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." 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. 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

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

^{35 &}quot;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 Galilei⁴¹ and Omar Khayyam⁴² in different times and territories during the history, were the ones who came up

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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 &}quot;....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. 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,

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 arguments⁴⁵ 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 EPO⁵¹, 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

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 propositions⁵⁸ that European ordre public and morality should refer to the values enshrined in the ECHR⁵⁹. 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

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. 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-

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.

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

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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. 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. 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

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 Steinbock⁸⁰ 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. 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. If they are not used within a certain period of time, they lose their suitability to be implemented in the uterus of a woman. 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.