HUMAN EMBRYONIC STEM CELLS: LEGAL POLICY IN EUROPEAN UNION, THE UNITED STATES AND THE RUSSIAN FEDERATION

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Abstract

The purpose of the present thesis is to see how ethically controversial issue as hESC research is reconciled on the legislative level by European Union, the United States and the Russian Federation. The reason for analysis of the given issue is, on the one hand, its promising therapeutic benefits in medicine and, on the other hand, moral and ethical considerations that undermine its success. European countries and the United States, being economically leading countries in the world, also have taken forward steps in this direction, while the Russian Federation is left far behind in its legislation. Preliminary research showed that the Russian Federation has no specific law on hESC. As regards the EU and the US legislation on hESC, it should be kept in mind that the legislative comparison will be only on the federal level which is limited by regulation of federal funding. Any privately funded hESC research as such is not out of law if it complies with national legislation and ethical considerations of any EU member state and any state of the US, where the research is conducted. The thesis demonstrates that the EU and the US have comparatively advanced legislation on hESC and serve as models with its own advantages and disadvantages for Russia to start with. The details of comparative analysis of each legal regime will be showed in the thesis below.

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List of Abbreviations

Directive	European Union 1998 Directive on the legal protection of biotechnological inventions
EGE	European Group of Ethics in Science and New Technologies
EPC	European Patent Convention of 1973.
EPO	European Patent Organization
EU	European Union
FP7	Seventh Framework Program for research, technological development and demonstration
hESC	Human embryonic stem cells
IVT	*In vitro* fertilization
MAP	Medically assisted procreation
NBAC	National Bioethics Advisory Commission
PTO	United States Patent and Trademark Office
RF	Russian Federation
SCNT	Somatic cell nuclear transfer
US	United States

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Introduction

Legal attitudes towards cloning and stem cell research are subject of controversial legal and political debates worldwide.

Generally cloning is understood as "asexual production of a new human organism that is, at all stage of development, genetically virtually identical to a currently existing or previously existing human being"[1]. The President's Council on Bioethics gave a comprehensive explanation on cloning. In its report on July 2002[2] cloning is identified as of two types: reproductive and therapeutic. Reproductive cloning is a cloning of the human embryo for the purpose of producing a child, while therapeutic is the cloning of human embryo for the purpose of research, or in other words "extracting [cloned human embryo's] stem cells, with the (ultimate) goal of gaining scientific knowledge of normal and abnormal development and of developing cures for human diseases"[3].

There is a consensus in the world on prohibition of reproductive cloning, i.e. a "degree of unanimity in opposition to cloning [that is] astounding, often uniting liberal and conservative, pro-life and pro-choice, and secular and religious people of various persuasions"[4]. Roger Brownsword[5] made a comprehensive overview to explain the fear among nations by emphasized such issues: (1) "threat to the replicant's sense of self and autonomy", (2) "the creation of confusion and ambiguity in familial relationships", (3) "unnatural intervention in the human reproductive process" and many others. However, unlike reproductive cloning stem cell research, including therapeutic cloning creates differences among nations. Roger Brownsword argues that there is a tendency in the world to

[1] President's Council on Bioethics, *Human Cloning and Human Dignity: Ethical inquiry* (2002), http://www.bioethics.gov/reports/cloningreport/index.html (last visited May, 2008).
[2] Id.
[3] Christopher L. Logan, *To Clone or not to clone: Should Missouri allow cloning for biomedical research?* 73 UMKCLR 861, at 1 (2005).
[4] Roger Brownsword, *Stem Cells and Cloning: Where the Regulatory Consensus Fails*, 39 New Eng. L. Rev. 535 (2005), cited in John Charles Kunich, The Naked Clone, 91 Ky. L.J. 1, 3 (2002).
[5] Id.

treat favorably ethically controversial issues which has a potential therapeutic application in medicine. Thus reproductive cloning does not raise any doubts in its status to be completely prohibited due to its lack to bring any medical benefits. From this perspective it seems very interesting to analyze how hESC research, with promising research and therapeutic potential on the one hand, and with controversial ethical considerations that it raises on the other hand, is addressed by legal policy of different nations.

On the international and regional level it is possible to track the development in the regulation of hESC research.

The United Nations as a universal international organization took steps in this direction. Initial idea of the United Nations was to adopt a treaty on cloning, whether to prohibit only reproductive cloning or therapeutic cloning as well. As a result of hot debates of member states, no treaty came to existence. Finally General Assembly issued Declaration on Human Cloning, which called states to prohibit all forms of cloning 'inasmuch as they are incompatible with human dignity and the protection of human life'[6]. Many scholars argue that adoption of the given Declaration was a failure of states to agree on the issue of cloning, because it contains very significant ambiguities[7]. One of the main ambiguities of the Declaration was in the avoidance of drafters to distinct between cloning for reproductive and therapeutic/research purposes[8]. However, it is important to mention other ambiguities as well to have a clearer picture:

> Several countries pointed to the ambiguity of the text as a reason for not supporting the Human Cloning Declaration, including the United Kingdom (which stated that the reference to human life 'can be interpreted as a call for a total ban on all forms of human cloning'), China ('the Declaration's wording is too confusing'), Spain (which deemed that the term human life 'is imprecise and could be subject to various interpretations'), India (which voted against the Declaration 'because some of its provisions could be interpreted as a call for a

[6] The United Nations Declaration on Human Cloning, G.A. Res. 59/150, U.N. Doc. A/R/59/80.
[7] Channah Jarrell, *No world consensus: the United Nations Declaration on human cloning*, 35 Ga. J. Int'l & Comp. L. 205, 2 (2006), cited in United Nations Declaration on Human Cloning, G.A. Res. 59/150, U.N. Doc. A/R/59/80 (Mar. 23, 2005).
[8] Declan Heavey, Consideration by the United Nations of a Declaration on Human Cloning for Therapeutic Reasons, http://www.gopetition.com/online/14861.html

total ban on all forms of human cloning'), and South Africa (which 'would have preferred much clearer language that would clearly permit therapeutic cloning')[9].

On the regional level, Council of Europe, supranational European institution, before adoption of the European Convention on Human Rights and Biomedicine, issued two recommendations of 1986 and 1989[10]. Later the European Convention on Human Rights and Biomedicine of 1997[11] (as of November of 2008, there are 22 ratifications and 12 signatures, not followed by ratification)[12] was adopted as the first legally binding document. The given Convention was aimed to "protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine"[13]. Convention prohibits the creation of human embryos for purposes of research, however did not mention the issue of cloning. However, it gives wide margin of appreciation to member states by article 18: if research on *in vitro* embryos is allowed by national law, a proper (adequate) protection shall be provided.

Later in 1998 Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings of 1998[14] was adopted that explicitly prohibited the creation of "a human being genetically identical to another human being, whether living or dead")[15]. However, the given Protocol didn't specify the notion "human being", leaving another room for state parties to interpret.

[9] Declan Heavey, supra note 8.
[10] Nordic Committee on Bioethics, *Stem Cell Research in the Nordic countries: Science, Ethics, Public Debate and Law* (2007).
[11] Full name: Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, at: http://www.coe.int.
[12] http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=11/19/2008&CL=ENG
[13] Nigel M. de S. Cameron, Anna V. Henderson, *Brave new world at the General Assembly: the United Nations Declaration on Human Cloning*, 9 Minn. J. L. Sci. & Tech. 145, at 2 (2008).
[14] As of November of 2008, there are 17 ratifications and 14 signatures, not followed by ratification, information available at: http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=168&CM=8&DF=11/19/2008&CL=ENG
[15] Nigel M. de S. Cameron, Anna V. Henderson, supra note 13, at 3. Art. 1 of Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings, available at:

In the framework of UNESCO (the United Nations' Educational, Scientific, and Cultural Organization) Declaration on the Human Genome and the Protection of Human Rights (1997) explicitly outlawed reproductive cloning[16]. However, Declaration carries only recommendation character[17].

The following questions are those legal questions of hESC research that will be discussed later in the paper: whether to prohibit research on hESC at all and if not, then what exactly should be allowed/prohibited: (a) whether to allow the creation of embryos for derivation of hESC or for research purposes; (b) or whether to allow hESC derivation only from excess embryos; (c) whether to allow only imported hESC lines; (d) whether patenting should be allowed on hESC lines or not; (f) if hESC is allowed, then how should egg donation be regulated and (e) are there any controversies between hESC research and freedom of research. These and many other questions are being addressed in many jurisdictions. But my focus will be only the European Union, the United States and the Russian Federation[18].

Generally legal policy of stem cells around the world could be grouped into 3 broad categories: restrictive, intermediate and liberal. Restrictive policy itself could be subdivided into three other types: prohibition of hESC derivation, prohibition of using hESC lines or their products (except for imported hESC lines) and prohibition of government funding[19]. The following countries are examples of restrictive policy: Austria, Ireland, Cyprus, Costa

http://conventions.coe.int/treaty/en/treaties/html/168.htm . In the Explanatory Report of the Additional Protocol, the Council states that although the Convention prohibits the creation of embryos for research purposes and "reproductive cloning," it takes no position on cloning for research purposes.

[16] Channah Jarrell, supra note 7.

[17] Text of the Universal Declaration on the Human Genome and Human Rights, UNESCO, Dec. 3, 1997, available at: http://portal.unesco.org/shs/en/ev.php-URL_ID=2228&URL_DO=DO_TOPIC&URL_SECTION=201.html. (last visited in February 2008).

[18] Due to the fact that Russia lacks specific regulation on hESC, it will be taken as a special case in the present thesis.

[19] Rosario M. Isasi & Bartha M. Knoppers, *Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries*, 23 (2006).

Rica and Italy[20]. The majority of states are considered to have intermediate policy[21]. Under this policy therapeutic cloning is prohibited, but stem cells research on spare embryos from IVF treatment is allowed. India and Taiwan, Canada, Denmark, Estonia and Australia are the countries in point[22]. The liberal approach permits only therapeutic, thus excluding reproductive cloning[23]. Belgium, Sweden, Singapore, South Korea, the United Kingdom, and Japan are the examples. This is how legal policy varies from country to country.

As it was mentioned earlier, the aim of the thesis is to compare three legal regimes on hESC research. My intent is to analyze these models from legal perspectives and to identify the advantages and disadvantages of each of them.

[20] Id.
[21] Id.
[22] Rosario M. Isasi & Bartha M. Knoppers, supra note 19.
[23] Id.

Chapter 1. Human Embryonic Stem Cells (hESC)

Before explaining the controversy with hESC research, it is more than necessary to understand the basic notions in stem cells area, namely the followings.

1.1. Stem cell and its types

Stem cells are undifferentiated cells which are able to produce the same cells as of their nature, i.e. undifferentiated (self-renewal)[24] or differentiated of one or several types of cells, such as liver cells, kidney cells and brain cells[25].

Types of stem cells are divided according to their extent or ability to differentiate[26]. There are three of them[27]: progenitor stem cells, multipotent stem cells and pluripotent stem cells. Progenitor stem cells are characterized by their ability to differentiate into one single cell type only. For example, epidermal stem cells or spermatogonial stem cells can transform only into keratinocytes and spermatozoa. Multipotent stem cells have the ability to produce several differentiated cell types. The example could be neural stem cells, which can produce all types of cells of the nervous system. Pluripotent stem cells are the most promising ones because they can differentiate into different types of cells, but they cannot create an embryo.

Progenitor and multipotent stem cells can be derived from an adult or fetus. These stem cells are important (1) for fetus for the formation of its tissues and organs, and (2) for adults for sustaining the tissues and cells, which have a limited life span like skin stem cells for instance. It means that both fetal and adult stem cells are crucial to keep life. And these two types are naturally produced stem cells, while pluripotent stem cells are not. Pluripotent stem cells are the ones which are derived from an embryo at its blastocyst stage through the destruction of an embryo.

[24] European Group on Ethics, *Opinion No. 15: Ethical aspects of human stem cells research and use* (2000), http://ec.europa.eu/european_group_ethics/docs/avis15_en.pdf (last visited March 13, 2008).
[25] President's Council on Bioethics, *Monitoring stem cell research*, at 2 (2004)., http://www.bioethics.gov/reports/stemcell/chapter2.html#_ednref8 (last visited March 13, 2008).
[26] Opinion No. 15, supra note 24.
[27] Id.

In this paper I will focus on human embryonic stem cells, which are pluripotent, because of (1) the great potential of hESC to differentiate into several cell types and (2) artificial way of deriving hESC by destroying an embryo that raises ethical controversy.

1.2 Techniques of hESC derivation

The area of scientific activity with human embryonic stem cells raises many ethical problems. But why is it so? In order to answer this question it is necessary to look at the whole process of hESC derivation.

Three techniques known today[28]: (1) *in vitro* fertilization (IVT) technique (either for the purposes of assisted reproduction, which later are not used because of its excess or for the purposes of pure research and stem cells procurement), (2) somatic cell nuclear transfer (SCNT) and (3) parthenogenesis.

In vitro fertilization technique creates embryos (by fertilizing an egg and a sperm[29]) outside the human body, i.e. in the laboratories, which are not able to develop further after the blastocyst stage without being implanted into the woman's uterus[30]. Blastocyst stage is between the 5th and 7th days of embryo development following the fertilization, which is characterized by the hollow in the center of the "morula"[31] and by differentiation of cells into inner and outer cells[32]. Outer cells comprise the placenta, which is composed of tissues around the fetus, while inner cells are the ones which give impact for the development of the fetus itself. It is important to note that once these inner cells are derived from the outer cells, and further developed with the help of certain chemical substances, they become "pluripotent

[28] Commission of the European Communities, *Report on human embryonic stem cell research*, Commission staff working paper, at 27 (2003).
[29] Explanation for IVF is given in the following website: http://www.americanpregnancy.org/infertility/ivf.html (last visited March 13, 2008)
[30] Opinion No. 15, supra note 24.
[31] In *Embryol*. „ A solid cluster of cells (blastomeres) formed by the first cleavage divisions of a fertilized ovum and subsequently developing into a blastula", Oxford English dictionary online, http://dictionary.oed.com/cgi/entry/00316168?single=1&query_type=word&queryword=morula&first=1&max_to_show=10 (last visited March 13, 2008).
[32] Opinion No. 15, supra note 24.

cells" (this means that these cells will not be able to become an embryo anymore even in case of being transferred to the woman's uterus)[33]. Embryo is destroyed to derive hESCs from its inner mass.

Somatic cell nuclear transfer is better from the previous technique in terms of avoiding the problem of immune system rejection. In this case an embryo is created by inserting an adult somatic cell (it will be the cell of a potential patient) into the nucleus of a donated egg without being fertilized unlike IVT technique (it is called "therapeutic cloning")[34].The further process is the same as IVT in terms of reaching the same blastocyst stage and deriving stem cells from the inner mass of an embryo.

Parthenogenesis is the rarest technique of getting hESC. It is characterized as a technique of the development of female gamete (sex cell) without fertilization into an embryo[35]. Originally the word "parthenogenesis" is translated from the Greek language as "virgin birth"[36].

It means that in all three techniques hESC are derived from an embryo, which needs to be destroyed. And this very moment creates moral and ethical arguments against the possible use of hESC in science.

1.3. What are stem cells good for?

As European Group on Ethics formulated in its Opinion No. 15 there are five potential uses of stem cells: for studies of basic developmental biology, for studies of human diseases on animal models, for culturing specific differentiated cell lines to be used for pharmacology studies and toxicology testing, for use of stem cells in gene therapy and for the production of specific cell lines for therapeutic transplantation[37] . The most promising is the use of stem

[33] Opinion No. 15, supra note 24.
[34] Commission of the European Communities, *Report on human embryonic stem cell research*, Commission staff working paper, at 27 (2003).
[35] Encyclopædia Britannica online, http://www.britannica.com/eb/article-9058585/parthenogenesis
[36] Encyclopædia online, http://www.encyclopedia.com/doc/1E1-partheno.html
[37] Opinion No. 15, supra note 24.

cells for therapeutic transplantation. Mainly it means the possibility of repairing diseased and damaged tissues with pluripotent stem cells[38].

1.4. Advantages of hESC

Compared to hESC, adult and fetal stem cells are considered to be less flexible due to their ability to transform only into same broad type of tissue (like muscle stem cells, neural stem cells etc)[39]. Also it is argued that adult stem cells are short-lived[40].Adult stem cells are taken from different tissues of adult organisms[41], while fetal stem cells are from fetal tissues or umbilical cord blood[42]. These stem cells are derived from adult tissues, umbilical cord and other so called "non-embryonic" sources[43]. However, this statement is disputed by some scholars[44]. They state that adult stem cells can transform into other tissues and cell types than their origin as well[45].

1.2. Religious views on hESC research

The religious perspective is important to consider, because churches are the major opponents to hESC research. The following summary of the religious views on this issue is taken from Bela Sonfai's article "Religious Traditions and Stem Cells Research"[46].

Views vary from religion to religion and even within one religion there is a division on this issue within one religion stream depending on the interpretation of the authoritative sources of their religion. The most liberal ones are Jewish and Muslim perspectives, they coincide in the determination of the time, when an embryo gets its moral status. It is the 4th

[38] Opinion No. 15, supra note 24.
[39] Opinion No. 15, supra note 24, at 10.
[40] Opinion No. 15, supra note 24.
[41] Steering Committee on Bioethics, *The protection of the human embryo in vitro*, Report by the Working Party on the Protection of the Human Embryo and Fetus, CDBI-CO-GT3 (2003). http://www.coe.int/t/e/legal_affairs/legal_co-operation/bioethics/activities/human_embryo_and_foetus/gt3(2003)13e%20final%20public%20report%20embryo.asp#P544_88509 (last visited March 13, 2008).
[42] Id.
[43] Opinion No. 15, supra note 24.
[44] Id.
[45] Id.
[46] Bela Sonfai, *Religious Traditions and Stem Cells Research*, Society and Genetic information: codes and laws in the genetic era, Judit Sandor (ed.), 81-95.

month or 40 days of embryo's development (when the mother experiences the first movements of the fetus in the uterus), when an "ensoulment" occurs[47]. This tradition was the influence of ancient and medieval biological knowledge in Christian theology, where it is argued that there are three stages of life evolution[48]. The first stage is the lowest one called "vegetative", it applies only plants, their ability to grow and multiply. The second level is that of the "sensitive soul", which applies to animals which in the stage of capacity of sensitive perception to react to external stimulation and dangers. And the highest level of life development is the "intelligent soul", applicable only to human being because of the presence of intelligence, consciousness and inner freedom. And only starting from the last stage of life evolution it is possible to talk about the personality, personhood, and individuality.

The official Roman Catholic position states that stem cells research is immoral, because an intentional creation of an embryo with the purpose of its destruction is not permissible even for the benefit of people who need it. On the other hand, they agree to stem cells research, where cells are obtained from adults or from miscarriages. There was an official statement of the medical advisory board of the Vatican, where they proposed research on pluripotential adult stem cells without using an embryo[49]. And any other ways of obtaining hESC is regarded as a crime against humanity as Pope John-Paul II put it[50].

The other opposition to stem cells research comes from Buddhism. At a conference of 52 member organizations in spring of 2001, it was unanimously agreed that research involving the destruction of the embryo should be illegalized, including also pre-implantation diagnosis, cloning for purposes of therapy or reproduction, germ-line therapy, acquisition of

[47] Bela Sonfai, supra note 46.
[48] Id.
[49] Declaration of the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells, at: http://www.vatican.va/roman_curia/pontifical_academies/acdlife/documents/rc_pa_acdlife_doc_20000824_cellule-staminali_en.html.
[50] Id.

patent rights on the living beings[51]. It is because there should be respect towards any kind of life and any kind of living being, be it embryo in the earliest stage of development and even outside the uterus.

1.3. Other views on the status of embryo

Determination of the status of an embryo depends on when life begins so that to afford a moral value. The Steering Committee on Bioethics of the Council of Europe gives three types of arguments[52]. The first is based on biology, the second is based on the "potentiality" from philosophical perspective and the last is based on "personhood" argument.

The biology-based argument stresses the importance of the time when the so-called "unique human being" starts to exist. Some argue that it starts from the moment of fertilization when we can talk about the unique entity in the form of the fertilized egg (for them it is not important whether twinning will occur and that the genetic identity will be shared in this case), while others propose the later stage of its development. This moment is between the 15th day of life of an embryo and the appearance of primitive streak. From this time an embryo will result into only one or more individual embryos.

The "Potentiality" argument, as its name already suggests, means that an embryo, i.e. fertilized egg has a potential to become a person. Therefore embryos should be respected due to their potentiality to become a person; however it does not mean that an embryo has the same rights as a born human individual. And coming from the same logic that any research on human beings needs "informed consent" it is argued that the same principle should apply to embryos as well. But due to the fact that embryos cannot give their consent, it is impossible to carry out research on them.

[51] Declaration of the Production and the Scientific and Therapeutic Use of Human Embryonic Stem Cells, supra note 49.
[52] Steering Committee on Bioethics, *The protection of the human embryo in vitro* (2003), supra note 41.

And the last argument is the most controversial, because the concept of "personhood" means more then mere membership of "human species", and requires some "additional qualities", which are diverse depending on the region and culture. These additional qualities determine the moral worth of human species. Some examples of such qualities were mentioned by the Steering Committee on Bioethics of the Council of Europe, in its report "The protection of the human embryo in vitro": "height" of a person, "autonomy", "legal protection" etc. However these qualities are not perfect, because they have some negative consequences. In case of equating legal protection with the moral worth of a human being would mean excluding a vulnerable group of people which has less favorable legal treatment from the entitlement to moral value and respect. The biological explanation can be another type of additional qualities.

Chapter 2. Legal regulation in European Union and United States

2.1. Legislative competence

The states in the United States have autonomy in the area of science and technology based on the principle of sovereignty of states. Therefore the regulation on the state level is not uniform. For example, New Jersey and California have the most liberal approach, which allows therapeutic cloning, while such states as Arizona, Louisiana, Michigan, North Dakota and Pennsylvania prohibit research on living human embryos and hESC derived by therapeutic cloning[53].

In the United States IVF started to be practiced from 1970's and 1980's. Since then the issue of legal treatment of embryos came on the agenda. However the focus will be on the federal regulation.

The Dickey Amendment (named after former Representative Jay Dickey of Arkansas), added to each of the Labor, Health and Human Service (further HHS), and Education Appropriations Bill since 1996, deals with regulation of *in vitro* embryos[54]. This law prohibits federal funding of the research which involves the creation of an embryo for the research purposes or with the purpose of its destruction[55].

The legislative competence of the EU, particularly the European Community is limited by so called 'conferred or enumerated powers' (this principle reinforced by Treaty of Maastricht[56]), which means that Community 'has the right to intervene only within those limited spheres reserved to it in the Treaties'[57]. However by the time such constitutional rules

[53] Nordic Committee on Bioethics, *Stem Cell Research in the Nordic Countries: Science, Ethics, Public Debate and Law*, at 60 (2007).
[54] President's Council on Bioethics, *Monitoring stem cell research*, at 2 (2004), supra note 25.
[55] Id.
[56] Nottingham Group of researchers (coordinated by A. Plomer), *Stem Cell Patents: European Patent Law and Ethics Report, FP6 'Life Sciences, genomics and biotechnology for health' SSA LSSB-CT-2004-00525,* at 36 (2006).
[57] Id., at 37.

and judicial decisions as doctrine of 'implied powers'[58], 'open-ended nature of Article 308 TEU'[59] and many others broadened EC competence. Now the EU cannot imagine its existence and functioning without such universal principles as principle of pluralism, subsidiary and proportionality. Particularly the principle of pluralism is codified in article 22 of the Charter on Fundamental Rights as cultural, religious and linguistic diversity and in article 6 of the Amsterdam Treaty as a fundamental right and respect for the national identity of all member states of the EU[60].

For better understanding of the legislative approach of the EU and the US taken towards hESC research, the present chapter will be divided into the following levels.

2.2. *In vitro vs. in vivo*

First of all, it is important to distinguish between two kinds of embryos. Embryos created *in vivo* (from Latin, '(of processes) taking place in a living being')[61], created naturally inside woman's reproductive system, i.e. by traditional method[62]. However with scientific development, it became possible to use non-traditional method of fertilization, which is *in vitro* fertilization. The initial purpose of scientists in inventing this method was to help infertile couples to conceive a child[63]. Year of 1978 is remarkable for a first baby (Louise

[58] Id., at 36, cited in Hartley, T., '*The Foundations of European Community Law. An Introduction to the Constitutional and Administrative Law of the European Community'* at 106 (OUP: Oxford 2003); Cremona, 'External Relations and External Competence', in: Craig, P. and De Búrca, G., 'The Evolution of EU Law' (Oxford University Press: Oxford 1999), 137 ff., at 138 ff.
[59] Id., cited in The latter provision authorizes the Council (on the initiative of the Commission and after consultation with the European Parliament) to take the appropriate measure "if action by the Community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the Community and this Treaty has not provided the necessary powers."
[60] Opinion No. 15, supra note 24.
[61] Oxford: Advanced Learner's Dictionary.
[62] Erin P. George, *The stem cell debate: the legal, political and ethical issues surrounding federal funding of scientific research on human embryos*, 12 Alb. L.J. Sci. & Tech. 747 (2002).
[63] Id.

Brown) to be born by IVF[64]. The word '*in vitro'* has the opposite meaning to *in vivo*, from Latin is translated as '(of processes) taking place outside a living body')[65].

In vitro fertilization (further IVF) is the following medical procedure:

> In vitro fertilization (IVF) includes the processes of ovulation induction, egg retrieval, fertilization, and embryo transfer. Drugs that manipulate hormones to promote ovulation are injected into the female. After an appropriate interval to allow oocyte maturation, eggs are typically retrieved with ultrasound-guided aspiration through the vagina and cervix, and are incubated with 50,000 to 1,000,000 sperm for 14-18 hours. Following transfer to a new growth medium, the eggs are examined for the presence of two pronuclei, an indicator that normal fertilization has occurred. Approximately three days later, the embryos are morphologically assessed for quality, and two to four embryos chosen by the embryologist are flushed into the uterus through a catheter[66].

In vivo embryos are regulated by laws on abortions and case law, thus outside the scope of the paper. Most of the US federal and state case-laws as *Scott v. McPheeters* ('late-term fetuses are a unique and separate being, apart from the mother')[67], *Bonbrest v. Kotz* ('a fetus capable of life outside of the mother is no longer a part of the mother […] and has all the characteristics of a human being.')[68], *Roe v. Wade* ('there was no language in the Constitution that supported the view that life begins at conception')[69], *York v. Jones* ('the embryo was to be treated as property')[70], *Santana v. Zilog* ('a nonviable fetus could not bring a wrongful death action')[71] and many others are cases about fetuses[72]. It is because in these above-mentioned cases embryos don't have any relationship with 'scientific advancement'[73]. Even

[64] Erin P. George, supra note 62.
[65] Oxford: Advanced Learner's Dictionary.
[66] Emilie W. Clemmens, Creating *human embryos for research: a scientific perspective on managing the legal and ethical issues*, 2 Ind. Health L. Rev. 95, at 1 (2005).
[67] Id., cited in Scott v. Mcpheeters, 92 P.2d 678 (Cal. App. Ct. 1939) (dealing with a seventh month old fetus that was injured during delivery).
[68] Id., cited in Bonbrest v. Kotz, 65 F.Supp. 138, 140 (D.D.C. 1946).
[69] Allison B. Newhart, *The intersection of law and medicine: the case for providing federal funding for embryonic stem cell research*, 49 Vill. L. Rev. 329 (2004), cited in 410 U.S. 113 (1973).
[70] Id, cited in 717 F. Supp. 421 (E.D. Va. 1989).
[71] Id, cited in 95 F.3d 780 (9th Cir. 1996). In this case, the plaintiffs sued defendant Zilog for wrongful death resulting from Mrs. Santana's employment at Zilog. While she worked for Zilog, a computer manufacturing facility, Mrs. Santana became pregnant and miscarried six times. She and her husband then sued Zilog for wrongful death of her six miscarried fetuses, alleging that Zilog had exposed Mrs. Santana to dangerous chemicals and did not warn her of the potential danger of the chemicals.
[72] Erin P. George, supra note 62.
[73] Id.

though subsequently many courts came to the conclusion that embryos, even though are not equalized to the status of persons, deserve special attention[74], the legal protection of embryos are better addressed in statutes.

2.2.1. Legal regimes of EU member states

All 27 members of EU can be classified into such broad categories as permissive, permissive with restrictions, restrictive and no specific regulation[75].

Such countries as Belgium, Spain, Sweden and the UK allow the procurement of stem cells and the research on them. Czech Republic, Denmark, Finland, France, Greece, Netherlands and Portugal permit the use of hESCs in the research, which are derived only from surplus embryos (these embryos are left over from assisted reproduction technology and in vitro fertilization, which will no longer be used for the purposes of pregnancy due to various reasons[76]). Germany and Italy have restrictive position by prohibiting the creation of new stem cells line, but by allowing their import into the country (Germany explicitly allows the importation of new stem cells line by its 2002 Stem Cell Act, but Italy prohibits explicitly only the introduction of new stem cells lines and not regulating at all the existing stem cell line and the importation of hESC)[77]. Such countries as Bulgaria, Cyprus, Estonia, Ireland, Luxemburg, Latvia and Romania are considered to be the countries which either don't have any specific legislation or regulate hESC through indirect legislation. Some of them, such as Austria, Lithuania, Malta, Poland and Slovakia even though do not regulate hESC any how, still expressed their opposition (these countries voted against the hESC research within the 7th Framework Program as representatives of EU Council[78]). Hungary and Slovenia could be

[74] Erin P. George, supra note 62, cited in Kass v. Kass, 1995 WL 110368, at *2 (N.Y. Sup. Ct. Jan. 18, 1995) (unpublished decision), rev'd on other grounds, 663 N.Y.S.2d 581, 585 (App. Div. 1997); (concluding that pre-embryos are neither persons nor property but somewhere in the middle, as their potential for human life entitles them to special respect).
[75] Opinion No. 22, supra note 75, at 19.
[76] Id.
[77] Id.
[78] Id.

distinguished as countries with indirect regulation (it is applied only to embryo research, not hESC)[79].

2.2.2. Legal regime on the federal level

On the European Union level there is the Seventh Framework Program for research, technological development and demonstration (further FP7) adopted by European Parliament and Council by co-decision on December 18, 2006 for the time period of 2007-2013[80]. The FP7 regulates EU funding of any research proposal which involves the use of human embryos and human embryonic stem cells. And this regulation concerns only *in vitro* embryos. The regulation of *in vivo* embryos is totally left to the EU member states. It is because of the analogical legislative approach taken by the EU towards *in vivo* and *in vitro* embryos.

2.3. Sources of hESC: surplus vs. newly created embryos

The very low success rate of IVF necessitates extracting more number of eggs than it is necessary[81]. It is estimated as 31 percent chance of embryo loss upon placing an embryo into the woman's womb[82] or the problem could be in an embryo itself[83]. As a result there are frequently surplus embryos, which later either destroyed; or kept frozen for later use by the donating couple; or donated to another couple anonymously; or donated for research[84]. Thus one of the sources of obtaining embryos for research purposes is surplus embryos. Apart from it, embryos could be created solely for research purposes as either through in vitro

[79] Id.
[80] Decision No 1982/2006/EC of the European Parliament and the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013).
[81] Emilie W. Clemmens , supra note 66.
[82] Id.
[83] Id., cited in Karen Dawson, Introduction: An outline of scientific aspects of human embryo research, in Embryo Experimentation 3, 9 (Peter Singer et al. eds.1990) (noting that "the current success rate for IVF is between 15 and 25% per cycle of egg collection; expressed in a different way, about three out of each hundred eggs collected will result in live birth).
[84] Emilie W. Clemmens , supra note 66.

fertilization or somatic cell nuclear transfer ("SCNT") or parthenogenesis, which were discussed earlier in the first chapter.

2.3.1. What says Dickey Amendment?

Particularly Dickey Amendment sets the following requirements for federal funding:

> (a) None of the funds made available in this Act may be used for —
> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b))[85].

For the purpose of the given provision, 'human embryo or embryos' means 'any organism […], derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells'[86].

The creation of a human embryo or embryos for research purposes is explicitly excluded from federal funding according to the textual reading of the law. Surplus embryos are excluded only if they are 'destroyed, discarded, or knowingly subjected to risk of injury or death'. However, it is possible to derive hESCs only by destroying embryos, which automatically excludes them from funding.

2.3.2. What says FP7?

In the European Union FP7 requires any research proposal to fulfill the restrictions and conditions set up in the 6th Framework Program for research, technological development and demonstration, called "integrating and strengthening the European research area" (2002-2006)[87]. Any research proposal which involves the use of human embryos and human embryonic stem cells should not be conducted in the following three fields: 1) reproductive

[85] Allison B. Newhart, supra note 69.
[86] Id.
[87] Decision No 1982/2006/EC, supra note 80.

cloning; 2) germ gene line therapy (involves modifying the genetic heritage of human beings); and 3) the creation of embryos for research and stem cells procurement[88].

The creation of embryos for research purposes is explicitly stated as one of the exceptions of the EU funding. One of the possible kinds of research on surplus embryos is harvesting stem cells, i.e. stem cells procurement. However, any other research, which does not involve stem cells procurement, complies with the EU funding requirements. There are also two issues which need to be taken into account according to Ethical Review Procedures in FP7: informed consent and data protection[89].

The creation of embryos is explicitly prohibited in both jurisdictions. However the status of surplus embryos depends on whether it is not 'destroyed, discarded, or knowingly subjected to risk of injury or death' in the US or whether it is not for stem cells procurement in the EU.

2.4. Harvesting hESC (creating stem cells lines)

One of the first possibilities of deriving stem cells was from mouse embryos. Later in 1998 it became possible to get the same results from human embryos[90]. In 2004 Korean scientist Woo Suk Hwang in its publication in *Science* magazine entitled '*Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst*' announced that hESC lines were created through SCNT[91]. However later it turned out that all the data and results were faked[92]. But still SCNT stays as an optional method of hESC derivation.

[88] Id.
[89] Opinion No. 22, supra note 75, Annex II.
[90] Angela Campbell, *Ethos and Economics: examining the rationale underlying stem cell and cloning research policies in the United States, Germany, and Japan,* 31 Am. J.L. & Med. 47 (2005).
[91] Russell Korobkin, *Stem cell research and the cloning wars* (2007).
[92] Id., cited in Nicholas Wade & Choe Sang-Hun, *Human Cloning Was All Faked, KoreansReport,* N.Y. TIMES, Jan. 10, 2006. (The difference between cell and cell line: cell stops growing in a dish after a while, but it is possible to change cell for it to grow indefinitely, which is called cell line)

It is argued that the United States has the most permissive policy towards hESC research, because there is no criminal liability *per se* for any embryonic stem cell research, including for any type of cloning[93].

2.4.1. Interpretation of Dickey Amendment by Clinton and Bush administration

Dickey Amendment prohibits federal funding for the research which involves the creation of an embryo for the research purpose or with the purpose of its destruction. However the given Amendment was interpreted differently during Clinton and Bush administration. Clinton Administration stated that newly obtained stem cells lines from privately funded research are eligible for further federal funding as the funding will not involve per se the creation of embryos for the research[94]. However on August 9, 2001 President Bush changed the policy by interpreting the Dickey Amendment in a way that would allow federal funding for the research involving only of existing human embryonic stem cell lines[95]. Particularly it was required that existing hESC lines should be derived with the informed consent of the donors, be from surplus embryos created solely for reproductive purposes and without any financial inducements to the donors in order to qualify for federal funding[96]. Generally speaking, both reproductive and therapeutic cloning under Bush administration doesn't qualify for federal funding, but research on human embryonic stem cells does qualify, if cell lines were created before August 9, 2001[97]. It was called '*Bush*

[93] Kenneth C. Cheney, *Patentability of stem cell research under TRIPS: can morality-based exclusions be better defined by emerging customary international law*? 29 Loy. L.A. Int'l & Comp. L. Rev. 503 at 5 (2007), cited in Michael Woods, U.S. Relatively Hospitable to Stem-cell Research, Pittsburgh Post-Gazette, June 5, 2005, http://www.post-gazette.com/pg/05156/516098.stm .

[94] White House, *Advancing Stem Cell Science Without Destroying Human Life*, Domestic Policy Council (2007), http://www.whitehouse.gov/dpc/stemcell/2007/index.html#section2 (last visited March 13, 2008).

[95] Judith A. Johnson and Erin D. Williams, *Stem Cell Research: Federal Research Funding and Oversight* , Congressional Research Service Report for Congress for members and committees of the Congress, 10 (Updated April 18, 2007), http://fas.org/sgp/crs/misc/RL33540.pdf , cited in The Aug. 9, 2001, Remarks by the President on Stem Cell Research, available at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html

[96] Id., cited in The White House, Fact Sheet on Embryonic Stem Cell Research, Aug. 9, 2001, available at http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html

[97] Kathryn Wheat and Kirstin Matthews, *World Human Cloning Policies*, http://www.ruf.rice.edu/~neal/stemcell/World.pdf (last visited in March, 2008).

compromise'[98], because as Carly Goldstein put it, 'Bush tried to balance the need to protect life and improve life. However, many feel he went too far while others argue he did not go far enough. President Bush's decision has been regarded as a great political decision, but ethically no decision at all'[99]. Even though, it is argued that most Americans do support embryonic stem cell research[100]. And any privately funded research on deriving hESC as such is not prohibited by federal law[101].

2.4.2. US soft law

The lack of the federal regulation of hESC was compensated by "Voluntary guidelines for deriving, handling and using human embryonic stem cells"[102]. These soft provisions were prepared by Committee on Guidelines for Human Embryonic Stem Cell Research (released on April 26, 2005), which was established by the National Academies in July 2004[103]. Particularly the Committee suggest the following recommendations: 1) first, for any kind of hESC research a certain oversight committee, composed of competent people in the fields of science, ethics and law, and of representatives from the public, should be established, which will conduct a review; 2) second, additional body in the form of national panel also need to be established to oversee 'the issue in general on a continuing basis' etc[104].

[98] Angela Campbell, supra note 90, cited in The NIH had discovered a total of 64 different embryonic stem cell lines obtained before August 9, 2001. It is creating an Embryonic Stem Cell Registry that will list and give details about these lines. See George, supra note 38, at 804. See also Cynthia Donley Young, A Comparative Look at the US and British Approaches to Stem Cell Research, 65 ALB. L. REV. 831, 846; Monachello, supra note 61, at 597.
[99] Angela Campbell, supra note 90.
[100] Kenneth C. Cheney, supra note 93, at 5, cited in Mary Dalrymple, Bush Vetoes Stem Cell Bill as Promised, Breitbart, July 19, 2006, http://www.breitbart.com/article.php?id=D8IV7E080&show_article=1.
[101] President's Council on Bioethics, *Monitoring stem cell research,* available at: http://www.bioethics.gov/reports/stemcell/chapter2.html#_ednref8 (last visited March 13, 2008).
[102] Judith A. Johnson and Erin D. Williams, supra note 95.
[103] Id.
[104] Id.

2.4.3. Explicit EU prohibition of 'stem cells procurement'

In the EU, research in the area of 'stem cells procurement' is explicitly prohibited from the EU funding by article 6 (2) of FP7[105].

Both jurisdictions have the same policy concerning the prohibition of funding the research which as such involves the derivation of hESC or hESC lines. The difference between them in this regard is the following: in addition to the first prohibition the US does not provide funding for research which involves the usage of hESC derived after August 9, 2001. So it means the US has stricter requirements.

2.5. Using hESC

Only stem cell lines created before August 9, 2001 are eligible for being funded under Dickey Amendment. Therefore in the United States in terms of using hESC, it is allowed as long as hESC are from existing stem cell lines.

Research involving the usage of hESC is not listed as one of the areas of prohibition for EU funding. Article 6 (3) of FP7 states the following:

> 3. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved.
>
> Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided.
>
> As regards the derivation of human embryonic stem cells, institutions, organizations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved[106].

This provision necessitates any research proposal to consider first, national framework, including national ethical approval, where the research will be conducted. On the national level Germany is the only country which explicitly allows conducting research on

[105] Decision No 1982/2006/EC, supra note 80.
[106] Decision No 1982/2006/EC, supra note 80.

imported ones[107]. Italy unlike Germany allows derivation of hESC by not regulating it at all[108].

Therefore, the US unlike the EU makes distinction in terms of the usage of hESC for research purposes between hESC lines before August 9, 2001 and after.

2.6. Patenting hESC

The issue of hESC patenting came to the floor of discussion in 1998 when first human pluripotent stem cells were derived from human embryo[109]. Therefore patenting is as much ethical issue as the research on hESC is. As EGE has pointed out in its Opinion No. 16, 'patent law has always had an ethical dimension since its inception at the end of the 18th century'[110]. Patenting itself means that an inventor will have an exclusionary right to limit the others from 'making, using, selling, offering to sell or importing the claimed invention for a fixed period of time in exchange for public disclosure of the invention'[111].

2.6.1. EU patent law

In the European Union patenting is covered by two documents, which is European Union 1998 Directive on the legal protection of biotechnological inventions (further Directive)[112] and European Patent Convention (further EPC) of 1973 (adopted by the Council of Europe, is relevant to consider as all EU member states are parties to this Convention)[113].

[107] Samantha A. Jameson, *Comparison of the patentability and paten scope of biotechnological inventions in the United States and the European Union*, 35 AIPLA Q.J. 193 at 15 (2007), cited in Angela Campbell, Ethos and Economics: Examining the Rationale Underlying Stem Cell and Cloning Research Policies in the United States, Germany, and Japan, 31 AM. J.L. & MED. 47, 60-62 (2005).
[108] Opinion No.22, supra note 75.
[109] European Group on Ethics in Science and New Technologies, *Study on the patenting of inventions related to human stem cell research,* European Commission (2002).
[110] Brian Salter, *Patenting, morality and human embryonic stem cell science: bioethics and cultural politics in Europe*, Regenerative Med. (2007) 2(3), 301-311, cited in European Group on Ethics in Science and New Technologies: Ethical Aspects of Patenting Inventions Involving Human Stem Cells. Opinion No. 16. European Commission, Brussels, Belgium (2002).
[111] Kenneth C. Cheney, supra note 93, at 5, cited in Donald S. Chisum, Chisum on Patents § 1 (Matthew Bender & Co., 2007).
[112] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.
[113] Brian Salter, supra note 110.

Discovery vs. Invention

In the application of the Directive, clear distinction should be made between invention and discovery according to article 5 (1) and (2)114:

> 1. 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, cannot constitute patentable inventions.
>
> 2. 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, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Article 52(2) of EPC contains the same exclusion on discovery from patentability[115]. Particularly, it should be understood that it is an invention only when one can reproduce the same product or the same process[116]. The German Court gave the following example on antibiotic to make a clear borderline between these two notions:

> As long as [antibiotic] is only observed that antibiotically active substances are present in a soil sample, it is a discovery; as soon as the antibiotic has been isolated and characterized and a person skilled in the art could in turn prepare the now characterized antibiotic by either culturing the microorganism that produces the antibiotic or by a synthetic route, it can be seen as an invention[117].

Therefore referring to the present court ruling, it is possible to conclude that *in vivo* stem cells are not patentable, because they are received as a result of natural processes taking place in the organism of a living being, while, on the other hand, *in vitro* stem cells, i.e. stem cells or stem cell lines which can be reproduced identically can be eligible for patenting[118].

The present statement is supported by the ruling of the European Court of Justice, which specifically clarified the patentability of hESC[119]. In the given case, application of

[114] Art.5 (1) (2) of the Directive, supra note 112.
[115] European Patent Convention (1973), which is available at the official web-site of EPO: http://www.epo.org/ .
[116] Murat Metin Hakki, *European Directive on the Legal Protection of Biotechnological Inventions: Scope, Status and Controversies in a Nutshell* (2004).
[117] Dr. Heike Vogelsang-Wenke, *Patenting of stem cells and processes involving stem cells according to the rules of the European Patent Convention* (EPC), 23 Biotechnology L. Rep. 155 (2004).
[118] Id.
[119] European Group on Ethics in Science and New Technologies, *Study on the patenting of inventions related to human stem cell research, European Commission,* at 55 (2002), cited in the Judgment of the Court of Justice, 9 October 2001, Case C-377/98, Kingdom of the Netherlands, supported by Italian Republic and by Kingdom of

Netherlands to the Court of Justice was aimed at nullification of article 5 (2) of the EU Biotechnology Directive, which by granting patent on isolated parts of the human body, in the view of Netherlands, undermines human dignity. The Court, having reviewed the provisions of the Directive, came to the conclusion that the Directive ensures proper protection of human dignity by prohibiting the patentability of human body and its parts as such defining them as discoveries. However, the court decided that "inventions which combine a natural element with a technical process enabling it to be isolated or produced for an industrial application can be the subject of an application for a patent"[120].

Patentability of hESC is also confirmed by European Group on Ethics in Science and New Technologies (further EGE), which was established by article 7 of the Directive to develop ethical guidelines on issues relating to biotechnology[121]. EGE expressed its position by stressing the patentability of only "modified hESCs"[122]:

> Isolated stem cells which have not been modified do not, as a product, fulfill the legal requirements, especially with regard to industrial applications, to be seen as patentable [and that] only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application fulfill the legal requirements for patentability[123].

Also EGE in its Opinion No. 15 pointed that there is "no ethical obstacle to patentability attached to processes involving human stem cells, whatever their source ..."[124]

Norway v. European Parliament and Council of the European Union, supported by Commission of the European Communities.

[120] European Group on Ethics in Science and New Technologies, *Study on the patenting of inventions related to human stem cell research, European Commission,* at 55 (2002).

[121] Russel Korobkin and Stephen R. Munzer, *Stem cell research and the law*, 56 (2006), Research Paper No. 06-05. This paper may be downloaded without charge at: The Social Science Research Network Electronic Paper Collection: http://ssrn.com/abstract=878392

[122] European Group on Ethics in Science and New Technologies, *Study on the patenting of inventions related to human stem cell research, European Commission,* at 55 (2002).

[123] Opinion No.15, supra note 24.

[124] R. Stephen Crespi, *The human embryo and patent law- a major challenge ahead*, E.I.P.R. 2006, 28(11), 569-575.

Products or processes

Article 3(1) (2) of the Directive grants patent only to products or to processes. Possible product claims are stem cells, stem cell lines, genetically modified stem cells or stem cell lines and others, while possible processes include isolation, concentration and/or selection of stem cells, culturing of stem cells etc[125]. Additionally inventions in the form of products or proocesses should be new, based on inventive step (modification of natural state of biological material) and which is susceptible of industrial application[126]. The same requirements are present in EPC, in articles 54, 56 and 57[127].

'Ordre public' or morality exclusion

The other exception on the patentability generally of any biological material and particularly of hESC is codified in article Art.6 (1) of the Directive. The given article prohibits the commercial exploitation of any invention which is contrary to 'ordre public' or morality, however, it should not equated with mere legal prohibition of any EU member state, "[commercial] exploitation [of inventions] shall not be deemed to be so ['ordre public' or morality] contrary merely because it is prohibited by law or regulation"[128]. Prior to the adoption of the Directive, several patents were granted to human cell lines in the EU[129].

In all other cases, when the status of certain invention is debatable, it is decided on case-by-case basis. However, European Patent Organization[130] (further EPO) adopted its own guidelines clarifying morality principle by trying to answer to the following question:

[125] Id.
[126] Id.
[127] Art. 54, 56 and 57 of EPC, supra note 115.
[128] Directive, art. 6 (1), supra note 112.
[129] Samantha A. Jameson, supra note 107, at 15, cited in European Patent No. 428, 656 (filed May 14, 1990) (issued May 29, 1991) (patenting a human cell line).
[130] The European Patent Organization (the EPO) was established on 7th October 1973 on the basis of the European Patent Convention (EPC), which was signed in Munich in 1973 and entered into force in 1978.

'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'[131].

'Industrial or commercial'

Article 6(2) of the Directive and the rule 23d of EPC is important, because it states four inventions which are as such excluded from patenting even if they fulfill all aerlier mentioned general requirements of the Directive and EPC:

> (a) processes for cloning human beings;
> (b) processes for modifying the germ line genetic identity of human beings;
> (c) uses of human embryos for industrial or commercial purposes;
> (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

European parliament in its resolution argues that hESC are not patentable because it involves the destruction of human embryo and does not qualify under the paragraph (c): 'uses of human embryos for industrial or commercial purposes'[132]. And 'industrial or commercial' is interpreted as 'direct, repetitive use of a human embryo as a raw material in a mechanical, chemical or technical process and/or any uses involving a trade in human embryos per se'[133].

Preparatory Works on the Directive confirm the position that the primary purpose of the legislators was to preserve the legislative diversity in EU by abstaining from prohibition of patenting research on human embryos, which is permitted in any EU member state[134].

2.6.2. US patent law

Congress by the United States Constitution is empowered "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the

[131] Samantha A. Jameson, supra note 107, at 15, cited in European Patent Office, Guidelines for Examination, pt. C, ch. IV, § 3.1 (2005), http://www.european-patent-office.org/legal/gui_lines/e/c_iv_3_1.htm.
[132] Samantha A. Jameson, supra note 107, at 15, cited in European Parliament Resolution on Patents for Biotechnological Inventions, 2006 O.J. (C 272 E) 440, 442, available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/ce272/ce27220061109en04400442.pdf. Similarly, the European Parliament has emphasized that germ cells are not patentable under the Directive because they are part of the human body. Id. resolution 9.
[133] Nottingham Group of researchers, *Stem Cell Patents: European Patent Law and Ethics Report, FP6 'Life Sciences, genomics and biotechnology for health'*, supra note 56, at 74.
[134] Id.

exclusive Right to their respective Writings and Discoveries."[135] In the framework of the given Constitution clause Patent Act was adopted in 1952 and in subsequent years was amended[136]. The Patent Act grants twenty years of monopoly power to a person who (1) "invents or discovers" (2) a "process, machine, manufacture, or composition of matter" and (3) 'whose invention is novel, useful, and nonobvious', and (4) 'who discloses the invention as part of the patent application in a way that enables others to replicate it'[137] .

Even though text of US Constitution mentions "inventions and discoveries", in fact US patent law does not issue patent on 'mere discovery of something'[138]. In 1948, the US Supreme Court made a ruling that "he who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it."[139] In more recent case, Diamond v. Chakrabarty (1980), the United States Supreme Court decided to exclude 'natural discoveries' from patenting, because they are 'manifestations of . . . nature, free to all men'[140] and stated that only new discoveries created and existing in laboratory are patentable[141]. Therefore both hESC and hESC lines are patentable under Chakrabarty case, because hESC lines are not able to survive outside laboratory and 'are discovered, cultured, and grown by scientists'[142], while hESC are patentable, because they are created in laboratories. For instance, in *In re Bergy*

[135] Russel Korobkin and Stephen R. Munzer, *Stem cell research and the law*, 56 (2006), Research Paper No. 06-05. This paper may be downloaded without charge at: The Social Science Research Network Electronic Paper Collection: http://ssrn.com/abstract=878392=, cited in U.S. CONST. art I, § 8, cl. 8.
[136] Id., at 40 (2006).
[137] Id., cited in 35 U.S.C. §§ 101, 102, 103, 112 (2005).
[138] Id., at 49 (2006).
[139] Id., cited in Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).
[140] Matt Massar, *Restricting human embryonic stem cell research: creating life or destroying freedom?* 10 SCHOLAR 43 at 7 (2007), cited in Diamond v. Chakrabarty, 447 U.S. 303 at 309 (1980) (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)). In Diamond, the United States Supreme Court held that the Respondent's micro-organism qualifies as a patentable product because it is not natural, but rather a manufactured product. Id. On the other hand, in Funk, the United States Supreme Court held that bacteria cells did not qualify as patentable subjects due to their naturally occurring existence. Id. at 310.
[141] Id., at 7, cited in Diamond v. Chakrabarty, 447 U.S. 303 (1980) (describing the Respondent's discovery as a nonnaturally occurring phenomena).
[142] Id., at 9, cited in Davis, 842 S.W.2d at 597 n.19 (stating that a pre-embryo has merely a 13-21% chance of survival if implanted into a woman).

case the United States Court of Customs and Patent Appeals granted patent on 'cultured cells'[143].

Patent either granted to "process" or to "composition of matter". The process related to hESC consists of the following variations:

> (1) 'the isolation of hESCs from embryos and tissues; (2) the purification of hESCs from a mixture of cells; (3) the replication and culturing of hESCs; (4) the differentiation and genetic modification of ESCs into specific cell types; and (5) therapeutic and other uses of hESCs and differentiated cells; (6) cloning techniques relating specifically to human cloning.[144].

Novelty of an invention or discovery requires its disclosure to the general public to take place not earlier than one year before the date of the patent application[145]. Usefulness is measured by "specific, substantial, and credible" real-world application of an invention or discovery[146]. To qualify as nonobvious, invention/discovery 'must not be so trivial as to have been anticipated by a person having ordinary skill in the art'[147]. The last condition means that a person of ordinary skill in the art should be able to reproduce it[148].

United States Patent and Trademark Office (further PTO) is a state body which issues patents on inventions/discoveries upon the fulfillment of aforementioned four conditions[149]. As of December 28 of 2005, PTO granted 1,146 where there was a mentioning of the phrase "stem cells"[150].

For instance Federal Circuit granted patent on new human cell line[151]. The same is with embryonic stem cells; patents are allowed to be granted[152].

[143] Id., at 9, cited in In re Bergy, 596 F.2d 952 at 973 (C.C.P.A. 1979) (defining the scope of patentable material).
[144] Russel Korobkin and Stephen R. Munzer, supra note 135, at 46 (2006).
[145] Id, cited in 35 U.S.C. § 102(b) (2005).
[146] Id., cited in 35 U.S.C. § 101 (2005)
[147] Id., cited in 35 U.S.C. § 103(a) (2005).
[148] Id., cited in 35 U.S.C. § 112, ¶ 1 (2005).
[149] Id., at 41.
[150] Id., at 42.
[151] Samantha A. Jameson, supra note 107, at 15, cited in In reLundak, 773 F.2d 1216, 1217, 1224, 227 U.S.P.Q. (BNA) 90, 91, 96 (Fed. Cir. 1985). The Federal Circuit considered the issue of deposit. Id. at 1217, 227 U.S.P.Q. (BNA) at 91.

US Patent Act does not contain any provision on morality[153]. However, it is possible to trace in the court decisions some ruling decided based on morality argument. In the early 19th century in *Lowell v. Lewis* case Justice Story held 'that an otherwise patentable invention that lacks a morally permissible use may not receive a patent'[154]. Later court inclined to the position that they should be morally neutral[155]. In *Juicy Whip v. Orange Bang* case (1999), the Federal Circuit rejected the given doctrine referring to the textual reading of the Patent Act[156]. However later by initiatives of PTO, Congress enacted the Weldon Amendment in 2004 and 2005 of the following content: '"None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directly related to or encompassing a human organism."'[157]. Much depends on the interpretation of PTO and courts, on how much hESC will be close or far enough 'related to […] to a human organism".

Even though Weldon Amendment added morality clause to US patent law, still the textual reading does not give much in understanding what is "related to […] to human organism" as is the case with the Directive provision on 'ordre public' or morality. In the EU, the morality provision of both Directive and EPC gives wide discretion to the member states in its interpretation. Therefore it depends, where the research is conducted. It is possible that in one member state the invention could be excluded from patenting for being contrary to morality or 'ordre public', while in another state it could be vise versa.

[152] Id., cited in U.S. Patent No. 6,200,806, at [57] (filed June 26, 1998) (issued Mar. 13, 2001) (claiming "[a] purified preparation of primate embryonic stemcells"). Patents similarly do not appear prohibited on embryonic germ cells. SeeU.S. Patent No. 6,562,619 (filed Apr. 20, 2000) (issued May 13, 2003) (patenting human embryonic germ cells that resemble embryonic stemcells); U.S. Patent No. 6,090,622 (filed Mar. 31, 1997) (issued July 18, 2000) (same).
[153] Russel Korobkin and Stephen R. Munzer, supra note 135, at 57.
[154] Id., at 58 (2006), cited in 12 F. Cas. 1018, 1018-19 (C.C.D. Mass. 1817) (No. 8568).
[155] Id.
[156] Id., cited in Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999). In that case the validity of a patent was challenged on the ground that the invention allegedly served the purpose of deceiving the public.
[157] Id., at 60, cited in P.L. 108-199, § 634 (2004) and P.L. 108-447, § 626 (2005).

2.7. *Funding hESC research*

2.7.1. US jurisdiction: Clinton and Bush administration

Since the introduction of Dickey Amendment by the Congress to National Institutes of Health (NIH) appropriations bills, 'the creation of a human embryo or embryos for research purposes' and 'research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death' are excluded from federal funding[158].

Clinton Administration

In 1998 when first human embryonic stem cell lines were derived in the United States, it created a debate over the possibility of hESC funding[159]. Thus Department of Heath and Human Services (DHHS) stated that 'human pluripotent stem cells are not embryos', thus are eligible for funding[160]. And DHHS adopted guidelines, which didn't allow funding the creation of hESC by the destruction of human embryos, and allowed only 'the cells […] derived (without Federal funds) from human embryos that were created for the purposes of fertility treatment and were in excess of the clinical need of the individuals seeking such treatment'[161].

[158] Francesca Crisera, *Federal regulation of embryonic stem cells: can government do it? An examination of potential regulation through the eyes of California's recent legislation*, 31 Hastings Const. L.Q. 355 at 5 (2004).
[159] Id., cited in Press Release, Johns Hopkins Med. Inst., Hopkins Research Team Cultures Long-Awaited Human Embryonic Stem Cells (Nov. 5, 1998), http:// www.hopkinsmedicine.org/press/1998/981105 .
[160] Id., at 6, cited in Statement of Harold H. Varmus, M.D., Director, National Institutes of Health, Before the Senate Appropriations Committee on Labor, Heath and Human Services, Education and Related Agencies (Jan. 26, 1999), at http://stemcells.nih.gov/policy/statements/statement.asp. The reasoning of the DHHS was as follows: The statute that bans the use of Federal funds for embryo research defines embryo as an organism derived by fertilization and other means. The statute does not, however, define organism. Therefore, the legal opinion relied on the broadly accepted science-based definition of organism: an individual constituted to carry out all life functions. By this definition--and as you heard from all the witnesses that responded to that question at your hearing on this matter on December 2, 1999--pluripotent stem cells are not and cannot develop into organisms. Therefore, human pluripotent stem cells are not embryos and are not covered by this prohibition on Federal funding. In addition, the legal opinion states that DHHS funds can be used for research using human pluripotent stem cells that were derived from fetal tissue if the existing laws and regulations governing fetal tissue research are obeyed.
[161] Id., at 6, *cited in* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,979 (Aug. 25, 2000).

Bush Administration

However with Bush administration it became possible to apply for federal funding of only hESC lines created before August 9, 2001[162]. Moreover, there are two other requirements: use of only surplus embryos left after *in vitro* fertilization; and protection of informed consent and the prohibition of financial inducements[163]. Any other research which involves any kind of cloning is not prohibited if it is privately funded, but still subject to individual state regulation[164].

2.7.2. Conditions for funding under EU FP7

FP7 includes the same conditions for any research proposal to be funded by EU as FP6[165]. First of all, following three fields are excluded from funding: reproductive cloning, germ gene line therapy and the creation of embryos for research and stem cells procurement[166] as it was mentioned earlier.

Apart from these three restrictions there are also several conditions[167], which need to be fulfilled (under FP6). First of all, research must be in conformity with all legal and regulatory requirements of a country, where the research will be carried out (in accordance with article 6(3) of FP7[168]). Second, research proposal should ensure that it will involve only surplus embryos[169]. Thirdly, the protection of personal data and privacy of the donors of embryos for the creation of stem cell lines should be guaranteed. And the last not the least, freedom of donation should be protected, which means the absence of any financial inducements, allowing only the reimbursement of sustained costs (this is in line with article 12 of the Directive 2004/23/EC of the European Parliament and of the Council of 31 March

[162] Id., at 6, *cited in* George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), at http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html
[163] Matt Massar, supra note 140, at 8, cited in National Institutes of Health, Stem Cell Information: Federal Policy, http://stemcells.nih.gov/policy/ (last visited July 18, 2007).
[164] Matt Massar, supra note 140, at 8.
[165] Opinion No. 22, supra note 75.
[166] Id.
[167] Id.
[168] Id.
[169] Id.

2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[170]).

All these restrictions and conditions are reviewed and evaluated by a panel of independent experts, which follow the procedure set out in the "Guidelines on Proposal Evaluation and Selection Procedures" (Decision C (2003)883)[171]. This panel will see whether an application is in conformity with FP7 and Council Decision of 30 September 2002 adopting a specific program for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006)[172]. And then it is submitted to the Programme Committee (this committee is established according to article 7(1) of Decision 2002/834/EC) for the selection in accordance with article 6(3) of Decision 2002/834/EC[173].

So the EU is considered more permissive. In the EU, any research proposal needs to make sure that funding will not be contrary to legal framework of member state, where the research is conducted. It is also important to exclude the use of funding for stem cells procurement as such. And there are several minor limitations such as prohibition of financial inducements; protection of data protection and privacy; and use of hESC, derived only from non-implanted IVF embryos.

The US limitation on funding in terms of time of derivation of hESC significantly decreases the possible benefits due to the following: (1) there are only twenty-one officially

[170] Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=32004L0023&model=guichett (last visited March 13, 2008)

[171] Procedural modalities for research activities involving banked or isolated human embryonic stem cells in culture to be funded under Council Decision 2002/834/EC, http://ec.europa.eu/european_group_ethics/activities/docs/opinion_22_final_follow_up_en.pdf (last visited March 13, 2008)

[172] Id.

[173] Id.

registered stem cell lines[174] and (2) 13 of which are under the monopoly of National Stem Cell Bank[175], (3) the existing stem cell lines are predominantly stem cells of mice[176] and (4) the statement of scientists that existing stem cell lines qualified for federal funding have characteristics which does not allow medical treatments in humans[177].

2.8. Egg donation

Risks to the health of women donors are very high due to the hormonal treatments and super ovulation in order to obtain eggs from the organism of a woman[178]. In order to avoid the exploitation of women in case of egg donation certain guarantees should be provided.

2.8.1. Informed consent of donors and the prohibition of financial inducements

In the United States, under the current federal policy on hESC research, i.e. under the Dickey Amendment, there are two main requirements in regard of donor's right[179]. However these two requirements relate only to federal funding and only those stem cell lines, which were derived before September 9 of 2001[180]. It is because only pre-existing stem cell lines are eligible for federal funding. So these two requirements are informed consent of donors and the prohibition of any financial inducements[181], which are the same as pre-conditions for the EU funding.

[174] Matt Massar, supra note 140, at 52.
[175] Id.
[176] Celeste Biever, US Stem Cells Tainted by Mouse Material, New Scientist, Nov.2004, available at: http://www.newscientist.com/article.ns?id=dn6604
[177] Id.
[178] The President's Council on Bioethics, *Human cloning and human dignity: an ethical inquiry*, at 90 (2002), http://www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf , cited in Rimington, M., et al. "Counseling patients undergoing ovarian stimulation about the risks of ovarian hyper-stimulation syndrome." Human Reproduction, 14: 2921-2922, 1999; and Wakeley, K., and E. Grendys. "Reproductive technologies and risk of ovarian cancer." Current Opinion in Obstetrics and Gynecology, 12: 43-47, 2000.
[179] President's Council on Bioethics, *Monitoring stem cell research* (2004), supra note 25.
[180] Id.
[181] Bush Administration National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells (NIH) Guidelines for Embryonic Stem Cell Funding, Appendix C to Monitoring stem cell research, A report of the President's Council on Bioethics (2004), available at: http://www.bioethics.gov/reports/stemcell/appendix_c.html .

In medical treatment informed consent doctrine generally includes such elements as (1) the nature of the treatment, (2) the likelihood of success, (3) reasonably foreseeable risks, (4) alternative treatments, and (5) clinical prognosis if the patient declines treatment[182].

These two requirements are not new and already existed under the Clinton's Administration[183]. Particularly informed consent under the Clinton Administration meant to be consisted of the following statements[184]:

> (i) A statement that the embryos will be used to derive human pluripotent stem cells for research that may include human transplantation research;
> (ii) A statement that the donation is made without any restriction or direction regarding the individual(s) who may be the recipient(s) of transplantation of the cells derived from the embryo;
> (iii) A statement as to whether or not information that could identify the donors of the embryos, directly or through identifiers linked to the donors, will be removed prior to the derivation or the use of human pluripotent stem cells;
> (iv) A statement that derived cells and/or cell lines may be kept for many years;
> (v) Disclosure of the possibility that the results of research on the human pluripotent stem cells may have commercial potential, and a statement that the donor will not receive financial or any other benefits from any such future commercial development;
> (vi) A statement that the research is not intended to provide direct medical benefit to the donor; and
> (vii) A statement that embryos donated will not be transferred to a woman's uterus and will not survive the human pluripotent stem cell derivation process.

On the European Union, level protection of donor's right was recommended by EGE as one of additional requirements to the 7th Framework Program[185]. As a general condition there should be compliance with the fundamental ethical principles, human rights standards in force for EU members and EU institutions, national legislation where the research will be conducted and any other relevant regulations in the framework of European Union[186]. Particularly the following should be ensured: (1) the risk to donor's health should be

[182] Russel Korobkin and Stephen R. Munzer, supra note 135, cited in Peter H. Schuck, Rethinking Informed Consent, 103 YALE L.J. 899, 916-17 (1994).
[183] President's Council on Bioethics, *Monitoring stem cell research* (2004), supra note 25.
[184] Clinton Administration National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells (NIH) guidelines for embryonic stem cell funding, Appandix D to Monitoring stem cell research, A report of the President's Council on Bioethics (2004), http://www.bioethics.gov/reports/stemcell/appendix_d.html
[185] Opinion No. 22, supra note 75.
[186] Id., cited in European Directive EC 2004/23 "Setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells".

eliminated, (2) informed consent should be guaranteed, which means that donor should be aware of the fact for what purposes the embryos will be used, and its consequences[187], (3) donor should be aware of the fact that consent could be withdrawn until stem cells are derived from embryos[188], (4) there should be clear distinction between donation for infertility treatment and for research purpose in terms of obtaining informed consent procedure, (5) and lastly there is a prohibition of any financial inducements[189] with some exceptions such as reduction of infertility treatment. In compliance with Directive on the protection of personal data, the proper level of data protection should be ensured such as anonymity and confidentiality in relation to personal information of donors[190].

However for now, donor's rights are protected under the general data protection and privacy provision[191].

Generally the regulation of egg donation in both jurisdictions is aimed at ensuring the proper level of protection of donors' rights. Both jurisdictions require the use of only surplus embryos to be funded.

2.9. Freedom of research

2.9.1. 'Expressive activity' under US law

In the United States freedom to conduct research falls under the scope of one of the fundamental liberties, which is freedom of expression[192]. It is argued that research is some form of expression or 'expressive activity'[193]. American Bar Association took also an approach of referring to First Amendment's protection in issuing a resolution, which

[187] Id., cited in ISSCR guidelines, available at: http://www.isscr.org/guidelines/
[188] Opinion No. 22, supra note 75.
[189] Id., cited in art.12 of Directive 2004/23: "Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells".
[190] Id., cited in Directive on the protection of personal data (/95/46/EC).
[191] Id., at 42.
[192] Angela Campbell, supra note 90, at 12.
[193] President's Council on Bioethics, *Monitoring stem cell research*, at 61 (2004), http://bioethics.gov/reports/stemcell/pcbe_final_version_monitoring_stem_cell_research.pdf .

supported limited therapeutic research using cloned human embryos[194]. Therefore any governmental intrusion into the exercise of these rights should be specific and justified, which means that strict scrutiny test is applied[195]. It is argued that, for instance, prohibition of human cloning will violate this fundamental liberty[196]. In the adoption of 1997 report by NBAC, scientific freedom was one the main arguments against ban on human cloning[197].

2.9.2. Conduct under US law

On the other hand, others argue that 'scientists may have the right to pursue knowledge in any way they want cognitively, intellectually', but 'when it comes to concrete action in the lab, that becomes conduct and the First Amendment protection for that is far, far weaker'[198]. Moreover, federal regulation concerns only funding. In Supreme Court decisions from 1977 to 1991, it was established that governments are not obliged to fund even those activities, which are protected by the Constitution[199].

2.9.3. Balancing under US law

In the American jurisprudence freedom of research is balanced against the legal status of human embryo, in case hESC are harvested because it is possible only through destroying human embryo[200]. The present case law of United States is not recognizing human embryos as 'persons', because according to the law life starts at birth, not at conception[201]. But still

[194] Id.
[195] Id, cited in Washington v. Glucksberg, 521 U.S. 702, 720-21 (1997).
[196] Angela Campbell, supra note 90, at 12, cited in Katheryn D. Katz, The Clonal Child: Procreative Liberty and Asexual Reproduction, 8 ALB. L.J. SCT. & TECH. 1, 58 (1997), at 58-59; Melissa K. Cantrell, International Response to Dolly: Will Scientific Freedom Get Sheared?, 13 J.L. & HEALTH 69, 72 (1998-99) at 102; ANDREA L. BONNICKSON, CRAFTING A CLONING POLICY: FROM DOLLY TO STEM CELLS 146 (2002). The First Amendment provides, "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances." U.S. CONST. amend. I.
[197] Id, cited in National Bioethics Advisory Commission (NBAC), Cloning Human Beings (1997).
[198] President's Council on Bioethics, *Monitoring stem cell research*, supra note 25, at 61.
[199] Id. at 62, cited in Maher v. Roe 432 U.S. 464 (1977); Harris v. McRae 448 U.S. 297 (1980); Rust v. Sullivan 500 U.S. 173 (1991).
[200] Angela Campbell, supra note 90, at 12.
[201] Id., cited in Cynthia Donley Young, A Comparative Look at the US and British Approaches to Stem Cell Research, 65 ALB. L. REV. 835.

there is federal protection as 'potential persons' afforded to fetuses, which are viable[202].

2.9.4. EU legal regime

On the European Union level, freedom of research is regulated by European Patent Convention (as it was mentioned earlier, all member states of the EU are parties to this convention)[203] and European Union 1998 Directive on the legal protection of biotechnological inventions[204]. Both of these documents contain the similar limitations, which concern only patenting of biotechnological invention. However it is relevant for research as well, because any invention is the product of some kind of research. Article 6 (1) of Biotechnological Directive excludes any invention, which is contrary to morality and is related to 'plant or animal varieties' or any 'biological processes for the production of plants or animals' with the exception of microbiological processes (Article 53 (b))[205].

ECJ stressed the importance of giving wide margin of appreciation to member states in the interpretation of what is moral, because of '[…] the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State'[206]. Paragraph two of the same article as opposed to first paragraph contains specific moral exclusions: 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; processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes[207]. The general EU principles such as principle of subsidiary,

[202] Id., cited in Cynthia Donley Young, A Comparative Look at the US and British Approaches to Stem Cell Research, 65 ALB. L. REV. 835; 18 U.S.C.S. § 1841 (2005).
[203] Brian Salter, supra note 110.
[204] Id, cited in European Parliament and Council: Directive 98/44/EC: Directive on the legal protection of biotechnological inventions. Brussels, Belgium, 6th July 1998.
[205] Id., cited in European Patent Office: European Patent Convention (2006), available at: www.european-patent-office.org/legal/epc/e/ma1.html
[206] Nottingham Group of researchers, *Stem Cell Patents: European Patent Law and Ethics Report, FP6 'Life Sciences, genomics and biotechnology for health'*, supra note 56, at 63, cited in Case C-377/98 Netherlands v European Parliament and Council [2001] ECR I-07079 at para. 38.
[207] Directive, supra note 112.

proportionality and pluralism, which especially give wide margin of appreciation to member states in morality questions, does not preclude absolute prohibition of research and patenting in certain areas[208].

So, freedom of research in the US could qualify as one of the fundamental liberties, the limitation of which requires strict scrutiny, while the EU does regulate it through its law on patenting.

[208] Nottingham Group of researchers, *Stem Cell Patents: European Patent Law and Ethics Report, FP6 'Life Sciences, genomics and biotechnology for health',* supra note 56, at 64.

Chapter III. Russian Federation: special case

Generally legislation of Russian Federation on achievements of biomedicine is considered to be non-systematic and fragmented, while those related to stem cells almost absent[209]. Therefore legal regulation of hESC in Russia should be understood as the regulation only by general and indirect provisions.

In analyzing the Russian legislation hierarchy of legislation needs to be taken into account, which is the following: First of all, there is a Constitution. Article 21 of the given basic document provides the protection of human dignity by the state, particularly prohibiting any medical, scientific or other experiments on persons without a person's voluntary consent[210].

Constitution also prescribes that principles and norms of international law and international agreements of Russian Federation are part of Russian legal system (para. 4, article 15). Out of all relevant international agreements Russia has ratified only European Convention for the Protection of Human Rights and Fundamental Freedoms (came into force for Russia in 1998)[211]. Convention on Human Rights and Biomedicine of 1997 and its Additional Protocols[212] have no binding force for Russia (adopted in the framework of the Council of Europe). In the framework of the UNESCO, there are two more declarations (non-binding force):

[209] Hazova O.A., *Stvolovie kletki: problemy pravovogo regulirovania* ("Stem cells: the problems of its legal regulation"), (2005), http://www.cmbt.su/rus/publications/publication124.html (last visited in March, 2008).
[210] *Konstitusia Rossiiskoi Federasii*, the Constitution of Russian Federation, http://www.constitution.ru/en/10003000-03.htm (last visited in March, 2008).
[211] http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=005&CM=7&DF=3/23/2008&CL=ENG (last visited in March, 2008).
[212] Full name: Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine of 1997, and several protocols to it (Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings of 1998, Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin of 2002, Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research of 2005). Council of Europe's official web-site, list of the treaties coming from the subject-matter: "**biomedicine**", http://conventions.coe.int/Treaty/Commun/ListeTraites.asp?MA=9&CM=7&CL=ENG (last visited in March, 2008).

the Universal Declaration on the Human Genome and Human Rights of 1997[213] and the Universal Declaration on Bioethics and Human Rights of 2005[214]. Even though two of them are not binding on the member states of UNESCO (including Russia), however, they were adopted unanimously or by acclamation by the General Conference, where Russia expressed its positive attitude. Apart from the Council of Europe and the UNESCO, there is a Declaration of Helsinki (1964) adopted by General Assembly of World Medical Association (organization composed of physicians around the world, including Russian representative, Russian Medical Society)[215].

What is uniting all these international documents are the following principles in the research: need for informed consent, prohibition of financial gain, confidentiality, transparency of research results, ethical expertise of the research by the independent competent body etc[216]. So it means that Russia, despite the fact that it is not a member to international conventions and protocols in the framework of the Council of Europe, still need to observe the general principles which were codified in the declarations because it expressed its commitments during their adoption in the framework of UNESCO and World Medical Association (even though formally Russian Medical Society is not officially representing a state).

Federal Law goes after international agreements. There is a Federal Law on Fundamentals of Legislation of RF on Protection of Citizens Health of 1993, Section VI and VII of the given law contains provisions concerning the rights of patients, the need for informed consent in case of medical interference, women's right to artificial fertilization, the right for independent decision-making in the question of maternity etc[217]. Also it is established that any biomedical research

[213] The Universal Declaration on the Human Genome and Human Rights (1997), available at official website of UNESCO: http://portal.unesco.org/shs/en/ev.php-URL_ID=1881&URL_DO=DO_TOPIC&URL_SECTION=201.html (last visited in March, 2008).
[214] Available at official website of UNESCO: http://portal.unesco.org/.
[215] Official website of World Medical Association, http://www.wma.net.htm (last visited in March, 2008).).
[216] Hazova O.A., supra note 209.
[217] *Osnovy zakonodatelstva Rossiiskoi Federasii ob ohrane zdorov'ya grajdan* ("Fundamentals of Legislation of RF on Protection of Citizens Health of 1993"), Section VI-VII.

involving human being shall be conducted only by state or municipal institutions, after preliminary conducted laboratory experiment and with written informed consent of a patient[218].

There are some acts of federal level, which regulate some aspects of medicine, however, they does not cover both stem cells research and assisted reproduction methods in curing infertility[219]. Article 2 of Law "On transplantation of organs and/or tissues of human being of 1992" (in the edition of 2007) limit the applicability of the present Law to organs, its parts and tissues, which relate to the process of human reproduction, including reproductive tissues, as oocyte, sperm, ovary and embryos, also to blood and its components[220].

In order to have a broad picture of RF legislation on hESC, following issues will be covered.

3.1. Legislative approach to the notion "human being"

If to start from the determination of human being in Russian legislation, article 17 RF Civil Code, grants legal capacity only from moment of one's birth[221]. Voluntary abortion is not prohibited before the pregnancy term of 12 weeks (article 36 Federal Law on Fundamentals of Legislation of RF on Protection of Citizens Health)[222]. RF Criminal Code (article 106) recognizes as a murder deprivation of life only during or after delivering a child[223]. RF Ministry of Health Order 2003 # 67 "On Application of assisted reproductive technologies (ART) in therapy of female and male infertility" permits the reduction of

[218] Hazova O.A., supra note 209.
[219] Hazova O.A., supra note 209.
[220] *Zakon RF o transplantasii organov i (ili) tkanei cheloveka* ("Law of the Russian federation on transplantation of human organs and (or) tissues of 1992"), currently in force with amendments, http://ntc.duma.gov.ru/bpa/ (last visited in March 30, 2008).
[221] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L., *Perspektivy razvitia nasionalnogo zakonodatelstva rossiiskoi federasii v oblasti issledovania i primenenia stvolovyh kletok* ("Perspectives of development of RF national legislation in the area of research and application of stem cells"), (2007), http://gerontology-explorer.narod.ru/a506c11c-9336-4f82-a993-2c251ddf4f8f.html
[222] *Federalnii zakon ob osnovah zakonodatelstva Rossiiskoi Federasii ob ohrane zdorov'ya grajdan* ("Federal law on Fundamentals of Legislation of RF on Protection of Citizens Health of 1993"), art.36.
[223] *Ugolovnii Kodeks Rossiiskoi Federasii* ('RF Criminal Code of 1996'), article 106, available at: http://ntc.duma.gov.ru/bpa/ .

developing embryos during extra corporal fertilization if there is medical evidence for it and with the consent of expectant mother[224]. Thus legal capacity of embryos is not recognized according to Russian legislation, except the cases of heritance, when conceived child is born alive after the death of testator so that to be eligible to inherit[225]. Draft Law, which was going to introduce the recognition of legal capacity of human being from one's conception, was presented to the Parliament in 2003, however, rejected in 2004[226].

3.2. Legal regime of blood, organs and tissues of human being, and its elements

Article 1 of the RF Law "On transplantation of organs and/or tissues of human being" directly prohibits considering human organs and tissues as subject-matter of sale[227]. Donor has no right to gain financial compensation, however, can receive treatment in the health institution due to the conducted operation[228]. The same approach is built towards the regulation of blood of human being and its components (RF Law "On donated blood and its components")[229].

However there are no legislative limitations to any other biological materials. By default, trade of hairs, donated sperm is allowed for payment[230]. There is a principle "all is permitted, which is not explicitly prohibited". However still there are problems with the determination of property rights over embryos, sperms and other biological substances. In Russian legislation there is a legislative ban on commercial transaction in the relations, which can lead to the health harm or human death[231].

[224] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L, supra note 221.
[225] Id, cited in article 1088, 1089, 1116 of RF Civil Code.
[226] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L, supra note 221.
[227] *Zakon RF o transplantasii organov i (ili) tkanei cheloveka* ("Law of the Russian federation on transplantation of human organs and (or) tissues of 1992"), article 1, currently in force with amendments, http://ntc.duma.gov.ru/bpa/ (last visited in March 30, 2008).
[228] Id, see article 12.
[229] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L, supra note 221.
[230] Id.
[231] Id.

3.3. Procurement, storage and use of biological materials for medical purposes

There is a special RF Ministry of Health Order 2003, # 325 "On development of cellular technology in the Russian Federation", which is dedicated to stem cells research and RF Ministry of Health Order from 26.07.2002 №238 "On licensing of medical activity"[232]. However, the given Orders permit to grant license only for banks of umbilical/placenta blood. The Order # 325 established three documents: Instruction on procurement of umbilical/placenta blood for scientific and research purposes; Instruction on isolation and storage of stem cells from human umbilical/placenta blood and Regulation on stem cells bank from human umbilical/placenta blood[233]. For implementation of the given Order, on the level of each state of RF, for instance, Health department of Moscow city adopted Order # 702 (2003), which regulates the organization and activity of stem cells bank on the territory Moscow[234].

Moreover, it is necessary to mention RF Ministry of Health Order 2003 # 67 "On Application of assisted reproductive technologies (ART) in therapy of female and male infertility"[235]. The given Order covers broad frame of issues, related to the application of assisted reproductive methods, however, does not cover use of stem cells. Meanwhile Instruction, adopted for the implementation of the given Order, regulates the opportunity of donation of left-over oocytes, sperms and embryos after the completion of the extra corporal fertilization program. The Instruction permits also the donation of embryos, which were gained as the result of fertilization of donated oocyte with donated sperm. Unused embryos in compliance with the Instruction can be donated for married couple, and also single women.

[232] Davydova A.G., *Normativno-eticheskie aspekty primenenia stvolovyh kletok* ("Normative and ethical aspects of stem cells application"), http://gerontology-explorer.narod.ru/51eedaf6-fb7b-41d9-85a4-4c776f1ed6d9.html
[233] Id.
[234] Id.
[235] Id.

Willingness of a person to undergo corresponding procedures is regarded as general agreement for any further use of biological material. The given regulation poses danger, first of all, due to the vague formulation, which can lead to uncontrolled use of the given materials, secondly, due to the fact that it is not regulated by federal laws, but rather by-laws of ministries and agencies[236].

3.4. Prohibition of reproductive cloning

The Law on the Temporary Prohibition of Human Cloning was adopted as Federal law, by initiative of the RF Government, by Federal Assembly and signed by the RF President on May 20, 2002[237]. This initiative was stipulated by need for limitation of attempts of reproductive cloning, until the increase of knowledge in biomedicine, development of prognosis methods of risk-assessment of genetic consequences of cloning, and until the final decision on social appropriateness and ethical acceptability of human cloning[238].

Specifically Law prohibits creation of "a human being, genetically identical to another one, dead or alive, by means of implantation of a human body cell into a female gamete preliminarily deprived of its nucleus"[239]. However moratorium does not apply to cloning for therapeutic purposes[240]. Also it is prohibited to import or export any cloned human embryos[241]. Any breach of the above mentioned Law leads to the prosecution under Federal law[242]. However, neither Criminal nor Administrative Codes does include any specific punishment for such acts[243].

[236] Id.
[237] Id.
[238] Id.
[239] *St. 2 Zakona RF "O vremennom zaprete na klonirovanie cheloveka"* ("Art.2 of the Federal Law of Russian Federation on Temporary prohibition of reproductive cloning of 2001").
[240] Hazova O.A., supra note 209.
[241] *Zakon RF "O vremennom zaprete na klonirovanie cheloveka"*, art.3.
[242] Id, art. 4.
[243] UNESCO, *National Legislation concerning Human Reproductive and Therapeutic Cloning* (2004), http://unesdoc.unesco.org/images/0013/001342/134277e.pdf (last visited in March, 2008).

The Law was adopted only for five years and from 2007 it was supposed to be no longer applicable, but still this Law is in force without amendments[244].

3.5. Therapeutic cloning

RF federal Law from July 15, 1996 # 86 "On state regulation of genetically engineered activity" created legal basis for scientific development in gene therapy[245]. As Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L argue therapeutic cloning is one of gene therapies. Thus scientific developments in the area of creation of human organ cells and tissues by transfer of nucleus of human somatic cell into female germ cell have great positive effect. Transplantation of cells, created in such manner, enables to differentiate into cells of any tissues of adult organism, is considered as one of the possible means to cure serious somatic and hereditary diseases[246].

3.6. Egg donation

In Russian Federation the regulation of egg donation for hESC research poses some confusion due to the lack of specific regulation. However the answer could be found in article 6 (2) of the Civil Code of the Russian Federation which sets the rule of application of civil legislation in case of gaps in legislation[247]. These gaps are filled through the application of: (1) law, regulating the analogous relations; (2) purposes and goals of civil legislation and requirements of the principle of bona fide, reasonableness and honesty[248]. However, there are certain pre-conditions to be fulfilled before its application: lack of regulation of corresponding relations by legislation or by agreement of parties, absence of business custom,

[244] You can find the law without any amendments, which is still in force at: http://ntc.duma.gov.ru/bpa/ (last visited in March 30, 2008).
[245] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L, supra note 221, cited in *Federalnii zakon O gosudarstevnnom regulirovanii v oblasti genno-injenernoi deyatelnosti*" (RF Federal Law "On state regulation of genetically engineered activity of 1996").
[246] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L., supra note 221.
[247] *Grajdanskii Kodeks RF* ("Civil Code of Russian Federation of 1994"), article 6(2), currently in force without amendments, http://ntc.duma.gov.ru/bpa/ (last visited in March 30, 2008).
[248] Institute of legislation and comparative jurisprudence under the Government of Russian Federation (ed. O. Sadikov), *Kommentarii k Grajdanskomu Kodeksu* RF ("Commentary to the Civil Code of Russian Federation"), article 6 (1995).

presence of analogous legislation, and also its consistency to the essence of corresponding relations[249]. Therefore on the basis of what have been said one can refer to RF Ministry of Health Order "On the Application of assisted reproduction technologies (ART) in therapy of female and male infertility" for an answer which particularly states that donation of oocytes is implemented through informed consent of donors[250]. Also donors of oocytes can be only persons of the age 20-35, with one's own child, with non-existence of explicit phonotypical manifestations and of good somatic health[251]. There is no mention about the financial compensation, which leaves choice open for clinics.

Apart from the given Order, it is possible to apply the provisions of two non-binding sources of law: Ethical code of Russian doctor and Code of doctoral ethics of Russian Federation[252]. Article 11 of the Ethics code of Russian doctor adopted by the Assembly of doctors of RF states that there should be informed, recognized and voluntarily consent of the donor as well as refusal. Code of doctoral ethics of Russian Federation adopted by the doctors at Over-Russian Pirogov Assembly in 1997 requires explicitly expressed consent of donor after he/she is aware of the purpose, methods, potential benefits and possible risks of the research[253].

Law on transplantation of human organs and (or) tissues grants more protection to donors. But it is impossible to apply its provisions due to the explicit exclusion of reproductive tissues from its applicability[254].

[249] Id , article 6.
[250] *Prikaz Ministertva zdravoohranenia 2003 No. 67 o primenenii vspomogatelnyh reproduktivnyh tehnologii v terapii jenskogo i mujskogo besplodia* ("RF Ministry of Health Order 2003 No. 67 "On the Application of assisted reproduction technologies (ART) in therapy of female and male infertility"), http://www.inpravo.ru/data/base282/text282v646i228.htm (last visited in March 30, 2008).
[251] Id.
[252] *Eticheskii kodeks rossiiskogo vracha* ("Ethical code of Russian doctor") and *Kodeks vrachebnoi etiki RF* ("Code of doctoral ethics of Russian Federation"), available at: http://stem-cells.ru/ .
[253] *Kodeks vrachebnoi etiki RF* ("Code of doctoral ethics of Russian Federation)' Section 5 (1) on scientific research and biomedical experiments (1997).
[254] *Zakon RF o transplantasii organov i (ili) tkanei cheloveka cheloveka* ("Law of the Russian federation on transplantation of human organs and (or) tissues of 1992"), currently in force with amendments, http://ntc.duma.gov.ru/bpa/ (last visited in March 30, 2008).

In the report "Replies by the member states to the questionnaire on access to medically assisted procreation (MAP) and on right to know about their origin for children born after MAP» of the Steering Committee of Bioethics (CDBI) of the Council of Europe, RF gave the following official reply to the question 'Are there specific compensation arrangements for such donation(s) (e.g. financial compensation, reduced fees for a MAP procedure in the case of oocyte donation)?':

> Sperm donors are compensated. With regard to compensation for oocyte or embryo donation the situation is not quite clear. It all depends on a particular IVF clinic; some clinics practice reduced fees for a MAP procedure in case of oocyte or embryo donation. Egg donors are sometimes directly paid, and the price varies significantly dependently on the region and a particular clinic.[255]

RF Legislation in research and use of human biological materials, including stem cells, is spontaneous, is not formulated by one common system, does not guided by one general principle, thus can be concluded that intuitively coming from the concept of 'least harm'[256].

[255] Steering Committee of Bioethics, *Replies by the member states to the questionnaire on access to medically assisted procreation (MAP) and on right to know about their origin for children born after MAP* (2005).
[256] Miheeva L. U., Portnov I. G., Balezin S.L., Lisovskii D.L., supra note 221.

Conclusion

hESC is relatively a new area in biomedicine, which at the same time raises ethical questions. The focus of the present paper has been the legislation of the United States, the European Union and the Russian Federation that regulates main issues in this area.

However the thesis in its comparative analysis of three legal regimes, were limited by considering only the regulation on the federal level. The analysis of hESC legal regime in the European Union and the United States has been taken together due to the relative advanced legislation in this area. For the simplification of such a complicated legal issue as hESC research the comparison has been undertaken through the prism of such issues as (1) *in vitro* v. *in vivo* embryos, (2) surplus v. newly created embryos, (3) harvesting, (4) using of hESC (5) patenting of hESC, (6) egg donation and (7) freedom of research. The research has shown that, it is important to take into account that the European Union and the United States are federal entities, therefore such principles as pluralism, subsidiary and proportionality prevail, limiting the regulation of hESC research by federal funding.

It is possible to say that the EU and the US have similar legal regimes in terms of excluding the creation of new hESC and hESC lines from federal funding. If we do not consider federal funding, any research involving the creation of hESC as such is legal both in the US and in the EU. There are some peculiarities in each of the states. (in case of the EU, only if it does not contradict the national legislation and ethical considerations of the member state where the research is conducted), while the EU does not fund any research *per se* which involves stem cells procurement. The US has a different approach in terms of permitting research only on those hESCs derived prior to August 9, 2001. Patenting and freedom of research are interrelated issues because freedom of research mostly depends on the degree of protection granted by intellectual property rights law, including patent law. In the US if freedom of research qualifies as one of the fundamental liberties then there is strict scrutiny

applied. And in the EU freedom of research is covered by the law on patenting. The EU regulates patenting through its European Union 1998 Directive on the legal protection of biotechnological inventions on patenting, which contains such pre-conditions to fulfill as novelty, inventive step and industrial application. Thus, first, hESC or hESC lines should qualify either as product or as process. Second, only invention is granted patent, not just discovery. In addition, industrial or commercial application of invention should not be in place. The US has almost the same patent requirements but formulated in other words: novelty, usefulness and non-obviousness. However, the most problematic pre-condition is morality clause. The US Patent Act does not contain any morality clause, however, later Weldon Amendment was adopted, which excluded the patentability of an invention "related […] to a human organism". The given formulation is vague and subject to interpretation by the US courts and PTO. As regards the EU, the Directive includes morality clause, but which is also subject to the interpretation by EU member states.

Analysis of the Russian legislation showed that Russia legally regulates only stem cells derived from blood/placenta blood. By default hESC research can be considered as an area permitted on the basis of the general principle "everything is permitted which is not explicitly prohibited". Moreover, there is a federal law "On state regulation of genetically engineered activity", which gives the legislative basis for conduct of any research in gene therapy", where one of its types is therapeutic cloning. There is also the concept of the least harm traditionally used in Russian legislation, which can be applied in cases of gaps in legislation. Additionally there are some non-binding international documents, which oblige Russia to comply with, on the basis of which some soft law on ethics has been adopted on the national level.

Having done the comparative analysis I have come to the following conclusion. Both the EU and the US have total ban on federal funding of stem cells procurement, including

hESCs. However, the US unlike the EU, in the usage of derived hESCs sets time limits: only those derived before August 9, 2001. That was the main difference between the above-mentioned two jurisdictions. The analysis of the Russian Federation law on hESC has brought many difficulties, because it is almost absent. Thus, the approach was taken differently from the EU and the US. The Russian legislation as it was mentioned earlier has no specific regulation on hESC research, but still is considered as an area not prohibited based on general principles of law, some indirect legislation and soft laws adopted for regulation of broader areas of biomedicine. Apart from it, on the international level there are some non-binding international documents, which were adopted unanimously with the participation of Russia.

The thesis argues that both the EU and the US can be a starting model for Russia to follow depending on what core values Russia adheres. From (1) the legislative overview of Russian legislation and (2) Russian voting in adoption of many declarations on the international level, it can be generalized that Russia does eager to develop this new area of biomedicine. Many local and foreign scientists and practitioners who are carrying out their activity in Russia have many opportunities to freely conduct researches. However, the worst side of such freedom is the consequences of lack of regulation. Therefore for Russian it is recommended to have a legislation on hESC, so that to eliminate future commercialization of biological materials, especially reproductive cells and embryos in their early stage. The EU and the US serve as models only in terms of state financing of hESC research. The EU and the US models are also far from the excellence, however, at the present time it is effective due to great amount of investment necessary to carry out that kind of research and not readiness and inability of private individuals to invest in this risky area. In addition, the US and the EU are not empowered on the federal level to regulate more than federal funding of hESC research. The thesis admits that Russia is not fully covered due to the limitations set for MA thesis. However, it is a good basis for any further deep research.

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