



**FACULTY OF LAW**  
**Lund University**

**Salome Khachiauri**

**Human Embryonic Stem Cell  
Controversy (Patents Involving  
Ethical and Human Rights Concern)**

**Master thesis**  
**30 credits**

**Dr. Anna Maria Andersen Nawrot**

**Master's Programme in International Human Rights  
Law and Intellectual Property Law**

**Spring 2012**

# Contents

|  |           |
|--|-----------|
| <b>SUMMARY.....</b>  | <b>1</b>  |
| <b>PREFACE.....</b>  | <b>2</b>  |
| <b>ABBREVIATIONS.....</b>  | <b>4</b>  |
| <b>1 INTRODUCTION.....</b>   | <b>6</b>  |
| <b>1.1 OVERVIEW.....</b>   | <b>6</b>  |
| <b>1.2 OUTLINE.....</b>  | <b>7</b>  |
| <b>1.3 METHODOLOGY.....</b>  | <b>7</b>  |
| <b>2 HUMAN EMBRYONIC STEM CELLS AND ITS POTENTIAL... </b>  | <b>8</b>  |
| <b>2.1 WHAT ARE HUMAN EMBRYONIC STEM CELLS?.....</b>   | <b>8</b>  |
| <b>2.1.1 BASIC SCIENCE OF HES CELLS.....</b>   | <b>9</b>  |
| <b>2.2 HES CELL RESEARCH AND ITS POTENTIAL.....</b>  | <b>9</b>  |
| <b>2.3 WHY IS HES CELL RESEARCH SO CONTROVERSIAL?...</b>   | <b>11</b> |
| <b>3 HES CELL RESEARCH AS INTERNATIONAL PUBLIC CONCERN, ETHICS AND OTHER RELATED ISSUES.....</b> | <b>14</b> |
| <b>3.1 ETHICS AS A CONCEPT AND ITS INTERLINK WITH LAW</b>  | <b>14</b> |
| <b>3.2 HUMAN RIGHTS AND ETHICS (BIOETHICS).....</b>  | <b>17</b> |
| <b>3.2.1 THE CONCEPT OF HUMAN DIGNITY IN HUMAN RIGHTS DISCOURSE.....</b>                         | <b>17</b> |
| <b>3.2.2 UNESO DECLARATION ON BIOETHICS AND HUMAN RIGHTS (UDBHR).....</b>                        | <b>22</b> |
| <b>3.3 ETHICS OF HES CELLS (IS AN EARLY EMBRYO PROTECTABLE HUMAN LIFE?).....</b>                 | <b>24</b> |

|   |    |
|---|----|
| 3.4 ETHICS OF HES CELL PATENTS.....   | 27 |
| 3.5 OTHER RELATED ISSUES- FEMINIST APPROACH.....                                | 29 |
| 4 HES CELL PATENTS IN INTELLECTUAL PROPERTY LAW...                              | 31 |
| 4.1 BASICS OF PATENT LAW AND PATENTABILITY<br>CRITERIA.....                     | 31 |
| 4.2 INTERNATIONAL LEGISLATIVE FRAMEWORK FOR<br>PATENTS.....                     | 33 |
| 4.2.1 PARIS CONVENTION.....   | 34 |
| 4.2.2 PATENT COOPERATION TREATY (PCT).....                                      | 34 |
| 4.2.3 TRIPS AGREEMENT.....  | 35 |
| 4.3 HES CELL PATENTS IN US AND EUROPE<br>(COMPARATIVE<br>STUDY).....            | 36 |
| 4.3.1 EUROPEAN PATENT CONVENTION (EPC).....                                     | 36 |
| 4.3.2 US PATENT ACT (GENERAL OVERVIEW OF PATENT<br>LEGISLATION IN US).....      | 37 |
| 4.3.3 HES CELL PATENTS IN US.....   | 39 |
| 4.3.4 HES CELL PATENTS IN EUROPE.....   | 41 |
| 4.3.5 COMPARISON BETWEEN EUROPEAN AND US<br>APPROACHES TO HES CELL PATENTS..... | 44 |
| 5 HES CELL PATENTS AND HUMAN RIGHTS.....  | 46 |
| 5.1 RELATIONSHIP BETWEEN HRS AND IPS(TOWARD HRS<br>FRAMEWORK FOR IP).....       | 46 |
| 5.2 HRS RELATED ISSUES IN HES CELL DEBATE.....                                  | 50 |
| 5.2.1 IP ISSUES ADDRESSED IN INTERNATIONAL HRS<br>INSTRUMENTS.....              | 50 |

|   |    |
|---|----|
| 5.3 INTRODUCTION OF RIGHT TO LIFE ARGUMENTS IN HES CELL DEBATE..... | 52 |
| 5.3.1 RIGHT TO LIFE (INTERNATIONAL LEGAL FRAMEWORK).....            | 52 |
| 5.3.2 RIGHT TO LIFE ARGUMENTS.....                                  | 55 |
| 6 CASE LAW ANALYSIS.....  | 59 |
| 6.1 EUROPEAN CASE LAW RELATED TO HES CELL PATENTS.....              | 59 |
| 6.1.1 WARF CASE.....  | 59 |
| 6.1.2 ECJ CASE BANNING HES CELL PATENTS IN EUROPE.....              | 61 |
| 6.2 CASE LAW RELATED TO THE LEGAL STATUS OF UNBORN.....             | 64 |
| 6.2.1 ANALYSIS OF CASE LAW OF ECTHR.....                            | 65 |
| 6.2.1.1 VO. V. FRANCE.....  | 66 |
| 6.2.1.2 TYSIAC V. POLAND.....                                       | 68 |
| 6.2.1.3 A.B.C. V. IRELAND.....                                      | 70 |
| 6.2.2 ROE V. WADE (LANDMARK CASE IN US).....                        | 74 |
| 6.3 THE FINDINGS OF CASE LAW ANALYSIS.....                          | 75 |
| 7 CONCLUSIONS.....  | 77 |
| BIBLIOGRAPHY.....   | 79 |
| TABLE OF CASES.....   | 85 |

# Summary

Present thesis concerns one of the controversial topics of this era - the embryonic stem cell debate, more precisely in connection with their patents, ethics and human rights. The thesis deals with various alternative opinions that make this issue a hot topic. While different viewpoints will be discussed, I bring up human rights issues into this debate, which will emphasize a possible conflict between embryonic stem cell patents and human rights. This thesis aims to introduce human rights perspective into the patent laws in regards to the embryonic stem cell research. Other than that, the thesis will highlight the importance of ethics in this discussion, which has to lead into the reflection of some ethical aspects in intellectual property legislation. Hence, the thesis addresses embryonic stem cell debate and suggests the consideration of human rights and ethical perspectives in intellectual property law, resulting in building human rights framework for the Intellectual Property law.

**KEYWORDS:** Embryonic stem cell, patents, ethics, bioethics, human rights, intellectual property, right to life of unborn, human dignity.

# Preface

This master thesis shows my personal worries about the specific issue. Since I tend to write this thesis in the light of respecting dignity of all humans and right to life of unborn, I dedicate this work to all the children of the world.

Firstly, I want to give a big thanks to my precious parents, little brother, my dearest grandma, uncle and other closed ones, who were the main supporters during the whole study period.

Secondly, I would like to thank my supervisor Dr. Anna Maria Andersen Nawrot, for letting me be who I am and bring the best out of me.

Thirdly, I would like to give a big thanks and appreciation to Mr. and Mrs. Kurkus, who handed helping hand and were supportive in many possible ways. I will be always grateful and will always remember them as my family in Sweden.

Fourthly, I want to thank the RWI for giving me a chance to use the wonderful library for my studies.

Fifthly, I send my regards to the Lund University, Faculty of Law for giving me a chance to be part of the two-year amazing professional and life experience.

And finally, I thank all my close beloved friends, who were supporting me from very far.

*Salome Khachiauri*

Lund, Sweden  
May 2012

# წინასიტყვაობა

ეს სამაგისტრო ნაშრომი გამოხატავს ჩემს პირად წუხილს აღნიშნულ საკითხთან დაკავშირებით. ვინაიდან ამ ნაშრომს ვწერ ადამიანის ღირსებისა და ემბრიონის სიცოცხლის უფლების პატივსაცემად, იგი ეძღვნება ყველა ბავშვს მსოფლიოში.

უპირველესად, მინდა მადლობა გადავუხადო ჩემს ძვირფას მშობლებს, პატარა ძმას, ჩემს საყვარელ ბებიას, ბიძას და ყველა ჩემს ახლობელ ადამიანს, რომლებიც გვერდით მედგნენ მთელი სწავლის პერიოდში.

ასევე მადლობას ვუხდის ჩემი თემის ხელმძღვანელს დოქტორ ანა მარია ანდერსენ ნავროტს, რომელმაც საშუალება მომცა წარმოემჩინა თავი ისეთი, როგორც ვარ.

დიდ მადლიერებას გამოვხატავ ბატონი და ქალბატონი კურკუსების მიმართ, რომლებმაც გამომიწოდეს დახმარების ხელი და მხარს მიჭერდნენ ყველა შესაძლო გზით. მე ყოველთვის მადლიერი ვიქნები მათი და მემახსოვრება ისინი როგორც ჩემი ოჯახი შევდეთში.

აგრეთვე მადლობას ვუხდის რაულ ველენბერგის ადამიანის უფლებათა და ჰუმანიტარული სამართლის ინსტიტუტს, რათა მქონდა შესაძლებლობა მეხელმძღვანელა მათი მდიდარი ბიბლიოთეკით.

უდიდეს მადლიერებას გამოვხატავ ლუნდის უნივერსიტეტის, სამართლის ფაკულტეტის მიმართ, რომელმაც მომცა საშუალება მიმეღო ორ წლიანი არაჩვეულებრივი პროფესიული და ცხოვრებისეული გამოცდილება.

და ბოლოს, მადლობას ვუხდის ყველა ჩემს მეგობარს, რომლებიც მიუხედავად შორი მანძილისა მთელი სულით და გულით მედგნენ მხარში.

*სალომე ხაჩიაური*

ლუნდი, შვედეთი  
მაისი, 2012

# Abbreviations

|                   |   |
|-------------------|---|
| ACHPR             | African Charter on Human and Peoples' Rights  |
| ACHR              | American Convention on Human Rights   |
| Biotech Directive | Directive 98/44/EC of European Council on the Legal Protection of Biotechnological Inventions |
| CAT               | Convention against Torture and Other Cruel, Inhuman and Degrading Treatment                   |
| CEDAW             | Convention on the Elimination of All Forms of Discrimination against Women                    |
| CESCR             | Committee on Economic, Social and Cultural Rights   |
| CRC               | Convention on the Rights of Child   |
| DNA               | Deoxyribonucleic Acid   |
| DRC               | Declaration on the Rights of the Child (1959)   |
| EBoA              | Enlarged Board of Appeal of the European Patent Office  |
| EC                | European Community  |
| ECHR              | European Convention for the Protection of Human Rights and Fundamental Freedoms               |
| ECJ               | European Court of Justice   |
| ECtHR             | European Court of Human Rights  |
| EPC               | European Patent Convention  |
| EPO               | European Patent Office  |
| EU                | European Union  |
| hES               | Human Embryonic Stem  |
| HHS               | Department of Health and Human Services of the United States of America                       |
| HRs               | Human Rights  |
| ICESCR            | International Covenant on Economic, Social and Cultural Rights                                |
| ICCPR             | International Covenant on Civil and Political Rights  |
| IP (Rs)           | Intellectual Property (Rights)  |
| iPS               | Induced Pluripotent Stem  |
| Paris Convention  | Paris Convention for the Protection of Industrial Property                                    |

|                 |   |
|-----------------|---|
| NIH             | National Institutes of Health of the United States of America |
| PCT             | Patent Cooperation Treaty                                     |
| TRIPS Agreement | Trade-Related Aspects of Intellectual Property Agreement      |
| UDBHR           | Universal Declaration on Bioethics and Human Rights           |
| UDHR            | Universal Declaration of Human Rights                         |
| UK              | United Kingdom  |
| UKIPO           | Intellectual Property Office of the United Kingdom            |
| UN              | United Nations  |
| UNESCO          | United Nations Economic, Social and Cultural Organization     |
| US              | United States of America                                      |
| USPTO           | United States Patent and Trademark Office                     |
| VCLT            | Vienna Convention on the Law of Treaties                      |
| WARF            | Wisconsin Alumni Research Foundation                          |
| WIPO            | World Intellectual Property Organization                      |
| WTO             | World Trade Organization                                      |

# 1 Introduction

## 1.1 Overview

The era where we live now, is era of advanced technologies and research. The development of new technologies and biological research has been going on so rapidly, that pretty soon, humans will be able to cure or prevent many crucial diseases affecting the population of the world. However, how far can technology go? When we address this issue is matter of individual understanding. An opinion in regards to this aspect will be influenced by individual perceptive of the subject, for instance, some scientists in the field of biology will be in favor of doing as much as possible to find new breakthrough ways in biotechnology and research. Maybe, for example, legal scholars will be influenced by the legal norms and legal way of reasoning or a person belonging to religious group, will be prejudiced by the principles of the religion he/she believes in.

The purpose of this paper is to address one of the most debatable topics, concerning the human embryonic stem cell controversy, addressing patents that involve ethical and human rights concern. Firstly, since this matter is quite sensitive in a way, I will try to bring up some arguments influenced with different opinions on this subject matter. My goal is not to be on the one side of the flow of argumentation, but to show, how important this issue is and how can it be possibly addressed from different perspectives.

Secondly, the aim of the thesis is to show the possible clash between intellectual property law and human rights in regards to human embryonic stem cells. And also to address the essential ethical issues, which need to be taken into consideration.

Hence, my thesis deals with human embryonic stem cell and its patents, covered from possible ethical, human rights and intellectual property perspectives. Thus, the research brings up the issues that indicate the possible clash between human rights law and intellectual property law and on the other hand, ethics and intellectual property law. Therefore, these are the research questions of this master thesis: are human embryonic stem cell patents violating human rights; more precisely is it contrary to the idea of “human dignity” and right to life? And are this research and its patents contrary to ethical norms? And if the answer to these questions is yes, can we argue that there is a clash between human rights norms and intellectual property? And if it is the case, what can be possible solutions to this inconsistency?

## 1.2 Outline

Following the Introductory chapter, the Chapter 2 is basically based on the scientific information concerning human embryonic stem cells. This chapter aims to have the basic understanding of the issue from technical biological/scientific perspective. This chapter will discuss embryonic stem cell research itself and its potential etc.

The Chapter 3 aims to introduce main controversy in embryonic stem cell debate, precisely deals with main ethical issues.

The Chapter 4 intends to bring up the intellectual property issues, which will mainly discuss various patent laws, this chapter will introduce main patentability criteria set by different legislations and will discuss important international treaties in the field of patents. This chapter will also address the issue from comparative viewpoint and will invoke comparison between regional approaches, in particular will make comparison between European and US legislation.

The Chapter 5 will address the human rights discussion into the topic. This chapter will analyze the relationship between human rights and intellectual property law, and will introduce arguments about the possible clash between human rights and intellectual property, in connection to human embryonic stem cell research and its patents.

The Chapter 6 will basically provide functional part of the thesis, analyzing the landmark cases relevant for the current topic.

And lastly, the Chapter 7 will serve as the final section, emphasizing the closing remarks, possible solutions and conclusions for the whole debate in the thesis.

## 1.3 Methodology

This research is dealing with many theories in the fields of law, science and ethics. This thesis, will also involve the theories concerning the relations between human rights and intellectual property. In order to answer research questions historical, critical and legal analysis is conducted. Hence, the sources include various legal publications, such as books and articles. The thesis also covers many international and regional legal acts in the field of intellectual property law. The research analyzes the human rights instruments and provides the interpretation of the provisions of these instruments. Moreover, to have the clear picture of the current practice, the thesis provides the case law. Other than these, reference the thesis is based on is the information gathered on online sources.

# 2 Human Embryonic Stem Cell Research and Its Potential

## 2.1 What are Human Embryonic Stem Cells?

‘Stem cells have the capacity for prolonged self-renewal and can produce at least one type of highly differentiated or specialized descendent. In adults, they are present in many tissues, blood and skin, for example. They enable the body to regenerate tissues or cells such as bone marrow. Until recently, it was commonly assumed that stem cells from specific tissues could generate only tissues of those types; hence, they were understood to be powerful in capability, but limited in direction.’<sup>1</sup> In general, stem cells can be divided into three types: embryonic (fetal) stem cells; umbilical cord stem cells<sup>2</sup> and adult stem cells.<sup>3</sup>

Characteristics of the stem cells differ in the case of adults and embryos. These differences make the human embryonic stem cells (hES cells) more unique compared to the adult stem cells. More precisely, ‘cells of the early embryo are not limited in the way that adult stem cells were assumed to be. As the fertilized egg divides, each cell is able to be separated out and form an entire new organism. Hence these cells (or blastomeres) are *totipotent*<sup>4</sup>- they have potential to form any and all human tissues and to become a complete organism. At the point at which dividing cells develop into a hollow ball, the embryo is called blastocyst<sup>5</sup>. The hES cells are derived by destroying the outer shell of the blastocyst, which would normally become the placenta, and culturing cells from inner cell mass.’<sup>6</sup>

As mentioned earlier, ‘the hES cells are important because they have certain critical characteristics. Most important they are *pluripotent*- they are able to develop into many types of tissues. They are also *immortal*- able to continue dividing indefinitely without losing genetic structure. Moreover, hES cells are *malleable*- they can be manipulated without losing the cell

---

<sup>1</sup> S. Holland, K. Lebacqz & L. Zoloth, (eds.), *The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy*, (MIT Press, Cambridge, Mass., 2001) p.xvii.

<sup>2</sup> Umbilical Cord Stem Cells-the blood from the umbilical cord contains stem cells which are multipotent, meaning that they can differentiate into only a limited range of cell types.

<sup>2</sup> A. Biswas & R. Hutchins, *Embryonic Stem Cells*, (Stem Cells and Development Vol. 16, 2007) pp.213-221, p.214.

<sup>3</sup> *ibid.*

<sup>4</sup> Totipotent –*in biology*: (of an immature or stem cell) capable of giving rise to any cell type or (of a blastomere) a complete embryo:totipotent embryo cells can differentiate into a hundred different cell types specialized to form such tissues as skin, marrow, and muscle.

<sup>5</sup> Blastocyst-*in embryology*: a mammalian blastula in which some differentiation of cells has occurred.

<sup>6</sup> Biswas & Hutchins, *supra* note 2, p.214.

function. Indeed, studies with animal stem cells suggest they can be moved into another blastocyst and it will continue development.<sup>7</sup>

Thus, all above-mentioned characteristics make these cells very important for developing medical science. 'Put simply, because hES cells appear to be able to become any kind of tissue, once mechanisms for differentiation are understood, they might provide banks of skin, bones, liver and other tissues to repair or replace body parts.'<sup>8</sup>

In order to have a clear idea what are hES cells and how they are derived, it is necessary to understand the process by simple basic scientific excursion, which will be provided by next sub-chapter.

## 2.1.1 Basic Science of hES Cells

What is hES cell and how is it produced? 'Fertilization normally occurs in the oviduct, and during the next few days a series of cleavage divisions occurs as the embryo migrates down the oviduct and into the uterus. All of the cells (blastomeres) of these cleavage-stage embryos are undifferentiated; that is, they do not look or act like the specialized cells of the adult, and the blastomeres are not committed to becoming any particular type of differentiated cell. Indeed, each blastomere has the potential to form any cell of the body. The first differentiation event occurs at about five days of development when an outer layer of the cells committed to become part of the placenta (trophoblast) separates from the inner cell mass (ICM). The ICM cells maintain the potential to form any cell of the body.'<sup>9</sup>

After fertilization one-cell embryo forms a blastocyst, at about six days of development. The blastocyst is a sphere of about 150 cells, with an outer layer (the trophoblast), a fluid-filled cavity (the blastocoel), and a cluster of cells on the interior (the inner cell mass).<sup>10</sup> The hES cells are derived from the inner cell mass (ICM). 'Human ES cell lines were derived from blastocyst-stage pre-implantation embryos produced by in vitro fertilization.'<sup>11</sup>

## 2.2 hES Cell Research and Its Potential

The new millennium has brought with it extraordinary advances in biomedical sciences. Among these outstanding advancements is successful derivation of the hES cell, a self-renewing cell line that gives rise to all cells and tissues of the body. The potential of these cells is to allow permanent repair of failing organs by injecting healthy functional cells

---

<sup>7</sup> *ibid.*

<sup>8</sup> *ibid.*, p.xviii.

<sup>9</sup> *ibid.*, p.15.

<sup>10</sup> For more information please visit: <<http://stemcells.nih.gov/info/cellmovie.htm>> visited on October 20, 2011.

<sup>11</sup> Holland, *supra* note 1, p.18.

developed from them, this approach is called regenerative medicine.<sup>12</sup> Simply, if a person loses or damages a lung during the car accident, the new lung will be created and transplanted through using stem cells. Most stem cells have limited potential to form only certain differentiated progeny cells. For instance, ‘hematopoietic cells<sup>13</sup> can produce only blood cells, skin cells can produce only skin cells, and so on ‘.

The only certain exception is the embryonic stem cell, which can give rise to literally all cells and tissues of the body.<sup>14</sup> For this reason, hES cells are called pluripotent cells which means that under the right circumstances, a stem cell that is isolated from an embryo can produce almost all of the cells in the body.<sup>15</sup> Another essential trait of hES cells is its ability to renew and to divide into other cells. ‘Because of pluripotency and infinite self-renewal, hES cells are perhaps the most extraordinary cells ever discovered.’<sup>16</sup>

A goal of this research is to cure various diseases, including heart diseases, along with, Parkinson’s, diabetes and some forms of cancer. As a small example, let us take diabetes, which is one of the widespread diseases of all time. The person who has insulin-dependent diabetes has to take insulin injections in order to maintain normal glucose level in the blood. ‘Researchers showed that mouse embryonic stem cells can produce functional insulin-secreting cells that when purified and transferred to diabetic animals, restored normal glucose balance within a week.’<sup>17</sup>

These early studies are encouraging, yet many problems remain.<sup>18</sup> How will this advancement look like in reality is still under question. Since, there’s a possibility of various implications, such as immune rejection of transplanted organs created with stem cells, etc.

According to Thomas B. Okarma, this hES research can solve many existing problems in today’s biology and medicine. This research can provide a chance to improve the biomedicine in general. Firstly, it will help the scientists to understand human reproductive and development biology better. The research will assist to learn the reasons for female fertility disorders, premature pregnancy losses etc. Secondly, the research will help to identify potential teratogens (compounds that induce fetal abnormalities). Hence, hES cell screening can be used “to identify and study environmental toxins and pharmaceuticals that could cause abnormalities.”<sup>19</sup> Thirdly, with help of hES cells, “it will soon be possible to develop normal lines of cells that represent specific tissues and organs for testing the toxicity of new or existing drugs. Fourthly, hES cells will

---

<sup>12</sup> *ibid.*, p. 3.

<sup>13</sup> Hematopoietic cells are those cells that are lodged within the bone marrow, and which are responsible for producing the cells which circulate in the blood (red blood cells, white blood cells, and platelets).

<sup>14</sup> Holland, *supra* note 1, p. 5.

<sup>15</sup> For detailed information please visit:

<<http://www.explorestemcells.co.uk/pluripotentstemcells.html>> visited on October 21, 2011.

<sup>16</sup> Holland, *supra* note 1, p.xvii.

<sup>17</sup> *ibid.*, p.9.

<sup>18</sup> *ibid.*, p.10.

<sup>19</sup> *ibid.*, p.7.

be widely used in regenerative medicine, because it has the potential to cultivate new organs for transplantation and they can be produced in large quantities in the laboratory under standard conditions.” Other potential use of hES cells are generating human cardiomyocytes from them for therapy of congestive heart failure and myocardial infarction.<sup>20</sup> The one of the most important hopes for this research is to cure one of the widespread diseases -insulin dependent diabetes. Researchers showed that mouse embryonic stem cells can produce functional insulin-secreting cells that, transferred to diabetic animals, restored normal glucose balance within a week and normal body weight within a month. And lastly, the most near-term clinical application of hES cell lies in the treatment of neurologic disease. This can cure the neurologic diseases such as Parkinson’s and Alzheimer’s. Hence, in animal experiments, neural cells derived from the mouse embryonic stem cells and injected into sites of spinal cord damage appropriately integrated into the damaged area and resulted in partial recovery of paralysis. Therefore, the researches show that hES cells can partially restore lost function of the central nervous system.<sup>21</sup>

Thus, the scientists see the great future for the improvements in the medical care, but there are still some problems that need to be solved. Even though early studies are promising, there are many issues that need to be taken into consideration. One of the most problematic matters relates to immune rejection of transplanted differentiated cells and thus, tissue matching and immunosuppressive strategies would be required to control the rejection of transplanted cells.<sup>22</sup> Also, ‘because hES cell-based transplantation therapies are new and unproved, it will be essential to demonstrate their safety and efficacy in a accurate animal model. Rhesus monkey ES cells are very similar to hES cells and rhesus monkeys share a close evolutionary and physiologic relationship with humans.’<sup>23</sup>

To conclude, even though this research is potentially promising, there are many other issues which are emerging and they need to be taken into account. Another thing is how easily achievable is everything in reality and what will be the real results in the end.

## 2.3 Why is the hES Cell Research so Controversial?

‘Embryonic stem cell research has been source of ethical, legal, and social controversy since the first successful culturing of hES cells in the laboratory in 1998. The controversy has slowed the pace of stem cell science and shaped many aspects of its subsequent development.’<sup>24</sup>

---

<sup>20</sup> *ibid.*, p.8.

<sup>21</sup> *ibid.*, p.9.

<sup>22</sup> *ibid.*, p.11.

<sup>23</sup> *ibid.*, p.23.

<sup>24</sup> J.A. Robertson, *Embryo Stem Cell Research: Ten Years of Controversy*, (38 J.L. Med. & Ethics 191, 2010) pp. 191-203, p.191, available at: <http://heionline.org>.

The hES cells were first cultured in mice in 1981, but not in humans until 1998, when James Thomson at Wisconsin and John Gearhardt at Johns Hopkins managed to do so. ‘The ability to culture hES cells in the laboratory was an important breakthrough because it opened the door to understanding and controlling human development and thus to cell replacement or regenerative therapies in humans.’<sup>25</sup>

The crucial aspect in this debate is that ‘of course, embryonic stem cell research has attracted enormous interest in the United States and internationally not only because of its scientific and medical potential, but also because of its commercial promise. Forecasts of the market for stem cell technologies range from a fairly modest \$100 million to a more optimistic \$10 billion by year 2010.’<sup>26</sup>

The most important part of the ongoing debate is the controversy of the hES cell research among different members of society. However, what are the main issues at the bar, which cause this big controversy?

Many tend to believe that an embryo is a full human being and for this reason, it is not right to have it killed for the purposes of research. This set of argumentation is based on the idea of the importance of human DNA and the potential to become a person. Each embryo has its own unique human DNA,<sup>27</sup> it must be treated as living. ‘This is a religious-type belief, and there is no way to argue around it.’<sup>28</sup>

While many argue from the right to life perspective, the other side thinks that the embryo is too simple in development’ to have interests or rights, and thus should not be protected at the cost of legitimate and important scientific research.’ For those who favor this opinion it is ‘clear enough that unimplanted embryos, which are a collection of undifferentiated cells, lack the physical characteristics to have the attributes which they view as essential for moral status.’ However, even they are ‘willing to acknowledge that embryos have status greater than other tissue because chance that they could implant and come to term, and thus deserve special respect.’ For this special respect, they deem it is a good reason to create, discard and experiment on them, for treating infertility, etc.<sup>29</sup>

Another issue worth to mention is the capacity of hES cell research to turn into reality. More precisely, theoretically hES cell research can cure many diseases, but the problem still lies within how theory will be applied in the reality. ‘Getting there will require "translation" of hES cell research into clinical research and eventually clinical medicine. The translation process poses its own set of ethical and regulatory issues.’<sup>30</sup> Thus, the

---

<sup>25</sup> Robertson, *supra* note 24, p.192.

<sup>26</sup> R. Korobkin & S.R. Munzer, *Stem Cell Research and the Law*, (UCLA School of Law Research Paper No. 06-05, February 2007) p.3, available at SSRN: <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=878392](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=878392)> viewed on April 4, 2012.

<sup>27</sup> DNA -in *Biochemistry*: deoxyribonucleic acid, a self-replicating material which is present in nearly all living organisms as the main constituent of chromosomes. It is the carrier of genetic information. Available at: <http://oxforddictionaries.com/definition/DNA>.

<sup>28</sup> Robertson, *supra* note 24, p.192.

<sup>29</sup> *ibid.*, p.192.

<sup>30</sup> *ibid.*, p.198.

many aspects need to be taken into consideration and this is not the easy thing.

The other important discussion lies within the field of ethics. Mainly, this matter is argued from ethical point of view, because the “with current technology, harvesting stem cells from a human embryo requires destroying the embryo.”<sup>31</sup> As moral controversy and legal restrictions have hampered hES cell research, there have been discussed alternative ways that can change the situation. This would simply solve the main ethical or other controversy around hES cell research. This alternative is referred as cell reprogramming, which can provide an alternative to hES cells. This major breakthrough in cell reprogramming was achieved in 2006 by Dr. Shinya Yamanka and his team at Kyoto University in Japan. ‘These new techniques enable *somatic cells*<sup>32</sup>, or bodily cells not involved in the production of sperm or ova, to be reprogrammed to enter embryonic stem cell-like state.’<sup>33</sup> These cells are called iPS cells<sup>34</sup>, which similar to hES cells, can be differentiated into various cell types such as insulin-secreting pancreatic cells, etc. ‘However, the big advantage of iPS cells is that they can be derived from almost any individual.’<sup>35</sup>

The science of cell reprogramming is advancing rapidly, but it still depends heavily on hES cell research. And talk of iPS cells as an alternative of the hES cells at this stage is early.<sup>36</sup> However, this could solve the ethical issue of the hES cell research, but some can even challenge ethicality of the cell reprogramming itself. ‘As cell reprogramming enters the field of reproductive medicine, it will challenge out common-sense understanding of human fertility and value of human existence. In fact, it is already doing so. Some bioethicists have argued that cell reprogramming undermines the core tenet of the prolife position: the idea that human embryo deserves full moral status because it possesses the intrinsic potential to become a person.’<sup>37</sup>

The controversy of the hES cell research lies not only around the research as such, but also other related aspects, such as hES cell patents. Some consider that patents in the field of hES cells are immoral and unethical on the grounds that it aims for commercial or industrial interests.

Thus, in order to understand more about the current debate it is necessary to go into deep and have the clear picture of the problematic issues, which need to be taken into consideration, while discussing the topic.

---

<sup>31</sup> Korobkin, *supra* note 26, p.6.

<sup>32</sup> Somatic Cell- in *Biology*: any cell of a living organism other than the reproductive cells. Available at: <http://oxforddictionaries.com/definition/somatic%2Bcell?q=somatic+cells>.

<sup>33</sup> Power & J.E.J. Rasko, *Will Cell Reprogramming Resolve the Embryonic Stem Cell Controversy? A Narrative Review*, (*Annals of Internal Medicine*, Vol. 155, 2011) pp.114-121, p.115.

<sup>34</sup> iPS cells (Induced Pluripotent stem cells) are adult cells that have been genetically reprogrammed to an embryonic stem cell-like state by being forced to express genes and factors important for maintaining the defining properties of embryonic stem cells. For more information see: <http://stemcells.nih.gov/info/basics/basics10.asp>, viewed on April 9, 2012.

<sup>35</sup> Power & Rasko, *supra* note 33, p.115.

<sup>36</sup> *ibid.*

<sup>37</sup> *ibid.*, p.119.

# 3 hES Cell Research as International Public Concern, Ethics and Other Related Issues

As seen from the introductory part of the thesis, attention is drawn towards ethical perspectives concerning hES cells and its patents. Since hES cells are derived from early human embryos, this issue carries big moral and ethical status. Ethical aspects regarding this issue, varies among different parts of society, diverse view point of people is influenced by their backgrounds and understandings. However, in order to have a clear picture of ethics into the discussion, this chapter will address all ethical issues in hES cell debate.

Firstly, I will introduce the basics of ethics and its interaction with law. And secondly, will discuss the relationship between ethics and human rights, more precisely will introduce” human rights ethics” of hES cell research. And later on will address the ethicality of hES cell research and the ethical issues of the hES cell patents. The last sub-chapter will deal with other important issues related to the controversy of hES cells.

## 3.1 Ethics as a Concept and Its Interlink with Law

‘Ethics are the set of moral rules that govern human conduct.’ But the ethics and the law are two different spheres. Even though there are different, they still have some similarities. So, the ethical and legal rules differ from each other, ethical rules show us the way to conduct ourselves in order to behave humanly. Hence, ethical rules have universal nature. The ethical norms are based on consciousness of a person, but even if the breaking of these rules does not risk the punishment as a result, we still deem that our act is unethical and usually regret it. On the other hand, the legal rules ‘do not need to be accepted in consciousness since they rely on the support of the public force to enforce their observance.’ The infringement of these types of rules will basically result in related punishment provided in these rules.<sup>38</sup>

Another important trait of ethical norms is that they “pursue the avoidance of evil and the achievement of good.” But the understanding of the good and evil will be diverse among different persons. Whereas, legal

---

<sup>38</sup> A.V. Ramos, *Ethics and Law*, (AIP Conference Proceedings, ISSN 0094-243X, 04/2007) pp. 234-237, p. 234-235. Available at: <http://scitation.aip.org/getpdf/servlet/GetPDFServlet?filetype=pdf&id=APCPCS00090500001000234000001&idtype=cvips&doi=10.1063/1.2737022&prog=normal> viewed on April 9, 2012.

norms can only “prevent people from doing evil, but they can't force them to do good.”<sup>39</sup>

The ethics has broader scope than law, it “aims at promoting tendencies towards the good”, whereas the law just “ensures that human relationships are governed by the principle of justice.”<sup>40</sup> The fundamental question of ethics is: ‘what should I do to become a better person? And the important question of law is: ‘what rules do we need to promote a peaceful and fair society?’<sup>41</sup>

Hence, to sum up the main similarities between law and ethics are that:

- ‘both of them regulate the relations between human beings through a set of rules’;
- both legal and ethical rules are of” imperative nature”;
- ‘Both of them respond to the same social need: the regulation of human relations’.

The difference between legal and ethical norms stands in the following:

- Ethics demand the “internal conviction” on the part of an individual, whereas law does not;
- Imposition of ethical rules is internal (inside of an individual), while legal rules are external;
- ‘Ethics affect all the relations of coexistence between human beings, and Law is the vehicle through which human relations are regulated in order to ensure the State's good governance’;
- ‘Ethics are intrinsic to the person and, therefore, do not need the existence of a social order; whereas, law is the organization of a society.’

‘Despite the differences between Ethics and Law, their connection and inherent historical relation are permanent. Ethics expand, at the expense of Law, as persons observe the basic rules of coexistence voluntarily, not through coercion. It would be possible to state that the ethical sphere reduces gradually the legal sphere, since, as a society progresses, legal rules are increasingly replaced by moral rules.’<sup>42</sup>

Hence, we can conclude that ethics plays a big role in the development of law.

As the main of the debate deals with the hES cell research, which is the part of biomedicine, there is the necessity to involve the term”bioethics” into the discussion. This term can be vague sometimes and lead us into the confusion. Thus, there are two ways to define the term”bioethics”, one is

---

<sup>39</sup> Ramos, *supra* note 38, p.235.

<sup>40</sup> R. Andorno, *Human Dignity and Human Rights as a Common Ground for a Global Ethics*, ( *Journal of Medicine and Philosophy*, ISSN 0360-5310, Vol. 34, Issue 3, 06/2009) pp. 223 – 240, p. 224.

<sup>41</sup> *ibid.*

<sup>42</sup> Ramos, *supra* note 38, p.236.

narrow and another is broad definition.<sup>43</sup> From the narrow meaning, it is “purely ethical dimension of life sciences” and is a “just part of ethics.”<sup>44</sup> However, the term “bioethics” can be defined broadly, which along the biomedical ethics, also includes legal aspects of biomedical issues, more simply- biomedical law.<sup>45</sup>

Therefore, the role of the bioethics as the part of the ethics and law as well, is significant when we address the issue concerning the controversy of hES cells.

## 3.2 Human Rights and Ethics (Bioethics)

We have seen from the previous sub-chapter that law and ethics have a lot in common. I also emphasized the role of bioethics as an ethical dimension, which is often used in human rights discussions. Hence, in order to have the clear idea how human rights and bioethics interact, it is necessary to introduce the connecting concept “human dignity”. ‘Dignity, as a global notion, is singularly appropriate to the Universal Declaration of Human Rights (UDHR) and also as a part of a global ethical response to the challenges of technology.’<sup>46</sup> This concept has its roots in both discourses and is vital, to define the relation between human rights law and ethics, more precisely bioethics. The understanding of this concept is very crucial to argue that hES cell research and its patents are contrary to the idea of human rights and bioethics, in connection to “human dignity”. Many important questions can be raised, including: ‘does the concept of “human dignity”, commonly understood as being at the basis of “human rights”, and establishing certain actions as categorically impermissible, apply to humans in all their different stages of development and capacity?’<sup>47</sup> Hence, in regards to ‘the research with human subjects, the ethical issues concern not only safeguarding the subject’s life and health but also respecting his humanity.’<sup>48</sup> This question is relevant in many bioethical or human rights debates, including stem cell research. Therefore, in this part of the thesis, I will address ethics of human rights, which can be brought into the discussion and will deal with the idea of “human dignity”, which is both ethical and human rights concept.

---

<sup>43</sup> Andorno, *supra* note 40, p.224.

<sup>44</sup> *ibid.*

<sup>45</sup> *ibid.*, p. 225.

<sup>46</sup> W. Sweet & J. Masciulli, *Biotechnologies and Human Dignity*, (Bulletin of Science, Technology & Society, ISSN 0270-4676, , Vol. 31, Issue 1, 02/2011) pp. 6 – 16, p.13. Available at: <http://bst.sagepub.com.ludwig.lub.lu.se/content/31/1/6.full.pdf+html>.

<sup>47</sup> H. Schmidt, *Whose Dignity? Resolving Ambiguities in the Scope of “Human Dignity” in the Universal Declaration on Bioethics and Human Rights*, (Journal of Medical Ethics, ISSN 0306-6800, Vol. 33, Issue 10, 10/2007) pp. 578 – 584, p. 578.

<sup>48</sup> L.R. Kass, *Defending Human Dignity*, (Commentary, ISSN 0010-2601, Vol.124, Issue 5, 12/2007) pp. 53 – 61, p.53.

### 3.2.1 The Concept of Human Dignity in Human Rights Discourse

Most of the moral opposition to hES cell patents in Europe is based on the belief that these patents offend, devalue, infringe, or otherwise violate “human dignity.”<sup>49</sup>

Therefore, main moral argument critics have marshaled against hES cell patents has been, that these patents offend, compromise, go against, or violate human dignity.<sup>50</sup> But first of all we need to understand the concept of human dignity itself. This concept is not only used in ethics related works, but also is used in various binding or non-binding human rights instruments. Thus, the concept of human dignity was from the beginning basic principle of human rights. In simple way, human rights were simply based on human dignity. We have to bear in mind, that human dignity is not the merely the concept of human rights. This concept has its roots in ethics and morality. The interesting aspect is that this concept connects human rights and ethics together, thus one can argue that hES cell research and its patents are opposing the concept of human dignity in both discourses

In order to have more clear idea what the “human dignity” stands for, it is necessary to explicate this concept into details. In 18<sup>th</sup> century German philosopher Immanuel Kant has developed the most influential view of “human dignity”. According to Kant’s perspective, “human dignity” is as an “absolute inner value all human beings possess.”<sup>51</sup> “This value is characterized with attributes such as ‘absolute’, ‘inner’, or ‘unconditional’. These attributes emphasize that “the value of human beings does not depend on anything else.”<sup>52</sup> Hence,” human beings simply have this value in virtue of being human. This value is often said to be the normative reason why one should respect human beings.”<sup>53</sup> Kant is clear in his ethical views stating that the human beings have human dignity from the moment of conception.<sup>54</sup> Kant insists elsewhere that ‘humanity itself is a dignity.’<sup>55</sup> Thus, basically when we discuss the concept of “human dignity” is related

---

<sup>49</sup> D.B. Resnik, *Embryonic Stem Cell Patents and Human Dignity*, (Health Care Anal 15, 2007) pp. 211–222, p. 213.

<sup>50</sup> *ibid.*

<sup>51</sup> O. Senger, *Kant’s Conception of Human Dignity*, (Kant-Studien, ISSN 0022-8877, Vol. 100, Issue 3, 09/2009) pp. 309 – 331, p.309.

<sup>52</sup> *ibid.*, p.311.

<sup>53</sup> *ibid.*

<sup>54</sup> M. Rothhaar, *Human Dignity and Human Rights in Bioethics: the Kantian Approach*, (Medicine, Health Care and Philosophy, ISSN 1386-7423, Vol.13, Issue 3, 08/2010) pp. 251 – 257, p.254.

<sup>55</sup> D.P. Sulmasy, *Human Dignity and Human Worth*, (Perspectives on Human Dignity: A Conversation, ISBN 9781402062803, 2007) pp. 9 – 18, p.11. Available at: <http://www.springerlink.com/ludwig.lub.lu.se/content/k1v6336x032221p1/fulltext.pdf>.

to the idea of human worth.<sup>56</sup> The “human dignity” is something that differentiates human beings from other living creatures, such as animals.<sup>57</sup>

The concept of dignity is sometimes deemed to be the close to the concept of “respect, but it is not correct to identify these concepts.<sup>58</sup> The idea of the “human dignity” being the same as respect has no basis for only one simple reason, that ‘the dignity is what provides rationale to the requirement of respect for persons.’<sup>59</sup> It was Kant who put the notions of respect and dignity as important parts of his moral theory. This can be clearly understood in Kant’s so called “Second Formulation of the Categorical Imperative”<sup>60</sup>, ‘it can be said that we give ourselves this second kind of dignity by making good choices.’ Unlike to inherent dignity (the same for all humans), moral dignity is not possessed by all individuals in the same degree and it is more of the individualist character. Hence, some human can bear more moral dignity than others, for instance, an honest man has more “moral dignity” compared to a thief.<sup>61</sup> Kant simply advocated the idea that use of human beings as “mere means to an end” is forbidden.<sup>62</sup> Hence, ‘no human being, regardless of whoever he or she is or whatever his or her condition, can ever be reduced to the status of means. This is what is meant by human dignity from the practical perspective. The human being is an end, never simply a means.’<sup>63</sup> That is why some ethicists come to the conclusion that ‘we are not simply free to pursue good ends via unethical means. Of all human beings, embryos are the defendless against abuse (Center of Bioethics 1999).’<sup>64</sup>

Along with Kantian approach toward “human dignity”, there are other viewpoints. According to the Judeo-Christian understanding of “human dignity”, it is “based on mankind’s connection to God: human beings are created in the image of God.”<sup>65</sup> While Christianity believes in this type of concept, other religions simply do not share the same understanding. While Christian understanding connects human dignity to God, the natural law approach “holds that human nature is the basis for human dignity. Human nature consists of the biological, psychological, and social characteristics that distinguish human beings from other animals, such as reasoning, language, morality, aesthetic appreciation, and religious conviction.”<sup>66</sup>

---

<sup>56</sup> J. Malpas, *Human Dignity and Human Being*, (Perspectives on Human Dignity: A Conversation, ISBN 9781402062803,2007) pp. 19– 25, p.19. Available at: <http://www.springerlink.com/ludwig.lub.lu.se/content/k1v6336x032221p1/fulltext.pdf>.

<sup>57</sup> Resnik, *supra* note 49, p. 215.

<sup>58</sup> Andorno, *supra* note 40, p. 230.

<sup>59</sup> *ibid.*

<sup>60</sup> Rothhaar, *supra* note 54, p.252.

<sup>61</sup> Andorno, *supra* note 40, p. 232.

<sup>62</sup> Rothhaar, *supra* note 54, p.252.

<sup>63</sup> T.D. Koninck, *Protecting Human Dignity in Research Involving Humans*, (Journal of Academic Ethics, ISSN 1570-1727, Vol. 7, Issue 1-2, 06/2009) pp. 17 – 25, p.24. Available at:

<http://www.springerlink.com/ludwig.lub.lu.se/content/8j22518w67683116/fulltext.pdf>.

<sup>64</sup> Holland, *supra* note 1, p.129.

<sup>65</sup> Resnik, *supra* note 49, p. 215.

<sup>66</sup> *ibid.*, p. 216.

The most crucial part when we address the “human dignity” is to determine who can be considered as a bearer of it. A very interesting thing is that even Kant’s philosophy can be easily ‘exploited both by the so called “pro-life’ advocates as well as from so-called “liberals”, who support embryonic stem cell research.’<sup>67</sup> That is why some authors such as Gerhardt interprets Kant’s ideology that since “human dignity” is grounded in human’s rational morality, embryos does not possess self-awareness, independence and for these reasons cannot be the bearers of “human dignity”. The same approach can be shown in regards to the small children and people who are mentally disabled.<sup>68</sup> However, this interpretation can be easily overturned by Kant’s conception of persons being on one side *homo noumenon* and on other side *homo phaenomenon*. As *homo phaenomenon*, humans are sensible beings, that is ‘an animal with reason’<sup>69</sup> Thus, humans can only be distinguished from other animals, by reasoning. On the other side, as *homo noumenon*, humans are ‘free persons subject only to reason’s universal legislation’. This noumenal side makes humans as human beings and the bearers of “human dignity”. That is the reason why author such as Margalit thinks that belonging to *homo noumenon* does not mean ‘to possess an empirical property, but rather a determination belonging to every human being as such’.<sup>70</sup> Hence, Kant’s approach towards early embryos as bearers of “human dignity” is clear, because he establishes the moment of conception as the beginning of personhood, also evidence of this ideology, is seen in his remarks towards suicide, when he states that ‘suicide can be crime against not only one’s own person, but against the person of another, in regards to a pregnant women who commits a suicide.’<sup>71</sup>

Other philosophers who have interpreted Kant have also written very interesting remarks. For instance, Heidelberg and Wieland state that ‘reason for having “human dignity” cannot be the actual performance of moral acts, but only the capacity in principle to act morally.’<sup>72</sup> According to these authors, this capacity can belong to every human organism, therefore already belongs to human embryos, ‘even though they have not reached a stage to actualize this capacity.’<sup>73</sup> This argument was more expanded by Robert Spaemann, by stating that human beings from the moment of conception to actual death are actual persons and ‘never merely potential’. This point can be clarified by saying that, a human organism is at every stage of its existence is an actual person, because it is *homo noumenon* at

---

<sup>67</sup> Rothhaar, *supra* note 54, p.254.

<sup>68</sup> *ibid.*

<sup>69</sup> M. Betzler (ed.), *Kant's Ethics of Virtue*, (de Gruyter, 2008) p.205. Available at: [http://books.google.se/books?id=04hyCVYc4D4C&pg=PA205&lpg=PA205&dq=homo+noumenon+meaning&source=bl&ots=UqYuWKBxn6&sig=aJRM9A59YJj7M8SVI67p5cVt hMM&hl=en&sa=X&ei=hYiOT9eiFMjp4QTOg7GpDw&redir\\_esc=y#v=onepage&q=ho mo%20noumenon%20meaning&f=false](http://books.google.se/books?id=04hyCVYc4D4C&pg=PA205&lpg=PA205&dq=homo+noumenon+meaning&source=bl&ots=UqYuWKBxn6&sig=aJRM9A59YJj7M8SVI67p5cVt hMM&hl=en&sa=X&ei=hYiOT9eiFMjp4QTOg7GpDw&redir_esc=y#v=onepage&q=ho mo%20noumenon%20meaning&f=false).

<sup>70</sup> Rothhaar, *supra* note 54, p.254.

<sup>71</sup> *ibid.*

<sup>72</sup> *ibid.*, p.256.

<sup>73</sup> *ibid.*

every stage.<sup>74</sup> However, in Aristotelian viewpoint ‘fetus’s essential potentiality is what makes it actual human being.’<sup>75</sup>

Hence, all these philosophical and ethical theories lead us to the point that a human being (including humans from the moment of conception) are the bearers of “human dignity”. This attribute cannot be taken away, simply because early humans have not developed the capacity to act morally. The “human dignity” attributes a human merely because he/she belongs to humankind. If we attach this character to the rational reasoning, then we will reach the absurd point that some humans such as children, mentally handicapped persons are not the bearers of “human dignity”.

I have addressed some of the main ideas behind the “human dignity,” now will introduce issues related to this principle as it is set in major human rights instruments. The “human dignity” as stated previously is not only a philosophical or bioethical notion, but one of the main principles of international human rights law. This term is used several times in various human rights treaties such as the UDHR, in the preamble we read: “recognition of inherent dignity and of the equal and inalienable rights of all members of the human family...”

The idea of the human dignity has been at the heart of the major human rights instruments such as the International Covenant on Civil and Political Rights (ICCPR) and the International Covenants on Economic, Social and Cultural Rights (ICESCR).<sup>76</sup> The same principle of the “inherent dignity” can be read in the preamble of the Convention on the Rights of the Child (CRC).<sup>77</sup> The same term of “inherent dignity” is used in preambles of many other international human rights instruments such as the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment of Punishment (CAT)<sup>78</sup>, the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW),<sup>79</sup> etc.

The important aspect that needs to be considered is the role of the “human dignity” both in human rights and bioethics. As human rights sees the human dignity as the inherent and inviolable, the bioethics does the same, because ‘biomedical practice is closely related to the most basic human rights, namely right to life, to physical integrity,’<sup>80</sup> etc. ‘If human dignity is generally recognized as the foundation on which human rights are based, then it is not surprising that it is invoked as the ultimate rationale of the legal norms governing biomedical practice.’<sup>81</sup>

A very interesting approach is provided by Roberto Andorno, who states that even though international human rights instruments do not explicitly

---

<sup>74</sup> *ibid.*

<sup>75</sup> M. G. Kuczewski & R. M. Polansky (eds.), *Bioethics: Ancient Themes in Contemporary Issues* (MIT Press, Cambridge, Massachusetts., 2000) p.165.

<sup>76</sup> Andorno, *supra* note 40, p. 227.

<sup>77</sup> See, the Convention on the Rights of the Child, New York, 20 November, 1989, United Nations, *Treaty Series*, vol. 1577, Preamble, para. 2.

<sup>78</sup> See, the Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment of Punishment, New York, 10 December 1984, United Nations, *Treaty Series*, vol. 1465.

<sup>79</sup> See, the Convention on the Elimination of All Forms of Discrimination Against Women, New York, 18 December 1979, United Nations, *Treaty Series*, vol. 1249.

<sup>80</sup> Andorno, *supra* note 40, p. 227.

<sup>81</sup> *ibid.*

define what is meant under “human dignity”, they provide “valuable guidance for the understanding the concept of it.”<sup>82</sup> Andorno uses three important phrases which are used in these instruments to understand the meaning of the “human dignity” in human rights law. These three phrases are the following:

- “inherent dignity to all member of human family” (Preamble of UDHR);
- “all the human beings are free and equal in dignity and rights” (UDHR, Article 1);
- “these rights derive from the inherent dignity of the human person” ( Preambles of ICCPR and ICESCR).<sup>83</sup>

The term inherent in the first phrase means essential character of something, which is intrinsic. As this word stands together with word “human”, this highlights the fact that ‘dignity is *inseparable from the human condition*.’<sup>84</sup> ‘Thus, dignity is not an accidental quality of some human beings, or a value derived from some specific personal features such as the fact of being young or old, man or woman, healthy or sick, but rather an unconditional worth that everyone has simply by virtue of human being.’<sup>85</sup> This concept was historically included in many human rights related laws. For instance, ‘the concept of humans having intrinsic value was given expression in the early Roman law principle that human beings have fundamental natural rights which they possess by virtue of their humanity as opposed to their being conferred upon them by the State or the law.’<sup>86</sup> The same approach is visibly seen in 1789 declaration of the Right of Man and the Citizen of France and also in the American Declaration of Independence. These concepts were reaffirmed later on in international instruments such as previously mentioned UDHR and also UN Charter.<sup>87</sup>

The second phrase, which involves term “equal”, this merely means that all the basic rights are equal for all, meaning that human dignity is the same for all, which is the basic ground of all human rights. Hence, all human beings have the same basic rights.<sup>88</sup>

The last point which states that the rights derive from the dignity leads us to the interesting consequence: ‘if basic right are not given by authority, but are pre-existing values which are inherent in every human beings then they cannot be legitimately taken away.’<sup>89</sup>

Certainly the main problems remain into clearly defining the “human dignity”, which often leads to misinterpretation, etc.<sup>90</sup> However, I agree with Andorno, that recourse of “human dignity” in international human

---

<sup>82</sup> *ibid.*, p. 229.

<sup>83</sup> *ibid.*

<sup>84</sup> *ibid.*, p. 227.

<sup>85</sup> *ibid.*

<sup>86</sup> S. G. Green, *Human Dignity and the Law*, (Perspectives on Human Dignity: A Conversation, Issue 2, 2007) pp. 151-156, p.152.

<sup>87</sup> *ibid.*

<sup>88</sup> Andorno, *supra* note 40, p. 227.

<sup>89</sup> *ibid.*

<sup>90</sup> *ibid.*

rights or bioethics instruments, reflects a real concern about the need to ensure respect of inherent worth of human being. According to him, this concern is far broader than simply ensuring “respect of autonomy”, because it also includes the protection of those who are not yet or are no more, morally autonomous (newborn infants, senile elderly, people with mental disorders).<sup>91</sup> Hence, I agree with Andorno that broad view of the concept “human dignity” is clearly enshrined in human rights instruments, “which assumes that the worth of human beings does not rest on their actual intellectual or moral abilities, but merely on their human condition.”<sup>92</sup> Thus, “human dignity” can be considered as an inherent value of every human being.

Hence, we can conclude that the hES cell research and its patents as it involves early embryos that are the bearers of “human dignity” can be deemed to be contrary to the idea of “human dignity” both in human rights and ethical discourses.

### 3.2.2 UNESCO Declaration on Bioethics and Human Rights (UDBHR)

While discussing ethics and human rights related debate on hES cell research and its patents, it’s relevant to bring up the Universal Declaration on Bioethics and Human Rights (UDBHR). The UDBHR was adopted by UNESCO on 19 October 2005, which is an ‘important step in the search for global minimum standards in biomedical research and clinical practice.’<sup>93</sup> Above mentioned declaration covers one of the main principles of bioethics and its interaction with human rights. ‘There is a widely diffused idea that these documents are purely ethical or rhetorical recommendations deprived of any legal effect. This view probably stems from the fact that, unlike treaties, the UNESCO declarations, as any “soft law” agreements, are usually characterized as “non binding instruments.” Although this depiction is not entirely wrong, it may be misleading because while soft law does not have a binding effect *per se*, it is *conceived to have such effect in the long term.*’<sup>94</sup> The most notable example of the significant role that soft law can play in the development of binding norms is provided by the UDHR of 1948. This document, which took the form of a soft law instrument, is today widely recognized as the cornerstone of the entire international human rights.<sup>95</sup>

Thus, UDBHR itself is mainly based on the idea of ethics and morality of scientific advancements. In the Preamble of the Declaration we read,

---

<sup>91</sup> *ibid.*, p. 230.

<sup>92</sup> *ibid.*

<sup>93</sup> R. Andorno, *Global bioethics at UNESCO: in Defence of the Universal Declaration on Bioethics and Human Rights*, (Journal of medical ethics, ISSN 0306-6800, Vol. 33, Issue 3, 03/2007) pp. 150 – 154, p.150. Available at:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2598251/pdf/150.pdf>.

<sup>94</sup> Andorno, *supra* note 40, p. 225.

<sup>95</sup> *ibid.*, p.226.

“recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the *recognition of the dignity of the human person* and universal *respect for, and observance of, human rights and fundamental freedoms...*”.<sup>96</sup> In total, UDBHR uses term “human dignity” nine times in its text.<sup>97</sup> One of the essential aims of the UDBHR is emphasized in Article 2(d), stating: aim “to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms”.<sup>98</sup> And also in Article 2(c), stipulating its aim: “to promote *respect for human dignity* and protect human rights, *by* ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law”.<sup>99</sup>

As some authors such as Harald Schmidt considers that the UDBHR causes ambiguities in regards to the scope of “human dignity” in it. He provides the possibility of interpreting Article 2(c) (when using “*by*” ensuring respect of life is crucial in ensuring respect for “human dignity”)-and arguing that destruction of an embryo for a stem cell research would constitute lack of “respect of life of human beings” and following the logic provided by Article 2(c), lack of respect of human dignity.<sup>100</sup>

The important aspect is that the UDBHR itself does not define the term “human dignity”, however, the concept of it can be understood while reading its text. The notion of “human dignity” is understood firstly ‘as intrinsic worth of human beings’ and secondly as ‘the value of humanity as such.’<sup>101</sup>

Therefore, the UDBHR is very explicit in regards to any scientific development being compatible with the idea of “human dignity”, ethics and basic principles of human rights. Thus, the UDBHR is very obvious, confirming linkage between concept of morality, ethics and human dignity, both in ethics and human rights understandings. And there is no doubt that the UDBHR is a very important instrument in both bioethics and human rights, assigning ‘a very central role to the principle of respect of “human dignity”.’

---

<sup>96</sup> Preamble of Universal Declaration on Bioethics and Human Rights of 19 October 2005, UNESCO, available at: [http://portal.unesco.org/en/ev.php-URL\\_ID=31058&URL\\_DO=DO\\_TOPIC&URL\\_SECTION=201.html](http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html).

<sup>97</sup> Schmidt, *supra* note 47, p. 578.

<sup>98</sup> Article 2(d) of the Universal Declaration on Bioethics and Human Rights of 19 October 2005, UNESCO.

<sup>99</sup> Article 2 (c) of the Universal Declaration on Bioethics and Human Rights of 19 October 2005, UNESCO.

<sup>100</sup> Schmidt, *supra* note 47, p. 579.

<sup>101</sup> Andorno, *supra* note 40, p. 238.

### 3.3 Ethics of hES Cells (Is an Early Embryo Protectable Human Life?)

Another arguable issue in regard to hES cell lies in ‘ethical debate on embryo research, particularly on whether to destroy human embryos for stem cell research, is sometimes said to involve a confrontation between religion and science.’<sup>102</sup> This idea is shared by Richard D. Doerflinger,<sup>103</sup> who has studied this subject very thoroughly from ethical perspective. Doerflinger agrees with the idea that ‘the human embryo, even in the first week of development before implantation, is a human being - a living, developing individual of the human species, not just a part of another member of the species.’ He supports this opinion with the help of embryology textbook, which simply states that ‘A zygote is the beginning of a new human being’.<sup>104</sup> While addressing the issue of an early embryo having basic human rights-such as not to be killed (right to life), Doerflinger introduces the following reasoning: ‘basic human rights, such as the right not to be killed solely to benefit others, are inherent in being a living member of the human species; science shows us that the week-old human embryo is a living member of the human species; therefore the embryo has these basic rights.’<sup>105</sup> Thus, Doerflinger considers the moral status of the human embryo in light of the historic conviction that each human individual has basic and equal human worth.<sup>106</sup>

Doerflinger introduces conclusions to so called “personhood theory”, drawn by the ethicists after ten years of debate. Personhood theory stands in the following:

1. The indicators of the personhood are certain qualities and abilities that are necessary features to be considered as a human being. These qualities and abilities include: ability to think, ability to feel, ability to anticipate something etc.;<sup>107</sup>
2. If the first point is correct, “this raises the question: since many of these qualities admit of degrees, can personhood be a matter of degree as well?” Does there exist nonpersons or semi-persons...? ‘Or are there only persons or things, and we have to choose a more or less arbitrary cutoff point for each quality so we can determine

---

<sup>102</sup> R. M. Doerflinger, *Old and New Ethics in the Stem Cell Debate*, (8 J.L. Med & Ethics 212, 2010) pp.212-219, p.212, available at: <http://heionline.org>.

<sup>103</sup> Richard M. Doerflinger is the Associate Director of the Secretariat of Pro-Life Activities, United States Conference of Catholic Bishops, and an Adjunct Fellow at the National Catholic Bioethics Center in Boston and serves on the Advisory Board to the Center for Bioethics and Human Dignity in Bannockburn, Illinois. For detailed information: < <http://www.etopiamedia.net/empnm/pdfs/richarddoerflingerbio1.0.pdf> > viewed on April 10, 2012.

<sup>104</sup> Doerflinger, *supra* note 102, p.212.

<sup>105</sup> *ibid.*, p.213.

<sup>106</sup> G.H. Outka, *The Ethics of Human Stem Cell Research*, (Kennedy Institute of Ethics Journal, Vol.12:2,06/ 2002) pp. 175-213, p.178.

<sup>107</sup> Doerflinger, *supra* note 102, p.214.

who is in and who is out? How would any two ethicists, let alone an entire society, ever agree on exactly where that line is to be drawn?’<sup>108</sup>;

3. ‘If this divide between simple humanity and personhood is valid, with basic rights belonging only to the latter, then the traditional idea of inherent and unalienable human rights is dead. Obviously abilities, qualities, and stages of developmental maturity vary widely throughout humanity. If basic rights such as life depend on those features, then basic rights are not inherent in being human and all are not created equal in rights. To be more precise, there are no human rights, only privileges won by those who measure up to the quality test...’<sup>109</sup>;
4. The fourth conclusion to this theory is the most provocative that states: ‘if unborn humans are not persons, then some born humans are not persons either.’ ‘This conclusion is often associated with ethicist Peter Singer, partly because of his famous or infamous statement that a pig has a greater claim on personhood than a human infant with disabilities.’ Another ethicist- Professor Green has written the conclusion to this theory that ‘if the fetus is not a person, neither is the newborn or young infant.’ Other ethicist- Dan Brock, explained this “personhood theory” by giving the example of a person with dementia<sup>110</sup> and has written that “severely demented patients “lack personhood” and in some respects ‘are even worse off than animals such as dogs and horses, who have a capacity for integrated and goal directed behavior that the severely demented substantially lack.’ Thus, it may be objected that the born human being with severe dementia poses a different problem than the embryo not yet developed enough to have conscious thoughts. However, this can be logically opposed by the argument that ‘the embryo at least has the innate potential to develop such activities, whereas the patient with severe dementia not only lacks them but has irretrievably lost all potential to exercise them in the future.’<sup>111</sup>

Doerflinger then provides with comparison between old and new ethics, older ethics ‘as the root of our traditions on inherent human rights – an ethic that believes in the importance of maintaining moral absolutes when it comes to human life’ and newer ethics- ‘suited to an age of technological

---

<sup>108</sup> *ibid.*

<sup>109</sup> *ibid.*

<sup>110</sup> Dementia- *in Medicine*: a chronic or persistent disorder of the mental processes caused by brain disease or injury and marked by memory disorders, personality changes, and impaired reasoning. See the definition at:

<<http://oxforddictionaries.com/definition/dementia?view=uk>>viewed on April 10, 2012.

<sup>111</sup> Doerflinger, *supra* note 102, p.214.

progress, cost/benefit analysis, and social planning'. Thus, he concludes that 'it is an ethic that relativizes the value of the individual - especially of weaker or unproductive individuals - in an effort to serve the greater good for the greater number.'<sup>112</sup>

Doerflinger sees both abortion and the destruction of embryos as treating fetuses and embryos merely as means to other ends and, as going against inviolability. Doerflinger reviews and assesses various arguments about complicity in the act of harvesting stem cells. Here, he states that even certain differences between abortion and the destruction of embryos do appear, they give no comfort to the advocates of research on embryos. He also criticizes the argument that derivation of stem cells from "spare" embryos donated by fertility clinics differs morally from using embryos created solely for research purposes and that only the latter uses embryos as a mere means to other peoples' ends.<sup>113</sup> Among these, 'Doerflinger accents the advances that researchers have made in their work on adult stem cells. One major advantage of using adult cells on which everyone agrees is the avoidance of possible tissue rejection by treating a patient with his or her own cells.'<sup>114</sup>

Doerflinger also emphasizes that 'at the same time, the effort to promote embryonic stem cell research - to provide an ethical justification for pursuing this because of its future benefits - has run into some difficulties.' 'As NIH stem cell expert Ron McKay famously said, when asked why so many people believe hES cells will cure Alzheimer's disease despite the absence of any evidence of this: "To start with, people need a fairy tale..."'<sup>115</sup>

'While exaggeration and overpromising is often a problem among researchers, including all kinds of stem cell researchers, and especially so for biotechnology firms trying to show that their approach is a good investment, the embryonic stem cell field has disproportionately been plagued by cases of outright deception and fraud, culminating in the massive fraud perpetrated by cloning researchers in South Korea.'<sup>116</sup>

The final irony of the situation Doerflinger sees is that 'the old ethic is helping to open doors to the new in science, while the new utilitarian ethic may turn out in the long run not to be so very useful after all.'<sup>117</sup>

On the other hand, we have more liberal view point on this matter. Those who have more liberal understanding of this issue state, that stem cells derived from adults are necessary but not sufficient - if one wants to maximize the data available and hence the possibility of breakthroughs - to support all clinically important areas of research. Research using each of the "sources" should go forward, for each has its own advantages and disadvantages, and they complement one another. The settled verdict is that

---

<sup>112</sup> *ibid.*, p.215.

<sup>113</sup> Outka, *supra* note 106, p.179.

<sup>114</sup> *ibid.*

<sup>115</sup> Doerflinger, *supra* note 102, p.218.

<sup>116</sup> *ibid.*

<sup>117</sup> *ibid.*

hES cell research holds promise for which at present there is no adequate substitute.<sup>118</sup>

Thus, the debate is ongoing and will be going in the future as well. ‘The views taken exert vast influence. Between those who evaluate embryos as equally protectable human life and those who evaluate embryos as only “clumps of cells in petri dishes,” there is no peace.’<sup>119</sup>

### 3.4 Ethics of hES Cell Patents

The ethics of the hES cell patents has been the issue at the bar. Many who criticize the ethicality of the hES cell research, also criticize the ethicality of the granting patents on them. This ethical debate in hES cell patents where more or less raised by the EU, with its patent legislation and case law. The moral objection in the US is not that vivid, but still as US had introduced restrictions on the federal funding of the research, which declares that even US is not completely ignorant of the morality of hES cell research and its patents.

The main ethical controversy of hES cell patents lies in ‘the special moral and cultural significance attached to the human embryo. This moral concern attends not only to debates about the innate value of human life in the context of abortion, but also to the potential diminution of the status of the embryo from person to ‘thing’ through instrumental use or exchange.’<sup>120</sup> Another ethical aspect which is often brought into the discussion is that the process of the research, which uses isolation process that results the destruction of an early embryo.<sup>121</sup>

But one of the biggest opposition regarding hES cell patents lies in introducing ‘cultural concerns about the moral appropriateness of property rights (primarily product claims) being applied to living, especially human-derived, matter.’<sup>122</sup> ‘Historically, there has been a prohibition, at least in Western countries, in granting any form of property rights in the human body as being contrary to human dignity and the laws of many countries explicitly prohibit any form of commercial trade in bodies or body parts.’<sup>123</sup>

While addressing this matter we have to bear in mind, the idea and main purpose of patents. Patent simply serves commercial and industrial purpose, as patent entitles its holder to prohibit third parties from exploiting it for industrial and commercial purposes. ‘Patents, as a means of capturing and co modifying the otherwise intangible capital of new knowledge have a core role in both the economic strategies of states and in the business models of

---

<sup>118</sup> Outka, *supra* note 106, p.181.

<sup>119</sup> *ibid.*, p.179.

<sup>120</sup> G. Bahadur & M. Morrison, *Patenting Human Pluripotent Cells: Balancing Commercial, Academic and Ethical Interests*, (Human Reproduction, Vol.25, No.1, 2010) pp. 14–21, p. 15, available at: <http://humrep.oxfordjournals.org/>.

<sup>121</sup> J. Shum, *Moral Disharmony: Human Embryonic Stem Cell Patent Laws, Warf, and Public Policy*, (33 B.C. Int'l & Comp. L. Rev. 153, 2010) pp. 153-178, p.155, Available at: <http://lawdigitalcommons.bc.edu/iclr/vol33/iss1/8>.

<sup>122</sup> Bahadur & Morrison, *supra* note 120, p. 15.

<sup>123</sup> *ibid.*

biotechnology entrepreneurs.’<sup>124</sup> The overall good that needs to be achieved by patent laws is to strike a balance between overcoming the tendency to under-invest in research and development activities and stimulating economic growth on one side, and on other: to promote the freedom of academic research and ensure ‘public benefit from new discoveries on the other’.<sup>125</sup>

Other crucial implication which is discussed is that patent system nowadays is not able to keep balance between the economic and public benefits of IP law, which tends to favor economic gain. The public benefit in this case is defined broadly including ‘the preservation of common cultural values about the moral status of living entities and the desirability or otherwise of granting ownership over them’.<sup>126</sup> Hence, the need of balance in this case is very crucial, if we want to use IP laws not merely for economical but other essential purposes, such as public benefit, etc.

Another important issue lies in the consequences of overly restrictive or excessive pricing practices by patent holders on public health and academic research, and the potential exploitation of donors who are voluntarily giving biological material or information for commercially - directed research.<sup>127</sup>

Nevertheless, the main problem remains in solving and reaching a patent system that considers all of the issues at the bar. However, some solutions which are suggested by Shum can be helpful. Shum proposes a global harmonization of patent laws that may ‘enhance the effectiveness in enforcing intellectual property rights. This increased certainty in the value and security of global intellectual property rights may also lead to greater disclosures by inventors, which ultimately benefits the public.’<sup>128</sup> But, balancing moral and ethical issues can be still problematic, since morality and understanding of it is subjective and can differentiate among different cultures. Thus, Shum suggests that ‘patents be granted and individual states can then invalidate the patents, if necessary, according to their national norms.’<sup>129</sup> More precisely, will adjust to their understanding of what is moral and what is not.

The more issues concerning moral disharmony in hES cell patents will be discussed later, on the example of the European patent law approach. The European Patent Office’s (EPO) rejection to grant a patent to the Wisconsin Alumni Research Foundation (WARF) on hES cells due to the fact that they were derived from embryos “marks a significant divergence in patent policy between the EPO and the world’s other major patent issuing bodies, notably the US Patent and Trademark Office (USPTO).”<sup>130</sup> However, WARF’s patents are still subject to controversy in the US due to their “overly broad scope of their claims and the manner of their licensing.”<sup>131</sup> According to some scholars, this broad scope of the WARF patents has constrained the

---

<sup>124</sup> *ibid.*

<sup>125</sup> *ibid.*

<sup>126</sup> *ibid.*, p.16.

<sup>127</sup> *ibid.*

<sup>128</sup> Shum, *supra* note 121, p.169.

<sup>129</sup> *ibid.*, p.172.

<sup>130</sup> Bahadur & Morrison, *supra* note 120, p. 14.

<sup>131</sup> *ibid.*

ability of many scientists to conduct hES cell research.<sup>132</sup> The WARF has been accused for having monopoly in the sphere. The WARF patents have been considered to be the most powerful, as they cover all primate and human ES cells as compositions of matter, that effectively grant WARF ‘the legal right to exclude everyone else in the United States from making, using, selling, offering for sale or importing any hES cells covered by the claims until 2015.’<sup>133</sup> Thus many deem, ‘WARF’s patents are substantial impediments to the ideal of granting patents to “promote the Progress of Science”.’<sup>134</sup> Therefore, ‘granting a monopoly on a basic scientific research tool can severely limit subsequent research’ and ‘the public benefit is not at all commensurate with the monopoly rights’.<sup>135</sup>

Hence, all of the mentioned problems are still unsolved, the issue remains the same, no matter how will we argue, there is big opposition to hES cell patents as being contrary to ethics and morality, there is no consensus and it is hard to reach it.

### 3.5 Other Related Issues- Feminist Approach

While the main issues which were argued in the hES cell debate, from the perspective of ethics, embryo’s moral status, etc, some have raised the issue from a very interesting standpoint. More precisely, for instance Holland argues this matter from the perspective of women, especially those who belong to marginalized groups, such as poor people and persons of color. Holland addresses the issue of jeopardizing moral status of women and those who belong to marginalized groups.<sup>136</sup> Holland basically questions the health care access in the case of women in marginalized groups. Hence, Holland is inquiring the possibility of constructing public policy ‘that adequately accounts for the full personhood of those on the margins, especially women of color and working-class women.’<sup>137</sup>

She thinks that research is never neutral, and the hES cell research conducted in private sector has certain implications for some groups, which will lead to the oppression in the society.<sup>138</sup> It is a very common that they put women’s personhood against of embryos. As Harrison argued ‘before the sanctity of human life will include genuine regard and concern for every female already born...’<sup>139</sup> The problem which will raise will be that egg donations will result in inequitable and unethical situation of supply and demand, because it happens that some look for egg donors who are for example, of high intelligence, belonging to white race. In this case it means

---

<sup>132</sup> Shum, *supra* note 121, p.165.

<sup>133</sup> Bahadur & Morrison, *supra* note 120, p. 17.

<sup>134</sup> Shum, *supra* note 121, p.174.

<sup>135</sup> *ibid.*

<sup>136</sup> Holland, *supra* note 1, p.73.

<sup>137</sup> *ibid.*

<sup>138</sup> *ibid.*, p.74.

<sup>139</sup> *ibid.*, p.76.

that some eggs are worth more than others. Hence, the eggs of well-educated Caucasians will worth considerably more on the reproductive-fertility market than eggs of non-Caucasian, less educated women.<sup>140</sup>

Thus, Holland's feminist ethical analysis, aims to ask a following question: who is suffering and at whose expense? To her mind, hES cell therapies will be so costly beneficial only for wealthy part of the society. In her idea, poor, who are largely female, and most persons of color will simply be marginalized from the regenerative medical therapies, even as it is possible that their eggs will be commercialized downstream for profit.<sup>141</sup> Thus, according to feminist approach, women will be excluded, from the benefits of research anyway on the ground that it will not be affordable to them, especially those who belong to different races and groups of society.

However, to my mind, the affordability of hES cell therapies is not only a problem in women, but in anyone who comes from the poor part of the society. Therefore, we can conclude that even though hES cell research is very promising, the big section of society will not be able to benefit from it anyway. Thus, what is the idea behind it if that does not profit the public in general but only those belonging to rich segments of society?

Hence, there are many other ethical issues at the bar that cannot be ignored when we discuss hES cell controversy.

---

<sup>140</sup> *ibid.*, p.80-81.

<sup>141</sup> *ibid.*, p.83.

# 4 hES Cell Patents In Intellectual Property Law

## 4.1 Basics of Patent Law and Patentability Criteria

Intellectual property law in general regulates the creation, use and exploitation of mental or creative labor. ‘The term ‘intellectual property has been used for almost one hundred and fifty years to refer to the general areas of law that encompasses copyrights, patents, designs, ad trademarks, as well as a host of related rights.’<sup>142</sup>

Hence, the patents are the one of the areas of intellectual property. Patent law concerns new, industrially applicable inventions.<sup>143</sup> A patent is a limited monopoly that is granted in return for the disclosure of technical information.<sup>144</sup> The state issues the applicant with patent that gives them the exclusive right to control the way their patented invention is exploited for a 20-year period.<sup>145</sup> The applications for granting patent are done through local patent offices of the state, where person wants protection or e.g. in Europe, through European Patent Office.<sup>146</sup> However, as mentioned above patent law grants a monopoly for a limited period of time in respect of an invention in return for disclosure of the details concerning the invention. These details are available for public inspection and are sufficiently comprehensive so that a person skilled in the particular art would be able to make practical use of the invention, in other words, he would be able to work the invention.<sup>147</sup>

Many debates have been going on about the justification of need of patents. There are different opinions around the topic. ‘The proponents of patent protection have emphasized the natural rights of inventors to the products of their mental labor.’<sup>148</sup> While commentators have occasionally drawn on natural rights in support of the grant of patents, the most common

---

<sup>142</sup> L. Bently & B. Sherman, *Intellectual Property Law*, 3 ed., (Oxford University Press, Oxford, 2009) p.1.

<sup>143</sup> D. Bainbridge, *Intellectual Property*, 4 ed., (Financial Times Pitman, London, 1999) p.317.

<sup>144</sup> Bently & Sherman, *supra* note 142, p.335.

<sup>145</sup> *ibid.*

<sup>146</sup> For the detailed information < <http://www.epo.org/>> visited on April 1, 2012.

<sup>147</sup> Bainbridge, *supra* note 143, p.317.

The person skilled in the art is defined as an ordinary practitioner aware of what is common general knowledge in the art at a relevant date. <

<http://www.pronovem.com/infoip/patents/patentabilitycnt.php>> visited on April 1, 2012.

<sup>148</sup> Bently & Sherman, *supra* note 142, p.339.

form of argument has concentrated on the public benefits that flow from the grant of patent monopolies.<sup>149</sup>

‘Another notable and consistent trend has been that whenever commentators talk about the patent system in a *positive* sense, that is a system that regulates and controls behavior in a desirable way, they have almost always seen it as a tool to promote economic ends, such as the encouragement of new industries, research and development, or innovation. In contrast, whenever non-economic factors such as health, human rights, the environment, or ethics are discussed, they have either be treated as external (*negative*) constraints upon the core activities of the patent system, or as undesirable side effects that need to be mitigated.’<sup>150</sup>

Hence, the justification of the patent system is mainly based on its economical worth, that they play big role in macro-economic policy. But when we discuss patents from other perspectives than economic, many opposite ideas will emerge, such as the more benefit for public, as it seems that patents sometimes serve the interest of business rather than the profit for the whole public in general.

When we address the patentability, we have to bear in mind that not every invention is patentable, thus an invention needs to comply with three specific criteria in order to be able to receive a patent. These three important criteria are:

- subject matter should be patentable;
- invention must be new (novelty);
- must involve an inventive step.<sup>151</sup>

Firstly, when we talk about the patentability of subject matter, the important and necessary characteristic is its capability of having ‘industrial application’.<sup>152</sup> ‘This reflects the long-held view that patent protection should not be available for purely abstract or intellectual creations. The need to show industrial applicability also reflects the image of patentable invention as having a concrete technical character.’<sup>153</sup> Hence, an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.<sup>154</sup> Thus, an invention without industrial purpose will not be patentable.

When we discuss ‘industrial application’, there are some restrictions that will exclude patentability of certain subject matters. These exceptions are prescribed by patent laws e.g. exclusion of the patentability of inventions due to being immoral and against ‘*ordre public*’.<sup>155</sup> Patent laws often provide the list of subject matters that are not patentable inventions. For example, EPC 2000 provides the list of the subject matters that are not

---

<sup>149</sup> *ibid.*, p.339.

<sup>150</sup> *ibid.*, p.341.

<sup>151</sup> *ibid.*, p.391.

<sup>152</sup> EPC 2000, Art. 52(1) provides that European patents shall be granted in all fields of technology, if they are new, involve an inventive step and are capable of industrial application.

<sup>153</sup> Bently & Sherman, *supra* note 142, p.392.

<sup>154</sup> See, EPC 2000, Art. 57.

<sup>155</sup> See, EPC 2000, Art. 53(a).

regarded as the inventions within the meaning of patentable inventions, which are the following: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.<sup>156</sup> Precisely, this restriction according to EPC 2000 will be later discussed to see the European approach towards the patentability of hES cell research.

Thus, after addressing patentability subject matter it is important to mention other necessary criterion - novelty of an invention. In brief, “an invention is said to be new if it does not form part of the ‘state of art’. The ‘state of art’ is defined very broadly to include all matter that is available everywhere in the world before ‘priority date’<sup>157</sup> of the invention.<sup>158</sup> According to US patent law, although invention may meet the novelty test, it still may be denied a patent if the patent examiner finds that the invention is obvious.<sup>159</sup>

Another criterion in order to grant a patent on invention is involvement of inventive step. An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a ‘person skilled in the art’.<sup>160</sup>

As we have discussed briefly the basic patentability issues it is worthy to have a look into regional or international patent laws and see how are hES cell research patents regulated.

## 4.2 International Legislative Framework for Patents

Patent legislation framework is wide for many states and it depends on which region a state belongs to. Each state has own patent legislation. Among these, there stands international legislation, that is important and regulates patents internationally or only in specific regions. More or less patents laws are similar among different states of the world.

Thus, this sub-chapter will be focused on various existing patents laws which are regional or international. Hence, I will introduce the following treaties: international- Paris Convention of the Protection of Industrial Property (Paris Convention), the Patent Cooperation Treaty (PCT); Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and regional- The European Patent Convention (EPC) applicable in European Community (EC); US Patent Act - US. This part will also provide comparison between two different patents systems concerning

---

<sup>156</sup> See, EPC 2000, Art. 52 (2).

<sup>157</sup> According to EPC 2000 Art. 54(2), Priority Date- filing date of the patent application. May differ in other patent regimes.

<sup>158</sup> Bently & Sherman, *supra* note 142, p.464.

<sup>159</sup> S. Elias & R. Stim, *Patent, Copyright and Trademark*, (Nolo Press, Berkeley, California, 2000) p.299.

The quality of an obvious invention is such that a person with ordinary skill in the art could reasonably believe that, at the time of its conception, the invention was to be expected.

<sup>160</sup> See, EPC 2000, Art.56.

hES cell research. More precisely this will be the comparison between European and US approaches toward the issue.

## 4.2.1 Paris Convention for the Protection of Industrial Property

The Paris Convention belongs to the treaties administered by the World Intellectual Property Organization (WIPO). The signing of the Paris Convention in 1883 was a landmark event in the history of WIPO and the whole world's intellectual property system.<sup>161</sup> The Paris Convention was 'the first effort of several countries to adopt a common approach to intellectual property.'<sup>162</sup> The Paris Convention applies to industrial property in the widest sense, including patents, trademarks, industrial designs etc.<sup>163</sup> The Paris Convention entered into force in 1884, with 14 member States and was revised at Brussels in 1900, at Washington in 1911, at The Hague in 1925, at London in 1934, at Lisbon in 1958 and at Stockholm in 1967, and it was amended in 1979.<sup>164</sup> For the moment, it counts 174 contracting parties.<sup>165</sup>

One of the main principles of the Paris Convention is a national treatment principle, which means that nationals of a state being party to the Convention must enjoy the same protection and legal remedies in other state party of the Convention with regard to intellectual property.<sup>166</sup> Hence, the state parties to the Paris Convention should treat nationals of other state parties as they would treat their own.

Thus, in general the Paris Convention played a big role in development of intellectual property law and as mentioned previously has set the beginning line of the development of intellectual law as a part of the legal system.

## 4.2.2 Patent Cooperation Treaty (PCT)

'The PCT was set up in order to rationalize patent applications for Member States. Its aim is to centralize, simplify and render more economical patent applications for a series of countries. It is world-wide

---

<sup>161</sup> For detailed information visit WIPO web page: <

<http://www.wipo.int/treaties/en/general/>> viewed on April 3, 2012.

<sup>162</sup> G. Tritton, *Intellectual Property in Europe*, 2 ed., (Sweet & Maxwell, London, 2002) p.54.

<sup>163</sup> For detailed information visit <

[http://www.wipo.int/treaties/en/ip/paris/summary\\_paris.html](http://www.wipo.int/treaties/en/ip/paris/summary_paris.html)> viewed on April 3, 2012.

<sup>164</sup> For detailed information visit <

[http://www.wipo.int/treaties/en/ip/paris/summary\\_paris.html](http://www.wipo.int/treaties/en/ip/paris/summary_paris.html)> viewed on April 3, 2012.

<sup>165</sup> Contracting Parties to the Paris Convention

<[http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty\\_id=2](http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2)> viewed on April 3, 2012.

<sup>166</sup> Paris Convention for the Protection of Industrial Property, Article 2(1).

treaty administered by WIPO and has 144 contracting states.<sup>167</sup> The PCT was signed in 1970 and came into operation from 1978. ‘The PCT only provides for an international application and search: the authority to grant the patent remains with the national patent office.’<sup>168</sup>

‘The PCT procedure thus gives great advantages to the applicant than parallel applications in many national patents offices. Not only is it more cost-effective but the applicant has a considerable period of time to consider the desirability of obtaining protection in foreign countries.’<sup>169</sup>

Thus, PCT is considered one of the world’s wide and easiest ways to protect one’s invention in many countries of the world.

### 4.2.3 TRIPS Agreement

The TRIPS Agreement is a very important international instrument, which regulates trade related aspects of intellectual property law. TRIPS Agreement can be said to be an agreements signed between the members of the WTO, which includes all European countries.<sup>170</sup> The TRIPS covers all the areas of intellectual property including the patents. The TRIPS Agreement provides certain basic principles ‘such as national and most-favored-nation treatment, and some general rules to ensure that procedural difficulties in acquiring or maintaining IPRs do not nullify the substantive benefits that should flow from the Agreement.’<sup>171</sup> In general, The TRIPS Agreement is a minimum standards agreement, allowing members states to have more extensive protection of intellectual property if they wish so. Hence, members have free choice ‘to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.’<sup>172</sup>

There are certain provisions in the TRIPS which deal with patents. Firstly, Article 27 of the TRIPS provides that patents shall be granted for any inventions, whether products or processes in all fields of technology, if they are new, involve inventive step and are capable of industrial application.<sup>173</sup> Moreover, ‘it is also required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced.’<sup>174</sup>

The most interesting part of the TRIPS is provided by Article 27, which sets three exceptions to the basic rules of the patentability. The first

---

<sup>167</sup> As of 2 April, 2012 , For detailed information please visit: < [http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax\\_a.pdf](http://www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf)> viewed on April 2, 2012.

<sup>168</sup> Bently & Sherman, *supra* note 142, p.352.

<sup>169</sup> Tritton, *supra* note 162, p.62.

<sup>170</sup> *ibid.*, p.55.

<sup>171</sup> For detailed information: < [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm)> viewed on April 3, 2012.

<sup>172</sup> For detailed information: < [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm)> viewed on April 3, 2012.

<sup>173</sup> Tritton, *supra* note 162, p.55.

<sup>174</sup> For detailed information: < [http://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm)> viewed on April 3, 2012.

exception deals with inventions that are contrary to 'ordre public' and morality.<sup>175</sup> In this case, 'members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment.'<sup>176</sup> The second exception excludes the patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals.<sup>177</sup> And the lastly the members may exclude inventions concerning plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.<sup>178</sup>

Thus, the TRIPS Agreement plays a big role in international trading of the intellectual property, which was said to have a dramatic impact on developing countries rather than developed ones.<sup>179</sup> Hence, the connection of TRIPS's specific provisions to the thesis topic will be discussed later in this chapter.

## 4.3 hES Cell patents in US and Europe (Comparative Study)

### 4.3.1 European Patent Convention (EPC)

EPC was signed in Munich in 1973 and came into operation on 1 June 1978. The original convention –'EPC 1973', was replaced by the European Patent Convention ('EPC 2000') on 17 December 2007.<sup>180</sup> The provisions of the EPC 2000 apply unless the transitional provisions provide otherwise for the applicability of the EPC 1973. EPC is based upon the patent law of the various member states in force at the time. EPC is an intergovernmental treaty that is distinct for the European Community (EC).<sup>181</sup>

The treaty currently has 38 member states, comprising all the member states of the European Union together with some other countries.<sup>182</sup> European patents are granted in accordance with the EPC by the European Patent Office (EPO), the organization which was set up on October 7

---

<sup>175</sup> TRIPS Agreement, Article 27 (2), available at:<

[http://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm3c\\_e.htm#5](http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5)> viewed on April 3, 2012.

<sup>176</sup> *ibid.*

<sup>177</sup> TRIPS Agreement, Article 27 (3) (a).

<sup>178</sup> TRIPS Agreement, Article 27 (3) (b).

<sup>179</sup> Bently & Sherman, *supra* note 142, p.353.

<sup>180</sup> *ibid.*, p.341.

<sup>181</sup> *ibid.*

<sup>182</sup> As of 2 April 2012, the 38 members are: Albania, Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, United Kingdom, Greece, Croatia, Hungary, Ireland, Iceland, Italy, Liechtenstein, Lithuania, Luxembourg, Latvia, Monaco, the Former Yugoslav Republic of Macedonia, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Sweden, Slovenia, Slovakia, San Marino, Turkey. For more information see:< <http://www.epo.org/about-us/organisation/member-states.html>> viewed on April 2, 2012.

1977.<sup>183</sup> ‘When an applicant wishes to protect his/her invention in a number of European countries, the EPO provides them with the benefit of a single application and search procedure, and a single grant of a bundle of national patents in each of the member states.’<sup>184</sup> Applications are made to the EPO, which is submitted to the Examining Divisions. The appeals can be made either to the Technical or Legal Board of Appeal. In rare cases, the Board of Appeal may refer to the Enlarged Board of Appeal for opinions on some legal issues.<sup>185</sup> ‘Upon grant, a European patent becomes a bundle of national patents that have effect in each of the member states for 20 years from the date of filing.’<sup>186</sup>

Due to various reasons, there emerged a need to change European patent system and thus, a conference took place in Munich in November 2000 to discuss the revision of the EPC. As the result of the conference, the members states of the EPC agreed to make a number of changes to the EPC. Thus, the revised Convention, known as the ‘EPC 2000’, and new Implementing Regulations, were adopted by EPO on 28 June 2001, that came into force on 13 December 2007.<sup>187</sup> ‘For the most part, the EPC 2000 did not bring about (or at least was not intended to bring about) many changes in the existing law.’ The main change was that Article 54(4) EPC has been deleted. This will include all previous European applications irrespective of their designation.<sup>188</sup> And in other cases made some provisions more transparent, e.g. in Article 53(c) states that methods are excluded from patentability, while EPC 1973 said that “methods of treatments and diagnosis were lacking industrial applicability and as such as excluded from patentability.”<sup>189</sup> Hence, the revised version of EPC has made some changes in European patent law, aiming the improvement of the European patent legislation.

### 4.3.2 US Patent Act (General Overview of Patent Legislation in US)

‘The US patent system has its roots in the US Constitution, which states in Article I, Section 8, clause 8: “The Congress shall have power ... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries ...”’<sup>190</sup>

---

<sup>183</sup> EPO web page: <http://www.epo.org/about-us/organisation/foundation.html>> viewed on April 2, 2012.

<sup>184</sup> Bently & Sherman, *supra* note 142, p.342.

<sup>185</sup> See for detailed information:< <http://www.epo.org/about-us/boards-of-appeal.html>> viewed on April 2, 2012.

<sup>186</sup> B Bently & Sherman, *supra* note 142, p.342.

<sup>187</sup> *ibid.*, p.343.

<sup>188</sup> *ibid.*

<sup>189</sup> *ibid.*, p.344.

<sup>190</sup> G. Elliott, *Basic of US Patents and the Patent System*, (The APPS Journal, EISSN 1550-7416, , Vol. 9, Issue 3, July 2007) pp. E317 - E324, p. E317, available at: < [http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2751480/pdf/12248\\_2008\\_Article\\_930317.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2751480/pdf/12248_2008_Article_930317.pdf)> viewed on April 3, 2012.

US patent system is quite complex. The main organization dealing with patent applications is USPTO, which administers the process for obtaining a patent.

The core legislation concerning patents is provided in Patent Act, found in Title 35 of United States Code. The Patent Act is a major legal act in the area of patents. Sections 101-376 of the Patent Act deals with patents and related aspects such as: patentable inventions, conditions of patentability, patent applications etc.<sup>191</sup> Section 101 of the Patent Act stipulates: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”<sup>192</sup> Hence, ‘processes, machines, articles of manufacture, and compositions of matter, as well as improvements of any of these, may be patented, provided they are new and useful.’<sup>193</sup> The way in which section 101 has been interpreted and applied has undergone significant changes. In 1980, the US Supreme Court took up the question of whether a living organism could be the subject of a patent. The decision in *Diamond v Chakrabarty*, 447 United States 303, 206 USPQ 193 (1980), not only proclaimed the patentability of living organisms, but also cited a phrase from the committee reports accompanying the Patent Act of 1952, that “anything under the sun that is made by man” is subject to patenting.<sup>194</sup> Thus, the Patent Act sets no exclusions in regards to the patentability of inventions.

The basic two criteria of the patentability according US legal system is the novelty and non-obviousness of an invention.<sup>195</sup> The novelty of an invention is important criterion to be able to obtain a patent, which basically means that invention must be different from prior art. An invention is considered to be novel -”when no single prior art item describes all of the invention’s elements.”<sup>196</sup> This requirement is set in the Patent Act, Section 102. ‘The quality of non-obviousness refers to the ability of the invention to produce unexpected or surprising new results-results that were not anticipated by the prior art.’ Hence, in order to be patentable, an invention must be non-obvious to a person who has an ordinary skill in art. ‘Analyzing an invention for non-obviousness is difficult primarily because it is a subjective exercise.’ The patent examiner is the person who assesses the criterion of non-obviousness while deciding to grant a patent or not. But once a patent is issued, it can be attacked through court on the ground that the patent examiner made a mistake, while assessing the non-obviousness of an invention.<sup>197</sup>

---

<sup>191</sup> United States Code, Title 35, Chapter 10, available at: <<http://www.law.cornell.edu/patent/patent.part2.table.html#chapt10>> viewed on April 3, 2012.

<sup>192</sup> United States Code, Title 35, Chapter 10, Section 101.

<sup>193</sup> Elliott, *supra* note 190, p. E319.

<sup>194</sup> *ibid.*

<sup>195</sup> United States Code, Title 35, Chapter 10, Sections 102, 103.

<sup>196</sup> Elias & Stim, *supra* note 159, p.299.

<sup>197</sup> United States Code, Title 35, Chapter 10, Section 103.

Duration of the patents is 20 years after the filing date of a patent application to the USPTO.<sup>198</sup>

Thus, there are some differences in US patent system compared to European one that will be discussed later on in this chapter.

### 4.3.3 hES Cell Patents in US

Even though US legislation is allowing granting patents of the hES cells, the issue has been subject to debate for many years, this debate is still active. Since 1998, when scientists at the University of Wisconsin has succeeded in isolating and producing hES cell lines, ‘there has been no shortage of scientific experts and political leaders predicting that stem cell research will lead to the most important medical care advances in our lifetimes.’<sup>199</sup> ‘Senator Orin Hatch has called stem cell research “the most promising research in healthcare perhaps in this history of the world,” and more than 200 members of Congress signed a letter to President Bush claiming that “stem cells have the potential to be used to treat and better understand deadly and disabling diseases that affect more than 100 million Americans, such as cancer, heart disease, diabetes, Parkinson's, Alzheimer's, multiple sclerosis, spinal cord injury, and many others”.’<sup>200</sup>

However, along with amazing potential in hES cell research there has been variety of concerns, that ought to be take into account. ‘One set of issues concerns whether, in spite of potential health benefits, ethical considerations should cause society to prohibit or refuse to fund certain types of stem cell research. Another set concerns, how the relationship between researchers and the donors of the biological matter that is the raw material for stem cell research ought to be regulated.’<sup>201</sup> Hence, there have been many issues of legal or ethical concern in the US in regards to hES cells.

As mentioned above the federal law of the US does not prohibit hES cell research and also does not prohibit obtaining patents on it. However, the federal government has put restrictions of the federal funding of the research itself. These restrictions have quite massive practical effect, as ‘for the federal government provides most of the nation’s funding for basic medical research -- as much as 90 percent or more by some estimates.’<sup>202</sup> In 1992, President Clinton asked National Institutes of Health (NIH) to develop guidelines for hES cell research. The NIH Human Embryo Research Panel recommended ‘several instances in which embryo research should be funded, including some cases in which creating embryos solely for research was justified.’<sup>203</sup> However, later on when Republicans came into power, in 1995 the Congress has banned the federal funding of hES cell research that destroys and endangers human

---

<sup>198</sup> *ibid.*, p.265.

<sup>199</sup> Korobkin & Munzer, *supra* note 26, p.2

<sup>200</sup> *ibid.*

<sup>201</sup> *ibid.*, p.3.

<sup>202</sup> *ibid.*, p.10.

<sup>203</sup> J.A. Robertson, *Embryo Stem Cell Research: Ten Years of Controversy*, ( 38 J.L. Med. & Ethics 193, 2010) p.194.

embryos.<sup>204</sup> This change is known as known as the Dickey-Wicker amendment.<sup>205</sup>

Shortly, this issue became more active among the society, when in 1998 WARF reported first successful culturing of hES cell lines. The crucial issue was if this research was capable to be funded by federal funds. The legal opinion was provided by Harriet Raab the General Counsel of the Department of Health and Human Services (HHS). ‘Raab's legal opinion was that embryonic stem cells were not organisms and thus not embryos within the meaning of Dickey-Wicker. As a result, although hES cells are derived from embryos, they are not themselves embryos, and thus not covered by the federal ban on funding research with embryos.’<sup>206</sup> Then, the NIH developed guidelines and was ready to provide grants for the research, but ‘new Bush administration in 2001 halted such efforts’.<sup>207</sup> ‘The President’s position rested on the view that it is morally wrong to destroy embryos, to which the President accords the status of “life,” and morally wrong to encourage others to destroy embryos...’<sup>208</sup>

The issue was still active when President Obama came into power. Hence, the 2008 election of Barack Obama has radically shifted the federal funding situation. In March 2009, President Obama ordered the lifting of the moratorium on funding of hES cell research with new lines. In his statement accompanying the lifting of the funding moratorium, President Obama said: “When it comes to stem cell research... our government has forced... a false choice between sound science and moral values. In this case the two are not inconsistent. As a person of faith, I believe we are called to care for each other and work to ease human suffering. I believe we have been given the capacity and will to pursue this research and the humanity and conscience to do so responsibly...”<sup>209</sup>

‘The conclusion of the funding saga is that federal funding will inject new resources and energy into stem cell science. No funding is available for the destruction of human embryos or for research with lines derived from embryos created for research purposes, but it may be provided for research on the hundreds of hES cell lines created from leftover embryos since 2001 and which will be created in the future.’<sup>210</sup>

Along the federal laws, the diverse approaches are held by different state laws. For example, four states have enacted statutes that prohibit the use of state funds for hES cell research. States of Arizona, Nebraska, and Virginia explicitly prohibit the use of state funds for such research. ‘Missouri law defines an embryo, even if in vitro, as a “child,” and it prohibits the use of state funds for research on a “living child” if the purpose or likely result of such research is to kill, harm, or target the child for destruction.’<sup>211</sup> Three states such as: California, New Jersey and Massachusetts have taken the opposite position, by initiating and enacting laws that permit or promote

---

<sup>204</sup> Korobkin & Munzer, *supra* note 26, p.10.

<sup>205</sup> Robertson, *supra* note 203, p.194.

<sup>206</sup> *ibid.*, p.195.

<sup>207</sup> *ibid.*

<sup>208</sup> Korobkin & Munzer, *supra* note 26, p.15.

<sup>209</sup> Robertson, *supra* note 203, p.195.

<sup>210</sup> *ibid.*, p.196.

<sup>211</sup> Korobkin & Munzer, *supra* note 26, p.15.

hES cell research. For example, ‘in 2004 California used its initiative process to amend its constitution to establish a right to conduct hES cell research, as well as approving \$3 billion worth of bonds to fund such research.’<sup>212</sup>

As for hES cell patents, the most significant issues concern the extent to which stem cells themselves - the biological material on which future applied research relies - can be patented. Despite the relative infancy of this area of research, as of December 28, 2005, the USPTO had already issued 1,146 patents that contain the phrase “stem cells” in the claims.<sup>213</sup>

While, ‘most commentators agree that time-limited monopoly rights provided by patents are necessary to encourage socially valuable innovations that would otherwise not occur because the costs and risks of the inventive process would outweigh the potential for financial gain. Yet, even if patent policy seeks to satisfy this single principle, doing so becomes complicated when one invention serves as a basis for further innovation.’<sup>214</sup>

The most important stem cells patents in the US are held by the Wisconsin Alumni Research Foundation (WARF) and Johns Hopkins University.<sup>215</sup> WARF’s patents have aroused the main controversy, when in 1998 reported the use of left over human embryos from in vitro fertilization for research purposes. Dr. James Thomson who was the pioneer in isolating hES cell lines in the US received two patents, which were assigned to WARF.<sup>216</sup> WARF has received two additional stem cell patents later on in 2001 and 2006.

Thus, to conclude, according to US legislation there is no prohibition of granting patents on hES cells. But the issue lies in restrictions concerning the federal funding of the research and its patents. In general, there are many patents in the field and the major players in the field are WARF and Johns Hopkins University.

#### 4.3.4 hES Cell Patents in Europe

Unlike US, the main issue, which is still active in Europe, stands in morality of patentability of hES cells. The Europe has been discussing the patentability criteria from moral perspectives; the good example of this approach was seen by the decision of EboA of EPO in WARF case. This case will be introduced later on in this chapter.

As in 2004, the EPO has refused to grant a patent on hES cells, this issue has been highly criticized. The main reason for banning patents on hES cells in Europe has its roots in the current legislation. However, many Member States of EU have their own laws regulating hES cell research and its patents. Several countries, including Belgium, Sweden, and the UK, allow research using surplus human embryos up to 14 days of age. Whereas, other

---

<sup>212</sup> Korobkin & Munzer, *supra* note 26, p.15-16.

<sup>213</sup> *ibid.*, p.42.

<sup>214</sup> *ibid.*, p.43.

<sup>215</sup> *ibid.*, p.44.

<sup>216</sup> *ibid.*, p.45.

countries have more restricted approach and prohibit hES cell research entirely, such as Ireland and Austria. For instance, according to German and Italian legislation, there is the prohibition of derivation of hES cells, but at the same time scientists are allowed to import these cells for research use.<sup>217</sup> Even though these differences exist, the EU has taken an approach that stands in exclusion of patentability of certain inventions according to the current legislation. This legislation includes the EPC 2000 and European Directive on the Legal Protection of Biotechnological Inventions (Biotech Directive) in attempt to harmonize European laws and polices relating to biotechnology patents.

EPC 2000 in Article 53 sets the exceptions to the patentability, which includes:

- a) inventions the commercial exploitation of which would be contrary to “*ordre public*” or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
- b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
- c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.<sup>218</sup>

The one of these exceptions is important for the hES cell research, that is Article 53 (a), which stipulates that the inventions may be excluded from patentability on “*ordre public*” and morality grounds. The Rule 28 (c) in Implementing Regulations to the EPC 2000 sets that under Article 53(a), “European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: c) uses of human embryos for industrial or commercial purposes; ...”<sup>219</sup> Thus, Rule 28(c) specifies that any biotechnological invention which uses human embryos for industrial or commercial purposes are excluded from patentability. ‘The exclusion of uses of human embryos for industrial or commercial purposes is relatively straightforward. To a large extent, the scope of the exclusion will depend on what is meant by ‘industrial’ or ‘commercial’ purpose.’<sup>220</sup> Therefore, the provisions of the EPC 2000 are clear to make us understand that hES cells may be excluded from patentability on these grounds, since they involve human embryos and have industrial or commercial purposes.

Another legal act that deals with the similar issues is the Biotech Directive of EU, which was enacted by European Parliament and the

---

<sup>217</sup> L. Bonetta, *European Stem Cell Patents: Taking the Moral High Road ?*( Cell 132, February, 2008) pp. 514-516, p.515.

<sup>218</sup> EPC 2000, Article 53. Available at: < <http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar53.html>> viewed on April 5, 2012.

<sup>219</sup> EPC 2000, Rule 28(c).

<sup>220</sup> Bently & Sherman, *supra* note 142, p.460.

Council in 1998. The Biotech Directive deals with legal protection of biotechnological inventions; its aim was to harmonize legislation of European patent legislation and policies. The Article 6 (1) of the Biotech Directive provides that "inventions shall be considered unpatentable where their commercial exploitation would be contrary to *"ordre public"* or morality" More precisely, in Article 6 (2) (c), excludes patentability of inventions involving: "uses of human embryos for industrial or commercial purposes."<sup>221</sup>Hence, the Biotech Directive similarly to EPC 2000, may exclude the patentability of hES cells, as they might be contrary to the *"ordre public"* or morality and specifically, as they involve human embryos for commercial or industrial exploitation. Hence, the provisions of both EPC 2000 and the Biotech Directive set the same rule.

The Biotech Directive was implemented in national laws of EU Members States, because they had no other choice. The Directive was meant to harmonize patent law in Europe and thus stimulate the competitiveness of the biotech industry. However, "it has created considerable uncertainty and disruption to patent law," says Aurora Plomer, a professor of law at the University of Sheffield, UK. According to Helen Brearley, English patent attorney- there is no need of regulation by the EPO, since many Member States have their own legislation in this respect.<sup>222</sup> Hence, the issues in regards to the exceptions from patentability on the grounds of morality were and are often criticized. Some even consider that such exclusions can stifle research and innovation.<sup>223</sup>

Another interesting aspect of the implementation of the Biotech Directive is that even some Member States tend to interpret the rules set by the Directive differently. E.g. "UK has interpreted the Directive narrowly". Therefore, The UK Intellectual Property Office (UKIPO) will not grant patents relating to processes of obtaining stem cells from human embryos or for totipotent hES cells, which have the potential to develop into an entire human body. However, in contrast to the EPO, it will issue patents relating to pluripotent hES cells because they do not have the potential to develop into an entire human body.<sup>224</sup>

The TRIPS Agreement similarly to the EPC 2000 and the Biotech Directive sets the important exceptions to the general requirements of the patentability among its signatory states. According to TRIPS, Article 27 (2) : "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. "<sup>225</sup>

As we had a look on legislation which is applicable for European states, the other matter lies in how these legal provisions are used in practice and how European case law exercises it.

---

<sup>221</sup> Article 6 of the Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, available at: <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML>> viewed on April 5, 2012.

<sup>222</sup> Bonetta, *supra* note 217, p.515.

<sup>223</sup> *ibid.*

<sup>224</sup> *ibid.*, pp. 515-516.

<sup>225</sup> TRIPS Agreement, Article 27 (2).

The main debate in Europe was started when WARF decided to have its patents in Europe. The whole story of this controversy began in when The European WARF patent application entitled “Primate embryonic stem cells” was filed in 1996 and was initially rejected by the examining division of the EPO in 2004.<sup>226</sup> The landmark cases will be discussed later in details in the last section of the thesis.

### 4.3.5 Comparison between European and US Approaches to hES Cell Patents

As we have discussed the main aspects related to legislative or practical side of the hES cell research both in Europe and US, it may be necessary to make a comparison and final conclusions in this regard.

We have to bear in mind that the whole controversy among Americans and Europeans began when James Thomson was granted with first hES cell patent in the US, which was assigned to WARF. Later on the WARF was the same organization, which was denied a patent in Europe, as it was deemed to be against European legislation.

Thus, the main differences between American and European approaches lie within their legislations. As according to the United States Code, the ‘inventions as long as they are useful, novel and non-obvious’<sup>227</sup> can be patented. ‘In stark contrast to EU patent law, no provision in the U.S. Patent Act explicitly conditions patentability on the morality of an invention or its consistency with public policy. However, the “moral utility” or “beneficial utility” doctrine, which dates back to Justice Story’s opinion in *Lowell v. Lewis* in the early 19th century, holds that an otherwise patentable invention that lacks a morally permissible use may not receive a patent. This doctrine was originally used to deny patents on gambling machines and early medical frauds and fell into disuse in the 20th century.’<sup>228</sup> However, later on, the US courts moved to the view that patent law is intended to be morally neutral.<sup>229</sup> For instance, in 1999, the Federal Circuit rejected the doctrine in *Juicy Whip v. Orange Bang* as unsupported by the Patent Act. In that case the validity of a patent was challenged on the ground that the invention allegedly served the purpose of deceiving the public. Some scholars have argued, however, that courts should revive the doctrine and use it to create a public policy limitation on patentability similar to the European Union’s “*ordre public*” clause.<sup>230</sup>

Thus, as mentioned previously the US legislation does not have morality clause attached to the issue of patentability of the hES cells, along as the application meets the main criteria set for obtaining a patent. While US was already granting patents on hES cells, in 1998 the EU was debating about the same issue from moral perspective, that resulted in adopting the

---

<sup>226</sup> R. Fitt, *New Guidance on the Patentability of Embryonic Stem Cell Patents in Europe*, (Nature Biotechnology, ISSN 1087-0156, Vol. 27, Issue 4, 04/2009) pp. 338-340, p.338.

<sup>227</sup> United States Code, Title 35, Chapter 10, paras. 101-103.

<sup>228</sup> Korobkin & Munzer, *supra* note 26, pp. 57-58.

<sup>229</sup> *ibid.*, p.58.

<sup>230</sup> *ibid.*

Biotech Directive, which was determined to harmonize European laws. Thus, unlike the US, the Europe has few provisions in current legislation (including EPC 2000, the Biotech Directive, the TRIPS Agreement), which occur to ban hES cell patents on the grounds of morality. The European approach has been noticeably seen in the case law, which indicates the practice of law.

Therefore, in order to conclude, regardless vast differences the both US and Europe tend to consider this issue to be a very controversial and very substantial in a sense.

# 5 hES Cell Patents and Human Rights

Throughout the legal history, the connection between human rights law and intellectual property law was vague and never addressed. However, the significant development of these legal regimes along with new technological era, have expanded the interrelation of these dissimilar legal spheres.<sup>231</sup> Ten years after the conclusion of the TRIPS has triggered a globalization IPRs, the relationship between Intellectual Property Rights (IPs) and Human Rights (HRs) is the 'subject of public debate in the media as well as in various academic and political fora.'<sup>232</sup>

The relationship between HRs and IPRs has become recent subject of interest among international organizations, governments, legal scholars etc.<sup>233</sup> Hence, while addressing hES cell patents as the part of intellectual law regime, many human rights related aspects come into play. Many still argue that there is a big clash among these two legal regimes and often discuss how to find a solution to this problem. However, it is not the question that patents in general are often criticized for not taking into consideration human rights issues. The same is in case of hES cell patents which can be often criticized for being not compatible with human rights law. Therefore, this part will deal with the main theories about the interaction of HRs and IPRs and also about applying special HRs based framework for IP regime. This chapter will also bring some main human rights related discussions concerning hES cell patents.

## 5.1 Relationship between HRs and IPs (Toward HRs Framework for IP)

We can say that IP and HR law share the same origin having roots in Western societal developments (industrialization, scientific and technological innovations, economic growth, expansion of international commerce and others) starting in 19<sup>th</sup> century.<sup>234</sup> The IP law was shaped in the beginning of 19<sup>th</sup> century, which was marked by adopting two main fundamental instruments such as the Paris Convention of 1883 on industrial

---

<sup>231</sup> L.R. Helfer & G.W.Austin, *Human Rights and Intellectual Property: Mapping the Global Interface*, (Cambridge University Press, United States, 2011) p. xii.

<sup>232</sup> J. Cornices, *Human Rights and Intellectual Property: Conflict or Convergence*, (The Journal of World Intellectual Property, ISSN 1422-2213, Vol. 7, Issue 2, 03/2004), pp. 135 – 167, p.135.

<sup>233</sup> Helfer & Austin, *supra* note 231, p. 31.

<sup>234</sup> W. F. Grosheide (ed.), *Intellectual Property Rights and Human Rights: a Paradox*, (Edward Elgar, Cheltenham, 2010) p. 3.

property law and the Berne Convention of 1886 on copyright law.<sup>235</sup> The HR law regime on the other side was emerged after founding the United Nations after the World War II and particularly by adopting the UDHR in 1948.<sup>236</sup> However, it appears, that in spite of the fact that these branches of law are both rooted in the indicated societal developments,' from their beginning and over the years they have evolved largely separately, from being not interrelated at all into a rather problematic relationship.'<sup>237</sup> Therefore, the main reason for the isolation of these legal regimes was that both of them were occupied with their own concerns not seeing the possible threat or aid of one regime to another in their interaction.<sup>238</sup>

The important is to note that it was the HRs law that first time addressed IPs in its regime. This can be seen on the example of Article 27<sup>239</sup> of the UDHR and Article 15<sup>240</sup> of ICESCR. The importance of IP law in HR law discourse was emphasized by the UN Committee on Economic, Social and Cultural Rights (CESCR) in its general comments No. 17 and No. 21, underlining the issues of IPs in HR law. However, on the other hand you cannot find any human rights related provisions in the IP related treaties.

The emergence and recent development of both IPs and HRs caused introduction of the discussion concerning the relationship among HR and IP laws. That is why theories of coexistence and conflict were introduced. Those who believe in the conflict theory share the opinion that IPs are incompatible with HRs. HRs in this case are deemed to be restrictive legal instruments for execution and enforcement of IPs. Thus according to those supporting the conflict theory, conflict among IP and HR regimes, result in hierarchal predominance of HR law.<sup>241</sup> The problem of the conflict of IP and HR regime was also raised in 2001 by the CESCR which concluded that 'any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.' In order to resolve these conflicts, UN human rights bodies urged the member states to recognize "the primacy of human rights obligations over economic policies and agreements".<sup>242</sup>

The theory of coexistence on the other hand sees, HRs and IPs as essentially compatible, but as in tension over where to strike balance between protection and access.<sup>243</sup> This coexistence theory supports the idea

---

<sup>235</sup> *ibid.*, p. 4.

<sup>236</sup> Helfer & Austin, *supra* note 231, p. xi.

<sup>237</sup> Grosheide, *supra* note 234, p. 5.

<sup>238</sup> Helfer & Austin, *supra* note 231, p. 34.

<sup>239</sup> Article 27 of the UDHR: 1. the right to freely participate in cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits; 2. the right of everyone to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

<sup>240</sup> Article 15 of the ICESCR: right of everyone : (a) to take part in cultural life; (b) to enjoy the benefits of the scientific progress and its applications; (c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

<sup>241</sup> Grosheide, *supra* note 234, p. 5.

<sup>242</sup> Helfer & Austin, *supra* note 231, p. 65.

<sup>243</sup> *ibid.*, p. 73.

as provided by Grosheide that human rights law is seen as the fundament of intellectual property law. Grosheide states that these two legal regimes pursue the same goals. And there the need of balance on one hand private monopoly powers of inventions and on the other hand the access to these intellectual products by public.<sup>244</sup> The key concern in the coexistence approach lies in the means of modifying IP rules in a way that it will consider HR aspects in it.<sup>245</sup> This is when the idea of applying human rights framework to IP law becomes relevant.

The HRs approach in IPs will be a solution to some inconsistencies among these regimes. For example, Drahos sees HRs as fundamental rights and states that ‘human rights would guide the development of intellectual property rights and intellectual property rights would be pressed into service on behalf of human rights’, (calling IPs –“ instrumental rights”).<sup>246</sup> Drahos believes that HRs and IPs can exist, and IPs can serve as instrumental rights in promoting and protecting HRs. According to him the IP through the prism of HR discourse will encourage everyone’ to think about ways in which the property mechanism might be reshaped to include interests and needs that it currently does not.’<sup>247</sup>

Chapman agrees with the idea of HRs approach in IP laws, which should strike a balance between interests of inventors/creators and interests of public in general. Chapman thinks that HRs approach is based on ‘protecting and nurturing human dignity and the common good’.<sup>248</sup> Chapman’s viewpoint suggests after analyzing that the international HR instruments’ provisions (e.g. UDHR and ICESCR) obliges it Member states to have explicit HRs approach in their IP regimes.<sup>249</sup> Chapman’s HRs framework proposes some obligations for State parties. The obligations include the following:

- IP law should include explicit HRs and ethical provisions as criteria for evaluating applications for patents and trademarks. Along this must create an institution which will deal with this type of evaluations. This body will have the jurisdiction to invalidate an existing or pending patent by its ruling on the basis that it infringes human rights or becomes inconsistent with ethical or cultural norms.
- The nature of IP regimes must consider each country’s development requirements and must be consistent with cultural orientations of major groups.
- In order to build this HRs based framework it is necessary to adapt IP laws to these principles or even adopt new IP legislation which is in harmony with HRs and ethical norms.

---

<sup>244</sup> Grosheide, *supra* note 234, p. 5.

<sup>245</sup> Helfer & Austin, *supra* note 231, p. 73.

<sup>246</sup> Grosheide, *supra* note 234, p. 22.

<sup>247</sup> *ibid.*

<sup>248</sup> Helfer & Austin, *supra* note 231, p. 76.

<sup>249</sup> Grosheide, *supra* note 234, p. 23.

- IPs related to science should promote scientific progress and broad access to its benefits for the public etc.<sup>250</sup>

However among conflict and coexistence theories, there are some other scholars who went beyond these theories, such as Peter K. Yu and Laurence R. Helfer. For instance, Yu criticizes the conflict or coexistence theories by stating that some attributes of IPs are protected in international or regional HRs instruments, while other attributes have no HRs origin at all. For these reasons it is misleading to state that HRs and IPs conflict or coexist with each other. Therefore, because of overlapping HRs attributes, these two regimes both conflict and coexist with each other.<sup>251</sup>

Helfer thinks that there is a need of developing a comprehensive and coherent HRs framework for IP law and policy.<sup>252</sup> Helfer states that historically, trace of HRs framework for the IP first was seen in the UDHR (Article 27). Protecting the material and moral interests of an author was not an accident but the UDHR drafters' intention.<sup>253</sup> Helfer introduces three possible futures of building HRs framework in IP law. The first suggested framework is called "Using Human Rights to Expand Intellectual Property". According to this framework, there should be the expansion of IP protection property standards at the expense of other HRs and the interests of licensees, users and consumers. Hence, 'industries and interest groups that rely on IPs for their economical well-being would invoke the authors' rights and property rights provisions in human rights treaties to further augment existing standards of protection.'<sup>254</sup>

Second framework suggests "Using human rights to Impose External Limits on Intellectual Property". In this framework, the owners of IPs who has invoked authors' and property rights in HRs laws to demand additional legal protections will be resisted by user groups. These groups will be able to use their fundamental rights and freedoms in order to create 'competing version of the framework', that will use HR law to restrict IP.<sup>255</sup>

While the first two frameworks have the same basis, the third suggested framework 'proceeds from very different premise'.<sup>256</sup> This framework is called "Achieving Human Rights Ends through Intellectual Property Means". Firstly, there are minimum outcomes (in health, education, poverty etc.) is required of states by HR law. IP will play only secondary role in this framework in order to help states to reach these outcomes. Hence, where IP laws support to achieve HRs outcomes governments of states should embrace it.<sup>257</sup>

---

<sup>250</sup> Helfer & Austin, *supra* note 231, pp. 77-78.

<sup>251</sup> *ibid.*, p. 81-82.

<sup>252</sup> L.R. Helfer, *Toward a Human Rights Framework for Intellectual Property*, (40 U.C. Davis L. Review, 2007) p. 977.

<sup>253</sup> *ibid.*, p. 978.

<sup>254</sup> *ibid.*, p.1015.

<sup>255</sup> *ibid.*, p.1017.

<sup>256</sup> *ibid.*, p.1018.

<sup>257</sup> Helfer & Austin, *supra* note 231, p. 84.

In order to conclude this part, the relationship between IPs and HRs has become more evident and of a big importance, thus if we want to have these different legal regimes to coexist, we ought to have a certain approach which will consider interests of both spheres. Therefore, the need for creating HRs framework in IP is a main issue at the bar. HRs framework will lead to avoid all current inconsistencies that are problematic for both HR and IP laws. This HRs based approach in IP is very crucial for partially solving the hES cell patent debate.

## **5.2 HRs Related Issues in hES cell Debate**

Many ethical issues have been raised in regards to the hES cell controversy. I have brought ethical arguments in the debate, these arguments included ethics of human rights as well, which precisely were meant in context of the “human dignity”. As “human dignity” is not merely human rights concept it was discussed in the part related to ethics, however we have to remember that main HRs related issue in hES cell controversy is based on “human dignity” as it is enshrined in many human rights instruments as the founding principle of it. Hence, this part will exclude “human dignity” and will mainly focus on other issues: including the right to life arguments in hES cell controversy.

### **5.2.1 IP Issues Addressed in International HRs Instruments**

It is evident that the first step taken in regards to the addressing IPs and HRs in the HRs instruments is the UDHR and the ICESCR. These treaties as mentioned previously have addressed IPs in the context of HRs. The Article 27 of the UDHR sets: “1. the right to freely participate in cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits; 2. the right of everyone to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” This article acknowledges both author’s and public’s protection of interests. Firstly, emphasizes that public has the right participate in cultural life, enjoy arts and share and benefit from scientific advancement. Secondly, it states that author’s material and moral interest need to be protected. This provision from the UDHR is clear to state that there’s a need of balance between authors/inventors’ and public’s interests. IPs aim is to provide enjoyment of everyone’s rights. That is why it is often disputable, when we discuss the benefit of IPs for the public in general. This debate is very relevant when we argue different patents. And hence, is applicable in case of hES cell patents. These patents were often criticized for being merely concentrated on the benefits of private actors rather than public. The good example of this is the monopoly of the WARF/Geron<sup>258</sup> in the US, in the field of hES cell patents,

---

<sup>258</sup> Geron-is biotechnological/biopharmaceutical company in US that holds the WARF licenses (possessing exclusive commercial rights) on some types of stem cells (including

that are considered to hinder the scientific research as well as its the public benefit in general.

The similar provision to the Article 27 of the UDHR is provided by Article 15 of the ICESCR, stipulating: “right of everyone : (a) to take part in cultural life; (b) to enjoy the benefits of the scientific progress and its applications; (c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.” Both the UDHR and the legally binding - the ICESCR oblige it Member states to protect/promote these rights. Thus, in order to be consistent with legal norms in the ICESCR, ‘it requires that the type and level of protection afforded under any intellectual property regime directly facilitate and promote scientific progress and its applications and do so in a manner that will broadly benefit members of society on an individual, as well as collective level.’<sup>259</sup>

This HRs based approach establishes a higher standard for evaluating patent applications, namely that the proposed invention also be consistent with the inherent dignity of the human and with central human rights norms. The HRs approach also ‘entails a right of protection from possible harmful effects of scientific and technological development, again on both individual and collective levels.’<sup>260</sup> Even though the ICESCR obliges the Member states under Article 15, ‘economic globalization and increasing privatization and commercialization of science has made it even more difficult to achieve the various balances envisioned in Article 15.’<sup>261</sup>

The economic globalization in general has introduced many complications for the HRs and IPs related to science. As Chapman states HRs approach is based on the centrality of protecting and nurturing human dignity and the common good. It evaluates science according to its ability to promote these goals. In contrast, commercialization and privatization place greatest emphasis on the profitability of the science and its contributions to economic competitiveness.<sup>262</sup>

Hence, it is very important that development of IPs in the field of science can bring not good but quite opposite result for the people. This issue is very crucial in the case of hES cells, because as addressed previously, the overall “goodness” of their patents can be questioned. Since in reality the breakthrough results of hES cells research and its patents will be unaffordable to the general public, it is illogical to state that it will merely affect public in good way. Therefore, it is hard to argue that this research and its patents really serve “common good “of people as referred by Chapman. Other important issue is how the patent monopolies will

---

neural, pancreatic stem cells). For detailed information, please visit: < <http://www.geron.com/> >, < [http://www.lifesciencesfoundation.org/events-Geron\\_and\\_WARF.html](http://www.lifesciencesfoundation.org/events-Geron_and_WARF.html) > viewed on April 25, 2012.

<sup>259</sup> A. R. Chapman, *A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science*, (Intellectual Property and Human Rights, WIPO Publication No.762(E), 2007) p. 128, Available at: <

<http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/chapman.pdf>.

<sup>260</sup> *ibid.*

<sup>261</sup> *ibid.*, p. 129.

<sup>262</sup> *ibid.*, p. 130.

hinder the innovation and creativity in the field of science and biotechnology.

And final problematic aspect stands in the protection of human dignity and ethical issues. That is the reason why the Committee on Economic, Social and Cultural Rights (CESCR) has provided the interpretation of Article 15 of the ICESCR in its General Comment No. 17. In the Comment, Committee states that, State parties should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity, including the rights to life, health and privacy, e.g. by excluding inventions from patentability whenever their commercialization would jeopardize the full realization of these rights.<sup>263</sup> Hence, the Committee is very clear and obvious that, any scientific progress, which might be contrary to human rights and dignity should be prevented by contracting states. Thus, if we think that hES cell research and its patents are contrary to human rights and human dignity, as ICESCR has binding effect for its member states to prevent contradictory usage of science and should simply ban issuing patents in this regard.

## **5.3 Introduction of Right to Life Arguments in hES Cell Debate**

'Life is tantamount to human existence. First of all, a human being must be present in the world before being able to fill in a space where he/she can unfold and assert his/her identity'.<sup>264</sup> Hence, for many the right to life is a beginning of everything, if you simply do not have this right guaranteed you will be not able to exercise other rights. However, it is always a controversial topic to find the scope of this right. Many deem that person becomes the bearer of this right from the moment of the conception, while others state that it starts when the person is actually born. The main problem is that this debate does not only belong to human rights related issues but also morals and ethics. That is why many still argue. However, I think it is quite relevant to introduce the right to life arguments in the hES cell discussion, as it involves the early embryos. Hence, this part will address the legal framework of the right to life and main related arguments in connection to hES cells.

### **5.3.1 Right to Life (International Legal Framework)**

The right to life is undoubtedly the most fundament of all human rights. For those who believe in hierarchy of rights the right to life is on the top of the hierarchy. However, there is no doubt that right to life is still the most

---

<sup>263</sup>See E/C.12/GC/17, General Comment No. 17 (2005), Committee on Economic, Social and Cultural Rights, para. 35.

<sup>264</sup>C. Tomuschat, E. Lagrange & S. Oeter (Eds.), *The Right to Life*, (Martinus Nijhoff Publishers, Leiden, 2010) p.3.

controversial right, as it is often problematic to set and define scope of it. That is why many argue when to consider the beginning or end of life according to the human rights law.<sup>265</sup>

The right to life is enshrined in various international or regional human rights instruments including: UDHR (Art. 3)<sup>266</sup>, ICCPR (Art. 6)<sup>267</sup>, ECHR (Art. 2)<sup>268</sup>, CRC (Art. 6)<sup>269</sup>, ACHR (Art. 4)<sup>270</sup>, ACHPR (Art. 4)<sup>271</sup>.

We have to bear in mind that even though the right to life is fundamental it is still not absolute, it can be violated for example during armed conflicts etc. The states are obliged to take positive steps in order to protect the right to life, states' actions should include enacting proper legislation, adequate full investigation when deprivation of this right occurs, suitable punishment of culprits etc. States' obligations to protect right to life, is linked to duty of providing appropriate health care as well.

The essential part of states' obligations in regards to the right to life is to abolish death penalty, which has been problematic issue for decades. Even though international law condemns any form of capital punishment, it is still used as method of punishment in some countries such as the United States of America, Saudi Arabia and China.<sup>272</sup> International legal system took steps in order to improve situation regarding to prohibiting death penalty and enacting Second Optional Protocol to the ICCPR, which abolishes capital punishment. This Protocol states in the Article 2 that no reservation is admissible, "except for a reservation made at the time of ratification or accession that provides for the application of the death penalty in time of war pursuant to a conviction for a most serious crime of military nature

---

<sup>265</sup> R. K .M.Smith, *Textbook on International Human Rights 4 ed.*, (Oxford University Press, Oxford, 2010) p.210.

<sup>266</sup> Article 3 of the Universal Declaration of Human Rights (1948) states:"Everyone has the right to life, liberty and security of person."

<sup>267</sup> Article 6 of the Covenant on Civil and Political Rights (1966) states: "Every human being has inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life...."

<sup>268</sup> Article 2 of the European Convention for the Protection of Human Rights and Fundamental Freedoms (1950) states: 1. "Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law. 2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than absolutely necessary: (a) in defence of any person from unlawful violence; (b) in order to effect a lawful arrest or to prevent the escape of a person lawfully detained; (c) in action lawfully taken for the purpose of quelling a riot or insurrection.

<sup>269</sup> Article 6 of the Convention on the Rights of the Child (1989) states: "1. States Parties recognize that every child has the inherent right to life. 2. States Parties shall ensure to the maximum extent possible the survival and development of the child."

<sup>270</sup> Article 4 of the American Convention on Human Rights (1988) states: 1. Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life...."

<sup>271</sup> Article 4 of the African Charter on Human and Peoples' Rights (1981) states: " Human beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person. No one may be arbitrarily deprived of this right."

<sup>272</sup>Smith, *supra* note 265, p.197.

committed during wartime.”<sup>273</sup> The death penalty abolition was also provided by regional human rights instrument, such as Protocols No. 6 and 13 of the ECHR.<sup>274</sup>

The main problem in regards to the right to life still stands in the scope of this right and understanding when life begins or ends. This has been debated quite often and still there is no clear answer to the problem.

The beginning of life is usually addressed in the cases which deal with the right to life of unborn and abortions. Since the actual legal text is vague using terms such as “everyone” or “inherent”. The vagueness of the actual legal text causes different interpretations of the legal norms. These questions are often asked: does term “everyone” include unborn children or does right to life as it is stated is “inherent” starts from the moment of conception within the meaning of the human rights law? The main problem is that this matter is often argued and never reached a solution of the interpreting legal norms. However, many international or regional human law courts play a big role in interpreting the provisions of the treaties. Like the European Court of Human Rights (ECtHR) that uses its case law to define the scope of the ECHR’s provisions. But still some argue that there is often misinterpretation which ignores main aim and the purpose of treaty’s drafters.<sup>275</sup>

Therefore, the most of the international or regional human rights treaties tend to abstain from being clear in regard to its scope when life begins. The only exception is the American Convention on Human Rights (ACHR), stating in Article 4 that the right to life “in general, is protected from the moment of conception”. However, if we have a look at ECtHR’s interpretation of the right to life, in regards to the beginning of it, attempts to extend this right to the unborn have not proven successfully.<sup>276</sup> But there are many diverse opinions even in the various decisions of ECtHR.

The same problems occur in regards to the end of life, when the scholars usually discuss if the right to life includes the right to end it. This debate is often raised in regards to euthanasia. However, if we take the ECtHR again, its case law interpreted the right to life as not including a right to die.<sup>277</sup>

Thus, the scope of the right to life can be debatable and too vague to understand among many human rights instruments. And still one can argue that the right to life can be expended to the right to life of unborn and thus will be relevant for discussing it in the context of hES cell debate.

---

<sup>273</sup> Second Optional Protocol to the International Covenant on Civil and Political Rights, 1989, UN, General Assembly.

<sup>274</sup> K. Douwe, *The Right to Life, A Guide to the Implementation of Article 2 of the European Convention on Human Rights*, (Human Rights Handbooks No. 8, The Council of Europe, F-67075 Strasbourg Cedex, 2006) p.85.

<sup>275</sup> See, R. Joseph, *Human Rights and the Unborn Child*, (Martinus Nijhoff Publishers, Leiden, 2009).

<sup>276</sup> Smith, *supra* note 265, p.213.

<sup>277</sup> See *Pretty v. U.K.* (2002), 35 E.H.R.R. 1 (ECtHR).

### 5.3.2 Right to Life Arguments

The right to life is deemed to be one of the most fundamental rights of all time. However, how can we extend this right to unborn life? As hES cells are early embryos we can bring right to life arguments in the hES cell debate. This set of argumentation is based on interpretative and historic analysis of the international human rights treaties. Right to life is enshrined in various human rights instruments including UDHR (Article 3), ICCPR (Article 6), CRC (Article 6), ECHR (Article 2), but none of them include word 'before birth' or 'conception' in legal provisions. Only exception in this regards, is American Convention on Human Rights, stating in the article 4 (1): "Every person has the right to life....in general, from the moment of conception." Hence, ACHR is only one of all international or regional human rights instruments, which literally states that right to life is being protected from the moment of conception.

Therefore, since the most of the human rights treaties do not include phrases such as: 'from the moment of conception' or 'before birth', understanding of beginning of life depends on interpretation of a specific legal norm.

The UDHR is the one of the most important document and is deemed to be a foundation of human rights, regardless its non binding nature *per se*. According to Article 1 of UDHR, "All human beings are born free and equal in dignity and rights...". But does the word 'all' in this norm includes life before birth?

Rita Joseph in her book applies interpretative analysis of this instrument, stating that, term all human beings includes the child before birth. The General Assembly of the UN examined the promised protection of the children's rights in the UDHR and created ten principles which were included in the 1959 Declaration of the Rights of the Child (DRC). This document was preliminary outline for the principles and rights which would be codified in the CRC later on. The DRC's Preamble specifically included "appropriate legal protection for the child before the birth as well as for the child after birth."<sup>278</sup> Joseph underlines the fact that international community has already understood and agreed that the UDHR is legally binding as customary law. According to Joseph the UDHR recognized the legal status of the child before birth and this can be easily seen from the draft history of this treaty.<sup>279</sup>

From both historical and modern meaning of term "child" as provided in the UDHR, did include the unborn child as well. 'It was the "ordinary" meaning in the sense of it being well established tradition, that the child before birth, at birth, and after birth, was owed the duty of care because of the inherent vulnerability concomitant with his level of immaturity.'<sup>280</sup>

In her idea, a careful and throughout reading of the negotiating history of Article 1 confirms that there is no evidence whatsoever that the word 'born' was used intentionally to exclude fetus or any antenatal application of

---

<sup>278</sup> Joseph, *supra* note 275, p.47.

<sup>279</sup> *ibid.*, p.3.

<sup>280</sup> *ibid.*, p.7.

human rights.<sup>281</sup> Diverse understandings of the term ‘born’ enunciated during negotiations on the text included following: moral birth took place when people were born into human family etc. In Joseph’s opinion there was no proposal to drop “born” to protect right to life from the moment of conception. Because there was no perceived necessity - the right to life for unborn was accepted by the international community at that time as given.<sup>282</sup>

Rita Joseph brings up not only textual, but historical analysis of the issue. She analyses historical backgrounds of admitting various human rights treaties such as ICCPR, CRC and so on. For instance, she discusses the First Draft of the International Covenant on Human Rights (1947), which included term ‘from the moment of conception’ in its original text for Article 1, stating: “It shall be unlawful to deprive any person, from the moment of conception, of his life...”.<sup>283</sup> The unborn children are protected under Article 6(5) of the ICCPR, which asserts: “sentence of death shall not be imposed for crimes committed by persons below eighteen years of age and shall not be carried out on pregnant women”. According to Joseph’s interpretation, prohibition of execution against pregnant women indicates that ‘the child from the State’s first knowledge of child’s existence, is to be protected.’<sup>284</sup> Joseph states that during 5<sup>th</sup>, 6<sup>th</sup> and 8<sup>th</sup> Session of the UN Commission on Human Rights, the *travaux preparatoires* for the ICCPR are clear in referring that the right to life should extent to the unborn children. Later on in 1957 on the 12<sup>th</sup> Session of the Third Committee, the right to life of innocent unborn child, states:

“The principle reason for providing in paragraph 4[now Article 6(5)] of the original text that the death sentence should not be carried out on pregnant women was to save the life of an innocent unborn child.”<sup>285</sup> Only recorded attempt to introduce exceptions to the right to life in Article 4 (now Article 6) in the ICCPR Draft occurred in the Working Group’s 2<sup>nd</sup> Session in 1947 that underlines that it shall be unlawful to procure abortion except in the case when it is permitted by law to safeguard the life of the woman, or in case of mentally disabled parents or in case of rape.<sup>286</sup> However, these exceptions were never actually written in the text of the original document. Hence, Joseph is confident to state that the aim of the ICCPR drafters was to protect children both before and after birth.

In regards to the CRC, Joseph emphasizes the fact that the Convention itself does not protect children before birth because the right of unborn in the CRC is only mentioned in its Preamble. The Preamble of the CRC stipulates: “Bearing in mind that, as indicated in the Declaration of the Rights of the Child, the child, by reason of his physical and mental immaturity, needs special safeguards and care, including appropriate legal protection, before as well as after birth.”<sup>287</sup> As no other provisions of the

---

<sup>281</sup> *ibid.*, p. 54.

<sup>282</sup> *ibid.*, p. 56.

<sup>283</sup> *ibid.*, p.12.

<sup>284</sup> *ibid.*, p.26.

<sup>285</sup> *ibid.*, p.27.

<sup>286</sup> *ibid.*, p.27.

<sup>287</sup> *ibid.*, p.4-5.

CRC use term unborn, some state that Preamble has no binding force for the State parties to protect the rights of unborn. However, Joseph argues this opinion by stating that then this type of interpretation is contradictory to the Article 31 of the Vienna Convention on the Law of the Treaties (VCLT) that states that 1. “A treaty must be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. 2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its *preamble* and annexes.” Therefore, Joseph’s comes to the conclusion that unborn child is to be protected by the CRC, if it is interpreted in good faith (without discrimination of the unborn) in accordance to ordinary meaning to be given to terms of the treaty in their context (both text and preamble) and in the light of its object and purpose (to recognize of the inherent dignity and of equal and inalienable rights of all members of human family is the foundation of freedom, justice and peace in the world).<sup>288</sup>

The interesting interpretative analysis is provided in connection with the ECHR (1950). According to Joseph’s interpretation, the Preamble of the ECHR provides confirmation by including following phrases: “governments of European countries which are like-minded and have a common heritage of political traditions, ideals, freedom and rule of law to take the first steps for the collective enforcement of certain of the rights stated in the Universal Declaration...” ‘This “common heritage of ...the rule of law” included, we must remember not only a tradition of common law for the unborn child, but also widespread legal protection for the child at risk of abortion. And it is wrong to state that right to life in the ECHR is different from the right to life set by the UDHR. Indeed, for the High Contracting parties to exclude the child before birth from the jurisdiction cannot make sense in the light of the fact that these same Council of Europe member governments subsequently agreed in 1959 that the need for legal protection for the child before as well as after birth recognized in the Universal Declaration and in the statutes of specialized agencies and international organizations concerned with welfare of children. If the Council of Europe had indeed excluded the child before birth from its human rights jurisdiction in the 1950 Convention, why did their member governments recognize need for legal protection for the child before birth in 1959?’<sup>289</sup> In regards to the ECHR, Joseph again brings up the Article 31 of the VCLT and its “General Rule of Interpretation” So, if the object and purpose of the treaty was a protection of life before birth, treaty should be interpreted in relevant way. Therefore, Joseph criticizes The ECtHR and jurists for wrong interpretation of the ECHR’s provisions.

Among the above mentioned treaties, Joseph mentions Geneva Conventions in the field of international humanitarian law, which also indicate the protection of unborn under international humanitarian law. For example, Fourth Geneva Convention (1949) in Articles 14, 33(5) and 50 sets special protection measures for “children under fifteen, expectant mothers and mothers of children under seven.” According to Joseph use of term “expectant mother” indicates the fact that she has to receive special

---

<sup>288</sup> *ibid.*, p.5-6.

<sup>289</sup> *ibid.*, pp.21-22.

treatment, because carries unborn entitled to the same protection as children under seven.<sup>290</sup>

Along with human rights instruments, Joseph points out at medical and ethical codes of that time. Such as World Medical Association Declaration of Geneva (1948), also known as *Physician's Oath*, which asserts "I solemnly pledge myself to consecrate my life to service humanity: I will maintain the utmost respect for human life from the time of conception...."<sup>291</sup>

The issues I've raised above cause many debates, among different parts of society, because of conflicting interests of women. This feminist approach involves arguments related to women's private life that was often brought up in the cases in front of ECtHR. These issues are addressed in regards the legalization of abortion. There are so called "pro-choice"<sup>292</sup> movements that work in this field and are in favor of legalizing abortion, giving women full freedom to make their own choices and exercise their right to private life. Hence, sometimes when we discuss the right to life of unborn, there are conflicting interests arising that need to be taken into consideration.

As many prefer to defend to protect women's rights rather than embryos, on the other hand there are various "pro-life" feminist groups advocating protecting the right to life of unborn. For example, the movement called Pro life is the group of feminists, who support right to life of unborn.<sup>293</sup> Thus, matter of understanding this issue stands in one's point of view and it will offend someone if we say that one opinion is true and other false or one is good or other bad.

Therefore, in order to sum up this part, if we follow right to life arguments and Rita Joseph's interpretation of legal provisions, we have to interpret life as the right of every human being, starting from the moment of conception, and if it is the case, we can argue that hES cell research and its patents for sure violates right to life of unborn and generally is contrary to human rights principles.

Still if we simply do not think that hES cells, which is at very early stage of development, falls within the category of embryos for the protection of right to life, we can simply argue that even it is a case, producing of embryos for research purposes simply devaluates the concept of life as such.

---

<sup>290</sup> *ibid.*, p.13.

<sup>291</sup> *ibid.*, p.16.

<sup>292</sup> For more information, visit, <<http://www.prochoice.org/>> viewed on April 25, 2012.

<sup>293</sup> For more information, visit <<http://www.feministsforlife.org/>> visited on April 25, 2012.

# 6 Case Law Analysis

## 6.1 European Case Law Related to hES Cell Patents

There have been few cases ruled on the issue of hES cell patents in Europe. The most important cases that are introduced in this chapter deals with the case before the Enlarged Board of Appeal (EBoA) of the EPO, known as WARF case and the recent landmark case decided by the European Court of Justice (ECJ) concerning the ban of granting patents on hES cells. The both of these cases are very crucial for having deep understanding of the aspects related to hES research and its patents.

### 6.1.1 WARF Case

European view point in regards to hES cell and its patents can be clearly understood in the decision of the case G 2/06 by the Enlarged Board of Appeal (EBoA)<sup>294</sup> of the EPO. Appellant in this case was Wisconsin Alumni Research Foundation (WARF), asking for granting patent for invention involving destruction of human embryos. WARF's application was rejected by the EPO based on the EPC 2000 and the Biotech Directive's provisions. WARF later on appealed this decision in the Technical Board of Appeal of the EPO in late 2005. The Technical Board of Appeal had referred to the EBoA of the EPO with four questions, as EBoA serves as the supreme judicial body of the EPO and has to ensure uniform applicability of EPC 2000 and the Biotech Directive. WARF also requested that the EBoA should submit the issue of the interpretation of the Biotechnology Directive to the ECJ as it involved the application of EU law.

The four questions that were submitted to EBoA were the following:

1. Did the prohibition in respect of biotechnological inventions concerning the use of human embryos for industrial or commercial purposes apply retrospectively to applications filed before the implementation of the Biotech Directive into the EPC?
2. If the answer to question 1 was yes, did it make any difference to the validity of the application that the method involving the destruction of human embryos did not form part of the claims?

---

<sup>294</sup> See, Case G0002/06, Decision of the Enlarged Board of Appeal of 25th November 2008.

3. If the answer to question 1 or question 2 was no, did the prohibition under the EPC 2000, Article 53(a) to inventions contrary to morality apply?
4. In the context of question 2 and question 3, did it make any difference that after the filing date the products claimed could have been obtained without using the method which involved the destruction of human embryos?<sup>295</sup>

On assessing question 1 the EBoA noted that as no transitional provisions were made when the Biotech Directive was implemented by the EPO and there was no sign that the commercial exploitation of embryos had previously been regarded as patentable. Therefore, the prohibition regarding prohibition of human embryos for industrial or commercial purposes applied to all pending applications retrospectively.<sup>296</sup>

On evaluating question 2, the EBoA noted that the aim of the implementing rules was to align the EPC with the Biotech Directive and that the Directive was to be used as a supplementary means of interpretation.<sup>297</sup> “The EBoA noted that the prohibition was not limited to claims to the use of human embryos so it was necessary to consider the teaching of the application as a whole rather than just the explicit text of the claims.”<sup>298</sup> As it was described in the WARF’s patent application, the process “could be performed only by destroying human embryos and the invention was of commercial and/or industrial benefit, it clearly fell within the scope of the prohibition on using human embryos for industrial or commercial purposes.”<sup>299</sup> EBoA has noted that “this use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c) of EPC.”<sup>300</sup> Furthermore, the EBoA observed that the exception for inventions for therapeutic or diagnostic purposes (which are applied to the human embryo and are useful to it) cannot be applied in this case, as the invention for therapeutic or diagnostic purposes had to benefit the embryo itself.<sup>301</sup> “That this is not the case here is evident, since the embryos used to perform the invention are destroyed.”<sup>302</sup>

As the answers to the question 1 and 2 were replied by yes, the EBoA left the question 3 unanswered, since did not see the necessity of answering it.<sup>303</sup> “With respect to question 4, the EBoA ruled that technical developments which became publicly available only after the filing date

---

<sup>295</sup>Fitt, *supra* note 226, p.338-339.

<sup>296</sup> *ibid.*

<sup>297</sup> *ibid.*

<sup>298</sup> *ibid.*

<sup>299</sup> *ibid.*

<sup>300</sup> Case G0002/06, Decision of the Enlarged Board of Appeal of 25th November 2008., para 25.

<sup>301</sup> Fitt, *supra* note 226, p.339.

<sup>302</sup> Case G0002/06, Decision of the Enlarged Board of Appeal of 25th November 2008., para 27.

<sup>303</sup> *ibid.*, para 32.

could not be taken into consideration. Therefore, it was irrelevant that after the filing date the same products could have been obtained without having to use the method which necessarily involved the destruction of human embryos.”<sup>304</sup>

Thus, in order to conclude, EBoA rejected appeal of WARF on the moral grounds, because processes that were used included destruction of human embryos, which by EBoA was deemed to be violation of the provisions of the EPC 2000 and the Biotech Directive. This case had analogous judgment to the previous case decided by EBoA rejecting to grant a patent on the grounds of the similar moral aspect of using human embryonic stem cell culture.<sup>305</sup> EBoA in its decision emphasized that ‘legislators have decided, remaining within the ambit of Article 53(a) EPC, and there is no room for manoeuvre.’<sup>306</sup> EBoA reiterated that its ‘decision is not concerned with the patentability in general of inventions relating to human stem cells or human stem cell cultures. It holds unpatentable inventions concerning products (here: human stem cell cultures) which can only be obtained by the use involving their destruction of human embryos.’<sup>307</sup> Hence, EBoA basically attached morality aspect to the methods used in the biotechnological research, which was destruction of embryos, but not merely to the fact that it involved hES cells as such.

## 6.1.2 ECJ Case Banning hES Cell Patents in Europe

One of the most important cases which were decided in Europe concerning hES cell research was the ECJ case, ruled on October 18, 2011. This case can be viewed as one of the controversial cases judged these days. Main opposition of ECJ’s decision comes from the scientists and researchers, who argue that ECJ’s judgment will be implication to the future of medical research. Why was ECJ’s ruling opposed? The answer to this question is simple, as ECJ has banned hES cell related patents in Europe. That’s a reason why ECJ has been criticized a lot. But on the other hand, they are still many who favor Court’s decision and think that a very important step has been taken in this regard. In order to understand how ECJ came up with decision, we need to follow the argumentation of the Court’s judgment.

ECJ’s ruling concerned an interpretation of Article 6 (2) (c) of the Biotech Directive, which has already been addressed in this paper. The case was brought by Greenpeace seeking annulment of German patent which relates to neural precursor cells and the processes for their production from embryonic stem cells and their use for therapeutic purposes.

---

<sup>304</sup> Fitt, *supra* note 226, p.339.

<sup>305</sup> Case T 1374/04, Decision of the Enlarged Board of Appeal of 6<sup>th</sup> April 2006.

<sup>306</sup> Case G0002/06, Decision of the Enlarged Board of Appeal of 25<sup>th</sup> November 2008., para. 31.

<sup>307</sup> *ibid.*, para 35.

Mr. Brüstle, the holder of a German patent, filed on 19 December 1997, which concerns isolated and purified neural precursor cells, processes for their production from hES cells and the use of neural precursor cells for the treatment of neural defects. It is claimed in the patent specification filed by Mr. Brüstle that the transplantation of brain cells into the nervous system is a promising method of treatment of numerous neurological diseases. The first clinical applications have already been developed, in particular for patients suffering from Parkinson's disease. Because of the pluripotency trait of hES cell, the patent at issue seeks, in those circumstances, to make it possible to resolve the technical problem of producing an almost unlimited quantity of isolated and purified precursor cells having neural properties, obtained from hES cells. The application against this patent was brought in front of the Bundespatentgericht (Federal Patent Court of Germany), which addressed the ECJ to interpret Article 6 (2)(c) of the Biotech Directive. More precisely, German Court referred to the ECJ with three questions:

1. What is meant by the term "human embryos" in Article 6(2)(c) of [the Directive]? (a) Does it include all stages of the development of human life, beginning with the fertilisation of the ovum, or must further requirements, such as the attainment of a certain stage of development, be satisfied? (b) Are the following organisms also included: (a) unfertilised human ova into which a cell nucleus from a mature human cell has been transplanted; (b) unfertilised human ova whose division and further development have been stimulated by parthenogenesis? (c) Are stem cells obtained from human embryos at the blastocyst stage also included?

In regard to the first question, ECJ states that the text of the Directive does not define human embryo, nor does it contain any reference to national laws as regards the meaning to be applied to those terms. It therefore follows that it must be regarded, for the purposes of application of the Directive, as designating an autonomous concept of European Union law which must be interpreted in a uniform manner throughout the territory of the Union.<sup>308</sup> Therefore, the lack of a uniform definition of the concept of human embryo would create a risk of the authors of certain biotechnological inventions being tempted to seek their patentability in the Member States which have the narrowest concept of human embryo and are accordingly the most liberal as regards possible patentability, because those inventions would not be patentable in the other Member States. Such a situation would adversely affect the smooth functioning of the internal market which is the aim of the Directive.<sup>309</sup>

As regards the meaning to be given to the concept of 'human embryo', it should be pointed out that, although, the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple

---

<sup>308</sup> ECJ, Case C-34/10 [2011], para. 25.

<sup>309</sup> *ibid.*, para. 28.

traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive. In that regard, the preamble to the Directive states that although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person. Recital 16 in the preamble to the Directive, in particular, emphasizes that ‘patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person’. The context and aim of the Directive thus shows that the European Union legislature intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive must be understood in a wide sense. Accordingly, any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being. Hence, any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a ‘human embryo’ within the meaning of Article 6(2)(c) of the Directive. Along with a stem cell obtained from a human embryo at the blastocyst stage.<sup>310</sup>

2. What is meant by the expression “uses of human embryos for industrial or commercial purposes”? Does it include any commercial exploitation within the meaning of Article 6(1) of [the Directive], especially use for the purposes of scientific research?

In regard to this question, the Court pointed out that the purpose of the Directive is not to regulate the use of human embryos in the context of scientific research, as it is limited to the patentability of biotechnological inventions. ECJ states clearly, that the grant of a patent implies, in principle, its industrial or commercial application. The Court also emphasizes, that the aim of scientific research must be distinguished from industrial or commercial purposes, thus use of human embryos for the purposes of research which constitutes the subject-matter of a patent application cannot be separated from the patent itself and the rights attaching to it. Hence, the Court states, that the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes in Article 6(2)(c) of the Directive also covers use for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable.<sup>311</sup>

---

<sup>310</sup> *ibid.*, paras. 30-38.

<sup>311</sup> *ibid.*, paras. 40,43, 46.

3. Is technical teaching to be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching: because the patent concerns a product whose production necessitates the prior destruction of human embryos, or because the patent concerns a process for which such a product is needed as base material?’

To answer the third question, the Court reiterated: an invention must be regarded as unpatentable, even if the claims of the patent do not concern the use of human embryos, where the implementation of the invention requires the destruction of human embryos. It is apparent from the observations presented to the Court that the removal of a stem cell from a human embryo at the blastocyst stage entails the destruction of that embryo. Hence, ECJ concludes: Article 6(2)(c) of the Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, whatever the stage at which that takes place and even if the description of the technical teaching claimed does not refer to the use of human embryos.<sup>312</sup>

ECJ’s case has enlightened interpretation of European Union law in regard to hES cell patents. Therefore, no matter how many people will criticize it, the Court is definitely clear stating that EU law bans patentability of hES cells, including those produced at blastocyst stage.

## **6.2 Case Law Related to the Legal Status of the Unborn**

As I have addressed the European viewpoint in regards to the hES cells patents, it is necessary to have a look at right to life, as it was argued previously in our discussion on hES cells. This part will enlighten the understanding of how legal norms are put into practice, concerning the protection of the embryo’s right to life. This section will analyze the case law of the ECtHR according to the Court’s interpretation of Article 2 and other relevant articles of the ECHR. And lastly will address the landmark case of the US Supreme Court that has highlighted legal status of an embryo by legalizing abortion in the US.

---

<sup>312</sup> *ibid.*, paras. 47-52.

## 6.2.1 Analysis of the Case Law of ECtHR

The Article 2 (1) of the ECHR states “Everyone's right to life shall be protected by law.” But the main problematic aspect of the scope of this provision lays in the term “everyone”. However, ‘the question whether the word ‘everyone’ includes an unborn child - and if so from what point in its development and the extent to which protection is offered-has yet to be fully decided.’<sup>313</sup> The question of whether unborn child is protected under Article 2 has been raised in regards to the abortion and conflicting rights of pregnant women, such as right to private life (Article 8 of the ECHR).

Nevertheless, there is no clear resolution made if the unborn has to be considered as a person for the purpose of the Article 2. Hence, the overall view of the situation can be made by addressing some main cases chronologically dealing either with Article 2 or Article 8 of the ECHR. The interesting phrase that was used in the ECtHR’s (at the time Commission) decision of the *Bruggemann and Scheuten v. Germany* case was the following: “pregnancy cannot be said to pertain uniquely to the sphere of private life. Whenever a woman is pregnant her private life becomes closely connected with the developing foetus.”<sup>314</sup> The applicant in this case argued that she had the sole right to decide to have an abortion under Article 8 of the Convention, which guarantees the right to respect for “private life”. However, the Commission held that: *Article 8 § 1 cannot be interpreted as meaning that pregnancy and its termination are, as a principle, solely a matter of the private life of the mother,* but at the same time declined to address the issue under Article 2.<sup>315</sup>

Later on, in the case of *X v. the United Kingdom*, the Commission noted, that Article 2 of the Convention does not mention abortion. And if the Article 2 grants an absolute right to life to the fetus such an interpretation would not allow to take into account of any risk to the mother’s life: that “would mean that the ‘unborn life’ of the foetus would be regarded as being of a higher value than the life of the pregnant woman.”<sup>316</sup>

Thus, both the general usage of the term “everyone” (“toute personne”) in the Convention and the context in which this term is used in Article 2 tend to support the view that it does not include the unborn.<sup>317</sup> However, later on in *H. v. Norway*, the Commission went somewhat further in the direction for “not excluding unborn” that “in certain circumstances” the foetus may enjoy “a certain protection under Article 2, notwithstanding the “considerable divergence of views” in the Contracting States on whether or to what extent Article 2 protects the unborn life.”<sup>318</sup>

---

<sup>313</sup> D.J.Harris, M. O’Boyle, & C.M. Warbrick, *Law of the European Convention on Human Rights*, 2.ed., (Oxford University Press, Oxford, 2009) p.53.

<sup>314</sup> C.Byk, *Medical and Biological Progress and the European Convention on Human Rights*, (Council of Europe, Directorate of Human Rights, Strasbourg, 1992) p.11.

<sup>315</sup> *ibid.*, p.10.

<sup>316</sup> *ibid.*

<sup>317</sup> *ibid.*

<sup>318</sup> *ibid.*

### 6.2.1.1 Vo. v. France

The one of the important cases concerning right to life of unborn was ruled by the ECtHR is *Vo. v. France* in 2004. The applicant was Ms. Thai Nho Vo., who was a French citizen. The applicant went to the hospital for regular pregnancy check, because she was 20-21 weeks pregnant. However, another patient who shared the same last name was going to have a coil removed in the same hospital. The mix up between two patients resulted in carrying medical procedures on Ms.Vo. without any medical examination that led to the termination of her pregnancy. Ms. Vo. who was planning to have a baby lodged criminal complaint for unintentional physical injury to herself and for unintentional killing of her baby. The national Court of Cassation held that it did not constitute the involuntary homicide, because the fetus is not considered as a human entitled for the protection of French criminal law. Then, the applicant brought up the application in front of ECtHR, alleging a violation of Article 2 of the ECHR on the ground that the conduct of a doctor who was responsible for the death of her child *in utero* was not classified as unintentional homicide.

The ECtHR in its assessment of the case stated that Article 2 of the Convention is silent as to the temporal limitations of the right to life and, in particular, does not define “everyone” (“*toute personne*”) whose “life” is protected by the Convention. Hence, the Court had yet to determine the issue of the “beginning” of “everyone’s right to life” within the meaning of this provision and whether the unborn child has such a right.<sup>319</sup>

The Court reiterated the Commission’s previous case of *X v. the United Kingdom* where the Commission held that the general usage of the term “everyone” (“*toute personne*”) and the context in which it was used in Article 2 of the Convention did not include the unborn.<sup>320</sup> The Court stated that the issue of when life begins comes within the margin of appreciation, which the Court generally considers that States should enjoy in this sphere, notwithstanding an evolutive interpretation of the Convention, a “living instrument which must be interpreted in the light of present-day conditions”. The Court states that reasons for that conclusion are, firstly, that the issue of such protection has not been resolved within the majority of the Contracting States themselves, including France in, where it is still the subject of debate and, secondly, that “there is no European consensus on the scientific and legal definition of the beginning of life.”<sup>321</sup>

Therefore, the Court has emphasized that “it is neither desirable, nor even possible as matters stand, to answer in the abstract the question whether the unborn child is a person for the purposes of Article 2 of the Convention (“*personne*” in the French text). And as to the Vo. case, it considers unnecessary to examine whether the unexpected termination of the applicant’s pregnancy falls within the scope of Article 2. The Court seeing that, “even assuming that that provision was applicable, there was no failure on the part of the respondent State to comply with the requirements relating

---

<sup>319</sup> See, *Vo v. France*, ECHR, [no. 53924/00], Judgment of 8 July, 2004, para.75.

<sup>320</sup> *Vo v. France*, ECHR, [no. 53924/00], Judgment of 8 July, 2004, para.77.

<sup>321</sup> *ibid.*, para.82.

to the preservation of life in the public-health sphere.”<sup>322</sup> Lastly, the Court concluded that, even assuming that Article 2 was applicable in the instant case, there has been no violation of Article 2 of the Convention by fourteen votes to three.<sup>323</sup>

Hence, the ECtHR in *Vo.* has shown its unwillingness to say when life begins within the purposes of the ECHR. The Court abstained from saying whether unborn child is the person for the purposes of the Convention.

The basic problem of the Court’s approach in *Vo.* case according to Tanya Goldman is that the ECtHR judges failed to address the main issue at bar, and in so doing may have side-stepped their judicial role to interpret the language of the Convention. The Court chose the easier path of holding, that even if Article 2 applied, France had not violated its provisions. In reality, the Court was unsuccessful to decide whether a fetus falls under “everyone” for the purposes of Article 2 protection. Goldman brings up the evaluation of the dissenting opinions of the judges to the case. Two judges expressed their dissenting opinions examining the word “everyone”; they found article 2 applicable and sought to extend its protection to the fetus. To support the universality of their argument, dissenting judges argued that without the assumption that the fetus is a life to be protected, abortion legislation would be unnecessary.<sup>324</sup>

It is interesting how the judges to this case differed in their opinions, for example four judges in their separate opinion have not agreed with the Court’s ruling that Article 2 was inapplicable in this case.<sup>325</sup> Another two judges expressed their opinion by stating that there is “no good legal reason or decisive policy consideration for not applying Article 2 in the present case. These judges stated: “on a general level, I believe (as do many senior judicial bodies in Europe) that there is life before birth, within the meaning of Article 2, that the law must therefore protect such life, and that if a national legislature considers that such protection cannot be absolute, then it should only derogate from it, particularly as regards the voluntary termination of pregnancy, within a regulated framework that limits the scope of the derogation. The actual circumstances of Mrs *Vo.*’s case made it all the more appropriate to find that Article 2 was applicable.”<sup>326</sup> While majority of dissenting judges deemed that Article 2 was applicable, but not violated, judge Ress thought that there was the violation of Article 2 in this case. In judge Ress’s opinion all the Court’s case-law and the Commission’s decisions are based on the “assuming that” argument (*in eventu*). Yet the failure to give a clear answer can no longer be justified by reasons of procedural economy. According his opinion, nor can the problem of protecting the embryo through the Convention be solved solely through the protection of the mother’s life. As the *Vo.* case illustrated, the embryo and the mother, as two separate “human beings”, needing separate protection.

---

<sup>322</sup> *ibid.*, para.85.

<sup>323</sup> *ibid.*, paras. 95, 85.

<sup>324</sup> T. Goldman, *Vo v. France and Fetal Right: the Decision not to Decide*, (Harvard Human Rights Journal Vol.18 2000) pp.277-282.

<sup>325</sup> See, *Vo v. France*, Separate Opinion of Mr Rozakis joined by Mr Caflisch, Mr Fischbach, Mr Lorenzen and Mrs Thomassen.

<sup>326</sup> *ibid.*, Separate Opinion of Mr Costa joined by Mr Traja.

Mr. Ress stated that similarly, the practice of the Contracting States, virtually all of which had constitutional problems with their laws on abortion (voluntary termination of pregnancy), clearly shows that the protection of life also extends in principle to the foetus. Specific laws on voluntary abortion would not have been necessary if the foetus did not have a life to protect and was fully dependent until birth on the unrestricted wishes of the pregnant mother.<sup>327</sup>

Other two judges also shared Judge Ress's opinion on the violation of Article 2. According to their opinion the legal protection France afforded the applicant did not satisfy the procedural requirements inherent in Article 2 of the Convention. According to these judges, the abortion constitutes an exception to rule that the right to life should be protected even before birth. These dissenting judges consider that, Article 2 must be interpreted in an evolutive manner so that the great dangers currently facing human life can be confronted. That has made necessary by the "potential that exists for genetic manipulation and the risk that scientific results will be used for a purpose that undermines the dignity and identity of the human being."<sup>328</sup>

Hence, in order to sum up *Vo. case*, the ECtHR did not interpret the scope of Article 2 and it is until vague to understand if the ECHR protects the right to life of unborn. However, like on the example of *H. v. Norway* case the Commission admitted that the unborn might enjoy the protection of Article 2 in certain cases. Nevertheless, this type of differentiated reasoning of the ECtHR leads us to the absurd conclusion that ECHR in some cases protects unborn and in some - does not.

### **6.2.1.2 Tysiac v. Poland**

The other important case that was judged by the ECtHR was *Tysiac v. Poland* (2007). This case deals with the alleged violations of Article 8 (right to private life), Article 3 (prohibition of inhuman and degrading treatment) and two other rights under the ECHR. The applicant in this case was a Polish citizen, who suffered severe form of myopia (this is the disease of eyes, when a person cannot see far objects clearly and well). The applicant consulted doctors when she discovered that was pregnant on her third child, because she was concerned that pregnancy might risk her health (her eye vision). Three different ophthalmologists consulted the applicant that if she was planning to have a baby, would cause serious risk to her eyesight. However, these ophthalmologists on request of the applicant refused to issue a certificate to their patient for having therapeutic abortion. After this the applicant visited general practitioner who issued certificate, that stated all the risks this pregnancy would cause to the patient's eyesight and other grounds such as previously delivered two children by caesarean. By the second month of the applicant's pregnancy her myopia was already become worst. When she again visited the hospital in Warsaw concerning the termination of her pregnancy, the head of the department Dr. R.D. consulted her, by refusing to conduct therapeutic abortion on the ground that there was no medical necessity of it. Therefore, the applicant was not able to have abortion and delivered her third child by caesarean. Soon after the delivery

---

<sup>327</sup> *ibid.*, Dissenting Opinion of Mr Ress.

<sup>328</sup> *ibid.*, Dissenting Opinion of Mrs Mularoni joined by Mrs Strážnická.

of the child, the applicant's eyesight deteriorated badly and she was declared as significantly disabled by the panel of doctors and is still registered and receiving monthly pension on the ground of her disability. The applicant then lodged a criminal complaint against Dr. R.D. However, the criminal investigation was discontinued on the ground that there was no casual link between doctor's decision and the applicant's worsen eye vision. Thus, the applicant alleged the violation Articles 3, 8, 13 and 14 of the ECHR.<sup>329</sup>

In the case assessment, the ECtHR observed that according to Polish legislation abortion is allowed in the cases when pregnancy poses a risk to mother's health and life. Hence, for this reason the Court decided not to examine if the right to have an abortion is guaranteed by the ECHR.<sup>330</sup> The Court observed reiterated that the legislation on interruption of pregnancy touched upon the private sphere of life, since whenever woman is pregnant her private life becomes closely connected with the developing fetus.<sup>331</sup> The ECtHR then decided to examine the positive obligations of the State to protect physical integrity of pregnant women under Article 8 of the ECHR.<sup>332</sup> The Court observed that abortion is prohibited in Poland, but has some exceptions. The Court concluded "that it has not been demonstrated that Polish law as applied to the applicant's case contained any effective mechanisms capable of determining whether the conditions for obtaining a lawful abortion had been met in her case. It created for the applicant a situation of prolonged uncertainty. As a result, the applicant suffered severe distress and anguish when contemplating the possible negative consequences of her pregnancy and upcoming delivery for her health."<sup>333</sup> Therefore, the Court emphasized that Polish government failed to meet its positive obligations to respect the applicant's private life and found the breach of Article 8 of the ECHR.<sup>334</sup>

The interesting aspect of this case is that some scholars criticized ECtHR's decision quite often. Rita Joseph shared the idea that this judgment is "shameful evasion of truth", that denied the mandatory protection of the right to life of unborn under ECHR. Joseph declares her sympathies toward Judge Borrego Borrego who has expressed his thoughts in his dissenting opinion in the judgment.<sup>335</sup> Judge Borrego Borrego criticizes the Court's approach to this case that he deems to be frightening and gone very far.<sup>336</sup> Noting the lack of consensus among the member states of the Council of Europe with regard to abortion, he considered the Court to have neglected the debate in Poland, whereas in previous decisions such considerations were central.<sup>337</sup> The central criticism of *Tysiact* case is that 'far from

---

<sup>329</sup> See, *Tysiact vs. Poland*, ECHR, [no.5410/03], Judgment of 20 March, 2007.

<sup>330</sup> *ibid.*, para. 104.

<sup>331</sup> *ibid.*, para. 106.

<sup>332</sup> *ibid.*, paras. 107-108.

<sup>333</sup> *ibid.*, para. 124.

<sup>334</sup> *ibid.*, paras. 129-130.

<sup>335</sup> Joseph, *supra* note 275, p.183.

<sup>336</sup> See, *Tysiact vs. Poland*, ECHR, [no.5410/03], Judgment of 20 March, 2007, The dissenting opinion of Judge Borrego Borrego, para. 15.

<sup>337</sup> N. Priaulx, *The Margin of Appreciation: Therapeutic Abortion, Reproductive 'Rights' and the Intriguing Case of Tysiact v. Poland*, (European Journal of Health Law, Vol.15,2008) pp. 361-379, p.370.

“creates the right to abortion”<sup>338</sup> Many condemn this judgment, because they think it is contrary to the Court’s previous decisions. For instance, the Commission’s judgment in *Bruggemann and Scheuten v. Germany* case that ‘the Article 8(1) cannot be interpreted as meaning that pregnancy and its termination are, as a matter of principle, solely a matter of the private life of the mother’.<sup>339</sup> Since the ECtHR chose the broader context to address the issues in the case, many argue that it was for the reason to promote the liberalization of women’s reproductive rights in Poland.<sup>340</sup> Therefore, I somewhat agree with the idea that *Tysiack* case is little off the track and has some inconsistencies with the Court’s previous judgments.

### 6.2.1.3 A.B.C. v. Ireland

The most recent case concerning the rights of unborn and conflicting rights of the mother was the case *A.B.C. v. Ireland* ruled in 2010 by the Grand Chamber of the ECtHR. This case is important in a sense, because the Court has shown different approach toward abortion rights. This case became matter of attention of so called “pro-lifers”, because they deemed that this decision was in some sense aiming at protecting the right to life of unborn. *A.B.C. v. Ireland* became the landmark case in regards to Article 8 of the ECHR, because of one simple reason. The Court affirmed that the ECHR does not contain a “right to abortion”. The paragraph 214 of the judgment states: “Article 8 [of the Convention] cannot ... be interpreted as conferring a right to abortion”. Thus, the Court came up with very different approach from its previous cases including *Vo* and *Tysiack*.

The applicants in this case were three women who resided in Ireland. Due to the prohibition of abortion in Ireland, these women had to go to England to have an abortion done. The first applicant (A) was 9 ½ weeks pregnant when travelled to England to have an abortion. She became pregnant unintentionally believing that her partner was infertile. At the time she already had four children, was unemployed, unmarried and living in poverty. The youngest of her children was disabled and all of her children were in the foster care due to applicant’s alcoholism. The applicant A had the history of depression and considered that further child would pose a risk to her health and future reunion with her children (because year before her fifth pregnancy she kept herself sober and had been in constant contact with social workers to return the custody of her children). Therefore, the applicant borrowed money and travelled to England to have an abortion. On the way back to Ireland, on train she started bleeding and was taken to the hospital for a dilation and curettage, she claimed that suffered nausea, pain and bleeding for weeks thereafter, but did not seek for further medical advice. After filing the application to the ECtHR, the applicant A became pregnant again and gave birth to her fifth child. The applicant A complained on the alleged violation of the Articles 3, 8, 13 and 14 of the ECHR.

The second applicant (B) was 7 weeks pregnant when travelled to England to have an abortion. She became pregnant unintentionally after her

---

<sup>338</sup> *ibid.*, p.373.

<sup>339</sup> *ibid.*, p.374.

<sup>340</sup> *ibid.*, p.378.

“morning after pill” failed. Two doctors consulted her for having the risk of ectopic pregnancy. The applicant B was certain that could not afford having a baby at that time, so, she decided to have an abortion in England. However, after visiting a doctor again she affirmed that by the time she travelled to England it was confirmed that it was not ectopic pregnancy. The applicant scared of the family’s reactions to her decision, travelled to England alone and did not list anyone on her next of kin. The doctors in the UK advised her to inform Irish doctors that she had miscarriage. Two weeks after her return she started passing blood clots, being unsure of the legality of having travelled for an abortion, sought follow-up care in a clinic in Dublin affiliated to the English clinic. The applicant B alleged the violation of the Articles 3, 8, 13 and 14 of the ECHR.

The third applicant (C) decided to go to England for an abortion when she was in her trimester of pregnancy. The applicant C has been undergoing chemotherapy for rare form of cancer for 3 years. She wanted to have children, but was concerned on implications of her illness and as regards her desire to have children and was advised that it was not possible to predict the effect of pregnancy on her cancer. She was told that, if she did become pregnant, it would be dangerous for the fetus if she were to have chemotherapy during the first trimester. The cancer went into remission and the applicant C unintentionally became pregnant. After consultation by General Practitioner and other doctors, she alleged that, because of the chilling effect of the Irish legal framework, she received insufficient information as to the impact of the pregnancy on her health and life and of her prior tests for cancer on the foetus. Then decided to check these risks on internet and she was unsure and decided to have an abortion in England. The applicant C wanted to have a medical abortion, but could not find a clinic that provided this type of abortion to non-residents. Therefore, she had to wait for further 8 weeks to have surgical abortion done. After returning to Ireland, the applicant C suffered complications of incomplete abortion such as prolonged bleeding and infection. She alleged that doctors provided inadequate medical care and alleged that her General Practitioner after few consultations failed to refer to the fact that she was visibly no longer pregnant. The applicant C filed the application to the ECtHR on alleging the violation of Articles 2, 3, 8, 13 and 14 of the ECHR. She argued that she had no appropriate means of establishing her right to a lawful abortion in Ireland on the grounds of a risk to her life.<sup>341</sup>

It was important to note that according to Irish Constitution Article 40 (3) (3): “The State acknowledges the right to life of the unborn and, with due regard to the equal right to life of the mother, guarantees in its laws to respect...” However, according to Irish legislation abortion is allowed when it poses risk to mother’s life, but not merely health or other interests.

After assessing the facts and the parties’ submission in the case, the ECtHR found out that the applicant A travelled for an abortion for reasons of health and well-being, the applicant B for well-being reasons and the applicant C as she mainly feared her pregnancy constituted a risk to her

---

<sup>341</sup> See, *A.B.C. v. Ireland*, ECHR, [no. 25579/05], Judgment of 16 December, 2010.

life.<sup>342</sup> The Court did not find it established that the present applicants lacked access to necessary medical treatment in Ireland before or after their abortions.<sup>343</sup> The Court reiterates that “citing with approval the case-law of the former Commission, that legislation regulating the interruption of pregnancy touches upon the sphere of the private life of the woman.” The Court emphasized: “Article 8 cannot be interpreted as meaning that pregnancy and its termination pertain uniquely to the woman’s private life as, whenever a woman is pregnant, her private life becomes closely connected with the developing foetus.” Therefore, women’s right to respect of private life must be weighed against other competing rights and freedoms invoked including those of the unborn child (also highlighted by the Court in *Vo.* and *Tysiack* cases).<sup>344</sup> While, *Article 8 cannot, accordingly, be interpreted as conferring a right to abortion*, the Court stated that the prohibition in Ireland of abortion where sought for reasons of health and/or well-being about which the first and second applicants complained, and the third applicant’s alleged inability to establish her qualification for a lawful abortion in Ireland, came within the scope of their right to respect for their private lives under Article 8.<sup>345</sup> Concerning the first two applicants the Court found that the prohibition of the termination of the first and second applicants’ pregnancies required for reasons of health and/or well-being was an interference with their right to respect for their private lives. However, if this interference could be justified was necessary to find out.<sup>346</sup>

The Court stated that intervention in regards to the applicants A and B was according to the law, as it was clear that Irish law prohibits an abortion on for health and/or well-being reasons. However, allows travelling outside of Ireland to have abortion done.<sup>347</sup> The Court’s emphasized finding in the above-cited *Vo v. France* case that it was neither desirable nor possible to answer the question of whether the unborn was a person for the purposes of Article 2 of the Convention, so that it would be equally legitimate for a State to choose to consider the unborn to be such a person and to aim to protect that life.<sup>348</sup> The Court concludes that the impugned restriction therefore pursued the legitimate aim of the protection of morals of which the protection in Ireland of the right to life of the unborn was one aspect.<sup>349</sup> Concerning the necessity of intervention in democratic society, the Court stated that, “there is no consensus within the Member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it. Particularly where the case raises sensitive moral or ethical issues, the margin will be wider.”<sup>350</sup> However, at the same time, the Court considered that there is indeed a consensus amongst a considerable majority of the Contracting States of the Council of Europe towards allowing abortion on broader grounds than allowed under Irish

---

<sup>342</sup> *ibid.*, para.125.

<sup>343</sup> *ibid.*, para.127.

<sup>344</sup> *ibid.*, para.213.

<sup>345</sup> *ibid.*, para.214.

<sup>346</sup> *ibid.*, paras. 216-218.

<sup>347</sup> *ibid.*, para.221.

<sup>348</sup> *ibid.*, para.222.

<sup>349</sup> *ibid.*, para.227.

<sup>350</sup> *ibid.*, para.232.

law.<sup>351</sup> On the other hand, the Court did not consider that “this consensus decisively narrows the broad margin of appreciation of the State.”<sup>352</sup> Hence, the ECtHR concluded that Ireland did not exceed its margin of appreciation in respect to the first two applicants’ rights to private life. The Court did not consider that the prohibition of abortion for health and other reasons in Ireland based as it is on the profound moral views of the Irish people as to the nature of life and as to the subsequent protection to be allowed to the right to life of the unborn. Moreover, thus found no breach of Article 8 in connection to applicants A and B.<sup>353</sup>

All other alleged rights were dismissed by the Court, including the Article 2 (right to life) argued by the applicant C. However, the Court assessed the alleged violation of Article 8 on behalf of the applicant C. The Court held that the authorities failed to comply with their positive obligation to secure to the third applicant effective respect for her private life. Because of the absence of any implementing legislative or regulatory regime providing an accessible and effective procedure by which the third applicant could have established whether she qualified for a lawful abortion in Ireland in accordance with Article 40.3.3 of the Constitution. For this reason, the Court found out the violation of Article 8 of the ECHR in regards to the applicant C.<sup>354</sup>

This judgment has showed different perspectives in regards to the interpretation of Article 2 and Article 8 of the ECHR. Nevertheless, many still argue that the Court’s decision finding breach of Article 8 in the case of third applicant was incorrect. For instance, European Dignity Watch<sup>355</sup> in the article criticized the Court for deciding the case not on facts but on subjective emotions, beliefs and sentiments. According to the article, ‘the applicant C, who was in remission from cancer, claimed that she had feared that the continuation of her pregnancy put her life at risk. This fear was not based on any medical fact and appears to have been unfounded.’ In any case, if there had been a *real* risk for her life, the law would not have prevented her from having an abortion. All three complainants claim to have been afraid of seeing a doctor when, having returned from their trips to England (for the abortions), they suffered from the complications often associated with abortions. ‘Yet again, these fears were completely unfounded.’<sup>356</sup>

---

<sup>351</sup> *ibid.*, para.235.

<sup>352</sup> *ibid.*, para.236.

<sup>353</sup> *ibid.*, paras. 241-242.

<sup>354</sup> *ibid.*, paras. 267-268.

<sup>355</sup> European Dignity Watch (founded in 2010) is a non-governmental and non-profit organization based in Europe’s capital Brussels. European Dignity Watch defends the three most vital pillars of society: Life, the family and fundamental freedoms. For further information please visit: < <http://www.europeandignitywatch.org/about-us/about-us.html>> viewed on May 5, 2012.

<sup>356</sup> *ABC vs. Ireland European Court Decides Abortion Case*, please visit: < <http://www.europeandignitywatch.org/day-to-day/detail/article/abc-vs-ireland-european-court-of-human-rights-decides-on-abortion-case.html>> viewed on May 5, 2012.

## 6.2.2 Roe v. Wade (Landmark case in the US)

The *Roe v. Wade* case is the landmark decision of the US Supreme Court on the abortion and legal status of an embryo in the US. As the US Constitution does not state there is a right to privacy in its legal text, however several Supreme Court decisions had made clear that right to privacy is protected under US Constitution. However, the 14<sup>th</sup> Amendment to the US Constitution is considered as a basis for the right to privacy. This right was also extended to a woman's decision to have an abortion and the *Roe v. Wade*<sup>357</sup> was the first case ruled in 1973 when the Supreme Court stated that woman has a right to privacy that includes her right to have an abortion.<sup>358</sup>

The lawsuit was brought by the single pregnant woman, who was aiming to challenge constitutionality of Texas legislation on abortion. According to Texas law, it was a crime to have an abortion except the situations when pregnancy would pose a risk to mother's life. Other plaintiffs in the lawsuit was Hallford, a doctor who faced criminal prosecution for violating the state abortion laws; and the Does, a married couple with no children, who sought an injunction against enforcement of the laws on the grounds that they were unconstitutional. The District Court found that Roe's and Hallford's lawsuit was justifiable, however, stated that Does complaint was unjustifiable. The District Court ruled in favor of Roe and Hallford and held that Texas laws were 'void as vague' and were breaching plaintiffs' rights under 9<sup>th</sup> and 14<sup>th</sup> Amendments of the US Constitution. As Does lost the trial, they appealed to the Supreme Court of US and the same was done by Wade (defendant-County District Attorney).<sup>359</sup>

The first important issue in front of the Supreme Court was to answer these questions: 1. Do abortion laws that criminalize all abortions, except those required on medical advice to save the life of the mother, violate the Constitution of the United States? In regards to this question, the Supreme Court held that YES, Such laws that do not take into consideration the stage of pregnancy and other interests, are unconstitutional for violating the Due Process Clause of the 14<sup>th</sup> Amendment.<sup>360</sup> 2. Does the Due Process Clause of 14<sup>th</sup> Amendment to the United States Constitution protect the right to privacy, including the right to obtain an abortion? The Supreme Court ruled that YES, the Due Process Clause protects the right to privacy, including a

---

<sup>357</sup> See, *Roe v. Wade*, 410 U.S. 113 (1973), available at: <<http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=case&court=US&vol=410+&page=113>> viewed on May 7, 2012.

<sup>358</sup> Summary of *Roe v. Wade* and Other Key Abortion Cases, available at: <<http://old.usccb.org/prolife/issues/abortion/roevwade/CaseSummariesforwebsite4-18.pdf>> viewed on May 7, 2012.

<sup>359</sup> *Roe v. Wade* Case Brief Summary, available at: <<http://www.lawnix.com/cases/roe-wade.html>> viewed on May 7, 2012.

<sup>360</sup> *ibid.*

woman's right to terminate her pregnancy, against state action.<sup>361</sup> 3. Are there any circumstances where a state may enact laws prohibiting abortion? The Supreme Court held that even though a state cannot completely deny woman's right to have an abortion, it has legitimate interests to protect both the pregnant woman's health and the potentiality of human life at various stages of pregnancy.<sup>362</sup>

The Supreme Court also emphasized that, in regard to abortions during the 1<sup>st</sup> trimester, the decision must be left to the pregnant woman's doctor. In regard to 2<sup>nd</sup> trimester pregnancies, states may promote their interests in the mother's health by regulating abortion procedures related to the health of the mother. Concerning 3<sup>rd</sup> trimester pregnancies, states may promote their interests in the potentiality of human life by regulating or even prohibiting abortion, except when necessary to preserve the life or health of a pregnant woman.<sup>363</sup>

Hence, this case was solely considered to overturn the situation in the US by affirming women's right to have an abortion. However, the Supreme Court still underlined that states can aim to protect woman's health and the potential new life.

### 6.3 The Findings of Case Law Analysis

The main finding from the European case law in regards to hES cells and its patents is that both EBoA and ECJ has expressed clearly that European legislation prohibits granting patents on hES cell, as they involve early embryos and it is prohibited by EU legislation on patents. Both EBoA and ECJ state that hES cells cannot be patentable as the process of obtaining them results in destruction of an embryo. The ECJ went even further stating that embryos at any stage of development are considered as a "human embryo" for the purpose of the Biotech Directive. Moreover, it is a life as soon as fertilization occurs. For this reason, the "human embryo" under the Biotech Directive includes the embryos at blastocyst stage as well, when usually hES cells are cultivated. The ECJ affirmed that it is the patent and its nature (commercial and industrial exploitation) that needs to be taken into consideration. The ECJ does not address the ethicality or unlawfulness of the hES cell research as such. From this standpoint we can conclude, that hES cell patents are prohibited in Europe due to ethical and other issues.

However, when we discuss hES cell debate from the right to life perspective there are many divergent arguments rising, that questions the application to the right to life to embryos. Even though Rita Joseph opposes the ECtHR's interpretation of the ECHR, the Court is the one body that interprets the provisions of the ECHR. Thus, no matter how much will argue, the reality will be the same as it is now.

The overall picture of the ECtHR's approach to the right to life of unborn is still vague. One thing is clear that all these cases neither protect

---

<sup>361</sup> *ibid.*

<sup>362</sup> *ibid.*

<sup>363</sup> *ibid.*

nor deny the right to life of unborn. In many cases, the Court considers that states enjoy wide margin of appreciation in regards to sensitive issues like this. The Court admits the fact that embryos' and mothers' rights are interlinked. The Court's case law also confirms that Article 2 can be in certain cases expanded to the unborn. Also states that there is no explicit right to abortion in the ECHR. However, admits that right to life of unborn is closely attached to the interests of a pregnant woman in regards to the protection of her private life. Therefore, all that can be understood from this big mess is that the Court does not feel comfortable either to expand the scope of the right to life to unborn or to solely prohibit consideration the rights of unborn under the ECHR. Thus, the ECtHR's different approaches leave unclear resolution on the status of the fetus/embryo in connection to right to life set by the ECHR. For this reason, I think that ECtHR's different approaches cause uncertainty, in regards to the legal status of unborn that will result in complications for future cases as well.

The same approach has shown US Supreme Court that considered woman's right to abortion as a matter of her privacy. However, stated that specific state can balance both rights of a mother and unborn. Thus, similarly to the ECtHR, the approach of US's judicial body neither protects nor denies the protection of unborn under the US federal legislation.

Therefore, if we apply these cases to our debate - hES cell research and its patents, it is hard to argue from taking into consideration of the ECtHR case law that these cells as early embryos have the right to life guaranteed under the ECHR. The same is if we take the example of the Constitution of the US.

Among these judicial views, there are still many who oppose the courts' approach toward hES cells and right to life of unborn. For instance, Pro-life organizations in the US as well as the National Right to Life Committee<sup>364</sup> are against killing embryos and human cloning because they believe that each human being begins as an embryo. In their opinion, stem cells can be obtained from alternative ways such as umbilical cord blood and from adults.<sup>365</sup>

However, if we have a look on the issue from different perspective, one can even argue that hES cell research as it involves early embryos either created for the research or are leftover of already produced embryos, simply devaluates the concept of life as such.

---

<sup>364</sup> National Right to Life Committee is the most powerful Pro-Life organization in the US, working against abortion, human cloning, healthcare issues, euthanasia and other related issues.

<sup>365</sup> A. M. Destro, *National Right to Life Committee*, (*Encyclopedia of Stem Cell Research*. Ed., SAGE, Thousand Oaks, CA, 2008) pp. 368-370.

# 7 Conclusions

The main issue that was discussed in this thesis is the embryonic stem cells and their patents, which are often opposed and criticized on moral, ethical and other grounds. The problem still is not solved and it is even complex to do so. The second chapter of the thesis mainly dealt with the scientific information about the embryonic stem cells, their function and future potential. It is true that research has shown a big potential for curing many serious diseases that affect big portions of the society. Nevertheless, the complex is the reality, how the theory will be put into practice, more precisely how it will be conducted in clinics. Only having hope that everything will be carried out positively will be wrong attitude. Many aspects need to be taken into consideration, because there is a big possibility of failures and complications.

The third chapter brought up the main issues at the bar, addressing the concern of those who question ethicality of the embryonic stem cell research and its patents. This dealt with ethics and bioethics, has introduced human rights ethics, emphasizing the importance of the concept of “human dignity” in both bioethics and human rights discourses. This chapter stressed that hES cell research and their patents contradicts the idea of “human dignity”.

The fourth chapter summarized basic law of patents, patentability criteria etc. This part provided information about various international and regional patent laws. In this chapter, as a component of conducted research I brought up comparative studies in regards to embryonic stem cell patents in US and Europe. This section showed the main differences between these two regions that Europe denies hES cell patents and US allows.

The fifth chapter dealt with introduction of human rights aspects into the discussion. In this part, I tried to introduce main existing theories on coexistence or conflict of human rights and intellectual property law. As my aim in this thesis, was to point out if there were inconsistencies between embryonic stem cell patents and human rights; I came to the conclusion that there are some. Even though these two fields of law either are deemed to conflict or coexist. I came to the answer that these spheres can coexist. However, there is a necessity to build human rights framework for the intellectual property law. In the case of embryonic stem cell patents, I think that Chapman’s version of human rights approach is the best fit. This framework includes: necessity of intellectual property law to have explicit human rights and ethical criteria for granting patents; the need to adapt intellectual property laws to the human rights and ethical principles or adopt new intellectual property legislation; requirement to balance innovation and public benefit out of scientific advancements. If we apply this framework to current intellectual property laws many existing inconsistencies will be solved.

The fifth chapter also introduced the possibility to argue the right to life of unborn in the case of human embryonic stem cells, as early embryos. This section provided analysis of Rita Joseph’s interpretation of various human rights instruments’ provisions in regard to the status of unborn. If we

will get convinced with Rita's set of ideas, then we can come to the conclusion that embryos even at early, blastocyst stage have a right to life that can be argued in our debate. However, this is still matter of interpretations and hard to undoubtedly state.

The sixth chapter of the thesis has clearly shown how the legal norms are put into practice and how they really work. In this functional part we saw that, EU law and its interpretation of current patent legislation prohibits granting patents on embryonic stem cells, because they involve embryos and are contrary to "*ordre public*" and morality. Also as emphasized by the ECJ, the unethicity of embryonic stem cell patents stands in the industrial and commercial purpose of patents. For this reason, the ECJ finally made it clear that EU patent law bans embryonic stem cell patents in Europe. However, even though the ECJ's judgment interpreted the Biotech Directive as banning embryonic stem cell patents in the whole Europe. The main problem is that many countries of Europe still have their own patent legislation, regulating patents in their own way. Like Sweden, that has more liberal patent legislation allowing patents on embryonic stem cells as well. Therefore, the big problem is that there are many different patent laws in Europe and maybe one simple solution to this dilemma would be the harmonization of patent laws there, advocated by Shum. While Europe has ethical clause in its legislation the US has shown totally opposite approach allowing embryonic stem cell patents, but even in the US this is controversial topic and was necessary to question the federal funding of the research. Some authors even agree that maybe US like EU has to introduce ethical clause in its legislation. Many also consider that embryonic stem cell patents are in monopoly of single research companies and its licensees that resists scientific progress and research.

The last part of the thesis, dealt with case law in regard to the legal status of unborn, as it could be argued in connection with embryonic stem cells. This section has clarified that it is quite difficult to argue the right to life of unborn in general and more precisely in case of embryonic stem cells. Whereas many deem that embryos at any stage are human beings, the problem is how the law approaches this specific issue. The ECtHR's case law has shown that there is no clear answer, if the ECHR protects or not unborn life, because it's not only matter of the rights of unborn baby, but the right of privacy of a pregnant woman. Thus, to argue the right to life in our debate based on practice is quite frightening and to some extent not easily achievable. The same is the status of unborn in the US, where the landmark case of *Roe v. Wade* clarified that embryos are not expressly bearers of right to life. Hence, the overall picture in this case is that, it is very difficult to argue the right to life in our debate, however it is fully possible.

Lastly in order to conclude, no matter how much one will discuss this topic it will still remain controversial, because there is not easy to find a consensus. However, it is clear that embryonic stem cells should not be used for merely business purposes; this is the main unethical part of the patents. As for the research itself, I think as the person who highly values "human dignity" and right to life of all, maybe it will be better if scientists/researchers look for alternative ways and methods that would totally leave this controversial discussion to the past.

# Bibliography

## Books

- S. Holland, K. Lebacqz & L. Zoloth      The Human Embryonic Stem Cell Debate: Science, Ethics, and Public Policy, (MIT Press, Cambridge, Mass., 2001)
- M. Betzler (ed.)      Kant's Ethics of Virtue, (de Gruyter, 2008)
- M. G. Kuczewski & R. M. Polansky      Bioethics: Ancient Themes in Contemporary Issues (MIT Press, Cambridge, Massachusetts, 2000)
- L. Bently & B. Sherman      Intellectual Property Law, 3 ed., (Oxford University Press, Oxford, 2009)
- D. Bainbridge      Intellectual Property, 4 ed., (Financial Times Pitman, London, 1999)
- S. Elias & R. Stim      Patent, Copyright and Trademark, (Nolo Press, Berkeley, California, 2000)
- G. Tritton      Intellectual Property in Europe, 2 ed., (Sweet & Maxwell, London, 2002)
- L.R. Helfer & G.W.Austin      Human Rights and Intellectual Property: Mapping the Global Interface, (Cambridge University Press, United States, 2011)
- D.J.Harris, M. O'Boyle et al.      Law of the European Convention on Human Rights, 2.ed., (Oxford University Press, Oxford, 2009)
- W. F. Grosheide (ed.)      Intellectual Property Rights and Human Rights: a Paradox, (Edward Elgar, Cheltenham, 2010)
- A. R. Chapman      A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science, (Intellectual Property and Human Rights, WIPO Publication No.762(E), 2007)
- C. Tomuschat et al. (eds.)      The Right to Life, (Martinus Nijhoff Publishers, Leiden, 2010)
- R. K .M.Smith      Textbook on International Human Rights 4 ed., (Oxford University Press, Oxford, 2010)



- D.B. Resnik Embryonic Stem Cell Patents and Human Dignity, (Health Care Anal 15, 2007) pp. 211–222
- O. Senser Kant’s Conception of Human Dignity, (Kant Studien, ISSN 0022-8877, Vol. 100, Issue 3, 09/2009) pp. 309 – 331
- M. Rothhaar Human Dignity and Human Rights in Bioethics: the Kantian Approach, (Medicine, Health Care and Philosophy, ISSN 1386-7423, Vol.13, Issue 3, 08/2010) pp. 251 – 257
- D.P. Sulmasy Human Dignity and Human Worth, (Perspectives on Human Dignity: A Conversation, ISBN 9781402062803, 2007) pp. 9 – 18
- J. Malpas Human Dignity and Human Being, (Perspectives on Human Dignity: A Conversation, ISBN 9781402062803, 2007) pp. 19– 25
- T.D. Koninck Protecting Human Dignity in Research Involving Humans, (Journal of Academic Ethics, ISSN 1570-1727, Vol. 7, Issue 1-2, 06/2009) pp. 17 – 25
- S. G. Green Human Dignity and the Law, (Perspectives on Human Dignity: A Conversation, Issue 2, 2007) pp. 151-156
- R. Andorno Global bioethics at UNESCO: in Defence of the Universal Declaration on Bioethics and Human Rights, (Journal of medical ethics, ISSN 0306-6800, Vol. 33, Issue 3, 03/2007) pp. 150 – 154
- R. M. Doerflinger Old and New Ethics in the Stem Cell Debate, (8 J.L. Med & Ethics 212, 2010) pp.212-219
- G.H. Outka The Ethics of Human Stem Cell Research, (Kennedy Institute of Ethics Journal, Vol.12:2,06/ 2002) pp. 175-213
- G. Bahadur & M. Morrison Patenting Human Pluripotent Cells: Balancing Commercial,

- Academic and Ethical Interests,  
(Human Reproduction, Vol.25,  
No.1, 2010) pp. 14–21
- J. Shum  
Moral Disharmony: Human  
Embryonic Stem Cell Patent Laws,  
Warf, and Public Policy, (33 B.C.  
Int'l & Comp. L. Rev. 153, 2010)  
pp. 153-178
- G. Elliott  
Basic of US Patents and the Patent  
System, (The APPS Journal,  
EISSN 1550-7416, Vol. 9, Issue 3,  
July 2007) pp. E317 - E324
- J.A. Robertson  
Embryo Stem Cell Research: Ten  
Years of Controversy, ( 38 J.L.  
Med. & Ethics 193, 2010)
- L. Bonetta  
European Stem Cell Patents:  
Taking the Moral High Road ?  
(Cell 132, February, 2008) pp.  
514-516
- L.R. Helfer  
Toward a Human Rights  
Framework for Intellectual  
Property, (40 U.C. Davis L.  
Review, 2007)
- R. Fitt  
New Guidance on the Patentability  
of Embryonic Stem Cell Patents in  
Europe, (Nature  
Biotechnology, ISSN 1087-  
0156, Vol. 27, Issue 4, 04/2009) pp.  
338-340
- J. Cornices  
Human Rights and Intellectual  
Property: Conflict or Convergence,  
(The Journal of World Intellectual  
Property, ISSN 1422-2213,  
Vol. 7, Issue 2, 03/2004), pp. 135 –  
167
- C.Byk  
Medical and Biological Progress  
and the European Convention on  
Human Rights, (Council of  
Europe, Directorate of Human  
Rights, Strasbourg, 1992)
- T. Goldman  
Vo v. France and Fetal Right: the  
Decision not to Decide, (Harvard  
Human Rights Journal Vol.18  
2000) pp.277-282
- N. Priaulx  
The Margin of Appreciation:  
Therapeutic Abortion,  
Reproductive 'Rights' and the  
Intriguing Case of Tysi c v.  
Poland, (European Journal of

A. M. Destro

Health Law, Vol.15,2008) pp. 361-379

National Right to Life Committee,  
(Encyclopedia of Stem Cell  
Research. Ed., SAGE, Thousand  
Oaks, CA, 2008) pp. 368-370

### **Law and Soft Law**

Convention on the Grant of European Patents (EPC 2000) 14th Edition,  
2010 of the European Patent Office

Directive 98/44/EC on the Legal Protection of Biotechnological Inventions  
of 6 July 1998 of European Parliament and of the Council

Paris Convention for the Protection of Industrial Property of  
March 20, 1883 of WIPO

Patent Cooperation Treaty (PCT) of June 19, 1970 of WIPO

Agreement on Trade Related Aspects of Intellectual Property  
Rights (TRIPS) 1994 of WTO

35 United States Code (U.S.C.)

Universal Declaration of Human Rights (UDHR), G.A. Res. 217A (III),  
U.N. Doc A/810 (1948)

International Covenant on Economic, Social and Cultural Rights (ICESCR),  
G.A. Res. 2200A (XXI), U.N. Doc. A/6316 (1966)

International Covenant on Civil and Political Rights (ICCPR), G.A. Res.  
2200A (XXI), U.N. Doc. A/6316 (1966)

Convention on the Rights of the Child (CRC), 1577 UNTS 3, 28 ILM 1456  
(1989)

Declaration of the Rights of the Child(DRC), G/A/RES 1386 (XIV) (1959)

Convention against Torture and other Cruel, Inhuman or Degrading  
Treatment or Punishment (CAT), G/A/RES 39/46 (1984)

Convention on the Elimination of All Forms of Discrimination against  
Women (CEDAW), G/A/RES 34/180 (1979)

Vienna Convention on the Law of Treaties (VCLT), United Nations (1969)

European Convention for the Protection of Human Rights and Fundamental  
Freedoms (ECHR), Council of Europe (1950)

American Convention on Human Rights (ACHR), OAS (1969)

African Charter on Human and Peoples' Rights, OAU (1981)

Second Optional Protocol to the International Covenant on Civil and Political Rights, UN, General Assembly (1989)

Committee on Economic, Social and Cultural Rights, General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from Any Scientific, Literary or Artistic Production of Which He is the Author (Art. 15 (1) (c)), UN Doc. E/C. 12/GC/17 (2006)

Committee on the Economic, Social and Cultural Rights General Comment No.21, UN Doc. E/C.12/GC/21 (2009)

Universal Declaration on Bioethics and Human Rights (UDBHR), UNESCO (2005)

### **Internet Sources**

Oxford Dictionaries: <http://oxforddictionaries.com>

UNESCO Website: <http://www.unesco.org/>

WIPO Website: <http://www.wipo.int/>

WTO Website: <http://www.wto.org/>

EPO Website: <http://www.epo.org>

USPTO Website: <http://www.uspto.gov/>

UKIPO Website: <http://www.ipo.gov.uk/>

Stem Cell Information NIH: <http://stemcells.nih.gov/>

Explore Stem Cells: <http://www.explorestemcells.co.uk/>

Intellectual Property Group: <http://www.pronovem.com/>

Legal Information Institute: <http://www.law.cornell.edu/>

Geron Website: <http://www.geron.com>

United States Conference of Catholic Bishops: <http://old.usccb.org/>

Lawnix: <http://www.lawnix.com>

Life Sciences Foundation: <http://www.lifesciencesfoundation.org/>

National Abortion Federation: <http://www.prochoice.org>

Feminists For Life: <http://www.feministsforlife.org/>

European Dignity Watch: <http://www.europeandignitywatch.org>

# Table of Cases

|                                    |  |
|------------------------------------|--|
| Oliver Brüstle v Greenpeace        | Case C-34/10, Grand Chamber of the European Court of Justice (2011)                                  |
| WARF Case                          | G 0002/06, the Decision of the Enlarged Board of Appeal of the EPO (2008)                            |
| Stem Cells Case                    | T 1374/04, the Decision of the EPO (2006)  |
| Bruggemann and Scheuten v. Germany | Application No. 6959/75, Commission Report of 12 July 1977, European Commission on Human Rights      |
| X v. the United Kingdom            | Application No. 8416/79, Admissibility Decision of 13 May 1980, European Commission on Human Rights  |
| H v. Norway                        | Application No. 17004/90, Admissibility Decision of 19 May 1992, European Commission on Human Rights |
| Vo. v. France                      | Application No. 53924/00, Judgment of 8 July 2004, European Court of Human Rights                    |
| Tysiac v. Poland                   | Application No. 5410/03, Judgment of 20 March 2007, European Court of Human Rights                   |
| A.B.C. v. Ireland                  | Application No. 25579/05, Judgment of 16 December 2010, European Court of Human Rights               |
| Roe v. Wade                        | 410 U.S. 113 (1973)  |
| Diamond v. Chakrabarty             | 447 U.S. 303, USPQ 193 (1980)  |
| Juicy Whip Inc v. Orange Bang Inc. | 185 F. 3d 1364, Federal Circuit (1999)   |
| Lowell v. Lewis                    | 15 Federal Case, 1019 (1817)   |