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Patentability of  
**Human Embryonic Stem Cells**  
*Finding the Balance between  
the Moral Hazard in Europe  
and the Wide Scope in the US*

*Abstract:* This thesis investigates the patentability of human embryonic stem cells in Europe and the US. It focuses on Europe and the interpretation of the Biotech Directive in relation to the lack of integration between EC law and the EPO system, and shows the difficult task to define a European moral norm on the embryo itself. The divergent approaches leads to the question whether HESC are excluded from patentability on moral grounds in Europe, while in the US, the patent on HESC is too broad to be effective.

Conclusively, the isolated stem cells are in a completely different state than their origin and should therefore be a patentable subject matter.

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**Front side picture:** *Differentiated Human Embryonic Stem Cells:*

Cell nuclei (blue), Glial cells (green), Neurons (red).

Derived from human embryonic stem cells, precursor neural cells grow in a lab dish and generate mature neurons (red) and glial cells (green), in the lab of UW-Madison stem cell researcher and neurodevelopmental biologist Su-Chun Zhang.

**Photo by:** Su-Chun Zhang, Ph. D. M.D. University of Wisconsin, Madison

**Date:** 11/01

**Available at:** [www.alsa.org/images/stem\\_cells\\_fig3.jpg](http://www.alsa.org/images/stem_cells_fig3.jpg)

2008-01-30

# Summary

Stem cells are the first type of cells developed in an embryo. They have the ability to divide, self-replicate, for indefinite periods. Under the right conditions or given the right signals, stem cells can give rise to the many different cell types. The isolation of *human* embryonic stem cells (HESC) and the ability to cultivate them in a laboratory has given hope to treat diseases like cancer, Alzheimer's, diabetes, HIV, Parkinson's, spinal cord injuries and heart diseases.

Stem cell research not only creates possibilities but also raises fundamental ethical issues concerning what constitutes human life and the value of such research compared to the feared violation of human life.

In the EU, there is no unified law for patents, both the intergovernmental European Patent Convention (EPC) and national laws govern. The EPC provides for a centralized search and examination process by the EPO, which results in the issuance of a European patent that translates into national patents for the states designated in the application. The issued patents are then governed by the respective national laws.

The Biotech Directive, addressed the patent protection of biotechnological inventions. While the EPO did not need to comply with the Directive because it is independent of the EU, it voluntarily decided that the Directive was essentially a summary of its case law, and thus reframed its interpretation to comply with the Directive. EU members have been slow to adopt the Directive based on moral concerns, and there may be deviations from the Directive even in countries that have adopted it. The goal was harmonization among EU members, which was seen as necessary to encourage investment in biotechnology and avoid barriers to trade that, would arise from different members offering different protections.

However, the interpretation of the Directive has led to divergent implementation of the moral clauses, and since there is no European definition of the term "*embryo*", controversial national legislation is met. The principal problem seems to be the destruction of the embryo, which at present is necessary for derivation of embryonic stem cells. There are however new technologies advancing towards creating embryonic stem cells without destroying the embryo.

In the US, the human embryonic stem cells are patentable subject matter. The WARF patents and all what they include, have undoubtedly a hindering effect on the research climate on the other side of the Atlantic. This broad patent grants, makes it more or less impossible to continue research on embryonic stem cells, no matter their origin or the way they are produced, without the consent of WARF. The question whether those stem cells should be regarded as research tools and kept in the public domain and how to narrow their scope, is widely discussed.

This thesis investigates the patentability of human embryonic stem cells in Europe and the US. It focuses on Europe and the interpretation of the Biotech Directive in relation to the lack of integration between EC law and the EPO system, and shows the difficult task to define a European moral norm on the embryo itself. The divergent approaches leads to the question whether HESC are excluded from patentability on moral grounds in Europe, while in the US, the patent on HESC is too broad to be effective.

Conclusively, the isolated stem cells are in a completely different state than their origin and should therefore be a patentable subject matter.

# Preface

I would like to dedicate this thesis firstly, to my Grandmother *Britta*, whom I always have been looking up to and have been my great prototype. But also to my Grandfather *Lars Erik Gelin*, who I unfortunately never had the opportunity to meet, but was a great Professor of surgery that invented an anticoagulant, for which he never applied for a patent...

All my life I wanted to study medicine, but life is not always as you have planned it to be. Therefore, I started law school instead which I thought was a good alternative, being a wide education with plenty of opportunities. Struggling through the first two years, I still was not convinced that I had chosen the right way. I can say that I have not loved my education until the last year, when I finally could choose the courses I wanted to study. I fell in love with the EC law and Sports law while doing the European Moot Court Competition.

However, Science and Biology has always been a great interest of mine, so when it came to choosing a subject for my Master Thesis I knew exactly which direction to go. Within the Intellectual Property law, I could finally practice my huge interest for Biology! Therefore, I have chosen to write about the patentability of human embryonic stem cells, the small parts where life begins, which can develop into fantastic creatures!

I would like to thank:

<i>My beautiful family</i>	No words can express my gratitude of having You!
<i>Hans Henrik Lidgard</i>	My supervisor, with a very big patience.
<i>Xavier Groussot</i>	For giving me my interest in law back, while coaching the Moot Court Team.

Last but not least, I would like to thank my wonderful friends  
*Anna, Alexandra, Charlotte, Lena, Nina and Sofia*  
without you I would have dropped out of Law school the first year.  
Thank you for your support and for always being there.

*"... the one thing that I think is extremely important, is that anyone can do it, if given a chance, if given the opportunity."*<sup>1</sup>

Carpe Diem!

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<sup>1</sup> Mario R. Capecchi, Nobel Prize Laureate in Medicine 2007.



# Abbreviations

AG	Advocate General
CFI	Court of First Instance
CFREU	Charter of Fundamental Rights of the European Union
COMPAT	Community Patent
CPC	Community Patent Court
Directive	The Biotech Directive 44/98 EG
EBA	Enlarged Board of Appeal (EPO)
ECHR	European Convention on Human Rights and Fundamental Freedoms
ECJ	European Court of Justice
ECrHR	European Court of Human Rights
ED	Examining Division (EPO)
EEA	European Economic Area
EFTA	European Free Trade Association
EGE	European Group on Ethics
EPC	European Patent Convention
EPO	European Patent Office
EG	Embryonic Germ Stem Cell
ES	Embryonic Stem Cell
HESC	Human Embryonic Stem Cell
HR	Human Rights
IPR	Intellectual Property Rights
MOU	Memorandum of Understanding
MS	Member State
NIH	National Institute of Health (US)
OD	Opposition Division (EPO)
TBA	Technical Board of Appeal (EPO)
Treaty	Treaty establishing the European Community
USPTO	US Patent and Trademark Office
WARF	Wisconsin Alumni Research Foundation

# Little Dictionary

<i>artefact</i>	Something which is made or introduced artificially
<i>blastocyst</i>	Early stage in the development of an embryo
<i>embryo</i>	Any human totipotent cell which has the potential to divide and to develop into a human being if the necessary conditions prevail
<i>in vitro</i>	In the laboratory
<i>in utero</i>	In the body / natural state
<i>oocyte</i>	Cell which forms from an oogonium (cell produced at the beginning of the development of an ovum) and becomes an ovum by meiosis
<i>pluripotent cell</i>	Do not have the potential to develop into a human being but still great potential for research purposes
<i>reproductive cloning</i>	Cloning human beings
<i>somatic</i>	Referring to the body
<i>supernumerary</i>	Leftovers (Eg from IVF)
<i>therapeutic cloning</i>	A nucleus from a human cell would be transferred to an oocyte, which would be used to produce an early embryo in cultures (Eg used for the production of stem cell lines)
<i>totipotent cell</i>	Do have the potential to develop into a human being if implanted in a woman's womb

## *Stages of early human development*<sup>2</sup>

0-	fertilised egg (zygote)
2-3 days	morula
4-5 days	blastocyst
7 days	embryo
8 weeks	foetus
40 weeks	baby

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<sup>2</sup> [http://pharmalicensing.com/public/articles/view/1119630334\\_42bc33fe14906](http://pharmalicensing.com/public/articles/view/1119630334_42bc33fe14906), 2007-12-28.

# 1 Introduction

*“As time and science move forward, the law struggles to keep pace while, at the same time, resisting change in order to maintain stability.”*<sup>3</sup>

The human body has always been something special in the context of patent and research. Patent on life raises many controversial issues. The moral standard around the world changes with time and upon cultural environments. However, lately the research in biotechnologies has reached a point where those questions have appeared in the limelight. Namely, the patent of human embryonic stem cells (HESC) is at stake.

This year’s Nobel Prize winner in medicine was a group of stem cell researchers. The Laureates got the prize for their discoveries of *"principles for introducing specific gene modifications in mice by the use of embryonic stem cells"*.<sup>4</sup>

They have made a series of ground-breaking discoveries concerning embryonic stem cells and DNA recombination in mammals. Since only mice embryonic stem cells are used, the ethical problem never springs to mind. The Nobel Prize illustrates how topical the subject is and the potential of stem cell research, but what we can see now is just the top of the iceberg. The appearing legal problems regarding stem cell research are complex and divergent. In this thesis, I will discuss the moral aspects on HESC research in Europe and the US, comparing the two systems and trying to find the best balance.

## 1.1 Purpose

The purpose of this thesis is to investigate and compare the patentability of human embryonic stem cells in Europe and the US and trying to find the best balance between the two systems. My focus will be on Europe and it is hereby necessary to examine the Biotech Directive and its implication on the European approach and moral hazard of the HESC’s patentability. Thereinafter, to compare the broad scope of HESC patentability in the US, which hinders more or less all future research on the stem cells, no matter their origin or purpose.

## 1.2 Complexity of Problems

Biotechnology patents have always been controversial to moral standards. Just the thought of patenting life in any form leads to endless discussions.

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<sup>3</sup> Han, S. S. *Analyzing the Patentability of “Intangible” Yet “Physical” Subject Matter*, 3 COLUM. SCI. & TECH. L. REV., at 12 (2002), <http://www.stlr.org/cite.cgi?volume=3&article=2>.

<sup>4</sup> Nobel Prize in Medicine 2007: Mario R. Capecchi, Martin J. Evans and Oliver Smithies. [http://nobelprize.org/nobel\\_prizes/medicine/laureates/2007/press.html](http://nobelprize.org/nobel_prizes/medicine/laureates/2007/press.html), 2007-10-18.

Most countries do not allow patent on human beings, which sounds like an agreeable limitation of the patent system. However, the problem arises when trying to define what is human and where to draw the line.

The main controversial problem in the EU seems to be the fact that an embryo is destroyed when producing embryonic stem cells. This creates an ethical problem within many different societies and organisations, since there is no European definition of the term “*embryo*”.

How to interpret the Biotech Directive and how to intervene EC with the EPO for a European patent is another problem, since the EU is in need of a reorganisation when it comes to a Community patent, to be able to compete with other parts of the world in biotechnology.

However, in the US, the problem is instead the WARF patents wide scope that delimitates other inventors from exploring the broad possibilities within stem cell research. Should not basic knowledge be kept in the public domain? How can the scope be narrowed and by whom?

I will try to investigate what the right kind of balance contains. Therefore, to do that, an investigation of the Directive and its implementation and interpretation, the relationship EU - EPO and a comparing study with the US is necessary.

Principally, five issues will be discussed:

- 1.) *Scientific background and the potential of human embryonic stem cells*
- 2.) *Moral norms on the human embryo in Europe*
- 3.) *The Directive in the EU legal order*
- 4.) *The Directive in the EPC legal system*
- 5.) *How does the US approach the problem?*

## **1.3 Method and Materials**

I have used a classic legal method with a comparing approach. The focus will be on Europe and its development but comparing it with the US makes the subject more interesting, since the US is way ahead of Europe in the biotechnology industry. Even other countries approaches to the problem, such as Sweden, Germany and UK, will show up as examples in the thesis.

Books and articles have of course been used, but mainly a lot of internet web pages and articles via databases, since this is a very topical subject and there is an ongoing debate. The majority of my used sources are journal articles from West Law etc, which sometimes can be quite angled, but it is important to look at them in its full context. There are so many articles that

it is difficult to choose which ones that are relevant for this thesis. I have done my choice and I hope it will contribute to a deep analysis.

## **1.4 Delimitations**

Even though I think this is an extremely interesting area, some limitations must be made. Therefore, there will be just a short presentation on the patent system in general, when the reader hopefully already has a little knowledge about patent law.

Excluded is the EU and basic principles of EC law such as sovereignty, direct effect of directives etc.

I have chosen not to consider the Convention on Human Rights and Biomedicine, even though it brings up several interesting issues, such as patent on the human body, use of embryos in research and commercialization, but it would make the scope of this thesis too broad.

As you will notice this thesis is quite long. I could have chosen not to have the US part at all, since I then would have had the perfect amount of pages. But I realized that it is the comparative analysis of the two systems and the different solutions that brings this thesis to an interesting end, so I could not just skip that part! Therefore, I hope you will be indulgent with the “a little” too long final version of this thesis.

## **1.5 Disposition**

Firstly, I would like to give the background on what a stem cell is, its potential application and its use in research.

Secondly, I would like to go briefly through the basic concepts in patent law in Europe and the USA.

Thirdly, the moral problems, which arise in Europe in relation to stem cell patents and the implementation of the Directive according to EC law and according to the EPC system. Furthermore, I will go through the relevant case law in Europe.

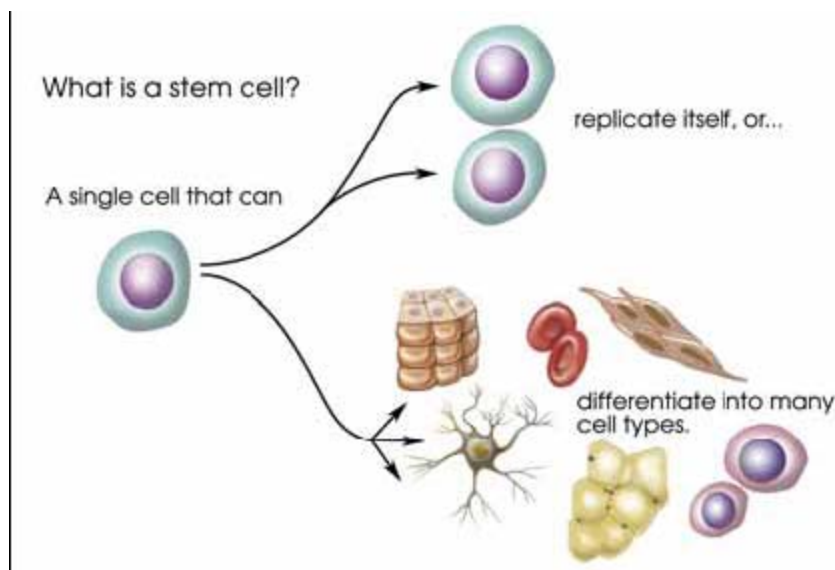
Thereinafter, the US approach and wide scope of HESC related patents and relevant case law.

Finally, I will try to analyse the complexity of problems and finding the balance regarding the future development in the legislation of stem cells patentability.

## 2 Background

All living organisms are made of cells,<sup>5</sup> which is the fundamental unit of life. The adult human body is composed of 50 trillion cells of around 200 different kinds, each with a particular function, be it an eye cell, a muscle cell or a blood cell. In the beginning, however, it is not so complicated. When human life begins with the union of the sperm and egg there is but one cell, the zygote. Over a matter of hours, this cell divides and divides again and at this stage the cells that are created have no dedicated function, they are said to be *undifferentiated*. Within this initial period of division, which lasts no more than three to four days, these undifferentiated stem cells are *totipotent*, each has the capacity to become a complete and separate embryo. By days five to seven, this quality is lost and the organism has become a *blastocyst*, a ball of around 100 cells of which is now *pluripotent*, that is, each has the capacity to develop into any of the 200 cell types that make up the human body, but it is no longer possible for them to develop into separate embryos.<sup>6</sup> It is in this inner embryo, that we will start to investigate the importance of stem cell research.

### 2.1 What is a Stem Cell?



<sup>5</sup> They consist of many biological elements that are enclosed in a cell membrane, one such organ being the *nucleus* that contains 23 pairs of chromosomes that control the functioning of the human body.

<sup>6</sup> Laurie G. p. 60, 2004, *Patenting Stem Cells of Human Origin*, pp. 54 ff., 2004, E.I.P.R. As time passes, the organism, which we might now wish to call an embryo will continue to grow so long as it is furnished with an appropriate environment and nutrition. These are provided by implantation in the lining of the womb from which a blood supply can be drawn (occurring around day eight of development). It is arguable that it is not until this point that the organism achieves the potential for "*humanness*", a distinction which is very important in one's consideration of the status of the embryo. See also Cooper G. M. and Hausman E. H., *The Cell*, p. 621 ff, 2004.

Stem cells are the first type of cells developed in an embryo. They have the ability to divide, self-replicate for indefinite periods, often throughout the life of the organism.<sup>7</sup> All cells carry the same DNA but in a stem cell, all or most of the genetic code is available for activation.<sup>8</sup> Under the right conditions, or given the right signals, stem cells can give rise to the many different cell types, the specialized cells, which make up the organism. Stem cells are of different kind and are found in fertilized embryos, in foetal tissue but also in adult tissue.<sup>9</sup>

Although all cells of an individual human body contain the same DNA and hence the genetic make-up, different cell types of cells have different expression of genes and different functions. Such cells are said to have undergone differentiation. Stem cells on the other hand, are undifferentiated cells that have the potential to differentiate into particular cell and tissue types. They are therefore seen as the precursor of all body parts.<sup>10</sup>

Conclusively, stem cells have two important characteristics that distinguish them from other type of cells. Firstly, they are unspecialized and can renew themselves for long periods through self-replication. Secondly, under certain physiologic or experimental conditions, they can be induced to become cells with special functions (specialized) such as the muscle cells of the heart or insulin-producing cells of the pancreas.<sup>11</sup>

## 2.2 Different Kinds of Stem Cells

Generally, there are three areas from which stem cells can be obtained: the human embryo, which produces embryonic stem cells (ES); the foetus, which gives rise to embryonic germ stem cells (EG); and the adult, which provides adult stem cells.

A stem cell has the potential to develop into more than 200 tissues and organs in the human body and is known as *totipotent*. Stem cells, whose potential is not quite as great as that of a totipotent cell is called *pluripotent*, and are still capable of giving rise to most tissues of an organism. A *unipotent* stem cell is one that gives rise to one single type of tissue.<sup>12</sup>

### 2.2.1 Adult Stem Cells

Adult stem (somatic) cells exist in the body and are occupied on its repair and replacement. This type is an unspecialized cell found within a specialized tissue<sup>13</sup> and is capable of developing into the cell types in the

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<sup>7</sup> Hellstadius, Å. p. 8, 2002.

<sup>8</sup> Lidgard H.H. p. 85, 2004.

<sup>9</sup> Hellstadius, Å p. 8, 2002.

<sup>10</sup> National Institute of Health, *Stem Cells: Scientific Progress and Future Research Directions* ES-2, 2001 (hereinafter Scientific Progress).

<sup>11</sup> Laurie G. p. 60, 2004.

<sup>12</sup> *Scientific Progress* ES-2, 2001.

<sup>13</sup> Currently, in the blood, cornea, and retina of the eye, brain, skeletal muscle, dental pulp, bone marrow, skin, liver, pancreas, and the lining of the gastrointestinal tract.

specialized tissue or organ in which it is found. Their primary role is to maintain and repair this tissue. Research on adult stem cells has recently generated a great deal of excitement since they have been found in far more tissues than one thought possible. Certain types may even have the ability to differentiate into a number of different cell types if given the right conditions.<sup>14</sup> Mammals appear to contain some 20 major types of somatic stem cells that can regenerate the various tissues but they are rather difficult to find and isolate and they do not seem to have the same development potential as embryonic or foetal stem cells.

## 2.2.2 Foetal Stem Cells

Foetal stem cells can be retrieved from the umbilical cord blood. Foetal tissue obtained after pregnancy termination can be used to derive multipotent stem cells like neural stem cells, which can be isolated from foetal neural tissue and multiplied in culture. Even though they have a limited life span, also foetal tissue can give rise to pluripotent EG cells isolated from the primordial germ cells of the foetus.<sup>15</sup>

## 2.2.3 Embryonic Stem Cells

Embryonic stem cells are as the name suggest, derived from embryos. An embryo develops typically from a fertilized egg. Human ES's are derived from the embryo when it is four or five days old and a hollow microscopic ball of cells called a blastocyst<sup>16</sup> exist.

The embryonic stem cells can be derived from surplus embryos. Perhaps originally created for an infertile couple in an infertility treatment program and then donated by the couple for use in medical research. They can also be derived from embryos created by somatic cell nuclear transfer, a technique involving use of cloning technologies to create embryos.<sup>17</sup>

## 2.3 The Potential of Embryonic Stem Cells

The isolation and purification of ES in 1998 sparked a raging fire of enthusiasm across the medical arena.<sup>18</sup> Millions of people suffering from painful and life-threatening diseases, such as a neurological disorder, heart failure, and diabetes, are hopeful that novel stem cell therapies are on the horizon. Their dreams and futures depend not only on the abilities of

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<sup>14</sup> *Scientific progress* ES-1, 2001.

<sup>15</sup> Cooper G M and Hausman EH, *The Cell*, p. 621 ff, 2004.

<sup>16</sup> A blastocyst is an embryo that has developed to the three germ layers of the endoderm, mesoderm and the eoderm.

<sup>17</sup> *Scientific Progress* ES-1, 2001.

<sup>18</sup> Wright, S. J., Human Embryonic Stem-Cell Research: Science and Ethics, 87 Am. Scientist 352 (1999), available at 1999 WL 3555448.



scientists, but also on the wisdom of lawyers and judges to help transform this achievement into commercial products.<sup>19</sup>

As we know the stem cell research not only creates possibilities but also raises fundamental ethical issues concerning what constitutes human life and the value of such research compared to the feared violation of human life.<sup>20</sup> Therefore, it is important to have clear indications on where to strike the line.

The isolation of *human* embryonic stem cells (HESC) and the ability to cultivate them in a laboratory is a recent scientific advancement and such cells have only been studied since 1998. Scientists want to study stem cells to learn more about their essential properties and what makes them different from specialized cell types.<sup>21</sup> The most promising research on stem cells has centred upon those embryonic stem cells, which researchers believe may be used to treat diseases like cancer, Alzheimer's, diabetes, HIV, Parkinson's, spinal cord injuries and heart diseases.<sup>22</sup> A major possibility is that the cells can be used for therapy, screening new drugs and toxins and understanding birth defects as well as degenerative illnesses like Alzheimer's.<sup>23</sup>

In order to develop such treatments scientists are intensively studying the fundamental properties of such cells that include: determining how stem cells remain unspecialized and self renewing for many years, and identifying the signals that cause stem cells to become specialized cells.<sup>24</sup>

There are many more potential benefits, which are still unknown, and only a continuation of the research will lead to new discoveries and inventions. Scientists are attempting to generate a large volume of undifferentiated cells *in vitro*, which means in the laboratory.<sup>25</sup> The aim is to determine what cellular environment signals that are necessary to cause an undifferentiated batch of cells to develop into functioning specialized cells.<sup>26</sup> When those signals are discovered, the cells are ready to develop into specialized tissue

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<sup>19</sup> Miller, J. p. 556, 2003, *A Call to Legal Arms: Bringing Embryonic Stem Cell Therapies To Market*, 13 Alb. L.J. Sci. & Tech. 555, Albany Law Journal of Science and Technology 2003

<sup>20</sup> Hellstadius, Å. p. 8, 2002.

<sup>21</sup> *Scientific Progress*, ES-4, 2001.

<sup>22</sup> Lidgard H. H., p.85, 2004.

<sup>23</sup> The future benefits that stem cells offer are immense. For example, one goal of human ES cell research is to be able to develop heart muscle cells and then transplant them into the failing heart muscle in order to augment the function of the heart. Type 1 Diabetes is another one, when there is evidence that transplantation of either the entire pancreas or isolated islet cells could mitigate the need for insulin injections. Islet cell lines from human pluripotent stem cells could be used ultimately for transplantation into the unhealthy patient. Further, the testing and screening of drugs and toxins will be revolutionized, since the drugs could avoid the animal model and be directly tested against a stem cell line, which is developed to mimic the disease process in humans. Finally, the stem cells research may help to improve the comprehension of birth defects and how to reduce or even eliminate them.

<sup>24</sup> *Scientific Progress*, ES-4, 2001.

<sup>25</sup> *Ibid.*

<sup>26</sup> *Ibid.*

and can then be transplanted to help repair or regenerate damaged tissue of the patient.<sup>27</sup>

An example of this potential was presented recently at the Stockholm Lung Congress, when a very happy stem cell researcher Sile Lane and her group, have succeeded in culturing mice stem cells and develop them into specialized lung cells.<sup>28</sup> Thereinafter, the lung cells were injected with a colour visible in microscopes and then injected into the mouse. After two days, the specialized cells could be found just where they were hoping, in the lung. But she underlines that the application on human beings is many years ahead, since first it has to be shown that the stem cells make no other harm and it will take another century, but this is at least a step in the right direction which proofs that the potential of stem cells are enormous.<sup>29</sup>

## 2.4 The Distinction between Therapeutic and Reproductive Cloning

Cloning has been defined as “*the production of a cell or organism with the same nuclear genome as another cell or organism*”.<sup>30</sup> The cloning technology to create and bring to birth a live human being is known as *reproductive cloning*. While *therapeutic cloning*, is generally used to define three distinct approaches: somatic cell nuclear transfer, embryonic stem cell therapies and adult stem cell therapies. The main purpose is to produce human stem cells, tissues and organs.<sup>31</sup> In both technologies an embryo may be formed or used for research.

Therapeutic and reproductive cloning differ only in the way in which the resulting embryos are treated, namely whether they are converted to a tissue culture or transplanted into the womb. An obvious concern is whether permitting therapeutic cloning, as the UK government has done recently, also will make reproductive cloning more likely as in essence the phenomena cannot really be kept apart. In the sense of generating the know-how necessary for improving the efficiency of obtaining healthy cloned conspectuses, it will certainly do so. Since such technical advances are normally published in the open scientific literature, this information will be just as freely available in countries that do not have relevant legislative controls as in those that do.<sup>32</sup>

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<sup>27</sup> *Scientific Progress*, ES-2, 2001.

<sup>28</sup> GP, p 9, Madeleine Sahlman, September 19, 2007.

<sup>29</sup> Ibid.

<sup>30</sup> Standing Committee of Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and human stem cell research*, House of Representatives, Parliament of Australia, 2001.

<sup>31</sup> Ibid.

<sup>32</sup> Whittaker, P A, *Stem Cells, Patents and Ethics*, 2003.

## 2.5 Ethical Issues Raised by Human Embryonic Stem Cell Research

The past has shown us that innovative research which leads to new and revolutionary technologies, inevitably leads to ethical and policy concerns. Sometimes it seems like those debates serve nothing more but to delay the pioneers of research from receiving a reward for their efforts, by the means of patent grant.<sup>33</sup>

Since the first isolation of human embryonic stem cells by James Thomson, at the University of Wisconsin in 1998,<sup>34</sup> this extremely sensitive area of research has received a significant amount of public attention. Almost a decade later, the debate is still so controversial that it has not yet been resolved. The heart of the controversy, of course, is the ethical acceptability of the use of cells derived from human embryos and the fact, that in the current state of technique it is necessary to destroy an embryo to obtain stem cells from it.<sup>35</sup> Most of us are of the opinion that the human embryo deserves respect as a form of human life, but there is considerable disagreement about the stages of development.<sup>36</sup>

The major opponents believe that the embryo is a full human being from the earliest moments of the conception period, and therefore deem any use of human embryos other than for achieving a pregnancy.<sup>37</sup> Any activity that destroys an embryo is hence unacceptable and unethical, since it would mean murdering a human being.<sup>38</sup>

Moreover, since the scientists are not completely sure what the research will lead to, if embryonic stem cells are much more useful than adult stem cells and the future application of the results of their research, it is according to those groups point of view, not enough to justify such research.

On the other hand, the proponents, argue that it is more ethical to use the spare embryo left over from *in vitro*<sup>39</sup> (IVF) fertilization procedures in

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<sup>33</sup> The Harvard Oncomouse case, that took more than a decade of discussion before the patent was granted by the EPO.

<sup>34</sup> Who isolated pluripotent stem cells from their inner cell mass of the human embryo at the blastocyst stage. Cell lines derived from this source have been termed embryonic stem cells.

<sup>35</sup> Lenoir, N. *Confronts the Embryonic Stem Cell Research Challenge* Science, 25 February 2000, Vol 287, No. 5457, p.1425.

<sup>36</sup> Oestreich, S. *Implications of Policy decisions on Human Embryonic Stem Cell Research in the United States*, Harvard Health Policy Review, 2001.

Grinell, F. *Defining embryo death would permit important research*, The Chronical of Higher Education, 2003.

<sup>37</sup> Primarily expressed by the Catholic Church and anti-abortion groups. See also McCloskey, P. *Is Stem Cell Research Moral?*

<sup>38</sup> Ibid.

<sup>39</sup> There are thousands of human embryos frozen in infertility clinics, left over from IVF (in vitro fertilization) efforts for infertile couples. These so-called "spare" embryos are created when a woman's eggs are collected during the infertility treatment. Since human eggs cannot be frozen and then fertilized, all the eggs collected must be fertilized, and the embryos not transferred to a woman's womb are frozen for later use. But many end up unused and left with an uncertain future-remaining frozen indefinitely, being donated for research or being thawed and discarded. Given the choices above, many couples may see

research, of which results could possibly save numerous of lives,<sup>40</sup> than to simply let them die, which they are destined to do. Hence, scientific research is not in effect preventing human births.

According to the EGE, the potential benefits of stem cell research are staggering, but they cannot come at the cost of commodifying human embryos or the donors from whom they come. It is hereby, submitted that the research on embryonic stem cells should be allowed but safeguards are definitely going to be needed to prevent a market emerging in embryos themselves. Therefore, strict regulations must be introduced in this kind of research, so it could only be conducted on embryos left over from IVF procedures and donated by their owners.<sup>41</sup>

There seem to be two main ethical arguments: Firstly, the opponents of patenting claim that allowing patents for embryonic stem cells represents a commodification of human life. If the issue is patentability of totipotent stem cells, this argument might be sustainable, since those cells have the potential to grow into a human being and no human has the right of ownership over another human being.<sup>42</sup> However, ethical concerns about patenting of pluripotent stem cells, which only have the potential of growing into a specific type of tissue or organ, and could therefore be considered human body parts only, could easily be surpassed by the same arguments, which were used when patenting of genes or hormones was at stake. Namely, a patent is only a right over information contained in the particular human substance or body part and not a tangible right over them. Note that a common misconception is that a patent confers a property right in the physical thing that is patented.<sup>43</sup> In reality, it merely enables the patentee to prevent unauthorized commercial dealings in the invention.<sup>44</sup>

Even if we could presume that such moral distinctions exist, we can ask ourselves the question whether or not there is a greater morality in patenting embryonic stem cells than in omitting to do so, given their vast

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the value of donating embryos for research. Kahn, J. *Making a market for human embryos?* See also Grinell.

<sup>40</sup> Standing Committee of Legal and Constitutional Affairs, *Human Cloning: scientific, ethical and regulatory aspects of human cloning and human stem cell research*, House of Representatives, Parliament of Australia, 2001.

<sup>41</sup> Opinion of the European Group on Ethics in Science and New Technologies to the European Commission. *Ethical Aspects of Patenting inventions involving Human Stem Cells*, No. 16, May 2002 4-5.

<sup>42</sup> Patenting of such cells could be considered as a form of slavery. See Scott, R. *The body as property*, 1981, p. 191.

<sup>43</sup> Domeij B. p. 57, 2007.

<sup>44</sup> Sheard, A. *Patenting Human Genes: Reflection on the Public Debate*, 8(3) *Journal of Commercial Biotechnology*, 2002, p. 235-236.

See also the renowned Relaxine case (*Hormone Relaxine*, 1995 Official Journal of the EPO 388: (1995) E.P.O.R. 541.), where the OD clearly and convincingly made the point that patents covering DNA sequences encoding proteins do not confer on the proprietors any rights whatsoever to individual human beings, no more than do patents directed to other human products. In principle, the OD saw no moral distinction between the patenting of genes on the one hand, and of other human substances on the other.

potential in medicine. Is it not considered to be a moral good to seek to put an end to human suffering?<sup>45</sup>

Secondly, the opponents argue that patenting of embryonic stem cells would cause unequal distribution of benefits of the research. In other words, that it would be unethical to give anyone a broad monopoly over what may prove to be an entirely new way of treating wide range of otherwise incurable human diseases since patents could cause a significant increase in the price of those treatments.<sup>46</sup> The financial interest in a free market creates more funding for research, and faster overall progress in research in important areas has been the result of intense research efforts. Patenting the results of embryonic stem cell research will hasten the development of treatments and thus assist in saving more lives.

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<sup>45</sup> Basheer, S. *Patenting of genes and sequences: The next El Dorado*, available at <http://users.ox.ac.uk/~edip/basheer.pdf>.

<sup>46</sup> Working Group on Bioethics Church and Society Commission, *Human Stem Cell Patents would be Unethical*, Conference of European Churches, available at <http://www.srtp.org.uk/stempat1.htm>. But the same argument could be placed against the pharmaceutical industry, as it exists now, for their patents on drugs for treating life-threatening diseases such as AIDS. Nevertheless, patents on drugs are given despite of the fact that they increase the prices of drugs. Simply because rewarding the inventor creates a positive environment for progress of research that leads to the betterment of society.

# 3 The Patent System in General

## 3.1 The Purpose of a Patent

The IPRs in general, is a legislative tool chosen to protect the moral rights and keep an appropriate balance between the incentive to invent and anti-competitive effects. The patent serves to ensure that researchers and investors have the incentives to continue the research in an unexplored area and to ensure a reward for a creative effort.<sup>47</sup> A patent grant gives the patentee a monopoly for a maximum of twenty<sup>48</sup> years, to exploit the new and inventive product or process. It is intended to increase the perceived financial reward from investment and to encourage such investments in the discovery of new technologies.

Without the patent system, it would be easy for free-riders to gain unfairly on the investors fame and expenses. The patent protection eliminates that risks and augments the likelihood that profits of research can cover the costs of production and the will to invest in new discoveries.<sup>49</sup> To keep the balance and avoid complete monopoly, the compulsory licence system was created where the patentee sometimes is requested to give a licence not to hinder future research.<sup>50</sup>

## 3.2 Patent in the EU

The basic requirements for a patentable invention in European patent law are according to Art. 52 EPC: novelty, inventive step and industrial application.

*“European patent shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.”<sup>51</sup>*

### 3.2.1 Novelty

The *novelty* requirement is applied in most countries, but its definition and scope differ significantly depending on where and what the invention is intended to be protected.<sup>52</sup> In the EPC, novelty is an essential requirement for being patentable and it can lie either in the process or in the product.<sup>53</sup>

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<sup>47</sup> Thumm, N. p. 1411, 2005.

<sup>48</sup> In the EU 20 years is the most common (even if it differs a bit in the MS) maximum patent, with extension for pharmaceuticals. A US patent is generally 20 years.

<sup>49</sup> Jones, A. and Sufrin B. p. 557, 2001.

<sup>50</sup> Byrne N. and McBratney A. p. 20 ff, 2005.

<sup>51</sup> Art. 52 (1) EPC.

<sup>52</sup> Lidgard H. H., p. 27, 2004.

<sup>53</sup> Ibid.

In Europe, we use the *first to file* principle, which means that if there are two applications for the same invention, the application, which was filed first will be granted the patent.<sup>54</sup>

Art. 54 EPC also gives an e contrario definition of novelty:

- (1) *An invention shall be considered to be new if it does not form part of the state of the art.*
- (2) *The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of the filing of the European patent application.*

It is important to distinguish between invention and discovery. The European patent law excludes discoveries from the definition of an invention.<sup>55</sup>

### 3.2.2 Inventive step

Everything that falls within the claims of a patent must be *inventive*. An invention shall be considered to involve an inventive step if, having regard to the state of the art, it is not obvious<sup>56</sup> to a person skilled in the art.<sup>57</sup> The definitions of the state of the art is found in Art 54(2) and 3 EPC.

### 3.2.3 Industrial application

Initially, the *industrial application* and the concept of “*inutility*” were used by the EPO for the purpose of excluding attempts to patents ideas which evidently did not achieve the claim ends.<sup>58</sup>

Biotech inventions have had a more tolerant industrial application than other inventions, because of its complex area. But maybe it is time to change and challenge this application in order to be able to limit the to wide patent scopes. This will be discussed in the final chapter below.

One example is an invention that has to be claimed as “*a method of treating human or animal body by surgery or therapy or of diagnosis practiced on human or animal body*” is not to be patentable. The explanation states that it does not meet an “*industrial application*” test, as its application is not “*industrial*” per se.<sup>59</sup>

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<sup>54</sup> Ibid. p. 29.

<sup>55</sup> Art. 52 (2) EPC.

<sup>56</sup> The term “obvious” means that which does not go beyond the normal progress of technology but merely follows plainly or logically from prior art, that is something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. The non-obvious requirement is often not so easy in biotechnology inventions, since the field is moving so fast forward. See Lidgard HH, p. 46, 2004.

<sup>57</sup> Art 56 EPC.

<sup>58</sup> Lidgard, H. H. p. 21, 2004.

<sup>59</sup> Ibid.

## 3.3 Patent in the US

The US Patent Act provides that:

*“Whoever invents or discovers any new any useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof, may obtain a patent therefore, the subject to the conditions and requirements of this title.”*<sup>60</sup>

Stated in the *Diamond v. Chakrabarty*<sup>61</sup> case, *“everything under the sun that is made by man may be patentable”*. This creates a very broad scope of the patent provisions.<sup>62</sup>

### 3.3.1 New

In order for an invention to be patentable, it must be *new or novel* as defined under the patent law, which provides that an invention can not be patented if:

- a). *“the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent or*
- b). *the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than on year prior to the application for patent in the US...”*<sup>63</sup>

### 3.3.2 Non-obvious

Even if the subject matter sought to be patented is not exactly shown by the prior art, a patent may nevertheless be refused if the subject matter sought to be patented is not sufficiently different from what has been used or described before. In other words, it must be *non-obvious* to a person having ordinary skill in the area of technology related to the invention.<sup>64</sup>

### 3.3.3 Useful

The patent law specifies that the subject matter must be useful, meaning that the subject matter must have a *useful* purpose and operativeness.<sup>65</sup> We will see further of the use of useful, and its special application in biotechnology. However, the scope of this thesis is too limited to go further into depth with the general provisions of the patent laws in the EU and the US. The matters of the Offices in charge, future changes, development and politics behind the legislation will be presented in the beginning of each part.

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<sup>60</sup> 35 U.S.C. § 101.

<sup>61</sup> *US Diamonds v. Chakrabarty*, 17 June 1980, 447 US 303.

<sup>62</sup> See: P.T.O. General information. *General Information Concerning Patents* provided by the USPTO, available at:

<http://www.uspto.gov/web/offices/pac/doc/general/index.html#patent>.

<sup>63</sup> *Ibid*.

<sup>64</sup> 35 U.S.C. § 103.

<sup>65</sup> See P.T.O. General Information.



## 4 Europe – Part I

The problem with human embryonic stem cells (HESC) in Europe remains to be their origin. The fact that they are derived from human embryos and that the embryo is necessarily destroyed in the process of the derivation. This is where the *ordre public* and *morality* exclusion to patentability comes into perspective.

Unlike the patent law of the USA, the EPC law explicitly excludes from patentability certain specific types of inventions as matters of principle or public policy even though they might otherwise fulfil the usual conditions of patentability.<sup>66</sup> As an example, the refusal of patents on inventions like in Art. 53 (a) EPC, “*the publication or exploitation of which is contrary to ordre public or morality*”. This issue has now been referred to the EBA, in connection with a patent application on primate embryonic stem cells.<sup>67</sup>

### 4.1 The Current Legal Environment in Europe

The implementation of the Biotech Directive<sup>68</sup> has been a difficult task for the legislators in Europe. The fact that each MS has the right to implement the Directive into its legal order as it wishes as long as it is implemented, preferably on time, has led to an emerging range of national interpretations on the moral clauses. The fragmented legal landscape and the resulting legal uncertainty on the scope of application of the moral exclusion clause on HESC carries the risk of a threat to research and investment in the life science and innovation in Europe.<sup>69</sup>

To illustrate where the problem lies, one example is when, the European Parliament adopted a resolution in October 2005, calling on the EPO to adhere to a strict restrictive interpretation on the patentability of HESC.<sup>70</sup> Notwithstanding this, the European Parliament is not an institution vested with legal authority over the interpretation of the Directive in the EU legal order, nor indeed under the EPC. Legal authority over the interpretation of the Directive within the EU legal order lies with the national courts of MS in the first instance and ultimately with the ECJ.<sup>71</sup> At the same time, the ECJ has no legal authority over the European Patent Office. However,

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<sup>66</sup> Crespi, S R, ”The Human Embryo and Patent Law” p. 569 E.I.P.R. Issue 11.

<sup>67</sup> Ibid. See also T 1374/04 (Wisconsin Alumni Research Foundation, WARF).

<sup>68</sup> Directive 98/44 EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213 of 30.07.98 p. 12.

<sup>69</sup> COM (93)700 Final Commission Communication to Parliament and Council, *Community Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21<sup>st</sup> century*.

<sup>70</sup> Resolution of 26th October 2005. The resolution welcomes the decision of the OD in the Edinburgh case and “Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive;” at § 14. P6\_TA(2005) 0407.

<sup>71</sup> Art 234 EC Treaty.

whilst the EPO administers the European patent system and has the authority to issue a European patent which translates into a bundle of national patents, this is done under the aegis of the EPC, which is an independent international treaty whose contracting MS includes States which are not members of the EU.<sup>72</sup>

Even though the list of moral exclusions contained in the Directive has been transposed into Rules 23(a)-(d) of the EPC it is essential to understand that EPO is independent from the EU legal order and therefore the Directive is operating within two distinct separate legal frameworks. Furthermore, that there is at present no inter-institutional links or procedures to integrate those two frameworks, and therefore no European judicial system to resolve differences of interpretation.<sup>73</sup>

## 4.2 The European Patent Office and the European Patent Convention

The European Patent Convention (EPC) was signed in 1973, creating the European Patent Office (EPO) in München. The EPO provides a uniform application procedure for individual inventors and companies seeking patent protection in up to 37 European countries. It is the executive arm of the European Patent Organization and is supervised by the Administrative Council. Currently, there are 32 MS<sup>74</sup> of the Convention and all 25 of the EU MS have signed. The EPO is independent of the EU and is an example of intergovernmental approach to integration.

The main objectives of the EPC are to strengthen co-operation between the States of Europe in respect of the protection of inventions and to ensure that protection may be obtained in the Contracting States by a single procedure for the grant of patents and by the establishment of certain standard rules governing patents so granted.<sup>75</sup> The EPC regulates the granting process but not the legal effects of a patent. The patent granted is not a unitary European patent as such, but a bundle of national patents resulting from the joint application procedure.<sup>76</sup>

The Convention, (which is currently under revision)<sup>77</sup>, establishes a system of law, common to the contracting states, for the grant of patents for invention. A patents granted by virtue of the Convention is called a European patent and in each contracting state for which it is granted has the effect of and is subject to the same conditions as a national patent granted by the State. Enforcement of a patent granted by virtue of the Convention is

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<sup>72</sup> Plomer A, *Stem Cell Patents: European Patent Law and Ethics Report*, p. 13, 2006.

<sup>73</sup> *Ibid* p. 14.

<sup>74</sup> The European Patent Organisation will thus comprise the following 32 member states as from 1 March 2007.

Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

<sup>75</sup> Note that the grant of European patents is a complex process. See more at: [www.epo.org](http://www.epo.org).

<sup>76</sup> Art 2 and 135 ff.

<sup>77</sup> The new EPC 2000 will enter into force 13.12.2007, On 28.6.2001, the Administrative Council adopted the new text of the EPC 2000.

thus regulated not by the Convention but by national law and procedure.<sup>78</sup> In case of a dispute over a patent, only the national courts are competent. This may lead to a divergent position on the same dispute. Therefore, a suggestion of a Community Patent (COMPAT) is under discussion.<sup>79</sup> A European patent granted by the EPO may be registered in any of the states belonging to the EPC, to avoid multiple applications from the inventors<sup>80</sup>

Under the EPC, the requirements for patentability are that the invention is novel, involve an inventive step, have an industrial application and not be excluded from patentability.<sup>81</sup> The claims contained in the application must be clear and supported by the description, while the technical disclosure must be enabling so as to make the invention workable by a third party.<sup>82</sup> These requirements are, in the field of biotechnology, complex and have resulted in much legal writing.<sup>83</sup>

Lately the EPO has included the Biotech Directive 98/44 in its practice. It will be discussed below as one of the main problems when interpreting the European moral norms.

### 4.3 The EPO – EU Relationship

The objectives of the EPC and the EPO are much more limited and specific than those of the EU or Community. Since the EPC establishes a single unitary system only for the examination and grant of patent applications, it is not a complete system covering the lifespan of a patent. Once a European patent has been granted, questions of infringement and the assessment of validity under Article 138 EPC fall back on the national systems.<sup>84</sup> It is thus obvious that national courts can invalidate a patent granted by the EPO, thereby providing for a system where different national views on some issues, such as *ordre public* and morality, can be upheld.<sup>85</sup>

The Directive has been referred to as a “*supplementary means of interpretation*” (Rule 23b) for the EPO. However, in the event of a clash between the EPO’s construction of the provisions imported from the Directive and the ECJ’s construction of the said provisions, EU MS are still bound by the ECJ’s interpretation of the Directive because of the supremacy of Community law over national law. By contrast, under the EPC system the legal validity of a patent granted by the EPO is ultimately a matter for national law.<sup>86</sup> In the event of the EPC’s interpretation of the Directive being inconsistent with the ECJ’s, there is no institution to resolve the matter. The ECJ has no jurisdiction over the EPC, since the EPC is not a

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<sup>78</sup> AG Jacobs Opinion in C-377/98 Netherlands vs. Commission, § 21.

<sup>79</sup> See next chapter.

<sup>80</sup> www.epo.org 2007-06-08.

<sup>81</sup> Articles 52 and 53 EPC.

<sup>82</sup> Articles 83 and 84 EPC.

<sup>83</sup> Schertenleib, D, p. 203, 2004.

<sup>84</sup> Dybdahl, L. p. 109 ff, 2001.

<sup>85</sup> Plomer A, p. 89, 2006.

<sup>86</sup> Ibid. p. 92.

party to the EU Treaty.<sup>87</sup> The inevitable conclusion is that, as regards MS of the European Union, the ECJ's interpretation will prevail.

## 4.4 The Need for a New European Patent System?

The idea of a “*Community Patent*” (COMPAT), which would allow individuals and companies to obtain a unitarian patent throughout the EC, dates back to the 1960's. To be able to tackle the weakness of the EPC system a “*Community Patent Court*” (CPC) was suggested by the Commission in 2000, which would rule on disputes, languages regimes, costs and the role of national patent offices. There have been several attempts to achieve consensus on the creation of a CPC and a COMPAT, but they have so far been unsuccessful.<sup>88</sup>

Despite the fact that there is a single application and granting procedure, which saves some time and money for the applicants, the EPC system has deficiencies in that it generates large enforcement costs for businesses, because of translation costs and the fact that the implementations must be handled via national courts.

The importance of the legal protection of biotechnological inventions, together with the monopoly risks arising from excessive protection and conversely the damage to commercial research resulting from insufficient protection, require that for example the Directive is implemented properly and uniformly. Such uniformity can seldom be achieved by recourse to separate national jurisdictions and it is submitted that the creation of a COMPAT and its corresponding judicial jurisdictions, able to rule on infringement, is a necessity in order to achieve the biotechnological development that is expected across the enlarging EU.<sup>89</sup>

Otherwise, the EU will have serious consequences for the competitiveness in relation to the challenges of the US and Japan and emerging powers such as China. In the current system, Europe is lagging behind on several patent activities. Considering that, a European patent, because of translation and processing costs, is 11 times more expensive than a US patent and 13 times more expensive than a Japanese one!<sup>90</sup> Hence, there is an urgent need for action. Making the COMPAT a reality and improving the system would

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<sup>87</sup> COM(2002) 545 final Report from the Commission to the European Parliament and the Council; Development and implications of patent law in the field of biotechnology and genetic engineering, p. 10.

<sup>88</sup> See *The communication from the Commission to the European Parliament and the Council –Enhancing the patent system in Europe*, Brussels, COM (2007) p. 3, available at: [http://ec.europa.eu/internal\\_market/indprop/docs/patents/strategy\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/patents/strategy_en.pdf).

<sup>89</sup> Schertenleib, D, p. 213, 2004.

<sup>90</sup> See *The communication from the Commission to the European Parliament and the Council –Enhancing the patent system in Europe*, Brussels, COM (2007) p. 2, available at: [http://ec.europa.eu/internal\\_market/indprop/docs/patents/strategy\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/patents/strategy_en.pdf).

better equip Europe for the competitive climate of today's increasing global economy.<sup>91</sup>

## 4.5 The Biotech Directive 98/44 EC<sup>92</sup>

In the introduction of this Directive, it is explained why the biotechnology and genetic engineering are playing an increasing important role in a broad range of industries. The protection of those kinds of inventions will certainly be of essential and fundamental importance for the Communities industrial development and a harmonised protection is necessary to maintain and encourage the risky investments within this field. Nevertheless, the importance of such research reaches far over Europe's borders while it has a huge impact in the development countries struggle against famine and epidemics.<sup>93</sup>

The original justifications for the Directive were primarily of economic nature. The biotechnology was, and still is, viewed with dramatic growth and possibilities during the 21<sup>st</sup> century.<sup>94</sup> The EC needed a strategy in order to take maximum advantage of the coming opportunities, where a harmonization and the Directive would be the most efficient solution.<sup>95</sup> Even though the important arguments on a harmonized protection, it took several years to compile a document. The resistance was strong but finally after 10 years, a majority of the MS reached an agreement and the European Parliament accepted the Directive in 1998.<sup>96</sup>

The first proposal of this Directive was by the European Commission in October 1988 and at this time, it contained no provisions relating to morality.<sup>97</sup> After extensive discussion between the Commission, the Council and the European Parliament, the final version included a more prominent role for ethics and morality as evaluative criteria within European patent law. Most notably, the morality clause in Art 6, which provides a non-exhaustive list of specific examples to be excluded from patentability.<sup>98</sup> The fact that seven countries<sup>99</sup> were sewed by the Commission in 2003 for not implementing the Directive on time and the fact that the Netherlands

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<sup>91</sup> See Commission's Press Release *Patents: Commission sets out vision for improving patent system in Europe*, Reference IP/07/463, available at: <http://europa.eu/rapid/pressReleaseAction.do?reference=IP/07/463&language=EN>.

<sup>92</sup> Directive 98/44 of July 6, 1998 (1998) O.J.L. 213.

<sup>93</sup> Ibid. Introduction (1-3).

<sup>94</sup> SEC (91)/629 Communication from the Commission to the European Parliament and Council: Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community and COM (93) 700 final Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21st Century White Paper from the European Commission to the Council of Ministers.

<sup>95</sup> Ibid.

<sup>96</sup> Renow L. *To Patent or Not To Patent*, Huston Journal of International Law, spring 2001.

<sup>97</sup> Crespi, S. R. *The Human Embryo and Patent Law* p. 571 E.I.P.R. Issue 11.

<sup>98</sup> Plomer A, p. 17, 2006.

<sup>99</sup> Sweden, Netherlands C-395/03, France C-448/03, Luxemburg C-450/03, Belgien C-454/03 .

tried to get it null and void<sup>100</sup> shows the difficulties and diversity in the attempt to harmonize.

The scope of a patent in Europe, is decided under the terms of the EPC, while infringement is judged solely in terms of national law.<sup>101</sup> The Directive has effects in national law and is incorporated in the EPC.<sup>102</sup> Therefore, it affects patentability at EU and national levels, together with the extent of national protection. It also restates part of the provisions of the EPC, presumably to ensure uniformity of national patent law regimes.<sup>103</sup> A number of controversial issues captured the attention of Europe but the main problem that divides the MS is the question of the patent on human related materials. Whilst the Directive was intended to harmonize patent law in the field of biotech inventions, the wording of the adopted text has finally left uncertain and precise legal scope of exclusion in regard of HESC.

#### **4.5.1 Does Patent on Life Create a New Intellectual Property Right?**

One argument raised in the *Netherlands v. Parliament and Council*<sup>104</sup> was the question whether the Directive, by providing for a patent on life, creates a new intellectual property right. But a patent is a legal right conferred on an inventor in respect of a specific invention and entitling him or her to prevent others from making, using or selling the invention for the duration of the patent in the territory in which the patent has effect without his or hers consent.<sup>105</sup> It confers no right of ownership as such, nor any absolute right to manufacture or otherwise exploit the invention.<sup>106</sup> Normally, only exploitation for industrial and commercial purposes constitutes infringement of a patent.<sup>107</sup> Experiments aimed at perfecting, improving or further developing protected inventions do not infringe the patent.<sup>108</sup>

#### **4.5.2 Key points of the Directive**

The key points in the Directive and the best known provisions relating to morality questions are Art. 5 and 6. They were new in the sense of being made explicit for the first time and it is clear that they were influenced by the ongoing debate concerning patents on genes, DNA sequences and recently the possibility of human cloning.<sup>109</sup> Although the final text was intended to guide the interpretation of the general moral exclusion in Art 6(1), the emerging range of divergent interpretations of specific exclusions

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<sup>100</sup> Case C-377/98 *Netherlands vs. Parliament and Council*.

<sup>101</sup> Art.64(3) EPC, confirmed by G2/88.

<sup>102</sup> Directive 98/44 on the legal protection of biotechnological inventions, which is incorporated into the EPC by r.23b(1) EPC.

<sup>103</sup> Schertenleib, D, p. 204, 2004.

<sup>104</sup> Case C-377/98 *Netherlands v. Parliament and Council*.

<sup>105</sup> AG Jacobs Opinion C-377/98 §, 19.

<sup>106</sup> *Ibid* § 25.

<sup>107</sup> Domeij B. p. 57, 2007 and *Relaxine* case, OJ EPO 1995 s. 388.

<sup>108</sup> AG Jacobs Opinion § 27.

<sup>109</sup> Crespi, S R, "The Human Embryo and Patent Law" p. 571 E.I.P.R. Issue 11.

under Art 6(2) have since cast considerable uncertainty on the scope of exclusion of the exceptions, Most notably Art 6(2)(c).<sup>110</sup>

#### **Art. 5**

*“1. The human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

*2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*

*3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”*

#### **Art. 6**

*“1. Inventions shall be considered unpatentable where exploitation or publication would be contrary to public policy or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.*

*2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:*

*a. Processes for cloning human beings.*

*b. Processes for modifying the germ line genetic of human beings.*

*c. Use of human embryos for industrial or commercial purposes.*

*d. Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”*

### **4.5.3 Fundamental Rights**

The right to human dignity is recognised by the ECJ as a fundamental right. The human body is a vehicle for human dignity. The right to human dignity is perhaps the most fundamental right of all, and it is now expressed in Art 1 of the Charter of Fundamental Rights of the European Union<sup>111</sup> (CFREU), which states that human dignity is inviolable and must be respected and protected.

The Netherlands claimed that the Directive was contrary to human dignity concerning the donor’s right and personal rights.<sup>112</sup> As discussed above, a patent confers no right to ownership. Even though circumstances in which the grant of a patent for an element isolated from the human body offends against human dignity may perhaps be imagined, such inventions would however unquestionably be unpatentable under the Directive by virtue of the exclusion from patentability in Art. 6(1) of inventions whose commercial exploitation would be contrary to morality.<sup>113</sup>

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<sup>110</sup> Plomer A, p. 22, 2006.

<sup>111</sup> Done at Nice, 7 December 2000, OJ 2000 C 364, p 1.

<sup>112</sup> For more details, see the claims in the case.

<sup>113</sup> AG Jacobs Opinion, C-377/98, § 201.

Thus the Directive provides an essential safeguard against the issue of such a patent and that safeguard is framed as to accommodate future developments. It is no doubt for that reason that the legislature chose not to lay down in Art. 6(2) an exhaustive list of examples of inventions which are to be considered unpatentable by virtue of Art. 6(1). A case-by-case evaluation of patent applications in the light of moral consensus is the surest guarantee that the right to human dignity will be respected, and that is the framework established by the Directive.<sup>114</sup>

*“It thus seems to me that Art 5 and 6 of the Directive draw a careful line between cases where elements of human origin should not be regarded as patentable and those where they can properly be regarded as patentable.”<sup>115</sup>*

#### **4.5.4 Effect of the Directive on European law**

This Directive was addressed to each MS in respect of their own national patent law and had no direct authority over the law of the EPC. But after a decision of the Administrative Council of the EPO in September 1999, many of its provisions were introduced into the Implementing Regulation of the EPC. Consequently, these provisions are now binding on the various divisions of the EPO and the Appeal Boards. Some of these rules have now been invoked in two cases under appeal, namely the WARF<sup>116</sup> case and the Edinburgh<sup>117</sup> patent case.<sup>118</sup>

The Biotechnology Directive and its incorporation into the EPC have now created a new and important source of law in the field of biotechnology patent law, which is distinct from both national and EPO case law. It affects the patentability of biotechnologies at the level of the EPC and in national legal systems. It also creates a new set of rules at the level of EU MS for biotechnology patent protection and the assessment of infringement.<sup>119</sup> Finally, as of 9 June 2006, all EU MS had implemented the Directive in their national laws.<sup>120</sup> It also had an impact on patent legislation in non-EU countries.<sup>121</sup> However, there is already examples of differing

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<sup>114</sup> Ibid.

<sup>115</sup> Ibid § 202, The Directive also reflects the conclusions of the Group of Advisers to the European Commission on the ethical implications of biotechnology. In this report on the ethical aspects of patenting inventions involving human origin, the Group of Advisers does not recommend excluding the patentability of such inventions as a matter of principle, but considers that it should be subject to certain ethical principles, with the result that fundamental human rights are respected. See The Group or advisers to the European Commission, Opinion of 25 September 1996.

<sup>116</sup> T 1374/04 (Wisconsin Alumni Research Foundation), WARF.

<sup>117</sup> Edinburgh University Patent, European Patent 0 695 31, granted to the University of Edinburgh on Dec 8, 1999.

<sup>118</sup> Crespi, S R, "The Human Embryo and Patent Law" p. 571 E.I.P.R. Issue 11.

<sup>119</sup> Schertenleib, D, "La Directive Européenne sur la Biotechnologie: La Brevetabilité des Séquences Génétiques" (2003) 50 Décideurs Stratégie Finance Droit 82.

<sup>120</sup> Plomer A, p. 24, 2006.

<sup>121</sup> The acceding candidate countries of Bulgaria, Croatia, Romania and Turkey are in process of implementing the Directive, and EEA countries Norway and Iceland have adopted legislation implementing the Directive. EFTA Switzerland's process is delayed but



implementations across the EU. Some MS has implemented the exclusions with a narrow scope and others with a wide.

Whether these alterations constitute a valid interpretation of the Directive is arguably questionable. In a case brought by the *Commission vs. Italy*, the ECJ held that the list of exclusions has to be transposed specifically into national laws.<sup>122</sup> The AG had correctly argued that an express transposition of the principle that commercial process involving the use of human embryos are not patentable, was required.<sup>123</sup> As Italy had failed to expressly transpose the exclusions into national law, ECJ concluded that Italy was in breach of its obligation.<sup>124</sup>

Analysis of the wording of these national legislative texts implementing the moral exclusion clauses, also reveals that the differences appear to be influenced by the respective national attitudes towards the moral permissibility of research on human embryos and HESC.<sup>125</sup>

#### 4.5.5 Some National Patent Offices

The *German Patent Office* has granted one patent on a method involving the use of pluripotent HESC.<sup>126</sup> The German equivalent to Art 6(2) is found in the Embryo Protection Act,<sup>127</sup> which aims to prevent the misuse of artificial fertilisation and of the human embryo<sup>128</sup> in vitro. It prevents any use of the embryo that is not for its own preservation. Nevertheless, it is prohibited to extract HESC from embryos, irrespective of these cells being totipotent or pluripotent, thus making it impossible to establish HESC lines in Germany. It is however, possible to research on imported pluripotent HESC in accordance with the German Stem Cell Act.<sup>129</sup>

The German Patent Office has not issued any policy statements clarifying its approach to HESC related patent applications until recently in the *Greenpeace vs. Oliver Brüstle* case.<sup>130</sup> Where in summary, the exemption from patentability is limited to where the generation of ES cells involves a

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on its way. See European Commission, State of Play of the Implementation of Directive 98/44.

<sup>122</sup> Case C-465/03 *Commission v. Italy* (2005) ECR I-5335.

<sup>123</sup> *Ibid* at § 81, and in AG Opinion.

<sup>124</sup> *Ibid*.

<sup>125</sup> Plomer A, p. 28, 2006.

<sup>126</sup> German Patent DE 10136702 B4, "System zur zell- und entwicklungsspezifischen Selektion differenzierender embryonaler Stammzellen, adulter Stammzellen und embryonaler Keimbahnzellenatent".

<sup>127</sup> Gesetz zum Schutz von Embryonen (ESchG) 01.01.1991, available at: <http://bundesrecht.juris.de/eschg/index.html>.

<sup>128</sup> For further definition of a human embryo see Section 8 of the Embryo Protection Act

<sup>129</sup> If the cells originate from culture lines established and cultivated before 1 January 2002.

Act ensuring protection of embryos in connection with the importation and utilisation of HESCs, Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (StZG), 28.06.2002, at <http://bundesrecht.juris.de/stzg/index.html>.

<sup>130</sup> 3 Ni 42/04 *Greenpeace vs. Oliver Brüstle*.

*human embryo*. Cells derived from HESC generated by other methods<sup>131</sup> are not excluded from patentability. The first decision of the Federal Patent Court is subject to appeal to the Federal Supreme Court.

The *UK Patent Office*, on the other hand, has adopted an express policy based on its understanding of the Directive's effect on patentability exclusions relating to HESC. Patents will not be granted for processes for obtaining stem cells from human embryos,<sup>132</sup> neither will it be issued for human embryonic totipotent cells, which are claimed to be excluded by Art 5(1), and have the potential to develop into an entire human body. On the other hand, none of the moral exclusions in the Directive are thought to exclude patentability of pluripotent HESC.<sup>133</sup>

The *Swedish Patent Office* has also granted a patent for a method of differentiation of pluripotent HESC's into haematopoietic cells.<sup>134</sup> The Office considered the application to fall outside the scope of the exclusion of uses of the human embryos for industrial and commercial purposes (Article 6(2)(c)). The Swedish Patent Office reasoned that the particular application did not require direct, repetitive, use of a human embryo. Instead, the application could be performed by using existing, deposited lines. Thus the application did not fall within the scope of exclusion of Article 6(2)(c).<sup>135</sup>

Thus, the emerging common view in Europe of the national patent offices which have granted patents involving the use of pluripotent HESC, is that Art 6(2)(c) has to be read narrowly.

#### **4.5.6 The European Group on Ethics and its Opinion**

In May 2002, the EGE<sup>136</sup> published its Opinion No. 16, "Ethical Aspects of patenting Inventions Involving Human Stem Cells", with the EGEs

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<sup>131</sup> The amended patent still encompasses cells derived from HESC which are not prepared from human embryos but from different sources such as from human oocytes after nucleus transplantation or from human EG cells. It is interesting to note that the above mentioned method of nucleus transplantation into oocytes is widely known as the method by which the first cloned sheep Dolly was generated.

<sup>132</sup> In April 2003, the UK Patent Office issued a Practice Notice outlining its policy. Available at: <http://www.patent.gov.uk/patent/notices/practice/stemcells.htm>

<sup>133</sup> The UK Patent Office has on basis of this granted at least 14 patents with references to HESC. See Plomer A, p. 30. 2006.

<sup>134</sup> Patent No. SE 526490: "Method of differentiation of pluripotent human embryonic stem cells into hematopoietic cells".

<sup>135</sup> Plomer A, p. 30, 2006.

<sup>136</sup> The European Group on Ethics in Science and New Technologies. Art 7 of the Directive states that the Commission's EGE "evaluates all ethical aspects of biotechnology". Recital 44 points out that the EGE may be consulted only where biotechnology is to be evaluated "at the level of basic ethical principles, including where it is consulted on patent law".

considerations on the meaning and scope of Art 6(2)(c) of the Directive in relation to HESC related patent applications.<sup>137</sup>

Opinion No. 16 drew a distinction between the “*modified*” and “*unmodified*” stem cells and stem cell lines.<sup>138</sup> The report argues that isolated stem cells which have not been modified are not patentable, on the grounds that:

“...*such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body*”.<sup>139</sup>

In addition, the EGE argued that such isolated stem cells can not, in any event, satisfy the requirement of industrial application.

The Group further suggested that unmodified stem cell lines should not be patentable either, on the grounds that:

“*unmodified stem cell lines do not have indeed a specific use but a very large range of potential undescribed uses. Therefore, to patent such unmodified stem cell lines would also lead to too broad patents.*”<sup>140</sup>

However, in the EGE’s opinion, the kinds of modified stem cell lines that will fulfil the legal requirements for patentability, are those HESC lines modified by in vitro treatments or genetically modified so that they acquire characteristics for specific industrial application.

Unlike the EPO’s interpretation of Rule 23d(c), the majority view in Opinion No. 16 did not consider that “*embryo destruction*” was the determining moral consideration on patentability of HESC. At the same time, it has to be acknowledged that it is unclear why the EGE thought that “*closeness to the human body*” was a relevant moral consideration and where in European culture this particular norm is to be found.<sup>141</sup>

## 4.6 European Moral Norms on the Human Embryo<sup>142</sup> (according to the Directive)

This chapter analyses the range of European morality from which the relevant and appropriate moral norms should be interpreted in the light of the moral exclusion in Art 6 of the Directive. The ECJ has given MS a wide margin of discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public and morality under Art 6(1).<sup>143</sup> The wide moral exclusion norm raises the

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<sup>137</sup> EGE to the European Commission, Opinion 16, 7 May, 2002, available at: [http://europa.eu.int/comm/european\\_group\\_ethics/docs/avis16-en.pdf](http://europa.eu.int/comm/european_group_ethics/docs/avis16-en.pdf).

<sup>138</sup> Ibid § 1.3.

<sup>139</sup> Ibid § 2.3.

<sup>140</sup> Ibid § 2.3.

<sup>141</sup> Plomer A, p. 33, 2006.

<sup>142</sup> The Directive itself does not contain a legal definition of the term “*human embryo*”, neither is there a legal definition to be found in European or international law instruments. Legal definitions do exist in national laws but these definitions vary considerably. See Plomer A, p. 79, 2006.

<sup>143</sup> Case C-465/03 *Commission vs. Italy*, § 78.

question of how the applicable European moral norms on the protection of the human embryo are to be identified.

#### 4.6.1 ECJ

The ECJ has under a long period of time used *ordre public* and morality in their jurisdiction.<sup>144</sup> The concepts of *ordre public* and morality have a long and distinguished history as criteria for lawfulness of the grant or exercise of intellectual property rights. As reminded in AG Jacob's opinion in the Netherlands case, the concepts morality and *ordre public* (in English more often translated as public policy) are not foreign to Community law.<sup>145</sup> Morality justifications have been involved in the context of both Free Movement of Goods and Services, but discussing those cases, would bring this thesis to a too broad scope.

Conclusively, "*MS are, in principle free to determine the requirement of public policy and public security in the light of their national needs,*"<sup>146</sup> and that an area of discretion to be recognised for the national authorities.<sup>147</sup> However, the application by national authorities of *ordre public* and morality will always be subject to review by the ECJ, so MS do not have an unlimited discretion to determine their scope.<sup>148</sup> It may be added that the discretion of a MS to determine the scope of public morality in accordance with its own scale of values, so defined by the ECJ more than 20 years ago<sup>149</sup>, should perhaps now be read with some caution. In this area, as in many others, common standards evolve over the years.

#### 4.6.2 ECHR

The Directive indicates that the fundamental principles of human dignity and integrity have to be interpreted in accordance with the legal rights and obligations of MS arising from international treaties, most notably the European Convention on Human Rights (ECHR).<sup>150</sup> It has not yet been interpreted in the EU legal order, but the ECJ has started to consider ECtHR decisions in its most recent jurisdiction, and confirms that the ECHR's fundamental principles and rights "*has special significance*" and form an integral part of the general principles observed by the Court.<sup>151</sup> As the interpretation of the moral norms invoked in the Directive is presupposed to be compliant with the rights and obligations of MS guaranteed by the ECHR, the answer to the question of which uses of

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<sup>144</sup> Craig P, de Burca G, p. 626 ff. 2003.

<sup>145</sup> AG Jacob's Opinion, § 97, C-377/98, Netherlands vs. European Parliament and Council. (2002) ECR I-07079.

<sup>146</sup> Case C-54/99 *Eglise de scientology*, (2000), ECR I-1335, § 17

<sup>147</sup> Case C-41/74 *Van Duyn* § 18-19

<sup>148</sup> Case 30/77 *Bouchereau* (1999) ECR, § 35 of the judgement

<sup>149</sup> Case- 34/79 *Henn and Darby*, (1979) ECR 3795

<sup>150</sup> Recital 43 of the Directive

<sup>151</sup> Case C-36/02 (2004) *Omega Spielhallen und Automatenaufstellungs GmbH gegen Oberbürgermeisterin der Bundesstadt Bonn* ECR I-9609, § 33, The ECJ stated that the ECHR has special significance in the respect of general principles of law that the Court ensures.

human embryos are contrary to morality under the Directive has to be such, that the applicable moral norms comply with the fundamental values and moral norms reflected in European HR law.<sup>152</sup>

The ECtHR has consistently held that the scope of application of Art 2 ECHR,<sup>153</sup> guaranteeing the right to life, in the question of whether the human embryo has a right to life, comes with the “margin of appreciation” of each MSs.<sup>154</sup> The question of whether the human embryo in vitro has a right to life under Art 2 of the ECHR, has recently been considered specifically by the ECtHR in the case of *Evans v. UK*.<sup>155</sup>

The Court reasoned that:

“... in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law ... an embryo does not have independent rights or interests and cannot claim – or have claimed on its behalf – a right to life under Art 2.”

Conclusively, the level of legal protection granted to the human embryo, including the circumstances under which it is considered morally permissible to conduct research on human embryos resulting in the destruction of the embryo, varies across Europe, as do the limiting criteria on the stage of development or purposes for which the research is permitted.<sup>156</sup> Currently, thirteen MS in Europe allow for the procurement of HESC from supernumerary embryos by law under varying conditions<sup>157</sup> whilst four MS prohibit, by law, the procurement of HESC from supernumerary embryos.<sup>158</sup> Two MS prohibit the procurement of HESC from supernumerary embryos but allow by law the import and use of HESC under certain conditions.<sup>159</sup> Three MS<sup>160</sup> allow for the creation of human embryos for research purposes, by law, under strict conditions.<sup>161</sup>

### 4.6.3 Conclusion from the Construction of the Moral Exclusions

There is an obvious need for considerable caution and carefully qualified approach on the identification of European wide moral values on the sensitive questions relating to human embryo and its utilisation may be classified immoral under Art 6 of the Directive.

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<sup>152</sup> Plomer A, p. 53, 2006

<sup>153</sup> See Supplement A, for full text of Art 2 ECHR.

<sup>154</sup> Plomer A, *A Foetal Right to Life? The case Vo v. France*, Human Rights Law Review 2005 5(2):311-338.

<sup>155</sup> Case 6339/05, March 2006.

<sup>156</sup> Isasi R and Knoppers B, 2006, (all data have been updated by the authors).

<sup>157</sup> Belgium, Denmark, Estonia, Finland, France, Greece, Hungary, the Netherlands, Spain, Slovenia, Switzerland, Sweden and the UK.

<sup>158</sup> Austria, Ireland, Italy, Norway, Poland.

<sup>159</sup> Germany and France.

<sup>160</sup> Belgium, Sweden and the UK.

<sup>161</sup> Plomer A, p. 55, 2006.

### **Art 6(1)**

The application of the morality test to biotechnological inventions in Art 6 of the Directive requires the application of two distinct tests. On the one hand, Art 6(1) states a *general morality test*. On the other, Art 6(2) lists a series of *specific applications*, which are to be excluded on morality grounds. The ECJ has held that the interpretation of the general moral exclusion clause in Art 6(1) calls for different considerations from the interpretation of the specific exclusions listed in Art 6(2)(c).<sup>162</sup>

Regarding the interpretation of the general morality exclusion in Art 6(1), the ECJ has held that MS and national courts are to be granted a wide margin of discretion and scope of manoeuvre in the implementation and interpretation of the provision.<sup>163</sup> The ECJ considered this is necessary in order to:

*“...take account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each MS”*.<sup>164</sup>

In general, it follows from what has been said that, whilst some MS may justifiably rely on Art 6(1) to refuse a patent application for certain processes or cells derived from human embryos, it may be equally be permissible for other MS with different national cultures to grant the same application. Whilst the validity of each of these diverse national interpretations would ultimately be legally reviewable by the ECJ, it is clear that the ECJ will refrain from imposing a uniform moral standard where there is instead a diversity of national moral cultures.

### **Art 6(2)**

The position under Art 6(1) is altogether different to the construction of the specific lists of exclusions listed under Art 6(2). In this regard the ECJ emphasis that:

*“Art 6(2) allows the MS no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Art 6(1) ... It is apparent from the 40<sup>th</sup> Recital in the preamble to the Directive that processes for cloning human beings must be excluded “unequivocally” from patentability, since there is a consensus on this question within the Community. It follows that, by expressly excluding from patentability the processes and uses to which it refers, Art 6(2) of the Directive seeks to grant specific rights in this regard”*.<sup>165</sup>

The next chapter will analyse this scope.

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<sup>162</sup> Case C-377/98 Netherlands v. European Parliament and Council [2001] ECR I-0707.

<sup>163</sup> Ibid § 37

<sup>164</sup> Ibid § 38

<sup>165</sup> Case C-465/03 Commission v. Italy at § 78-79

## 4.7 European Moral Norms on the HESC (according to the Directive)

This chapter will start with examining whether the human embryo itself and totipotent HESC are excluded from patentability under Art 5.

Art 5 of the Directive states that:

“1. *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*  
2. *An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.*”

The natural reading of Art 5(1) is that patenting of human embryos is precluded, since a human embryo constitutes one of the stages in the formation and development of the human body.

It should be noted that the exclusion extends to in vitro embryos per se, irrespective of the purposes for which the embryo may have been originally created, or the particular national regulatory framework regulating the creation of in vitro embryos. Hence, the exclusion would extend not only to human embryos who were created in accordance with national laws permitting the creation of human embryos for research purposes but also extend to supernumerary embryos originally created for the purpose of assisting procreation through IVF.<sup>166</sup>

### 4.7.1 Totipotent Cells: Art 5(1)

Totipotent HESC are elements isolated from a human embryo by means of a technical process.<sup>167</sup> Therefore, the question of whether totipotent HESC are necessarily excluded by Art 5 is perhaps less clear, as in order for totipotent cells to be used for the derivation of therapeutic tissues or products, the cells have to be extracted from a human embryo at the blastocyst stage.<sup>168</sup> As noted by Webber, once extracted, totipotent HESC cannot strictly be said to be a “*stage*” of development of the human body, and if so, should prima facie be patentable under Art 5(2).<sup>169</sup>

Thus, for the scope of exclusion of Article 5(1) to extend to totipotent HESC, the text has to be read as presupposing that both the human embryo in vitro from which the cells are extracted, and the totipotent cells

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<sup>166</sup> Plomer A, p. 67, 2006

<sup>167</sup> Cooper G M, and Hausman R E, *The Cell*, p. 622 ff. 2004.

<sup>168</sup> Ibid.

<sup>169</sup> Webber, P.M, *Patentability of Human Embryonic Cells under the EPC*, Bioscience Law Review, 28 June 2005.

themselves, fall under the description “*human body*”. This would arguably not necessarily be the case if the words were given their natural meaning.<sup>170</sup> But since totipotent cells have the potential to develop into a human being if implanted, and the intention of the Community legislators was to proscribe the grant of related “*product*” and “*process*” patents on reproductive cloning, totipotent cells are excluded from patentability under Art 5(1) as subject matter of a patent.<sup>171</sup>

#### 4.7.2 Pluripotent Cells: Art 5(2)

It is an important finding that the above considerations do not extend to pluripotent HESCs, which lack the potential to develop into a human being. Hence, those elements isolated from the human body by means of technical process, fulfil the patentability requirements under Art 5(2). If such cells were to be excluded from patentability on the grounds that the derivation of pluripotent HESC cells necessarily involves an immoral use of the human embryo, its destruction, the exclusion would have to be based on the general morality provision in Art 6(1).<sup>172</sup>

Some particular indications are found in the Directives Recitals:<sup>173</sup>

##### **Recital 20**

*“Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is **not excluded from patentability**, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment.”*

##### **Recital 21**

*“Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the **result** of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.”*

It follows from these Recitals together with Art 5(2) that pluripotent HESC and the associated processes to derive or isolating the cells are prima facie patentable providing the invention fulfils the technical criteria of novelty, inventive step and industrial application. This leads to the conclusion that pluripotent HESC and processes to derive them could only be excluded from patentability if patenting would be contrary to ordre public or morality under Art 6(1).<sup>174</sup>

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<sup>170</sup> Plomer A, p. 68, 2006.

<sup>171</sup> Ibid.

<sup>172</sup> Ibid p. 69.

<sup>173</sup> Recital 17, 20 and 21 of the Directive.

<sup>174</sup> Plomer A, p. 70, 2006.



### 4.7.3 Cloning of Human Beings: Art 6(2)(a)

The process of human cloning is defined as:

*“Whereas a process for cloning human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as a another living or deceased human being...”<sup>175</sup>*

The related exclusions for processes involving the use of totipotent cells or human embryos is listed under Art 6(2)(a), which prohibits granting of patents on “*processes to clone human beings*”<sup>176</sup>, which must be excluded unequivocally from patentability since there is a consensus on this matter within the Community.<sup>177</sup>

The definition of cloning suggests that the exclusion is confined to processes of human reproductive cloning. Hence, it seems most likely that therapeutic cloning could be patentable since there is no European moral consensus on this matter.<sup>178</sup>

According to the ECJ, this limits the margin of discretion granted to MS in the implementation and interpretation of the specific exclusion. Unlike Art 6(1) of the Directive, which allows the administrative authorities and courts of the MS a wide discretion in applying the exclusion from patentability of inventions whose commercial exploitation would be contrary to ordre public and morality, Art 6(2) allows the MS no discretion with regard to the unpatentability of the processes and uses which it sets out, since the very purpose of this provision is to give definition to the exclusion laid down in Art 6(1)<sup>179</sup>

### 4.7.4 The Use of Human Embryos for Industrial or Commercial Purposes Art 6(2)(c)

Since the same interpretive approach applies to Art 6(2)(c), the uses of human embryos listed under this provision have also to be expressly transposed into the national laws of MS and excluded unequivocally, which means that diverging approaches have been adopted by the national patent offices. According to the UK Patent Office, Art 6(2)(c) excludes processes

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<sup>175</sup> Recital 41 of the Directive-

<sup>176</sup> Further affirmed in Recitals 40-41 of the Directive.

<sup>177</sup> Case C-465/03 Commission v. Italy § 78.

<sup>178</sup> Plomer A, p. 71, 2006.

<sup>179</sup> See, to this effect, Netherlands v Parliament and Council, § 37 to 39, See also Commission v. Italy § 79-82. In the Italy case, the ECJ ruled that Italy was in breach of its obligations under the Treaty in failing to take measures to implement the Directive because it had, inter alia, failed to expressly transpose into national law the specific list of exemptions listed under Article 6(2).

for obtaining HESC from embryos.<sup>180</sup> The Swedish Patent Office instead interprets the exclusion as referring to “*repetitive*” use of the embryo.<sup>181</sup> There is an important distinction between the EPO defined scope of exclusion of Art 6(2) through a moral exclusion norm,<sup>182</sup> and the national patent offices policy to interpret the scope of the exclusion in terms of the subject matter at stake.<sup>183</sup> In line with the reasoning of the ECJ in the Italy case,<sup>184</sup> the construction of Art 6(2)(c) should proceed on the basis that whilst the justification for the specific exclusion of “*industrial*”<sup>185</sup> or “*commercial*”<sup>186</sup> uses of the human embryo undoubtedly has a moral or ethical basis, the scope of the exemption itself is to be determined by reference to whether the excluded subject-matter of the invention falls under the terms of the description in the list. This in turn, requires an examination of the meaning or definition of the qualifying terms.<sup>187</sup>

A logical consequence of this approach is that the scope of exclusion of the listed invention is primarily defined by the terms “*industrial*” or “*commercial*” uses. Thus, inventions involving the use of human embryos which fall outside these qualifications cannot be excluded under 6(2)(c), although they may still be conceivably excluded under the general moral exclusion in Art 6(1). More specifically, it follows that “*uses*” of the embryo or processes to derive pluripotent HESC cannot be excluded from patentability under Art 6(2)(c), unless the uses or processes in questions involve direct, repetitive use of the human embryo as a raw material in a chemical, mechanical or technical process. To the extent that that the derivation of HESC from a human blastocyst involves direct or repetitive use of the human embryo as a raw material, it comes under the scope of exclusion of Art 6(2)(c). Both the interpretations of the UK and the Swedish patent offices are therefore consistent with this analysis.<sup>188</sup>

In the Common Position adopted by the Council, the latter stated that the exclusion from patentability of the use of human embryos only applied when such use was for industrial or commercial purposes. It can be seen from the Recital<sup>189</sup> of the Directive that it was the wish of the Council, as well as of the Parliament, that inventions for therapeutic or diagnostic

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<sup>180</sup> UK Patent Office, Practice Notice “*Inventions involving human embryonic stem cells*”, April 2003 at: <http://www.patent.gov.uk/patent/notices/practice/stemcells.htm>.

<sup>181</sup> Plomer A, p. 72, 2006.

<sup>182</sup> Decision of the OD of 21st July 2003 on European patent No. EP0695351 (University of Edinburgh).

<sup>183</sup> Plomer A, p. 72, 2006.

<sup>184</sup> Case 465/03, *commission v. Italy*.

<sup>185</sup> The term ‘*industrial*’ in patent law, has historically been used to refer to processes which involve repetitive mechanical, chemical or technical processing of raw materials. (See Plomer note 237, p. 74, 2006 for more information on definition).

<sup>186</sup> The term ‘*commercial*’ ordinarily refers to market transactions in which products are traded for money or profit. (See Plomer note 237, p. 74, 2006 for more information on definition).

<sup>187</sup> Plomer A, p. 73, 2006.

<sup>188</sup> *Ibid* p. 74, 2006.

<sup>189</sup> Mainly Recital 42.

purposes, which are applied to the human embryo and are useful to, should not be affected by this exclusion.<sup>190</sup>

### **4.7.5 Conclusion from the Moral Norms of the HESC**

Since the MS have no common definition of what constitutes a human embryo, and since there exists a wide scope of definitions in national laws, the derivation of pluripotent HESC can take place lawfully in a large number of countries in Europe, although the precise circumstances and purposes for which the research is permitted vary from country to country. Not only is there no evidence to suggest that it is contrary to European views on morality to derive pluripotent cells from human embryos, but as was argued earlier, the Preparatory Works on the Directive further confirm that the intention of the legislator was not to render unpatentable research on human embryos, which was at the time lawful in MS. It is therefore suggested that there is no legal basis for the exclusion of patents on human embryonic pluripotent stem cells or related process for their derivation under Article 6(1).

## **4.8 Moral Exclusions in the EPC System**

As it is well known, the EPO voluntarily transposed the wording of the provisions of the Directive into the EPC in form of amendments to the EPC Implementing Regulations.<sup>191</sup> The degree to which the EPO is bound by the general operating principles of EU law is unclear. A question which therefore arises in the EPO context is whether the EPO is also obliged to adopt the same construction of the exclusionary moral rules on human embryos and the patentability of HESC.<sup>192</sup>

### **4.8.1 Moral Exclusions in Patent Law Art 53(a)**

The morality exclusion in the EPC is found in Article 53(a), and stipulates that:

*“European patents shall not be granted in respect of 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.”*

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<sup>190</sup> OJ C110, 8.4.1998, p. 30, point 37.

<sup>191</sup> Decision of the Administrative Council of 16th June 1999, see Notice dated 1 July 1999 concerning the amendment of the implementing regulations of the European Patent Convention, O.J.E.P.O. 1999, 437, 573.

<sup>192</sup> Rule 23d (c) EPC.

The morality exception in Article 53(a) is based on Article 2(a) of the Strasbourg Convention,<sup>193</sup> which provided for the exclusion of inventions from patentability on the basis of ordre public and morality concerns. The purpose of Article 53(a) is to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour.<sup>194</sup> However, Article 53(a) only applies when the non-permissible use of the invention can be deduced from the very nature of the invention.<sup>195</sup> In other words, the approach is narrow.

The wording of Article 53(a) EPC probably inspired the drafters of the TRIPS Agreement, to which both the EU and its MS are contracting parties. According to TRIPS, “Morality” is “*the degree of conformity to moral principles (especially good)*”. The concept of morality is relative to the values prevailing in a society. Such values are not the same in different cultures and countries, and change over time.<sup>196</sup>

The next Chapters examines whether the transposition of the morality exclusions from the Directive into the EPC Implementing Regulations has achieved a degree of convergence on the question of whether HESC inventions are excluded from patentability under each system.

## 4.9 The Directive’s Moral Exclusions under the EPC

The EPC Regulation itself, states that the Directive is to be used as a supplementary means of interpretation.<sup>197</sup> The moral exclusions contained within the Directive’s Art 6(1) and 6(2) are transposed as Rule 23(d) EPC and states that:

*“Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:*

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

In the WARF case the TBA has held that the construction of the Directive’s list of moral exclusions, which have been transposed into the EPC rules, should proceed on the basis of the wording of the legislative text and the intentions of the legislators in drafting the specific exclusions.<sup>198</sup> In its

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<sup>193</sup> Many of the essential concepts of substantive patent law in the EPC were adopted from the Strasbourg Convention on the Unification of Certain Points of Substantive Law of 27th November 1963.

<sup>194</sup> Guidelines for Examination in the European Patent Office, Part C, Chapter IV, 3.1.

<sup>195</sup> Ibid.

<sup>196</sup> Plomer A, p. 95, 2006.

<sup>197</sup> Rule 23(b) of the Implementing Regulations of EPC.

<sup>198</sup> T 1374/04 (Wisconsin Alumni Research Foundation, WARF), at § 25 and 33.

earlier decision in G 1/98 concerning the patentability of genetically modified plants, the EBA arrived at its "narrow" construction of Art 53(b) EPC after having analysed the meaning of the terms used in their legislative context, in particular its historical background and the object and purpose of the provision.<sup>199</sup> In both cases, the TBA and EBA respectively have, arguably correctly, held that since the purpose of the exclusion in each instance is closely related to considerations pertaining to the specific subject matter, the substantive tests to be applied in each case vary depending on the specific nature and purpose of the exclusion.<sup>200</sup>

The EPO also has to consider the decisions of national courts.<sup>201</sup> As we have seen above the EPC MS's practice divert and it is therefore suggested that that in relation to the determination of the scope of the moral exemptions falling within the field of application of the Directive, the EPO's has to weigh appropriately the interpretation adopted by national patent offices, as reflecting the competence of national member states to interpret the Directive under EU law.<sup>202</sup>

There seem to be a convergence with the ECJ's approach on a dual test approach,<sup>203</sup> the general and specific, even though the TBA did not expand the reason behind such an approach.<sup>204</sup>

## 4.10 EPO Case Law

By contrast to national patent offices in Europe, the EPO has so far taken the view that Art 6(2)(c), which is transposed in the EPC rules as rule 23d(c), should be construed broadly as precluding not only patents on totipotent HESC, but also pluripotent and multipotent HESC related inventions. In the two detailed rulings that dealt with HESC-related inventions, the OD in the Edinburgh case and the Examining Division (ED) in the WARF case have both relied on the morality exemptions imported from the Directive to refuse grants on inventions involving HESCs. In both cases the EPO has taken a broad interpretation of Article 6(2)(c), or in the EPO context Rule 23d(c) EPC, to exclude not only patents detailing the process of extracting stem cells from a human blastocyst, and therefore

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<sup>199</sup> Ibid § 33.

<sup>200</sup> Ibid § 43-44.

<sup>201</sup> Art 31.3(b) of the Vienna Convention.

<sup>202</sup> Plomer A, p. 102, 2006.

<sup>203</sup> As concluded above.

<sup>204</sup> "...If a case falls within one of the four categories of exceptions set out in Rule 23d EPC... then it must ipso facto be denied a patent under Article 53(a) EPC. However, cases not falling within the limited exclusions of Rule 23d EPC... must then be considered under Article 53(a) EPC. There are thus in effect two quite different Article 53(a) EPC objections – on the one hand, a "Rule 23d-type" Article 53(a) objection which requires only that the is assessed as to whether or not it falls in one of the four limited categories set out in the Rule and, on the other hand, a "real" Article 53(a) objection which requires an assessment as to whether or not exploitation of the invention in question would be contrary to morality or ordre public." See: T 315/03, Headnote II and 10.1 Reasons for the Decision.

which directly entail a direct use of the human embryo, but also patents relying on already established HESC lines as their starting point.<sup>205</sup> Hereinafter, follows a summary of the relevant EPO case law.

#### 4.10.1 The Harvard Onco-mouse<sup>206</sup>

The first major case in which the morality objection arose for decision was the Harvard Onco-mouse, which is an invention that includes a method to introduce a gene-sequence into an embryo and has the ability to reproduce characteristics of various human cancers. The patent was granted in the US 1988, but it took more than a decade before it was proceeded in the EU. The admission from 1992 met great opposition and the process of the Directive complicated the legal situation.<sup>207</sup> The Regulation referred to was the 23(b)-23(e) of the Implementation Regulation, just like in the other cases below. The EPO used a rather useful approach when judging whether the Onco-mouse was a “*moral invention*” and found that the positive consequences outweighed the negative. The TBA ruled that the exception to patentability under Art. 53(b) of the EPC applied to certain categories of animals but not to animals as such. It noted that Art. 53(b), as an exception, must be narrowly construed.<sup>208</sup> Therefore, the invention was justified and a patent was accordingly granted.<sup>209</sup> The EPO decided that the benefit to cancer research outweighed the other factors and sustained the patent. Appeal were filed and the OD was not concluded until April 2006 by which time the TBA were able to take the specific provisions in the Directive into account and hold that the benefit to mankind outweighed the morality objection.<sup>210</sup> This method was also used in the case of *Upjohn’s hairless mouse*<sup>211</sup>, where an application was rejected on the grounds that the positive effects did not equal the suffering of the animal. This mode of argumentation has been questioned and there is an ongoing discussion about what qualifies a patent office to balance ethical problems in this way.<sup>212</sup>

#### 4.10.2 The Edinburgh University Patent<sup>213</sup>

This patent addresses the problem of separating the desired stem cells from other types of cells, which may overgrow and supplant the stem cells during subsequent culturing steps. It achieves this, by means of selective markers present in the cells or introduced into them for this purpose. The patent description lists a variety of stem cell sources for use in the method and defines the term “*animal cell*” very broadly, including “*human cells*”. By

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<sup>205</sup> Laurie G, *Patenting Stem Cells of Human Origin*, pp. 54 ff., 2004, E.I.P.R.

<sup>206</sup> Harvard Onco Mouse, T-19/90 1990, O.J. EPO 12/1990, 476 and 1992 O.J. EPO 110/1992, 588.

<sup>207</sup> EPO press release, [www.european-patentoffice.org/news/pressrel](http://www.european-patentoffice.org/news/pressrel).

<sup>208</sup> AG Jacobs Opinion C-377/98, § 38.

<sup>209</sup> EPO, Examination Division, Onco-mouse/Harvard, 3 April 1992, OJ EPO 1992, 568.

<sup>210</sup> Crespi, R S, p. 570, 2006.

<sup>211</sup> Patent application EP0868847 and US patent 6040495.

<sup>212</sup> Calvert, J. and Lynch, D. *Patentability and Morality*, Patent Proze November – December, 1998, available at [www.bsw.com/articles/proze15.html](http://www.bsw.com/articles/proze15.html).

<sup>213</sup> European Patent 0 695 31, granted to the University of Edinburgh on Dec 8, 1999.

oversight this latter term was retained in the description as accepted by the EPO although there was no specific mention of human cells in the granted claims. The EPO conceded the mistake in accepting the application thus written and the applicant later filed revised claims in which the cells were defined as “*other than embryonic stem cells*”. The patent is now under Opposition and the matter rest with the TBA.

The OD identified as crucial the question whether Rule 23d (c) of the Implementation Regulations, equivalent to Directive Art. 6(2) must be interpreted in a broad or narrow fashion. Where the narrow interpretation is whether the intention of the legislator is to ban the patenting uses of “*human embryos as such*” or the broad interpretation, which is to ban the patenting of uses of “*human embryos together with the cells being retrieved there from by destruction of the embryos, namely human ES cells*”. The conclusion was that only a broad interpretation of this rule can have been intended. Nevertheless, the matter is now under appeal on other issues and since reference to HESC has been removed from the patent, this issue is no longer of central importance to the outcome or the appeal and therefore, may nor require discussion by the TBA.<sup>214</sup>

The OD decided to list what kind of stem cells would fall within the amended and acceptable claims of this patent. This list includes pluripotent and multipotent stem cells isolated from adults or from umbilical cord blood. It is noteworthy that the list also includes pluripotent and multipotent cells “*which can be isolated from foetal tissues obtained after pregnancy termination*”.<sup>215</sup>

A former EPO Appeal Board member Claudio Germinario, has an opposite opinion to that of the OD.<sup>216</sup>

He begins by distinguish between totipotent stem cells and pluripotent stem cells. Addressing EPC Rule 23e(1) and its precursor Art 5(2) of the Directive, Germinario concludes that only totipotent cells are ruled out of patentability by these provisions, whereas pluripotent and multipotent stem cells would be permitted as “*elements isolated from the human body*”.<sup>217</sup>

Turning to Rule 23d(c), Germinario focuses on the function of the patent claims in defining the scope of protection. In so far as the patent claims omit any references to the embryo or any preceding step in which the embryo is actually used to provide the claim ended product, he would se such a claim as escaping the condemnation under this rule. “*The destruction of the embryo is immaterial to the issue insofar as the prohibited step<sup>218</sup> is not claimed.*”

In conclusion, Germinario considers the broad construction of 23d(c) given by the OD in the Edinburgh case to be out of conformity with several

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<sup>214</sup> Opposition Decision re EP 0 695 351, Edinburgh University. Not published in OJEPO.

<sup>215</sup> Ibid.

<sup>216</sup> Germinario, C. *The Values of Life*, 163 Patent World 16-18, 2004.

<sup>217</sup> Ibid.

<sup>218</sup> By prohibited step Germinario means, the prohibited stage of producing the first generation of freely disaggregated embryonic cells.

previous findings of the Appeal Boards that all exclusions from patentability must be interpreted narrowly.<sup>219</sup>

### 4.10.3 The WARF Case<sup>220</sup>

The main claim of the WARF case is as follows:

*“A cell culture comprising primate embryonic stem cells which (i) are capable of proliferation in vitro culture for over one year, (ii) maintain a karyotype in which all chromosomes normally characteristic of the primate species are present and are not noticeably altered through culture for over one year, (iii) maintain the potential to differentiate to derivatives of endoderm, mesoderm and ectoderm tissues throughout the culture, and (iv) are prevented from differentiating when cultured on a fibroblast feeder layer.”*

This claim is directed to a culture of cells having a list of desired characteristics. The claim is totally silent as to the derivation of the cells and there is no process claim to the methods used to achieve this. The application includes two method claims but these are directed to what is done with the cells as regards their culturing and subsequent differentiation.

This case again involves the debatable question of the scope of 23 d(c)<sup>221</sup> of the Implementation Regulations as first raised in the Edinburg case above. The Examination Division had insisted that the Rule 23 d(c) was not directly exclusively to the claimed subject matter and they were influenced by the fact that no other starting material than preimplantation embryos was indicated in the application for the production of the claimed product. Consequently, the application was refused. On appeal, the TBA referred the matter to the EBA of its own motion, after the appellant had already suggested that specific questions be put to the EBA to determine whether the rule could legitimately be applied to *“a product derived from human embryos”* or *“a product which can in any way be traced back to the use of a human embryo”*.<sup>222</sup>

The TBA identified the issue as follows:

*“The main issue in this respect involved a question of construction of a provision of the law, namely whether Rule 23d(c) EPC should be construed narrowly, thereby excluding from patentability only applications whose claims were directed to the use of human embryos, or broadly, thereby extending the exclusion to products whose isolation necessitated the direct and unavoidable use of human embryos.”*

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<sup>219</sup> The UK Patent Office adheres to this position.

<sup>220</sup> T 1374/04 (Wisconsin Alumni Research Foundation, WARF).

<sup>221</sup> Rule 23(d)(c) EPC which excludes uses of human embryos for industrial or commercial purposes from patent.

<sup>222</sup> Crespi, R S, p. 573, 2006.



It is clear from this statement, that the contested matter is purely one of construction of legal wording and carries no moral undertone in itself.<sup>223</sup> In the continuing case of *Oncomouse II*,<sup>224</sup> the TBA had found it necessary to analyse the function of Rule 23d in relation to Art 53(a) and they concluded that the morality provisions by which they now are bound encompass two distinct tests.<sup>225</sup>

In approaching this issue in the WARF case the appellant had insisted on the primacy of the patent claims in deciding what might be excluded by this rule. They had also referred to the legislative history as confirming that the term “*use of human embryos*” could only relate to “*procedures which used embryos directly as distinct from downstream products or processes.*” The appellant also challenged the conclusion in the Edinburgh case on the question of narrow or broad construction of the rule.<sup>226</sup>

The appellants had asserted that HESC “*could now be obtained readily without handling or disposition of an embryo*”. This was presumably to be achieved from cell lines<sup>227</sup> already established as distinct from those “*established de novo from an embryo*”.<sup>228</sup>

The TBA decided to refer the following questions to the EBA:<sup>229</sup>

– *Does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: HESC cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims?*

– *If the answer to the question above is no, does Article 53(a) EPC forbid patenting such claims?*

If Rule 23d(c) can be properly applied to the WARF case, the answer to the referred question 2 will presumably require examination of the legal history of the Directive to see whether it shows an intention that Art 6(2) is to be

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<sup>223</sup> Ibid.

<sup>224</sup> *Oncomouse II*, TBA 3.3.8. Decision T315/03, OJ EPO 1/2006, 15-82 see s.10.1 on p.51 for the dual test factor.

<sup>225</sup> Discussed earlier in this thesis, but to make it crystal clear: First a test based on the wording of the relevant individual subsection of the rule and secondly, a so-called “real” Art 53(a) test which must be applied if the invention under scrutiny survives the first test.

<sup>226</sup> Crespi R S, p. 573, 2006.

<sup>227</sup> This point is similar to the Germinario’s opinion on “the prohibited step”.

<sup>228</sup> Crespi R S, p. 573, 2006.

<sup>229</sup> The whole text of the referred questions: “(1) Does Rule 23d(c) EPC apply to an application filed before the entry into force of that rule? (2) If the answer to question 1 is yes, does Rule 23d(c) EPC forbid the patenting of claims directed to products (here: human embryonic stem cell cultures) which – as described in the application – at the filing date could be prepared exclusively by a method which necessarily involved the destruction of the human embryos from which the said products are derived, if the said method is not part of the claims? (3) If the answer to question 1 or 2 is no, does Article 53(a) EPC forbid patenting such claims? (4) In the context of questions 2 and 3, is it of relevance that after the filing date the same products could be obtained without having to recur to a method necessarily involving the destruction of human embryos (here: e.g. derivation from available human embryonic cell lines)?”.

applied either to 1) *only the claims of the application in question or 2) to the invention as a whole, in the light of the supporting description.*<sup>230</sup>

If the EBA choose to go on the narrow construction of the Rule it will then be necessary to answer question 3 under the general scope of EPC Art 53(a).

As we stated earlier in this thesis, the history of the Directive is complex and its interpretation differs in each MS. Unless it is possible to obtain guidance from any authoritative source of information on the matters in question, one is left only with the Directive itself.

Practical examples or commercial uses of whole embryos are not easy to envisage. The reservation in Recital 42, in relation to therapeutic or diagnostic uses, which benefits the embryo, is perhaps the basis for the emphasis on the relevance of harm to or destruction of the embryo which has emerged in the WARF case. The inevitable destruction of embryos does not figure as an explicit foundation for this exclusion in any of the readily accessible public documents, although it cannot be summarily dismissed as irrelevant to the point. In March 2000, the European Parliament issued a resolution on the granting of the Edinburgh patent, which confirms the Parliaments previously declared position which include *“the refusal of research on human embryos which destroys the embryo”*.<sup>231</sup> However, the question whether this is relevant or not remains to be seen.

In conclusion, as Crespi states it: *“It could be reasonably argued that the use of embryos as source material for the isolation of stem cells for potential therapeutic value is a topic on which a high degree of moral uncertainty and division prevails in the public mind. In these circumstances, the answer might be that the matter is so controversial as to be impossible to resolve under this provision of European patent law.”*<sup>232</sup>

#### 4.10.4 Conclusions from the Edinburgh and WARF Cases

*“On the one hand the **“human embryo destruction”** test is undoubtedly a **“real”** moral test, and as such logically falls primarily to be applied under Art 53(a). On the other hand, to the extent that moral considerations may still conceivably play a **“background”** role in helping clarify the scope of exclusion of specific provisions, such as Rule 23d(c), the relevant moral principle(s) to be applied here cannot be the principle of **“embryo destruction,”** since there is no moral consensus in Europe precluding uses of human embryos which necessarily involve what can be called **“embryo destruction”**”*<sup>233</sup>

The OD decisions in both the Edinburgh case and the pending WARF case rely on the moral principle of *“embryo destruction”*. But instead, as argued above, the moral purpose of the provisions is to preclude the

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<sup>230</sup> Crespi R S, p. 574, 2006.

<sup>231</sup> Common Position EC No.19/98 of the European Parliament and the Council of the EU (1998) O.J. C110/17-34.

<sup>232</sup> Crespi R S, p. 574, 2006.

<sup>233</sup> Plomer A, p. 104, 2006.

instrumentalisation of the human embryo through direct use of the embryo as a raw material in a repetitive (technical) process or alternatively, embryo commodification through trade of human embryos involving monetary exchanges.<sup>234</sup> Further, in the Edinburgh case the OD held that Rule 23d(c) had to be interpreted broadly,<sup>235</sup> since the narrow interpretation would render Rule 23e(1)<sup>236</sup> redundant. However, the purpose behind the insertion of these two provisions is distinct. Whilst Rule 23e(1) was intended to preclude patents on human embryos and totipotent cells per se, the aim of Rule 23d(c), as expressly stated in the Common Position,<sup>237</sup> was to preclude only certain uses of human embryos.

Above, we have seen the TBA's referral in the WARF case, and it is suggested that the two test methodology<sup>238</sup> will be used. Whereby patent examiners have to consider in the first instance whether the application falls under the list of specific exemptions, and in the event it does not, then consider whether patenting is precluded under general moral test in Art 53(a).<sup>239</sup>

Thus, the purpose of the EU legislator was not to insert prohibitions with a view to strictly reflecting patent law categories of "*product or process*" claims,<sup>240</sup> instead the aim was to "*define the essence*" of the inventions which it had been agreed, should not be morally patentable.<sup>241</sup> In the light of the analyses in the first part of this thesis, which discussed the scope of Art 6(2)(c) based on the Directive's text and legislative intent, it is suggested that Rule 23d(c) should be interpreted the same way with the same methodology.<sup>242</sup>

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<sup>234</sup> Ibid.

<sup>235</sup> "not only the industrial or commercial use of human embryos but cells retrieved there from by destruction of human embryos."

<sup>236</sup> Rule 23e: "The human body and its elements:(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions...."

<sup>237</sup> Common Position (EC) No. 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/44/EC.

<sup>238</sup> The relationship between the two tests is explained in the following way: "As regards cases such as the present which fall within Rule 23d(d) EPC, the effect of this interpretation is to insert a test which, depending on the facts and thus on the outcome of the test, may be either additional or alternative to that previously established by the case law.", T315/03 at § 7.7.

<sup>239</sup> Plomer A, p. 106, 2006.

<sup>240</sup> WARF case § 42.

<sup>241</sup> WARF case § 46.

<sup>242</sup> T 1374/04 (Wisconsin Alumni Research Foundation, WARF), referral by the TBA to the EBA, case pending under Ref. No. G 2/06, see O.J.E.P.O. 2006, p. 393.

## 4.11 National Case Law

### 4.11.1 Greenpeace vs. Oliver Brüstle <sup>243</sup>

On December the fifth, 2006 the Federal patent Court in Germany, decided to uphold the German patent<sup>244</sup> in amend form a patent containing claims directed to neural precursor cells derived from ES cells and methods for producing the neural precursor cells. The patent was subject to the limitation because cells are excluded which are derived from ES cells prepared from *human embryos*. Cells derived from HESC prepared from other sources such as human oocytes, or human embryonic germ cells were, however, found to be patentable.<sup>245</sup> The claims did not mention the use of embryos for producing the ES cells. The patent was granted on April 29, 1999.

Greenpeace filed a nullity action before the German Federal Patent Court for partial revocation of the German patent insofar as the claims comprised neural precursor cells derived from HESC. The nullity action was exclusively based on the ground that the subject matter claimed would not comply with the morality requirement of Section 2 (2) No. 1 in combination with Section 2 (2) No. 3 German Patent Act. Insofar as it related to neural precursor cells derived from HESC, Greenpeace alleged that the practice of the invention would inevitably require destruction of human embryos, the latter being considered to be immoral.

According to the patent specification, the ES cells include HESC. It further defines several possibilities for obtaining the ES cells useful in the invention, e.g. the ES cells could be obtained from oocytes after transplantation of the cell nucleus, from EG, or from embryos. Alternatively, established ES cell lines could be used. Thus, the preparation of HESC did not inevitably require the destruction of human embryos since according to the patent specification alternative sources for HESC did exist. The Federal Patent Court decided to uphold the German patent in a limited form which cells were excluded which are derived from ES cells prepared from human embryos. This could be interpreted as also excluding HESC lines prepared from human embryos.<sup>246</sup>

The amended patent still encompasses cells derived from HESC, which are not prepared from human embryos, but from different sources such as from human oocytes after nucleus transplantation or from human EG cells. It is interesting to note that the above mentioned method of nucleus transplantation into oocytes is widely known as the method by which the first cloned sheep Dolly was generated.

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<sup>243</sup> 3 Ni 42/04 Greenpeace vs. Oliver Brüstle

<sup>244</sup> DE 1975864 C1

<sup>245</sup> Dr Thomas Friede reported in The Bardehle Pagenberg Dost Altenburg Geissler IP Report, p. 3, 2006/VI available at [www.bardehle.com](http://www.bardehle.com) (2007-09-10)

<sup>246</sup> It is interesting to note that the Federal Patent Court in its decision retroactively applied the exemption clauses in the German Patent Act, which only entered into force on February 28, 2005 while the patent was filed in 1997 and granted in 1999.

In summary, the exemption from patentability is limited to where the generation of ES cells involves a *human embryo*. Cells derived from HESC generated by other methods are not excluded from patentability. The first decision of the Federal Patent Court is subject to appeal to the Federal Supreme Court.

## 4.12 Conclusion Europe

We have now seen part of the case law and how the EPO voluntarily has interpreted other European legislation norms. The conclusion from this case law suggests that there is some uncertainty as to the nature of the evidence that the EPO considers adequate to identify the relevant applicable European moral standards under existing EPC rules. Be that as it may, it is suggested that as regards the relevant standards to be applied under the provisions imported from the Directive, the EPO is obliged under its own rules to apply moral standards which are in conformity with the fundamental principles of the EU Treaty, the ECHR and the constitutional traditions of MS.

The Directive draws a clear distinction between the unpatentability of the human body in its natural state as against elements isolated from the human body, which constitutes a patentable invention. It can be argued that the stem cell in its isolated state is in a complete different state than their origin, and therefore should be patentable under the Directive. Hence, pluripotent stem cells and the derivation of pluripotent stem cells should be patentable unless falling under the terms of the exception.

Therefore, the argumentation which follows from Germinario's opinion, where he underlines the distinction of pluripotent and totipotent stem cells, should be followed. Only the totipotent cells are ruled out of the patentability by the provisions, while the pluripotent cells should be permitted as elements isolated from the human body, no matter their origin, since there is no uniform European definition of the term "*human embryo*" and the destruction of the human embryo is immaterial to the issues at stake. Since there nowadays are methods, which do not necessarily destroy the embryo when deriving stem cells, and other ways of producing fully good stem cells.

## 5 US - Part II

### 5.1 The Current Legal Environment in the US and its System

Unlike in the EU, there does not appear to be an institution in the US willing and able to expressly consider policy concerns related to biotechnology.<sup>247</sup> After *Diamond v. Chakrabarty*,<sup>248</sup> most biotechnology patent issues have been resolved by the Court of Appeals for the Federal Circuit,<sup>249</sup> but the Federal Circuit has claimed to be largely uninterested in policy concerns in general.<sup>250</sup> While the US Patent and Trademark Office (USPTO) has incorporated policy considerations into its guidelines, the rules receive no deference from the courts because the USPTO has no substantive rulemaking authority.<sup>251</sup> There is also a concern that the USPTO lacks the expertise to make these policy determinations.<sup>252</sup>

Nevertheless, while the US asserts it does not treat biotechnology inventions differently from other inventions, there may in fact be technology specific standards.<sup>253</sup> For example, biotechnology appears to have a lowered standard for non-obviousness and a heightened written description requirement when compared with other technologies. Thus, a different application of the same patentability standards may result in special treatment for biotechnological inventions, as is found in Europe.<sup>254</sup>

The patentable subject matter has been interpreted broadly by the courts in biotechnology cases. In *Diamond v. Chakrabarty* the Supreme Court ruled that patentable subject matter included “*anything under the sun made by man*”. Congress' intent is not to place any restrictions on the subject matter for which a patent may be obtained.<sup>255</sup> The courts have even recently held

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<sup>247</sup> Rai, A. K., *Engaging Facts and Policy: A Multi-Institutional Approach to Patent System Reform*, 103 COLUM. L. REV. 1035, 1072 (2003), p. 1040-1041.

<sup>248</sup> 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980). This distinction between modified and natural products found further expression in the seminal 1980 decision, *Diamond v. Chakrabarty*. There the Supreme Court held that a live, man-made microorganism was patentable, a decision that “opened the door to patenting the organisms, molecules, and research techniques emerging from biotechnology”.

<sup>249</sup> Gifford, D J, *Government Policy Towards Innovation in the United States, Canada, and the European Union as Manifested in Patent, Copyright, and Competition Laws*, 57 SMU L. REV. 1339, 1340, 1358 (2004) and Rai A K, p. 1037-1038, 2003.

<sup>250</sup> Jameson S. A. p. 201, 2007.

<sup>251</sup> Rai A. K., p. 1031-1032, 2003.

<sup>252</sup> Ibid.

<sup>253</sup> Aerts, R. J., *The Industrial Applicability and Utility Requirements for the Patenting of Genomic Inventions: A Comparison Between European and U.S. Law*, 26 EUR. INTELL. PROP. REV. 349, 350 (2004).

<sup>254</sup> Jameson S. A. p. 199, 2007.

<sup>255</sup> *State St. Bank & Trust v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373, Fed. Cir. 1998. The Federal Circuit cited the passage of *Chakrabarty* in *State Street*. The patent in question in *State Street* was drawn to a business method, which, it was asserted, was not statutory subject matter under 35 U.S.C. § 101. The court ruled that the use of the word

that patentable subject matter should be broadly construed. Thus, absent the continuing existence of a strong Moral Utility Doctrine, humans and human embryos should be patentable subject matter, insofar as they are made by man and are novel.

## 5.2 What has Morality Got to Do with It?

Inventors may obtain patents on stem cells, transgenic animals, methods of cloning mammals, and more. However, quite a few of the biotech inventions that are eligible for patent protection are morally<sup>256</sup> controversial. But moral norms are not static. Societal views about what is right and what is wrong change all the time, for a variety of reasons.<sup>257</sup>

How do patents on morally controversial biotech subject matter issue? There are certain statutory requirements for patentability. The invention must fall within one of the specified subject matter categories: machine, composition of matter, manufactured process; it must be useful; it must be novel and non-obvious; and it must be properly described. But those requirements do not say anything about the invention being moral. Compared to the countries in the EU and Japan where they have statutory bars to the issuance of morally offensive patents,<sup>258</sup> there is no statutory morality requirement in US patent law.<sup>259</sup> Moreover, the statute says that “*a person shall be entitled to a patent unless*” he or she does not meet one of the specified requirements.<sup>260</sup> Therefore, you are entitled to a patent if the examiner cannot find a statutory basis for denying it. As started in *Diamond v. Chakrabarty*,<sup>261</sup> the Supreme Court concluded that Congress intended patent subject matter to “*include anything under the sun that is made by man.*” It does not matter whether the invention is living or non-living, moral or immoral.<sup>262</sup>

### 5.2.1 Moral Utility Doctrine.

Interestingly, there was previously a morality requirement in US patent law. The Moral Utility Doctrine was first mentioned in *Lowell v. Lewis*,<sup>263</sup> stating that inventions that are, “*injurious to the well-being, good policy, or sound morals of society*” are unpatentable. Moreover, they defined the term “*useful*” as the antonym of “*mischievous or immoral.*” Under this judgement an invention that was immoral would not be considered to be useful, and that reasoning was used to deny patents on gambling machines and

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“*any*” in 35 U.S.C. § 101 shows Congress' intent not to place any restrictions on the subject matter for which a patent may be obtained.

<sup>256</sup> Webster's Dictionary: “*The rightness, or wrongness of an action.*”

<sup>257</sup> Bagley, M. A. p. 502, 2004-2005.

<sup>258</sup> Eg Art 53 (a) EPC (as discussed above).

<sup>259</sup> Margo A. Bagley, p. 505, 2004-2005.

<sup>260</sup> 35 U.S.C. § 102 (2004).

<sup>261</sup> 447 U.S. 303 (1980).

<sup>262</sup> Bagley, M. A. p. 506, 2004-2005.

<sup>263</sup> *Lowell v. Lewis*, 15 F. Cas. 1018 (C.C.D.Mass. 1817).

deceptive or fraudulent devices.<sup>264</sup> However, this doctrine has not been used as broadly recently.<sup>265</sup> Over time, though, courts became uncomfortable making those kinds of ad hoc determinations without statutory authority. Ultimately, the rule developed that if an invention had at least one useful purpose, it was eligible for patent protection.<sup>266</sup>

The moral utility doctrine has never been applied to biotechnology cases. The Supreme Court's *Diamond v. Chakrabarty* decision, however, leaves no room for reading a morality requirement into the existing patent statute. The Supreme Court held that bacteria changed by scientists to be more efficient at digesting oil were patentable, despite the fact that organisms were not specifically defined as patentable subject matter by the utility statute.<sup>267</sup> The moral utility doctrine is not mentioned, despite the fact that the invention at issue was controversial at the time. The only issue in *Chakrabarty* was whether Congress intended 35 U.S.C. § 101,<sup>268</sup> the statute which defines patentable subject matter, to cover genetically modified organisms. The court suggested in *Chakrabarty* that moral questions about biotechnology inventions should be left for Congress to decide.<sup>269</sup> The Court noted that since Congress had spoken, it was “*without competence*” to consider moral questions in determining the scope of patent eligible subject matter.<sup>270</sup> It concluded that determining what Congress meant by the statute is the province of the courts, nothing more. Likewise, in a later decision, the Court of Appeals for the Federal Circuit also pointed out that the interpretation of the patent statute is not a matter of discretion for the USPTO.<sup>271</sup>

It seems that the moral utility doctrine has disappeared from patent law in the US. However, it may still be good law in certain extreme situations. The doctrine would not prevent the patenting of humans or human embryos on its own if they were held to have some legitimate use.<sup>272</sup> Insofar as cloned humans or human embryos have some legitimate utility, they would not be subject to the moral utility doctrine.<sup>273</sup>

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<sup>264</sup> *Brewer v. Lichtenstein*, 278 F. 512 (7th Cir. 1922) (patent invalid because only utility of machine patented is to appeal to gambling instinct of customers); *Nat'l Automatic Device Co. v. Lloyd*, 40 F. 89 (C.C. Ill. 1889), (patent invalid because horse race machine can only be used for gambling).

<sup>265</sup> *Fuller v. Berger*, 120 F. 274 (7<sup>th</sup> Cir. 1903). At 276. For example, on appeal, the court reasoned that a Colt's revolver is an instrument of death, but would still allow a patent on it, if it were shown to the court that, “*the instrument were susceptible to good uses*”

<sup>266</sup> *Ibid.*

<sup>267</sup> *Juicy Whip, Inc.*, 185 F.3d at 318.

<sup>268</sup> “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>269</sup> Coughlin, S. M. p. 7, 2006.

<sup>270</sup> *Diamond vs. Chakrabarty*, 447 U.S. at 317.

<sup>271</sup> *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 930 (Fed. Cir. 1991).

<sup>272</sup> E.g. the Colt revolver, had moral utility because it could be used in self defense, not merely as a tool of destruction.

<sup>273</sup> Coughlin, S. M p.7, 2006. Since the Examiner rejected the utilities asserted by Newman, it would have been consistent to use the moral utility doctrine, although still unnecessary and controversial.



## 5.3 Where Do We Draw the Line and Who Decides Where to Draw it?

Who is deciding if morally controversial biotech subject matter gets patented? Many of the arguments surrounding controversial biotech subject matter converge on fundamental questions such as “*when does human life begin*” and “*what does it mean to be human*”. Patent applicants are no better equipped to make that determination than the average person,<sup>274</sup> and yet they are the ones making these high policy decisions by virtue of the content of the applications they file with the USPTO.<sup>275</sup>

It is necessary to look at what should be patented, and who should be making the decision. The authority and institutional competence in this area lies with Congress. The Constitution authorises Congress to create a patent system in the first place. Unlike scientists or the courts, Congress is accountable to the public, it holds hearings and takes testimony on relevant topics. Of course, this is a politically sensitive subject. It is very difficult for Congress to grapple with questions such as “*what is human*” on which society itself is deeply divided. Nevertheless, in the current system, Congressional failure to act is an action in and of itself.<sup>276</sup>

### 5.3.1 Intent of Congress

The Constitution authorizes Congress 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.*” This provision is a grant of authority to Congress to create a patent system and Congress chose to utilise it.<sup>277</sup> The USPTO interprets the law in light of the intent of Congress, despite the difficulty in ascertaining this intent.<sup>278</sup> The USPTO had stated in 1987 that they had no intention of patenting humans.

The Congress amended the patent statutes many times between 2003 and 1987. If they wanted to allow patents to humans, they could have specifically made amendments to the laws that would allow them. Further, the subject matter is contentious, and the USPTO did not want to step into the shoes of the Congress in making such an important decision.<sup>279</sup>

Even the USPTO, in answering a public question about whether DNA should be patent-eligible admitted that: “*Congress creates the law and the federal judiciary interprets the law. The USPTO must administer the laws*

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<sup>274</sup> As noted earlier, the patent statute says that a person entitled to a patent, unless he or she fails to meet the statutory requirements.

<sup>275</sup> Bagley, M A. p. 507, 2004-2005.

<sup>276</sup> Ibid.

<sup>277</sup> U.S. Const. art. I, § 7, cl. 8.

<sup>278</sup> See 35 U.S.C. § 131 (2000) (responsibility of USPTO to decide whether an applicant is entitled to a patent under law) and *FDA v. Brown & Williamson Tobacco Corp.*, 120 S.Ct. 1291 (2000) (when Congress does not specifically address a question of statutory interpretation the statutory provision should be interpreted with a view to its place in the overall statutory scheme).

<sup>279</sup> Bagley M A. p. 507, 2004-2005.

*as Congress has enacted them and as the federal courts have interpreted them. Current law provides that when the statutory patentability requirements are met, there is no basis to deny patent applications. . . .*<sup>280</sup>

Despite these clear pronouncements, and without statutory authority, the USPTO has also stated that it will not grant patents on humans. Unfortunately, that position statement has caused some to believe that the agency has the authority to deny such patents, when, as a statutory matter, it does not. Arguably, Congress had declared its intent regarding patent protection on claims drawn specifically to humans by never passing legislation undoing Supreme Court decisions regarding reproductive privacy.<sup>281</sup>

There are several approaches that Congress could take in addressing patents on morally controversial biotech subject matter. Obviously, it could continue with the existing system, consciously understanding that there are no limits, and that applicants are ever expanding the range of morally controversial patented biotech subject matter.<sup>282</sup> Or, it could come up with a general morality provision, similar, perhaps, to EPC Article 53(a), but would it be helpful, since the EPO itself does not have much success with that provision.<sup>283</sup> Alternatively, it could add specific prohibitions or it could take an intermediate approach, which is probably the most viable option. Another option would be to have a pre- or post-grant opposition period at the USPTO for people to oppose patents on some morality-related basis. There are many approaches that Congress could adopt if lawmakers gain the political will to adequately address this issue.<sup>284</sup>

Conclusively, patents on some categories of morally controversial biotech subject matter are here to stay. It is very hard for Congress to retrench and remove subject matter from patent eligibility after patents covering such subject matter have issued. There is most likely no going back in the area of

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<sup>280</sup> Utility Examination Guidelines, 66 Fed. Reg. 1092, 1095 (Jan. 5, 2001).

<sup>281</sup> *Griswold v. Connecticut*, 381 U.S. 479 (1965).

The birth of a patented near human could potentially be an act of patent infringement (35 U.S.C. § 271(a) 2000), but the enforcement of this infringement could interfere with the mother's right to privacy. (*Roe v. Wade*, 410 U.S. 113, 114, 1973). If a mother has a right to privacy in terminating her pregnancy, she would seem to have a right to privacy if she chose to have the baby despite potential patent infringement. Also, the 13th Amendment forbidding slavery would conflict with patent rights on a human. A patented human being would not be able to gain employment, because such an employment would be an infringing use. (35 U.S.C. § 271(a) and R. Weiss, *U.S. Denies Patent for a Too-Human Hybrid*, WASHINGTON POST, Feb. 13, 2005, at A3.) Employment may be considered a use of the patented invention (the organism) by the organism itself in employment. Prevention of a person from working, except for the patentee, would amount to slavery or involuntary servitude forbidden by the 13<sup>th</sup> Amendment of the Constitution.

<sup>282</sup> It would be great if Congress still had an Office of Technology Assessment to advise it, a body that could actually study these issues, bringing in people on different sides of the debate, to help Congress make informed decisions about whether there should be morality-based limits and if so, what those limits should be. Intermediate approaches, developed after study and analysis, could include having the USPTO flag patents for review and assessment by a special board.

<sup>283</sup> Bagley, M A. p. 507, 2004-2005.

<sup>284</sup> *Ibid.*

stem cell patents or transgenic animal patents. Hence, the patent eligibility of other subject matter, such as humans, is still in flux.

Until Congress takes the necessary action to figure out what is human, to decide what societal values to promote, and to delineate what types of inventions should be eligible to receive the Government's patent imprimatur, the categories of morally controversial biotech subject matter on which patents have issued will continue to grow. Such “*high policy*”<sup>285</sup> decisions should not be delegated to the USPTO. It would be unrealistic, impractical, and ultimately inefficient to expect examiners to resolve these issues on an ad hoc basis. Ultimately, where we go from here is a question for Congress. They must clarify the limits of patent-eligible subject matter, and the extent to which moral issues should be considered in patenting decisions, or there will be no limits.<sup>286</sup>

## 5.4 The Newman Application and the Non-Patentability of Humans<sup>287</sup>

Inventor Stuart Newman filed an application drawn to human/animal chimeric organisms, embryos and methods of making and using the same. This application was not necessarily filed to acquire a patent on this invention,<sup>288</sup> but to serve as a *de facto* petition to the USPTO to clarify the Office's stance on the patentability of this and similar controversial inventions.<sup>289</sup>

The USPTO, while refusing to give Newman an advisory opinion, and despite having plenty of other more mundane reasons to reject the Newman application, accommodated him by rejecting his claims for not being drawn to a statutorily permitted subject matter, *i.e.* stating that claims “*embracing*” humans and human embryos are not patentable.<sup>290</sup>

The primary basis of this rejection was an interpretation of Congress' intent regarding patenting humans,<sup>291</sup> which was later confirmed by the addition of a provision to the Consolidated Appropriations Act of 2004, forbidding the patenting of “*human organisms*”.<sup>292</sup>

There is no need to specifically prevent the patenting of a human being or a human embryo. First, human beings and embryos are unpatentable subject

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<sup>285</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

<sup>286</sup> Bagley M. A. p. 509, 2004-2005.

<sup>287</sup> U.S. Application Serial No. 08/993,564 (filed on December 18, 1997) 08/993,564, and divisional application U.S. Application Serial No. 10/308,135 (filed on December 3, 2002). The specifications are substantively identical.

<sup>288</sup> It seems that Newman does not have a patentable invention at all. He provides the idea of using techniques already know in the art, to create human chimeric clones, but never bothers to iron out the technical details crucial for making cloning in a new species functional. This is because his reasons for filing are not to put forth or protect an “*invention*”, but to put the USPTO on the spot, to decide whether this sort of invention would be patentable or not. See Coughlin, S. M. p. 1, 2006.

<sup>289</sup> *Ibid.*

<sup>290</sup> The claims were rejected for anticipation, obviousness, lack of enablement, written description and utility. *See generally* the File History of U.S.S.N. 08/993, 564.

<sup>291</sup> *Ibid.*

<sup>292</sup> *Ibid.*

matter in any case because they are not novel or made by man, as required for patentability. Second, there is currently no commercial reason to patent a genetically modified near-human. If a reason develops, laws should be enacted to deal with the specific organism created in response to that reason. Third, preventing patent coverage of humans, without even a precise definition of what a “human” entails in the patent law, does not prevent people from making and patenting ethically questionable inventions in this area and chills invention in areas that may be considered drawn to “humans” including those that are not ethically questionable.<sup>293</sup>

Advanced Cell Technology has obtained a patent on a technique for creating cloned embryos produced from human cell nuclei and cow eggs. Further, Geron Corporation, which held licenses for patents to embryonic stem cells, acquired the Scottish company that cloned Dolly the sheep. Newman worries<sup>294</sup> that these companies and others have set the ground work for human cloning to begin without any guidelines on what lines the researchers could not cross. Human cloning in the US is currently legal. At the time Newman was writing his article, outlawing human cloning, was before the Senate.<sup>295</sup> However, this bill has never passed.<sup>296</sup> Thus, the invention claimed in Newman's application would have been legal to make, use and sell if a patent had issued.

All decisions made by the USPTO apply only to the specific facts of the patent application for which the decisions were made. Despite its ability to reject Newman's application, the USPTO ultimately gave an opinion, since there was no reason that the USPTO had to reach any decision on whether his claims were unpatentable because they “embraced a human”. However, the USPTO responded to Newman's provocation and gave him what he wanted by rejecting his claims for “embracing a human”.<sup>297</sup>

By doing so, the USPTO invented an ambiguous and unwieldy new patentable subject matter rule out of whole cloth. The Examiner stated during the prosecution of Newman's application that despite the ruling in Chakrabarty, “For more than 10 years, the USPTO has consistently taken the position that a claim drafted to or including within its scope a human being is not considered patentable subject matter under 35 U.S.C. § 101.” While the Court only seemed to exclude laws of nature, abstract ideas and physical phenomena in Chakrabarty, the Examiner stated that the USPTO must judge the patentability in light of the intentions of Congress. Based on Congressional silence in light of the publicly known policy of the USPTO, Congress did not intend to permit the patenting of humans.<sup>298</sup>

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<sup>293</sup> Coughlin, S. M. p. 1, 2006.

<sup>294</sup> Newman's primary worry about human cloning is that, once breakthroughs were made using the cloning technology he described in his application, “production of quasi-humans for research or therapy ... cannot be too far behind.”

<sup>295</sup> R. Weiss, *U Firm Aims To Clone Embryos for Stem Cells*, WASHINGTON POST, July 11, 2001, at A1.

<sup>296</sup> Petersen, S E. *A Comprehensive National Policy to Stop Human Cloning: An Analysis of the Human*, 17 Notre Dame J.L. Ethics & Pub. Pol'y 217, 223 (2003).

<sup>297</sup> Coughlin, S. M. p. 4, 2006.

<sup>298</sup> See e.g., file history of U.S.S.N. 08/993,564 at Office Action mailed on August 2, 2004 at 10-11.

## 5.4.1 The Politics of Human Patenting and the Consequences of the Rejection of the Newman's Claim

In the case of Newman's application, there was clearly no need to invoke a ban on human patents. If the USPTO wanted to avoid the question altogether, it easily could have. It is difficult to say why it did not. Easy or not, Newman did make a point using the USPTO. After his most recent Office Action, rejecting his claims, and after the passage of the Consolidated Appropriations Act of 2004,<sup>299</sup> Newman declined to continue prosecution. Newman did get an Examiner to state that claims that, “*embrace a human*”<sup>300</sup> are unpatentable, but it is unclear what this really means.<sup>301</sup> Humans remain unpatentable, but the question remains of what constitutes a human? Clearly, the broad scope of Newman's claims encompassed a human.<sup>302</sup>

In light of Congress' passing of the Consolidated Appropriations Act of 2004,<sup>303</sup> Congressional intent seems obvious now, but at the time of Newman's application it was difficult to say for sure what Congress' intent was from its previous lack of legislation in this area. However, the intent of Congress was what the USPTO relied on primarily to reject humans and human embryos as patentable subject matter in Newman's application.<sup>304</sup>

In a sense, by putting the patentability of claims in terms of a confusing definition, like “*human*”, the USPTO and Congress have made it even less clear what is patentable and what is not. By using it here, the USPTO has created some small amount of precedent that it will not allow claims embracing humans, but has made absolutely no statement as to the limits of that embrace.<sup>305</sup> Ultimately, the USPTO ruling in the Newman case and the subsequent legislation pushes back any real decision on the question of patentable subject matter. The codification of the rule of no patenting of humans simply puts forth the question of what is a human, and how much genetic engineering of a human would it take to make a human no longer a human.<sup>306</sup> If the worry is that human experimentation would take place

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<sup>299</sup> The unpatentability of Newman's claims would not have changed under the Consolidated Appropriations Act of 2004.

<sup>300</sup> Thus, as long as the embryo from which an organism was generated contained any amount of human and animal cells, and the adult derived from this embryo also contained any amount of human and animal cells, this would be a chimera under Newman's claims. Thus, the claims encompassed, e.g. a human who contained one chimpanzee cell, as long as the one chimpanzee cell originated in the human's embryo. So, Newman's claims contained *de facto* humans within their scope and this was the basis of the rejection by the USPTO

<sup>301</sup> Coughlin, S. M. p. 9.

<sup>302</sup> *Ibid.*

<sup>303</sup> It almost seems as if there was a policy decision made at the higher levels of the USPTO to prevent the patenting of humans, which was later translated into the amendment of the Consolidated Appropriations Act of 2004 to prohibit patenting of human organisms. See Coughlin S M, p. 8, 2006.

<sup>304</sup> Coughlin S. M. p. 8, 2006.

<sup>305</sup> *Ibid* p. 10.

<sup>306</sup> *Ibid* p. 11.

during an attempt to develop human cloning, drafting a law to simply make this experimentation illegal would be much more effective than only making it unpatentable. With the current legislation, inventors may use genetically modified organisms, which should be considered to embrace humans in their experiments.<sup>307</sup> However, generally, if there is a desire or need for an invention it will eventually be made. Certainly, genetic manipulation of humans presents as many different ethical problems as nuclear energy does, but these problems will never be developed unless the technology is.<sup>308</sup>

## 5.5 The White House Policy and Bush Decision to Limit Stem Cell Research

Embryonic stem cell research has become a polarising political issue in the last few years. Since 1978, federal law has prohibited federal funding for research on human embryos.<sup>309</sup> Because it was understood that the prohibition extended to research on HESCs derived from embryos, efforts to isolate embryonic stem cells were privately funded.<sup>310</sup> The announcement that Thomson had isolated embryonic stem cells in 1998 launched the issue of federal funding of embryonic stem cell research on to the political agenda.<sup>311</sup> In August 2000, NIH issued guidelines that provided for federal funding of embryonic stem cell research if the stem cells were derived from spare embryos leftover from IVF attempts. In August 2001, President George W. Bush addressed the issue and announced his decision to scale back federal support for such research.<sup>312</sup> Under the new policy, federally funded researchers can experiment with cells from any of the NIH designated cell lines.<sup>313</sup>

This limit on federal funds will hamper the expansion of research for scientists and universities in the US. The scientific community has reacted with alarm and concern to the President's decision. Many believe this decision will have a slowing effect on research and will also increase the cost of research.<sup>314</sup> Already, the US is losing prominent scientists who wish to continue research in a less restrictive environment.

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<sup>307</sup> Ibid p. 12. For example, to make patentable organisms which do not resemble humans.

<sup>308</sup> Coughlin S. M. p. 13 2006.

<sup>309</sup> Gertzen J, 2001.

<sup>310</sup> Miller J, p. 564, 2003.

<sup>311</sup> National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 Fed. Reg. 51,976, 51,979, Aug. 25, 2000, corrected at 65 Fed. Reg. 69,951, Nov. 21, 2000.

<sup>312</sup> Ibid. Press Release, President George W. Bush, Remarks by the President on Stem Cell Research (Aug. 9, 2001), at <http://www.whitehouse.gov/news/releases/2001/08/20010809-2.html> (last visited Apr. 5, 2003). The President stated that because “*embryonic stem cell research offers both great promise and great peril... “we must proceed with great care.”*”

<sup>313</sup> Ibid. A stem cell line must have been initiated before 9:00 p.m. eastern daylight time, August 9, 2001, to receive federal funding. See U.S. Dep't Health and Human Servs. Nat'l Insts. See also U.S. Dep't of Health & Human Servs., NIH Human Embryonic Stem Cell Registry (listing the laboratories and companies that have developed stem cell lines eligible for federal funding because they meet the President's criteria), at <http://escr.nih.gov/>.

<sup>314</sup> Fleis, P. J., p. 208, 2003.

Three possible solutions seem viable. The US patent system may fall more in line with the European system, which allows exemptions from patent infringement for experimental use or research of a patented invention. There may be more cross-licensing of patents, with more of the profits determined from downstream revenues. Finally, the industry may look to Congress to give it more direction so as to alleviate the problems arising in the field today, by passing legislation that may encourage the President to rethink his decision, or possibly give other incentives besides early patent rights to companies involved in biotech research.<sup>315</sup>

Congressional action is the biggest threat to the Bush Compromise. Even before the Bush Compromise, members of Congress repeatedly made their opinions clear, that the benefits of embryonic stem cell research would certainly outweigh any moral restraints.<sup>316</sup> With the medical potential to cure many diseases of the growing elderly population, it is no wonder that Congress favours embryonic stem cell research so strongly.<sup>317</sup>

### **5.5.1 The Guidelines for HESC Research<sup>318</sup>**

Since 1998, the volume of research being conducted using HESC has expanded primarily using private funds because of restrictions on the use of federal funds for such research. Although privately funded HESC research is currently subject to many of the same oversight requirements as other biomedical research, given restricted federal involvement and the absence of federal regulations specifically designed for HESC research, there is a perception that the field is unregulated. More accurately, there is a patchwork of existing regulations that are applicable to HESC research, many of which were not designed with this research specifically in mind, and there are gaps in how well they cover HESC research. The guidelines<sup>319</sup> are intended to enhance the integrity of privately funded HESC research both in the public's perception and in actuality by encouraging responsible practices in the conduct of that research.

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<sup>315</sup> Ibid p.223.

<sup>316</sup> Davison, Scott p. 420, 2002.

<sup>317</sup> Ibid p. 421.

<sup>318</sup> *2007 Amendments to the National Academies' Guidelines for Human Embryonic Stem Research* Human Embryonic Stem Cell Research Advisory Committee, National Research Council 2007.

<sup>319</sup> What the guidelines cover: The guidelines are intended for the use of the scientific community, including researchers in university, industry, or other private-sector organizations. They cover all derivations of hES cell lines and all research using HESC derived from

1. Blastocysts made for reproductive purposes and later obtained for research from IVF clinics.
2. Blastocysts made specifically for research using IVF.
3. Somatic cell nuclear transfer (NT) into oocytes.

## 5.6 WARF - The Patent on HESC

Even though we already have looked into the WARF case from an European perspective, it is not exactly the same issues that are important in the US granted patents, where the HESC are subject of very broad patent claims. To give an understanding for the involved matters, a detailed case study will now follow.

James Thomson of the University of Wisconsin at Madison first isolated HESCs in 1998 and received three patents related to his discovery. The Thomson patents were assigned to the Wisconsin Alumni Research Foundation (WARF), a non-profit organization that manages the intellectual property assets of the University of Wisconsin at Madison. They claim, respectively: (1) *primate embryonic stem cells*,<sup>320</sup> (2) *a purified preparation of human embryonic pluripotent stem cells*,<sup>321</sup> and (3) *methods of hematopoietic differentiation of human embryonic pluripotent stem cells*.<sup>322</sup>

WARF has granted an exclusive license for these patents to Geron Corporation, a private biotechnology firm that had sponsored Thomson's research because federal regulations prohibited funding for research involving human embryos. So Wisconsin researchers obtained private funding for their research instead, which allows Geron to commercialize products based on six cell types that Thomson has developed.<sup>323</sup>

An examination of WARF's patents reveals their immense breadth.<sup>324</sup> Because of this breadth, the claim relating to the purification and culturing of HESCs effectively encompasses all HESCs that can live in culture for over one year, maintain the normal (euploid) number of chromosomes for the human species, and retain the pluripotent capacity to differentiate into any type of tissue. In short, this claim encompasses virtually all HESCs of significant research value.<sup>325</sup> Though Thomson's inventive step was discovering the method for isolating and culturing HESCs, his patents also cover the stem cells themselves. Furthermore, the patents' claims cover all

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<sup>320</sup> U.S. Patent No. 5,843,780 (filed Jan. 18, 1996).

<sup>321</sup> U.S. Patent No. 6,200,806 (filed June 26, 1998).

<sup>322</sup> U.S. Patent No. 6,280,718 (filed Nov. 8, 1999). Hematopoietic cells are a type of cell normally found in blood and bone marrow.

<sup>323</sup> Ligler, A. *Egregious Error or Admirable Advance: The Memorandum of Understanding That Enables Federally Funded Basic Human Embryonic Stem Cell Research*, 2001 DUKE L. & TECH. REV. 37 (2001), <http://www.law.duke.edu/journals/dltr/articles/pdf/2001DLTR0037.pdf>.

<sup>324</sup> Yun-Hyoung Lee, P. p. 89, 2005. Only Claim 1 of the patent on a purified preparation of HESCs covers: A purified preparation of pluripotent human embryonic stem cells which: (i) will proliferate in an in vitro culture for over one year, (ii) maintains a karyotype in which the chromosomes are euploid and not altered through prolonged culture, (iii) maintains the potential to differentiate to derivatives of endoderm, mesoderm, and ectoderm tissues throughout the culture, and (iv) is inhibited from differentiation when cultured on a fibroblast feeder layer. U.S. Patent No. 6,200,806, filed June 26, 1998.

<sup>325</sup> Yun-Hyoung Lee, P. p. 89, 2005.



HESCs, and not just the cell lines that Thomson isolated.<sup>326</sup> Therefore, “any researcher must negotiate with WARF before using HESCs, even if that researcher isolates new HESCs or uses a new method to do so.”<sup>327</sup> Even foreign biotechnology companies and research institutions fear potential infringement suits that could arise from selling their stem cell lines in the US.<sup>328</sup> If those cells match the claims contained in WARF's patents, potential importers who wish to distribute their cells in the US must obtain a license in order to avoid potential infringement.<sup>329</sup> As Hazuka observes, the HESC patents “cede a remarkable amount of territory to WARF.”

The patent on the method for isolating and culturing these cells also creates potential barriers to future research. A technique for maintaining undifferentiated cells in laboratory environments is critical in attempts “to use these cells to make mature cells, organs, and tissues that can be used therapeutically.”<sup>330</sup> Therefore, even if another party were able to derive useful stem cells without infringing a patent claim, it would likely be forced to infringe WARF's patent on the only known method for maintaining the cells' viability.<sup>331</sup>

An agreement between HESC patent holders and NIH has somewhat eased concerns over access to HESCs for research purposes. In October 1999, WARF established WiCell Research Institute, Inc., a non-profit organization that now holds the licenses to WARF stem cells.<sup>332</sup> Under the terms of a Memorandum of Understanding (“MOU”), WiCell agreed to offer WARF cells to scientists at NIH laboratories at only the cost of preparation.<sup>333</sup> Furthermore, WiCell agreed to allow other federally-funded non-profit researchers access to the stem cell lines upon negotiating similar arrangements.<sup>334</sup> Although the MOU grants NIH researchers rather liberal use of Wisconsin stem cells for research purposes, the agreement includes strict reach-through provisions for commercial applications. Researchers using WARF HESCs may patent any discoveries made in the course of research, but they may not commercialize these discoveries without first

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<sup>326</sup> Hazuka, C. D. *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 198 (2002), p. 173.

<sup>327</sup> *Ibid* at 158.

<sup>328</sup> Ligler, A. p. 7, 2001.

<sup>329</sup> *Ibid*. Companies across the globe are challenging WARF's position by questioning the validity of the patent and declaring that they have derived embryonic stem cells through different methods. (Miller, J. p. 565, 2003. See also, Gertzen, J. *Stem Cell Patents Put UW Agency in Spotlight: Foundation Seeks to Share Technology, Protect Rights*, Milwaukee J. Sentinel, Aug. 26, 2001, at 1A.) At least one group of researchers has reported that it shipped HESCs to the US without a license. (Vergano, D, *Stem Cells From Israel are Sent to Harvard Lab*, USA Today, Sept. 5, 2001, at A.02.) Patent applications have been filed for alternative methods for deriving HESCs. (D'Silva, J, *Reliance Life Patent Portfolio's Growing*, Econ. Times, Aug. 2, 2002.)

<sup>330</sup> Hazuka, C. D. p. 158, 2002.

<sup>331</sup> Yun-Hyoung Lee, P. p. 89, 2005.

<sup>332</sup> WiCell Research Institute, Inc.: About Us, <http://www.wicell.org/aboutus> (last visited Nov. 21, 2005).

<sup>333</sup> Memorandum of Understanding Between WiCell Research Institute, Inc., and Public Health Service, U.S. Department of Health and Human Services 5 (Sept. 5, 2001), available at <http://ott.od.nih.gov/pdfs/WiCellMOUhuman.pdf>.

<sup>334</sup> Ligler, A. p. 7, 2001.

negotiating a license with WARF.<sup>335</sup> Finally, the agreement promises academic and government scientists that they can perform non-commercial research on stem cells without being charged.

Although WiCell's agreement with NIH has allowed relatively liberal and inexpensive access to HESCs for research purposes, it is important to note that this MOU is a voluntary agreement. WiCell still retains broad legal rights over the WARF HESCs, it may exclude any party from using the HESCs, charge whatever license fee it desires for their use, or pursue infringement suits against those who use the HESCs without its permission. The only limitation on these rights arises from the march-in provisions of the Bayh-Dole Act,<sup>336</sup> which apply because of the federal government's funding of Thomson's original primate research.<sup>337</sup>

Indeed, scholars have criticized WiCell's apparent "*largesse*" by noting that, "*the federal government is funding the expanded basic research of two private companies (WiCell and Geron) that already have a legal monopoly on a broad set of stem cell products and methods.*"<sup>338</sup> WiCell's apparent generosity in allowing at-cost access to its patented cells may ultimately prove quite self-rewarding. Setting aside the voluntary MOU, the broad patent grant over HESCs raises the question of how such expansive patents can affect basic research. As noted, Hazuka has warned that WARF's broad patents could constrain exploration of the properties of these cells.<sup>339</sup> A patent on this upstream research tool creates an extremely wide zone of exclusivity, since "*...decades of discoveries, innovations, and inventions remain in determining how HESCs may be utilized.*"<sup>340</sup> HESCs are critical to achieving fundamental new insights into basic biology, and granting individual property rights over them seems contrary to the policy objective of keeping basic scientific knowledge freely available to the public.<sup>341</sup>

## **5.7 Legal Tools to Narrow the Scope of the Patent by Invalidating the Claim to Embryonic Stem Cells**

The conclusion that policy considerations warrant a narrowing of the WARF mandates a thorough discussion of the legal tools that could be used by a court to narrow the patent. The question whether the WARF patents are desirable from a policy perspective leads to several legal arguments that can be advanced to invalidate the claim to HESC. Among others: embryonic stem cells are not patentable subject matter; claims to stem cells should not

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<sup>335</sup> Yun-Hyoung Lee, P. p. 91, 2005.

<sup>336</sup> Bayh-Dole is codified in 35 U.S.C. § 200-212.

<sup>337</sup> Ibid.

<sup>338</sup> Ligler, A. p. 1, 2001.

<sup>339</sup> Hazuka, C. D. p. 157-158, 2002.

<sup>340</sup> Ibid, p. 183.

<sup>341</sup> Yun-Hyoung Lee, P, p. 92, 2005.

be allowed under the moral utility doctrine; embryonic stem cells are research tools. Some of these arguments will be discussed below.<sup>342</sup>

### 5.7.1 Products found in nature

It could be not argued that HESCs are products found in nature.<sup>343</sup> Even though, the biological material has not really been altered in any way and only separated from the rest of the body, courts have long held that isolated or purified materials may be patented even though those materials exist in nature. As early as 1958, the Fourth Circuit held that Vitamin B in a purified and isolated state could be patented,<sup>344</sup> and courts have consistently held that patent protection is available to purified and isolated proteins and genes. Finally, although there are no cases holding that cell lines are patentable subject matter, the USPTO has routinely granted such patents.<sup>345</sup>

### 5.7.2 Patenting Human Life

It is arguable that stem cells constitute a form of human life that is not patentable. Although the Supreme Court has declared that “*anything under the sun that is made by man*,” including a living organism, is patentable subject matter,<sup>346</sup> courts have not defined the extent of their willingness to uphold patents on living organisms. It is also arguable that the claim to HESC is directed to or includes within its scope a human being. Some scientists maintain that HESCs are capable of developing into full embryos. Indeed, even the patent concedes the possibility that HESCs can develop “*into any organ or tissue type or, at least potentially, into a complete embryo*.”<sup>347</sup> However, even if it could be proven that HESCs can become full embryos, a court could not use this argument to invalidate the patent, since a court would have to find that the patent falls within the USPTO's prohibition by holding that a stem cell is the equivalent of a human.<sup>348</sup>

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<sup>342</sup> Ibid p. 575.

<sup>343</sup> In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), the inventor applied for a patent on a mixed culture of different species of bacteria. The Supreme Court held that “*patents cannot issue for the discovery of the phenomena of nature*.” In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Court held that a genetically engineered micro-organism was patentable subject matter. In emphasising that the microorganism was altered by human intervention and therefore not a product of nature, the Court declared that “*a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter*.”

<sup>344</sup> *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 161-62, 164 (4th Cir. 1958).

<sup>345</sup> Miller, J, p. 577, 2003.

<sup>346</sup> *Diamond vs Charkabarty* see above.

<sup>347</sup> Wright, S. J. 1999.

<sup>348</sup> Miller, J. p. 579, 2003.

In *Davis v. Davis*, (No. E-14496, 1989 Tenn. App. LEXIS 641, at 1 (Tenn. Cir. Ct. Sept. 1989), rev'd, 1990 Tenn. App. LEXIS 642, at 1, Tenn. Ct. App. Sept. 1990, aff'd, 842 S.W.2d 588, 604, Tenn. 1992), a Tennessee trial court treated cryopreserved pre-embryos as equivalent to children for purposes of determining custody in a divorce. The ruling was motivated by the fact that the embryos had a unique, individual genetic complement. The trial court ruling was overturned by the Tennessee Supreme Court, (*Davis*, 842 S.W.2d at 597), and several other courts considering the status of pre-embryos have also rejected the

Even if a court could find a way to define stem cells as human beings, it would also have to conclude that the USPTO prohibition on patenting human beings is legitimate. Although it is arguable that the USPTO policy is mandated by the Constitution or can be divined from congressional intent, neither argument is particularly compelling.<sup>349</sup> Patents provide only a right to exclude others from making, using, and selling an invention, not an affirmative right to use an invention or possess a physical embodiment of the invention. Therefore, patenting a human being probably does not violate the Thirteenth Amendment's prohibition of involuntary servitude.<sup>350</sup>

A ban on patenting human life probably cannot be divined from congressional intent either. Although the USPTO argued that the Newman application would be rejected on the basis that "*Congress did not intend 35 U.S.C. 101 to include the patenting of human beings,*" there is no basis for this assertion. Because the USPTO does not have rulemaking powers, their interpretations of the meaning of the statutory provisions are accorded no deference. Furthermore, courts have been unwilling to find implied limitations on patentable subject matter.<sup>351</sup>

### 5.7.3 HESCs as Research Tools

One of the primary goals of the patent system is to promote scientific progress. As the prohibition against patenting natural laws, natural phenomena, and abstract principles reveals, patent doctrine reflects an underlying policy of encouraging innovation by keeping basic tools of science within the public domain and outside the realm of individual property. Lee writes in his article<sup>352</sup> that, "*the HESCs are research tools and the patent of such tools has greater potential to create monopolies over basic scientific knowledge than do patents on the products of other applied knowledge*". In the case of contemporary biomedical research tools such as HESCs, common law doctrine counsels a narrowing of their patentability.<sup>353</sup>

HESCs, which possess a unique potential to enable insights into fundamental biological processes, illustrate the importance of exempting basic research tools from patentability. WARF's patents on this basic tool of

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trial court's analysis. (*Doe v. Irvine Scientific Sales Co.*, 7 F. Supp. 2d 737, 742 (E.D. Va. 1998) and *Janicki v. Hosp. of St. Raphael*, 744 A.2d 963, 971, Conn. Super. Ct. 1999). Indeed, under *Roe v. Wade*, (410 U.S. 113, 1972), a stem cell cannot be considered a person. (Patricia A. Martin & Martin L. Lagod, *The Human Preembryo, the Progenitors and the State: Toward a Dynamic Theory of Status, Rights, and Research Policy*, 5 High Tech. L.J. 257, 272-76, 1990; John R. Harding, Jr., Comment, *Beyond Abortion: Human Genetics and the New Eugenics*, 18 Pepp. L. Rev. 471, 506-09, 1991) The Supreme Court has unequivocally stated that the word person "*does not include the unborn.*" (*Roe*, 410 U.S. at 158.)

<sup>349</sup> Miller, J. p. 580, 2003.

<sup>350</sup> U.S. Const. amend. XIII, § 1.

<sup>351</sup> Miller, J. p. 581, 2003.

<sup>352</sup> Yun-Hyoung Lee P, "*Inverting The Logic Of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents On Biotechnology Research Tools*" 19 Harv. J.L. & Tech. 79, Harvard Journal of Law and Technology, Fall 2005.

<sup>353</sup> Miller J, p. 582, 2003.

science contravene the principles underlying common law limitations on patentable subject matter, since patents on HESCs have the practical effect of conferring the ability to exclude others from exploring basic knowledge.<sup>354</sup> Scientists can only evaluate theories about stem cells if they have access to them. The ability to investigate and develop theories regarding HESCs is therefore effectively the property of WARF.<sup>355</sup> The critical difference is that the novel information one can gain from most patented technologies is particularised and narrowly limited to that subject matter, whereas the novel information to be gained from investigating HESCs is generally relevant to a broad range of basic biological questions.<sup>356</sup> WARF's patents on HESCs are effectively patents on biological knowledge, since they establish individual ownership of a research tool that is necessary for accessing that knowledge.

*“HESCs are a fountain from which vital scientific knowledge springs. Just as patent law prohibits property rights over that knowledge, it should also prohibit individual ownership of the source of that knowledge, the fountain itself.”*<sup>357</sup>

Lee, has in his article specifically argued for constraining patents on human embryonic stem cells. HESCs are research tools of immense theoretical interest and represent the key to understanding basic cellular and developmental processes. In this regard, they have no adequate substitute.<sup>358</sup> WARF's patents on usable HESCs, as well as on the technologies for maintaining them in culture, create rights that exclude others from exploring broad areas of scientific research. While voluntary licensing agreements have allowed federally-funded non-profit scientists to access these vital research tools, the potential remains for patents on knowledge-generating resources such as HESCs to fundamentally frustrate the production of basic knowledge or, at the very least, to allow a single patent-holder broad power to determine the scope and contours of such research. Patent laws were never intended to facilitate this kind of privatisation of control.<sup>359</sup>

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<sup>354</sup> Yun-Hyoung Lee P, p. 100, 2005.

<sup>355</sup> Miller J, p. 583, 2003.

<sup>356</sup> Yun\_Hyoung Lee P, p. 105.

<sup>357</sup> Ibid.

<sup>358</sup> Yun-Hyoung Lee P., p. 102, 2005.

<sup>359</sup> Ibid, p. 109.

## 5.8 Conclusion US

There are two central conclusions on the WARF patents. First, the breadth of the patent on embryonic stem cells is antithetical to the goal of fostering commercial development<sup>360</sup> of stem cell products. The claim to human embryonic stem cells provides ownership rights over all HESCs and downstream products, regardless of how the stem cells were derived. Although WARF has adopted a policy of making HESCs widely available to non-profit researchers and granting non-exclusive licenses to firms pursuing commercial development of HESCs, a single biotechnology company, Geron, owns exclusive rights to cardiac, neural, and pancreatic cell lines. The difficulties associated with negotiating licensing agreements with Geron will deter firms from engaging in research, development, and commercialization of cardiac, neural, and pancreatic cell line products. This is unfortunate because competition in these markets is necessary to bring life-saving products to the market in a timely manner.

Second, the patent doctrine provides courts with the flexibility to narrow the scope of the patent. Although several tools in the legal arsenal can be advanced to limit the reach of the patent, the most powerful case for judicial action is a court, which can and should use its legal arms to invalidate the claim to embryonic stem cells.

Is the WARF patent desirable? Concerning the liberal approach in the US where patents on embryonic stem cells are allowed, it is a step forward compared with the European approach. But as have been shown in this part, there are many negative effects of this liberalism. To keep the HESCs in the public domain is not what the author suggests, instead, trying to limit the scope of the patents. How this could be approached will be discussed in the next chapter.

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<sup>360</sup> The goal of the patent system is to provide incentives to innovate, therefore patent law must be carefully calibrated so as not to concomitantly stifle invention; unwarranted monopoly power must be vigilantly guarded against. Although it may be true that patents are necessary to encourage innovation, they may also stifle it if the property rights awarded are too broad. One must always keep in mind the effect of a property right on subsequent innovators. See Hazuka, C. D., p.172, 2002.

## 6 Finding the Balance

The moral hazard in Europe and the too broad scope in the US create problems each in its own way. How to find some kind of balance and harmony between those two extremes will be discussed in this chapter.

### 6.1 Ethical Perspectives

Of course, the ethical diversity in the US is just as wide as the one in Europe. But the solution used is allowing patents on HESCs, since the moral aspects and the moral utility doctrine are not at all considered in the question of a patent. Therefore, avoiding the complexity of the moral diversity, but arriving at other major problems such as the too broad scope of the patents. The moral aspects of HESC research are treated in the National Academies Guidelines, which are intended to explicit how HESC research can be pursued most responsibly and to give some kind of policy applicability.

While in Europe, the moral diversity is the main reason of hindering the harmonization of stem cell patents. The EGE has mainly put forward two ethical arguments against patenting of human stem cells. They argue firstly that *“isolated stem cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialization of the human body”*<sup>361</sup>

However, the concept *“close”* is not defined and, as a matter of fact, genes and gene products are already patentable.<sup>362</sup> The point in this context is that what is commercialized is not something *“close to a human body”* but a product being a result of an advanced biotechnical process, a technique which human nature is *“incapable of accomplishing by itself”*. The ethical discussion about commercialization of human body parts is far from settled, but the similarity with human body parts has never been a matter of consideration regarding patenting of biotechnical products. Instead, the drive in many technological developments, has been trying to develop something that is close to nature.<sup>363</sup>

Secondly, EGE and the Netherlands<sup>364</sup> argue in accord with Art. 3 of the Charter of Fundamental Rights and with recital 26 of the EU Patent Directive, which states that: *“the person from whose body the material is*

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<sup>361</sup> Opinion EGE, 2002 p. 16.

<sup>362</sup> See Westerlund Li, Life science inventions: The hurdles of Law, Uppsala, 2004, Iustus Förlag, and Hansson MG, and others, p. 1509, 2007.

<sup>363</sup> Hansson Mats G, Helgesson G., Wessman R., Jaenisch R and others, p. 1510, 2007.

This article *“Commentary: Isolated Stem Cells- Patentable as Cultural Artifacts?”* is a result of an unique cooperation between the researchers in ethics at the centre for bioethics Uppsala, Mats G Hansson and Gert Helgesson, Richard Wessman at the Faculty of Law and Rudolf Jaenisch a leading researcher within stem cells at the White Head Institute for Biomedical Research, Massachusetts Institute of Technology.

<sup>364</sup> In C-377/98 Netherlands v European Parliament and Council of the EU.

*taken must have had an opportunity of expressing free and informed consent thereto”*.<sup>365</sup>

It should be observed that the right to withdraw a previously given consent is limited in relation to stem cell research, even though the Convention of Biomedicine and Human Rights grants such a right with regard to all kinds of research using human tissue.<sup>366</sup> However, the stem cells placed in a culture medium being viable are results, and the right to withdraw consent does not apply regarding the result of a research study. The donor can therefore not require that the cells should either be destroyed or made unidentifiable.<sup>367</sup>

## 6.2 Distinguish Stem Cells in the Human Body and Isolated Stem Cells

An isolated stem cell should be distinguished as something other than the stem cell still existing as a part of human body. This opens a possibility for legal consideration of patenting the method for manipulating growth conditions but also for patenting an isolated stem cell as a unique result of modifying the cell by placing it in an appropriate medium.<sup>368</sup>

The EGE claims in its Opinion<sup>369</sup> that one should distinguish among three different stem cell types. Namely; “a.) stem cells freshly derived from an organ or tissue which have not yet been subjected to any modification and which are capable of being propagated as stem cell lines, b.) “*unmodified*” stem cell lines which refer to cultured lines of cells which have not been modified in any other way c.) and modified stem cell lines which refer to cultured lines of cells, propagated from stem cells or stem cell lines, which have been modified by genetic manipulation, or by treatment that causes the cells to differentiate in a particular way.”<sup>370</sup> Only the last kind of cells may be patented as products, according to EGE.

However, the only “*unmodified*” human stem cells are those still present in the human body or embryo. HESC are isolated from IVF embryos that have been cultured in vitro up to the blastocyst stage. If not used for infertility treatment but for the derivation of an ES cell line, the blastocyst are explanted into a special culture medium and cultured in vitro for an extended period of time, generating a novel cell type that is not part of the blastocyst. Already, the act of placing a cell into a culture medium implies modification, hence even a freshly derived stem cell has been subject to modification. The result of adaptation to tissue culture is the outgrowth of

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<sup>365</sup> EGE Opinion, 2002.

<sup>366</sup> Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: Convention on human rights and biomedicine. Council of Europe. 1997.

<sup>367</sup> Hansson M. G., and others, p. 1510, 2007.

<sup>368</sup> Hansson M. G., and others, p. 1508, 2007.

<sup>369</sup> The European Group on Ethics in Science and New Technologies, Opinion on the ethical aspects of patenting inventions involving human stem cells, 5 7, 2002.

<sup>370</sup> Ibid.



cells that have no equivalent to cells in the embryo.<sup>371</sup> Although ES cells can contribute to normal development when introduced into a host embryo, they do not have the potential to generate an organism in contrast to the blastocyst from which they were derived. *“Thus, the process of ES cell derivation creates a novel cell type that is not present and is not a part of the normal blastocyst and that has vastly different molecular and biological characteristics from the cells both in the embryo and in the foetus.”*<sup>372</sup>

### **6.3 International Perspective on the Moral Status of HESC**

The legal argumentation for different national patent policies is complex. It should be clear by now, that there is today no international consensus on the moral status of HESCs, and there are different policies for patenting among national patent offices that reflect a wide diversity of moral cultures.

However, there seems to be one moral consideration that is common to the policies excluding patentability of HESC. According to this view, patentability implies research on embryos or variants thereof that carry the potential of developing into a mature human being, and therefore it is wrong. An associated argument is that the research involves destruction of embryos carrying such potentiality.<sup>373</sup> The author argues that since the extra numerous of embryos created through IVF would be destroyed anyway,<sup>374</sup> and therefore there are embryos that are really “*spare*”. As argued above, the derivation of ES cells is a process that leads to a novel cell type with novel intrinsic qualities that do not exist in the embryo. The ES cells do not carry any potential to develop into a human being, and should therefore be, in principle, patentable.

### **6.4 Research vs. Morality**

It must be said that the degree of concern for embryonic life is surprisingly wide, compared to the blind eye so many people turn to the thousands of abortions carried out in Europe every year. It would be more efficient to see the embryo as a life saving tissue generator.

The use of IVF to alleviate infertility problems has produced large numbers of frozen embryos, which if not used for implantation in utero, will have to be disposed of either according to law and the wishes of their “*owners*”.<sup>375</sup> One alternative to inevitable destruction of the embryos when the legal time limit on storage arrives is donation for research purposes. Most scientists working in this field encourage this kind of donation. As to moral issues, such scientists will feel no inhibition from this course of action and many will even say that it would be more immoral not to take advantage of

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<sup>371</sup> Hansson MG and others, p. 1508, 2007.

<sup>372</sup> Ibid.

<sup>373</sup> Hansson MG, and others, p. 1508, 2007.

<sup>374</sup> According to law, if not used for research.

<sup>375</sup> Especially, the mother to be or not to be.

embryos that are otherwise doomed to destruction as required by law, especially when such research may one day lead to cures of diseases and disabilities of many kinds.<sup>376</sup>

It is already envisaged that the scientists will want to create human embryos by nuclear transfer (cloning) from somatic cells of individual patients. The stem cells derived from such patients will not be rejected by their immune system and can therefore give rise to products that are a tissue match for them.<sup>377</sup> The moral problem which this procedure stands out more clearly than in the case of spare embryos because the embryo is being created for the sole purpose of another human being.

## 6.5 The Embryo Destruction is no Longer a Threat to Patentability

As suggested in the German Brüstle case, there are many other ways of deriving stem cells than from human embryos. Therefore, the moral hazard concerning the embryo itself, should not be such a problem anymore.

Moreover, the very recent discoveries<sup>378</sup> which show how to use the embryo and derive stem cells without destroying the embryo, is another proof of the future research, that not necessarily will raise the question of the embryo's moral concerns, and will therefore be a breakthrough that could overcome the intense ethical objections to this kind of research.

Dr Lanza's group showed that the single cell removed from an embryo can be grown into many cells overnight, and some of those can then be turned into embryonic stem cells. In tests, the team took 91 clumps of cells from 16 embryos and created two sets of embryonic stem cells, according to Nature today. He said: *“Many people, including President Bush, are concerned about destroying life in order to save lives. We now have a technique to generate stem cells without destroying the embryo, and we think that with the right resources we have the capacity to create as many stem cells as the scientific community needs without harming any embryos whatsoever.”*

The most recent discovery, an US scientist who clones himself from skin cells,<sup>379</sup> is a big step forward, but the researchers did not go on to do the

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<sup>376</sup> Crespi, S R, p. 575, 2006.

<sup>377</sup> Cooper G. M. and Hausman R. E., p. 621, 2004.

<sup>378</sup> The 21 November 2007, two independent teams of researchers, one in Japan and one in the US, discovered how to use stem cells from an embryo without destroying it. This discovery is of Nobel Prize character and will certainly help a lot in the moral discussion of the embryo.

See [http://www.guardian.co.uk/genes/article/0,,1857036,00.html#article\\_continue](http://www.guardian.co.uk/genes/article/0,,1857036,00.html#article_continue),

see also the Times Top Ten Scientific Discoveries 2007 available at:

[http://www.time.com/time/specials/2007/top10/article/0,30583,1686204\\_1686252\\_1690920,00.html](http://www.time.com/time/specials/2007/top10/article/0,30583,1686204_1686252_1690920,00.html)

<sup>379</sup> Samuel Wood, a researcher at Stemagen Corporation in La Jolla, California, plucked cells from his skin and injected them into donated eggs that had been treated to remove their own genetic material. The eggs developed into very early stage embryos that were genetically identical to the scientist's own DNA.

<http://www.guardian.co.uk/science/2008/jan/18/genetics.medicalresearch>

next step: to create embryonic stem cell lines from cloned embryos. The community is waiting with bated breath to see if anyone can do both steps.<sup>380</sup>

The author suggests that the inventions not using the destruction of an embryo would naturally be patentable under the European provisions.

## 6.6 Broad Patents Rises Monopoly

With our experience from across the Atlantic, it is shown that to broad patent grants do not give the right balance between incentive to invent, and anti-competitive effects.

An important concern that was also expressed when genes were proposed as patentable is the one of EGE, who argues that a right to patent unmodified stem cells implies too broad patents since several technological applications may be derived from the original achievement.<sup>381</sup> It is evident that this concern should not be taken lightly, when we look at the WARF patent in the US. The patents seem to give WARF far-reaching possibilities to hinder both academic researches and biotechnology companies from making, using, selling, offering sale, or importing HESC covered by the claims until 2015! If assumed that the scope of these patents is not changed when challenged in a court of law.<sup>382</sup> According to Loring and Campbell, “*WARF requires a license agreement for distribution of any HESC cell lines in the US*”, and they are charging both academic and commercially based researches large fees for a license.<sup>383</sup>

The fundamental principle of a patent is to protect reasonable commercial claims and inventive achievements as a means to promote technological development and application of research into different sectors of society.

By granting claims with an unreasonable scope, the WARF patents seem to have violated this principle and therefore leading to a situation that in fact, may be detrimental to stem cell research.<sup>384</sup> In analogy to the development in gene patenting, it has to be proven by the researcher, whether the result in terms of an isolated stem cell in a specific culture medium or a propagated stem cell line carries enough novelty, inventive step, and potential for industrial application.

Hansson and others suggests that: “*the patents authorities may consider them as an object both for product and method patents that fulfil, in principle, the legal requirements for such patents, but that the scope of the patents must be reasonable and well informed by the scientific development and the foreseen effects of a patent on research and other commercial interests.*”

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<sup>380</sup> Ibid.

<sup>381</sup> Westerlund Li, Life science inventions: The hurdles of Law, Uppsala, 2004 , Iustu Förlag.

<sup>382</sup> Hansson MG, p. 1509, 2007.

<sup>383</sup> Loring J. F., Campbell C., Science and Law, Intellectual Property and Human Embryonic Stem Cell Research, Science 2006, 311:1716-1717.

<sup>384</sup> Hansson M.G. and others, p. 1509, 2007.

The authors<sup>385</sup> suggest several guidelines, starting with that the patent authorities should take a conservative view regarding the scope of the patents, with a limitation to the intrinsic qualities of both the patented ES cells and the patented methodologies. Continuing with a categorisation of the product and method patents of ES cells; “a.) isolation of ES cells, b.) derivations of ES cells (through genetic modification or otherwise), c.) methods of culturing ES cells, and d.) methods of using ES cells (differentiation/transplantation).”

Restrictions according to a conservative policy would, for example be: claims with ES cells deriving from a particular species, and that the scope of potential differentiation derives of one specified tissue only. Moreover, the patent should only cover a particular cell line and only specific uses.<sup>386</sup>

There are two possibilities of limiting patents, on the one hand through restrictions on the area of patentability and on the other through determining the extent of protection for the patent. This is a question that must be decided in future infringement trials.

## 6.7 Narrow the Industrial Application

Looking at the conclusions from the EPO decisions in the Edinburgh and WARF cases, the court interpreted the moral exclusion very broadly and said that all of the claims of the patent which could be extended to HESC, were invalid on the ground of morality.

Well, here is where the criterion of *Industrial Application* comes into play. Basically the court said that, the use of an embryo as a starting material for the generation of a product of industrial application is considered equal to industrial use of this embryo and since the moral clause said there cannot be industrial use of an embryo, then they came to the conclusion that it would not be patentable.<sup>387</sup> While the moral concern goes far beyond patenting itself and extends to the general instrumentalization, it implies that mere involvement, the use of embryos in the research and development of an invention, is sufficient to bar the patentability of that invention.

However, the author is of the opinion that, the best way of limiting a too broad scope of a patent should be through limitation of the industrial application. It would not be fair to limit an invention that covers wide areas of species, cell lines or whatsoever, since that would actually limit the incentive to invent. Instead, it would be fairer to look into the application of the criteria of industrial application, trying to harmonize the scope with other parts of patent law, since the biotech always have had a rather weak industrial application criterion.

Finally, when using a cell line to produce stem cells is that really an industrial application of that embryo? The answer to this question is too complicated to be solved overnight. Perhaps it will be avoided in the future,

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<sup>385</sup> Ibid.

<sup>386</sup> Ibid.

<sup>387</sup> Stem cells *Promise and Peril in Regenerative Medicine*, Stem Cell Research Conference, February 3-4, 2006, p. 101.

since there now are other ways of producing stem cells, which do not utilise the embryo at all. But the industrial application will probably still be used in the sense of limiting the too broad patent scope of HESC.

## 6.8 Future Development and Legislation

Considering Europe, each MS still has the last word in deciding how their national legislation should treat the ethical and moral problem regarding the patenting of the HESC. The attempt to harmonize on a European moral standard on the embryo and the HESCs has failed. Maybe, the answer might be that the matter of HESC is so controversial as to be impossible to resolve under the provisions of European patent law, until a harmonization has taken place.

Considering the US, scientist will attempt to narrow the scope of the WARF patents. Perhaps by trying to make them some kind of research tool, which will be kept in the public domain to encourage the incentive to invent and continue the private funding of HESC related research. But keeping the HESC available to the public and prohibit patents on them will not lead to a well developed future research, since the investments of research must be protected by patents. Instead, a limitation of the patent scope, as discussed above, is the best option for a sustainable solution. Scientists are trying to bring the WARF patents validity to court for a real policy decision. But so far no court has issued the question of validity.

As the authors Hansson and others suggest, it is important to keep the balance between patents and monopolies. To keep the patent scope in a narrow interpretation and to divide each application into divergent categories, considering the HESCs origin, species or derivation, could be a sustainable solution of narrowing the patent scope. This seems like a good beginning when trying to harmonize the European patent on HESCs.

The special difficulty facing the EPO arises from the fact that it is charged with issuing a European patent, which could be valid in all European States. Having reviewed the options in circumstances where no uniform European view on morality exists, this thesis concludes that the jurisprudence of the EPO interpreting the EPC, is that in the absence of a European wide moral norm the patent should be granted. MS may thereafter exercise their right to invalidate the patent to reflect distinctive national moral considerations precluding the grant of the patent. This seems to be the most adequate way of safeguarding all interests involved, including giving applicants, opponents and courts of EU MS the possibility of referring sensitive and unsolved morality questions of a European dimension for preliminary ruling by the ECJ.<sup>388</sup> However, this suggestion is not the most cost and time efficient solution to the problem, but currently it is the best that Europe can provide.

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<sup>388</sup> Plomer A, p.125, 2006.

In Europe, we are waiting eagerly for the WARF appeal, which will lead to the guiding judgement on how to interpret the moral questions regarding the HESCs.

The present discussion seems to have reached a point from which it cannot proceed further without references to fundamental belief systems that compete for an acceptance by society at large.

*“Whether the EBA will enter this moral minefield remains to be seen, but the notion that patent law can accommodate such profoundly difficult questions when society remains divided and confused over them has only to be stated to see how impossible it must be in the fast developing technologies that are a feature of bioscience today.”*<sup>389</sup>

If the EBA choose to go the broad construction of 23d(c), it may rule out any future prospects for the patenting of uses of HESC through the EPC route to legal protection, and therefore one must agree with the TBA that the WARF referral is of outstanding importance.

Just like in the article in Nature,<sup>390</sup> the author thinks that the EPO has put patent applications involving HESC technology on ice and there are no immediate prospects for a thaw. The EPO president, Alain Pompidou, said: *“basically there are too many ethical aspects that have not been resolved at the political level, and that the European office and the EU, even if they have different members and are ruled by different conventions, the EPO still needs to take note of the EU political climate”*.<sup>391</sup>

Perhaps the new discoveries of producing HESC without destroying the embryo will change the outcome of these cases.<sup>392</sup>

However, according to my analysis, it is important to underline the distinction of pluripotent and totipotent stem cells. Only the totipotent cells are ruled out of the patentability by the European provisions, while the pluripotent cells should be permitted as elements isolated from the human body, no matter their origin, since there is no uniform European definition of the term *“human embryo”*. Just as shown in the Brüstle case, there are other ways of producing stem cells than through destroying an embryo. New techniques make it possible to take just one stem cell from an embryo, which then can succeed its normal procedure to grow into a human being, without its destruction. However, as has been mentioned earlier, the embryos cultured in mediums for stem cell production are in a completely different state as to a normal embryo and has already lost its potential to develop into a normal human being, therefore this discussion, seems to me, to have lost its true meaning.

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<sup>389</sup> Crespi, S R, p. 575, 2006.

<sup>390</sup> Schubert, S. *Europe halts decisions on stem-cell patents* Nature. 435, no. 7043: 720, 2005.

<sup>391</sup> On 1st June 2005 the new President of the European Patent Office (EPO), Alain Pompidou, announced a halt on human embryonic stem cell patents because, as he put it, *“there are too many ethical aspects that have not been resolved at the political level”*.

<sup>392</sup> [http://www.nytimes.com/2007/11/21/science/21stem.html?\\_r=1&hp&oref=slogin](http://www.nytimes.com/2007/11/21/science/21stem.html?_r=1&hp&oref=slogin)

## 7 Conclusion

An isolated embryonic stem cell represents a cultural artefact that has no equivalent to cells of the embryo. Isolation of adult stem cells likely implies the same kind of modification. An implication of this is that isolated stem cells constitute research results that, in principle, fulfil the legal requirements of both product and method patents. In order for patents not to be detrimental to research and industrial application, it is vital that patent authorities assume a conservative approach in order to set a reasonable balance between different interests and limit the scope of the patents.

According to the European part above, it should be clear from the detailed discussion of the legal principles guiding the interpretation of the morality clauses under Community law and EPC law, that the question of when morality may be used as a basis to exclude patents on biotechnological inventions is not purely an ethical question, but is closely interconnected with fundamental constitutional issues. It must be kept in mind that Community law is premised on recognition and respect for diversity of moral traditions and culture in Europe.

However, because the goal of the patent system is to provide incentives to innovate, patent law must be carefully calibrated so as not to at the same time stifle invention, unwarranted monopoly power must be vigilantly guarded against. Although it may be true that patents are necessary to encourage innovation, they may also stifle it if the property rights awarded are too broad. One must always keep in mind the effect of a property right on subsequent innovators. Therefore, it is important to keep the balance between patents and monopolies, to keep the patent scope in a narrow interpretation and to divide each application into divergent categories, considering the HESCs origin, species or derivation. Thereinafter, it is also necessary to look profoundly into the requirements of industrial application, to be able to control the scope of the patents.

I suggest there should be no doubt in whether the pluripotent HESCs will be patentable in Europe. Maybe in the future, with the current speed of innovation and research even the totipotent cells can be patented, but that will not take place until a great change in the European moral provisions. While waiting for the WARF judgement, I hope Europe will not follow the broad scope in the US, instead being wise and limit the patentability according to suggested methods above. Hopefully, the US scientist will succeed to limit the patent scope via the courts, if not the WARF will have exclusive rights to all stem cells no matter their origin for another ten years! This is not a sustainable solution, that will benefit anyone but WARF in the long term. The development of HESC research must naturally be granted patents, therefore the balance between the patents and monopoly is so important, if we still want to encourage the researchers to invent and find new methods of treating serious illnesses.

*“As time and science move forward, the law struggles to keep pace while, at the same time, resisting change in order to maintain stability.”*<sup>393</sup>

Morality provisions change over time. Who would have thought that human related material, such as genes, could be patented 20 years ago? The question whether the morality should stay part of the patent system or if Europe will follow the US example is up to the future to decide.

Sometimes I wonder if this thesis really led to any clear conclusion, but then I realized that there is none. To investigate this subject has been truly interesting but at the same time very challenging. However, I will eagerly follow the future legal development within this field, and hopefully I have inspired you to do the same!

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<sup>393</sup> Han, S. S. *Analyzing the Patentability of “Intangible” Yet “Physical” Subject Matter*, 3 COLUM. SCI. & TECH. L. REV., at 12 (2002), <http://www.stlr.org/cite.cgi?volume=3&article=2>.



# Supplement A

## Necessary Legislation

### THE BIOTECH DIRECTIVE

#### Art. 5

- “1. The human body, at various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.”

#### Art. 6

- “1. Inventions shall be considered unpatentable where exploitation or publication would be contrary to public policy or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
- Processes for cloning human beings.
  - Processes for modifying the germ line genetic of human beings.
  - Use of human embryos for industrial or commercial purposes.**
  - Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”

### EPC – EUROPEAN PATENT CONVENTION

#### Art 53(a)

“European patents shall not be granted in respect of 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.”

#### Rule 23(d)

“Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

- processes for cloning human beings;
- processes for modifying the germ line genetic identity of human beings;

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

## **ECHR – European Convention on Human Rights**

### **Art 2**

“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.”

## **US CONSTITUTION**

### **35 U.S.C. § 101**

“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.”

# Supplement B

## National Policies Regulating HESC Research <sup>394</sup>

	I. Countries Allowing Human Embryo Research by LAW	II. Countries Allowing Human Embryo Research by GUIDELINES
<i>General Provisions (Countries with no specific legislation regarding HESC)</i>	Iceland Latvia Lithuania	None
<i>Allowing for Procurement of HESC from Supernumerary Embryos</i>	Denmark Estonia Finland France Greece Hungary Spain Slovenia Switzerland The Netherlands	Portugal
<i>Allowing for the Creation of Human Embryos for Research Purpose</i>	Belgium Sweden UK	
<i>Prohibiting the Procurement of HESC from Supernumerary Embryos, but Allowing for the Import and Use of HESC</i>	Germany	Italy
<i>Prohibiting the Creation of Human Embryos for Research Purposes and for the Procurement of Stem Cells by Law</i>	Cyprus Ireland Georgia Slovakia	

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<sup>394</sup> Plomer A, p. 139 ff, 2006.

## Policy Model Regarding HESC<sup>395</sup>

Definitions of regulatory models:

### **Restrictive:**

*Many techniques are prohibited (i.e. reproductive and therapeutic cloning, embryonic research) via tight regulations or blank prohibitions.*

### **Intermediate:**

*A wide range of techniques are allowed but controlled and closely monitored by modest state intervention. Under this approach, stem cell research on supernumerary embryos from IVF treatment is permitted, but the creation of embryos specifically for research purposes is prohibited.*

### **Liberal:**

*Most technologies are permitted provided procedural rules and governance are observed. These policies permit the creation of embryos for research purposes as well as for the derivation of stem cell lines and for research cloning (mostly by de facto or by case-by-case approval by a governmental agency or licensing authority).*

Austria	R	Spain	I
Belgium	L	Sweden	L
Bulgaria	I	Switzerland	I
Cyprus	I	The Netherlands	I
Denmark	R	The UK	L
Estonia	I	The US	L
Finland	I	Turkey	I
France	I	Ukraine	I
Georgia	I		
Germany	R		
Greece	I		
Hungary	I		
Iceland	R		
Ireland	R		
Italy	R		
Latvia	I		
Lithuania	R		
Moldova	I		
Norway	R		
Poland	R		
Portugal	I		
Romania	I		
Slovakia	I		
Slovenia	R		

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<sup>395</sup> Plomer A, p. 134 ff, 2006.

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Directive 98/44/EG on the legal protection of biotechnological inventions

##### EGE

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The European Group on Ethics in Science and New Technologies, Opinion on the ethical aspects of patenting inventions involving human stem cells, 5-7, 2002

##### COM

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COM (93)700 Final Commission Communication to Parliament and Council, *Community Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21<sup>st</sup> century*

Commission's Press Release Patents: Commission sets out vision for improving patent system in Europe, Reference IP/07/463, available at: <http://europa.eu/rapid/pressReleaseAction.do?reference=IP/07/463&language=EN>

European Commission, State of Play of the Implementation of Directive 98/44

COM *The communication from the Commission to the European Parliament and the Council –Enhancing the patent system in Europe*, Brussels, COM (2007) p. 3, available at: [http://ec.europa.eu/internal\\_market/indprop/docs/patents/strategy\\_en.pdf](http://ec.europa.eu/internal_market/indprop/docs/patents/strategy_en.pdf)

SEC (91)/629 Communication from the Commission to the European Parliament and Council: Promoting the Competitive Environment for the Industrial Activities based on Biotechnology within the Community and COM (93) 700 final Growth, Competitiveness and Employment: the Challenges and Ways forward into the 21st Century White Paper from the European Commission to the Council of Ministers.

The Group of advisers to the European Commission, Opinion of 25 September 1996

## **CP**

Common Position EC No.19/98 of the European Parliament and the Council of the EU (1998) O.J. C110/17-34.

Common Position (EC) No. 19/98 adopted by the Council on 26 February 1998 with a view to adopting Directive 98/44/EC

## **RES**

Resolution of 26th October 2005. The resolution welcomes the decision of the OD in the Edinburgh case and “Insists that the creation of human embryonic stem cells implies the destruction of human embryos and that therefore the patenting of procedures involving human embryonic stem cells or cells that are grown from human embryonic stem cells is a violation of Article 6(2)(c) of the Directive;” at para. 14. P6\_TA(2005) 0407.

### **7.1.1 Germany**

Act ensuring protection of embryos in connection with the importation and utilisation of HESCs, Gesetz zur Sicherstellung des Embryonenschutzes im Zusammenhang mit Einfuhr und Verwendung menschlicher embryonaler Stammzellen (StZG), 28.06.2002, at <http://bundesrecht.juris.de/stzg/index.html>

Gesetz zum Schutz von Embryonen (ESchG) 01.01.1991, available at: <http://bundesrecht.juris.de/eschg/index.html>.

### **7.1.2 UK**

UK Patent Office Policy in a Practice Notice  
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