a preliminary ruling, the Court made some important remarks. According to the Court, the purpose of the Biotech Directive is to incentivize with the patent protection the research in the biotechnology while the human dignity and integrity are not affected therefrom. As a result, a balance should be created between these interests. It is stated by the Court that this balance cannot be created when some processes are excluded from the patent protection with the reason that they are not able to develop into the human body, As stated further by the Court, the public health and the

224 For detailed information about patent applications *see* GB0621068.6 *available at* http://www.ipo.gov.uk/p-ipsum/Case/ApplicationNumber/GB0621068.6 (Last visited: Apr 29, 2013), GB0621069.4 *available at* http://www.ipo.gov.uk/p-ipsum/Case/ApplicationNumber/GB0621069.4 (last visited: Apr. 29, 2013.).

225 Office Decision by Dr. L.Cullen, Aug. 16, 2012, ¶79 http://www.ipo.gov.uk/pipsum/Document/ApplicationNumber/GB0621068.6/G101394E0913B4P1%20-1/GB2431411-20120816-Office%20decision.pdf (Last visited Apr.19, 2013.).

226 International Stem Cell Corporation v. Comptroller General of Patents [2013] EWCH 807 (Ch). *available at* http://bailii.org (last visited Apr.25, 2013.).

227 *See supra* Text accompanying note 173.

228 International Stem Cell Corporation, see *supra* note 226, ¶ 39.

European industry would be negatively affected considering important potential treatment benefits of the stem cell technology.[229] It should be underlined that this language of the Court make us recall the balancing approach mentioned above in the context of EPO practice.[230]

3. The EPO

What the possible reaction of the EPO after this case would be more important. After its WARF decision, the attitude of the EPO was to grant patents for hESC-related inventions with a filing date after May 2003 if they fulfill also other patentability requirements. The rationale is that these hESC lines are deposited to institutions such as the U.S. National Institute of Health and there is not any damage to human embryos to implement this invention.[231] Now, according to the CJEU's decision, as stated earlier, even these inventions would not be patentable because there could be a stage that these deposited hESC lines are generated by the destruction of human embryos. After the CJEU rendered its judgment on Brüstle case, the EPO's President made a declaration expressing that the EPO will follow this decision.[232] But it must be underlined that the EPO and EU are two independent institutions which means that the EPO is not bound by judgments of the CJEU. At the same time, we must not forget that all EU Member States are also Contracting States of the EPO. Once these patents are granted by the EPO, it would be up to national courts of EU Member States to make judgments in possible revocation proceedings. Interestingly, in the same declaration, the President of the EPO draws attention to the EPO's counterpart of the Brüstle's patent.[233] This patent was granted by the EPO even before the EBA's decision on the WARF case. The national and European patent applications have

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229 *Id.,* ¶ 57-58.

230 *See supra* Part V.B.2.

231 Gurpreet Solanki, *Preliminary Ruling of the Court of Justice of the European Union in Oliver Brüstle v. Greenpeace e.V: Impacts on Patenting of Human Embryonic Stem Cells in Europe,* 2 BIOTECH. L. REP. 135, (2012.).

232 "*If the judges rule in favour of a restrictive interpretation of biotech patentability provisions, the EPO will immediately implement it*." Posting of EPO's President's to http://blog.epo.org/uncategorized/patents-and-biotechnology (last visited: Nov. 03, 2011.).

233 European Patent No EP 1040185 B1, Feb. 22, 2006.

the same claim.[234] Following its grant, the patent was opposed by Geron Corporation on Jan. 01, 2007 but not on the morality ground.[235] This patent was revoked by the OD "on the ground that it covers subject-matter not disclosed in the original patent application."[236]

234 *See* for claims http://worldwide.espacenet.com.

235 Nick Bassil, *Developments in the Patentability of Inventions Relating to Human Embryonic Stem Cells*, 12 Bio-Science L. Rev., 6 (2011.).

236 As of today, the decision of the OD has not been published yet. *See* for the information for the revocation of this patent in EPO News dated Apr.11, 2013, *available at* http://www.epo.org/news-issues/news/2013/20130411a_de.html (last visited: Nov. 11, 2013.).

VIII. Conclusion

This research demonstrated some possible ways to approach the hESC-related inventions. However, to solve the polarization and to reach 'the middle-of-the road' position is not a straightforward task. Because current provisions dealing with the moral concerns for the patent eligibility of these inventions in Europe are not very elucidating. Moreover, those holding the decision making mechanism do not make the issue crystal clear.

As it is seen in the CJEU's *Brüstle* judgment, the avoidance of discussion of 'medical and ethical nature' proved again that judges do not interfere with the job of legislator by following a black letter focused interpretation not tailored to the science at issue. The result is surprisingly beyond what is expected: hESC-related inventions involving immoral precedent activities, in other terms, "bearing the fruit from the poisonous tree" will not get patent protection.[237] This decision creates worries that the research in this field would be hindered and Europe will not be a suitable environment for this purpose.[238] The CJEU's judgment was not successful to clarify the legal questions related to the stem cell technology. This fact is also proved by the new referral of the UK Court to the CJEU.[239] Despite its local character, the BGH decision does not follow an absolute prohibitive attitude and increases the radius of action in the human stem cell technology.[240] The value of the current legal development could only be assessed in light of beneficial effects of this scientific endeavour.[241] Therefore, it is vital to make pithy regulations related to this research field to avoid any uncontrolled judiciary intervention. Additionally, States must determine consistent attitudes towards the support of research involving stem cell technology as currently

237 Martin Grund&Stacey J. Farmer, *Brüstle v. Greenpeacce: The End of Road for Human Embryonic Stem Cell Patents*, 12 Bio-Science L. Rev. 44, (2011.).

238 *Dismay, Confusion Greet Human Stem Cell Patent Ban*, 334 Science (2011).

239 *See supra* Part E.2.

240 *See supra* Part E.1.

241 *Stem Cell Treatment Helps Heal Stroke Victims*, The Telegraph, June 15, 2012 *available at* www.telegraph.co.uk/archive/2012-6-15.html (last visited Sep. 2, 2012).

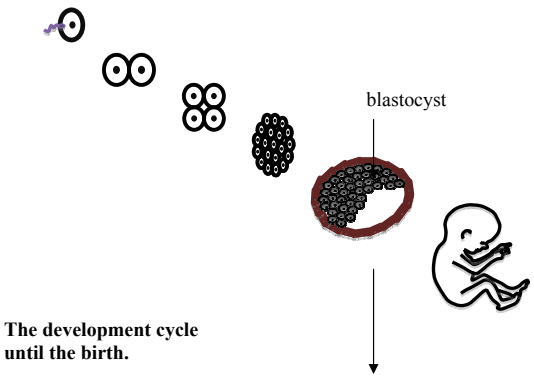
outlined in the Horizon 2020 program, which is on the agenda of the EU.[242]

To conclude, patent law should preserve its incentivizing role of seminal technology, especially, considering the continuous improvement in the field.[243] Therefore the boundaries of exclusionary provisions of patent law based on morality concerns should be determined clearly and be interpreted narrowly. In this debate not losing the momentum related to hESC-related inventions, other legal instruments regulating their commercialisation, effects to the environment and use in pharmaceuticals should be seen as the kernel of the solution.

242 *Renewed Vigour,* 486 NATURE 293 (2012.).
243 *See supra* Part II.B.3.

Annex

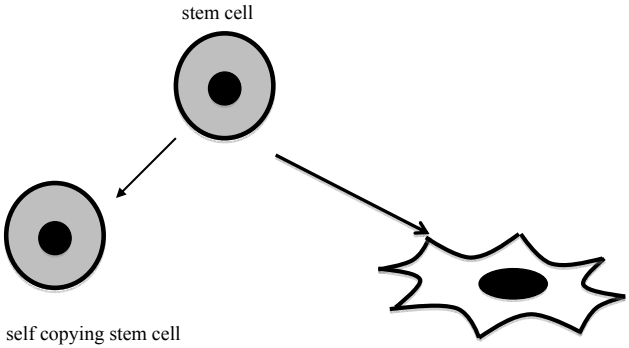
ANNEX I



The development cycle until the birth.

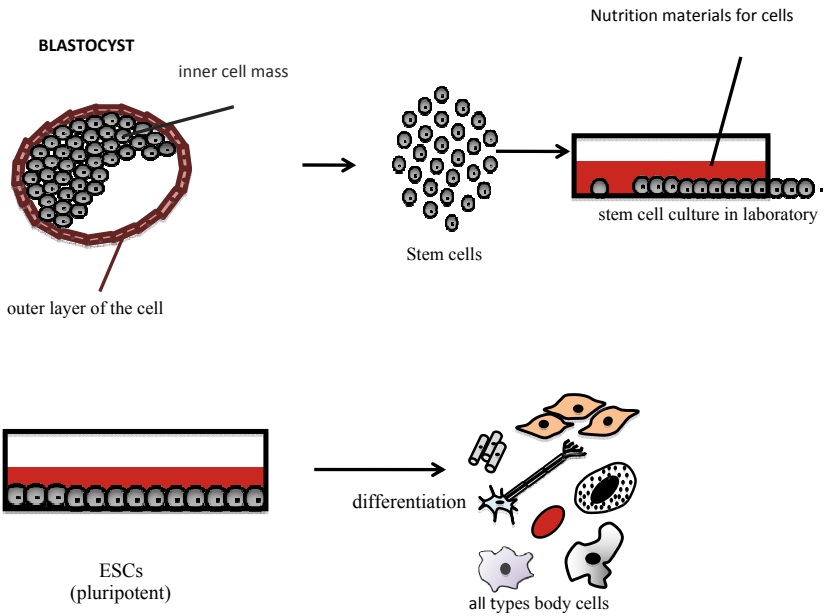
ANNEX II

TWO PATH FOLLOWED BY STEM CELLS: SELF COPYING AND DIFFERENTIATION



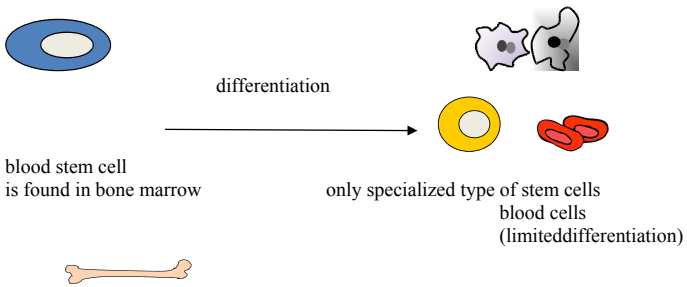
ANNEX III

EMBRYONIC STEM CELL EXTRACTION AND THEIR DIFFERENTIATION



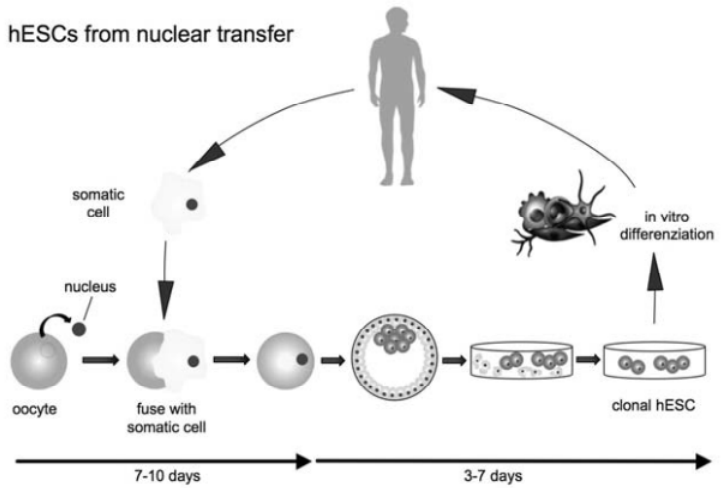
ANNEX IV

ADULT STEM CELLS (TISSUE STEM CELLS)



ANNEX V

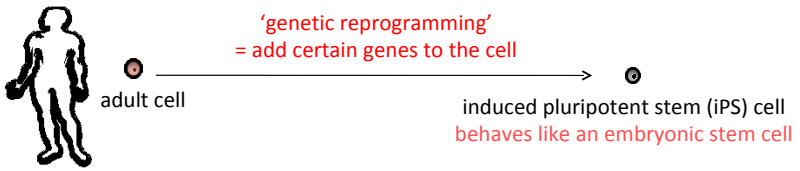
SOMATIC CELL NUCLEAR TRANSFER (SCNT)

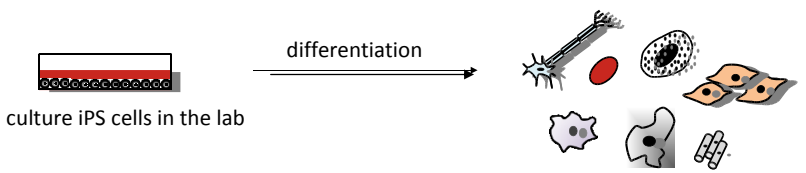


© R.Gambari&A.Finotti, Bioethics and Freedom of Scientific Research in Gene Therapy and Stem Cell Biology, in Biotech Innovation and Fundemental Rights (Bin R. et al. eds, Springer-Verlag Italia 2012)

ANNEX VI

INDUCED PLURIPOTENT STEM CELLS (iPSCs)





List of Works Cited

Articles

Annas, George J., *A French Homunculus in a Tennessee Court*, 19 The Hastings Center Rep. 20, 22 (1989) *available at* http://www.jstor.org/stable/3561982 (last visited 11.8.2012)

Bagley, Margo, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 Wm. & Mary.L. Rev. 469, 534 (2003)

Bassil, Nick, *Developments in the Patentability of Inventions Relating to Human Embryonic Stem Cells*, 12 Bio-Science L. Rev., 6 (2011)

Bonadio, Enrico, *Biotech Patents Morality After Brüstle*, 7 European Intellectual Property Review [E.I.P.R] 441 (2012)

Burley, Justine*, An Abstract Approach to the Regulation of Human Genetics: Law, morality and Social Policy* in The Regulatory Challenge of Biotechnology, Biotechnology Regulation Series 86 (Han Somsen ed., Edward Elgar Publishing 2007)

Byrne, J.A et al. *Producing Primate Embryonic Stem Cells by Somatic Cell Nuclear Transfer*, 450 Nature, 497, 497 (2007)

Ding, Sheng & Schultz, Peter G., *A Role for Chemistry in Stem Cell Biology*, 22 Nature Biotech. 833,839 (2004)

Egerer, Peter *Who in Our Society Should Take on the Responsibility of Deciding What Is Ethically or Morally Just, and What Are the Criteria Upon Which Decisions Should Be Based*, in Eposium 1992 Genetic Engineering -The New Challenge 332(Cookson et al.eds., European Patent Office, 1993)

Elstner, A. et al*., The Changing Landscape of European and International Regulation on Embryonic Stem Cell Research*, 2 Stem Cell Research 101,104-105 (2009)

Gambari, Roberto & Finotti, Alessia, *Bioethics and Freedom of Scientific Research in Gene Therapy and Stem Cell Biology*, in Biotech Innovation and Fundamental Rights 120 (Bin et al. eds, Springer 2012)

Goldman, Steve, *Stem and Progenitor Cell-Based Therapy of the Human Central Nervous System*, 23 Nature Biotech. 862, 867 (2005)

Grund, Martin & Farmer, Stacey J., *Brüstle v. Greenpeacce: The End of Road for Human Embryonic Stem Cell Patents*, 12 Bio-Science L. Rev. 44, (2011)

Isasi, Rosario M.& Knoppers, Bartha M., *Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe*, in Embryonic Stem Cell Patents (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009)

Karet, Bryan, *Moral Dilemmas in the History of Patent Legislation*, in Eposium 1992 Genetic Engineering -The New Challenge(Cookson et al.eds., European Patent Office, 1993)

Liddell, Kathleen, *Immmorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality in* New Frontiers in the Philosophy of Intellectual Property 140, 168 (Annabelle Lever, ed., Cambridge University Press, 2012)

Machlup, Fritz, *An Economic Review of the Patent System*, 15 Study of the Subcomittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary United States Senate 23 (1958)

Manninen, Bertha Alvarez, *Are Human Embryos Kantian Persons?: Kantian Considerations in favor of Embryonic Stem Cell Research*, 3 PHIL, ETHICS and HUMAN in MED 4 (BioMed Central, 2008), *available at* http://www.peh-med.com/content/3/1/4 (last visited 18.7.2012)

Moufang, Rainer, *Patenting of Human Genes, Cells and Parts of the Body? – The Ethical Dimensions of Patent Law,* 4 IIC 487 at 503, (1994)

Nielsen, T.Hviid, *What Happened to the Stem Cells?,* 34 J. MED. ETHICS 852, 853 (2008)

Oduncu, Fuat S., *Stem Cell Research in Germany: Ethics of Healing vs. Human Dignity*, MED., HEALTH CARE AND PHIL. 5, 12 (2003)

Plomer, Aurora, *After Brüstle: EU Accession to the ECHR and the Future of European Patent Law*, 2 QUEEN MARY JOURNAL OF INTELLECTUAL PROPERTY 110, 125 (2012)

Plomer&Torremans, *Towards Systemic Legal Conflict: Article 6(2)(c) of the EU Directive on Biotechnological Inventions*, *in* EMBRYONIC STEM CELL PATENTS (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009)

Porter, Gerard, *The Drafting History of The European Biotechnology Directive*, in EMBRYONIC STEM CELL PATENTS 10 (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009)

Porter, Gerard*, Human Embryos, Patents, And Global Trade: Assessing the Scope and Contents of the TRIPS Morality Exception*, EMBRYONIC STEM CELL PATENTS (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009)

Resnik, David, *Embryonic Stem Cell Patents and Human Dignity*, 15(3) HEALTH CARE ANAL, 211, 215 (2007)

Shell, Susan M., *Kant's Concept of Human Dignity as a Resource for Bioethics*, in HUMAN DIGNITY and BIOETHICS: ESSAYS COMMISSIONED by the PRESIDENT'S COUNCIL on BIOETHICS,334 (The President's Council on Bioethics, 2008)

Shevde, Nirupama, *Flexible Friends*, 483 NATURE, S23 (2012)

Solanki, Gurpreet, *Preliminary Ruling of the Court of Justice of the European Union in Oliver Brüstle v. Greenpeace e.V: Impacts on Patenting of Human Embryonic Stem Cells in Europe,* 2 BIOTECH. L. REP. 135, (2012)

Sterckx, Sigrid & Cockbain, Julian, *Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and The Relevance of Moral Complicity: Comments on the EPO's WARF Decision*, 7 SCRIPTed 83, 94 (2010) *available at* http://www.law.ed.ac.uk/ahrc/script-ed/vol7-1/sterckx.pdf (last visited 9.8.2012)

Steinbock, Bonnie, *Moral Status, Moral Value, and Human Embryos: Implications for Stem Cell Research* in THE OXFORD HANDBOOK OF BIOETHICS 416,421 (Bonnie Steinbock ed., Oxford University Press 2007)

Straus, Joseph, *Patenting Human Genes and Living Organisms – The Legal Situation in Europe*, in PATENTING of HUMAN GENES and LIVING ORGANISMS (F. Vogel & R.Grunwald, eds. Springer 1994)

Straus, Joseph, *Biotechnology and Patents*, 54 Chimia 294 (2000)

Straus, Joseph *Intellectual Property Rights: Ethical Aspects*, 11 International Encyclopedia of the Social&Behavioral Sciences, 7621 (Neil J.Smelser&Paul B.Baltes eds, Elsevier, 2001)

Straus, Joseph, *Implications of the TRIPs Agreement in the Field of Patent Law*, in From GATT to TRIPs the Agreement on Trade Related Aspects of Intellectual Property Rights 160, 180 (Friedrich-Karl Beier&Gerhard Scricker eds., VCH, 1996)

Torremans, Paul, *Legal Problems Raised by Patents on Human Stem Cell-Based Inventions,* in Translational Stem Cell Research, Stem Cell Biology and Regenerative Medicine 287, 305 (K.Hug&G. Hermerén, eds.,Humana Press, 2011)

Torremans, Paul, *The Construction of The Directive's Moral Exclusions under the EPC*, Embryonic Stem Cell Patents (Aurora Plomer&Paul Torremans, eds., Oxford University Press, 2009)

Treichel, Pierre, *G 2/06 and the Verdict of Immorality*, 4 IIC 450, 459 (2009).

Vrtovec, Katja Triller & Scott Christopher Thomas, *The European Court of Justice Ruling in Brüstle v. Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe*, 9 Cell Stem Cell 502, 503 (2011).

Warren-Jones, Amanda, *Finding a "Common Morality Codex" for Biotech – A Question of Substance*, 6 International Review of Intellectual Property and Competition Law [IIC] 644 (2008)

Warren-Jones, Amanda, *Vital Parameters for Patent Morality- A Question of Form*, 2 J. Intell. Prop. L& Prac. 832, 835 (Oxford University Press, 2007)

Yamanaka, Shinya, *Induced Pluripotent Stem Cells: Past, Present, and Future*, 10 Cell Stem Cell 678, 678 (2012)

Zimmerli, Walther Christoph, *Discussion Session Comment* in Patenting of Human Genes and Living Organisms 148, 148(F. Vogel & R.Grunwald, eds. Springer 1994)

Monographies

Budinger, Thomas F. & Budinger, Miriam D., Ethics of Emerging Technologies, 342 (John Wiley&Sons, 2006)

Cornish, W.et al., Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights ¶21-24 at 946 (Sweet&Maxvell,7.ed, 2010) (1981)

Pires de Carvalho, Nuno, The Trips Regime of Patent Rights, 298 (Kluwer Law International, 2010)

Singer, Margarate & Stauder, Dieter, European Patent Convention- A Commentary (3rd edition, Carl Heymanns 2003).

United Nations Conference on Trade and Development-The Information and Communication Services Division, Resource Book on TRIPS and Development 376 (Cambridge University Press 2005)

International Treaties

Agreement on Trade Related Aspects of Intellectual Property, Apr. 15, 1994

Convention on the Grant of European Patents ratified, Oct. 5, 1973, revised Dec.13, 2007

EPO Notice Concerning the Amendment of the Implementing Regulations to the European Patent Convention, 8-9/1999 O.J EPO, ¶1, at 573

European Convention of Human Rights [ECHR], Sep 3, 1953 (Council of Europe)

Vienna Convention on the Law of Treaties, May 23, 1969

European Union Legislative Sources

Council Directive 98/44 Directive, recital 1, 1998 O.J. (L 213) (EC)

European Parliament Resolution on *Patents for Biotechnological Inventions*, P6_TA(2005)0407, ¶I, Oct. 26, 2005

Cases

Bundespatentgericht [BPatG] [Federal Court for Patent Matters], Dec.5, 2006, 3 Ni 42/04 Entscheidungen des Bundespatentgerichts (F.R.G)

Bundesgerichtshof [BGH] [Federal Court of Justice] Dec. 17, 2009, Case No: Xa ZR 58/07, (Christopher Heath (trans.), 7 IIC at 853 (2010).

Bundesgerichtshof [BGH] [Federal Court of Justice] Nov. 27, 2012, Case No: X ZR 58/07, *available at* http://juris.bundesgerichtshof.de (last visited Nov. 11, 2013)

C-377/98, Netherlands v. Parliament and Council 2001 ECJ CURIA, ¶38 (Oct. 10, 2001)

C-456/03, Commission v. Italy, 2005 ECJ CURIA, ¶78 (June 16, 2005)

C-34/10, Oliver Brüstle v. Greenpeace e.V., Court of Justice of the European Union, [CJEU], 2011 CURIA (Oct. 18, 2011)

Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980)

Greenpeace UK v. Plant Genetic Systems N.V.,Opposition Division Decision EPO, (1992) 24 IIC, 618

International Stem Cell Corporation v. Comptroller General of Patents [2013] EWCH 807 (Ch). *available at* http://bailii.org

Onco-mouse/HARVARD,Decision of the Opposition Division, Nov. 07, 2001, O.J EPO, 10/2003

T 19/90, Onco-mouse/HARVARD, O.J EPO 12/1990 (Technical Board of Appeal of EPO)

T 0356/93, Plant Cells / PLANT GENETIC SYSTEMS, EPO O.J.1995, 511 (Technical Board of Appeal of EPO)

T 1374/04, Stem cells/ WARF, Apr. 07, 2006, EPO OJ 5/2007G 2/06, Use of embryos/ WARF, Nov. 25, 2008, EPO OJ 5/2009 (Technical Board of Appeal of EPO)

Reports, Opinions and Discussion Papers

Australian Government National Health and Medical Research Council*, Human Embryo, – A Biological Definition* (Discussion Paper)*available at* http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/reports/humanembryo.pdf (last visited 8.8.2012)

A.Plomer et al., *Stem Cell Patents: European Patent Law and Ethics Report* 78 (European Commission, 2006), 78. available at http://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf (last visited 1.8.2012)

Opinion of the European Group on Ethics in Science and New Technologies to the European Commission 16, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells*, § 2.3, May 7, 2002available at http://ec.europa.eu/bepa/european-group-ethics/docs/avis16_complet_en.pdf (last visited Aug. 05, 2012)

Opion of Advocate General Bot, Case 34/10 Oliver Brüstle v. Greenpeace eV. CJEU Mar. 10, 2011

Report on the Protection of the Human Embryo in vitro, Steering Committee on Bioethics, CDBI-CO-GT3 (Council of Europe, June 19, 2003) at 37 available at http://www.coe.int/t/dg3/healthbioethic/texts_and_documents/CDBI-CO-GT3(2003)13E.pdf (last visited 2.8.2012)

Member of European Parliament (Rothley), Report on the Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM/95/0661, June 25,1997 *available at* http://www.europarl.europa.eu

UK IPO, *Practice Notice, Inventions Involving Human Embryonic Stem Cells*, Feb. 3, 2009, http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20090203.htm

UK IPO, *Practive Notice, Inventions Involving Human Embryonic Stem Cells*, May 17 2012, http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm (last visited 10.8.2012)

Fact Sheets

California Institute for Regenerative Medicine, Stem Cell Definitions, http://www.cirm.ca.gov/StemCellBasics_Definitions#2 (last visited Aug. 11, 2012)

Euro Stem Cell, *FAQ about Stem Cells and Regenerative Medicine*, *available at* http://www.eurostemcell.org/stem-cell-faq/introduction-stem-cells#t14n43 (last visited Aug 11, 2012

Modern Biotechnology and the OECD, OECD Policy Brief at 1 (1999) *available at* http://www.oecd.org/science/biotech/1890904.pdf (last visited Nov. 08, 2013)

Reproductive Genetics Institute website available at http://reproductivegenetics.com/frozen_embryo.html (last visited 23.7.2012)

The Nat'l. Inst. of Health, *Stem Cells Basics, Resource for stem cell research*, www.stemcells.nih.gov (last visited Aug. 11, 2012)

News

BBC News Health, available at http://www.bbc.co.uk/news/health-15181015 (last visited Aug. 28, 2012)

Stem Cell Treatment Helps Heal Stroke Victims, The Telegraph, June 15, 2012 *available at* http://www.telegraph.co.uk/archive/2012-6-15.html (last visited Sep 2, 2012)

Renewed Vigour, 486 Nature 293 (2012)

Dismay, Confusion Greet Human Stem Cell Patent Ban, 334 Science (2011)

Dictionaries

The Oxford English Dictionary 421 (2nd ed. 1989)

MIPLC Class Materials

Prof. Joseph Straus, Protection of Biotechnological Inventions (June 5-6, 2012), (unpublished slides used in summer term class of the Munich Intellectual Property Law Center)

Prof. Margo Bagley, Biotechnology and IP course slides at Munich Intellectual Property Law Center on June 22, 2012