European Master's Degree in Human Rights and Democratisation

E.Ma Thesis

Cloning's cyclone: Therapeutic cloning and the Right to Enjoy the Benefits of Scientific Progress and its Applications

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Academic Year: 2010-2011

2nd Semester University: Irish Centre for Human Rights at the National University of Ireland (Galway, Ireland)

Thanks to:

Prof. William Schabas for his helpful supervision and for being a constant source of inspiration.

Hasan Hatzioglou for his unconditional support, his encouraging words, and for being always there for me.

Abstract:

This dissertation addresses the multidimensional controversial question of whether the method of therapeutic cloning is abusive as to the right to enjoy the benefits of scientific progress and its applications. While therapeutic cloning promises the cure for incurable diseases and many patients around the world have placed their hopes on that method, several social groups are opposed to this technique because of the use of embryos, claiming that the embryos' human dignity and also its right to life is at stake. However, the provisions envisaged in international human rights instruments regarding the notion of dignity, as well as the position of the embryo as to its use in biomedical research remain vague. The conceptualisation of scientific freedom in terms of scientific research as well as its limitations within the frame of the right to enjoy the benefits of science is rendered a necessity in order to define whether therapeutic cloning is an abusive medical method with regard to the right to enjoy the benefits of science. Meanwhile, patients' right to health as well as their right to enjoy the applications of therapeutic cloning in the future, is based on the continuation of scientific research on this specific biomedical field.

Table of Contents

ACRONYMS

CoE	Council of Europe
EU	European Union
ESC	Embryonic Stem Cells
Ibidem.	"The same place" referring to the note immediately preceding.
ICESCR	International Covenant on Economic, Social and Cultural Rights
Idem.	"The same place" referring to the note immediately preceding.
IVF	In vitro fertilization
ISSCR	International Society for Stem Cell Research
OHCHR	The Office of the United Nations High Commissioner for Human Rights
REBSPA	Right to Enjoy the Benefits from Scientific Progress and its Applications
SCNT	Somatic Cell Nuclear Transfer.
Supra	"The same as" referring to a preceding note.
UDHR	Universal Declaration on Human Rights
UNESCO	United Nations Educational, Scientific, and Cultural Organization
UN	United Nations
WHO	World Health Organisation

CLONING'S CYCLONE:

THERAPEUTIC CLONING AND THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS AND ITS APPLICATIONS

INTRODUCTION AND OBJECTIVES

The first cloning of a mammal in 1996 led to major controversies in the scientific community. The cloning of Dolly has created interest in cloning human embryos for therapeutic purposes. The first announcement of such an effort was made in October 2001, in the Institute of Advanced Cell Technology in Worcester. Even though four human embryos were unsuccessfully cloned, the technique generated great expectations for the future cure of incurable diseases. Ever since, there has been huge controversy worldwide implicating biologists, doctors, ethicists, and consequently legal science.

The central question I want to address in this dissertation is whether the method of therapeutic cloning constitutes an abuse of the right to enjoy the benefits of scientific progress and its applications. The issue of whether limits should be imposed on the freedom of scientific inquiry with regard to therapeutic cloning will be examined.

People suffering from debilitating diseases have placed their hopes on this method. The so far advancements are very encouraging and if this technique proves to be fruitful, it will be one of the most revolutionary of all times. According to the scientific community, cures for many diseases like diabetes, Parkinson's disease, Alzheimer's disease and many others, as well as afflictions such as strokes, will be found only through stem cell cloning. On the other hand, therapeutic cloning is socially a very divisive issue. Ethical thinkers supporting the traditional family values call therapeutic cloning "destructive" cloning. They claim that therapeutic cloning is the cloning of an embryo to research its stem cells and even if this is happening in the hopes that it will provide treatment for diseases, it still kills the embryo once it has the stem cells to do its

research. However, there are many controversial views surrounding this issue, all of them with strong argumentation.

The whole controversy will be explored principally within the Right to Enjoy the Benefits of Scientific Progress and its Applications. Nevertheless, following the fundamental principle that human rights are interrelated, indivisible and inalienable, references to other human rights such as the right to health and the right to life, where necessary, will not be excluded. This thesis will further argue that therapeutic cloning is a method which should implicate the right to enjoy the benefits of science and also that it could play an important role in the enforcement of this barely implemented right.

Part one of the thesis aspires to introduce the non-specialised reader to what stem cell research consists of. The detailed explanation of the method of therapeutic cloning aims at providing as much scientific background as possible in order to support the argument that therapeutic cloning is a promising method for which it is worth implicating the right to enjoy the benefits of science. However, in this part there will be highlighted some technical difficulties of the technique, which concurrently consist of controversial ethical issues, such as the increased need for oocytes and thus, the position of women as oocyte donors. What follows is the presentation of the main alternative research proposals to the method of therapeutic cloning, in order to clarify the picture on whether it can be replaced by another technique and to what extent. Additionally, this part will be dealing with the terminology related to the technique of therapeutic cloning, which is also an interesting part of the controversy.

Part two of the thesis will explore the legal status with regard to therapeutic cloning. There will be an extended reference to the effort of the Council of Europe to regulate the whole issue through the so called Oviedo Convention and especially to the margin of appreciation its controversial article 18 leaves. This led to a variety of interpretations by the member-countries which ratified the Convention. Additionally, UNESCO's position towards therapeutic cloning as well as the Universal Declaration on Human Cloning will be examined. What follows is the discussion of a European case law, coming from the European Court of Justice, whose final judgment is pending and deals

with a patent case concerning stem cell research. It has already created reaction due to the fact that, depending on the final decision, it might decisively impact upon the legislation regarding stem cell research as well as the regulation of the moral and legal status of the embryo across Europe.

Part three of the thesis will discuss the scientific freedom as envisaged in the Right to Enjoy the Benefits of Scientific Progress and its Applications. To begin with, there will be an attempt to define the term scientific freedom in general as well as its input to the realisation of the right to enjoy the benefits of science. In the effort to define scientific freedom, references to international human rights documents are used, whilst the challenge to define scientific freedom is presented, especially in relation with its conceptualisation regarding the freedom of scientific research in the specific field of stem cell research. Furthermore, the notion of scientific freedom within the frame of the right to enjoy the benefits of science is examined, in particular as interpreted in the Venice Statement, with the aim of highlighting the limitations imposed on the right of scientific freedom as to the method of therapeutic cloning. The discussion is steered towards elaborating on the question of whether therapeutic cloning falls into these cases of medical research that are considered abusive as to the right to enjoy the benefits of scientific progress and its applications.

Part four of the thesis constitutes an effort to present the main aspects of the multidimensional controversy surrounding medical research using the method of therapeutic cloning. The core of the controversy consists mainly of the position of the embryo in medical research as well as the definition of its moral status. A variety of views regarding this issue are discussed in an attempt to highlight the ethical grounds on which the controversy is mostly generated. Furthermore, the position of the patients suffering from debilitating diseases is presented as to the method of therapeutic cloning in a human rights context. That is, the dissertation argues that even if they are the most "invisible" part of this controversy, patients could invoke their right to enjoy the benefits of scientific progress and its applications, in an interrelation to their right to health.

What follows is the presentation of a series of observations with regard to this multidimensional controversy, indicating the main conclusions reached.

CHAPTER 1

THERAPEUTIC CLONING, A METHOD FULL OF CONTROVERSIES

1.1. Therapeutic cloning

According to Einstein, nothing can stop the evolution of science. Neither tradition, nor religious and social prejudices, not even the tremendous human fear of the unknown will ever block a procedure which was triggered by the very elements of evolution. Einstein's certainty, but also the sweeping impact of science on everything the insecure human being has created in order to cover the vanity of our existence, is a topical issue because of the latest advancements in therapeutic cloning. Prevalent views on cloning are characterized by lack of differentiation and by a social perception which is rather emotional than scientifically documented. In general, there is one view which supports cloning as part of the scientific evolution and also supports the scientific and research freedom which cloning entails, and another, which demonizes cloning, considering it the first step towards the catastrophe of humanity. In reality, there are two kinds of cloning: cloning which aims at the creation of human beings (reproductive cloning) and cloning of human embryos for research and therapeutic reasons (therapeutic cloning).

What will follow is a detailed definition and a further explanation of the technique of therapeutic cloning. Since this human rights dissertation addresses a biomedical issue, I consider it highly significant to provide as detailed as possible a documentation of every possible aspect of the issue from a scientific perspective in order for the method to be understood easily by the non-specialised reader. The stem cell world and more specifically therapeutic cloning and all similar or alternative methods are not easily understood by a wide readership. However, it is indispensable for the reader of my study to be able to consult the first chapter while reading the rest of the dissertation in order to have a clear picture of the method. The method itself is quite complex and could turn out to be chaotic for the non-specialised reader. Consequently, in order to avoid any misunderstanding, as well as to offer an overall picture of this very controversial issue that constitutes a social and bioethical cyclone, I consider the detailed explanation of the method indispensable. Moreover, in order to provide the opposing viewpoint and elucidate objections to the method, I consider the reference to alternative methods extremely important. The exposition of the controversies surrounding the terminology highlight the depth of the controversy and will further contribute to this study as a point of reference.

1.1.1 An approach to the stem cell world

What do a diabetical patient, a paralysed man after suffering a car accident, a woman lying in a hospital bed after a heart attack and a man walking around with rigid movements and tremors have in common? They have placed their hopes in the stem cell research, that stem cells may help them to regenerate tissues in their bodies. Regenerative medicine is a well promising scientific area and is expected to drastically improve treatments in the future as understanding of stem cells continues to improve.[1]

A stem cell has two basic characteristics that make it unique comparing it with other cell types: Firstly, it has the ability to continuously grow up and proliferate, maintaining a pool of cells just like itself, for possible future use. Secondly, it can differentiate into a particular specialized cell type, such as muscle or blood cell.[2] Some stem cells have more abilities; this flexibility is termed potency of the stem cell. A stem cell that is unipotent can form only one differentiated cell type. A multipotent stem cell can form multiple different cell and tissue types. A pluripotent stem cell can form most or all of the almost 200 or more differentiated cell types in the human body. A totipotent stem cell can form not only all adult body cell types, but also the specialized tissues needed for development of the embryo, such as the placenta.[3]

Embryonic stem cells are pluripotent and they are retrieved from an early stage embryo. They have an amazing ability for prolonged growth and self renewal. With regard to their capacity of differentiation, scientists have been able to directly differentiate these cells into many unique cell types, such as heart, nerve, immune, skin, etc.[4] . Because of the fact that they have this unique capacity of being developed into blood, muscle or many other kinds of the organs of the body, they are described as "blank"[5] cells. The main benefit to gain is the creation of tissue genetically identical to the gene donor. At present, when someone is receiving a transplant tissue, his body is trying to expel the transplanted cells, because it considers them "foreign" body. Doctors suppress this immune response by administering the patient strong drugs during all his life. On the contrary, cells originating from stem cell cloning will not face the same problem. They will be coming from the patient himself and the immune system will be recognizing them as its own.[6]

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[1] Cloning and Stem Cells, Produced by the Centre of Genetics Education, Fact Sheet 26, p.4 para. c, 2007.
[2] Davor Solter, 2005, p.3.
[3] MedicineNet website. Also, Human Cloning, *Ethical Issues*, Explanatory brochure, 2004, p.15.
[4] Human Cloning, *Ethical Issues*, Explanatory brochure, 2004, p.12.
[5] Idem.
[6] Explore Stem Cells website, "Why Are Stem Cells Important".

Embryonic stem cells (ESCs) were first isolated from the blastocyst stage of development in 1998.[7] This evolution was considered a real breakthrough and filled with hopes the scientific community, focusing on direct use in patients. However, being a scientific announcement in the field of biomedicine, following the panic that the cloning case of Dolly had caused two years before, caused controversial reactions and to the non experts more fear than excitement, depending on how media spread the word. The included word "embryo" in the term embryonic stem cells causes reaction in itself.

Returning to the features of ESCs, it should be noted that once scientists isolate these cells, we call this an embryonic stem cell line. These cell lines are continually growing and dividing. To keep them in a pluripotent, undifferentiated state, the cell line needs to be carefully cared for. Millions of ESCs are derived from the original 30 cells after several months of replating. Removing the inner cells destroys the embryo and that is why research on ESCs is so controversial. However, scientists continue to search for ways to derive ESCs without damaging the embryo. Independently, nevertheless, of how these cells have derived, some embryos have been, and will be destroyed during the scientific discovery process.[8] Another area of study using the knowledge coming from the ESCs is the examination of genetic abnormalities and/or environmental effects on differentiation for the purpose of prevention and treatment.[9] However, for more complex genetic diseases, scientists could use the genetic material from a person with that complex disease to make a new, unique ESC line[10] (this is therapeutic cloning and will be further discussed in the following paragraphs).

1.1.2 Possible uses of the Embryonic Stem Cells

Great hopes for the possible application of ESCs have been placed in regenerative medicine.[11] ESC derived tissue could provide an unlimited supply of tissue, which is impossible in light of the existing therapies. For example, some diseases are caused by loss or dysfunction of only one or few cell types, such as the case of diabetes, that insulin-producing pancreatic cells do not function,[12] or Parkinson's disease, that dopamine producing neurons are lost.[13]Scientists envision injecting a few ESC-derived pancreatic cells or neurons into the area in which they are needed and allowing the body

[7] "In 1998 James Thomson (University of Wisconsin -Madison) isolated cells from the inner cell mass of the early embryo, and developed the first human embryonic stem cell lines. In 1998, John Gearhart (Johns Hopkins University) derived human embryonic germ cells from cells in fetal gonadal tissue (primordial germ cells). Pluripotent stem cell lines were developed from both sources". God and Science - *History of the embryonic stem cell research*.
[8] Pluripotent Stem Cells, Explore Stem Cells website.
[9] Martin Evans, 2005, p.98.
[10] The Science Advisory Board, "Scientists on Science: The Cloning Controversy", 2004.
[11] Bernardo Nadal-Ginard, Piero Anversa, Jan Kajstura and Annarosa Leri, 2005, p. 142-149.
[12] Causes of Diabetes, Los Angeles Chinese Learning Centre website.
[13] Parkinson's Disease Causes, Holisticonline website.

to direct regeneration.[14] Moreover, with the method of therapeutic cloning, these cells could theoretically be customized to an individual to avoid immune rejection.[15]For example, if someone suffered a heart attack, scientists could take some of his DNA from, say, a skin cell and make new ESCs that contain his genetic material. These cells would be differentiated into heart cells and could be used to repair his damaged heart!

Apparently, there is still much to be learned. It is worth-mentioning that Geron, a company working to cure spinal cord injuries, surprised many when on March, 2008, decided to seek US Food and Drug Administration (FDA) approval to begin injecting ESC-derived cells into humans. It was the first company to have asked the permission to proceed with human clinical trial of embryonic stem cell-based therapy. As of July 2010 the corporation is free to proceed.[16]

1.1.3. Therapeutic cloning

Therapeutic cloning or research cloning, involves cloning to produce embryonic stem cells for medical therapies. ESCs are proving to be valuable, as discussed above. The idea of therapeutic cloning is to provide therapies for patients who suffer from debilitating diseases such as diabetes, Parkinson's disease and so forth, using ESCs. By performing Stem Cell Nuclear Transfer (SCNT)[17] with an enucleated egg, a cloned embryo of the patient is produced. Instead of implanting the embryo into a womb, (this would be reproductive cloning, that is, the aim is to gestate the embryos into full-grown human beings), ESCs are derived from the blastocyst stage and grown in vitro. Theoretically, these cells would be a perfect tissue match, getting around the problem of transplant rejection.[18] It should be noted that even if the cloned ESCs have not been used in patients yet, the technique is still a powerful one for basic research. As it will be discussed later in this study, the distinction between basic research and technological applications is highly important as regards the protection of the right to scientific research and further the right to enjoy the benefits of scientific progress and its applications. Examples of therapeutic cloning benefiting in basic research are the exploration of the molecular mechanisms that cause many inherited diseases[19] and the use of cloned cells in order to test drugs in pharmacology.

It is worth mentioning that in January 2008, Stemagen Corporation in California, suggests that therapeutic cloning is may be closer to reality in humans. They announced

[14] Anders Bjorklund , 2005, p.174-184.
[15] National Human Genome Research Institute webpage.
[16] Geron Corporation webpage.
[17] An explanatory image will follow.
[18] Devolder Katrien, The Stanford Encyclopedia of Philosophy, 2010.
[19] Scientists could derive various ESC lines from individuals with genetic diseases and watch exactly how these differentiated cloned cells function compared to normal cells.

that for first time in the world they created a human embryo in the blastocyst stage using SCNT. Dr. Samuel Wood, who was one of the donors of the cells from which the embryos were created, stated that: "This achievement is a critical milestone in the development of patient-specific embryonic stem cells for human therapeutic use, potentially including developing treatments for Parkinson's, Alzheimer's and other degenerative diseases".[20] The Pandora's Box, which was already open since the birth of Dolly, the first mammal cloned from an adult body cell, re-opened, causing again controversy or even panic. Patients suffering from debilitating diseases hoped that a big step forward is already done, scientists, even the most skepticists saw a new era arise for therapeutic cloning and ethicists posed again crucial questions as to the moral status of the embryo. Among the many issues raised concerning therapeutic cloning is the fact that many eggs or oocytes are needed in order the technique to become successful.

[20] Stemagen First to Create Cloned Human Embryos from Adult Cells, 2008. Also, Dr. French, 2008, pp.485-493.

Also, Dr. French, lead author, and five other researchers published their findings in the online research journal *Stem Cells*, in an article entitled "*Development of human cloned blastocysts following somatic cell nuclear transfer (SCNT) with adult fibroblasts",* Volume 26, Issue 2, pp.485-493, 17 January 2008.

[21]

[21] Whitehead Institute for Biomedical Research, "How therapeutic cloning might work".

1.2. The need for oocytes

Eggs are necessary to make clones. However, it takes more than one egg to make a clone. Even just to get the clone to the blastocyst stage, where stem cells can be harvested requires many eggs. At best, the current success rate to clone a human embryo to the blastocyst stage from a pool of eggs is approximately 10%.[22] With the current technology, many human eggs will be needed. Who will donate these eggs? How will the egg donation affect upon the women's health, status and well being? And what about the issue of the undue inducement of women? The effect of financial compensation and other offers for the women who will donate eggs raises additional ethical and human rights issues.[23]

1.2.1. Ethical issues related to oocyte donation

One of the most important issues with regard to egg donation is what model of informed consent would be applied. The duty of warning the patient of the possible risks to their health and well being is highly important as to the non violation of the donor's human dignity. Article 6 of the Universal Declaration on Bioethics and Human Rights states that "Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice"[24]. With regard to the informed consent there are also opposed voices, such as that of Katrina George[25] claiming even that "it is not entirely accurate to speak of "informed consent", when there is a lack of independent assessment about the long term health risks of egg harvesting". It is important, also, that the women donors of oocytes do not derive any benefit themselves, medical or other. With IVF techniques women still undergo the same process but have a chance of 10-40% of producing a baby.[26] Moreover, there is a certain difficulty in categorizing the donating women.[27]They cannot be classified as patients in order to being accorded the status of the IVF patients, which constitutes a form of discrimination, since women in both cases undertake the

[22] This rate is based upon Stemagen's announcement regarding SCNT to produce cloned human blastocysts.
[23] Supra no.18.
[24] See Annex 1.
[25] Katrina George is a lecturer in the School of Law, University of Western Sydney. Her main research interests are in health law and ethics, particularly end-of-life decision making and feminist approaches to bioethics.
[26] RBM online, 2007, pp.127-133.
[27] Emily Jackson, 2008, pp.286-302.

same medical risks, such as that of the Ovary Hyper Stimulation Syndrome. Neither can they classified as research subjects, because in therapeutic cloning it is themselves who undertake the risk. In most of other researches, the risk to the donor lies in the research itself. Magnus and Cho have proposed the term "research donors"[28] for those undertaking the risk only for the benefit of others.

Since there is not any great benefit to get –besides perhaps some psychological benefit deriving from altruism-, and also given that there are risks for the donors' well being, but also considering the uncertainty of the future results of therapeutic cloning, there are few altruistic women donors. But, as it is mentioned above, the need remains enormous. A financial incentive seems then more than necessary but it raises high concerns about undue inducement and exploitation of women. Undue inducement to donation of oocytes directly breaches the fundamental human rights principle of dignity. Article 3 of the Universal Declaration on Bioethics defines that dignity is one of the fundamental principles to be fully respected and also in Article 4 states "In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized". Considering these provisions it should be notes that although buying and selling eggs is permitted in many countries, for example in the UK[29], both ethical and human rights issues raise, namely that of commercialization of the woman's body.[30] On the other hand though, it is well justifiable that women donating their oocytes and getting through all this process, including all the possible risks, should be compensated for the inconvenience, as it is standard for other research donors. In that case, it would be difficult to set a price. It is rather difficult to avoid both exploitation and undue inducement. If the price set is high, the undue inducement is almost inevitable, especially among women in developing countries. If the price is too low, then, it can be considered exploitation.[31]

These ethical concerns cannot be eliminated; perhaps they could be minimized if there was applied a regulation concerning the oocytes donation. Some institutes, such as the California Institute for Regenerative Medicine have published guidelines for oocyte donation,[32] but, what is needed is probably an internationally binding regulation. Human rights advocates could highlight the issue and propose a code of conduct after having discussed the issue based both on ethical grounds and on medical facts. A suggestion weighing the increased need for oocytes and the women well being is women undergoing IVF techniques to donate one or two of their oocytes with a reduce fee for their fertility treatment. Given that these women will in any case suffer the oocyte stimulation, make this suggestion seem convenient for all the involved parts. But, in reality, there is again an ethical risk to be assumed. It will be then just the rich

[28] Magnus, D., Cho, M.K., 2005 pp. 1747-8.
[29] Devo Emily Jackson, 2008, pp.286-302.
[30] Supra no.18.
[31] Baylis F., McLeod C., 2007, pp. 726-31.
[32] CIRM Guidelines for Oocyte Donation for Stem Cell Research Review Drafts.

women considering IVF without donating their oocytes. The rest would be obliged, willingly or not to become egg donors. Additionally, it seems to me very unlikely that, women struggling to have a baby, under all the psychological pressure they find themselves as IVF patients, will donate their eggs for research purposes. If therapeutic cloning becomes a tangible reality, perhaps members of the families of sick people could very willingly donate their oocytes for the treatment of their sick relative.

1.3. Alternative research proposals to therapeutic cloning

Therapeutic cloning raises serious ethical considerations related to the use of human embryo. The questions imposed concern the moral status of the embryo. Of course there is a range of viewpoints regarding its status. This issue will be further discussed in part four of this dissertation. Among all participating parts in this debate, scientists have proven to be the less experts when it comes to bioethics, although eager to help the legal science to understand and regulate all the latest biomedical advancements. Researchers are attempting to find alternative sources for ESCs instead of dealing with ethical issues. A problem has been posed to them and their rational thinking leads them to find alternative ways in order to avoid the ethical dilemma of destroying human embryos. What follows is the presentation of some of these alternatives which consist concurrently of some of the latest advancements in biomedicine and biotechnology. The enumeration of some of the most important developments has a double aim. First, at indicating whether there are indeed some alternatives to therapeutic cloning and to what extent these alternative techniques could replace it, so that to supersede the majority of the ethical hesitations; secondly, at empowering the prevalence of the argument that basic research is significantly important regardless of the pursuing of technological applications, and therefore the right to scientific inquiry has to be well protected by international law regulations.

1.3.1 The main alternative proposals

Amniotic fluid-derived stem cells have recently been demonstrating similarities to embryonic stem cells. They show pluripotentiality, which is one of the main characteristics of ESCs, and also, have been differentiated into cells representing all three germ layers, such as muscle, brain and liver cells. Their strong aspect is that although they grow fast like the ESCs they do not show signs of aging or developing into tumors, even after two years of in vitro growth. Their weakness lies in the fact that they may not provide an alternative for all types of research. These cells can be easily

collected from amniotic fluid, as early as 10 weeks after conception or from the placenta at birth.[33]

Many scientific groups focus their investigation on determining what genes must be expressed to make a cell behave like a pluripotent ESC. In 2006, scientists from Japan first described induced pluripotent stem cells. These cells are a type of pluripotent stem cells derived artificially by reprogramming a non-pluripotent cell, typically an adult somatic cell. The great advantage of this method is that there is no use of human embryos. In 2007, scientists announced that they had used the same method to produce human induced pluripotent stem cells from differentiated skin cells. This advancement was cited as a major progress, as it may allow researchers to obtain pluripotent stem cells, which are necessary in research and perhaps for future therapeutic purposes, avoiding the controversy of the use of embryos. However, significant technical challenges may still need to be overcome to apply this technology, since the cancer promoting genes used and the inactivated viruses could generate tumors. Moreover, the induced pluripotent stem cells are not yet ready to be used in transplantation medicine.[34] Scientists keep working on the development of new techniques which would avoid the Another proposal that has been discussed for avoiding the destruction of embryos to obtain ESCs is to remove living stem cells from surplus IVF embryos that are not healthy enough to develop further. Two scientists at Columbia University proposed that some embryos with severe genetic defects that are arrested in development have individual cells that are healthy. However, there are obstacles with regard to that method also, because current technical methods cannot distinguish embryos that are healthy versus those arrested in development versus those that are dead.[35]

1.4. Terminology

The technique of therapeutic cloning has raised tremendous ethical controversy and this is well reflected in the terminology used. Scientists and other social and religious groups seem reluctant to adopt a common language while describing the method of "therapeutic cloning". The terms questioned are the term "therapeutic", the term "cloning" and even the term "embryo" in the context of description of the method. Despite the percentage of people opposed to each of these terms, -smaller or bigger-, it is worth mentioning their arguments because they reveal the depth of the controversy.

[33] Ornella Parolini, Maddalena Soncini, Marco Evangelista & Dörthe Schmidt, pp.275-291, 2009.
[34] 14th Stem Cell Workshop, "Ethics and the regulations for the use of stem cells", University of Sidney.
[35] Free Online Research Papers, "Alternative methods to obtain stem cells- Science research".

1.4.1. The term "therapeutic"

The greater part of the controversy focuses on the term "therapeutic". While this term is commonly used by scientists when referring to the Somatic Cell Nuclear Transfer, pinpointing its future potentials, there are concurrently others who do not accept the term "therapeutic" for the same reasons. That is, they claim that since the method has not proven to be fruitful yet, it is misleading for the society to use a term which implies cure to many diseases. In their opinion, this generates further hope to patients and enhances the perception that it is legitimate to destroy embryos, promising that many lives will be saved and even more sick people will be cured. UNESCO does not approve the use of the term "therapeutic" considering that it is a very positive connotation taking under consideration the non applicability of the method, while suggests the term research cloning.[36] The Science Advisory Board instead uses the term "therapeutic".[37] There are registered more polar views claiming that the term "therapeutic" should not be used since this method will not be therapeutic at all for the destroyed embryo.[38] But then again there is further controversy with regard to the term "embryo".

1.4.2 The term "embryo"

The word "embryo" carries socially a significant emotional burden. Nevertheless, the aim should not be to abolish a specific terminology just to avoid the controversy. The scientific community seems reluctant to set in order its own house, and be consistent to the use of solely one terminology. A possible explanation is that stem cell research turns out to be a huge political and financial issue. Not to forget that stem cell research requires large financial funding and if funding comes from the government, any government, and not from the private sector, then it is easy for the decision-making centres to fall into the pitfall of the political cost.

The controversy surrounding the term "embryo" is definitely related to its moral status and to the protection it deserves. Hansen[39] argues that embryos derived from SCNT do not have the same moral status as the other embryos. He calls the combination of a somatic nucleus and an enucleated egg "transnuclear egg", which, in his opinion, is a simple "artifact" with no "natural purpose" or potential "to evolve into an embryo and

[36] International Bioethics Committee report: The use of embryonic Stem Cells in therapeutic cloning, 2001.
[37] The Science Advisory Board, "Scientists on Science: The Cloning Controversy", 2004.
[38] This view was expressed by a member of the independent Committee (Dr Bridget Vout, executive officer for the Life Office of the Catholic Archdiocese of Sydney) , that Australia appointed in order to review the federal stem cell legislation on 2005. Beran Ruth, "The great divide: therapeutic cloning", Online Australian Lifescientist Magazine, 22 November 2005.
[39] Hansen, J.E., 2002, pp. 86–8.

eventually a human being" and therefore falls outside the category of human beings.[40] Paul Bello, programme manager for biotech company Stem Cell Sciences shares the same view: "embryos created from SCNT are never intended to ever give rise to a human, and I think that's the public's greatest fear".[41] Moreover, according to the (American) National Bioethics Advisory Commission (NBAC)[42], there is a moral difference between the IVF embryos and those used for research purposes. The first were created in the hope that they develop into a child and the second for solely instrumental use; these are created to assist the research and as means, they should not enjoy the same moral and legal protection.[43]

However, there are strong opposed views on this issue; some of them oppose only to the use of embryos for research reasons and others consider that killing embryos is wrong even for IVF reasons. The latter oppose also to the use of the surplus IVF embryos for research purposes. As to the correlation of the grade of protection of the embryos deriving from IVF techniques and those exclusively for research embryos, McHugh[44] and Kiessling[45] argue that obtaining stem cells from cloned embryos raises less ethical issues because "embryos" resulting from therapeutic cloning should be thought as human tissues; on the contrary IVF aims at human reproduction and thus embryos resulting from this technique should enjoy higher protection. Additionally, they claim that the terms "embryo" or "zygote" are misleading when they describe the products of SCNT. They suggest terms describing therapeutic cloning should include the words "clonote" or "ovasome".[46]

1.4.3 The term "cloning"

The term therapeutic "cloning" as to the description of SCNT technique is basically questioned because of the social fear it causes reminding subconsciously the case of Dolly as well as all the science fiction scenarios which fed the human imagination presenting clones attacking and destroying the humanity and so forth.

Professor Alan Trounson, head of the Monash Immunology and Stem Cell Laboratories said that the term "therapeutic cloning" is not precise because SCNT does not represent the common perception of cloning and secondly that the focus of the method is not necessarily on therapeutics. He suggests the term Somatic Cell Nuclear Transfer as

[40] Supra no.18.
[41] Beran Ruth, "The great divide: therapeutic cloning", Online Australian Lifescientist Magazine, 22 November 2005.
[42] National Bioethics Advisory Commission, *Issues in Humans Stem Cells Research* in "Ethical Issues in Stem Cell Research", Vol. 1, 1999.
[43] Supra no.39.
[44] McHugh, P.R., 2004, pp. 209–11.
[45] Kiessling, A.A., 2001, p. 453.
[46] Supra no. 18.

more descriptive and contextual to the scientific effort in this specific field.[47] Bert Vogelstein recommends the term "nuclear transplantation" in order to emphasize the distinction in purpose between production of stem cells and "cloning" to produce a copy of a human being. He says that the goal between reproductive cloning and the process of producing stem cells for regenerative medicine is completely different and the term therapeutic cloning is not clear enough and causes misunderstandings.[48]

However, not all experts agree on the use of "nuclear transplantation" term, even if they recognise that the use of sloppy language just to close off all future therapeutic possibilities is not the appropriate way to regulate the terminological issue. For example, Bart Hansen,[49] replying to Pr. Trounson with regard to the "nuclear transplantation" term, claims that this term runs the risk of circumvention of the ethical dilemma concerning the moral status of the embryo. He completely disagrees with Volgestein's statement that "The end product of nuclear transplantation is merely cells grown on a petri-dish". He stated that "nuclear transplantation is a technique that involves two successive steps. First, the procedure includes the (non-reproductive) cloning of the patient's genome, aimed at creating "matched" embryos. Second, stem cells of this embryo are cultured in a petri dish". He also added that "in other words, by merely changing the name of a technique, one will not solve the confusion that has arisen in public discourse about cloning".[50]

It has to be pointed out that scientists[51] are already researching and have outlined the value of the "nuclear transplantation" in order to treat certain human reproductive conditions. That does not blur in any case the distinction between reproductive and therapeutic cloning; however, it is worth mentioning that for example in UK reports and legislation, the terms cloning and nuclear transplantation are one and the same.[52]

It is more than clear, then, that a consistent language would result not only in the benefit of the scientific community which would succeed a better communication among its members but also would promote a better collaboration with the legal science and furthermore would achieve the use of common language with ethicists.

[47] Idem.
[48] Vogelstein Bert, Bruce Alberts and Kenneth Shine "Please, don't call it cloning", Science, 15 February 2002, Vol.295 (no.5558) p.1237.
[49] Bart Hansen is research fellow in the Centre for Biomedical Ethics and Law, Catholic University of Leuven, Belgium.
[50] Bart Hansen, "Terminological ambiguity may lead to ethical obscurity: A European perspective", published 25 March 2002.
[51] Martin H. Johnson, Reference 6 and 7 in "Working words are best", 15 February 2002.
[52] Idem, (the article not the references).

CHAPTER 2

THE LEGAL STATUS WITH REGARD TO THERAPEUTIC CLONING

As the analysis in chapter one indicates, therapeutic cloning is a well promising method which has already offered many exciting scientific developments. On the other hand, it has provoked enormous public discourse. Thus, the legal regulation of the controversies surrounding stem cell research is very challenging. International legal instruments are expected to relate science and human rights and concurrently to offer protection to all involving parts. Therapeutic cloning involves certain bioethical issues, such as the moral status of the embryo, which in turn raises the issue of its legal status. Bioethics have attracted much public attention in the last two decades and appeared in the international law. The debate surrounding therapeutic cloning raises issues such as the discussion on the right to life, the right to research and the interpretation of the fundamental principle of human dignity. The questions related to these issues cannot be answered without the bioethical contribution. Bioethics could extend the catalogue of human rights in new fields. On the other hand, human rights mechanisms could offer bioethics guidance towards a more sufficient enforcement mechanism and international recognition.[53] This part of the dissertation aims at highlighting international legal references specifically related to stem cell research and therapeutic cloning. The first multilateral treaty addressing biomedical human rights issues lies under a rather complicated title: " Convention for the Protection of Human Rights and the Dignity of the Human Being with Regard to the Application of Biology and Medicine, adopted by the Council of Europe in Oviedo, on April 4, 1997: Convention on Human Rights and Biomedicine (hereinafter Oviedo Convention)".

[53] Judit Sandor, 2008, pp.15-28.

2.1 The Oviedo Convention

2.1.1 The main characteristics of the Oviedo Convention

The European Convention on Human Rights and Biomedicine of 1997 is the first multilateral treaty dealing with biomedical human rights issues. Human dignity was the focus of the Convention and was regarded as the fundamental value in biomedicine. Article two of the Convention states the primacy of the human being. One of its most important characteristics is its binding character. It has been signed by thirty-one countries and has obtained 28 ratifications.[54] It is very interesting that the UK, France and Germany have not ratified the Convention for different reasons. While United Kingdom viewed the Convention to be very restrictive, Germany considered it to be too permissive, especially with regard to the controversial issue of embryo research. The Convention's binding character practically means that countries which have ratified it are obliged to introduce legislation in order to conform to the Convention's principles. Furthermore, comparing the Oviedo Convention to "soft-law" agreements developed mainly by UNESCO, such as the Declaration on Human Genome and Human Rights, whose focus is solely on genetics, the Oviedo Convention attempted to link human rights and biomedicine. That is, the Oviedo Convention consists of a great effort to cover extensively the whole domain of bioethics. Nevertheless, it does not provide precise answers nor does it regulate crucial bioethical questions, such as the legal status of the human embryo. It can be considered more as a "framework instrument" containing general principles which are left rather vague in order to be developed in the following years by additional protocols. In fact, there was some criticism on that, arguing that the Oviedo Convention contains rather "rhetorical principles and fails to face the most difficult challenges posed by biomedical advances". [55] In line with these observations stands the ambiguity of article 18, which deals with the controversial issue of embryo research.

[54] As of June 2011.
[55] Andorno Roberto, 2005, pp.133-143.

2.1.2 The controversial article 18

As mentioned-above, the Convention does not adopt a clear stance on the moral and legal status of the embryo. Since the meaning "person" is not clearly defined in the Convention, it depends on every State's interpretation in order to achieve conformity with its own national law. Paragraph one of article 18 states that "where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo". However, it is left vague as a definition what "adequate protection" means and how embryo protection could be compatible with its use as research material. What limits this practice is paragraph two of article 18 which practically prohibits the deliberate creation of fertilized eggs, i.e., the fertilization of eggs aimed exclusively at extracting stem cells, without the intention of a pregnancy. In order to answer the question of this prohibition has been imposed, while the use of surplus in vitro fertilized eggs is permitted according to paragraph one, as long as the relevant legislation offers "adequate protection" to the embryo, it should be noted that moral reservations concerning the surplus fertilized eggs which had been created for reproductive reasons are easier to be dealt. In contrast, when it comes to the deliberate creation of fertilized eggs with the aim of extracting stem cells in order for them to be used for therapeutic reasons, social consensus is difficult to reach, and most of the European legislators seem reluctant to face the social reaction. However, this reluctance should be overcome.

What is left unregulated because of the vague wording of article 18 is whether therapeutic cloning is allowed or not. It is unclear whether the reference to "creation of embryos" in paragraph two, also includes the technique of cloning or not. Various views have been developed regarding this issue. Even the States that have ratified the Oviedo Convention do not follow a common policy on embryo research. It is in general difficult to reach social consensus but when moral issues are involved in public discourse, extreme and passionate views are often triggered. The regulation of the human embryo research is a result of many components. The cultural and religious background of a

country is a contributing factor but also, in some cases, even certain political and social circumstances. It is rather difficult to categorize the reasons why different countries have legislated differently with regard to embryonic stem cell research and therapeutic cloning.

2.1.3 The interpretation of article 18

The regulation of such a controversial issue as stem cell research and further of therapeutic cloning constitutes a challenge for every State's legislator. Most of them have consulted the national bioethics committees of their country. The scientific developments in this specific field are fast and continuous. Researchers consider stem cell research a passionate area of study which probably means that the legal science has to move faster. UNESCO encourages Member States to consider the introduction of legislation regulating therapeutic cloning.[56]

Among the countries[57] which have ratified the Oviedo Convention, we can observe differences as regards the regulation of these contentious issues. For example, in Finland, embryonic stem cell research is permitted. The Medical Research Act of 1999 defines embryo as a fusion of gametes, and thus, therapeutic cloning is permitted as well. In the Czech Republic embryonic stem cell research is permitted, using lines created from unused IVF eggs. However, therapeutic cloning has not been regulated yet. These are random examples among all States that have ratified the Convention. It would be challenging but at the same time perhaps inappropriate to connect countries which follow a similar policy if the correlation between the countries is not based on concrete scientific statistical data resulting from a socio-political investigation in depth. For example, Italy, Spain and Ireland are considered to be countries where religion plays an important role and where the Catholic Church exercises a deep influence on

[56] UNESCO, "National Legislation Concerning Human Reproductive and Therapeutic Cloning", 2004.
[57] The data provided in paragraph 2.1.3 concerning the Member States' legislation on therapeutic cloning and stem cell research are based on UNESCO's document: "National Legislation Concerning Human Reproductive and Therapeutic Cloning", 2004.

the society. All three of them prohibit therapeutic cloning but embryonic stem cell research is permitted only in Spain. I consider it quite risky to jump to conclusions on how and to what extent religious views affect a country's national legislator despite the fact that such an association would be plausible. Another example could be Greece, which is commonly considered to be a rather traditional country whose Constitution does not even establish the separation of State from Church. It belongs to the countries which ratified the Oviedo Convention, and permits embryonic stem cell research. It also allows research on embryos using surplus embryos for therapeutic purposes. As regards therapeutic cloning, the Greek National Bioethics Committee has concluded that it is excluded from the ban of article 18. The same opinion is shared by many legal scientists.[58] However, the law is not absolutely clear on whether therapeutic cloning is explicitly or implicitly permitted. My point is that the vagueness of article 18 of the Oviedo Convention has left a very wide margin of appreciation to the national legislator, who, in turn, shows a certain grade of hesitation in regulating the whole issue.[59]

Meanwhile, as analysed in detail in chapter one, the advancements surrounding therapeutic cloning are rapid. Scientists are eager to help law-makers to regulate the issue but apparently the legal science has to take into account the various social aspects of the controversy. Bioethics is then exactly that, a combination, a synthesis of sciences and social perceptions.

[58] Έφη Κουνουγέρη – Μανωλεδάκη, 2009, σελ.15-27. Βλ. επίσης την Εισήγηση Εθνικής Επιτροπής Βιοηθικής , σελ. 45 επομ. (Efi Kounougeri - Manoledaki, 2009, pp.15-27. See also the Recommendation of the National Bioethics Committee, p.45).

[59] For a detailed list of countries and the relevant regulations consult UNESCO, Division of the Ethics of Science and Technology "National legislation concerning human reproductive and therapeutic cloning", July, 2004.

2.2 The legal status with regard to therapeutic cloning worldwide

Following the observations made in the last paragraph as far as the way the various countries legislate and regulate the controverstial issue of therapeutic cloning, there will be a series of references to what is happening at the same time in the rest of the world. Again, it has to be stressed that this dissertation does not provide any socio-political or ethical background which could justify the selections made by every national legislator or governmental policy regulating the controversial issue of therapeutic cloning. The purpose is to highlight the magnitude of this controversy, which has implicated almost every single country globally, and to provide some relevant information on how the method of therapeutic cloning is legally regulated worldwide.

2.2.1 Some examples in the Americas

This informational "journey" will start from the USA, not because of it being a super-power but because stem cell research has been the issue of an enormous debate between President Bush and president Obama and their respective electoral campaigns. The case was the federal funding and has attracted considerable public attention. It should be borne in mind that stem cell research is a very expensive method and also that the whole issue was one of the main contradictory pre-election themes between the Democrats and the Republicans in the elections of 2008. Officially, embryonic stem cell research, therapeutic cloning but even reproductive cloning are permitted, as there is no federal regulation overseeing it. However, some individual states have legislated on their behalf against reproductive and/or therapeutic cloning.

In Canada, embryonic stem cell research is allowed but therapeutic cloning is forbidden. Researchers can use an embryo from IVF if it is no longer needed for reproductive

purposes and consent is given by the donor.[60] Panama, Argentina, Brazil, Chile, and Peru allow embryonic stem cell research but prohibit therapeutic cloning. In Costa Rica, Trinidad and Tobago, El Salvador, and Ecuador both therapeutic cloning and embryonic stem cell research are banned. Colombia and Uruguay are two examples of permitting both of them.[61]

2.2.2 Asia

To begin with, in China, India, Japan, Singapore, South Korea and Thailand, both embryonic stem cell research and therapeutic cloning are permitted. However, in Japan, according to the Bioethics Committee of the Council for Science and Technology Policy, production of cloned human embryos is limited to basic research or regenerative medicine only. In Singapore, the law allows the extraction of stem cells from cloned human embryos, but it bans cloned embryos from developing for more than two weeks. Also, it should be noted that in Taiwan (Republic of China), therapeutic cloning as well as the creation of embryos for research purposes is prohibited while embryonic stem cell research is allowed on excess stocks of embryos produced naturally for artificial insemination.[62]

The purpose of the enumeration of the above-mentioned examples is not to provide an exhaustive list[63] of the Asian countries and the respective legislations, but to give a general idea.

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[60] UNESCO, "National Legislation Concerning Human Reproductive And Therapeutic Cloning", 2004. See also Kirstin Mathews, "World Cloning Policies", 2007. The same documents are used as sources to extract information on the legislation regarding therapeutic cloning as far as he following mentioned countries is concerned.

[61] Idem.

[62] Ibidem.

[63] For a comparative overview of the regulatory approaches to therapeutic cloning across 16 countries from all continents see the report of Isasi and Knoppers, "National regulatory frameworks regarding human cloning for reproductive and therapeutic research purposes", University of Montreal, Canada, August 2006.

2.3 United Nations and UNESCO on therapeutic cloning

Therapeutic cloning and in general stem cell research is a scientific field where human rights are called to play a pivotal role. International leading human rights organisations need to bridge the gap between the very contradictory aspects of the issue. The right to research, the right to life and the extent to which embryos used in stem cell research could implicate this right, as well as the rights to health and also to enjoy the benefits of scientific progress are all crucial issues , interrelated, which need further to be addressed and regulated.

2.3.1 UNESCO's position

In October 2005, UNESCO adopted the Universal Declaration on Bioethics and Human Rights. This was the first time that Member States had committed themselves to following and respecting the fundamental principles of bioethics. International human rights are enshrined in the Declaration on Bioethics, and Member States are called upon to make every effort in order to ensure the follow-up of the principles set out in the Declaration. It has to be recalled that UNESCO has dealt with bioethical issues also in previous documents, such as in the Universal Declaration on the Human Genome and Human Rights in 1997 and in the International Declaration on Human Genetic Data in 2003 providing ethical guidelines.

The Declaration on Bioethics and Human Rights stresses the importance of scientific research and concurrently points out that technological and scientific developments should occur "within the framework of ethical principles set out in the Declaration".[64] However, these principles that need to be followed are quite general. One of the main arguments of those opposing therapeutic cloning is the lack of protection of the embryo.

[64] UNESCO, Universal Declaration on Bioethics and Human Rights (SHS/EST/BIO/06/1), 2006, art. 2(d).

That is, that the embryo's right to life is violated. This argument is based on a series of personal and/or religious convictions. The controversy surrounding the beginning of life is multi-dimensional and implicates not only a variety of bioethical views but also different scientific perceptions. This is an issue which will be further analysed in this dissertation in chapter four. However, it is important to stress at this point that the Universal Declaration on Bioethics and Human Rights does not specifically address the issue of when the embryo becomes a "person" in legal and ethical terms. Like other legal instruments , such as for example the above-mentioned Oviedo Convention, it fails to indicate and further to regulate this focal point, i.e., when exactly embryo becomes a person and consequently acquires rights.

What prevails in all UNESCO documents concerning bioethics is human dignity as the dominant fundamental principle, which is to be fully respected.[65] And whilst UNESCO has decisively concluded on reproductive cloning, stating that "practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted",[66] there is considerable reluctance to reach definite conclusions as to whether therapeutic cloning is contrary to human dignity and on what grounds. Nevertheless, in 2001, a Round Table was organized at UNESCO Headquarters, composed of 101 Member States' science ministers to discuss bioethics. The participants supported the "imperative of freedom of research" but they encouraged the scientists to anticipate the problems occurring from the scientific developments rather than face them after the fact. They also concluded that "bioethical standards must be based on the practice of democracy". That is considered to be in line with the report published by UNESCO's International Bioethics Committee on "The use of Embryonic Stem Cells in Therapeutic Research".[67]

However, it is important to stress that UNESCO does not accept the term "therapeutic cloning", considering it inappropriate because of the positive meaning the notion

[65] UNESCO, Universal Declaration on Bioethics and Human Rights (SHS/EST/BIO/06/1), Preamble and art.3 par.1, also, preamble of UNESCO's Constitution "…the democratic principles of the dignity…", also Universal Declaration on the Human Genome and Human Rights, art. 1-4.
[66] UNESCO, Universal Declaration on Human Genome and Human Rights, art. 11.
[67] UNESCO, "Human Cloning, Ethical Issues", Explanatory brochure, p.16.

"therapeutic" carries, and suggests instead the term "research cloning".[68] Although that seems to be merely a linguistic issue of minor importance, it shows a tendency for UNESCO. That is, UNESCO does not seem willing to adopt a clearly supportive position on therapeutic cloning unless there is enough tangible medical evidence proving the benefits of the method which in turn, perhaps, would bend the majority of the social hesitations. Despite the so far major achievements as regards stem cell research, one of the arguments of the opponents, at least of the most moderate, is that the method is not yet applicable, and thus, they would not consent to embryonic research without real practical benefit existing for sick people.[69]

Moreover, in accordance with the ethical restraints UNESCO's International Bioethics Committee has suggested, research on embryos would be "clearly unethical" if it were for non medical purposes. And also, "if the research persisted beyond the very early stages[70] of embryonic development".[71]

2.3.2 The United Nations Declaration on Human Cloning

The Declaration adopted by the United Nations (UN) on 8 March 2005 has a special interest with regard to therapeutic cloning. Among its main provisions stands the prohibition of all forms of human cloning "as they are incompatible with human dignity and the protection of human life". [72]It also prohibits any genetic engineering techniques "that may be contrary to human dignity".[73] Nevertheless, the Declaration does contain a certain ambiguity as regards therapeutic cloning, and leaves it to the States to decide whether therapeutic cloning is compatible with human dignity or not and legislate accordingly. Several delegations had stated their regret for not having achieved

[68] Idem. p.11.

[69] See chapter 1 of this dissertation, 1.1.1- 1.1.3.

[70] As such is considered to be up to 13 days after fertilization.

[71] UNESCO, "The use of embryonic Stem Cells in therapeutic research", International Bioethics Committee report, 2001, p.12.

[72] United Nations Declaration on Human Cloning (A/RES/59/280), 8 March 2005.

[73] Idem.

consensus and they added that since reference to "human life" could be interpreted as a complete ban not only on reproductive but on therapeutic cloning too, they preferred to vote against.[74] 84 countries voted in favour, 34 against and 37 abstained.[75] A quote from the then Health Secretary of the UK indicates the political atmosphere after the adoption of the Declaration: "The UN declaration is non-binding and will make no difference whatsoever to the position of stem cell research in the UK: therapeutic cloning will continue to be allowed".[76] As most of the countries stated after voting, it was essential that reproductive human cloning be prohibited and this opportunity was lost due to the ambiguity of the text. Despite the fact that the UN Declaration on Human Cloning is a political statement and does not produce direct binding results, it reflects the reluctance to regulate the whole issue. The attempt to weigh human dignity and cloning has failed once more, mainly because of the blending of the two forms of cloning, therapeutic and reproductive. What was highlighted behind the scenes was the magnitude of the divergence of views and consequently of the followed policies by the Member States with regard to therapeutic cloning. The notions of dignity and human life, although used in the draft, were not specifically defined nor were they clearly related to therapeutic cloning.

2.4 The patent case – perhaps a milestone

A very challenging case[77] is triggering the legal regulation of stem cell research, of therapeutic cloning and also of the moral and legal status of the embryo in Europe. Scientists and researchers, ethical thinkers but perhaps most importantly patients coming from Europe who are suffering from debilitating diseases are waiting for the European Court of Justice decision on a stem cell patent case which is expected to have a far-reaching impact. In March 2011, the Advocate General of the European Court of

[74] UN, Press release GA/10333.
[75] Idem.
[76] The Guardian online edition, 09 March 2005.
[77] European Court of Justice C 34/10 Brustle v Greenpeace.

Justice concluded on a legal debate commenced several years ago in Germany on a patent case. In his opinion, patenting on applications using embryonic stem cells will be prohibited on moral grounds.[78] If the Court follows his suggestions, the funding of the embryonic stem cell research will be at stake and eventually the European governments' s policies concerning therapeutic cloning and in general stem cell research are expected to tighten and become more restrictive. Scientists are alarmed and there were major reactions.

2.4.1 The story

Mr.Brustle, the director of the Institute of Reconstructive Neurobiology at the University of Bonn in Germany holds a patent filed in 1997 concerning precursor cells[79] derived from embryonic stem cells used for the cure of neural defects. In fact, according to Mr. Brustle, there have been already clinical applications for patients suffering from Parkinson's disease. In 2004, Greenpeace challenged the patent claiming that the derived cell lines were "contrary to public order" because of the destruction of human embryos and also that the patent breached guidelines as set out in the European Patent Convention. In 2006, the German Patent Court ruled in favour of Greenpeace, so, Mr. Brustle appealed in the Federal Court of Justice, which, in turn decided to ask the European Court of Justice on the interpretation of the term "human embryo". The latter is not defined in the Directive on the legal protection of biotechnological inventions.[80] The most important question was whether the exclusion of the embryo from patentability concerns all stages of life from fertilisation or not.[81]

[78] Emma Kemp, "Open letter: stem cell patent case would have far-reaching impact", 28 April 2011.
[79] i.e. immature body cells which are still able to multiply. These precursor cells have the capacity to develop and differentiate into specific mature body cells.
[80] Directive 98/44/EC, 6 July 1998, OJ 1998 L 231, p.13.
[81] European Court of Justice, Press release No 18/11.

2.4.2 The recommendations of the Advocate General

The Advocate General begins his legal analysis by pointing out two things; first, that it is necessary for the embryo to have an autonomous definition in EU law, given that the harmonisation of the legal protection of the biotechnological inventions is the main objective of the Directive and secondly, he recognises the considerable divergence as regards the legislation across Europe as well as the sensitivity of the question posed including all the financial, cultural, moral and philosophical ramifications.

It is important to recall at that stage that article 5(1) of the directive protects "the human body, at the various stages of its formation and development". The Advocate General stated that totipotent cells, since they are capable of developing in a complete human being, "must be classified as embryos, the patentability of which must be excluded".[82] He also classifies the blastocyst stage of development as embryo. On the contrary, pluripotent embryonic stem cells which are not longer capable of developing into a complete human being[83] are not classified as embryos. These are the cells used by Mr. Brustle in his patent. However, according to the Advocate General "inventions relating to pluripotent stem cells can be patentable only if they are not obtained to the detriment of an embryo, be that it's destruction or its modification".[84] Moreover, he considers that even if a process does not contain any reference to the use of human embryos, if embryos have been destructed or used as base material, the invention cannot be patentable.[85] These are the main limitations he sets out in order to define the term "human embryo" but also in order to interpret the principle of human dignity as referred in the above-mentioned Directive 98/44.[86]

[82] Idem.
[83] See Chapter 1 of this dissertation paragraph 1.1.1.
[84] European Court of Justice, Press release No 18/11.
[85] Idem.
[86] Directive 98/44/EC, 6 July 1998, art.5 and 16th recital.

2.4.3 The reactions

Leaders of major stem cell projects –both embryonic and adult stem cells- in Europe and other biomedical experts directed an open letter published in the journal Nature pointing out the dangers for the non-continuation of the medical research in case the European Court of Justice makes a final binding ruling based on the recommendations of the Advocate General.

The experts addressing the open letter claim that "Embryonic stem cells are cell lines, not embryos". Also that "they are derived using surplus *in vitro* fertilized eggs donated after fertility treatment and can be maintained indefinitely".[87] They stress the importance of the biomedical industry in order to deliver clinical benefits and they argue that companies would never invest in Europe if they do not have patent protection as an incentive. Thus, they conclude, a decision following the General Advocate's recommendations would be a negative milestone, which would mark the end of years of effort concerning the scientific field of pharmacology and cell-replacement therapy.[88]

The International Society for Stem Cell Research (ISSCR) which represents 3800 scientists, both ethicists and clinicians reacted also and issued a statement where their strong concern is expressed. In the statement it is stated that a binding ruling prohibiting the patenting of embryonic stem cells applications would dramatically affect the policies in European Union concerning stem cell research and it would further "impede the development of new therapies from human embryonic stem cell research and related avenues of medical research".[89] The ISSCR highlights the fact that embryonic stem cell research is considered to be one of the most promising areas of biomedicine and also that it is necessary a broad international consensus on the standards used in embryonic stem cell research so as the latter to be exercised on ethical grounds.[90]

[87] Austin Smith, 2011, p.418.
[88] Idem.
[89] ISSCR, Statement, 12 April 2011.
[90] Idem.

The protection of intellectual property rights is undoubtedly critical as regards medical research. There would not be any development in producing techniques, devices and drugs without the guarantee of the protection of intellectual rights. The European Court of Justice is expected to decide within the next weeks and its decision will definitely affect European Member States in a multilevel way. Without the right to patent into force, companies will withdraw funds and researchers will not be competitive to their colleagues. Patients on the other hand will have to recourse outside Europe in order to be treated and that will affect them further economically. The legislation concerning stem cell research as well as the general social perception on therapeutic cloning will most probably be influenced. European Member States will adapt their legislation and policies regulating embryonic stem cell research to the Court's decision and consequently the common sense will not be unaffected.

CHAPTER 3

SCIENTIFIC FREEDOM AS PART OF THE RIGHT TO ENJOY THE BENEFITS OF SCIENTIFIC PROGRESS AND ITS APPLICATIONS

3.1 Scientific freedom

Scientific freedom constitutes a right, as well as a prerequisite to the evolution of science, and at the same time it has been the epicentre of many philosophical discussions. To be more precise, what is its most questionable part are the various limits and limitations imposed, so the discourse goes beyond philosophy, extending to all bioethical issues. This part of the dissertation will try to describe the notion of scientific freedom, or in other words, the right to scientific inquiry or right to research, and also to highlight its usefulness as an absolutely necessary factor in order for someone to exercise the right to enjoy the benefits of science. This study will further argue that it would be impossible for someone to invoke the right to enjoy the benefits of science, or to truly enjoy the scientific benefits if these benefits are not the fruit of free scientific inquiry. It would be a "lame" exercise of this right.

The right to scientific freedom consists part not only of the right to enjoy the benefits of science, but it is also stressed and protected - even if indirectly - in many international human rights documents, such as conventions, treaties, declarations etc.[91] It is also usually well protected in the constitution of every democratic state, belonging to the hard core of the constitution. At least so it should be, because it is interrelated to freedom of expression, freedom of thought and further directly affects the right to education, the right to health and so forth. The right to free inquiry can play the role of the guarantor of the democratic exercise of the above-mentioned rights (the enumeration of these rights is indicative and by no means exhaustive). That is, even if a state

[91] See par. 3.1.1 of this dissertation.

provides and ensures access to its citizens to a series of rights such as for example, the right to health or the right to education, it would be almost pointless without exercising the right to scientific freedom, which would guarantee the quality and the extent of the enjoyment of these rights. Concurrently, freedom of thought and freedom of expression are evidently exercised while exercising the right to free inquiry. Consequently, the right to scientific freedom could serve as a democratic "nest" where other rights find a hospitable environment so as to be developed, or even a shelter to seek refuge. Scientific freedom could also work in a more dynamic way, i.e. as the necessary starting point for the diffusion of ideas, the dissemination of information, and further the enjoyment of other rights, such as the right to health. As it will be argued in the following paragraphs, disadvantaged sick people would never be in a position to full enjoy their right to health if they did not have access to technological and medical achievements resulting, however, from an unrestricted complete exercise of the right to research. The more the right to scientific freedom is restricted the less the right to enjoy the benefits of science is rendered utilizable and consequently exercised.

3.1.1 Scientific freedom in international human rights documents

The Universal Declaration of Human Rights, which is considered to be the foundational text in human rights law, recognizes the right to science in article 27. It also recognizes the right to enjoy the benefits and advancements of science. Many other United Nations Declarations and Resolutions bear some relevance to the right to science.[92] Moreover, the Organization of American States recognizes the right to science and culture in the American Declaration of the Rights and Duties of Man in article XIII. As a matter of international law, all these are not binding instruments and consequently, do not create binding legal obligations upon any State. They belong to the "soft-law" body of international human rights norms; however, many States chose into incorporate these

[92] See Declaration of the Principles of International Cultural Co-operation, Declaration on the use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, Universal Declaration on the Human Genome and Human Rights, The Protection of Human Rights in the Context of Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS).

documents and into their domestic law, into a constitutional framework. In this case, national courts can interpret these non-binding instruments and attribute them legal effect through domestic law. Also, they can be used to interpret international treaties and thus, create legally binding obligations.

Other than the "soft-law" sources, two international treaties recognise the right to science and culture namely the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the Convention on the Rights of the Child (Children's Convention). These documents are legally binding and thus, they create against the nations that have signed and ratified them legally enforceable rights claims. As far as the Childern's convention is concerned, article 31 recognises the right of the child to "participate freely in cultural life and the arts", but the document does not make any reference to the right to enjoy the benefits of science. Therefore, it can be considered that this document recognizes the right to science in a rather narrow way. With regard to these treaties, the protection of the right to science results from the way the nations interpret, implement and apply them at domestic level. That further means that a wide margin of appreciation is left to the various states, even for those that have ratified the above-mentioned treaties, because several times states refuse to apply these documents in domestic law for reasons of sovereignty or cultural relativity. The ratifications are subject to a number of reservations, which prevent individuals from invoking the rights recognized by the treaties. Nevertheless ratifications alone do not tell the whole story.[93] That applies as well to the Oviedo Convention, which recognizes the freedom of scientific research in article 15, of course "subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being"[94]. The margin of appreciation left to the Member States of the Council of Europe that have ratified the Convention is again wide enough.

[93] Lea Shaver, 2010, p.121.
[94] Council of Europe, Oviedo Convention, art. 15.

3.1.2 Towards defining scientific freedom

As regards therapeutic cloning and the question of whether it constitutes an abuse of the right to enjoy the benefits of scientific progress, it is highly important to define what scientific freedom is and more specifically freedom of medical research, in order to understand the context in which science and medicine advance. However, this is not an easy task, in so far as the argumentation generated surrounding controversial medical advancements such as therapeutic cloning hide theoretical traps. The World Congress for Freedom of Scientific Research, which is self-defined as a "permanent forum of activities to promote freedom of research and treatment worldwide", has undertaken a project under the name "Freedom of medical research and treatment around the globe", which is currently ongoing, in an effort to define and set the limits of "freedom" in the context of medical research. In fact, one of the four areas selected "to lead to key insights as to the degree of freedom that researchers, health care professionals and patients enjoy",[95] is embryonic stem cell research.

Since the notion of scientific inquiry is vague, and also due to the fact that the indictment of science, and specifically of the method of therapeutic cloning is made mainly on ethical grounds, the contribution of bioethics is rendered a necessity. However, views claiming that a thorough study of bioethics literature reveals a cursory way of examining the central ethical issues are not unfounded. Another claim is that academics presumably serve their own interests when providing relevant argumentation in academic essays examining the issue of embryonic stem cell research; these interests prevent them from "thinking clearly about bioethics controversies".[96] The author of the above-mentioned views suggests providing evidence when expressing an opinion, and so he claims that he does, opposing embryonic stem cell research.[97] What is missing from the picture is the definition of what evidence consists of. As evidence religious views are used, rejecting dogmatically the method of therapeutic cloning with the same argumentation used in rejecting abortion. Also, examples of "immoral scientific

[95] Andrea Boggio, Mihai Romanciuc, Carmen Sorrentino and Marco Cappato, "Freedom of medical research and treatment around the globe-project", 2010.
[96] Don Marquis, 2006, pp.187-188.
[97] Ibidem, pp.188-197.

experiments" are presented as evidence, as well as it is taken for granted the extension to embryonic stem cell research of the bioethical principle that the inhuman treatment of human subjects is forbidden even if the research will promote the common good. Such an extension is abusive, especially given that the starting point of such argumentation are the Nazi's experiments on Jews. The presentation of the above-mentioned views does not aim at contradicting the views of a concrete writer but rather at highlighting through an illuminative example the magnitude of the controversy as well as the difficulty in defining the limits of medical research.

Nonetheless, two crucial questions remain: what are the limits of scientific freedom and most importantly, who has the jurisdiction, and/or, who is responsible for setting these limits. When an issue concerns the society as a whole and further every single individual, recourse to legal science is a rather safe path. Scientific freedom is a right, and as such cannot be absolute. The law has to regulate the frame of the right to research encapsulating, however, to a certain extent, all the controversial views, i.e. scientific, religious and others. The right to enjoy the benefits of scientific progress and its applications as set out in the ICESCR, article 15(b), being a right enshrined in a legally binding international treaty, as well as its interpretation, suggests a way out in order to avoid theoretical traps.

3.2 The Right to Enjoy the Benefits of Scientific Progress and its Applications (REBSPA)

The right to enjoy the benefits of science has been "neglected"[98] by the international human rights community for decades in terms of definition and conceptualization despite the fact that science and technological progress have played and keep playing a pivotal role in everyday life. Although mentioned both in the UDHR (1948) in Article 27 and in the ICESCR (1966) in Article 15(1)(b), the right to enjoy the benefits of

[98] Schabas , Chapman, "Report on the experts' meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications", Amsterdam, 2007.

science has attracted the attention of human rights experts and advocates only recently. UNESCO has contributed decisively sponsoring a series of workshops dedicated to conceptualise it in 2007, 2008 and 2009 respectively. Leading academic experts as well as intergovernmental and non-governmental organizations participated in these three meetings. The last one was held in Venice in collaboration with the European Inter-University Center for Human Rights and Democratisation where participants elaborated the Venice Statement (herein after the Venice Statement),[99]on the Right to Enjoy the Benefits of Scientific Progress and its Applications. This study will elaborate the Venice Statement in order to explore the right to enjoy the benefits of science without excluding references to the two previous experts' meetings where needed.

3.2.1 "Scientific freedom" in the Venice Statement

The method of therapeutic cloning is one of the most controversial medical developments, subject to heavy criticism. In order to discuss whether it constitutes an abuse of the right to enjoy the benefits of science it is important to conceptualise what science and scientific progress mean within the frame of the right to enjoy the benefits of scientific progress and its applications. Since the first workshop in 2007 in Amsterdam, the extent to which human rights could and should guide scientific research was explored, suggesting that the right to science could be the legal basis in order to protect people from adverse effects resulting from technological development.[100] The Venice Statement in section II discusses the conceptual challenges and in section III the normative content of the REBSPA in an attempt to concretise its content emphasizing however that it contains only "preliminary findings and proposals".[101]

[99] See Annex 2.
[100] Schabas, "Report on the experts' meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications", Amsterdam, 2007, Introduction.
[101] UNESCO, Venice Statement, 2009, para.2.

The Venice Statement does not define specifically the notion of "science" or "scientific progress"; however, it outlines the elements and principles which considers compatible with the REBSPA. In paragraph 12 (a) it is stated that "this right is applicable to all fields of science and its applications". Chapman concludes that "by its very nature basic scientific research is generally directed toward the pursuit of knowledge and not the goal of human betterment".[102] Also, Schabas[103] suggests using the definition of "science" offered in UNESCO Recommendation on the Status of Scientific Researchers. Paragraph 8 of the Venice Statement holds that "Science is not only about advancing knowledge of a specific subject matter…that may be useful for some practical purpose. It is also, at the same time, about enhancing the conditions for further scientific and cultural activity". Also, in paragraphs 8, 13(a), and 14(a) and (b) the Venice Statement stresses that the protection of freedom of scientific research is part of the REBSPA. Consequently, free scientific inquiry applies to all areas of science. Additionally, scientific research that does not aim exclusively, or better said directly, at human betterment is protected as well within the REBSPA.[104] Scientists invest in basic research to gain general knowledge without having the certainty that their efforts will lead to specific inputs. Basic research is absolutely necessary in the process of providing applicable advancements. Even if the goal is solely to solve practical problems and contribute to the human betterment, no scientific group would guarantee since the very beginning of the effort the realization of the pursued objectives. So, scientific efforts aiming exclusively at the pursuing of knowledge are also protected within the REBSPA. In addition, Article 15(3) ICESCR states: "The State Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity". Paragraph 12 (d) of the Venice Statement recognizes the link between the REBSPA and the provision of Article 15(3) ICESCR, and consequently the right to conduct scientific research without the goal of contribution to the human betterment.

[102] Chapman Audrey, 2009, p.7.
[103] Schabas, 2007 p.286.
[104] Muller Amrei, 2010, p.771.

Therapeutic cloning is a method that even if it does not reach its goals, i.e. the cloned embryonic stem cells to be used in patients, emerges as a powerful tool for basic research.[105] One of the arguments of the opponents to therapeutic cloning demanding the non funding of the research is the fact that it is not proven to be applicable yet. Of course there are reflections and hesitations expressed on ethical grounds too, but as regards the so far non applicability of the method, the biomedical research in this specific field could be protected in line with the provisions of the right to enjoy the benefits of science and the interpretation of the Venice Statement.

3.2.2 The limits of "scientific freedom" in the Venice Statement

The freedom of scientific research does not constitute an absolute right. Biomedical research, as any other form of scientific inquiry, is not allowed to be conducted outside the human rights framework. Articles 12(b) and 16(a) of the Venice Statement explicitly prioritise the conformity of the scientific inquiry with human rights principles rather than with the scientists' varying motivations and interests in order to engage in scientific research.

Consistency with human rights suggests that both the process of conducting research and the applications developed follow the principle of human dignity. The potential impact of medical or/and biomedical research on human rights and especially on human dignity has been addressed in several international documents, namely the Universal Declaration on the Human Genome and Human Rights, prepared by UNESCO and then adopted by the UN General Assembly in 1999, the International Declaration on Human Genetic Data in 2003, the Universal Declaration on Bioethics and Human Rights in 2005 and the United Nations Declaration on Human Cloning, also in 2005. As the analysis of the last two instruments indicates in chapter two of this study, the protection of human dignity has been the main concern while drafting these documents. The same observation applies to the Universal Declaration on the Human Genome and Human

[105] See chapter 1 of this dissertation, para. "Therapeutic cloning".

Rights. Article 2 states that "everyone has a right to respect for their dignity and for their rights regardless of genetic characteristics". The Declaration recognises the freedom of scientific research in Article 12(b) under the constraints of Article 13, where it states that the constraints are imposed to the human genome research "because of the ethical and social implications". Moreover, the Oviedo Convention as mentioned in chapter two of this study, recognises the human dignity as the fundamental human rights principle and guarantees commitment by the Member States that have ratified the Convention, to protect fundamental freedoms as regards biomedicine. It has to be recalled that in the Oviedo Convention prevails the principle of the prioritarisation of the interests of persons over them of society or science.[106]

The recapitulation of the references made in international documents with regard to human dignity indicates that there is consistency between them and the references made in the Venice Statement as regards the prevail of the principle of human dignity. However, human dignity remains a vague notion, as there is no explicit definition of dignity in these documents. As Chapman stresses, "policy documents and legal instruments…rarely…articulate how human worth might be degraded by a given technology or scientific activity".[107] The Venice Statement in Article 7 recognises the necessity of clarifying "the nature of scientific knowledge, progress or advancement and who decides on goals, policies, allocation of resources and possible conflicts between freedom of research and the protection of other human rights and human dignity".

The conceptualisation and the definition of human dignity raises then as a very complicated task. Chapman locates in the literature two opposing approaches with regard to the notion of dignity. The first conceives human dignity as means to "emphasize the right of individuals to make autonomous choices", while for the second approach "dignity is a means of constraint".[108] Having said that, to further complicate matters, in the controversial case of embryonic stem cell research where human dignity is cited by the opponents to prevent scientists from continuing elaborating the method of therapeutic cloning, which demands the destruction of human embryos, dignity reflects

[106] Council of Europe, Oviedo Convention, Art.2.
[107] Supra 102, p.7.
[108] Ibidem.

a moral and social position. The lack of agreement on the moral status of the embryo, which will be further discussed in chapter four of this study, precludes reaching agreement on what dignity consists of.

Additionally, the argument of invoking the right to dignity in relation to the destruction of embryos, does not belong only to those opposing to therapeutic cloning. Patients suffering from debilitating diseases could also claim along with their right to benefit from scientific progress, their right to dignity, in the context of dignity used "as a means of empowerment"[109], consistent to the first of the two above mentioned approaches to what dignity consists of. However, it cannot be considered as a dignity of embryos v dignity of patient's case. It would be quite naïve. The invocation of the right to dignity by patients could be justifiable, if only the argument that there is no destruction of human life prevailed in the embryonic stem cell debate.[110] Nevertheless, as far as therapeutic cloning and freedom of research are concerned, even if the argument of the destruction of human embryos collapsed, other human rights issues would emerge.

Paragraph 11 of the Venice Statement states that "the right to share in scientific benefits should not be predicated on participation, particularly where there is a direct threat to fundamental rights, most notably the rights to life, health and food". Also, in 14(d) sets out states' obligations to "take appropriate measures to prevent the use of science and technology in a manner that could limit or inderfere with the enjoyment of human rights and fundamental freedoms". Therapeutic cloning as method requires the donation of a considerable number of oocytes in order to be successful. This process raises several medical risks for women-donors, and further implicates important ethical issues.[111] Women could invoke the right to health[112] and also the right to dignity which is stressed throughout the Venice Statement as the prevailing human rights principle. However, to what extent they could invoke such rights depends upon a number of crucial matters,

[109] Ibidem.
[110] See chapter one of this dissertation, 1.4.2.
[111] Ibidem, 1.2.1.
[112] See ICESCR art.12. Also the WHO recognises "the limited power many women have over their sexual and reproductive lives and their lack of influence in decision-making" as "social realities which have an adverse impact on their health" WHO, fact sheet No 31, p.16, in relation to the problem of the undue inducement of donating oocytes.

such as that of the informed consent, or that of the undue inducement of women-donors (See paragraph 1.2.1 in chapter one of this study). Most probably, if the conditions of the informed consent are fulfilled and does not arise the issue of the undue inducement, the argument of invocation of the right to health and the right to dignity would considerably weaken.

Along with the articles of the Venice Statement mentioned above, which restrain the freedom of scientific research, stands the provision of article 13(c) of the Venice Statement, which belongs to the section that discusses the normative content of the right to enjoy the benefits of science. In this article the need for protection from abuse and adverse effects of science and its applications raises in an unequivocal manner. The possible harmful effects of science on human life was considered by commentators of the right to enjoy the benefits of science since the first experts' meeting in Amsterdam.[113] The Venice Statement in article 13 (c) highlights a series of contemporary controversial issues suggesting that "impact assessments should be seen as an integral part of the development of science". One of the issues mentioned is stem cell research. However, as for the latter, but for other controversial issues as well, the Venice Statement does not adopt any clear position in favour or against, i.e., on whether these areas of science along with their respective latest advancements constitute legitimate scientific benefits or abuse of the right to enjoy the benefits of scientific progress. Notably, the method of therapeutic cloning is the issue that attracts the major part of the controversy with regard to stem cell research. In an attempt to explain the hesitation of the Statement to conclude in relation with these controversies, I would argue that the controversy surrounding stem cells implicates a number of ethical issues, unsolved yet in terms of social consensus. Additionally, the continuous and to a certain extent unpredictable developments as regards the embryonic stem cell research would render promiscuous the determination of the latter as abusive. Nevertheless, it is important that in the Venice Statement controversial issues such stem are research but also cloning, are recognized as contemporary issues which need further exploration in terms of providing further input on the impact these developments might have on

[113] Schabas , " Report on the experts' meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications", Amsterdam , 2007, Introduction.

human life and/or also in terms of violation of other human rights. An observation that it has to be pointed out , in my opinion, is that the article 13 (c) of the Venice Statement uses the term "cloning" without making the distinction between reproductive and therapeutic. One might assume that by "cloning" is meant to be considered reproductive cloning, since the term "therapeutic cloning" is questioned as wording.[114]The bioethical background of the controversy and the conceptual disagreement of human rights experts on the differences between ethics and human rights concepts,[115] might be of an explanation of the use in article 13(c) of the word "cloning" and separately of the general term "stem cell research", which practically includes embryonic stem cell research, more specifically the method of therapeutic cloning, adult stem cell research, and so forth. The regulation of certain ethical issues for the realization of the right to enjoy the benefits of science emerges as a necessity, since controversies such the use of embryonic stem cells are generated mainly because of lack of consensus on ethical issues, such as the moral status of the embryo.

[114] As for the controversy surrounding the terminology see chapter one of this dissertation, 1.4.1.
[115] "Report on the experts' meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications", The REBSP and the role of Ethics, Amsterdam, 2007, pp. 39-41.

CHAPTER 4

EXPLORING THE CORE OF THE CONTROVERSY OF THERAPEUTIC CLONING

4.1 Ethics and science in therapeutic cloning: the undeclared war

The technique of therapeutic cloning has provoked heated debate mainly because of the implication of ethical issues. The question of whether science can help us frame ethical judgments or vice versa stands unanswered. An important distinction that has to be made is between morality and ethics. While morality is the result of a series of beliefs, personal convictions and the personal subjective way of facing life and its challenges, ethics "could be seen as a discipline that provides the intellectual framework to analyze concrete issues, some of which could be moral".[116] Another important distinction to be made is that between science and technology. Basic science, which is the attempt to understand the world, is mistaken for technology. Basic science is the search for truths about reality, whereas technology is the search for efficiency through the design of artifacts. This is why scientific findings are awarded the Nobel Prize, whereas technological designs can be patented, sold and implemented.[117] The importance of this distinction stands in the regulation of the ethics of scientific research, which is conceived of usually both as basic research and technology. Moreover, therapeutic cloning includes both, the one necessary to the other, so as to attain the desired goal, which is the relief of sick people suffering from debilitating diseases. At the same time, each of those two namely basic research and technological application, need separate protection. The input of a human rights approach in order to regulate controversial issues such as therapeutic cloning is that human rights mechanisms could work in convergence with ethics and provide protection to scientific freedom while constraining

[116] Mc Lean, "Report on the experts meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications", Amsterdam, 2007, "The REBSP and the role of Ethics".
[117] Paul Kurtz, 2007, pp.11-26.

the impact of technological applications when the latter clash with or violate other human rights and mainly human dignity. Ethics, on the other hand, take into consideration moral principles and judgments, philosophy, religious beliefs[118], and do not necessarily consider human rights principles. The right to enjoy the benefits of scientific progress and its applications, as interpreted in the Venice Statement, provides, as exposed in chapter three of this study, protection both to basic research and its applications, restraining it, though, to the extent that it can violate human dignity through harmful effects.[119] In the case of therapeutic cloning, however, the discussion involves a separate field of interest of ethics, namely bioethics, which is developed because of the rapid evolution in biomedicine and biotechnology. Bioethics is an institutional governance and a policy making tool.[120] With regard to therapeutic cloning, ethics and science seem to be located in rival camps, as to the moral status of the embryo. However, that would be an oversimplification, since there is a wide range of views surrounding this controversy. What follows is a summary of the main considerations and positions with regard to this issue.

4.1.1 Introductive remarks on the status of the embryo

To begin discussing the moral status of the embryo, it is necessary to clarify that it will be considered the embryo in its early stages and not the foetus. Throughout the international debate on embryonic stem cell research, three are the main positions that have been formed:[121]

(a) That the use of the embryo with the aim of harvesting embryonic stem cells is absolutely unethical

[118] Mario Bunge, 2007, pp.27-40.
[119] See paras. 6, 7, 8, 12(b) and 13(c) of the Venice Statement.
[120] See the definition of Bioethics in the Universal Declaration on Bioethics and Human Rights 2005, Art. 1. "This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions". Also, Richard e. Ashcroft, 2010, p.640.
[121] International Bioethics Committee, Report "The use of embryonic stem cells in therapeutic research", p.9, 2001. Also, UNESCO, Division of the Ethics of Science and Technology "National legislation concerning human reproductive and therapeutic cloning", July, 2004, p.3.

(b) That this kind of use of the embryo is ethically permissible for certain research purposes and subject to rigorous safeguards

(c) That, considering the risks of embryonic stem cell research in relation with the instrumentalisation of the embryo, this research should not be permitted.

If research on human embryos is forbidden at national level, then there is no space for embryonic stem cell research. In the event that it is, in principle, ethically permissible, the following ethical considerations proposed by the International Bioethics Committee could be followed and further taken into account.

The IBC identifies four main sources of embryo[122] in order for different ethical considerations to be applied:

1. the embryo created with in vitro fertilisation techniques aimed at being implanted in the uterus

2. the embryo created as in the first case but being supernumerary (during infertility treatments surplus embryos are created in order to raise the possibilities of a successful pregnancy)

3. the embryo created by oocyte-sperm fertilisation in order to conduct research in the laboratory or to develop stem cell lines, and

4. the "embryo" created by transferring the nucleus of a donor cell to the denucleated oocyte.

With regard to the status of the embryo in the cases above, before proceeding with ethical considerations, it has to be taken into account that the potential to develop into a person exists for the embryo. In case of no other option left but to destroy the embryo, its use for medical research would be ethically permissible.

In form of preliminary observations, it can be argued that in case 1, the embryo has a special status, and it should not be deprived of its development into a person (except in the case of abortion, where the legal system allows it). In case 2, the use of the surplus embryos for therapeutic purposes could me ethically permissible, since, in any case they would be destroyed. However, even if at national level the use of embryo is permissible, it should be pointed out that

[122] Idem.

some religions fully oppose the use of embryos with no exception. In cases 3 and 4, where embryos are created in the laboratory exclusively for medical and therapeutic purposes, further consideration is needed. It has to be recalled at this stage that as regards case four, which refers to the technique of therapeutic cloning, there is no consensus on whether the result of the nucleus transfer into an unnucleated oocyte can be regarded as embryo,[123] which further means that its potential to develop into a person is questioned.

4.1.2 The moral status of the embryo-acquisition of personhood

To raise the matter of the "moral status" of the embryo in the method of therapeutic cloning, it has to be answered whether an entity possesses the requisite qualities or characteristics that entitle it to moral consideration and concern. In therapeutic cloning, or else SCNT technique, the nucleus of an unfertilised egg is removed and replaced by the nucleus of a somatic stem cell. When reaching the blastocyst stage, after chemical inducement, the embryonic stem cells are removed from the blastocyst. The derivation of the embryonic stem cells results in the destruction of the embryo, but it is argued that at that stage it is nothing more than a cluster of cells.[124] Opponents, however, believe that the embryo should be accorded full moral status.[125] The time when moral status is acquired is crucial for the determination of when personhood is acquired as well. If we consider that the "embryo" at blastocyst stage has status which is assigned to personhood, then the right to human dignity is violated and therapeutic cloning falls into the limitations of scientific freedom as stressed in the provision of para 13(c) of the Venice Statement, being abusive. If the "embryo" does not obtain such a status, then it is ethically permissible to use it for research purposes. The acquisition of personhood

[123] See chapter 1 of this dissertation, 1.4.2.
[124] Alistair Brown, 2009, p.77. Also, Hansen, J.E. (2002) "Embryonic stem cell production through therapeutic cloning has fewer ethical problems than stem cell harvest from surplus IVF embryos", *Journal of Medical Ethics*, vol. 28(2) pp.86–88. See also Devolder Katrien, "Cloning", The Stanford Encyclopedia of Philosophy (Fall 2010 Edition), also, John A. Robertson, 2006, pp.133-134.
[125] Alistair Brown, 2009, p.78.

could be further discussed on philosophical, theological and ethical grounds[126]. There are three schools of thought as regards this issue: the genetic school places the acquisition of personhood at conception, the development school, while granting that human life begins at conception, locates personhood at a later developmental stage, and the social consequences school sustains that personhood is a process and an achievement over time.[127]Nonetheless, seeing as there is no consensus, it is impossible to conclude on the moral status of the embryo. It seems, however, that personhood is a matter of definition rather than a biological fact. As regards the view of biology as a science, it should be noted that what it is taken into account is the point when division into normal twins is not possible any more, i.e., up to 13 days after fertilisation, in order for personal individuality to be attributed to an embryo.[128] Many Member States of the Council of Europe allowing research on human embryos are based on this view to interpret the ambiguous provision of Article18(1) of the Oviedo Convention[129], setting a limit of up to 13 days after fertilisation as to the allowance of medical research on the embryo. With regard to the question of whether therapeutic cloning constitutes an abuse of the right to enjoy the benefits of science, human rights advocates should contribute to the debate, encapsulating bioethical and scientific views while interpreting the existing international legal provisions. The shift of interest from the unspecified beginning of life to the protection of personhood could be a suggestion of a way out or at least the starting point of regulation of the controversy surrounding therapeutic cloning. And this is a task belonging mainly to legal science. The determination of the attribution of personhood to an entity is admittedly most challenging and also reciprocally related to the position of the embryo in medical research. Considering further the vagueness of the notion of human dignity in international legal instruments and the margin of appreciation left to the national legislator as to the interpretation of social and cultural rights, the legal conceptualisation of the notion of personhood on international law grounds is rendered a necessity.

[126] Carson Strong, 1997, pp.457-478.
[127] Geron Ethics Advisory Board, 2006, pp.117-129.
[128] International Bioethics Committee, Report "The use of embryonic stem cells in therapeutic research" 2001, para.35.
[129] See Annex 3.

4.1.3 Potentiality

The human embryo, by nature, has a unique status as regards biological terms. In contrast with other living cells, it has the capacity to grow and develop into a human being, a very different entity of what it was. This process is described as the embryo's potential. This potential gives it a particular status, which requires protection and prevention from destruction. Consequently, the question to be answered as to therapeutic cloning is whether the embryo at blastocyst stage has that potential.

For those opposing Stem Cell Nuclear Transfer, it does have that potential and deserves protection from this very early stage. They argue that if implanted into a woman's womb, it would develop into a fully grown human being and therefore, its destruction for deriving embryonic stem cells is impermissible. However, there has been strong opposition to this argument. It is claimed that especially because of lack of intention of a pregnancy, it deserves even less protection than the spare or surplus embryos coming from IVF techniques, where ethical considerations could be raised more easily.[130] In support of this view comes the argument that the use of supernumerary embryos carries the ethical burden of the intention of the egg donors to become parents, while in therapeutic cloning the donors hold no such hope and it is left clear that the oocytes donated will be used exclusively for research purposes[131]. Consequently, the ethical dilemma is smaller. Another argument is that the zygote, which is the result of fertilisation of ova and sperm, becomes an embryo and later a foetus; that does not mean , however, that the sperm and ova should be accorded the status and respective protection of a foetus[132]. Accordingly, it is irrational for an embryo to acquire the moral status of a full human being, let alone if it is considered a cluster of cells. As to the potentiality of the embryo at blastocyst stage, even the sobering thought was expressed

[130] Devolder Katrien, The Stanford Encyclopedia of Philosophy, 2010.
[131] Idem.
[132] International Bioethics Committee, Report "The use of embryonic stem cells in therapeutic research", 2001, p.8.

that "potentially we are all dead but it does not necessarily follow that we treat each other, or that the law treat us, as if this were actually the case"[133].

The argumentation supporting the views of the contracting parts in this controversy sounds extreme sometimes, but it remains strong and thus, it is worth it to be taken into account by legislators and human rights commentators because they reflect different parts of society. Religious views may sound extreme or not , depending on one's beliefs, but fact is that even if they usually are expressed in a dogmatic way, they should be explored, given that they undoubtedly influence a big enough part of society and also contribute significantly to this bioethical debate.

4.1.4 The moral status of the embryo - religious views

Religion has played a significant part in the stem cell controversy. Major religions have contributed, providing their assessments as to the beginning of life. Since bioethics itself deals with a number of crucial issues regarding human life, these contributions have played an important role in the issue. There is a wide range of religious positions expressed, based on a variety of theological premises. To illustrate, let us consider tha even within the same religion there are varying opinions. Religions are answering the question of whether the permissibility of using the embryo for research purposes, including therapeutic cloning, is compatible with their beliefs as regards the sanctity of human life.

One of the main opponents of the use of embryos for therapeutic research is the Roman Catholic tradition. The Holy See provided the International Bioethics Committee (IBC) a note in August 2000 on embryonic stem cells and the status of the embryo.[134] In this note, it is explicitly stated that the embryo is considered a human individual having the right of its own life. In the Catholic view, the beginning of the existence of human life is placed at the time of fertilisation and thus, it is impermissible to use surplus embryos

[133] Alistair Brown, 2009, p.78.
[134] International Bioethics Committee, Report "The use of embryonic stem cells in therapeutic research", 2001, p.7.

coming from IVF techniques for therapeutic research. From the perspective of Orthodox Christianity, human life begins at conception (meaning fertilisation with creation of the single-cell zygote). According to the Orthodox Church, this conviction is grounded in the Biblical witness.[135] For Islam, the use of embryos for research and/or therapeutic purposes is permissible, as long as it does not take place beyond the 40th day after fertilisation. The Methodist Church condemns the creation of human embryos solely for research reasons, arguing that it shows a profound disrespect for life.[136] According to Baptists, human life begins at fertilisation and also a belief is held that embryonic stem cell research will lead to an increase in the number of abortions creating a market for aborted embryos. They are in favour, however, of the use of adult stem cells.[137] The United Church of Christ supports the funding of embryonic stem cell research within ethically sound guidelines, i.e., provided they are taken from frozen human embryos derived from in vitro fertilisation.[138] Also, the Presbyterian Church supports stem cell research provided that it aims at restoring health to those suffering from serious diseases.[139] In Judaism, embryos outside the womb do not have legal status unless parental intention and consensus for pregnancy gives them life potential. Therefore, when there is no potential for implantation for the embryos, Judaism consents to embryonic stem cell research for therapeutic purposes.[140] This brief list of religious views highlights the stark contrast even between religions as to the beginning of life and the position of the embryo.

4.2. The position of patients in the controversy

Although sick people suffering from degenerative diseases are those to be benefited from the method of therapeutic cloning and concurrently from the subsequent privileges of the right to enjoy the benefits of science, surprisingly in the literature dealing with

[135] Waters Brent., Cole-Turner Ronald, 2003, Appendix B, pp.172-176.
[136] Book of Resolutions 2000, p.254, 2000.
[137] Southern Baptist Convention, "Resolution on human embryonic and stem cell research, 1999", "God and the embryo", 2003, Appendix D, pp.179-180.
[138] Waters Brent., Cole-Turner Ronald, 2003, Appendix E, pp.181-182.
[139] Idem. pp.185-189.
[140] International Bioethics Committee, Report "The use of embryonic stem cells in therapeutic research", 2001, para. 29.

this issue they seem to be the most "invisible". The controversy surrounding the embryo and its moral status has displaced them to a certain extent from the core of the controversy. It is perhaps then up to human rights advocates to bring back to the epicentre of the stem cell debate along with the rest of the issues raised, the position of patients especially with regard to the invocation of their right to health and the right to enjoy the benefits of scientific progress.

4.2.1. Potential medical benefits - research purposes

Stem Cell Nuclear Transfer as a specialised form of stem cell therapy has attracted intense social debate not only because of the controversial use of embryonic stem cells but also because of its potential to relieve hundreds of people suffering from diseases such as diabetes, Parkinson's disease, Alzheimer's and a series of other illnesses. Major hopes are held also as to the transplantation field. The latest advancements of this technique, its future goals as well as the possibility of replacing this method with other techniques and to what extent that could be achievable, are exposed in part one of this study. Despite the fact that the so far medical evidence is promising, the truth is that it has not reached its goals yet. It should be noted also, that the scientific community is investing concurrently in developing any alternative solutions which would not include the use of embryonic stem cells, such as adult stem cell therapies. Nevertheless, the pluripotent potential of the embryonic stem cells to develop into a wide range of cells as well as the potential of Stem Cell Nuclear Transfer to create and culture transplant material, eliminating the risks of rejection remain unique.

The therapeutic purpose of Stem Cell Nuclear Transfer has led to the term "therapeutic cloning". Opponents of the method refuse to call it "therapeutic", claiming that since it has not provided therapy or cure to anyone yet, the method should not be accorded the term "therapeutic". However, I would argue that the term "therapeutic" does not imply the possible therapeutic results of the technique, at least not only, but rather the therapeutic purpose, the incentive of the whole effort in this area of biomedicine and

biotechnology. In support of this view, the International Bioethics Committee of UNESCO in its report "on the use of embryonic stem cells in therapeutic research" implies the therapeutic purpose of the method even from the title of the report, while it concludes that "nuclear transfer should be used only for therapeutic research"[141], making reference to its beneficial purposes[142]. However, it should be pointed out that the term is used throughout the report in quotation marks ("therapeutic"), and also that UNESCO has not adopted the term "therapeutic", based on the argument that such use would be premature, and suggests a "more neutral wording, viz. research cloning"[143]. Meanwhile, the term therapeutic cloning is widely used by the scientific community, medical texts, institutes etc.[144]

The wording used to describe the method of Stem Cell Nuclear Transfer does not constitute a linguistic challenge. On the contrary, it could contribute to the conceptualisation of the patients' rights and further to offer another point of view as regards the controversy surrounding this biomedical field of research.

The recognition of the patients' right to enjoy the benefits of the scientific advancements and applications by human rights advocates emerges as a necessary prerequisite in order for them to support their demand for governmental funding of stem cell research. The scientific and technological applications required for the cure of diseases such as Parkinson's, Alzheimer's and others are still defined as desired, given the non applicability of the method of SCNT currently. To result in clinical trials and further in applications, however, extensive basic research is required. There is not another way for the medical science to reach its goals. The protection of free scientific inquiry is then necessary. Of course, it should be borne in mind to what extent scientific freedom in terms of embryonic stem cell research can be exercised without undermining the human body and human dignity. As it is stressed in other parts of this study,

[141] UNESCO, "The use of embryonic Stem Cells in therapeutic research", International Bioethics Committee report, 2001, para 55(C).
[142] Idem. para. 47.
[143] Human Cloning, *Ethical Issues*, Explanatory brochure, 2004, p.12.
[144] Such as: American Medical Association (AMA), Coalition for the Advancement of Medical Research (CAMR), American Diabetes Association, Federation of American Societies for Experimental Biology (FASEB), National Health Council, Society for Women's Health Research and several research Universities.

scientific freedom might be the basis toward the realisation of the right to enjoy the benefits of scientific progress and its applications, but as a right it is not absolute.

4.2.2 Patients within the right to enjoy the benefits of science

The increase in scientific achievements and the use of technological applications in everyday life and especially their usefulness in facing development problems over the last decades have brought the science to the forefront within a human rights context. The conceptualisation of the right to enjoy the benefits of scientific progress and its applications and further its implementation could link science and human rights in an effective way. Commentators of the right to enjoy the benefits of science have already highlighted the link between this right and other human rights, such as the right to health.[145] Apart from the inter-relatedness of the latter with the right to enjoy the benefits of science, the right to health constitutes a human right in itself. It is included in many international and regional human rights instruments.[146] Its normative content in relation with the States' obligations has been addressed[147], indicating that the States should take all the appropriate measures so as for everyone to be as healthy as possible.

The Venice Statement, interpreting the REBSPA, also makes reference to its inter-relatedness to the right to health in paragraphs 3(ii) and 12 (d), highlighting at the same time in paragraph 16(b) the States' duty "to promote access to the benefits of science and its applications on a non-discriminatory basis including measures necessary to address the needs of disadvantaged and marginalised groups". Moreover, the World

[145] Shabas, Chapman, Report of the experts' meeting on the Right to Enjoy the Benefits of Scientific Progress and its Applications, Amsterdam, 2007.
[146] The right to health is included in the ICECSR (1966, Article 12); the Convention on the Elimination of All Forms of Discrimination Against Women (1979,Article 12); the Convention on the Rights of the Child (1989, Article24); the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families (1990, Article28); the European Social Charter (1996, Article 11), the Convention on Human Rights and Biomedicine (1996, Article 3), the American Declaration of the Rights and Duties of Man (1948, Article XI), The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador, 1988, Article 10), and the African Charter on Human and Peoples' Rights (1981, Article 16).
[147] Chapman, 2002.

Health Organisation (WHO) also recognises the link between these two rights, sustaining that the right to health does not mean being healthy, but enjoying "the highest attainable standard of physical and mental health". WHO also recognises the right to protection, treatment and control of diseases.[148] In addition, as far as the link between the conceptualisation of the right to health and scientific research are concerned, it should be noted that the International Bioethics Committee has formulated guidelines on social responsibility and health making references to the contribution of science and technology. For example the report states that "Improving health requires the effective application of research aimed at creating new knowledge and new technologies"; also, that "Health research can make a major contribution both to health and to more general social development".[149]

Based on the above provisions and suggestions, I would argue that patients suffering from debilitating diseases could invoke the right to enjoy the benefits of scientific progress and its applications through which and/or in interrelation to which, also their right to health, asking for the continuation of stem cell research and more precisely, the State's funding of the research including the SCNT technique. Putting aside the discussion on the justiciability of the Economic, Social and Cultural rights, which falls outside the scope of this contribution, I believe that sick people living under dreadful conditions because of their suffering from degenerative diseases fall into the category of disadvantaged people. Therefore, they should be accorded the right to enjoy the benefits of science as envisaged in the ICESCR 15(1) and further interpreted in the Venice Statement as regards the special status of disadvantaged people. The percentage of people suffering from diabetes, Parkinson's disease, Alzheimer's and of those being in urgent need for transplantation is globally considerably high. In addition, people who suffer from debilitating diseases, pending on the stage of the illness, and whose condition might result in paraplegia and other devastating consequences of their affliction, do not have access to the enjoyment of most of their economic, social and

[148] WHO, Right to Health, Fact sheet 31, pp. 3-6.
[149] Report on the International Bioethics Committee of UNESCO on social responsibility and health, 2010,
paras. 56-57.

cultural rights, let alone if they live in a developing country. Given that these diseases are debilitating, they might result in patients suffering a series of disabilities. In that case, they fall also into the category of Persons with Disabilities and to the provisions of the Convention on the Rights of Persons with Disabilities.[150] The technique of therapeutic cloning promises the relief of these people. Consequently, the allowance of conducting basic research in order to reach the goal of benefiting from its applications emerges as a necessity. Sick people could claim that this basic research can be made on legitimate grounds within the frame of the freedom of research included in the concept of the right to enjoy the benefits of scientific progress and its applications.

However, even if the REBSPA could raise justiciable claims, patients invoking this right would have to deal with the controversial issue of the embryo's right to life and to dignity. Having said that, it is also worth mentioning the case of women donating oocytes for the realisation of the SCNT technique, and the possibility of them claiming both violation of their right to dignity and to health.[151] Whether it has to do with a clash of rights case or not, claims such as these mentioned above could work as a key case towards the enforcement of the right to enjoy the benefits of scientific progress and its applications.

[150] The Convention on the Rights of Persons with Disabilities was adopted by the United Nations General Assembly on 13 December 2006 and came into force on 3 May 2008.
[151] Emily Jackson, 2008, pp.286-302.

CONCLUSION

The answer to the question this dissertation has imposed, namely whether the method of therapeutic cloning constitutes an abuse of the right to enjoy the benefits of scientific freedom and its applications cannot result in a one-dimension answer, because it would be an over simplification of an extremely controversial issue. What will be presented in this part of the study is most probably a series of findings and/or concluding remarks rather than a clear yes or no.

Therapeutic cloning, or else Stem Cell Nuclear Transfer, has been through a series of controversial debates mainly because of the use of embryos in the process of this technique. To address, however, the issue of the moral status of the embryo as regards this technique, two matters have to be solved. First, whether the entity used in this very early stage of existence, the blastocyst stage, is indeed an embryo or merely a cluster of cells, which would not fall into the provisions envisaged protecting embryos' right to life and right to dignity. Second, a form of consensus should be achieved as to the moral but also as to the legal status of the embryo. The views surrounding this issue are considerably controversial and therefore the following question emerged is who will decide on this.

Since the controversy includes views based on biological, theologian, ethical and philosophical grounds, I would argue that human rights community could contribute at most on this issue, not by deciding or regulating the controversy, neither by weighing the interests of the contradicting parts. It is up to States' obligations to promote a social dialogue, where all opinions held will be freely expressed and taken into account. Then, human rights community through its legal instruments, its advocates and also in collaboration with the civil society could scrutinize the process of this dialogue on human rights grounds and in line with fundamental human rights principles. It should be borne in mind that even if human rights are in an inter-relatedness with ethics, the former could encapsulate a much wider range of views and positions based on their universality whereas ethical views are subject sometimes to cultural relativity.

Other issues such as the position of the women oocyte donors should be also considered while addressing the issue of whether therapeutic cloning is abusive or not. Although women donors have not attracted as much attention as the embryo in the controversy surrounding therapeutic cloning and the possibility of violation of their right to dignity and right to health has not been discussed in the literature to the extent embryo's human rights have, egg donors remain indispensible participants to the process of Stem Cell Nuclear Transfer and thus their position as donors should be further addressed and regulated.

With regard to the right to enjoy the benefits of scientific progress and its applications, its role as to the conceptualisation of the notion of scientific freedom is rendered crucial. Free scientific inquiry can be intrinsically exercised through the realisation of the right to enjoy the benefits of science. Therefore, all efforts towards the implementation of the latter will concurrently be of a great benefit to a series of other human rights, as human rights commentators have already observed. While there must be protection from harmful and adverse effects of science, the right to scientific research should be also protected especially in terms of basic research. As it is stressed in the study, basic research is necessary but at the same time reflects the human being's thirst for learning, and as such it should not be prevented from being exercised unless very serious violations of human rights are at stake. In any case, scientific freedom should always be in balance with the principles of scientific responsibility, accountability and transparency. The scientific community should set in order its own house, in terms of scrutinizing all the new techniques and technologies using criteria on human rights grounds. The determination of certain codes of conduct applied to basic research as well as to the technological advancements could bridge some of the existing conflicts between scientists and certain social groups with regard also to the method of therapeutic cloning.

It is commonly accepted that sick people suffering from debilitating diseases live a hard life full of anxiety. Most of the times because of their condition of health, they live marginalised, without having access to education, to the cultural life or even to work. This study argues that these people could fall into the category of disadvantaged people

having an increased need for protection of their right to enjoy the benefits of scientific progress and its applications. Despite the fact that the method of therapeutic cloning has not reached the stage of applications, not even that of clinical trials, this does not mean that it is not promising. The so far scientific data and experiments, as indicated in chapter one of this study, show the potential of Stem Cell Nuclear Transfer. Even for the most skepticists, this technique is considered innovative and ambitious. Patients are waiting and hoping for the first application so that to be able to be benefited. But how will they exercise this right if the SCNT is banned? Even if not banned, if is not funded and supported, given that it is a very expensive research, there will not be any advancements in the near future. Consequently, sick people suffering from devastating diseases could invoke the right to enjoy the benefits of science in order to demand public funding and recognition of the method as legitimate. For a barely recognized and enforceable right such the right to enjoy the benefits of scientific progress, cases such this of patients demanding the continuation of basic research in therapeutic cloning based on this right could work as catalyst in order it be implemented.

All the above mentioned observations constitute aspects of the complex relation between a rather neglected right and an innovative yet very controversial biomedical technique. In the middle, however, stands the need for conformity with human rights principles, which constitutes also a proposal extracted by this study. That is, human rights as discipline but also as attitude in everyday life can challenge efficiently the regulation of controversies.

Considering the multidimensionality of the issue addressed in the present study, the latter does not claim that it was exhaustively addressed. As far as the exposed controversies surrounding the whole issue, this study is not adopting any particular position. The only conviction formulated concerns the therapeutic purposes of the Stem Cell Nuclear Transfer technique, given that the conducted research aims at curing sick people and not at other applications in cosmetology and so forth. Considering that a fact, the study adopts the term therapeutic cloning.

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ANNEXES

ANNEX 1: Universal Declaration on Bioethics and Human Rights

19 October 2005

The General Conference,

Conscious of the unique capacity of human beings to reflect upon their own existence and on their environment, to perceive injustice, to avoid danger, to assume responsibility, to seek cooperation and to exhibit the moral sense that gives expression to ethical principles,

Reflecting on the rapid developments in science and technology, which increasingly affect our understanding of life and life itself, resulting in a strong demand for a global response to the ethical implications of such developments,

Recognizing that ethical issues raised by the rapid advances in science and their technological applications should be examined with due respect to the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Resolving that it is necessary and timely for the international community to state universal principles that will provide a foundation for humanity's response to the ever-increasing dilemmas and controversies that science and technology present for humankind and for the environment,

Recalling the Universal Declaration of Human Rights of 10 December 1948, the Universal Declaration on the Human Genome and Human Rights adopted by the General Conference of UNESCO on 11 November 1997 and the International Declaration on Human Genetic Data adopted by the General Conference of UNESCO on 16 October 2003,

Noting the United Nations International Covenant on Economic, Social and Cultural Rights and the International Covenant on Civil and Political Rights of 16 December

1966, the United Nations International Convention on the Elimination of All Forms of Racial Discrimination of 21 December 1965, the United Nations Convention on the Elimination of All Forms of Discrimination against Women of 18 December 1979, the United Nations Convention on the Rights of the Child of 20 November 1989, the United Nations Convention on Biological Diversity of 5 June 1992, the Standard Rules on the Equalization of Opportunities for Persons with Disabilities adopted by the General Assembly of the United Nations in 1993, the UNESCO Recommendation on the Status of Scientific Researchers of 20 November 1974, the UNESCO Declaration on Race and Racial Prejudice of 27 November 1978, the UNESCO Declaration on the Responsibilities of the Present Generations Towards Future Generations of 12 November 1997, the UNESCO Universal Declaration on Cultural Diversity of 2 November 2001, the ILO Convention 169 concerning Indigenous and Tribal Peoples in Independent Countries of 27 June 1989, the International Treaty on Plant Genetic Resources for Food and Agriculture which was adopted by the FAO Conference on 3 November 2001 and entered into force on 29 June 2004, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) annexed to the Marrakech Agreement establishing the World Trade Organization, which entered into force on 1 January 1995, the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 and other relevant international instruments adopted by the United Nations and the specialized agencies of the United Nations system, in particular the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO),

Also noting international and regional instruments in the field of bioethics, including the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine of the Council of Europe, which was adopted in 1997 and entered into force in 1999, together with its Additional Protocols, as well as national legislation and regulations in the field of bioethics and the international and regional codes of conduct and guidelines and other texts in the field of bioethics, such as the Declaration of Helsinki of the World Medical Association on Ethical Principles for Medical Research

Involving Human Subjects, adopted in 1964 and amended in 1975, 1983, 1989, 1996 and 2000 and the International Ethical Guidelines for Biomedical Research Involving Human Subjects of the Council for International Organizations of Medical Sciences, adopted in 1982 and amended in 1993 and 2002,

Recognizing that this Declaration is to be understood in a manner consistent with domestic and international law in conformity with human rights law,

Recalling the Constitution of UNESCO adopted on 16 November 1945,

Considering UNESCO's role in identifying universal principles based on shared ethical values to guide scientific and technological development and social transformation in order to identify emerging challenges in science and technology taking into account the responsibility of the present generations towards future generations, and that questions of bioethics, which necessarily have an international dimension, should be treated as a whole, drawing on the principles already stated in the Universal Declaration on the Human Genome and Human Rights and the International Declaration on Human Genetic Data and taking account not only of the current scientific context but also of future developments,

Aware that human beings are an integral part of the biosphere, with an important role in protecting one another and other forms of life, in particular animals,

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

Recognizing that health does not depend solely on scientific and technological research developments but also on psychosocial and cultural factors,

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

Bearing in mind that cultural diversity, as a source of exchange, innovation and creativity, is necessary to humankind and, in this sense, is the common heritage of humanity, but emphasizing that it may not be invoked at the expense of human rights and fundamental freedoms,

Also bearing in mind that a person's identity includes biological, psychological, social, cultural and spiritual dimensions,

Recognizing that unethical scientific and technological conduct has had a particular impact on indigenous and local communities,

Convinced that moral sensitivity and ethical reflection should be an integral part of the process of scientific and technological developments and that bioethics should play a predominant role in the choices that need to be made concerning issues arising from such developments,

Considering the desirability of developing new approaches to social responsibility to ensure that progress in science and technology contributes to justice, equity and to the interest of humanity,

Recognizing that an important way to evaluate social realities and achieve equity is to pay attention to the position of women,

Stressing the need to reinforce international cooperation in the field of bioethics, taking into account, in particular, the special needs of developing countries, indigenous communities and vulnerable populations,

Considering that all human beings, without distinction, should benefit from the same high ethical standards in medicine and life science research,

Proclaims the principles that follow and adopts the present Declaration.

General provisions

Article 1 – Scope

1. This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.

2. This Declaration is addressed to States. As appropriate and relevant, it also provides guidance to decisions or practices of individuals, groups, communities, institutions and corporations, public and private.

Article 2 – Aims

The aims of this Declaration are:

(a) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies or other instruments in the field of bioethics;

(b) to guide the actions of individuals, groups, communities, institutions and corporations, public and private;

(c) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;

(d) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights and fundamental freedoms;

(e) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;

(f) to promote equitable access to medical, scientific and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;

(g) to safeguard and promote the interests of the present and future generations;

(h) to underline the importance of biodiversity and its conservation as a common concern of humankind.

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 – Human dignity and human rights

1. Human dignity, human rights and fundamental freedoms are to be fully respected.

2. The interests and welfare of the individual should have priority over the sole interest of science or society.

Article 4 – Benefit and harm

In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized and any possible harm to such individuals should be minimized.

Article 5 – Autonomy and individual responsibility

The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected. For persons who are not capable of exercising autonomy, special measures are to be taken to protect their rights and interests.

Article 6 – Consent

1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.

2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.

3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

Article 7 – Persons without the capacity to consent

In accordance with domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights. Refusal of such persons to take part in research should be respected.

Article 8 – Respect for human vulnerability and personal integrity

In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

Article 9 – Privacy and confidentiality

The privacy of the persons concerned and the confidentiality of their personal information should be respected. To the greatest extent possible, such information should not be used or disclosed for purposes other than those for which it was collected

or consented to, consistent with international law, in particular international human rights law.

Article 10 – Equality, justice and equity

The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably.

Article 11 – Non-discrimination and non-stigmatization

No individual or group should be discriminated against or stigmatized on any grounds, in violation of human dignity, human rights and fundamental freedoms.

Article 12 – Respect for cultural diversity and pluralism

The importance of cultural diversity and pluralism should be given due regard. However, such considerations are not to be invoked to infringe upon human dignity, human rights and fundamental freedoms, nor upon the principles set out in this Declaration, nor to limit their scope.

Article 13 – Solidarity and cooperation

Solidarity among human beings and international cooperation towards that end are to be encouraged.

Article 14 – Social responsibility and health

1. The promotion of health and social development for their people is a central purpose of governments that all sectors of society share.

2. Taking into account that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, progress in science and technology should advance:

(a) access to quality health care and essential medicines, especially for the health of women and children, because health is essential to life itself and must be considered to be a social and human good;

(b) access to adequate nutrition and water;

(c) improvement of living conditions and the environment;

(d) elimination of the marginalization and the exclusion of persons on the basis of any grounds;

(e) reduction of poverty and illiteracy.

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

(a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;

(b) access to quality health care;

(c) provision of new diagnostic and therapeutic modalities or products stemming from research;

(d) support for health services;

(e) access to scientific and technological knowledge;

(f) capacity-building facilities for research purposes;

(g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.

Article 16 – Protecting future generations

The impact of life sciences on future generations, including on their genetic constitution, should be given due regard.

Article 17 – Protection of the environment, the biosphere and biodiversity

Due regard is to be given to the interconnection between human beings and other forms of life, to the importance of appropriate access and utilization of biological and genetic resources, to respect for traditional knowledge and to the role of human beings in the protection of the environment, the biosphere and biodiversity.

Application of the principles

Article 18 – Decision-making and addressing bioethical issues

1. Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues.

2. Persons and professionals concerned and society as a whole should be engaged in dialogue on a regular basis.

3. Opportunities for informed pluralistic public debate, seeking the expression of all relevant opinions, should be promoted.

Article 19 – Ethics committees

Independent, multidisciplinary and pluralist ethics committees should be established, promoted and supported at the appropriate level in order to:

(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;

(b) provide advice on ethical problems in clinical settings;

(c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;

(d) foster debate, education and public awareness of, and engagement in, bioethics.

Article 20 – Risk assessment and management

Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted.

Article 21 – Transnational practices

1. States, public and private institutions, and professionals associated with transnational activities should endeavour to ensure that any activity within the scope of this Declaration, undertaken, funded or otherwise pursued in whole or in part in different States, is consistent with the principles set out in this Declaration.

2. When research is undertaken or otherwise pursued in one or more States (the host State(s)) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. This review should be based on ethical and legal standards that are consistent with the principles set out in this Declaration.

3. Transnational health research should be responsive to the needs of host countries, and the importance of research contributing to the alleviation of urgent global health problems should be recognized.

4. When negotiating a research agreement, terms for collaboration and agreement on the benefits of research should be established with equal participation by those party to the negotiation.

5. States should take appropriate measures, both at the national and international levels, to combat bioterrorism and illicit traffic in organs, tissues, samples, genetic resources and genetic-related materials.

Promotion of the Declaration

Article 22 – Role of States

1. States should take all appropriate measures, whether of a legislative, administrative or other character, to give effect to the principles set out in this Declaration in accordance with international human rights law. Such measures should be supported by action in the spheres of education, training and public information.

2. States should encourage the establishment of independent, multidisciplinary and pluralist ethics committees, as set out in Article 19.

Article 23 – Bioethics education, training and information

1. In order to promote the principles set out in this Declaration and to achieve a better understanding of the ethical implications of scientific and technological developments, in particular for young people, States should endeavour to foster bioethics education and training at all levels as well as to encourage information and knowledge dissemination programmes about bioethics.

2. States should encourage the participation of international and regional intergovernmental organizations and international, regional and national non governmental organizations in this endeavour.

Article 24 – International cooperation

1. States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge.

2. Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.

3. States should respect and promote solidarity between and among States, as well as individuals, families, groups and communities, with special regard for those rendered vulnerable by disease or disability or other personal, societal or environmental conditions and those with the most limited resources.

Article 25 – Follow-up action by UNESCO

1. UNESCO shall promote and disseminate the principles set out in this Declaration. In doing so, UNESCO should seek the help and assistance of the Intergovernmental Bioethics Committee (IGBC) and the International Bioethics Committee (IBC).

2. UNESCO shall reaffirm its commitment to dealing with bioethics and to promoting collaboration between IGBC and IBC.

Final provisions

Article 26 – Interrelation and complementarity of the principles

This Declaration is to be understood as a whole and the principles are to be understood as complementary and interrelated. Each principle is to be considered in the context of the other principles, as appropriate and relevant in the circumstances.

Article 27 – Limitations on the application of the principles

If the application of the principles of this Declaration is to be limited, it should be by law, including laws in the interests of public safety, for the investigation, detection and prosecution of criminal offences, for the protection of public health or for the protection of the rights and freedoms of others. Any such law needs to be consistent with international human rights law.

Article 28 – Denial of acts contrary to human rights, fundamental freedoms and human dignity

Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity.

ANNEX 2: Venice Statement on the Right to Enjoy the Benefits of Scientific Progress and its Applications

Introduction

1. In the light of the increasing relevance and continued neglect of the right to enjoy the benefits of scientific progress and its applications, as included inter alia in Article 27 of the Universal Declaration of Human Rights and Article 15(1)(b) of the International Covenant on Economic, Social and Cultural Rights (ICESCR), three expert meetings were convened by UNESCO in collaboration with the Amsterdam Center for International Law, the Irish Centre for Human Rights, and the European Inter-University Centre for Human Rights and Democratisation, in Amsterdam, the Netherlands, on 7-8 June 2007, in Galway, Ireland, 23-24 November 2008, and Venice, Italy, 16-17 July 2009.

2. The following preliminary findings and proposals emerged from the discussions at these meetings, with the aim of clarifying the normative content of the right to enjoy the benefits of scientific progress and its applications and generating a discussion among all relevant stakeholders with a view to enhance the implementation of this right.

I. The Contemporary Relevance of the Right

3. The acceleration of the production of knowledge in the context of globalization has increased the effects on human rights in both positive and negative ways, with consequences for inequalities among and within States and across generations. We have identified many examples of these conflicting trends, including the following:

i. In the area of food production, although scientific advances have significantly increased crop yields, they may also reduce crop genetic diversity, widen the gap between poor farmers and large-scale producers, and thus affect the right to food.

ii. Scientific advances in medicine have helped to cure more diseases and enhance the quality of life. However, these advances are driven primarily by market considerations that often do not correspond to the health needs of the world's population as a whole, thus affecting the right to health.

iii. Advances in information and communication technologies have expanded opportunities for education, freedom of expression and trade. But they have also widened the "digital gap," and facilitated infringements of privacy, incitement to hatred and censorship, and thus affect the full spectrum of human rights as well as cultural diversity.

4. Significant disparities are increasing among States concerning the availability of resources, capabilities, and infrastructure necessary to engage in research and development. The acceleration of scientific progress is widening the divide between the most and least scientifically and technologically advanced societies. The resulting lack of access reduces the ability to enjoy human rights, including the ability to hold governments accountable, particularly for the direction of scientific progress and its impact on human rights.

5. The relationship between human rights and science is further complicated by the fact that private and non-State actors are increasingly the principal producers of scientific progress and technological advances. It is the responsibility of States to ensure that all relevant interests are balanced, in the advance of scientific progress, in accordance with human rights.

II. Conceptual challenges

6. The ongoing process of science has different meanings and implications in different contexts and may pose significant challenges for human rights in the world today. The processes, products and applications of science should be used for the benefit of all humanity without discrimination, particularly with regard to disadvantaged and marginalized persons and communities. That requires attention to five main issues.

7. First, it is necessary to clarify the nature of scientific knowledge, progress or advancement and who decides on goals, policies, allocation of resources and possible conflicts between freedom of research and the protection of other human rights and human dignity. In addition, whereas the individual right to enjoy the benefits of scientific progress and its applications must be respected, the rights of communities to share in these benefits must be recognized as equally important.

8. Second, freedom of inquiry is a vital element in the development of science in its broadest sense. Science is not only about advancing knowledge of a specific subject matter, nor merely about procuring a set of data and testing hypotheses that may be useful for some practical purpose. It is also, at the same time, about enhancing the conditions for further scientific and cultural activity.

9. Third, States, commercial enterprise and the scientific community have a responsibility to ensure support for scientific inquiry and dissemination of scientific knowledge, and to actively pursue capacity building on a global scale, particularly in those countries which are relatively inactive in this regard.

10. Fourth, the right to enjoy the benefits of scientific progress and its applications may create tensions with the intellectual property regime, which is a temporary monopoly with a valuable social function that should be managed in accordance with a common responsibility to prevent the unacceptable prioritization of profit for some over benefit for all.

11. Fifth, in the context of Article 15 1(b) ICESCR, enjoyment as "participation" is distinct from enjoyment as actual "sharing" in the benefits of scientific progress and its applications. Participation in scientific progress is valuable in its own right, and while the benefits of science should be shared equitably, neither of these components of the right is a substitute for the other. The right to share in scientific benefits should not be predicated on participation, particularly where there is a direct threat to fundamental rights, most notably the rights to life, health and food.

III. Elements of the Normative Content and State Obligations

Fundamental Principles

12. In the elaboration of the right to enjoy the benefits of scientific progress and its applications, certain fundamental principles should be considered:

a) This right is applicable to all fields of science and its applications.

b) A human rights-based approach requires that science and its applications are consistent with fundamental human rights principles such as non-discrimination, gender equality, accountability and participation, and that particular attention should be paid to the needs of disadvantaged and marginalized groups.

c) In conformity with the principles of universality, indivisibility, interdependence and interrelatedness, this right is relevant to the realization of other civil, cultural, economic, political and social rights.

d) This right is inextricably linked not only to the freedom indispensable for scientific research as enshrined in Article 15(3) ICESCR and the rights of authors and creators as recognized in Article 15(1)(c) ICESCR, as well as those rights where reference to access to science and technology is made (i.e. the right to food (Article 11 ICESCR) and the right to health (Article 12 ICESCR)), but also to other rights, such as to a clean environment, education, information, labor rights, social security, sustainable development, water, where access to science is an implicit requirement for their full enjoyment.

e) This right can be enjoyed individually and collectively.

f) This right should be applied consistently with the precautionary principle according to which, in the absence of scientific consensus, caution and the avoidance of steps are required in case an action or policy might cause severe or irreversible harm to the public or the environment.

g) The implementation of this right requires close international cooperation and assistance as it is stipulated by the Universal Declaration of Human Rights and other international instruments.

Normative Content

13. The normative content should be directed towards the following:

a) Creation of an enabling and participatory environment for the conservation, development and diffusion of science and technology, which implies inter alia academic and scientific freedom, including freedoms of opinion and expression, to seek, receive and impart information, association and movement; equal access and participation of all public and private actors; and capacity-building and education.

b) Enjoyment of the applications of the benefits of scientific progress, which implies inter alia non-discriminatory access to the benefits of scientific progress and its applications, including technology transfer and capacity-building.

c) Protection from abuse and adverse effects of science and its applications. Areas of contemporary controversy include, for example, stem cell research, nanotechnologies, nuclear energy, GMOs, climate change, generic seeds that can be reused, cloning, ethics of science and technology, new technologies in the working environment. The possibility of adverse effects of science in these and other regards requires that impact assessments should be seen as an integral part of the development of science.

State Obligations

14. The duty to respect should include:

a) to respect the freedoms indispensable for scientific research and creative activity, such as freedom of thought, to hold opinions without interference, and to seek, receive, and impart information and ideas of all kinds;

b) to respect the right of scientists to form and join professional societies and associations, as well as academic autonomy;

c) to respect the freedom of the scientific community and its individual members to collaborate with others both within and across the country's borders, including the freed exchange of information, research ideas and results;

d) to take appropriate measures to prevent the use of science and technology in a manner that could limit or interfere with the enjoyment of the human rights and fundamental freedoms.

15. The duty to protect should include:

a) to take measures, including legislative measures, to prevent and preclude the utilization by third parties of science and technologies to the detriment of human rights and fundamental freedoms and the dignity of the human person by third parties;

b) to take measures to ensure the protection of the human rights of people subject to research activities by entities, whether public or private, in particular the right to information and free and informed consent.

16. The duty to fulfill should include:

a) to adopt a legal and policy framework and to establish institutions to promote the development and diffusion of science and technology in a manner consistent with fundamental human rights. The relevant policies should be periodically reviewed on the basis of a participatory and transparent process, with particular attention to the status and needs of disadvantaged and marginalized groups;

b) to promote access to the benefits of science and its applications on a nondiscriminatory basis including measures necessary to address the needs of disadvantaged and marginalized groups;

c) to monitor the potential harmful effects of science and technology, to effectively react to the findings and inform the public in a transparent way;

d) to take measures to encourage and strengthen international cooperation and assistance in science and technology to the benefit of all people and to comply in this regard with the States' obligations under international law;

e) to provide opportunities for public engagement in decision-making about science and technology and their development;

f) to institute effective science curricula at all levels of the educational system, particularly in the State-sponsored schools, leading to development of the skills necessary to engage in scientific research.

IV. Next Steps

17. The next steps for the further and comprehensive elucidation of the right to enjoy the benefits of scientific progress and its applications, raising awareness about this right, its implementation, and the monitoring of its realization, require the cooperation and participation of the following actors: the UN system and other intergovernmental organizations, regional organizations, States, the scientific and academic communities, civil society, and the private sector.

UN system and other intergovernmental organizations

UNESCO

18. Having taken the lead in promoting international action to advance this right, UNESCO should continue its leadership in raising awareness and contributing to the elucidation of the right. It can utilize its comparative advantage as an institution involving a wide range of relevant disciplines to engage both the scientific and human rights communities through inter-sectoral cooperation. Finally, it should promote wider

use of the existing complaint procedure under UNESCO Ex 104/Decision 3.3 to provide a recourse for individuals and groups seeking redress for violations of the right to enjoy the benefits of scientific progress and its applications.

Other Specialized Agencies, Funds and Programmes

19. Among the institutions with a particular contribution to make in elucidating this right in their fields of competence, FAO, ILO, UNDP, UNEP, UNICEF, WIPO and WHO each has responsibility for aspects of science and technology and could reexamine its role in this regard from the perspective of the right to enjoy the benefits of scientific progress and its applications.

OHCHR

20. In light of enhanced attention to this right, the OHCHR should devote sufficient financial and human resources to research aimed at clarifying the content, identifying obstacles, detailing positive examples of State practice, and emphasizing the inherent link between this right and other human rights. In servicing the Committee on Economic, Social and Cultural Rights it should provide information useful to strengthen the Committee's dialogue with States Parties in relationship to Article 15(1)(b), and Articles 15(2)-(4) as they relate to science.

Human Rights Council

21. Consistent with its commitment to giving due attention to economic, social and cultural rights, the Human Rights Council should consider including this right in its agenda and eventually the appointment of an independent expert or special rapporteur. Existing Special Procedures should pay increased attention to this right in the fulfillment of their mandate.

Treaty bodies

22. The treaty bodies should pay adequate attention to this right in relation to their monitoring of specific references to scientific progress and advances in their respective treaties. In particular, the Committee on Economic, Social and Cultural Rights should strengthen its dialogue with States Parties in relationship to Article 15(1)(b) by allowing adequate time during its consideration of States reports, and by reminding States of their need to provide information consistent with the Reporting Guidelines. It should also consider holding a day of general discussion towards the development of a General Comment on Article 15(1)(b).

Regional organizations

23. Given that the region of the Americas was the first to adopt an international document containing this right, the OAS should take steps to implement Article 14 of the San Salvador Protocol. In addition, other regional organizations should consider ways and means of implementing this right.

States

24. To ensure that science and technology policy serve human needs in addition to economic prosperity, States should apply human rights-based approaches to their policies and activities in the field of science and technology. Consistent with their obligations under the Covenant and the right to development, they should also promote international cooperation and assistance to countries that encounter difficulties in developing science and technology policy and science education. The right to enjoy the benefits of scientific progress and its applications implies a duty of States to take measures to protect individuals and communities from possible harmful effects of science and scientific development. States Parties to the ICESCR should report more

fully on the implementation of this right in their periodic reports. The realization of this right further requires that States provide remedies for violations in national law and by ratifying the Optional Protocol to the ICESCR.

Scientific community

25. Scientists and their professional organizations can manifest their commitment to this right by developing greater awareness of the meaning and significance of this right and an understanding of its application to the conduct of science, as well as participating in the elucidation of this right.

Civil society

26. Human rights organizations and other civil society groups have a critical role in promoting the implementation of this right through advocacy, such as the preparation of shadow reports to treaty bodies in their consideration of State reports, and by efforts to protect victims of violations of these rights, including by submitting complaints pursuant to UNESCO EX 104/Decision 3.3 and to the Optional Protocol to the ICESCR in cases of the violation of the freedom necessary for scientific inquiry and of individuals to benefit from advances in science and technology.

Private sector

27. It is not inconsistent with the economic objectives of the private sector for enterprises to act in ways that advance this right. The private sector plays a major role in advances in science and technology and should examine ways of contributing to this right, by giving greater attention to the basic needs of disadvantaged and marginalized groups, and in particular the right of all to enjoy the benefits of scientific progress (e.g. consider implementing the Guidelines on Pharmaceutical Companies and Human Rights).

ANNEX 3: 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

Oviedo, 4.IV.1997

The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Community shall be read as the European Union.

Preamble

The member States of the Council of Europe, the other States and the European Community, signatories hereto,

Bearing in mind the Universal Declaration of Human Rights proclaimed by the General Assembly of the United Nations on 10 December 1948;

Bearing in mind the Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950;

Bearing in mind the European Social Charter of 18 October 1961;

Bearing in mind the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights of 16 December 1966;

Bearing in mind the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data of 28 January 1981;

Bearing also in mind the Convention on the Rights of the Child of 20 November 1989;

Considering that the aim of the Council of Europe is the achievement of a greater unity between its members and that one of the methods by which that aim is to be pursued is the maintenance and further realisation of human rights and fundamental freedoms;

Conscious of the accelerating developments in biology and medicine;

Convinced of the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being;

Conscious that the misuse of biology and medicine may lead to acts endangering human dignity;

Affirming that progress in biology and medicine should be used for the benefit of present and future generations;

Stressing the need for international co-operation so that all humanity may enjoy the benefits of biology and medicine;

Recognising the importance of promoting a public debate on the questions posed by the application of biology and medicine and the responses to be given thereto;

Wishing to remind all members of society of their rights and responsibilities;

Taking account of the work of the Parliamentary Assembly in this field, including Recommendation 1160 (1991) on the preparation of a convention on bioethics;

Resolving to take such measures as are necessary to safeguard human dignity and the fundamental rights and freedoms of the individual with regard to the application of biology and medicine,

Have agreed as follows:

Chapter I – General provisions

Article 1 – Purpose and object

Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine. Each

Party shall take in its internal law the necessary measures to give effect to the provisions of this Convention.

Article 2 – Primacy of the human being

The interests and welfare of the human being shall prevail over the sole interest of society or science.

Article 3 – Equitable access to health care

Parties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.

Article 4 – Professional standards

Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards.

Chapter II – Consent

Article 5 – General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time.

Article 6 – Protection of persons not able to consent

1. Subject to Articles 17 and 20 below, an intervention may only be carried out on a person who does not have the capacity to consent, for his or her direct benefit.

2. Where, according to law, a minor does not have the capacity to consent to an intervention, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The opinion of the minor shall be taken into consideration as an increasingly determining factor in proportion to his or her age and degree of maturity.

3. Where, according to law, an adult does not have the capacity to consent to an intervention because of a mental disability, a disease or for similar reasons, the intervention may only be carried out with the authorisation of his or her representative or an authority or a person or body provided for by law.

The individual concerned shall as far as possible take part in the authorisation procedure.

4. The representative, the authority, the person or the body mentioned in paragraphs 2 and 3 above shall be given, under the same conditions, the information referred to in Article 5.

5. The authorisation referred to in paragraphs 2 and 3 above may be withdrawn at any time in the best interests of the person concerned.

Article 7 – Protection of persons who have a mental disorder

Subject to protective conditions prescribed by law, including supervisory, control and appeal procedures, a person who has a mental disorder of a serious nature may be subjected, without his or her consent, to an intervention aimed at treating his or her

mental disorder only where, without such treatment, serious harm is likely to result to his or her health.

Article 8 – Emergency situation

When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned.

Article 9 – Previously expressed wishes

The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account.

Chapter III – Private life and right to information

Article 10 – Private life and right to information

1. Everyone has the right to respect for private life in relation to information about his or her health.

2. Everyone is entitled to know any information collected about his or her health. However, the wishes of individuals not to be so informed shall be observed.

3. In exceptional cases, restrictions may be placed by law on the exercise of the rights contained in paragraph 2 in the interests of the patient.

Chapter IV – Human genome

Article 11 – Non-discrimination

Any form of discrimination against a person on grounds of his or her genetic heritage is prohibited.

Article 12 – Predictive genetic tests

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, and subject to appropriate genetic counselling.

Article 13 – Interventions on the human genome

An intervention seeking to modify the human genome may only be undertaken for preventive, diagnostic or therapeutic purposes and only if its aim is not to introduce any modification in the genome of any descendants.

Article 14 – Non-selection of sex

The use of techniques of medically assisted procreation shall not be allowed for the purpose of choosing a future child's sex, except where serious hereditary sex-related disease is to be avoided.

Chapter V – Scientific research

Article 15 – General rule

Scientific research in the field of biology and medicine shall be carried out freely, subject to the provisions of this Convention and the other legal provisions ensuring the protection of the human being.

Article 16 – Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

i. there is no alternative of comparable effectiveness to research on humans;

ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability;

iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Article 17 – Protection of persons not able to consent to research

1. Research on a person without the capacity to consent as stipulated in Article 5 may be undertaken only if all the following conditions are met:

i. the conditions laid down in Article 16, sub-paragraphs i to iv, are fulfilled;

ii. the results of the research have the potential to produce real and direct benefit to his or her health;

iii. research of comparable effectiveness cannot be carried out on individuals capable of giving consent;

iv. the necessary authorisation provided for under Article 6 has been given specifically and in writing; and

v. the person concerned does not object.

2. Exceptionally and under the protective conditions prescribed by law, where the research has not the potential to produce results of direct benefit to the health of the person concerned, such research may be authorised subject to the conditions laid down in paragraph 1, sub-paragraphs i, iii, iv and v above, and to the following additional conditions:

i. the research has the aim of contributing, through significant improvement in the scientific understanding of the individual's condition, disease or disorder, to the ultimate attainment of results capable of conferring benefit to the person concerned or to other persons in the same age category or afflicted with the same disease or disorder or having the same condition;

ii. the research entails only minimal risk and minimal burden for the individual concerned.

Article 18 – Research on embryos in vitro

1. Where the law allows research on embryos in vitro, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited.

Chapter VI – Organ and tissue removal from living donors for transplantation purposes

Article 19 – General rule

1. Removal of organs or tissue from a living person for transplantation purposes may be carried out solely for the therapeutic benefit of the recipient and where there is no suitable organ or tissue available from a deceased person and no other alternative therapeutic method of comparable effectiveness.

2. The necessary consent as provided for under Article 5 must have been given expressly and specifically either in written form or before an official body.

Article 20 – Protection of persons not able to consent to organ removal

1. No organ or tissue removal may be carried out on a person who does not have the capacity to consent under Article 5.

2. Exceptionally and under the protective conditions prescribed by law, the removal of regenerative tissue from a person who does not have the capacity to consent may be authorised provided the following conditions are met:

i. there is no compatible donor available who has the capacity to consent;

ii. the recipient is a brother or sister of the donor;

iii. the donation must have the potential to be life-saving for the recipient;

iv. the authorisation provided for under paragraphs 2 and 3 of Article 6 has been given specifically and in writing, in accordance with the law and with the approval of the competent body;

v. the potential donor concerned does not object.

Chapter VII – Prohibition of financial gain and disposal of a part of the human body

Article 21 – Prohibition of financial gain

The human body and its parts shall not, as such, give rise to financial gain.

Article 22 – Disposal of a removed part of the human body

When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.

Chapter VIII – Infringements of the provisions of the Convention

Article 23 – Infringement of the rights or principles

The Parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice.

Article 24 – Compensation for undue damage

The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law.

Article 25 – Sanctions

Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention.

Chapter IX – Relation between this Convention and other provisions

Article 26 – Restrictions on the exercise of the rights

1. No restrictions shall be placed on the exercise of the rights and protective provisions contained in this Convention other than such as are prescribed by law and are necessary in a democratic society in the interest of public safety, for the prevention of crime, for the protection of public health or for the protection of the rights and freedoms of others.

2. The restrictions contemplated in the preceding paragraph may not be placed on Articles 11, 13, 14, 16, 17, 19, 20 and 21.

Article 27 – Wider protection

None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention.

Chapter X – Public debate

Article 28 – Public debate

Parties to this Convention shall see to it that the fundamental questions raised by the developments of biology and medicine are the subject of appropriate public discussion in the light, in particular, of relevant medical, social, economic, ethical and legal implications, and that their possible application is made the subject of appropriate consultation.

Chapter XI – Interpretation and follow-up of the Convention

Article 29 – Interpretation of the Convention

The European Court of Human Rights may give, without direct reference to any specific proceedings pending in a court, advisory opinions on legal questions concerning the interpretation of the present Convention at the request of:

- the Government of a Party, after having informed the other Parties;
- the Committee set up by Article 32, with membership restricted to the Representatives of the Parties to this Convention, by a decision adopted by a two-thirds majority of votes cast.

Article 30 – Reports on the application of the Convention

On receipt of a request from the Secretary General of the Council of Europe any Party shall furnish an explanation of the manner in which its internal law ensures the effective implementation of any of the provisions of the Convention.

Chapter XII – Protocols

Article 31 – Protocols

Protocols may be concluded in pursuance of Article 32, with a view to developing, in specific fields, the principles contained in this Convention.

The Protocols shall be open for signature by Signatories of the Convention. They shall be subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve Protocols without previously or simultaneously ratifying accepting or approving the Convention.

Chapter XIII – Amendments to the Convention

Article 32 – Amendments to the Convention

1. The tasks assigned to "the Committee" in the present article and in Article 29 shall be carried out by the Steering Committee on Bioethics (CDBI), or by any other committee designated to do so by the Committee of Ministers.

2. Without prejudice to the specific provisions of Article 29, each member State of the Council of Europe, as well as each Party to the present Convention which is not a member of the Council of Europe, may be represented and have one vote in the Committee when the Committee carries out the tasks assigned to it by the present Convention.

3. Any State referred to in Article 33 or invited to accede to the Convention in accordance with the provisions of Article 34 which is not Party to this Convention may be represented on the Committee by an observer. If the European Community is not a Party it may be represented on the Committee by an observer.

4. In order to monitor scientific developments, the present Convention shall be examined within the Committee no later than five years from its entry into force and thereafter at such intervals as the Committee may determine.

5. Any proposal for an amendment to this Convention, and any proposal for a Protocol or for an amendment to a Protocol, presented by a Party, the Committee or the Committee of Ministers shall be communicated to the Secretary General of the Council of Europe and forwarded by him to the member States of the Council of Europe, to the European Community, to any Signatory, to any Party, to any State invited to sign this Convention in accordance with the provisions of Article 33 and to any State invited to accede to it in accordance with the provisions of Article 34.

6. The Committee shall examine the proposal not earlier than two months after it has been forwarded by the Secretary General in accordance with paragraph 5. The Committee shall submit the text adopted by a two-thirds majority of the votes cast to the Committee of Ministers for approval. After its approval, this text shall be forwarded to the Parties for ratification, acceptance or approval.

7. Any amendment shall enter into force, in respect of those Parties which have accepted it, on the first day of the month following the expiration of a period of one month after the date on which five Parties, including at least four member States of the Council of Europe, have informed the Secretary General that they have accepted it.

In respect of any Party which subsequently accepts it, the amendment shall enter into force on the first day of the month following the expiration of a period of one month after the date on which that Party has informed the Secretary General of its acceptance.

Chapter XIV – Final clauses

Article 33 – Signature, ratification and entry into force

1. This Convention shall be open for signature by the member States of the Council of Europe, the non-member States which have participated in its elaboration and by the European Community.

2. This Convention is subject to ratification, acceptance or approval. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

3. This Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Convention in accordance with the provisions of paragraph 2 of the present article.

4. In respect of any Signatory which subsequently expresses its consent to be bound by it, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of the deposit of its instrument of ratification, acceptance or approval.

Article 34 – Non-member States

1. After the entry into force of this Convention, the Committee of Ministers of the Council of Europe may, after consultation of the Parties, invite any non-member State of the Council of Europe to accede to this Convention by a decision taken by the majority provided for in Article 20, paragraph d, of the Statute of the Council of Europe, and by the unanimous vote of the representatives of the Contracting States entitled to sit on the Committee of Ministers.

2. In respect of any acceding State, the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of

deposit of the instrument of accession with the Secretary General of the Council of Europe.

Article 35 – Territories

1. Any Signatory may, at the time of signature or when depositing its instrument of ratification, acceptance or approval, specify the territory or territories to which this Convention shall apply. Any other State may formulate the same declaration when depositing its instrument of accession.

2. Any Party may, at any later date, by a declaration addressed to the Secretary General of the Council of Europe, extend the application of this Convention to any other territory specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings. In respect of such territory the Convention shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of such declaration by the Secretary General.

3. Any declaration made under the two preceding paragraphs may, in respect of any territory specified in such declaration, be withdrawn by a notification addressed to the Secretary General. The withdrawal shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of such notification by the Secretary General.

Article 36 – Reservations

1. Any State and the European Community may, when signing this Convention or when depositing the instrument of ratification, acceptance, approval or accession, make a reservation in respect of any particular provision of the Convention to the extent that any law then in force in its territory is not in conformity with the provision. Reservations of a general character shall not be permitted under this article.

2. Any reservation made under this article shall contain a brief statement of the relevant law.

3. Any Party which extends the application of this Convention to a territory mentioned in the declaration referred to in Article 35, paragraph 2, may, in respect of the territory concerned, make a reservation in accordance with the provisions of the preceding paragraphs.

4. Any Party which has made the reservation mentioned in this article may withdraw it by means of a declaration addressed to the Secretary General of the Council of Europe. The withdrawal shall become effective on the first day of the month following the expiration of a period of one month after the date of its receipt by the Secretary General.

Article 37 – Denunciation

1. Any Party may at any time denounce this Convention by means of a notification addressed to the Secretary General of the Council of Europe.

2. Such denunciation shall become effective on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 38 – Notifications

The Secretary General of the Council of Europe shall notify the member States of the Council, the European Community, any Signatory, any Party and any other State which has been invited to accede to this Convention of:

a. any signature;

b. the deposit of any instrument of ratification, acceptance, approval or accession;

c. any date of entry into force of this Convention in accordance with Articles 33 or 34;

d. any amendment or Protocol adopted in accordance with Article 32, and the date on which such an amendment or Protocol enters into force;

e. any declaration made under the provisions of Article 35;

f. any reservation and withdrawal of reservation made in pursuance of the provisions of Article 36;

g. any other act, notification or communication relating to this Convention.

In witness whereof the undersigned, being duly authorised thereto, have signed this Convention.

Done at Oviedo (Asturias), this 4th day of April 1997, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the European Community, to the non-member States which have participated in the elaboration of this Convention, and to any State invited to accede to this Convention.