INTERNATIONAL BIO LAW

Daniel García San José
Associate Professor of Public International Law
University of Seville (Spain)

INTERNATIONAL BIO LAW

AN INTERNATIONAL OVERVIEW OF DEVELOPMENTS IN HUMAN EMBRYO RESEARCH AND EXPERIMENTATION

EDICIONES LABORUM

EDICIONES LABORUM

Francisco Ortiz Castillo
Director editorial

Research done in the framework of the Research Project "Bioderecho Internacional: marco jurídico europeo relative a la investigación biomedical en transferencia y reprogramación celular DER 2010-14896 (subprograma JURI)". The current edition is economically co-financed by the Regional Government of Andalusia (Spain) trhough a competitive open call for supporting scientific work, launched by its Department of Science and Innovation in 2009 (Incentivos a trabajos científicos de la Consejería de Innovación, Ciencia y Empresa, III-2009)

1.ª edición Ediciones Laborum s.l. 2010

ISBN: 978-84-92602-28-5
DEPÓSITO LEGAL: MU-1527-2010
Impreso en España - Printed in Spain

Keywords: International Bio law - Juridical issues surrounding Life Sciences in Europe – Bioethics – Regulation of research on human cloning and human cell transfer and reprogramming exclusively for therapeutic purposes – Human Enhancement - Euro patent protection - Convergence of European Union Member States in ruling on human embryo cells research – Protection of fundamental rights – Public moral and conception of human life – Human Dignity - Right to Health Care – Global Health Ethics – Transplants -

To Daniel Antonio, my son,
and to María, my goddaughter.
They make the future today.

Acknowledgments

I want to thank to the Regional Government of Andalusia (Spain) by its economic aid to the publishing of this book through a public and competitive call for supporting the publishing of scientific works, launched by its Department of Science and Innovation in 2009 (Incentivos a trabajos científicos de la Consejería de Innovación, Ciencia y Empresa, III-2009)

I want also to express my gratitude to the colleagues of the Spanish Research Group *Bioderecho International SEJ-040* and to other colleagues from European Centers and Universities we are collaborating in biomedical research projects, for their stimulating intellectual companion.

I wish to thank to Mr. Francisco Ortiz, Head Publisher of *Laborum*, for supporting the birth of this book.

I want to make a special mention to my family, to my wife and son, for their patient and love.

CONTENTS

PART I

INTERNATIONAL BIO LAW TRASCENDING BIOETHICS

INTRODUCTION

A useful starting point for this study is to have a look at past. The first occasion Bioethics was enounced by Renssealaer Potter in 1970 was in an ecological context, as an interdisciplinary study in order to do research in the preservation of biosphere[1]. Nevertheless, technological and scientific breakthroughs on the last decades, has motivated that Bioethics refer ethical concern about the power that doctors and scientists may exercise in health and biomedical sciences[2]. Notably, the "New Renaissance" wanted for Europe in the research area for the next years, is conscious of this ethical concern. In a document prepared by the European Commission of the European Union in 2009, one can read:

> "We have learned that every powerful new technology can have bad as well as good consequences, and researchers can no longer ignore the ensuing political debate over how their discoveries will be used (…) Scientific excellence, therefore, must be paired with social awareness and responsibility. Integrating ethical, social and economic dimensions will make scientific endeavors even more valuable and relevant to society. At the same time, however, there should be a code of conduct for

1 Potter, Van Renssealer, "Bioethics, Science of Survival", *Biology and Medicine,* 1970, Vo. 14, pp. 127-153.

2 Kuhse, Helga and Singer, Peter, "What is Bioethics? A Historical Introduction", in *A Companion to Bioethics,* Kuhse, H., Singer, P. (eds.), 2nd ed., Wiley-Blackwell, Oxford, 2009, p. 3.

policy makers –standards for respecting fact and the product of research."[3]

The ethical concern of any society as regards what their scientists and researchers do is particularly evident in the field of research using live human embryos. As pointed out in Warnock and Braude, the ethical issues arising from the use of human embryos in research is not a matter of private morality but of public morality. In last instance, the key point is not so much whether individual scientist may be tempted to carry out such research, but whether people want to be members of a society that permit it to happen[4]. Nowadays everyone agrees that Bioethics needs legal regulation. Legislative approaches to Bioethics, however, have been anarchic and disaggregating. In the words of Professor Mazzoni who has written on the legislative history in the field of bioethics in the last three decades

"Some countries immediately adopted regulations disciplining specified sectors; others gave themselves legislation of a more general nature. Some countries have laws based on accepted principles; others have disciplines elaborated around concrete hypotheses. Some countries have given themselves legal codes that anticipate future developments, while others have laws clearly drawn up in fear of the future and of the evolution of new technologies, regulations consisting merely in a string of

3 European Commission of the European Union, *Preparing Europe for a New Renaissance. A Strategic View of the European Research Area*, Brussels, 2009, p. 19. For this reason it follows that researchers "must become better and more eager about explaining what they do. Communications training must become part of standard research training. A communications plan should be a prerequisite for research grant applications; it is not longer enough for 'dissemination of results' to use the classic channels (journals, websites) only. Where there is a disagreement about the outcomes of research, the public must be able to interrogate the data meaningfully." *Ibídem,* p. 20.

4 Warnock, Mary and Braude, Peter, "Research Using Preimplantation Human Embryos", in *A Companion to Bioethics,* Kuhse, H., Singer, P. (eds.), *op. cit.,* p. 489.

> prohibitions. In some countries the legislator simply allowed the laws to develop out of the growing social acceptance of new technologies, whereas in other countries the role of the laws in the field is seen more as one of fostering a new social ethics. Some countries waited for the international community, i. e., supranational Organizations, to intervene with general reference legislation, while others produced laws in an autonomous manner, reaffirming their legislative independence. Lastly, there are also countries which have produced no laws at all."[5]

It is not an overstatement to say that Bioethics and Law are condemned to understand each other if they want to resist, as the master of a castle, the attacks of "barbarian scientists" willing the instauration of a new order of unrestrained scientific and technological advances. One of the main features of the problem, however, is that the juridical approach to Bioethics has to be "fair" which it can be described, just as maintained by professor Christian Byk, like taking account "the two parts of the iceberg". This is possible –in this author's view- through the founding pillars of awareness, assessment and decision making of any juridical policy[6].

This "iceberg's approach" towards human embryo research seems totally convincing to face new developments in Bio Science and Biotechnology we are surprised with every day. To start with, let's consider nanotechnology; that is, the deliberate engineering of particles that are too small for the eye to see in order to create matter that has different properties than those at the conventional scale. What

---

5 Mazzoni, Cosmo M. (Ed.), "Bioethics Needs Legal Regulation", in *A Legal Framework for Bioethics,* Kluwer Law International, The Hague, 1998, p. 4.

6 Byk, Christian, "Juridical Policies and Bioethics: the three pillars of biomedical legislative wisdom", *Eubios Journal of Asian and International Bioethics,* 1995, Vol. 5, p. 59. Awareness (to be conscious that "icebergs" –new scientific and technological breakthroughs- exist and we may meet them; assessment, that is, to evaluate what kind of consequences would follow from such a meeting; and decision making, that is, the fact of wishing to take measures to organize such meetings and their consequences.

should be established at the very outset is that there are reportedly over three hundred products for human consumption containing nanomaterials and the figure is increasing since engineering nanoscale materials is revolutioning pharmaceuticals, semi-conductor manufacturing, communication technology, chemical production, consumers' products as cosmetics and others[7]. The issue of nanotechnology engineering could be approached from another angle. It could be claimed that due to their size[8], nanoscale materials have the potential to enter the blood and lymph circulation to reach potentially sensitive target sites such as bone marrow, lymph nodes, spleen and heart[9]. This example illustrates a growing public concern which has motivated, for instance, that the *European Group on Ethics for Science and New Technologies*, depending on the European Commission of the European Union has devoted a recent Opinion to address the bioethical issues surrounding the synthetic biology[10].

Let's now go on to consider regenerative medicine and the blooming future it promises: repairing, replacing or regenerating cells, tissues or organs, all this intended to restore impaired functions resulting from any cause, including congenital defects, disease, trauma or aging. It is evident that regenerative medicine uses a combination of several technological approaches (gene therapy, stem cell transplantation, tissue engineering, reprogramming of cells and tissues, among others) which have in common their ethical controversial. There is a widespread attitude nowadays that the foremost task of Law is the regulation of stem cell research, affecting such legislation the extent to which physicians will encounter regenerative medicine therapies in

---

7 Hartman, Barry M. and Naidu, B. David, "Nanotechnology: An Update on Business Opportunities and Regulatory Challenges", *The Journal of Biolaw & Business,* 2007, Vol. 10, No. 1, p. 25.

8 "Nanoscale" means that the materials are one ten-thousandth the diameter of human hair.

9 Hartman, Barry M. and Naidu, B. David, "Nanotechnology: An Update on Business Opportunities and Regulatory Challenges", *op. cit.*, p. 25.

10 Opinion No. 25 of 17 November 2009 on Ethics of synthetic biology. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm

practice, and the kinds of therapy that are at their disposal[11]. It would be naïve to suppose that Bioethics alone is sufficient to address this question in morally pluralistic societies where, by definition, many areas of moral disagreement arise where a public decision has to be made. Supposing you can manage it without Law and Policy makers, should people be allowed to act in the ways they want provided they do not cause harm to others? Paradoxically, authors like Soren Holm observe that the call for freedom often has to be combined with a call for State action[12]. In fact, it would be rather a question of deciding the way the State should allocate public resources between different claims. It would be open to question how to proceed then. Holm maintains here that the pure option of the majority rule would lead to highly problematic outcomes involving discrimination of minorities. He also holds that letting the philosophers the ruling power seems rather unattractive for being indistinguishable from other forms of oligarchy[13]. My own point of view is that Law is to attend the call of Bioethics, under the iceberg's approach, as described above.

In this connection, we could also point out that there exists a dialectic discussion confronting those who defend freedom for scientific embryo research, and those other who attack any research on embryos and the application of technical developments on human beings. Clearly, several questions arise up in connection with human embryo research, which later on a detailed analysis will be presented:

---

11 Greenwood, Heather L. and Daar, Abdallah S., "Regenerative medicine", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, Cambridge, 2008, p. 155.

12 "Many of the goals that are aimed at through an effective exercise of individual freedom can only be achieved if the legal order is arranged in such a way that the action creates the legal effects people want. E.g., stem cell researchers want to be able to patent stem cell lines… Whether or not legal regulations should be changed to enable people to accomplish these goals cannot be decided by a reference to their liberty interests." Holm, Soren, "Policy-Making in Pluralistic Societies", in *The Oxford Handbook of Bioethics* Steinbock, Bonnie (ed.), Oxford University Press, Oxford, 2007, pp. 156-157.

13 Holm, Soren, "Policy-Making in Pluralistic Societies", in *The Oxford Handbook of Bioethics* Steinbock, Bonnie (ed.), *op. cit.,* p. 158.

the question of human dignity and fundamental human rights which could be endangered with these bio techniques. The question of the purposes of any human embryo research, that is, for the benefit of mankind in general or for any individual or group of people, etc. Not all authors are against human embryo research[14]. Those who oppose or support this research do it for different reasons. Thus, there are who defend freedom for science under a regulation, national and international, as it will serve to cure severe illness in near future, or considering that any interdiction would have as a result opening the door for carrying on with such research clandestinely. Then, it would be almost impossible to guarantee acceptable security standards for human dignity and fundamental rights. Among those opposing this research are those who appeal the conceptionist approach to human life –and they oppose any kind of embryo research- whereas others adopt a gradualist or developmental views by which, the moral weight of the embryo and foetus is not established once and for all, but rather it increases over the course of a pregnancy as additional morally significant features make their appearance[15]. These moderate views seem willing to permit embryo research, including research that destroys the embryo, up to fourteen days of development[16].

We can see, then, that even a superficial look at this matter reveals as a highly controversial issue to determine which is the limit to the regulation of the human embryo research under the dignity principle. What should be established at the very outset is the moral status of

14 See the relevant contributions in Beauchamp, Tom L. (Ed.), *Contemporary issues in bioethics,* Thomson Wadsworth, 2003, 6. ed., Belmont: Gillow, Ranaan, "Human Reproductive Cloning: A Look at the Arguments Against It and a Rejection of Most of Them", pp. 621-632; Mcgee, Glenn and Caplan, Arthur L., "The Ethics and Politics of Small Sacrifices in Stem Cell Research", pp. 646-648.

15 These views stress the moral importance of qualities like sentience, brain activity, the presence of substantial bodily form or the viability of embryo, that is, the ability to survive independently of the mother. Green, Ronald M., "Embryo and foetal research", in *The Cambridge Textbook of Bioethics* Singer, Peter A. and Viens, A. M. (eds.), *op. cit.,* p. 234.

16 Green, Ronald M., "Embryo and foetal research", *op. cit.,* p. 235.

human embryo. At this regard, some ethics positions consider it as a person to provide it the highest possible protection[17]. Others, the majority of authors, present more moderate views. The former and the latter have in common, nevertheless, the need of due respect to embryos which cannot be considered as mere objects. They all disagree, however, in determining what does "due respect" mean in this context. There are, of course, authors refuting the need to provide such a due respect to human embryo, but they suppose, in my opinion, a residual position in doctrine. Most of authors, in a word, consider personhood as a matter of degree, so the question is whether potential personhood is morally significant. For those supporting the potentiality criteria, it might be relevant to distinguish between passive and active potentiality, in order to restrict morally relevant personhood only to active potentiatility[18]. Other authors consider it not worthy of our attention such distinction between active and passive potentiality. This is the view, for instance, of Michael Tooley, who explains himself through the following example,

> "Consider the following case, where there is a fully active potentiality. An artificial womb has been perfected, and it now contains an unfertilized ovum, along with a spermatozoon. There is also a device, however, that will ensure that fertilization will soon take place, and that if there is no interference, the result will be the emergence, in nine months time, of a normal human baby, who will then receive appropriate care so that it can continue to develop. This situation involves, accordingly, a fully active potentiality. What is the moral status of destroying the fully active potentiality by, say, turning off the machine before fertilization has taken place? Very few people, it seems, would hold that such an action is morally wrong. If this is right, then the

17 For them, personhood begins at conception so even very early extracorporeal embryos have full moral status, making embryonic stem cell research that destroys embryos unacceptable under moral grounds.

18 Tooley, Michael, "Personhood", in *A Companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.), *op. cit.*, p. 135.

> destruction of a fully active potentiality for personhood, rather than being morally comparable to the destruction of a person, is not morally wrong at all."[19]

Other authors, like Ronald Lindsay reach similar conclusion *ad absurdum*:

> "(T)hrough somatic cell nuclear transfer, a somatic cell is allowed to express its potential to be transformed into an embryo that is latent in its genes but has been suppressed. If gene-based potential to develop into a human person is sufficient to provide an entity with full moral status, then each somatic cell in a human person's body has the same moral status as the person herself, because each cell has the potential to become a person, just as embryo does. The argument from potential leads to absurd conclusions, and, for that reason alone, should be rejected."[20]

In fact, Ronald Lindsay goes far beyond than Michael Tooley in suggesting that an egg that has received its nucleus from a somatic cell should be called a "clonate" as distinguished from zygote, which is the term used to describe an egg successfully fertilized by sperm[21].

Conscious of controversial surrounding to moral status of potential personhood, authors like Bonnie Steinbock, prefer to assert that very early, extracorporeal embryos do not have moral status but moral value, consequently, any human embryo is to be respected and cannot be treated as 'stuff' of no moral significance[22]. The distinction this author proposes between moral status and moral value concerns the kind of reasons invoked for such respect: whereas in the moral status, protec-

---

19 Tooley, Michael, "Personhood", *op. cit.,* p. 136.

20 Lindsay, Ronald, A., *Future Bioethics*, 2008, Prometheus Books, New York, p. 258.

21 Lindsay, Ronald A., *Future Bioethics, op. cit.,* p. 236.

22 Steinbock, Bonnie, "Moral Status, Moral Value and Moral Embryos: Implications for Stem Cell Research", in *The Oxford Handbook of Bioethics, op. cit.,* p. 433.

tion for respect stems from their interest or welfare, in the moral value this is not possible because human embryos are non sentient beings (like works of arts, ancient oaks, wilderness areas and so on). The inevitable conclusion, therefore, is that due respect to human embryos as a form of human life is secured using them only for morally significant purposes, such as enabling infertile people to become parents and in research that could cure devastating diseases or save lives[23]. Other authors explore alternative moral justifications[24]. This is the case, among other authors, of the already referred Ronald Lindsay. In his view, in deciding whether the embryo is entitled to moral consideration equal to that extended to human persons, we need to ask ourselves whether such treatment serves the objectives of morality. Thus, he states that

> "We must bear in mind that morality has objectives, one of which is to protect our children because they embody our hopes and aspiration and any moral community is presumed a desire to survive for more than one generation. Consequently, babies who are wanted and intentionally gestated are entitled to the protection of our moral norms, but embryos that are designated for research use are, by definition, not entities that are, or have the potential to become, children and members of the moral community."[25]

---

23 Steinbock, Bonnie, "Moral Status, Moral Value and Moral Embryos: Implications for Stem Cell Research", *op. cit.,* p. 438. In this example, author argues that medical research having the potential to prolong and improve people's lives is at least as valuable as enabling infertile people to become parents, in order to which many of embryos that are created are not used to establish a pregnancy, but are frozen and ultimately discarded. Nothing to object the justification for the creation of excess embryos is to spare the woman several rounds of superovulatory drugs, which is both physically burdensome and expensive. Nevertheless, the similar treatment for medical research.

24 Álvarez-Díaz, Jorge A., "El estatuto biológico del embrión humano. Nuevas repercusiones bioéticas y biojurídicas", *Law and Human Genome Review,* 2008, Vol. 28, p. 210.

25 Lindsay, Ronald A., *Future Bioethics*, *op. cit.,* p. 253.

In this connection, we could also point out that not only is the creation of human embryo by sperm-ovule fecundation for research purposes and experimentation ethically controversial. Making human embryos by way of somatic cell nuclear transfer (SCNT) for reproductive or therapeutic purposes, pose also ethics issues because of the use of the stem cells (Stem cells are those that can both replicate and also differentiate into several types of cells) or so called "pluripotent cells" (that is, stem cells capable of giving rise to all cell types in the body). It should be mentioned in passing that somatic cell nuclear transfer to obtain stem cells by way of the creation of embryos brings up the following ethic problem: once the inner cell mass, from which the stem cell lines are derived, is removed from the cloned embryo this must be destroyed. Some countries, like the United Kingdom, has solved this dilemma by introducing the temporal limit of 14 days for a somatic cell nuclear transfer but other countries still consider that no matter the time, one would be facing the same technique of cloning although with two eventually different outcomes: the creation of human clones or the production of embryonic stem cells.

In order to overpass this controversial, Spanish authors have advocated for new juridical conceptualization further than biological definition for embryo[26]. BERIAIN for instance, maintains the description of the embryo as a cell or group of cells capable to self-develop up to originate a person and which are in the suitable conditions to do it[27]. Such definition seems particularly useful in the case of somatic cell nuclear transfer in Spain because current definition included in Article 3 of the Act 14/2007 of 3 July, on Biomedical Research in Spain[28], may be thus

26 DE MIGUEL BERIAIN, Íñigo, "El embrión humano después de Dolly: Nuevas pautas para nuevos tiempos", *Law and Human Genome Review,* 2008, Vol. 29, p. 45.

27 *Ibídem,* p. 63. We will see it back in Chapter 5 when we analyse the Spanish and Andalusian Biomedical Acts.

28 Such definition in the Spanish Act on Biomedical Research defines embryo as "a phase of embryonic development from the moment in which the fertilised ovocite is found in the uterus of a woman until the beginning of organ genesis and which ends fifty-six days from the moment of fertilisation, with the

consistent with the doctrine of Spanish Constitutional Court[29] and with Article 18.2 of the Biomedicine and Human Rights Convention, by which the creation of human embryos for research purposes is prohibited[30]. As Beriain asserts, such definition can be useful for avoiding a public moral debate in Spain as far as Somatic Cell Nuclear Transfer is concerned. This technique, not creating "human embryos", makes discussion unnecessary. Another way of looking at this definition, however, is that it raises the need of facing one day a dilemma –where a person to be born through this technique- of whether accepting this person is not human for never having been originated as a "human embryo" or whether accepting the inconsistency (and unlawfulness) of the Spanish regulation of human embryos[31].

Other factors that should be taken into account in determining the controversial ethical aspects of human embryo research is the fair balance to be struck between the regulation on human embryo research and the effective protection of human rights such as the right to health[32]. Historically, the right to health was first considered not as a human right but as a right of some groups of human beings, such as wounded combatants, under the *Martens clause* and the dictates of "elementary considerations of humanity"[33]. Later, according the con-

---

exception of the computation of those days in which the development could have been stopped."

29 See Barrero Ortega, Abraham, "Reflexiones Constitucionales a propósito de la investigación biomédica en Andalucía", in *Régimen Jurídico de la Investigación Biomédica en Andalucía,* García San José, Daniel (Coord.), Laborum, Murcia, pp. 81-94.

30 Convention on Human Rights and Biomedicine, made in Oviedo (Spain) the 4th April, 1997, ETS (European Treaty Series) No. 164.

31 De Miguel Beriain, Íñigo, "El embrión humano después de Dolly: Nuevas pautas para nuevos tiempos", *op. cit.,* pp. 57-58.

32 For instance, in case a particular person's fundamental right such as the right to the enjoyment of the highest attainable standard of health could require research on embryos, would this fundamental right prevail over any ban on this kind of research by national authorities who consider in the context of their national society to be contrary to human dignity?

33 *Corfu Channel, Merits, I.C.J. Reports* 1949, p. 22, paragraph 215.

ception of rights prevailing in the 18th and 19th Centuries, the human right to health was recognized for citizens but only restraining the State from actively denying it to them. Since its very first formulation in the preamble to the Constitution of the World Health Organization in 1946 "the attainment by all peoples of the highest possible level of health"[34], the human right to health for everyone, implying both, positive and negative obligations for States, has been included in the most relevant international human rights instruments.

According to the World Health Organization, health is "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". Any State assumes an own understanding of an "adequate standard of living for health and well-being". This conceptual divergence is evidenced in the very definition of the human right to health at national and international level: right to health, right to health care, right to medical care, right to health protection, etc. In practice, "right to health" is the most common expression. Nevertheless, the right to health is generally understood as a shorthand expression for "*Everyone's right to the highest attainable standard of physical and mental health, including reproductive and sexual health, without discrimination of any kind*".

In this connection, patients around the world suffering from some diseases such as Parkinson' disease, Alzheimer's disease and diabetes have applied scientists to engage in cloning for research invoking their right to health. Since 2001 the United Nations has been considering the elaboration of an international convention on the cloning of human beings. At present, clearly there is consensus in the international community to ban reproductive cloning but not as far therapeutic cloning as it proves the Resolution 59/280, which endorses the United Nations Declaration on Human Cloning, adopted on 8 March 2005 with the voting result of 85 states members in favour, 34 against and 37 abstaining. This Declaration does not define terms such as ´human cloning´,´human dignity´and ´human life´. The inevitable conclusion is that any State may consider which therapeutic

34 U.N.T.S. 186, 22 July 1946, entered into force 7 April 1948.

cloning should or should not be banned balancing moral issues and scientific knowledge.

I would even go as far as to say that in case the human right to health might be used to justify an international regulation which allowed human embryo research, we must raise the question of how other fundamental human rights should be protected against the risks of such human embryo research. Even a superficial look at this issue reveals that a fundamental right to not suffer discrimination could be in conflict with the right to health using human embryo research in the following way: firstly, genetic manipulation would serve to treat specific illnesses, such as Alzheimer, Parkinson, etc. Sooner than later, genetic researchers would study the brain and the five senses in order to get a better understanding of it's functioning. Thus, they would be able, for example, to improve the gene which works on memory. The next step would be intruding strange genes into the human genome. As an example –not unrealistic for some authors- thanks to the genes of bat, it will be possible to get human beings with night-vision capacity. It seems logical to believe that people with monetary resources will try to benefit from any social advantage the human cloning research could provide them, in a similar way to plastic surgery is used by people wanting just to look younger or supposedly more attractive. In this case, any society will divide into two social groups: those genetically improved and those who have not. Once a family has run with the expenses of the genetic improvement of its members, it would be rather unusual to get "dilapidated" its "genetic treasure" with non-improved individuals. So, as times goes by, social breach into that society will become wider and deeper[35].

The conclusion that can be drawn from previous considerations is that it is useless to keep on talking about the controversial ethical aspects of human embryo research. The Science is making enormous strides today and any simplification of the approach from Bioethics to

35 Lee, M. Silver, "U.S. Dream child or nightmare scenario?", *UNESCO The Courier,* September 1999. Available at:http://www.unesco.org/courier/1999_09/UK/dossier/intro02.htm

Bioscience and technological advances is to be disregarded because it will lead us to an end-up road. In my opinion, a holistic, multidimensional approach is preferred as being more consistent with the complexity surrounding research on human embryos. Undoubtedly, in the human embryo research enter into consideration ethical questions as it happens in any scientific development having social consequences. My view is, however, that this is a relatively minor problem when compared to the pros and cons of the human embryo research for the society as a whole. Everyone agrees that it is important to strike a balance between what a society can do and what it should or should not to do. Embryonic stem cell research does have the potential to provide us with revolutionary therapies and is a critical tool in learning about early human development, including the causes of birth defects. As Ronald Lindsay asserts, these potential benefits cannot by themselves justify scientific research. "We do not force adult humans to ingest drugs that are being developed merely because it would be helpful in advancing our scientific knowledge."[36] In addition, it is undeniable that research on human cloning risks not only the trivialization of human life and be contrary to human dignity in the sense that human beings can be considered as commodities and artefacts. This research may also endanger the respect of some fundamental rights such as the right to life, to psychical and physical integrity, to genetic privacy and to not suffer discrimination. In this final analysis, however, the risk of breaching these rights should not prevent us from the chances and benefits these techniques offer in finding out a cure for some severe illnesses. In this sense, the enjoyment of the highest attainable standard of health must also be balanced as a fundamental right to be preserved.

In other words, what seems to be the starting point of any debate about the use of human embryos for research and therapeutic purposes –the common assumption that to use other human beings for such purposes is something that must not be undertaken lightly[37]

36 Lindsay, Ronald A., "Future Bioethics", *op. cit.,* p. 239.

37 Warnock, Mary and Braude, Peter, "Research Using Preimplantation Human Embryos", *op. cit.,* p. 487.

–cannot be changed into the ending point of such debate. The fundamental argument for our approach is that those with a dogmatic belief that all human life is equally valuable must accept the fact that most people, who are sensitive to moral issues, share a biological gradualist view and they think of the developing embryo as more valuable the further it has developed[38]. Simplifying positions in this field might be as risky as skating on thin ice. For example, would it be enough just to say that the strongest opposition to human embryo research comes from religious grounds? As Eric Gregory has held, most Christian ethicists accept somatic cell gene therapy as an extension of non-genetic medical therapies which seek to cure or reduce the effects of disease. The Roman Catholic Church does not oppose stem cell research as such, but it officially rejects research that involves harvesting stem cells through the intentional destruction of embryonic life. Protestant positions on stem cell research are generally similar to Catholic argument. To a certain extent, approaches in their concerns come from putting in the same place reservations about an absolute protection of embryonic life assimilated to any person's life[39] and a "technological imperative" that risks crossing the line between therapy and enhancement in prideful search of human perfection[40].

---

38 Warnock, Mary and Braude, Peter, "Research Using Preimplantation Human Embryos", *op. cit.,* p. 492.

39 As this author reveals, Christian, Protestants and many Roman Catholic ethicists are not fundamentalist defenders of human personhood. Human embryos may deserve respect as bodies but they are not persons in the relevant sense and so their use in research, especially existing embryos bound to be discarded rather than embryos cultivated for research, should not be rejected given the potential benefits. Gregory, Eric, "Religion and Bioethics", in *A Companion to Bioethics, op. cit.,* p. 51.

40 Most religious ethicists although worried about the commoditisation of human bodies, also are concerned about power and distributive justice in the biotechnological marketplace. Thus, as Gregory points out, "this concern may lead some to argue for greater public funding of scientific research in order to alleviate further disparities of unequal access to health care and resources generated by private research. Gregory, Eric, "Religion and Bioethics", in *A Companion to Bioethics, op. cit.,* p. 52.

In short, my personal opinion on the matter is that a kind of arrangement between Bioethics and Law has to come into being, by which

> "Legislators cannot disregard the spontaneous, often unargued reactions of members of the public. One cannot take away the right of people to express their moral opinion. So, such a position of consensus will probably contain the proviso that human research material should not be used without serious beneficial purpose (for that society) that otherwise cannot be achieved"[41]

The general aim of this book is to present the research done in the late years by his author on the lights and shadows surrounding Biomedical research in International Law and, in particular, in European Law. It is wanted to value the normative approaches in the European context relating to research on Somatic Cell Nuclear Transfer and human cell reprogramming exclusively for research and therapeutic reasons. In this exam it will be continuous references to the current legislation in Spain and in Andalusia, the only Spanish Region with biomedical legislation on this issue[42].

One of the key issue concerns the question whether is it possible to recognise at European level a common normative framework (a *corpus iuris*) in the field of biomedical research and, in particular, as regards human embryo research. This *corpus iuris*, in case it exists, should provide normative answer to controversial bioethical issues at two levels: concerning the regulation of what can be object of research, by which means and procedures it should be done and relating

41 Warnock, Mary and Braude, Peter, "Research Using Preimplantation Human Embryos", *op. cit.*, p. 493. We will come back to this idea of consensus in Chapter 6.

42 At national level, Act 14/2007, 3 July 2007, *de investigación biomédica en España*, boe nº 159, 4 July 2007, pp. 28826 a 28848. In Andalusia, Act 1/2007, 16 March 2007, *por la que se regula la investigación en reprogramación celular con finalidad exclusivamente terapéutica en Andalucía*, boe nº 89, 13 April 2007, pp. 16299 a 16302.

the legal protection of result of such research by way of patents. The sound idea is that once we have identified such European *corpus iuris* in the field of human embryo research, then it will be easy to establish confining parameters (like a supranational frame) of any national legislation in Europe for this topic, by fixing the margin of how much discretional can be national authorities and private entities as well. It will also help for guaranteeing rights and freedoms of citizens and for providing security for researchers working with human embryos.

The content and extent of this *corpus iuris* is to be developed by taking reference to the European Union[43] and to the Organisation of the Council of Europe as well. It is also methodologically assumed that in order to identify this *corpus iuris* a multidisciplinary, integrative and transversal approach is necessary. From a multidisciplinary approach, firstly, all branches of Law are concerned with national and international regulation of human cloning and research on human cell transfer and reprogramming (Constitutional Law, Civil Law, Philosophy of Law and Bioethics, International and Comparative Law, etc.) From an integrative approach, secondly, it is defended a holistic vision of this topic and avoiding to fall into a dialectic speech (focusing only the "pros" or the "cons") of researching on human embryos. Finally, it is defended a transversal approach because it is considered that there is a global concern on human cloning. It must be admitted that any country in the world is directly or indirectly affected by this issue. Consequently, normative approach should be combined and complemented at national and international level. Similarly to what happens to other global concerns such as environmental protection, cooperation and coordination among States are essential for being successful, not being enough individual and isolated approaches.

Bearing in mind the specific situation of Spain, leading at European level the biomedical research on embryo cells reprogramming,

43 In this sense, it seems of particular relevance for assessing the task ahead to consider the four different approaches identified in Europe by the European Groups on Ethics in its Opinion No 22, *permissive position*, *permissive position with restrictions, restrictive position* and *no specific legislation or indirect legislation only.*

one of the specific objectives of this book is to consider such *corpus iuris* with regard to the new techniques of human cell reprogramming exclusively for therapeutic reasons. Thus, it will be worthy of our attention challenges and problems associated to these new techniques which seem to overlap the moral and ethical controversial of other research techniques implying the creation-destruction of human embryos.

In the final pages we propose the judicial approach as preferred to *Waiting for Godot* and for legal solutions which never arrive for dealing with old and new issues related to human embryo research with implications for human beings' rights and freedoms. Confronting the judicial reasoning of the European Court of Human Rights in controlling the obligations assumed by Contracting States as regards rights and freedoms under the European Convention, a useful tool may be presented to resolve juridically bioethical controversial surrounding research with human embryos. Furthermore, although no right to health is protected under the European System of Human Rights, nor any reference to embryo research, one can advance that this is not an obstacle for the European Court to grant its saying in this topic as experience has proved in past in similar situations, like considering the environmental dimension of some rights and freedoms proclaimed in 1950[44]. In all probability, new bioethical controversial issues will appear in next years concerning human embryo research and experimentation. We can not even envisage them but we can prepare ourselves to face them. As Professor BYK encouraged us to do, through the founding pillars of awareness, assessment and decision making of a right juridical policy for human embryo research in Europe and, why not, also expendable to the International Community of States.

The hidden purpose of this book is to try to give an answer to the following questions "Which is the best approach from International

44 See García San José, Daniel, *The Environment Dimension of the European Convention of Human Rigghts*, Council of Europe Publishing, Strasbourg, 2005.

and European Bio law to give satisfaction for legitimate expectations of citizens facing the non-stop advance of Science in human embryos research? Which are the subsequent legal implications derived from it, considering economic, moral and social aspects? Reader would judge if I succeeded or failed in the trial.

CHAPTER 1

THE NECESSARY INTERNATIONAL APPROACH TO BIO LAW

1.1. Introduction

By way of introduction, we can say that some authors have advocated for new and critical approaches to Bioethics to meet the complex emerging challenges to healthcare, medicine, the body and society[45]. For instance, the issue of inaccuracy of one of the most reputed bioethical principle, the free consent of subjects of the research, when applied to research in developing countries –something rather common in the latest years- has been maintained by some authors. One of these authors, Florencia Luna, asserts that

> "Developing countries' problems show that ethics does not end with the acceptance of a contract; the conditions under which it is accepted are also relevant. Individuals with no other choice may find it difficult to refuse to participate in research. They are not acting as contractors, and they may reflect the characteristics of the victim. The situation of a Swedish research subject who enjoys a public, efficient and accessible healthcare system is far cry from

45 Murray, Stuart J. and Holmes, Dave (eds.), *Critical Intervention in the Ethics of Healthcare,* Ashgate, Farnham, 2009, p. 2. In his own words, "Global bioethics calls us to be accountable for our actions and appetites in relation to these three spheres; and to examine how well society, our politics, economies (industry and commerce), religious and other traditions, as well as our personal lives, are in accord with the bioethical principles that unify these three spheres in the light and language of compassion, humility and reverence for the sancticity of life".

> the subject in Mozambique or Bolivia who has no access to vital medication. It is not enough just to have a clear initial contract."[46]

These critics to early accepted bioethical guidelines have let open the door to a "New Deal" for Bioethics, which in some way resembles a return to its origins as a discipline of study – a science of survival[47]- thanks to the idea of Global Bioethics[48]. By such, it is called to give equally fair consideration to three spheres of moral concern: human well-being (rights and interests), non-human well-being (rights and interests) and environmental well-being (biodiversity and ecosystem integrity)[49]. I feel most strongly that it is on the grounds of Global Bioethics that International Law is increasingly concerned as it could be claimed the international obligations among States to preserve environment[50] or to implement the hu-

---

46 Luna, Florencia, "Research in Developing Countries", in *The Oxford Handbook of Bioethics* Steinbock, Bonnie (ed.), *op. cit.,* p. 643. The principal reason for companies conducting clinical research overseas is to avoid regulations and human rights protection that control domestic research in United States and other developed countries. See Lee, Stacey B., "Informed consent: Enforcing pharmaceutical companies' obligations abroad", *Health and Human Rights,* 2010, Vol. 12, No. 1, p. 15.

47 See footnote 1.

48 Global Health Ethics appears as an idea through which to promote widely values that include meaningful respect for human life, human rights, equity, freedom, democracy, environmental sustainability and solidarity. See, Benatar, Solomon R., "Global health ethics and cross-cultural considerations in bioethics", in *The Cambridge Textbook of Bioethics* (Singer, P. A. and Viens, A. M., eds.), *op. cit.,* p. 341.

49 Fox, Michael W., *Bringing Life to Ethics,* State University of New York Press, New York, 2001, p. 38.

50 From this Global Bioethics approach it would be immoral and to be criticized the position of United States and of four other countries –Canada, Australia, Chile and Uruguay- when they opposed at the United Nations Bio safety Protocol meeting in Cartagena, Colombia, in February 1999 to a treaty supported by 130 other countries including the European Union. Such ratification would have required these five countries to obtain advanced approval from importing nations before they could export genetically altered plants, seed or other organ-

man right to health worldwide through a universal regulation on human embryo research.

In this sense, some authors call for Global Health to refer health issues and problems that are most efficiently addresses by transnational collaborative actions and solutions[51]. Refuting libertarian objections to a demand of distributive justice in the field of health care[52], they advocate for well-off people's obligations aimed at reducing unnecessary disease –related suffering and reasonably preventable deaths towards the poor. It is inside this Global Health movement that the Human Right Approach to Health (HRAH) is defended. By such approach, Governments are encouraged to follow through on what they have agreed to do in legally binding treaties by providing a framework for enhancing accountability of the achievement of health commitments[53]. Article 12 of the International Covenant on Economic Social and Cultural Rights, as it has authoritatively been interpreted by the *Committee on Economic, Social and Cultural Rights* in its General Comment No 14, as "a fundamental right indispensable for the exercise of other human rights"[54], is invoked at this regard. This is one of

---

isms. Instead, they choose to ignore the concerns expressed by the rest of the world about the potential risks and harms of this new technology –risks that an international bio safety treaty on genetically altered seeds and foods might be able to minimize. Fox, Michael W., *Bringing Life to Ethics, op. cit.,* pp. 105-106.

51 Lowry, Christopher and Schüklenk, Udo, "Global Health Responsibilities", in *A Companion to Bioethics, op. cit.,* p. 393.

52 These objections essentially refer to negative obligations instead of positive ones towards others. Thus, if a country abstains from harmfully interfering with other countries, its citizens have no positive and collective moral duty towards citizens of other countries. Similarly, so long as a person abstains from harmfully interacting with other people, she has no such individual positive moral duty towards them. Lowry, Christopher and Schüklenk, Udo, "Global Health Responsibilities", *op. cit.,* p. 395.

53 Bustreo, Flavia and Doebbler, Curtis F. J., "Making Health an imperative of foreign policy: the value of a human right approach", *Health and Human Rights,* 2010, Vol. 12, No. 1, p. 50.

54 Committee on Economic, Social and Cultural Rights, *General Comment No 14, The Right to the Highest Attainable Standard of Health*, UN Doc. E/C.12/2000/4, paragraph 1.

the most striking examples which although is not to be understood as a right to be healthy, nevertheless, "it does create States' obligations, and those obligations may be violated"[55]. The duties are defined generally as the "immediate obligations… (To)… guarantee that the right will be exercised without discrimination of any kind" and to take steps towards the full realization of the right that must be "deliberate, concrete and targeted towards the full realization of the right to health"[56].

Even the situation among developed nations if far from satisfactory. In this sense, access to medicines is moving from moral ground to juridical obligations, providing an example of the links of bioethics and International Law through the idea of global bioethics. In effect, many authors and it number is increasing day to day, see access to medicines for citizens of developed and in developing countries as a States' obligation to ensure such access under Article 12 of the United Nations International Covenant on Economics, Social and Cultural Rights[57], and under other universal[58] and regional[59] instruments of protecting human rights. Thus, for these authors,

---

55 *Ibídem*, paragraph 1.

56 *Ibídem*, paragraph 30.

57 This Article 12 outlines the right to the highest attainable standard of health, which for authors, include the right to the availability of essential medicines as defined by the World Health Organization. The United Nations Committee on Economic, Social and Cultural Rights would have recognised so in *General Comment No. 14, Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights,* E/C.12/2000/4. See Cohen-Kohler, Jillian C. and Illingworth, Patricia, "Access to medicines and the role of corporate social responsibility: the need to craft a global pharmaceutical system with integrity", in *The Cambridge Textbook of Bioethics, op. cit.,* p. 360.

58 See, for instance, International Convention on the Elimination of All Forms of Racial Discrimination; Convention on the Elimination of All Forms of Discrimination against Women; Convention on the Rights of the Child; International Labour Organisation Convention No. 169 concerning Indigenous and Tribal People in Independent Countries; International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families; and Convention on the Rights of Persons with Disabilities. Bustreo, Flavia and Doebbler, Curtis, F. J., "Making health an imperative of foreign policy: the value of human rights approach", *op. cit.,* p. 50.

59 Such as the African Charter on Human and Peoples' Rights; Protocol to the

> "Through the legal obligations to 'respect', 'protect' and 'fulfil' the right to health, governments have implicit duties to ensure that pharmaceutical system are institutionally sound, transparent, and have appropriate mechanisms to reduce the likelihood of corruption or undue influence. This includes sufficient regulation of the pharmaceutical industry to ensure that the 'appropriate' corporate behaviour is being practiced. Regulation of the pharmaceutical system is a core government responsibility."[60]

1.2. The International Law contribution to Global Bioethics

It is commonly asserted that, facing increased and more complex challenges, the international community needs a new paradigm of security, shifting from the security of State to the security of people. This new paradigm of security for the 21st Century centred on people is on the basis of the concept of *human security*, with its own content: "Human security means protecting fundamental freedoms, freedoms that are the essence of life. It means protecting people from critical (severe) and pervasive (widespread) threats and situations. It means using processes that build on people's strengths and aspirations. It means creating political, social, environmental, economic, military and cultural systems that together give people the building blocks of survival, livelihood and dignity." [61]

African Charter on Human and Peoples' Rights on the Rights of Women in Africa; African Charter on the Rights and Welfare of the Child; San Salvador Protocol to the American Convention on Human Rights; European Social Charter of the Council of Europe; Charter of Fundamental Rights of the European Union; Cairo Declaration on Human Rights in Islam; Arab Charter on Human Rights; and Charter of the Association of South East Asian Nations. Bustreo, Flavia and Doebbler, Curtis, F. J., "Making health an imperative of foreign policy: the value of human rights approach", *op. cit.,* p. 51.

60 Cohen-Kohler, Jillian C. and Illingworth, Patricia, "Access to medicines and the role of corporate social responsibility: the need to craft a global pharmaceutical system with integrity", *op. cit.,* p. 360.

61 *Human Security Now*, Report of the Commission on Human Security, New

"The Right to Health: A Duty for Whom?" was the title of an International Symposium held at Basel, Switzerland, on 2nd December 2004 hosted by the Novartis Foundation for Sustainable Development. That Symposium put on the table why pharmaceutical industry is frequently criticised: high drug prices inhibiting in least developed countries access to effective treatment for people and pharmaceutical industry's research priorities not taking into account the need of hundred of millions of people suffering from poverty-related diseases because the patients lack the purchasing power. The conclusion reached by people attending that meeting seems hopeful: The legitimate interests of the pharmaceutical companies and their shareholders in making money had to be appropriately balanced with the human right to health including the right of sick people to essential medicines. The keystone was that it could not be accepted that all legitimate interests had equal weight[62]. ONGs such as *Oxfam*, *VSO* and *Save the Children* had published two years before a study titled *Beyond Philanthropy* (London, 2002) where they suggested how pharmaceutical companies could dealt with people's access to medicines as part of a human right to health: publishing a list of pricing offers made to developing countries with any condition attached; introducing price reductions on products that are relevant to health priorities in developing countries, not just on one or two ´flagship drugs´; not lobbying governments to include TRIPS-plus provisions in bilateral or multilateral trade agreements that were under negotiation; ensuring that Joint Public Private Initiatives would benefit the most vulnerable members of communities; publishing their Research and Development target expenditure on infectious diseases; supporting and complying with World Health Organization Guidelines for Good Clinical Practice for trials on pharmaceutical products.

York, 2003, p. 4. The idea of creating such Commission was launched at the 2000 UN Millennium Summit and is co-chaired by Mrs Sadako Ogata, Mrs Amartya Sen and others.

62 Joseph, Sarah, "Pharmaceutical Corporations and Access to Drugs: the ´Fourth Wave of Corporate Human Rights Scrutiny", *Human Rights Quarterly,* 2003, Vol. 25, p. 451.

At the end of the day, it must be acknowledge that these recommendations have not been assumed by States[63]. So, many authors who had inquired in the different source of obligations to protect and promote public health throughout the world[64], have reached the conclusion that the real issue is the enforcement of those obligations rather than discussing on their moral grounds[65].

The issue of enforcement could be approached from the angle of an International Legal System with obligations flowing from human rights as specified in many binding instruments for States[66]. It should be pointed out; however, that International Law only has the potentiality to provide this enforcement if political will of States is accompanied. As Yamin holds "human rights can be useful tools insofar as they impose restrictions on the use of power and we need a human right framework than can impose meaningful restrictions on the hor-

63 See, for example, the Resolution 2004/26 of 16/April/2004 of the Human Rights Commission, on Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and Malaria. Commission on Human Rights, *Resolution 2004/26 of 16 April 2004 (E/CN.4/2004/L. 11/Add.3) Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*.

64 Macklin, Ruth, "Global Health", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), *op. cit.* p. 696: A global obligation of beneficence to maximize health benefits and minimize harms to health wherever those benefits and harms may exist? An obligation based on a principle of justice that calls for helping the least advantaged populations lacking the knowledge or technical capacity to help themselves? Or a matter of enlightened self-interest to ensure that the developing world is not a reservoir for deadly infectious diseases or instability steaming from the devastating effects of ill health in large numbers of the population?

65 For instance, Sándor, J., "Human rights and bioethics; competitors or allies? The role of International Law in shaping the contour of a new discipline", *Medical Law,* 2008, Vol. 27, No. 1, pp. 15-28.

66 In fact, there is no moral argument against the approach of International Law of Human Rights to Global Bioethics. As Macklin observes, "if the principle that mandates an equitable distribution of health-related benefits and burdens applies within a country, why should it no also apply across national boundaries?", Macklin, Ruth, "Global Health", *op. cit.,* p. 718.

rible abuses of power that occur across as well as within borders."[67] The weakness of some proposals some non iusinternationalists authors have made concerning the question of enforcement worldwide of Global Bioethics – like the creation of an international United Nations or World Health Organization type tribunal that would have the authority to police international trials, or the universal and mandatory adoption of an ethical guideline like the Nuremberg Code or Helsinki Declaration, among others[68] -is their reliance on the challenge of national sovereignty, one of the structural principle of International Law since its very beginning.

A problem that is often debated nowadays by many authors supporting the Global Bioethics approach is that without international institutions with enforcing powers, it seems rather difficult to address global issues like that of an international regulation for human embryo research, let alone for achieving an international objective regime which allows that the results of this research are for the benefit of the mankind as a whole. Speaking purely personally I disagree. International Organisations like United Nations have many defects, certainly, and detractors as well. They still, however, remain the chance of being the forum for international policy agenda. I feel most strongly that they should not be regarded as a "*Deus ex machina*" coming to solve the world but rather like the expression of a politically bounded community[69], helping discussion and agreement among States.

That is also the opinion of professor Klabbers –which I fully support- when he stresses the role of international institutions in a world of global concerns which demands multilateral answers. Thus, the international community of States, politically bounded, is pos-

67 Yamin, Alicia E., "Our place in the world: Conceptualizing obligations beyond borders in human rights-based approaches to health", *Health and Human Rights,* 2010, Vol. 12, No. 1, p. 11.

68 Lee, Stacey B., "Informed consent. Enforcing pharmaceutical companies' obligations abroad", *op. cit.,* p. 22.

69 Klabbers, Jean, *An Introduction to the Institutional International Law,* Cambridge University press, Cambridge, 2002, p. 342.

sible and wanted although we still lack International Organisations with supranational powers, like those of the European Union over its member States. Such international community of States politically bounded defended by this author is possible provided it is granted -similarly as it happens with internet- the consensus of all States integrating the international community as regards issues concerning all of them (global concerns or threats), and only if all integrating partners in such community speak a common language: the language of the Charter of United Nations[70].

It seems to me that the example of internet is pertinent to support my point of view. In internet there is not a central computer or a server centralizing all information moving every day worldwide, but rather a huge number of private and public servers and personal computers. Nevertheless, milliards of users everyday succeed in providing and receiving information and services in internet because all of them share a common technical language (the internet protocols) and they are convinced that some few common principles are to be respected for the general interest of all users: rejection of *spam,* protection against *hackers,* and prosecution of crimes committed through internet as purposely virus infection or child pornography dissemination. There is not international legislator on internet and most of States are incapable of managing all dimension of the *web* only by national legislation. Internet, however, is still alive and kicking. My viewpoint is that it is so mainly due to the fact that all users are sharing a common language and a set of basic principles, somehow of "inferring" or "structural" principles necessary for the whole system to work[71].

---

70 Namely, its articles 1 and 2 including the purposes and principles of the Organisation. In other words, what is looked for and how it must be reached.

71 According to this view I consider in Chapter 4 the possibility of assuming international principles concerning the human embryo research as a basis for an international regulation of this research for the benefit of the humankind as a whole.

1.3. An international objective regime on human embryo research for the benefit of the mankind as a whole

The striking example of internet is a useful starting point on the question we are going to tackle now. A problem that is often debated nowadays is that of the well documented "10/90 divide"[72]. Bio ethically speaking, one can wonder whether or not –or why- wealthy developed countries should be motivated to do more to help developing countries to improve their health-care situation. Although it will be further discussed the moral reasons for such positive answer – promotion of equality among nations, respect of human rights worldwide, etc. – what it is mainly concerned here is the international community of States. It seems to me that in a claim for a worldwide respect of the human right to health, there are self-interested reasons as well as an issue related to international peace and security[73]. Public health, even in the most developed nations seems now more closely connected than ever to health and diseases in impoverished countries[74]. Could anyone doubt about the negative implications for health in any country in the world when infectious diseases thrive in poor countries? Would anyone refute that when developing countries lack ad-

72 As Selgelid remembers, this is a phenomenon whereby less than ten percent of medical research resources are spent on diseases accounting for ninety percent of the global burden of disease. Thus, as he criticizes, "rather than addressing the world's most important health-care needs, a majority of funds is spent on research aimed at meeting the wants and needs of a minority of the world's population –those who are relatively healthy." Selgelid, Michael J., "Infectious Disease", in *A Companion to Bioethics,* Kuhse, H., Singer, P. (eds.), *op. cit.,* p. 434.

73 The European Centre for Disease Prevention and Control warned in 2006 that we could return in next years to a situation analogous to the pre-antibiotic era. See it in Ekdahl, K., "Ethical Issues from the ecdc Perspective. Bioethical Implications of Globalisation Processes", *Workshop on Globalisation and New Epidemics: Ethics, Security and Policy Making*. European Commission, Brussels, 2006.

74 Benatar, Salomon R., "Global health ethics and cross-cultural considerations in bioethics", *op. cit.*, p. 342.

equate health-care systems drug-resistant strains of disease emerge and threaten global health?[75]

The situation of the 10/90 divide and its consequences in developing countries may indeed be intolerable in an ethically significant way for being unnecessary. Lowry and Schüklenk seem totally convincing when they assert that "the mere fact that people suffer and die from disease is not as much ethically objectionable. What is objectionable, however, is that much of the world's suffering and premature death could be prevented but is not (…) Far too many, mostly poor, people suffer from curable or preventable diseases, and die preventable deaths. They suffer unnecessarily in today's world. The reason for this has much to do with their inability to purchase the health care that affluent citizens in wealthier nations can take for granted."[76] To put an end to this ethically objectionable situation is essential to ensure a reasonable long-term sustainability of health-care research, as well as delivery programs for which States still seem to be the proper agents, possibly bound by international treaties and monitoring regimes. [77]

Under the perspective of Global Bioethics, one of the bioethical principles acknowledged as governing research designed and conducted throughout the world, the principle of justice is particularly relevant in this context. Thus, some authors focus on the question of what, if anything, does justice require when industrialized countries sponsor or conduct research in resource-poor countries[78]. One may conjecture that the demands of justice in this context would imply the following peremptory premises: the need of that research being responsive to the health needs and priorities of the population where the research is conducted; the lack of justification for research subjects being made worse off afterwards than they were during the research (for instance, not being provided with the necessary treatment

75 Selgelid, Michael J., "Infectious Disease", *op. cit.,* p. 437.

76 Lowry, Christopher and Schüklenk, Udo, "Global Health Responsibilities", in *A Companion to Bioethics, op. cit.,* pp. 393 and 400.

77 *Ibídem,* p. 401.

78 Luna, Florencia and Macklin, Ruth, "Research Involving Human Beings", in *A Companion to Bioethics, op. cit.,* p. 464.

after their participation); and the unacceptability of external sponsors conducting research in developing countries without providing some kind of post-trial benefits to the Community when the research is over[79]. One might even suppose that all these premises are respected in practice if we lived in Wonderland…

International Law approach to Bioethics is also needed in its very essence. Being true that it is universally accepted the necessity to develop a response to the new technologies advances and discoveries in Life Sciences, the universality of answers, however, can be challenged[80]. This is particularly the case of principles -generally regarded as being at the heart of Western Bioethics- which is generally challenged by non-Western cultures still proud of their communal relations and spiritualistic ethos[81]. In a quotation of Salomon Benatar, "in a world characterized by many different value systems and cultures, wide disparities in wealth and health, and common threats, it is of special importance to give consideration to whether there are universal ethical principles that potentially bind us all more closely than we appreciate."[82] I would even go as far as to say that this challenge may arise inside the Western culture. Many European authors have criticized during years that apart from the common recognition of the significance of the advances made with respect to human biology, the environment and animals, the specific issues and the solutions suggested to the questions that have been raised show no uniformity. They conclude that there is no common unified bioethical project in Europe, let alone in the

79 *Ibídem*.

80 At level of principles, rules or practice. Gbadegesin, Segun, "Culture and Bioethics", in *A Companion to Bioethics,* Khuse, H. and Singer, P., (eds.), *op. cit.,* pp. 27 and ff.

81 *Ibídem*. Principles such as autonomy, individualism and secularism whose universal validity is refuted.

82 Benatar, Salomon R., "Global health ethics and cross-cultural considerations in bioethics", *op. cit.,* p. 343.

world[83]. This situation seems far from changing at present at least a common set of bioethical standards are accepted a European level. On this question we will come back in Chapter 5.

It could be claimed that in order to achieve bioethical principles common to all peoples and cultures represented in the Organisation of the United Nations, there are only three possible approaches: the cultural imperialism and value absolutism, the value relativism, and the transculturalism and value reciprocity, respectively[84]. Being preferred the third approach over the previous ones, for such transculturalism dialogue among nations in the world, it is firstly required a common language which at present only International Law can successfully provide. Considering the fore above mentioned "10/90 divides", inequities in access to pharmaceuticals are stark between developed and developing countries purely for market reasons. People in developing countries make up about 80 per cent of the population in the world but they represent no more than 20 per cent of global pharmaceutical sales[85]. Thus, from market reasons it may not seem worthwhile to do research in pharmaceuticals which are not to be sold at large. Legal obligations for States to put remedy to this situa-

83 Muñoz, Emilio, *Bioethics in Europe. Modern Science and Bioethics,* csic, 1992, Madrid, p. 23.

84 Gbadesegin, Segun, "Culture and Bioethics", *op. cit.,* p. 30. The first approach consists of defending and retaining Western values and imposing them on other cultures for universal application as principles and rules. The second one is to reject the universal validity of Western values and recognize a plurality of values as the basis for principles and rules in different cultures. In other words, no common morality is needed. The third approach which seems more suitable than the previous ones is to look out for common foundational values which transcend cultures and which could be used to formulate common bioethical principles.

85 *Ibídem*, p. 362. The World Health Organisation's Commission on Intellectual Property Rights, Innovation and Health made it explicit in it Report *Public Health, Innovation and Intellectual Property Rights* (2006), p. 6, "(p)overty affects purchasing power, and the inability of poor people to pay reduces effective demand, which in turn affect the degree of interest of for-profit companies".

tion starts from the very beginning from the United Nations duties on member States. Thus, articles 103, 56 and 57 can be considered as relevant dispositions to argue, for example, that the TRIPS Agreement is morally unsatisfactory because it does not help to improve global drugs access[86].

Human embryo research is a blooming business not only for pharmaceuticals but also for Governments up to the point it is talked about "bio economy"[87]. The biotechnological patents are mainly conferred in developed countries because developing countries, lacking the infrastructure to support the use of modern technologies, have no capacity to innovate in this area[88]. The UNESCO Universal Declaration on Human Genome, which was endorsed by the United Nations General Assembly[89], clearly stated that an international framework should be established to make the benefits of research on the genome available to all. From a perspective of public International Law, our way of looking at the problem could be the following: assuming that the human genome is to be considered as a resource apart from State sovereignty and private actors, according to the main international

86 COHEN-KOHLER, Jillian C. and ILLINGWORTH, Patricia, "Access to medicines and the role of corporate social responsibility: the need to craft a global pharmaceutical system with integrity", *op. cit.,* p. 363. These authors denounce, for example, that the Doha Declaration on the TRIPS Agreement and Public Health by the World Trade Organization in 2001 and the implementation of paragraph 6 in August 2003, suggested a mean for selective disengagement by permitting those countries that do not have the capacity to manufacture medicines to still use compulsory licensing by contracting-out agreements with firms in other countries. This unleashes the potential for more competition in the pharmaceutical market, more drug supply for those in need.

87 KINDERLERER, Julian and MILIUS, Djims, "The Patent System, Biotechnology and Synthetic Biology", Annex I to the European Group of Ethics for Science and New Technologies' Opinion No. 25 *Ethics of Synthetic Biology* (2010), p. 87.

88 *Ibidem*.

89 Universal Declaration on the Human Genome and Human Rights, UNESCO, Gen. Conf. Res. 29 C/Res.16, adopted by the UN General Assembly, G. A. Res. 152, UN GAOR, 53rd Sess., UN Doc. A/RES/53/152 (1999).

instruments, and as a consequence, economic results of any human embryo research should be for the benefit of mankind as a whole, and not for a part of the international community[90]. In this connection, for many authors in the Global Bioethics new stream, there is an inner contradiction in the regime of patents and the TRIPS Agreements which supports it, and the values endorsed in the Human Genome Declaration[91]. This critical view, however, is not unanimous. Authors like BOVENBERG and KINDERLERER, revisiting GROTIUS' concepts of *res nullius, res communis* and *res publicae,* hold that the genome itself is common property of humankind but derived inventions or discoveries –i. e., the use of genes to produce pharmaceuticals or probes for disease- can be owned privately. Is this an end-up controversial issue? Or is there still room to claim for alternative approaches taking on account the humankind's wealth willing? Let's examine it in greater detail.

History recalls that four legal answers are possible facing new scientific discoveries: a) the incentives of such activities throughout governmental financial support and their legal protection with patent law; b) the refusal of authorities to regulate it, according to the well known liberal principle of "laissez faire, laissez passer"; c) the option of legal regulation, controlling and banning an activity or a part of it as it happened after the crack in 1929 which followed the economic growth in the XIX Century; d) the most usual answer in past: the interdiction of a particular idea or discovery[92]. Considering these

90 In a similar way to the legal status of the seabed and ocean floor beyond the limits of national jurisdiction, as envisaged in Part XI of the International Convention on the Law of the Sea. It must be noticed, nevertheless, that the Part XI has been deprived of any effect in practice as result of an Agreement forced to reach in New York in 1995 by some reluctant states as a *conditio sine qua non* for them being part in this Convention.

91 BOVENBERG, J. A., "Mining the Common Heritage of our DNA: Lessons learned from Grotius and Pardo", *Duke Law & Technology Review,* 2008, p. 8. KINDERLERER, Julian and MILIUS, Djims, "The Patent System, Biotechnology and Synthetic Biology", *op. cit.,* p. 96.

92 MARTYN, S. R., "Human Cloning: the Role of Law", *University of Toledo Law Review*, 2001, vol. 32, p. 375.

four possible answers in connection with human embryo research, options b) and d) do not seem admissible ones because they could lead to sanctuaries out of the Law, some kind of modern versions of Dr. Frankenstein. Answer a) is not to be disregarded at first glance. Nevertheless, my personal opinion on the matter is that this answer a) seems not sufficient for dealing all the issues at stake. In the final analysis, my favorite option is c) and thus, human embryo research should be universally regulated, controlled and if necessary, banned in part.

Normative regulation of human embryo research, by its own nature and substantive object, is to be two ways qualified: on the one hand it should have an ethic ground in its formulation[93]. That is, it recognizes that human embryo research may be profitable for society if a strict line is traced in order to secure that, while advancing, technology does not bring up what it is morally unacceptable for such a society[94]. On the other hand, normative regulation of human embryo research should be at universal range, assuming principles and values suitable for all states of the International Community as a whole. Two reasons would support the necessity of such a universal regulation. First of all, giving the existing differences among the States at present as far as research and experimentation on human embryo, it is obvious that without an international approach any effort to preserve human dignity and fundamental rights will be unsuccessful. Otherwise, it will always be possible to find out a place where impunity is granted to those acting unlawfully[95]. Secondly, after the Universal Declaration on the Human Genome and Human Rights and it subsequent instruments, it is undoubtedly assumed that bioethics

93 Kluge, E. H., "Human Genome Research and the Law. The Ethical Basis of International Regulation", *Annual review of Law and Ethics,* 1999, No. 7, pp. 159-160.

94 Mon Post, M., "Human Cloning: New Hope, New Implications", *Temple International and Comparative Law Journal,* 2001, Vol. 15, No. 1, p. 193.

95 Hawkins, A., "Protecting Human Dignity and Individuality: the Need for Uniformity in International Cloning Legislation", *The Transnational Lawyer,* 2001, Vol. 14, p. 293.

is not any longer a matter of internal interest of States according to Article 2.7 of the United Nations Charter[96].

An universal regulation of bioethics and, specifically of human embryo research settled down upon principles and values which are able to be shared and assumed by a large number of States of the international community is possible although not easy. It is possible, firstly, for instance, considering human embryo research as a common concern of the international community as a whole, eventually in two ways: affirming general principles to be accomplished individually by any state in the world[97], or settling down an international regime with its own mechanisms and institution for implementing this objective regime[98].

The Universal Declaration on Bioethics and Human Rights has emphasized that scientific and technological developments "should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole …"[99] and also has recognized 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"[100] For this reason, the need for reinforcing international cooperation in this field is stressed, taking into account, particularly, the special needs of developing countries[101]. It is also and is asserted that "all human beings, without distinction, should benefit from the same high

96 In this sense, Lenoir, N., "Universal Declaration on Human Genome and Human Rights: the First Legal and Ethical Framework at the Global Level", *Columbia Human Rights Law Review,* 1999, Vol. 30, p. 577.

97 See, for instance, the asseveration of the principle of universal jurisdiction for some crimes against international law, namely severe violations of fundamental rights and violation of the humanitarian law.

98 Complementary to the principle of universal jurisdiction, the international community has established the International Criminal Court for judging the authors of such crimes against the international law.

99 See paragraph 12 of the Preamble.

100 Paragraph 14 of the Preamble.

101 Paragraph 21 of the Preamble.

ethical standards in medicine and life science research."[102] In this connection, read Article 24 of the Declaration[103]. Everything leads to the same questions: What is the legal scope of these considerations? Would they imply the basis for an international regimen in the field of embryo research? In my opinion, any answer to these questions should be prudent and must take into consideration the previous experience of the legal status of the seabed and ocean floor beyond the limits of national jurisdiction, as envisaged in Part XI of the International Convention on the Law of the Sea. At present, Part XI has been deprived of any effect in practice as result of an Agreement forced to reach in New York in 1995 by some reluctant States as a *conditio sine qua non* for them being part in this Convention.

It will be interesting to see whether common heritage of humankind is not any longer considered as traditionally but as a new reading of principle of sovereignty, which has been conforming International Law since XVII Century up to present date. Sovereignty should be read, according to some authors, in a functional way[104]. In this sense, Article 15.1 of the Universal Declaration on Bioethics and Human Rights envisaging that "benefits resulting from any scientific research and its applications should be shared with society as a whole within the international community, in particular with developing countries"

---

102 Paragraph 22 of the Preamble.

103 "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 benefit 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."

104 See DUPUY, P.-M.: *Droit International Public*, 8th edition, Dalloz, Paris, 2006, pp. 789-790. PUREZA, J. M.: *El Patrimonio Común de la Humanidad*, Trotta, Madrid, 2002, p. 376.

should be read together with Article 16[105] (protection of future generations) and Article 17[106] (protection of the environment, the biosphere and biodiversity) of the same Declaration.

A universal regulation of human embryo research and of bioethics in general, is not an easy task. To be successful it has, firstly, to overcome the fact that many different actors are concerned in these issues, not only States: International Organizations, private groups of people with profit or non-profit objectives, scientific community, pharmaceutical firms, etc. Secondly, and as a consequence, it can be predictable that reaching a consensus among all these actors may be rather difficult or impossible. The distortion that all these actors introduce as far as regulating the research on human embryo, together with the difficulties in reaching a consensus on values and principles embracing all of them, may well explain the scope of the International Law regulating human embryo research up to date. In effect, no treaties legally binding has been adopted at universal level but at regional European level, which besides, they have had little ratification. It has been preferred instead the way of general soft declarations for the political commitment around the world even if the price to be paid for such general agreement is that many of such declarations are too ambiguous and bluff in their statements. All these facts cannot be ignored.

My personal opinion on the matter, however, is that we face an emerging global community of States, in the sense of "Communauté des États *dans son ensemble* and not only *dans leur ensemble*"[107]. This global community of States as a whole is claiming for a new paradigm

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

106 "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."

107 As Professor Dupuy suggests. Dupuy, Pierre-Marie, *Droit International Public, op. cit.,* pp. 789-790.

of International Law, a post contemporaneous International Law integrated by a set of obligations assumed by international subjects and actors, by way of they willing or against their will, and whose aims are –according to the universal values of the United Nations Charter- to regulate the relationships of co-existence, cooperation and interdependence of those integrating this emerging global community, and the common wealth of the Community itself, throughout a responsible –and for this solidary- management of competences recognised to each partner integrating this global community[108].

It could be claimed that International Law is moving progressively towards an objective legal order[109] where its binding force is not only the sovereign will of States but the shared perception that International Law, as any Law, is necessary to safeguarding basic common values, namely those closely linked to the survival of humankind[110]. In this sense, Professor Tomuschat has asserted that the principle of sovereignty of States and their will as the basis for international obligations is still in the core of the International Legal System. However, interests of international community are pushing back the sovereign individualism of States and new forms of creating international norms are arising[111].

---

108 García San José, Daniel, *El Derecho Internacional Poscontemporáneo,* Tirant Lo Blanch, 2008, Valencia.

109 In my book *El Derecho Internacional Postcontemporáneo, op. cit.,* I have maintained the theory of the inferring principles of structural nature for the International Law -such as the principle of necessity- to explain the foundation and the legitimacy of a new normative order not yet completely developed. This new order which overtakes the limits of the principle of consent of States is based upon the perception of global threats as matters of general interest for the international community of States as a whole and upon the collective will of such international community of States as a whole, whose legitimacy is built up over a consensual basis.

110 Delbrück, J., "Structural Changes in the International System and Its Legal Order: International Law in the Era of Globalization", *SZIER*, 2001, Vol. 11, No. 1, p. 31.

111 Tomuschat, Christian, "The Complementarity of International Treaty law, Customary Law and Non-Contractual Law making", in Wolfrum, Rudiger, and Röben, V. (eds.), *Developments of International Law in Treaty Making,* Springer, Berlin, 2005, p. 407.

The stately consensual basis is now considered not only upon an individual basis –as traditionally- but upon a collective consensual basis, facing global threats which are of *general interest* rather than of *common interest*. That is, issues which are of more relevance for the International Community of States as a whole than for the States integrating such international community. The test of "but of course" proposed by Professor Thomas Franck to identify such issues of general interest -and the common sense it implies- would seem pertinent at this regards. Thus, when the interpretative community (governments, judges, iusinternationalists, etc.) converge around a principle and consider it a legitimate norm, should be a legal rule for all[112].

The fundamental argument for our approach is that the legitimacy of this new normative order, still in progress, is on the grounds of the perception of global threats as issues of general interest of the international community of States as a whole, and on a collective consensual basis which will be prevalent over the individual consensual basis considering inferring principles of International Law such as the principle of necessity[113]. Thus, the common sense and the "but of course" test proposed by Professor Franck would imply that when global concerns only can be addressed through multilateral approaches, then the unilateral position of one single State or a little group of States can not be an obstacle. In other words, their unilateral reluctance can not be relevant any longer in this issue. The snag

112 Franck, Thomas, "Non-Treaty Law-Making: When, Where and How?", in Wolfrum, Rudiger, and Röben, V. (eds.), *Developments of International Law in Treaty Making, op. cit.,* p. 215.

113 See, for instance, how this principle of necessity works in the international regime of telecommunications, where decisions adopted by the International Telecommunication Union are followed *de facto* by all States in the world, members and not members of this International Organisation, by the pure necessity of their obedience. Otherwise, States reluctant to obey such regulations would be isolated from the world of telecommunications, with standards of signal not fixing with those of the rest of States. Hinricher, J., "The Law-Making of the International Telecommunication Union (itu). Providing a New Source of International Law?" *Heidelberg Journal of International Law,* 2004, No. 64, p. 499.

about this argument is that it must be resolved how to distinguish a real situation demanding a multilateral approach from a situation some ones pretend to consider as such. My own point of view is that the human embryo research is one of these issues demanding a multilateral approach from International Law. Ethical controversial surrounding this issue- including Global Bioethics and their claims for a worldwide effectively protection of a human right to health- compel us to adopt such a multilateral approach. To be honest, hardly can I think other peremptory issue affecting the human being as species which would merit such multilateral approach more than this one.

1.4. Concluding observations

The best way of summing up what said in this Chapter is by the following:

1. New and critical approaches to Bioethics have been claimed for in order to meet the complex emerging challenges to healthcare, medicine, the body and society. These critical views have let open the door to a "New Deal" for Bioethics, which in some way resembles a return to its origins as a discipline of study – a science of survival- thanks to the idea of Global Bioethics. It is on the grounds of Global Bioethics that International Law is increasingly concerned as it could be claimed the international obligations among States to preserve environment or to implement the human right to health worldwide through a universal regulation on human embryo research.

2. As the main contribution of International Law to Global Bioethics it must be referred the issue of enforcement through obligations flowing from human rights as specified in many binding instruments for States. It should be pointed out, however, that International Law only has the potentiality to provide this enforcement if political will of States is accompanied. In a claim for a worldwide respect of the human right to health, there are self-interested reasons as well as an issue related to international peace and security. International Law approach to Bioethics is also needed in its very essence. Being true

that it is universally accepted the necessity to develop a response to the new technologies advances and discoveries in Life Sciences, the universality of answers, however, can be challenged. It could be claimed that in order to achieve bioethical principles common to all peoples and cultures represented in the Organisation of the United Nations, it would be preferred a transculturalism dialogue among nations in the world, for which it is firstly required a common language at present only successfully provided by International Law. An universal regulation of bioethics and, specifically of human embryo research settled down upon principles and values which are able to be shared and assumed by a large number of states of the international community is possible although not easy. It is possible, firstly, for instance, considering human embryo research as a common concern of the international community as a whole, eventually in two ways: affirming general principles to be accomplished individually by any State in the world, or settling down an international regime with its own mechanisms and institution for implementing this objective regime.

3. Human embryo research is a blooming business not only for pharmaceuticals but also for Governments up to the point it is talked about "bio economy". In this connection, for many authors in the Global Bioethics new stream, there is an inner contradiction in the regime of patents and the TRIPS Agreements which supports it, and the values endorsed in the Human Genome Declaration. Assuming that the human genome is to be considered as a resource apart from State sovereignty and private actors, according to the main international instruments, as a consequence, any human embryo research should be for the benefit of mankind as a whole, and not for a part of the international community in a similar way to the legal status of the seabed and ocean floor beyond the limits of national jurisdiction, as envisaged in Part XI of the International Convention on the Law of the Sea. The failure of Part XI of this Convention has led some authors to assert that common heritage of humankind should not any longer be considered as traditionally but as a new reading of principle of sovereignty which have been conditioning International Law

since XVII Century up to present date. Sovereignty should be read, according to these authors, in a functional way. In this sense, Article 15.1 of the Universal Declaration on Bioethics and Human Rights envisages that "benefits resulting from any scientific research and its applications should be shared with society as a whole within the international community, in particular with developing countries." This provision of procedural nature must be read together with Article 16 (protection of future generations) and Article 17 (protection of the environment, the biosphere and biodiversity) of the same Declaration.

4. Be as it may, it can indeed be proved that the stately consensual basis is now considered not only upon an individual basis –as traditionally- but upon a collective consensual basis, facing global threats which are of *general interest* rather than of *common interest*. That is, issues which are of more relevance for the international community of States as a whole than for the States integrating such international community. The fundamental argument for our approach is that the legitimacy of this new normative order, still in progress, is on the grounds of the perception of global threats as issues of general interest of the international Community of States as a whole, and on a collective consensual basis which will be prevalent over the individual consensual basis considering inferring principles of International Law such as the principle of necessity. Thus, the common sense and the "but of course" test proposed by Professor FRANCK would imply that when global concerns only can be addressed through multilateral approaches, then the unilateral position of one single State or a little group of States can not be an obstacle. In other words, their unilateral reluctance can not be relevant any longer in this issue.

5. The snag about this argument is that it must be resolved how to distinguish a real situation demanding a multilateral approach from a situation some ones pretend to consider as such. My own point of view is that the human embryo research is one of these issues demanding a multilateral regulation from International Law. Ethical controversial surrounding this issue- including Global Bioethics and their claims for a worldwide effectively protection of a human right to

health- compel us to adopt such a multilateral approach. To be honest, hardly can I think other peremptory issue affecting the human being as species which would merit such multilateral approach more than this one.

CHAPTER 2

HUMAN EMBRYO RESEARCH AND INTERNATIONAL LAW: SOME ISSUES AT STAKE

2.1. Introduction

A fact that cannot be ignored is that any international regulation of embryo research will be conditioned by the dialectic discussion confronting those who defend freedom for scientific cloning research, and those others who oppose any research on embryos and the application of technical developments on human beings. In the context of such discussion many reasoning can be found. Essentially, there is who postulate freedom for science and for profit of specific developments no matter if they concern human beings. In the other side of the coin, there are who consider the inherent risks for fundamental rights is such research is authorized and, furthermore, they believe that in any case, any research on human embryos is contrary to human dignity. In the light of this dialectic discussion, one could simplify it by sayings that in the end what seems to be opposite are the economic and ethical dimension of the topic. From the very outset it could be claimed that such a simplification of the problem should be disregarded because it would lead to an end-up road. In my opinion, a holistic, multidimensional approach is preferred as being more consistent with the complexity surrounding research on human embryos.

It seems clear that two set of questions arise up in connection with human embryo research from the point of view of International Law: firstly, it is the possibility of establishing an international regulation on the principle of human dignity and the moral consideration of human embryos. Secondly, it is the question of fundamental human

rights which could be affected by any international legal frame regulating human embryo research. In the development of these issues the guiding questions to be answered will be the following ones: What is the limit under the human dignity principle to the human embryo research? How fundamental human rights can be protected against the risks of the human embryo research? What is the fair balance to be struck facing other compelling human rights such as the right to health?

2.2. The possibility of establishing an international regulation on the principle of human dignity and the moral consideration of human embryo

The Universal Declaration on Bioethics and Human Rights[114] must be seen in the context of efforts made by the international community of States as a whole to conciliate rapid advances in Science and their technological applications with due respect to the dignity of the human being and universal respect for -and observance of- human rights and fundamental freedoms. Besides, it must be remembered previous international instruments and, particularly, the Universal Declaration on the Human Genome and Human Rights[115], which asserted in Article 3 that: "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."

It is an open question, however, whether there is an universally shared conception of human dignity to be fully respected in decisions or practices taken or carried out by those to whom this Declaration is addressed, namely but not only, States. Another question we are com-

114 Adopted by acclamation on 19 October 2005 by the General Conference of UNESCO.

115 Also adopted by acclamation the 11th November 1997 by the General Conference of UNESCO.

ing back in next pages deals with a particular person's fundamental right to the enjoyment of the highest attainable standard of health[116] which could require research on embryos. Would this fundamental right prevail over any ban on this kind of research by national authorities if they consider is in the context of their national society as being contrary to human dignity?

As it would be expected, no further agreement is found concerning the first question, probably due to the Human Rights' speech was politically used during the Cold War by both -Western democracies and by Soviet Union and other allies –to emphasize civil and political rights versus economic and social rights. Living without freedom of expression, for instance, would have been seen by Western countries similarly as being a slave and contrary to human dignity. Other countries sharing the Soviet Union's political view would have preferred to consider contrary to human dignity the fact of lacking housing or without the cover of a public system of healthcare.

A look at the main international instruments including references to the principle of human dignity allows us to conclude that the right to human dignity may have three different contextual meanings: the right to be born with human dignity; the right to live with human dignity and the right to die with human dignity[117]. Questions which pose the first dimension of human dignity are so complex[118] than

116 As the own Universal Declaration on Bioethics and Human Rights recognizes in Article 14.2.

117 Beyleveld, Deryck and Brownsword, Roger, *Human dignity in bioethics and biolaw,* Oxford University Press, Oxford, 2001.

118 For example, selecting the genetic characteristics of offsprings poses several questions: Does basing selection of genes on judgements of desiderable phenotypes or genotypes violate human dignity? Does selection that involves or exploits abortion or embryo destruction violate human dignity? Do techniques of selection violate human dignity because they instrumentalize the offspring or predetermine its phenotype? Are certain techniques of selection contrary to human dignity because they do not respect species integrity? Or, finally, do techniques of selection violate human dignity when they set up a slippery slope to activities that violate human dignity? Beyleveld, Deryck and Brownsword, Roger, *Human dignity in bioethics and biolaw, op. cit.,* pp. 145 and ff.

we must show self-restraint at them. It is evident, however, the need for further research in the others two dimensions of human dignity, namely, concerning the right to live with dignity[119], which can be illustrate with an example: Transplants.

In order to improve the living conditions of those who wait for a transplant, some authors have challenged the fundamental principle of human organs being donated altruistically and going to patients in the greatest need. Instead, they claim, donation rates would increase if potential donors could decide their organs going to people they particularly cared about rather than being taken by an anonymous establishment[120]. A further argument they invoke is the inner contradiction of donated organs being indeed regarded as public goods. On the contrary, being someone still alive, his body and organs are treated as private goods to the extent that someone is free to choose whether to donate them or not[121]. In words of Janet Richards,

> "This is like saying that although you can choose whether to offer your spare time for voluntary work, you cannot chose to offer it (altruistically) to the local Oxfam shop, but must make yourself available to some public agency that will send you to wherever it decides needs you most. Or –a closer analogy- it is like saying that you may not bequeath your worldly wealth to the Meth-

119 See, in this sense, the concern some authors have expressed about Life Science industry. Plants and animals are being genetically engineered and patented to produce 'nutriceuticals' such as various amino acids. These will be promoted as new generation 'super food' (sometimes called 'Frankenfood') thanks to billions of dollars in marketing to win public acceptance of genetically engineered food. In the meantime, many governments of countries, like the United States, still refuse to label as being genetically engineered, in total disregard of consumers right to know and to act consequently. Fox, Michael W., *Bringing Life to Ethics, op. cit.,* p. 116.

120 Richards, Janet R., "A World of Transferable Parts", in *A Companion to Bioethics, op. cit.,* p. 378. In the same sense, Volk, M. L., and Ubel, P. A., "A Gift of Life: Ethical and Practical Problems with Conditional and Directed Donation", *Transplantation,* 2008, Vol. 85, No. 11, pp. 1542-1544.

121 Richards, Janet R., "A World of Transferable Parts", *op. cit.,* p. 379.

odist Homes for the Aged: you can have it buried with you, if you like, but must otherwise hand it over to the government for impartial distribution. Nobody, presumably, would recommend either of these curious mixtures of choice and conscription."[122]

Looking at the problem, other authors, like Menikoff, pose the kind of questions many people can feel uncomfortable answering in an honest way: Is it inappropriate to allow the use of subjective criteria, for example, a person's merit, in allocating organs? Should we deny certain people a transplant, for example, convicted for first degree murder?[123] Contrary to what is happening in United States, this moral controversy have not yet arisen in Europe where a new Directive on Transplants has been approved in 2010[124], let alone in Spain with the average rate of post mortem organ donation of 30-35 organs donors per million, the highest in the world, and having been the pioneer country in the world to presume consent for cadaver donation[125]. However, it should be pointed out that the objective success of this system is not convincing for all authors, like Michele Goodwin who challenges the efficacy of an opting-out system in United States[126].

---

122 *Ibídem*.

123 Menikoff, Jerry, *Law and Bioethics. An Introduction,* Georgetown University Press, Washington, D-C., 2001, pp. 492-493.

124 Directive 2010/45/EU of 7 July 2010 on standards of quality and safety of human organs intended for transplantation. OJ L207, 06/08/10

125 Alkorta Idiakez, Itziar, "Human Tissue and Cell Regulation in Spain: looking at Europe to solve inner contradictions?" *Law and Human Genome Review,* 2008, Vol. 29, p. 30. The Act 30/1979 Transplant Act considers cadaver solid organs as sanitary resources that should be distributed in a way (under the principles of anonymity, solidarity and altruism) so that the greatest number of people has access to them following strict medical criteria, as a demand that stems from the principle of equity.

126 Goodwin, Michele, "Bio law: A few thoughts about altruism and markets" *Kansas Journal of Law & Public Policy,* 2009, Vol. xviii: 2, p. 210. In my view, rather than a matter of timing suggested to support such scepticism, is simply that the success of the Spanish system of organ donation is based in public trust which is only possible in public health care system not in a private one.

Drawing the attention to the right to be born with dignity, there is high controversial concerning the techniques of pre implantation genetic diagnosis and gene therapy; that is, the correction or prevention of disease through the addition and expression of genetic material that reconstitutes or correct missing or aberrant genetic functions or interferes with disease-causing processes[127]. Nobody would disagree in principle with therapies for treatment of diseases. Surprisingly, national attitudes vary country to country as regards pre implantation genetic diagnosis in Europe. As Christian Byk has analysed, "while some countries have no rules yet, others prohibit such actions and several impose strict conditions; only very few have a liberal approach based on a case-bay-case assessment"[128]. Controversy may come when physicians has to choose between somatic gene therapy and germ line gene therapy[129]. Germ line is considered to raise new issues of principle primarily because it will affect future generations who have not consented to it. However, as Chadwick points out, if it is regarded as permissible to take decisions regarding medical treatment on behalf of children who are too young to consent for themselves, why not for future descendants?"[130]

Confronting the situation in Europe, the option of prohibiting both techniques of pre implantation genetic diagnosis –somatic gene

---

127 Human Genome Organization (HUGO) Ethics Committee, Statement on Gene Therapy Research, April 2001. Available at http://www.hugo-international.org/img/gene_2001.pdf

128 As regards Spain, this technique is allowed since 2006 by the Medically Assisted Reproduction Act (Ley Española 14/2006 de 26 de mayo sobre técnicas de reproducción asistida) only to detect serious hereditary diseases in order to treat them if possible or to prevent their transmission. Byk, Christian, "Preimplantation genetic diagnosis: and ambiguous legal status for an ambiguous medical and social practice", *Law and Human Genome Review,* 2008, vol. 28, pp. 90-91.

129 Somatic cell gene therapy seems less controversial for two reasons: firstly, due to the fact that it offers the prospect of a cure for genetic disorder for which other treatment can at most alleviate symptoms. Secondly, because it alters the body chromosome of a person but not their eggs or sperm cells. Consequently, eventual changes are not transmitted to the person's offspring. Menikoff, Jerry, *Law and Bioethics. An Introduction, op. cit.,* p. 401.

130 Chadwick, Ruth, "Gene Therapy", in *A Companion to Bioethics, op. cit.,* p. 209.

and germ line gene therapies- facing the risks of a "slippery slope to a new social eugenics" seems not more convenient than the strict regulatory approach, as Professor Byk defends. By that, not only administrative and sanitarian supervision over the practice of this technique is required but also, and especially, "an ongoing state of ethical vigilance including interdisciplinary evaluation of the consequences of each extension of pre implantation genetic diagnosis and the consequent submission of the arguments to a public debate."[131]

Germ line gene therapy poses further ethical controversy related to enhancement of human embryos. An exam on the practice of States regulating on this topic shows that there are five basic positions in the enhancement debate[132]. Authors' opinions come from those, like Annas' calling it a "genetic genocide"[133] to others, like Savulescu's, defending enhancement as increasing the chances of leading a good life. In the words of the latter author,

> "Human enhancement through the use of drugs and other biological interventions is already occurring. Radical genetic enhancement has been possible in other animals and is possible

131 Byk, Christian, "Preimplantation genetic diagnosis: an ambiguous legal status for an ambiguous medical and social practice", *op. cit.,* p. 103.

132 Savulescu, Julian, "Genetic Enhancement", in *A Companion to Bioethics, op. cit.,* p. 221: 1. Enhancement being morally wrong and legally impermissible (the strongest negative position); 2. Enhancement being morally wrong and although legally permitted, people should be discouraged from employing enhancement technologies (moderate negative position); 3. Enhancement being morally neutral and legally permitted (the position of liberal eugenics); 4. Enhancement being morally right and people should be encouraged and facilitated to it (moderate positive position); finally, 5. Enhancement being morally right and legally required (the strongest position in favour not defended by any Sate, at least in public.)"

133 Annas, George, "The man on the moon, immortality and other millennial myths: the prospects and perils of human genetic engineering", *Emory Law Journal,* 2000, Vol. 49, No. 3, pp. 753-782. From the same author, "Genism, racism and the prospect of genetic genocide", 2001. Available at: http://www.thehumanfuture.org/commentaries/annas_genism.html

> in principle in human beings. Will the future be better or just disease-free? We need to shift our frame of reference from health to life enhancement. What matters is how we live. Genetic enhancement can now improve that. I believe one of the most admirable characteristics of humans is to be better. Or at least, to strive to be better. We should be here for a good time, not just a long time. Despite the widespread and numerous objections, many genetic enhancements will not merely be permissible, but may be morally required. We face the dawn of biological or genetic liberation."[134]

It is important to consider, as Murray does, the fact that exist many different means of enhancement, working through a variety of intermediary states, and towards a multiplicity of ends. The inevitable conclusion, therefore, is that no single ethical principle or distinction will be a reliable guide for reaching an international consensus among States. This author holds instead a thoughtful understanding of the ethics of human enhancement that takes into account "the possible types of enhancement coupled with a nuanced understanding of the goods sought, the dangers encountered, and the social and institutional context into which each putative enhancement will be thrust."[135]

Making human embryos by way of somatic cells nuclear transfer[136] for therapeutic or reproductive purposes, also would pose ethical controversial. Firstly, due to the fact that, although the two purposes for cloning are different, both are linked in the way the human matter is initially created and in the genetic similarity of ancestor and progeny[137].

---

134 Savulescu, Julian, "Genetic Enhancement", in *A Companion to Bioethics, op. cit.,* pp. 231-232.

135 Murray, Thomas H., "Enhancement", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), *op. cit.,* p. 514

136 The nucleus from an adult somatic cell is transferred to an enucleated cell (from which the nucleus has previously been removed). Thanks to electric current both, nucleus and the enucleated cell becomes one cell which is stimulated to divide

137 Pence, Gregory, "Cloning", in *A Companion to Bioethics, op. cit.,* p. 202. The

Somatic cell nuclear transfer to produce stem cells[138] by way of the creation of embryos brings up the following ethic problem in some societies: once the inner cell mass, from which the stem cell lines are derived, is removed from the cloned embryo, this supposedly must be destroyed[139]. In fact, that simplification of the problem very often listened to, is incorrect. As Ronald Lindsay maintains,

> "With respect to extracting a cell that can be used to create a stem cell line, the standard procedure is to separate the inner cell mass of the blastocyst from the outer sphere of cells and then have this inner cell mass cultured on a plate of feeder that will maintain the stem cells through a supply of nutrients. After the cells of the inner cell mass begin to proliferate, they are removed and plated into fresh culture dishes and, eventually, if the process is successful, an embryonic stem cell line will be established. This is the process the opponents of embryonic stem cell research characterize as destroying or killing the embryo. Technically, this is incorrect. The embryo will not develop into a fetus unless it is given a placenta and some other assistance. On the other hand, its cells remain alive. Indeed, they may remain alive for longer than they would have if the embryo had continued its development."[140]

---

two cloning techniques are distinct because, as this author recalls, the former produces batches of small-celled embryos the size of the tip of a fine-point pen and the latter produces human babes.

138 That is, stem cells capable of giving rise to all cell types in the body.

139 Of course, there are authors like Gregory Pence who does not support this concern. As he says. "Embryos are not babies and more exactly, embryonic tissue in a cell line is not a nursery full of human babies. Part of the pull of the conceptual objection is to think of these two as the same and, indeed, critics of cloning use language that reflects such thinking, speaking of the embryo-baby". Pence, Gregory, "Cloning", in *A Companion to Bioethics, op. cit.,* p. 202. In this similar sense, see the illustrative Chapter 7 (pp. 227-260) "Saving Embryos for the Trash –Our Illogical Policies on Embryonic Stem Cell Research", in Lindsay, Ronald Alan, *Future Bioethics,* 2008, Prome-theus Books, New York.

140 Lindsay, Ronald Alan, *Future Bioethics, op. cit.,* p. 232.

It is, however, an ethically controversial issue in many societies, even inside Europe. Some countries, like the United Kingdom, have solved this dilemma by introducing the temporal limit of 14 days for a somatic-cell nuclear transfer. Other countries still consider that no matter the time, one would be facing the same technique of cloning although with two eventually different outcomes: the production of human clones or the production of embryonic stem cells. In this context of European pluralism which later on a detailed analysis will be presented in Chapter 3, the first thing to be done should be to answer this question: What does human dignity implies? The unique Interpretative Declaration added to States signatures of the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings (ETS No. 168) was that of The Netherlands. It concerned the words "dignity of human beings" in Article 1 of the Convention on Human Rights and Biomedicine (ETS No. 164), as referred in last paragraph of the Preamble of this Additional Protocol[141]. In opinion of this country, the words "human dignity" in both texts, Convention and Protocol, were only referring to the dignity of any human being; that is, the dignity of a born person. The purpose of this interpretative declaration was evident: to let clear that The Netherlands stayed apart from other countries, like the Holy Siege[142], which invoked human dignity of the human being in a wide sense, like a species and thus including human embryos.

141 In the Preamble of the Additional Protocol one can read "Considering the purpose of the Convention on Human Rights and Biomedicine, in particular the principle mentioned in Article 1 aiming to protect the dignity and identity of all human beings." Article 1 of the Convention on Human Rights and Biomedicine states: "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 applications of biology and medicine."

142 See "Clonage et recherche embryonnaire", *La documentation catholique,* No. 2261, 2002. The Holy Siege took part in the drafting of this Additional Protocol although it finally did not sign it.

My own point of view is that such Interpretative Declaration by The Netherlands hardly would be compatible with the sense given to "human beings" in the Convention on Human Rights and Biomedicine where it is combined -without confusion- "person" (any particular and individual human being) and the "human beings", as including the human life in all its forms, embryonic and already born. Thus, the word "person" is used here with a similar meaning as it is employed in the European Convention for the Protection of the Human Rights and Fundamental Freedoms, of 11th November, 1950. That is, as referring to those who are subject of Law, with rights and duties. The words "human beings", on the contrary, is used in the Convention on Human Rights and Biomedicine meaning human life in all its forms to bring protection to human dignity and identity since the very moment of conception. Consequently, Article 13 of the Convention on Human Rights and Biomedicine, on interventions on the human genome gains a practical meaning[143].

Nevertheless, it still seems an open question the meaning of human dignity. As the *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings* recognised in point 6:

> "In conformity with the approach followed in the preparation of the Convention on Human Rights and Biomedicine, it was decided to leave it to domestic law to define the scope of the expression 'human being' for the purposes of the application of the present Protocol."

143 "Any 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." Supporting this interpretation, see among others, Requena Casanova, M., "Nota sobre la ratificación por España del Convenio para la protección de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la biología y la medicina", *Revista Española de Derecho Internacional,* 1999, Vol. li, p. 796.

The Universal Declaration on Human Cloning, adopted by the General Assembly of the United Nations on 8th March 2005, also let open the question revealing that the lack of consensus of the international community of States on this point could be considered as insurmountable[144].

In the already referred *Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings,* it is distinguished between three situations: cloning of cells as a technique, use of embryonic cells in cloning techniques, and cloning of human beings, for example by utilising the techniques of embryo splitting or nuclear transfer, to conclude that "whereas the first situation is fully acceptable ethically, the second should be examined in the protocol on embryo protection. The consequences of the third situation, that is the prohibition of cloning human beings, are within the scope of this Protocol."[145]

The explanation for considering deliberately cloning humans as a threat to human dignity is provided shortly after when it is asserted that otherwise

> "It would give up the indispensable protection against the predetermination of the human genetic constitution by a third party. Further ethical reasoning for a prohibition to clone human beings is based first and foremost on human dignity which is endangered by instrumentalisation through artificial human cloning. Even if in the future, in theory, a situation could be conceived, which might seem to exclude the instrumentalisation of artificially cloned human offspring, this is not considered a sufficient ethical justification for the cloning of human beings. As naturally ocurring genetic recombination is likely

144 According to the voting result of Resolution 59/280 which endorsed the United Nations Declaration on Human Cloning: 85 States members voting in favour, 34 voting against, 37 abstaining and 36 not voting.

145 Point 2 of the Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings.

> to create more freedom for the human being than a predetermined genetic make up, it is in the interest of all persons to keep the essentially random nature of the composition of their own genes."[146]

At European level, the controversy is inevitable since although fundamental rights, being the first of the right to life, are only enjoyable by any born person[147], the principle of human dignity can be considered also in connection with human embryos. The more recent international instrument for the protection of human right in Europe, the Charter of Fundamental Rights in the European Union[148] could be claimed to have let open this ambiguity. In Chapter I (Dignity) reference to human rights facing human cloning is in article 3 "right to physical integrity" and not in article 2 "right to life". In this way, in my opinion, it is evident that person (any individual human being already born) is not confused with "human being" in the broad sense of any human life whatever conception of such one share. That is, fundamental rights are only predictable regarding only a born person. Nevertheless, taking into consideration a specific fundamental right, such as the right to genetic privacy, a ban on any research using human embryos for reproductive purpose is supported for both, the protection of a funda-

146 Point 3 of the Explanatory Report to the Additional Protocol to the Convention on Human Rights and Biomedicine on the Prohibition of Cloning Human Beings.

147 As the European Court recalled in paragraph 46 of the judgment of 7 March 2006 in the case of Evans v. United Kingdom, observing the same that previously in *Vo v. France* [GC], no. 53924/00, § 82, ECHR 2004. In the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law an embryo does not have independent rights or interests and cannot claim—or have claimed on its behalf—a right to life under Article 2. Consequently, there had not been a violation of that provision in the present case (paragraph 47 of the judgment of 7 March 2006). We will further analyze it in Chapter 3.

148 Jo L 306/10, of 17th December 2007.

mental right of a born person to his/her genetic privacy and taking into consideration the principle of human dignity of any human embryo.

2.3. The question of fundamental human rights which could be affected by any international legal frame regulating human embryo research

2.3.1. How fundamental human rights can be protected against the risks of the human embryo research?

It is commonly stated that scientific developments and their implications on human beings can lead to a violation of fundamental rights. This can be illustrated with an example: human cloning. First of all, as already mentioned in the general introduction, right to life is to be considered as this regards. No matter if we consider such a right for the foetus or an already born person, there are arguments against human cloning research on the basis of the experience of the sheep Dolly. For the scientific success with Dolly, many other sheeps conceived with cloning reproductive techniques failed. Thus, it seems necessary to be cautious when cloning human cells because as it has been observed, any lost of sheep might be acceptable but just a single foetus died would be an excessively high price to pay[149]. A long-term research on human cloning has not already been carried out which casts doubts on those risks for human being's right to life really exist[150]. However, many people who grant that children produced this way might be genetically normal still they claim their creation could be immoral considering the psychological harm to the child[151].

149 Mon Post, M., "Human Cloning: New Hope, New Implications, New Challenges", *op. cit.*, p. 186.

150 Greenlee, S., "Dolly's Legacy to Human Cloning: International Legal Responses and Potential Human Rights Violations", *Wisconsin International Law Journal*, 2000, Vol. 18, No. 2, p. 552.

151 Pence, Gregory, "Cloning" in *A Companion to Bioethics* Khuse, Helga and Singer, Peter (eds.), *op. cit.,* p. 198.

It seems evident that other fundamental rights, such as the right to respect for psychical and physical integrity could also be endangered because any human clone would lack a normal social identity[152]. It can also be said the same in the case of the right to genetic intimacy, that is the right of anyone to determine when, where and how others –including public agencies without judicial permit- can access to genetic data concerning him/her. It should be mentioned in passing that although the obligation to maintain patients' confidentiality is one of the oldest codified moral commitments in health care (Hippocratic Oath *circa* 425 BC), it is generally accepted the exceptions to this duty, namely considering the public welfare)[153]. The duty to confidentiality is has become equally applicable to research and experimentation subjects in the similar way[154]. Such necessity to protect genetic data has even open the door for alternative ways, for instance considering the DNA as a copyright legally protected[155], or introducing new offences under penal law[156].

It is needless to say that the right not to suffer discrimination is part of those right directly endangered by scientific advances in the field of human embryo engineering[157]. Let's start by considering those

152 MON POST, M., "Human Cloning: New Hope, New Implications, New Challenges", *op. cit.,* p. 190.

153 GILLON, Raanan and SOKOL, Daniel K., "Confidentiality", in *A Companion to Bioethics, op. cit.,* p. 517.

154 MESLIN, Eric M. and DICKENS, Bernard M., "Research ethics", in *The Cambridge Textbook of Bioethics* (SINGER P. A. and VIENS, A. M. eds.), *op. cit.,* p. 189.

155 See in internet advertisements in this sense like that in www.dna-copyright.com

156 For instance, in the United Kingdom a new offence of non-consensual analysis of DNA has been established under the Human Tissue Act (2004) by which use of DNA is allowed for medical or research purposes and at the same time addresses concerns over the possibility of its malicious use. CHADWICK, Ruth, "Genetic testing and screening", *op. cit.,* p. 162.

157 In many countries there is specific legislation concerning disabilities and discrimination which can be of relevance in the context of genetics. Nevertheless, CHADWICK points out that it is a question controversial as to how disability

who defend genetic modifications in human embryos for preventive or therapeutic purposes, such as the pre implantation genetic diagnosis to avoid transferring illnesses to descendents. For those who think this way, national authorities can not intervene for or against such personal decision concerning exclusively parents. The snag about this argument is that in systems of private Health Care this abstention from national authorities would imply *de facto* opening the door for genetic differentiation of society. Thus, only those families with economic resources could be able to get their descendents free or genetic hereditary illnesses. The next step would be the genetic improvement of descendents and, thus, the consequence of dividing into separate groups the society[158]. Paradoxically, in the XXI Century we would return to the paradigm of society existing in France before the French Revolution in 1789 (Religious people, noble people and the rest of people). This time, modern society would be divided into two social groups: those genetically improved and those who have not due to the fact that once a family has run with the expenses of the genetic enhancement of its members, it will be rather unusual to dilapidate its "genetic treasure" with non-improved individuals. So, as time goes by, social breach into society becomes wider and deeper[159].

This is the main fear of those who criticize the eventual absolute right of parents to enhance their descendents by deleting not wanted genes or by introducing others "at choice". One may suppose that human embryo enhancement might be socially acceptable in some cases

---

is defined, specifically as to whether it could or should include persons with a presymptomatic genetic disorder. CHADWICK, Ruth, "Genetic testing and screening", in *The Cambridge Textbook of Bioethics* (SINGER P. A. and VIENS, A. M. eds.), *op. cit.,* p. 163.

158 CHADWICK, Ruth, "Gene Therapy", in *A Companion to Bioethics, op. cit.*, p. 214. Other authors assume this fact as inevitable. See BAYLIS, F. and ROBERT, J. S., "The inevitability of genetic enhancement technologies", *Bioethics,* 2004, Vol. 18, pp. 1-26.

159 LEE, M. Silver, "U.S. Dream child or nightmare scenario?", *UNESCO The Courier,* September 1999, *op. cit*. Available at: http:// www.unesco.org/courier/1999_09/uk/dossier/intro.htm

apart from hereditary illnesses for which there are no cure, such as some cancer. There is a chance, however, that once the door is open nothing could avoid one of the golden rules of free market: "whatever you want I will sell you". Thus, parents wishing to reach some idea of human perfection in their descendents will have to spend a lot of money, too much as not be dilapidated in future their descendent being with people who have not been genetically enhanced. Thus, society's division steadily will increase. Even, in a society with national health-care system covering some enhancement interventions it will still remain a problem of resources allocation, related to the selection of candidates for treatment[160].

These fears, nevertheless, are not generally shared. Some authors from a welfare approach distinguish between ethical and unethical human enhancements on the ground that the intervention brings about more benefits than harms to the individual, and indirectly to the society at large. Thus, authors like Savulescu maintain the convenience of enhancements which, to be ethical, should match the following premises

- is in the person's interest
- is reasonably safe
- increases the opportunity to have the best life
- promotes or does not unreasonably restrict the range of possible lives open to that person
- does not unreasonably harm others directly through excessive costs in making it freely available
- does not place that individual at an unfair competitive advantage with respect to others
- is such that the person retains significant control or responsibility for her achievements that cannot be wholly or directly attributed to the enhancement
- Does not reasonably reinforce or increase unjust inequality and discrimination -economic inequality, racism[161].

160 Chadwick, Ruth, "Gene therapy", in *A Companion to Bioethics, op. cit.,* p. 214.

161 Savulescu, Julian, "Genetic Interventions and the Ethics of Enhancement of Human Beings", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), *op. cit*, p. 532. An ethical enhancement for a child or incompetent human being is that including these premises but in addition three require-

In this connection, we could also point out that very common to those who defend human embryo research and experimentation is to refute the genetic determinism and to focus on serious risks of black market for this research –were it to be legally banned- with unpredictable consequences. According to genetic determinism, genes conditionate completely our existence and it plays a very residual role the environmental conditions where we grow up. Nowadays every genetist refutes such determinism as a fallacy[162]. Even two people sharing the hundred per cent of their genes would be different according to own personality and with physical features depending on environmental background[163]. Those who claim for a regime tolerating this research and experimentation use also as argumentation the adverse consequences derived from an interdiction, namely the creation of secret laboratories worldwide to carry on with such research, where security protocols, if they exist, could be impossible to control. This argument, however, is challenged with the "slippery slope argument" by which, even if research using human embryos might be justified by its results, it is nevertheless the kind of activity that will inevitably lead to even worse activities which nearly everyone would agree are wrong. In short, a law allowing research using human embryos will inevitably be abused[164].

---

ments for the intervention: the fact that it cannot be delayed until the child can make its own decision; the intervention being plausibly in the child's interest; and that being compatible with the development of autonomy. *Ibídem.*

162 Pence, Gregory, "Cloning", in *A Companion to Bioethics*, *op. cit.,* pp. 194-195. As he concludes, "how the genes are in specific patters will vary because, contrary to popular beliefs about genetic reductionism, how genes are expressed depends on what happens to them in uterus and in childhood… A child created by cloning and raised by different parents in another era would not be an exact copy of her ancestor, and anyone thinking or expecting such an exact copy would be disappointed."

163 Greenlee, S., "Dolly's legacy to Human Cloning: International Legal Responses and Potential Human Rights Violations", *op. cit.,* p. 553. See also Bell, D., "Human Cloning and International Human Rights Law", *The Sydney Law Review,* 1999, Vol. 21, p. 210.

164 For a critical view to the slippery slope argument, see Warnock, Mary and

Undoubtedly, in the human cloning research enter into consideration ethical questions as it happens in any scientific development having social consequences. Thus, it is important to strike a balance between what a society can do and what it should or should not to do[165]. Research on human cloning risks not only the trivialization of human life and it may be contrary to human dignity in the sense that human beings can be considered as commodities and artefacts[166]. This research may also endanger the respect of some fundamental rights such as the right to life, to psychical and physical integrity, to genetic privacy and to not suffer discrimination. The risk of breaching these rights, nevertheless, should not prevent us from the chances and benefits these techniques offer in finding out a cure for some severe illnesses. In this sense, it should be observed that the enjoyment of the highest attainable standard of health is also a fundamental right to be preserved.

2.3.2. What is the fair balance to be struck facing other compelling human rights such as the right to health?

Right to health care forms a part of a broaden family of positive "welfare" rights, like a right to education or the right to housing. It includes care that effectively promotes normal functioning by reducing the impact of disease and disability, thus protecting the range of opportunities that would otherwise be open to us[167]. It is interesting to note how this right finds further ground as a special case of a right to equality of opportunity in the sense that disease and disability restrict the range of opportunities that would otherwise be open to individuals[168].

Braude, Peter, "Research Using Preimantation Human Embryos", *op. cit.,* p. 491.

165 Kluge, E.-H., "Human Genome Research and the Law: the Ethical Basis of International Regulation", *op. cit.*, pp. 159-160.

166 Mon Post, M. "Human Cloning, New Hope, New Implications", *op. cit*., p. 191.

167 Daniels, Norman, "Is There a Right to Health Care and, if so, What Does It Encompass?", in *A Companion to Bioethics, op. cit.,* p. 367.

168 Daniels, Norman, "Is there a Right to Health Care…", *op. cit.,* p. 365. This approach is particularly useful in decision-making procedure for resolving

Any State assumes an own understanding of an "adequate standard of living for health and well-being." This conceptual divergence is evidenced in the very definition of the human right to health at national and international level: right to health, right to health care, right to medical care, right to health protection, etc. If one starts from that principle, then it is evident that there are two obstacles to the universal implementation of a human right to health: its lack of conceptual clarity and the scope of the Governments' obligations[169].

As far the first obstacle -conceptualising the core right and other rights related- everyone's right to the highest attainable standard of physical and mental health, including reproductive and sexual health, without discrimination of any kind seems to me the core right to health and must be read, in addition, relating other human rights. In this connection the Committee on Economic, Social and Cultural Rights' *General Comment No. 14 (11/8/2000) on the right to the highest attainable standard of health*, clearly stated the human right to equal access to adequate health care and health-related services without discrimination; the human right to an adequate standard of living, including the right to access to adequate food, drinking water, sanitation and housing; the human right to a safe and free-pollution environment, particularly in case of children; the human right to enjoy safe and healthy working conditions, particularly for pregnant women; the right to access to education on health, including sexual and reproductive health; finally, the right to human dignity and physical integrity preventing from female genital mutilation, prenatal gender selection and female infanticide[170].

It is evident that there is no specific legal instrument for the recogni-

---

moral disputes about health-care entitlements. When a disease or disability has little impact on the range of opportunities open to someone, it would not be as morally important to treat as other conditions that more seriously impair opportunity. Ibídem, p. 368.

169 Toebes, Brigit: "Towards an improved understanding of the international human right to health", *Human Rights Quarterly*, Vol. 21, 1999, p. 661.

170 Committee on Economic, Social and Cultural Rights, *General Comment No. 14 (11/8/2000) on the right to the highest attainable standard of health*, paragraph 4.

tion and protection of a right to health. Consequently, the core right to health and other human rights related to health have been asserted in several international legal instruments at universal level, such as: *The Universal Declaration of Human Rights*[171], Articles 7, 11 and 12 of the *International Covenant on Economic, Social and Cultural Rights*[172], Articles 10, 12 and 14 of the *Convention on the Elimination of All Forms of Discrimination Against Women*[173], Article 5 of the *International Conven-*

---

171 General Assembly Resolution 217(III), 10 December 1948: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age and other lack of livelihood in circumstances beyond his control. Motherhood and childhood are entitled to special care and assistance…"

172 Adopted the 16th December 1966, 3 U.N.T.S., entered into force the 3rd January 1976: "The States Parties to the present Covenant recognize the right of everyone to …just and favourable conditions of work which ensure …safe and healthy working conditions; …the right to …an adequate standard of living …; the enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for …the provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; the creation of conditions which would assure to all medical service and medical attention in the event of sickness."

173 Adopted the 18th December 1979, entered into force the 3rd September 1981: "States Parties shall …ensure to (women) … access to specific educational information to help to ensure the health and well-being of families, including information and advice on family planning…; States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning… States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation… Article 14: States Parties shall take all appropriate measures to eliminate discrimination against women in rural areas in order to ensure, on

tion on the Elimination of All Forms of Racial Discrimination[174], Article 24 of the *Convention on the Rights of the Child*[175]. In Regional Human Rights Instruments, the human right to health has been asserted as well: Articles 7 and 11 of the American Declaration of the Rights and Duties of Man (1948)[176], Articles 16 and 18 of the African Charter on Human and People's Rights (1979)[177], or Article 14 of the African Charter on the Rights and Welfare of the Child (1990)[178].

---

a basis of equality of men and women, that they participate in and benefit from rural development and, in particular, shall ensure to such women the right… to have access to adequate health care facilities, including information, counselling and services in family planning…"

174 Adopted 21st December 1965, 195 U.N.T.S., entered into force 4th January 1969: "…States Parties undertake to prohibit and to eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, or national or ethnic origin, to equality before the law, notably in the enjoyment of the following rights: economic, social and cultural rights, in particular …the right to public health, medical care, social security and social services…"

175 Adopted 20th November 1989, entered into force the 2nd September 1990: "States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health…"

176 "All women, during pregnancy and the nursing period, and all children have the right to special protection, care and aid… Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources."

177 "Every individual shall have the right to enjoy the best attainable state of physical and mental health. States Parties to the Present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick… The State shall ensure the elimination of every discrimination against women and also ensure the protection of the rights of the woman and the child as stipulated in international declarations and conventions. The aged and disabled shall also have the right to special measures of protection in keeping with their physical or moral needs."

178 "Every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health. States Parties to the Present Charter shall undertake to pursue the full implementation of this right…"

As mentioned above, the second obstacle to the universal implementation of a human right to health is the scope of the Governments' obligations. The right to health entails three kinds of obligations on government: *respect*, that is, absence of any direct or indirect interference with the enjoyment of the right to health; *protection*, that is, assuring the right to health by preventing third parties from interfering in any way with its enjoyment; and *fulfilment*, that is, taking all measures needed to achieve the full realization of the right to health. It is this third kind of obligations which challenges the effective implementation of a human right to health since the Governments' measures to be taken are severe for developing countries: increasing the distribution of clean water; establishing sanitary living conditions; maintaining sufficient food supplies; administering widespread vaccination and medications; providing prenatal and material care and educating people about disease prevention and malnutrition.

Considering States' obligations of result regarding the right to health seems totally convincing. States are compelled by the final goal of taking steps with a view to achieving progressively the full realization of the right to health. Consequently, although the concept of progressive realization constitutes recognition of the fact that the full realization of the right to health will generally not be able to be achieved in a short period of time, "progressively" should not be misinterpreted as depriving such an obligation of all meaningful content. It imposes for the State an obligation to move as expeditiously and effectively as possible towards that goal. Even where the available resources are demonstrably inadequate, the obligation remains for a State party to strive to ensure the widest possible enjoyment of the right to health under the prevailing circumstances. Moreover, the obligations to monitor the extent of the realization, or more especially of the non-realization, of the right to health, and to devise strategies and programmes for their promotion, are not in any way eliminated as a result of resource constraints. Furthermore, even in times of severe resource constraints whether caused by a process of adjustment, of economic recession, or by other factor the vulnerable members of so-

ciety can and indeed must be protected by the adoption of relatively low-cost targeted programmes[179].

It could be claimed as a consequence that patients around the world suffering from some diseases such as Parkinson' disease, Alzheimer's disease and diabetes -when they apply scientists to engage in genetic research invoking their right to health- must find out a positive attitude from the Legislator regulating those scientists' research. Since 2001 (see General Assembly Resolution 56/93 of 12 December 2001) the United Nations has been considering the elaboration of an international convention on the cloning of human beings. At present, clearly there is consensus in the international community to ban reproductive cloning but not as far therapeutic cloning (nuclear transfer) as it proves the Resolution 59/280, which endorses the United Nations Declaration on Human Cloning, adopted on 8 March 2005 with the voting result of 85 states members in favour, 34 against, 37 abstaining and 36 not voting.

By this Declaration, States are called on to adopt "all measures necessary" firstly, to protect adequately human life in the application of life sciences; secondly, to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protections of human life; and thirdly, to prohibit the application of genetic engineering techniques that may be contrary to human dignity. Not defining terms such as ´human cloning´, ´human dignity´and ´human life´in practice any State may consider which therapeutic cloning should or should not be banned balancing moral issues and scientific knowledge seeking to provide relief from suffering and to improve the health of individuals and humankind as a whole. In particular, the no definition of human dignity lets open the door to States forbidding both, reproductive and therapeutically cloning, whereas other States would only ban on reproductive cloning.

My personal opinion on the matter is that such situation is in con-

179 Committee on Economic, Social and Cultural Rights, *General Comment No. 3 (14/12/1990) on the nature of states parties obligations*, paragraphs 9, 11 and 12.

tradiction with steps made by the international community of States towards a universally protected human right to health. The particular position of many States also would entail their international responsibility for breaching obligations they freely assumed under the Convention on Economic, Social and Cultural Rights.

2.4. Concluding observations.

The best way of summing up what said in this Chapter is by the following:

1. Any international regulation of embryo research will be conditioned by the dialectic discussion confronting those who defend freedom for scientific cloning research, and those others who oppose any research on embryos and the application of technical developments on human beings.

Two set of questions arise up in connection with human embryo research from the point of view of International Law: firstly, it is the possibility of establishing an international regulation on the principle of human dignity and the moral consideration of human embryos. Secondly, it is the question of fundamental human rights which could be affected by any international legal frame regulating human embryo research. In the development of these issues the guiding questions to be answered will be the following ones: What is the limit under the human dignity principle to the human embryo research? How fundamental human rights can be protected against the risks of the human embryo research? What is the fair balance to be struck facing other compelling human rights such as the right to health?

2. It is an open question whether there is an universally shared conception of human dignity to be fully respected in decisions or practices taken or carried out by those to whom this Declaration is addressed, namely but not only, States. Another question we are coming back in next pages deals with a particular person's fundamental right to the enjoyment of them the highest attainable standard of health which could require research on embryos. Would this funda-

mental right prevail over any ban on this kind of research by national authorities if they consider is in the context of their national society as being contrary to human dignity?

As it would be expected, no further agreement is found concerning the first question, probably due to the Human Rights' speech was politically used during the Cold War by both -Western democracies and by Soviet Union and other allies –to emphasize civil and political rights versus economic and social rights.The Universal Declaration on Human Cloning, adopted by the General Assembly of the United Nations on 8th March 2005, also let open the question revealing that the lack of consensus of the International Community of States on this point could be considered as insurmountable. At European level, the controversy is inevitable since although fundamental rights, being the first of the right to life, are only enjoyable by any born person, the principle of human dignity can be considered also in connection with human embryos.

3. Undoubtedly, in the human cloning research enter into consideration ethical questions as it happens in any scientific development having social consequences. Thus, it is important to strike a balance between what a society can do and what it should or should not to do. Research on human cloning risks not only the trivialization of human life and be contrary to human dignity in the sense that human beings can be considered as commodities and artefacts. This research may also endanger the respect of some fundamental rights such as the right to life, to psychical and physical integrity, to genetic privacy and to not suffer discrimination. The risk of breaching these rights, nevertheless, should not prevent us from the chances and benefits these techniques offer in finding out a cure for some severe illnesses. In this sense, it should be observed that the enjoyment of the highest attainable standard of health is also a fundamental right to be preserved.

4. Right to health care forms a part of a broaden family of positive "welfare" rights, like a right to education or the right to housing. It includes care that effectively promotes normal functioning by reducing the impact of disease and disability, thus protecting the range of opportunities that would otherwise be open to us. It is interesting to

note how this right finds further ground as a special case of a right to equality of opportunity in the sense that disease and disability restrict the range of opportunities that would otherwise be open to individuals. However, any State assumes an own understanding of an "adequate standard of living for health and well-being." If one starts from that principle, then it is evident that there one of the main obstacles to the universal implementation of a human right to health is the scope of the Governments' obligations.

5. Considering States' obligations of result regarding the right to health seems totally convincing. It could be claimed as a consequence that patients around the world -when they apply scientists to engage in genetic research invoking their right to health- must find out a positive attitude from the International Legislator –the own States- regulating those scientists' research. Since 2001 the United Nations has been considering the elaboration of an international convention on the cloning of human beings. At present, clearly there is consensus in the international community to ban reproductive cloning but not as far therapeutic cloning as it proves the Resolution 59/280, which endorses the United Nations Declaration on Human Cloning, adopted on 8 March 2005. The no definition of human dignity lets open the door to States forbidding both, reproductive and therapeutically cloning, whereas other States would only ban on reproductive cloning. Such situation is in contradiction with steps made by the international community of States as a whole towards a universally protected human right to health. The particular position of many States also would entail their international responsibility for breaching obligations they freely assumed under the Convention on Economic, Social and Cultural Rights.

PART II

REGIONAL BIO LAW

CHAPTER 3

EUROPEAN LAW AND HUMAN EMBRYONIC STEM CELL RESEARCH: TOO FAR FROM NOWHERE

3.1. Introduction

The *European Group on Ethics in Science and New Technologies to the European Commission*, in its Opinion No 22 of 20 June 2007 titled *Recommendations on the ethical review of hESC FP7 research projects*[180], evidenced a situation, normatively speaking, of "variable geometrical" among European Union Member States regulations on human embryonic stem cells (from now on "hESC"). Geometrical, firstly, because it is possible to recognise four different approaches from European Union member States on hESC research[181]:

Permissive position. A few member States have specific legislation for hESC research, covering the procurement of stem cells and their use for research. In Belgium, Spain, Sweden and the United Kingdom, for example, embryo creation is allowed for research purposes.

Permissive position with restrictions. In other European Union member States as the Czech Republic, Denmark, Finland, France, Greece, Netherlands and Portugal, regulations allow the derivation of new hESCs from embryos created as a result of assisted reproduction technology (ART) and *in vitro* fertilisation to induce pregnancy, but only when they can no longer to be used for that purpose.

Restrictive position. Germany and Italy have stricter hESC research

---

180 *Recommendations on the ethical review of hESC FP7 research projects*, Opinion Nº 22, 2007, p. 32, Available at: http://europa.eu.int/comm/european_group_ethics

181 See pages 29 and ff. in the Opinion No 22.

regulations. Scientists in these countries cannot derive new hESC cell lines, but can import them. In Germany, a new discussion has arisen as regards the revision of the 2002 Stem Cell Act regulating the importation of hESC lines[182]. The Italian legislation covers Artificial Reproduction Technology and the production of new hESC (research involving the destruction of embryo is not allowed). Italy has therefore no legal provision as regards the use of imported hESC or existing hESC.

No specific legislation or indirect legislation only. In many Member States, hESC research has still no specific legislation (Bulgaria, Cyprus, Estonia, Ireland, Luxemburg, Latvia and Romania. Ireland, for instance, currently has no specific legislation dealing with embryonic stem cell research and furthermore does not have a legislative basis for the practice of *in vitro* fecundation. Some other European Union Member States have no 'specific' regulation on hESC research, but explicitly indicated that they are against it (Austria, Lithuania, Malta, Poland and Slovakia) by voting against hESC research during the Council decision for FP7. Lastly, in some countries hESC is at present regulated only by indirect legislation for embryo research (Hungary, Slovenia), but without specific references to hESCs.

Variable, secondly, because it is evident that Science moves faster than Law and this situation described by the European Group on Ethics in Science and New Technologies to the European Commission, in its Opinion No 22, should to be updated today, for example in the case of Germany[183].

182 In 2008 Germany changed its legislation and since then scientists there can do research on stem embryo cells imported into Germany provided they had been created before the 1st May 2007 (and not only those created before 1st January 2002).

183 Notwithstanding, big changes are not expected any time soon and lack of harmonization still keeps on as the major challenge for Europe: "how to respect diversity while unifying the different systems in order to foster advances in European research for the benefits of all", Druml, Ch., "Stem Cell Research: Towards Greater Unity in Europe?", *Cell,* No. 139, 2009, p. 651.

3.2. The European pluralism and a *variable geometry* in Europe as regards regulation of human embryo research

3.2.1. The lack of a European common conception of human life and concerning the beginning of human life as stated by the European Courts

In order to understand the variable geometry above commented, it should be pointed out the lack of a European common conception of human life and of its beginning, jus as it is maintained in the European Courts, namely, in the European Court of Human Rights.

The Court of Justice of the European Union has referred to human dignity as a legitimate interest which must be protected by the European Union itself and by its member States even if such protection is in contradiction with European Law dispositions[184]. What human dignity means, however, remains a mystery in Europe. The European Court of Human Rights has dealt with eventual connotations of the principle of human dignity as regards the European Convention for the Protection of Human Rights and Fundamental Freedoms, of 11th November 1950[185]. The exam of these judgments can be rather pertinent for biomedical research. Previously to the exam of the relevant jurisprudence of the European Court of Human Rights it is interesting to recall that in the Charter of Fundamental Rights of the European Union, in Chapter I (Dignity) it is made a reference to human rights facing cloning in Article 3 (right to physical integrity)[186] and

184 Case C-377/98, *Netherlands v. European Parliament and Council* (2001) ECR I-7079, paragraphs 70 and ff.. Case C-36/02, *Omega Spielhallen und Automatenaufstellungs GmbH v. Obergurgermeiterin der Bundesstadt Bonn* (2004) ECR I-9609, paragraphs 30 to 35. Case C-456/03, *Commission v. Italy* (2005) ECR I-5335.

185 ETS No. 5 as modified by Additional Protocol No. 14, in force since 1st June 2010, CETS No. 194.

186 Article 3. Right to the integrity of the person. "1. Everyone has the right to respect for his or her physical and mental integrity. 2. In the fields of medicine and biology, the following must be respected in particular: - the free and

not in Article 2 (right to life)[187]. Thus, it could seem evident for the drafters of this international instrument legally binding in Europe after the Lisbon Treaty[188] that dignity refers to a person, namely, any born person and not to the human being, like species, in the widest sense of any human life whatever conception one might have of it.

This fact could have served to the European Court of Human Rights –and indeed to the own Court of Justice of the European Union- for resolving the eventual controversy surrounding dignity under the European Convention. Nevertheless, human dignity is not understood in a uniform way around Europe and thus, States like Germany and Italy consider the dignity of the human being –human embryos included- as prevailing over the reductionist conception of dignity of a born person as evidenced in the Charter of Fundamental Rights of The Europe Union.

The pluralism of juridical orders is one of the main features of the European society and this fact is consistently recalled by the European Court of Human Rights when it has to interpret and implement dispositions of the European Convention on Human Rights of its Additional Protocols. As far as the conception of the beginning of human life and its juridical implications, two sets judgments seem to be of particular relevance. The first one, dealing with the nature and juridical condition of a human foetus is a judgment of the Grand Chamber of the European Court of Human Rights, of 8th July 2004

---

informed consent of the person concerned, according to the procedures laid down by law; - the prohibition of eugenic practices, in particular those aiming at the selection of persons, - the prohibition of making the human body and its parts as such a source of financial gain- the prohibition of the reproductive cloning of human beings."

187 Article 2. Right to life: "1. Everyone has the right to life. 2. No one shall be condemned to the death penalty or executed". Note that it is immediately after Article 1. Human dignity: "Human dignity is inviolable. It must be respected and protected."

188 Originally published in the Official Journal as "C" (non legislative acts), JO C364/1, 2001, after the Lisbon Treaty, Article 1.8 has included a new Article 6 in the European Union Treaty by which the Charter of Fundamental Rights of the European Union has binding legal force. Consequently, it has been published as "L" (legislative acts), JO L306/10, 17 December 2007.

in the case Vo versus France. The second one deals with human embryos and is represented by judgments of 7th March 2006 (Chamber) and 10th April 2007 (Grand Chamber) of the European Court, both given in the case Evans versus United Kingdom.

The European Court of Human Rights, ruling as a Grand Chamber, said previously the same with different words in 2004 in the *case of VO v. France*[189]. Then, the European Court considered that the issue of when the right to life begins is a question to be decided at national level: firstly, because the issue has not been decided within the majority of the States which had ratified the Convention, in particular in France, where this question has been the subject of public debate; and, secondly, because there is no European consensus on the scientific and legal definition of the beginning of life. It also established that:

> "At European level, there is no consensus on the nature and status of the embryo and/or foetus. At best, it can be regarded as common ground between States that the embryo/foetus belonged to the human race, its potential and capacity to become a person requires protection in the name of human dignity, without making it a person with the right to life for the purpose of Article 2."[190]

---

189 Judgment of 8 July, 2004. The case concerned an application brought by a French national, Mrs Thi-Nho Vo, who attended on 27 November 1991 the Lyons general Hospital for a medical examination scheduled during the six month of pregnancy. On the same day another woman, Mrs Thi Thanh Van Vo, was due to have a coil removed at the same hospital. Owing to a mix-up caused by the fact that both women shared the same surname, the doctor who examined the applicant pierced her amniotic sac, making a therapeutic abortion necessary. Having exhausted local remedies, Mrs Thi-Nho VO lodged an application before the European Court complaining of the authorities' refusal to classify the unintentional killing of her unborn child as involuntary homicide, relying on Article 2 of the European Convention on Human Rights.

190 Paragraphs 82 and ff. of the Judgment. The European Court of Human Rights also remembered that not even the Convention on Human Rights and Biomedicine of 1997 (Oviedo Convention) nor its Additional Protocol of 2005 concerning Biomedical Research include a definition of human being or of a person.

The same conclusion was achieved two years later in the *case Evans v. United Kingdom,* judgments of 7 March, 2006 (Chamber) and of 10 April, 2007 (Grand Chamber)[191]. In both judgments the European Court of Human Rights refused to recognise eventually the right to life under Article 2 of the European Convention of Human Rights to human embryos. Furthermore, this Court even self-restrained of willing to judge at European level on the question concerning the beginning of human life, considering the wide margin of appreciation any European country has been recognized on the matter.

On 10 October 2000 the applicant and J. (her partner at that time) were informed, during an appointment at the clinic that preliminary tests had revealed that the applicant had serious pre-cancerous tumors in both ovaries, and that her ovaries would have to be removed. They were told that because the tumors were growing slowly, it would be possible first to extract some eggs for *in vitro* fertilization ("IVF"). On 12 November 2001 the couple attended the clinic and eleven eggs were harvested and fertilized. Six embryos were created and consigned to storage. On 26 November the applicant underwent an operation to remove her ovaries. She was told that she should wait two years before attempting to implant any of the embryos in her uterus. In May 2002 the relationship of the couple broke up. The future of the embryos was discussed between the parties. On 4 July 2002 J wrote to the clinic to notify it of the separation and to state that the stock of embryos should be destroyed. Since that moment, a legal battle started between both parts reaching the European Court of Human Right's judgment of 7 March 2006.

Before the European Court the applicant claimed that the relevant provisions of the 1990 Human Fertilization and Embryology Act, which required her former partner's consent before the embryos made with their joint genetic material can be implanted in her uterus, violate her rights under Articles 8 and 14 of the Convention, and the embryos' right to life under Article 2.

Concerning the alleged violation of Article 2 of the European Con-

191 See paragraphs 45 to 47 in the former and paragraphs 54 to 56 in the latter.

vention, the Court recalled in paragraph 46 of his judgment what has already observed in *Vo v. France*[192], that, in the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law an embryo does not have independent rights or interests and cannot claim —or have claimed on its behalf— a right to life under Article 2. Consequently, there had not been a violation of that provision in the present case[193]. As far the rest of her allegation relating Articles 8 and 14, the European Court's assessment was the following to finally reach the conclusion that it had not been violation of Article 8 (held by five votes against two) nor of Article 14 (held unanimously):

The Court observed at the outset that since "private life" is a broad term, it incorporates the right to respect for both the decisions to become and not to become a parent[194]. The 1990 Act prevented the clinic from treating the applicant once J. had withdrawn his consent. Thus, for the European Court, the question which arises is whether there exists a positive obligation on the State to ensure that a woman who has embarked on treatment for the specific purpose of giving birth to a genetically related child should be permitted to proceed to implantation of the embryo notwithstanding the withdrawal of consent by her former partner, the male gamete provider (paragraph 58). To give an answer, the European Court firstly, observed that there is no international consensus with regard to the regulation of IVF treatment or to the use of embryos created by such treatment[195].

192 Grand Chamber, no. 53924/00, § 82, ECHR 2004

193 Paragraph 47 of the judgment of 7 March 2006.

194 Paragraph 57 of the judgment of 7 March 2006.

195 Paragraph 61 of the judgment. Thus, in certain States, it appears that consent may be withdrawn only up to the point of fertilization, whereas in other States such withdrawal may occur at any time prior to the implantation of the embryo in the woman; in still other States the point at which consent may be withdrawn is left to the courts to determine on the basis of contract or according to the balance of interests of the two parties.

In this context declared the European Court that: "Since the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments, and since the questions raised by the case touch on areas where there is no clear common ground amongst the Member States, the Court considers that the margin of appreciation to be afforded to the respondent State must be a wide one" (paragraph 62). Thus, even though the great sympathy for the plight of the applicant who, if implantation did not take place, would be deprived of the ability to give birth to her own child, the European Court did not considered contrary to Article 8 the 1990 Act which did not have a power to national authorities to override a genetic parent's withdrawal of consent. In other words: "in adopting in the 1990 Act a clear and principled rule, which was explained to the parties to IVF treatment and clearly set out in the forms they both signed, whereby the consent of either party might be withdrawn at any stage up to the point of implantation of an embryo, the United Kingdom did not exceed the margin of appreciation afforded to it or upset the fair balance required under Article 8 of the Convention" (paragraph 69 of the judgment).

As far Article 14, the applicant reasoned that a woman who was able to conceive without assistance was subject to no control or influence over how her fertilized eggs developed; from the moment of fertilization she alone determined the future of the embryo. In contrast, the applicant, together with all women dependent on IVF to have children, was at the whim of the sperm donor, who had the power under the 1990 Act to prevent her from having the embryos implanted. The European Court avoided to come into the point, in my opinion, and sentenced the question in paragraph 74 by saying: "The Court is not required to decide in the present case whether the applicant could properly complain of a difference of treatment as compared to another woman in an analogous position, because it considers, in common with the Court of Appeal, that the reasons given for finding that there was no violation of Article 8 also afford a reasonable and objective justification under Article 14."

It would be mentioned in passing that even the Enlarged Board of Ap-

peal of the European Patent Office (EBoA) -having to pronounce itself on the meaning of human embryo in the so called WARF case-, concluded that what is an embryo is a question of fact in the context of any particular patent application[196]. We are seeing it thoroughly in following pages.

3.2.2. The moral clause and its consequences in a European Patent system unsuitable for human embryo research

The situation described at the very beginning of this Chapter has important effects[197] and juridical consequences as far as commercialisation and patenting in Europe. A debate on patenting hESCs was ongoing at both institutional (European Patent Office, the European Commission) and academic level. And although the Directive on the legal protection

196 Points 19 and 20 of the EBoA Decision of 25 November 2008 in the WARF case: "Against a reading of Rule 28 c), formerly 23 d (c) EPC, being applicable to the invention in this case, the Appellant has put forward several arguments. Firstly it argues for a very specific meaning of embryo, as being embryos of 14 days or older, in accordance with usage in the medical field. Neither the EU legislator nor the EPC legislator have chosen to define the term 'embryo' as used in the Directive or now in Rule 28, formerly 23 d) EPC. This contrast with the German law (Gesetz zum Schutz von Embryonen of 13 December 1990, § 8) where embryo is defined as including a fertilized egg, or the United Kingdom law (Human Fertilisation and Embryology Act 1990, Section 1.1), where embryo includes the two cell zygote and an egg in the process of fertilisation. The European Union and the EPC legislators must presumably have been aware of the definitions used in national laws on regulating embryos, and yet chose to leave the term undefined. Given the purpose to protect human dignity and prevent the commercialization of embryos, the Enlarged Board can only presume that 'embryo' was not to be given any restrictive meaning in Rule 28, formerly 23 d) EPC, as to do so would undermine the intention of the legislator, and that *what is an embryo is a question of fact in the context of any particular patent application*." (Cursive is added).

197 See NIPPERT, I., "The pros and cons of human therapeutic cloning in the public debate", *Journal of Biotechnology* 98 (2002), pp. 53-60. PLOMER, A., "The European Group on Ethics: Law; politics and the limits of moral integration in Europe", *European Law Journal,* 2008, Vol. 14, No. 39, p. 859.

of biotechnological inventions (98/44/EC)[198] regulates patentability of biological material, including hESCs, it is also true that there is no European Union consensus on the moral status of embryo and its products. Consequently, reflecting this wide diversity of moral cultures, there are different policies for patenting among national patent offices which may difficult to achieve a European patent consensus at this regards.

The *European Groups on Ethics in Science and New Technologies* evaluated it so in its Opinion No 16 "Ethical aspects involving the patenting of human stem cells", and the Main Board of Appellation ("EBoA") in the European Patent Office showed coincidence in this point it in its decision of 25 November 2008 in the so called *WARF case*. It was a ruling in an appeal connected to the so-called WARF/Thomson stem cell application describing a method for obtaining embryonic stem cell cultures from primates, including humans, and was filed by the Wisconsin Alumni Research Foundation (WARF) in 1995. In 2006, the Technical Board competent for the case referred it to the EBoA whose final decision was a refusal to grant a patent for an invention which necessarily involves the use and destruction of human embryos since it would be contrary to public order or morality in Europe, which was prohibited in the European Patent Convention and on the EU Biotechnology Directive (98/44/EC)[199].

The decision of the Enlarged Board of Appellation of the European Patent Office was not a complete surprise. Certainly, surprised many observers who could have expected a similar decision to that given in 1992 to the patentability of the "Harvard Oncomouse". Then, although a controversial issue was at stake, the European Patent Office agreed that a mouse produced through the injection and incorporation of an oncogene into the embryo with the purpose to provide for research into cancer was patentable[200]. The Decision was favourable because, as the European Patent Office stated,

198 Official Journal L213, 30/07/1998, pp. 13-21.

199 Decision can be obtained in http://www.epo.org/topics/news/2008/20081127.html.

200 Decision of the European Patent Office No. 0 169762 (Onco.mouse/Harvard) 1992, OJ EPO 1992, pp. 588 and ff.

> "In the case at hand three different interests are involved and require balancing: there is a basic interest of mankind to remedy widespread and dangerous diseases; on the other hand the environment has to be protected against the uncontrolled dissemination of unwanted genes and moreover, cruelty to animals has to be avoided. The latter two aspects may well justify regarding an invention as immoral and therefore unacceptable unless the advantages, i. e., the benefit to mankind, outweighs the negative aspects."[201]

It was not a complete unexpected decision, however, because under the cover of Article 7 of the Directive 98/44/CE of 6 July, 1998 concerning the juridical protection of biotechnological inventions, the European Group of Ethics for Sciences and New Technologies redacted in 2002 an Opinion, No. 16, on the ethical aspects of patenting inventions involving human stem cells[202]. In this sense, it is relevant to recall the European Group on Ethics in Sciences and New Technologies' Opinion No.16:

> "The Group is well aware that all procedures involving directly or indirectly the human embryo are controversial in the sense that they are based on presuppositions for instance concerning the beginning of human life and the question whether there should be an absolute or a relative protection of human life in its different stages. Political and legal decisions in these ethical matters may change the self understanding of what it means to be a human being in a given epoch and society.

---

201 Decision of the European Patent Office No. 0 169762 (Onco.mouse/Harvard) 1992, OJ EPO 1992, p. 591.

202 In this sense, the Wisconsin Alumni Research Foundation issued a statement on November 29, 2008, following the rejection of its stem cell patent claims before the European Patent Office: "(…) WARF emphasizes that this ruling by the EPO Enlarged Board of Appeal was based on European Union patent rules that are peculiar to Europe. There is no counterpart in United States patent law and therefore the EPO decision does not in any way affect WARF's patent rights in the United States (…)".

> The question of the dignity and the moral status of the embryo remain indeed highly controversial in a pluralistic society as the European Union. Those who are opposed to human embryo research cannot, a fortiori, consider any patenting in that field. Among those who consider research on embryos ethically acceptable, some may feel great reluctance towards patenting the resulting inventions, while others consider patenting inventions derived from embryo research as acceptable, especially given their potential medical benefits (…)
>
> There is at present a tendency to accept double morality where there is no coherence between different positions adopted by one country. For instance, one could expect that to consider research on human embryos to derive stem cells as unethical, might imply the prohibition of the import for research of embryonic stem cells derived from human embryos as well as of the use of potential therapeutically applications resulting from such research, which is not always the case."[203]

We must not lose sight of the fact that the patent application No. 96903521.1[204] described a method by which primate embryonic stem cells derived from an embryo could be maintained *in vitro* for a long period of time without losing their potential to differentiate into any cell of a body. On 13 July 2004, an EPO examining Division refused to grant a patent for the application on the grounds that it was found to be not consistent with the European Patent Convention (EPC) essentially because the disclosed method of obtaining stem cells used as the starting material a primate (including human) embryo which was destroyed in the process. In late 2005, the Technical Board of Appeal competent in the case referred the case to the EPO's supreme judiciary body, the Enlarged Board of Appeal. The Enlarged Board

---

203 EGE Opinion No. 16 of 7 May, 2002, on Ethical aspects of patenting inventions involving Human stem cells, paragraph 1.21, p. 13. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm

204 Published as EP Nr. 0770125 under the title "Primate embryonic stem cells" filed by the Wisconsin Alumni Research Foundation, *WARF*, in 1995.

of Appeal considered that under the European Patent Convention and the EU Biotechnological Directive 98/44/EC it is not possible to grant a patent for an invention which necessarily involves the use and destruction of human embryos. It must also be remembered that Article 53 – Exceptions to patentability- of the EPC as amended by the Act revision the European Patent Convention of 29 November 2000[205] says that European patents shall not be granted in respect of: "(a) inventions the commercial exploitation of which would be contrary to 'ordre public' or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;"

According to *WARF*, the opinion of the Enlarged Board of Appeal focused on the issue of the issue of the patentability of cells made using an embryo: "The Board made no determination of the patentability of claims based on any of the traditional criteria used to assess patentability: usefulness, novelty and non-obviousness. In fact, the opinion makes clear that its decision does not address the question of patentability in general of inventions relating to human stem cell cultures."[206] Nevertheless, it should be pointed out the peculiarity of the European Patent System –including moral considerations- which make it different to the United States Patent system where there is no reference to moral objections to patentability of inventions. The inevitable conclusion, therefore, was observed by the Enlarged Board of Appeal of the European Patent Office in the *WARF Case*,

> "(…) Article 53 a) EPC excludes inventions from patentability if their commercial exploitation is against ordre public or morality… In this context, it is important to point out that it is not the fact of the patenting itself that is considered to be against ordre public or morality, but it is the performing of the invention, which includes a step (the use involving its destruction of

205 See it in http://www.epo.org/patents/law/legal-texts/epc/2000/e/ar53.html

206 See, the statement issued by Wisconsin Alumni Research Foundation on November 29, 2008, following the rejection of its stem cell patent claims before the European Patent Office.

a human embryo) that has to be considered to contravene those concepts."[207]

In a word, for the EBoA of the European Patent Office there is nothing else to discuss, since this is the legal frame for patents in Europe:

"(…) the legislators (both the legislator of the Implementing Regulations of the EPC and of the Directive) wanted to exclude inventions such as the one underlying this referral from patentability and that in doing so; they have remained within the scope of Article 53 a) EPC and of the TRIPS Agreement. In view of this result, it is not necessary nor indeed appropriate to discuss further arguments and points of view put forward in these proceedings such as whether the standard of ordre public or morality should be a European one or not, whether it matters if research in certain European countries involving the destruction of human embryos to obtain cells is permitted, whether the benefits of the invention for humanity should be balanced against the prejudice to the embryo, or what the point in time is to assess ordre public or morality under Article 53 a) EPC. The legislators have decided, remaining within the ambit of Article 53 a) EPC, and there is no room for manoeuvre."[208]

3.3. Public and private interests in reaching an international regulation: the European experience on umbilical cord blood banks

It is often said that commercial interests are threatening the research in human embryos. Thus, Lemmens and Luthers, in the *Cambridge Textbook of Bioethics* included these surprising words

207 Point 29 of the EBoA Decision of 25 November 2008 in the WARF case.
208 Point 31 of the EBoA Decision of 25 November 2008 in the WARF case.

"Recent controversies have indicated how pharmaceutical sponsors and academic investigator have participated in the conscious control over, or even manipulation of, research questions and dissemination of results. Research is increasingly coordinated by specialized contract research organizations, which either conduct research in specialized research centers or involve a multitude of clinicians. The final results are often written by ghost authors, offered as easy publications to established academics and published in the most prestigious medical journals. Academic authors are accustomed to giving credibility to publications…"[209]

The conflict of public and private interests with moral bioethical consequences seems to me evident and inevitable not only at international but also at domestic level. One example is enough to support my statement. Think about the decision of United Kingdom to allow hybrid embryos. Such decision has been taken with indifference and even reluctance in Spain, where there is not a scarcity of eggs donors like in United Kingdom. Some authors in Spain can be concerned by the possibility of creating hybrid embryos with an egg from a cow or a pig and a nucleus of human origin. They do not seem so concerned, however, about the fact of how is possible that Spain, a leading country in Europe in embryo research, does not have the same problem than its Northern neighbor. The Spanish' secret is revealed by Alkorta Idiakez:

"Spain is the European Country where most IVF and egg donor cycles are performed. Only in Cataluña, 4801 oocyte donation cycles were performed at 2007. These treatments are mainly offered to customers on a for-profit basis… The secret of the Spanish clinics' good performance is that they long ago stopped employing eggs taken from IVF users… Instead, they use only eggs taken from 20 to 25 year old anonymous women who re-

209 Lemmens, Trudo and Luther, Lori, "Financial conflict of interest in medical research", in *The Cambridge Textbook of Bioethics, op. cit.,* p. 224.

> ceive up to 1200 euros for each donation. Donors are mainly students who have no regular salary and depend on their small allowances; and also immigrant women, from Eastern countries, who offer interesting 'karyotypes' for the North European clients of the centers. 'Good donors', i. e., women who respond adequately to the hormone stimulation programmed and produce large quantity of ova, are invited to undergo more than one cycle per year. Young donors are barely informed of the risks that stimulation and ova extraction entail. These risks are often minimized during the interventions."[210]

Another good example of conflicting private and public interests is also provided by Spain, this time concerning umbilical cord blood banks. On this issue, the Spanish Authorities have adopted a radically different position as seen before for egg donor cycles. If regarding eggs donation a liberal approach of "laissez faire" of markets have been preferred, regarding umbilical cord blood banks has been adopted the opposite approach with an absolute public intervention in a highly polemic way[211]. Only in the autonomous Community of Madrid, its Regional Government issued a specific Act on umbilical cord blood bank (Decree 28/2006, of March 23) allowing private umbilical blood cord banks in Madrid and authorizing these centers to charge for their service. Shortly after, the Spanish Ministry of Health and Consumption challenged the Community of Madrid Decree issuing its cautionary suspension on May 4, 2006 and enacting a new Regulation –Real Decreto 1301/2006- forbidding in

---

210 Alkorta Idiakez, Itziar, "Human Tissue and Cells Regulation in Spain: looking at Europe to solve inner contradictions?" *op. cit.,* p. 38. As the author recalls, scientific literature has reported several risks in IVF: ovarian hyperstymulation syndrome (reaction of the ovary to exogenous external hormonal stimulation, problems associated with the surgical aspiration of the follicles, and so on.

211 See García San José, Daniel, "De vuelta con las Células Madre: el Marco Europeo de la Clonación Humana y los Bancos de Cordones Umbilicales", *Revista de Derecho Comunitario Europeo,* 2006, pp. 481-516.

practice private umbilical cord blood banking in Spain. As Azkorta Idiakez has maintained, the Real Decreto 1301/2006 challenged the concept of private ownership of the sample deposited in these banks for autologous purposes[212] and, what is worse, it deepened the opposition between private and public healthcare systems in Spain up to the point that "some women are even deciding their giving birth in a public or private hospital upon the possibility of donating to public banks or keeping the cord for themselves."[213]

Another way of looking at this question is to focus on the European approach to it. The Opinion No. 19 of the *European Group on Ethics in Science and New Technologies* to the European Commission, of 16th March 2004, concerning some aspects of cord blood banking, and particularly, commercial cord blood banks[214], is quite illustrative of the European dilemma in this point, as in many other bioethical issues. Since the recent efforts by private firms to store the blood from umbilical cord of newborn children for one's own use (autologous transplantation) or for the use of close relatives (allogenic transplantation), questions have arisen as far as private or public, for-profit or non-profit cord banks should be allowed.

---

212 Private banks are only authorized under some operational principles that resemble those of public banks. In particular, Article 15.2 of the Real Decreto 1301/2006 states that in the event of insufficient availability of a tissue needed for a surgical implant, this would be fairly distributed (private banks included) in order to guarantee it will be used to maximum advantage. Consequently, the use of umbilical cord blood cells they hold in deposit cannot be reserved for allogenic use of the donor or for its relatives exclusively.

213 Alkorta Idiakez, Itziar, "Human Tissue and Cells Regulation in Spain: looking at Europe to solve inner contradictions?" *op. cit.,* p. 35.

214 By cord blood is to be considered residual placental blood collected from the cord of the new born. As it is explicated in page 3 of the Opinion: "There are concerns namely about the fact that promises about the benefit of cord blood transplantations to treat a number of diseases were made to convince future parents to store cord blood from newborn babies against payment with a view to using it to treat a disease incurred by the child or one of his family members and for which there is at present no medical evidence for the validity of the treatment."

It is not an overstatement to say as a previous question that Spanish Legislator could have avoid the problem by making a legal definition of umbilical cord as part of the newborn child and not as part of the mother[215]. Speaking purely personally, consider the umbilical cord, and its stem cells, as a part of the mother or of the newborn is of relevance because, the current regimen applicable to the conservation of umbilical cord blood is generally that of donation, assuming that is the mother who donates it to his or her baby. The regimen in Spain, for instance, to be applied to donation of human organs and tissues is ruled by the principles of solidarity and non-discrimination. Consequently, one of the main reasons for not allowing private blood cord banks is that these principles cannot be guaranteed by them but only by public banks. If the umbilical cord is legally considered part of the newborn and their parents decided to store it, that would not be a donation but a measure they take on him or her behalf and, in principle, such a measure could not be considered contrary to the general system of donation of human organs and tissues. On the contrary, it would be consistent with the Universal Declaration on Bioethics and Human Rights[216] whose article 3.2 asserted that: "The interests and welfare of the individual should have priority over the sole interest of science or society." In the same way, article 14 of the same Declaration, having proclaimed that "the promotion of health and social development for their people is a central purpose of governments that all sectors of society share" (paragraph 1) also attaches in paragraph 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…" (Emphasis added). In conclusion, one could claim for the possibility that those having economic resources for private

215 In a similar way as it has created a definition of human embryo in the Biomedical Acts passed in Spain and Andalusia in 2007, already commented and further analysed in Chapter 5.

216 Universal Declaration on the Human Genome and Human Rights, UNESCO, Gen. Conf. Res. 29 C/Res.16, adopted by the UN General Assembly, G. A. Res. 152, UN GAOR, 53rd Sess., UN Doc. A/RES/53/152 (1999).

conservation of the umbilical cord of her/her newborn if they expect that this act could help him or her to enjoy the highest attainable standard of health in future thanks to the development of Science and technical application on human beings. It seems to me, however, that this is also an ethically controversial issue no matter physicians may say at this regard to illustrate the point.

At European level, the legal framework for umbilical cord blood banks has been practically inexistent and many European countries have no specific legislation on this issue[217]. In the context of the European Union, the Directive 2004/23/EC of the European Parliament and the Council, setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells[218], does not cover blood and other blood products[219]. Nevertheless, this Directive could be applied to cord blood as hematopoietic stem cells –that is, those cells that give rise to cells present in blood- are considered tissues[220]. In consequence, my view is that article 12 of the Directive 2004/23/EC could be considered for supporting a ban on private blood cord banks[221].

---

217 Very few States, such as Italy, have ruled on the issue providing in essence the following: cord blood banking is only authorized as a public conservation structure; private cord banks are forbidden; the import or export of cord blood must be authorized by the Ministry of Health.

218 OJ L102, 7.4.2004, p. 48

219 As is also occurs with the Commission Directive 2006/17/EC of 8 February 2006, implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurements and testing of human tissues and cells (OJ L38, 9.2.2006, p. 40)

220 See Opinion No. 19 of the European Group on Ethics in Science and New Technologies to the European Commission, 16th March 2004, concerning some aspects of cord blood banking, and particularly, commercial cord blood banks, point 1.15, p. 13. Available at http://ec.europa.eu/european_group_ethics/avis/index_en.htm in the same circumstances could be applied to blood stem cells the Directive 2002/98/EC of 27 January 2003 (OJ L33, 8.2.2003, p. 30) concerning the quality and safety of collection, storage and distribution of human blood and components.

221 Article 12. Principles governing tissues and cell donation: 1. Member States shall endeavor to ensure voluntary and unpaid donations of tissues and cells.

In the context of the Council of Europe, other set of reasons would support only the existence of public, non-profit cord blood banks. See, for instance, the Convention on Human Rights and Biomedicine (Oviedo Convention)[222] which article 21 assures that "the human body and its parts shall not, as such, give rise to financial gain". Similarly, article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning transplantation of organs and tissues of human origin[223] prohibits any financial gain in the field of transplants. It is to be noticed that although blood and blood derivatives are excluded from the scope of this Protocol[224], cord blood stem cells are considered as human tissues and, consequently, covered by its dispositions.

In support of our argument, one can consider several facts. Firstly, private umbilical cord banks are paid for their services. Secondly, they could open, willingly or not, some way of market with cord stored. Imagine, for instance the striking example of a couple running financial problems at present and with an umbilical cord stored in one of these private banks. Supposing that such a cord was essential for

---

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted. Member states shall report to the Commission on these measures before 7 April 2006 and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measure it intends to take at Community level. 2. Member states shall take all necessary measures to ensure that any promotion and publicity activities in support of the donation of human tissues and cells comply with guidelines or legislative provisions lay down by the Member States. Such guidelines or legislative provisions shall include appropriate restrictions or prohibitions on advertising the need for, or availability of, human tissues and cells with a view to offering or seeking financial gain or comparable advantage. Member states shall endeavor to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis."

222 European Treaty Series No. 164 of 4th April 1997.

223 European Treaty Series No. 186 of 21st January 2002.

224 According to its Article 2.3.c)

other family's baby and they had not stored their own cord. In case these parents would pay a sum of money for the stored umbilical cord, if it was sold to them, they would be jumping over the queue of other couples waiting for the same cord stem cells to be donated in a public non-profit cord bank.

Other reasons for supporting a ban on private umbilical cord banks are also envisaged. According to article 1 (object and purpose) of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning biomedical research[225], "(States) 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 regards to any research involving interventions on human beings in the field of biomedicine." This provision is easily accomplished with by public authorities controlling the estimated five hundred research projects using umbilical cord blood. As it seems evident, such a control is more effective over a public, non-profit cord banking system.

In order to support Opinion No. 19, the *European Group on Ethics in Science and New Technologies* took into consideration many ethical principles[226], one of which is the principle of justice and solidarity as regards to fair access to healthcare services (and indirectly, the principle of protection of vulnerable groups) and it seems to be in conflict with the values of freedom and free enterprise[227]. In my opinion, how-

225 European Treaty Series No. 195, of 25th January 2005.

226 The principle of respect for human dignity and integrity, which asserts the principle of non commercialization of the human body; The principle of autonomy of the right to self-determination on the basis of full and correct information; The principles of justice and solidarity, as regards to fair access to health care services; The principle of beneficence, or the obligation to do good, in the area of health care; The principle of non-malfeasance, or the obligation not to harm, including the obligation to protect vulnerable groups and individuals, to respect privacy and confidentiality; The principle of proportionality which implies a balance between means and objectives. We will come back to this point in Chapter 4.

227 Point 1.20, p. 17 of the Opinion No. 19 of the *European Group on Ethics in Science and New Technologies*. Available at http://ec.europa.eu/european_

ever, one cannot well understand that the *European Group on Ethics in Science and New Technologies* forgot to mention other relevant values in conflict such as the right to enjoyment of the highest attainable standard of health.

The truth is that umbilical cord banking raises specific concerns in Europe. It was so recognized by the same *European Group on Ethics in Science and New Technologies*: "Cord blood banking for potential autologous uses raises additional ethical concerns. Tissue banks were up till now relying on free donation for treatment to the benefit of other persons or for research, and by the fact that it implies an act of solidarity or generosity it contributes to the social cohesion, while the commercial cord blood banks are running for profit. This reflects a more general shift to a privately funded health care system from a health system based on solidarity and motivated by public health considerations, which has characterized Europe in the last decades."[228]

Spanish authorities have unilaterally decided that blood from umbilical cord is to be given the same general treatment for donation of organs and tissues not considering the fact that it could be stored for one's use in future, let alone for someone's else use if it is implied a decision taken by the donor upon a principle different to that of solidarity or generosity. Such decision, not being unanimously followed in Europe, gives us to understand, in the words of Alkorta Idiakez, that

> "Future developments of stem cell therapies will continue to challenge the conception of actual health systems, not only because of the commercialization strategies of many of its biotech by-products, also because of the autologous -, self-healing-model they represent, which is just opposite to the gift relationship model embedded in 'old' solid, organ, tissue and cell therapies."[229]

---

group_ethics/avis/index_en.htm

228 Point 1.22, p. 18 of the Opinion No. 19 of the *European Group on Ethics in Science and New Technologies.*

229 Alkorta Idiakez, Itziar, "Human Tissue and Cells Regulation in Spain: looking at Europe to solve inner contradictions?" *op. cit.,* p. 41.

Assuming the premise that ethical aspect of human tissue banking in general (which was addressed in its Opinion No. 11 of 21 July 1998) the *European Group of Ethics in Science and New Technologies* considered what said then as also valid now for umbilical cord blood banking. Thus, the salomonic Opinion No. 19 of the *European Group on Ethics in Science and New Technologies* can be summarized in the following points:

First. The legitimacy of commercial cord blood bank for autologous use should be questioned as they sell a service, which has presently, no real use regarding therapeutic option.

Second. A strict ban on these banks would represent nevertheless an undue restriction of the freedom of enterprise and the freedom of choice of individuals/couples. Thus, a fair balance would be letting these banks operate although strict conditions.

Third. In any case, were these commercial blood banks were allowed, authorities should secure that appropriate information is given to the consumers willing to use their services. Such information must be particularly explicit as to the point that auto conservation has little value in the current state of scientific knowledge (even though there are at least five hundred research projects running on this field).

Fourth. Commercial cord blood banks have to observe the same standards as any other tissue bank. In this sense, the Directive of the European Parliament and of the Council adopted on 2nd March 2004 is to be respected.

Fifth. Finally, support for public cord blood banks for allogenic transplantations should be increased and long term functioning should be assured. In the exceptional cases where cord blood storage for autologous use were authorized in private banks, should be justified for families at risk of specific or rare diseases. In any case, public authorities should propose to these families that storage should be by public cord banks in order to ensure fair access to healthcare services to everybody needing it.

3.4. Concluding observations

The best way of summing up what said in this Chapter is by the following:

1. The jurisprudence of the European Courts of Justice directly has contributed to confirm the European pluralism as regards the beginning of human life and the concept of human being. Indirectly, it also has served to settle down the limits of biomedical research on human beings as it is reflected in the European regime of patents when dealing with biomedical patents implying human embryos. The *European Group on Ethics in Science and New Technologies* expressed the view in its Opinion No 22, on the ethical review of the hESC FP7 research projects, that "as far as human embryo stem cells research is concerned, there is no consensus on its social acceptability in the European Union, and divergent views co-exist. A debate on the best model (e.g. "minimal consensus" or "subsidiary" model) to regulate hESCs research at European Union level is therefore taking place within and across several European Union member States." *Nihil nobit sub solis*. The European Court of Human Rights, ruling as a Grand Chamber, said something very similar in the *case of VO v. France* some years before. The European Court considered that the issue of when the right to life begins is a question to be decided at national level: firstly, because the issue has not been decided within the majority of the States which had ratified the Convention, in particular in France, where this question has been the subject of public debate; and, secondly, because there is no European consensus on the scientific and legal definition of the beginning of life. It asserted that "At European level, there is no consensus on the nature and status of the embryo and/or foetus. At best, it can be regarded as common ground between States that the embryo/foetus belonged to the human race, its potential and capacity to become a person requires protection in the name of human dignity, without making it a person with the right to life for the purpose of Article 2."

2. The decision on appeal of the European Patent Office in the so called *WARF Case*, of 25 November 2008, is due to the principle of the

gradual conception of the human life protection and the prohibition in Europe of destroying human embryos to get human embryonic stem cells. In its proper measure, the EPO decision is showing that it is not allowed to patent at European level the process of creation of a human embryo specifically to the purposes of experimentation and research. Although this may be allowed in United States with private founds, in Europe such a research firstly would contravene Article 18 of the European Convention on Human Rights and Biomedicine (Oviedo Convention), and secondly, such a research implying the creation-destruction of human embryos finds out a solid opposition in part of the European Society under moral grounds, and ready to invoke Article 6 of the European Directive on patentability of biotechnological inventions and Article 53 a) of the EPC, as it is remarked by the EGE in its Opinion No. 16 of 7 May, 2002 on the Ethical Aspects of Patenting Inventions involving Human Stem Cells.

3. Recently, Opinion No. 19 of the European Group on Ethics in Science and New Technologies, of 16th March 2004, *Concerning some aspects of cord blood banking, and particularly, commercial cord blood banks* is quite illustrative of the European dilemma in this point placed at local level of some countries like Spain. The recent efforts by private firms to store the blood from umbilical cord of newborn children for one's own use (autologous transplantation) or for the use of close relatives (allogenic transplantation), have raised questions whether private or public, for-profit or non-profit cord banks should be allowed. Questions, which seem far of being out of controversy for the while.

CHAPTER 4

INFERRING PRINCIPLES OF INTERNACIONAL BIO LAW CONCERNING BIOMEDICAL RESEARCH ON HUMAN CLONING AND HUMAN EMBRYONIC STEM CELLS

4.1. Introduction

By way of introduction, we can say that speaking about informing principles on biomedical research demands to make a previous mention to the Belmont Report[230] published in United States in early 1979 by the *National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research*. Under the task of identifying the ethical principles which should regulate scientific research on human beings, the Report presented by this Commission contained the so known as the *principles of Bioethics*: respect for persons (which includes respect for autonomy), beneficence – sometimes called of non maleficence-, and justice. These principles were later complemented with additional or secondary principles introduced in 1994 by Beauchamp: utility, fidelity, veracity and confidentiality[231].

---

230 *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research,* 1979, usa.

231 Beauchamp T., and Walters L. (eds.), *Contemporary Issues in Bioethics,* Wadsworth Publishing Company, Belmont, 1994. 'Utility', in the sense that actions should achieve the most good for the greatest number of people. 'Fidelity' describes the idea that decision on controversial issues should demonstrate consistency with other similar cases. 'Veracity' means that decisions or policies should neither ignore established truths nor try to state beliefs as such. Finally, the 'Confidentiality' principle holds that an individual's right

The *principle of respect for persons* incorporates respect for autonomy, including a specific protection of persons with impaired or diminished autonomy[232]. It is obvious that voluntary informed consent of subject of research –or more accurately "informed choice"[233] -is indispensable for this principle being meaningful. In practice, nevertheless, this seems to be its Achilles' talon[234].

The *principle of respect of personal autonomy* entails the right of a person to know and not to know about her genetic data and other data of personal character which may be obtained in the course of biomedical research, including unexpected findings. This is under-

---

to privacy should be protected. See Harrison, Myron, "Applying bioethical principles to human bio monitoring", *Environmental Health,* 2008, 7 (Supple 1) S8. Available at: http://www.ehjournal.net/content/7/S1/S8

232 Luna, Florencia and Macklin, Ruth, "Research Involving Human Beings", in *A Companion to Bioethics, op. cit.,* p. 458. Respect for autonomy demands on its own that those who are capable of deliberation about their personal choices should be treated with respect for their capacity of self-determination. The requirement of the second obligation implied in this principle is that those who are dependent or vulnerable be afforded security against harm or abuse.

233 As Meslin convenes, informed consent is better understood as informed choice, "since a physician's legal duty is to inform the subject so that he or she may exercise choice-which does not always result in consent. Meslin, Eric M. and Dickens, Bernard M., "Research ethics", in *The Cambridge Textbook of Bioethics, op. cit.,* p. 188. On the right not to know (or not to consent) as regulated at European level see Torres Cazorla, M. Isabel, "El derecho a no ser informado en el Convenio sobre Biomedicina y sus Protocolos Adicionales: últimos avances de la mano del Protocolo relativo a los tests genéticos con fines médicos", in *La obra Jurídica del Consejo de Europa* (Fernández Sánchez, P.A. (Ed.), Sevilla, 2010, pp. 549-564.

234 Information must be conveyed either in writing (or orally when it does not make sense to have written documents) in terms that potential subjects can understand: in their mother tongue, obviously, free of medical jargon, at a language comprehensible… As Luna and Macklin suggest, "despite the reasonableness of these requirements, informed consent documents remain overly long, filled with technical information and far from user friendly". Luna, Florencia and Macklin, Ruth, "Research Involving Human Beings", in *A Companion to Bioethics, op. cit.,* p. 459.

stood in many juridical orders. In Spain, the insertion of this right to know and not to know in Article 4.5 of the Spanish Biomedical Research Act (2007) has received some critics in comparison with the European Council standards[235].

The *principle of beneficence* includes the ethical duty to maximize benefit and minimize harm, something rather easier to describe than to implement in practice as regards research studies where, benefits being largely unknown and difficult to anticipate, it may difficult to determine the reasonability of risks run by subjects participating in the research studies. The principle of non-maleficence finds out controversial in a blurred area, when it comes to experimentation[236] in the course of therapeutic treatment. Supposedly, medical doctors act in the best interest of their patients when they experiment with innovative procedures in their diagnosis and treatment. The *principle of non-maleficence* demands that any experimental procedure is considered in terms of the "reasonable medical alternatives" and being "based on evidence". Nevertheless, when a procedure is to be tried for the first time in a human being, it may be exceedingly difficult to determine what evidence is sufficient for not violating this principle[237]. Only in

235 Articles 26 to 28 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, of 25 January 2005, guarantee this rights in a more extensive and clear way than the Spanish Act, including any information collected on the participant's health as well as all information to which the research gives rise and which is of relevance to his current or future health or quality of life. See Nys, Herman and Fobelets, Geraldine, "The regulation of Biobanks in Spain", *Law and Human Genome Review,* 2008, Vol. 29, p. 185.

236 Experimentation may be defined, following to Macneill, as "procedures that pose a risk of harm to patients, or to human subjects of research, with a relatively lack of any benefit offered to them." Macneill, Paul Ulhas, "Regulating Experimentation in Research and Medical Practice", in *A Companion to Bioethics, op. cit.,* p. 482.

237 Macneill, Paul Ulhas, "Regulating Experimentation in Research and Medical Practice", in *A Companion to Bioethics, op. cit.,* p. 483. As this author observes, innovative surgery and experimental treatment within clinical medicine have had little scrutiny.

the United States the overall number of human subjects enrolled in research is between 10-19 million per year[238]. It is not surprising that in that country allegations of bodily injury, failure to warn and conflicts of interest had expanded to include therapeutic misconception, dignity harm or breach or contract[239].

The *principle of justice* has different contextual meaning but basically refer to distributive, compensatory and reciprocal justice. As explain Luna and Macklin, distributive justice calls for a fair distribution of benefits and burdens of research. Thus, "risks of research should not be borne by groups or populations that will not receive the benefits of the research; those who share in the benefits of research should also share in the risks; differences in distribution of burdens and benefits are justifiable only if they are based on morally relevant distinctions, such as vulnerability." Compensatory justice appeals for appropriate medical treatment and eventually monetary compensation for the subjects who are injured in the course of their participation in the research. Justice as reciprocity, maybe the most controversial, suggests that something is owed to research subjects who may still need treatment when their participation is ended in a trial that results in successful products[240].

238 Spicker, Stuart F., "The Resurgence of Biomedical Research Ethics. From Research Risks to Risks to Research", *Law and Human Genome Review,* 2002, No. 17, p. 25.

239 Goudsmit, Frank, et al., "Global Perspectives on the Life Sciences Industry", *The Journal of Biolaw and Business,* 2006, Vol. 9, No. 3, p. 6.

240 Luna, Florencia and Macklin, Ruth, "Research Involving Human Beings", in *A Companion to Bioethics, op. cit.,* p. 459.

4.2. The contribution of the Council of Europe to achieving a European minimum consensus as regards the research in human cloning and Human embryonic stem cells

4.2.1. Resolutions of the Parliamentary Assembly and the works of the Committee of Ministers of the Organisation of the Council of Europe

Since the early 80s the Organisation of the Council of Europe has been dealing with bioethical issues and their implications, essentially throughout the Recommendations periodically adopted by its Parliamentary Assembly and addressed to the Committee of Ministers and to member States of this International Organisation. The works of the Parliamentary Assembly can be illustrated with the following examples: Recommendation 934 (1982) on genetic engineering[241]; Recommendation 1046 (1986) on the use of Human embryos and foetuses for diagnostic therapeutic, scientific, industrial and commercial purposes[242]; Recommendation 1100 (1989) on the use of Human embryos and foetuses in scientific research[243]; Recommendation 1240 (1994) on the protection and patentability of material of human origin[244]; Recommendation 1425 (1999) on biotechnology and intellectual property[245]; or Resolution 1352 (2003) on Human stem cell research[246].

The Parliamentary Assembly also prepared several Opinions as regards the draft of treaties elaborated in the frame of the Organisation of the Council of Europe. In this sense, one can mention Opinion No. 198 (1996) on the draft Convention for the protection of human rights and dignity of the human being with regard to the application

241 Available in *Texts of the Council of Europe on Bioethical Matters,* Vol. II, Council of Europe, Strasbourg, 2005, p. 12.
242 In *Texts of the Council of Europe on Bioethical Matters,* Vol. II, *op. cit.*, p. 15.
243 *Ibidem,* p. 20.
244 *Ibidem,* p. 36.
245 *Ibidem,* p. 49.
246 *Ibidem,* p. 59.

of biology and medicine: Convention on human rights and biomedicine[247]; Opinion No. 202 (1997) on the draft additional Protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning of Human beings[248]; or Opinion No. 252 (2004) on the draft additional Protocol to the Convention on Human Rights and Biomedicine on biomedical research[249];

On its own, the Committee of Ministers of the Council of Europe has prepared interesting documentation on bioethical issues, some examples of which are: Recommendation No. R (90)3 concerning medical research on human beings[250], listing those principles called to rule the medical research on human beings[251]; Resolution No. 3 on human rights and scientific progress in the fields of biology, medicine and biochemistry, adopted in the European Ministerial Conference on Human Rights held in Vienna the 19-20 March of 1985[252]; Resolution No. 3 on bioethics adopted in the 17th Conference of European Ministers of Justice in Istanbul the 5-7 June of 1990[253]; of the Final Declaration resulting from the Second Summit of the Council of Europe, held in Strasbourg the 11 October 1997, which includes an explicit reference to the prohibition of the cloning of human beings inside point I "Democracy and Human Rights" of its Action Plan to strengthen democratic stability in the member States[254].

---

247 *Ibídem,* p. 39.

248 *Ibídem,* p. 42.

249 *Ibídem,* p. 61.

250 Available in *Texts of the Council of Europe on Bioethical Matters,* Vol. I, Council of Europe, Strasbourg, 2005, p. 25.

251 Understanding for such biomedical research, according to this Recommendation, "any trial and experimentation carried out on human beings, the purpose of which or one of the purposes of which is to increase medical knowledge."

252 In *Texts of the Council of Europe on Bioethical Matters,* Vol. I, *op. cit.*, p. 68.

253 *Ibídem,* p. 70.

254 "The Heads of State and Government undertake to prohibit all use of cloning techniques aimed at creating genetically identical human beings and instruct to this end the Committee of Ministers to adopt an additional protocol to the Oviedo Convention on Human Rights and Biomedicine as soon as possible." *Texts of the Council of Europe on Bioethical Matters,* Vol. I, *op. cit.*, p. 71.

In this connection, we must not lose sight of the fact that thanks to the Parliamentary Assembly and the Committee of Ministers paying continuous attention to Bioethics, some Conventions of great relevance in the field of research in Human Sciences have been signed in the frame of the Organisation of the Council of Europe. These Conventions in general have not been widely ratified by member States frustrating expectations of drafters. See, in this sense: Convention on Human Rights and Biomedicine, made in Oviedo (Spain) the 4th April 1997[255]; Additional Protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings, concluded in Paris (France) the 12th January 1998[256]; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of organs and tissues of human origin, signed in Strasbourg (France) the 24th January 2002[257]; Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, made in Strasbourg the 25th January 2005[258]; and the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Genetic Testing for Health Purposes, also adopted in Strasbourg the 27th November of 2008[259]. One may conjecture that the little success of these European Conventions among States members of the Council of Europe is due to the juridical pluralism which characterises Europe. As Octavi Quintana has asserted,

---

255 ETS (European Treaty Series) No. 164, with 26 ratifications. (status as of 12/8/2010) Note that the Council of Europe counts at present with 47 member States and that these Conventions are even open to signature by States with status of observers in the Organisation, such as Japan, United States, Canada, Australia, Holy See, and Mexico.

256 ETS (European Treaty Series) No. 168, with 20 ratifications (status as of 12/8/2010).

257 ETS (European Treaty Series) No. 186, with 8 ratifications (status as of 12/8/2010).

258 CETS (Council European Treaty Series) No. 195, with 6 ratifications (status as of 12/8/2010).

259 CETS (Council European Treaty Series) No. 203, with 4 signatures and 1 ratification (status as of 12/8/2010).

> "If the text is too vague it will easily permit a consensus but will add nothing to what already exists. If, on the other hand, the text is very specific, a consensus will not be possible. Given that the proposed convention will be legally binding all the usual obstacles faced in reaching consensus for a recommendation on bioethics –a non-binding document- are greatly magnified. Furthermore, when confronting similar ethical problems, countries react in quite different ways. Tradition plays a major role. Some countries are used to regulating everything very specifically, even foreseeing quite unusual situations. Such precision offends other countries who may resent it as a threat to their sovereignty and an imposition on their national will. Others already have legislation on these topics which may not fit exactly with the test proposed, particularly if the latter is very specific. A convention may not be regarded as a priority by some countries, and it may be feared by others for the additional structures and bureaucracy that they expect it might generate"[260]

It should be mentioned in passing that the use of Human embryos for replacing pieces of the body has strong opponents from ethical beliefs, something which it has been tried to be solved with the new technique of stem cells reprogramming, which later on a detailed analysis will be presented in Chapter 5. It seems evident that there is a pushing force worldwide, and also in Europe, trying to reduce the matter of the pros and cons of the research and experimentation on human cloning for therapeutic purposes to a narrow moral discussion between two sides. On the one hand, there are those supposedly defendants of human dignity and of inalienable rights of the human being; on the other side there are those supposedly defendant of the advance of scientific progress and at the same time supporting a liberal commercialisation of results under the regime of patents. Accepting the reductionism of any debate on research on human cloning for

260 Quintana, Octavi, "International bioethics? The role of the Council of Europe", *Journal of Medical Ethics,* 1993, Vol. 19, p. 6.

therapeutically purposes would amount to impoverish the efforts to materialize biomedical research in new therapies for the society's sake, dilapidating great expectations of patients in Europe and worldwide in a useless rhetoric speech.

The exam of the main documents produced by the Parliamentary Assembly and the Committee of Ministers of the Council of Europe and the short number of ratifications of Conventions signed in the frame of this International Organisation on this topic leads us to the same conclusion: it is still present a pushing force in Europe with the result of restraining the efforts to unify positions of European countries in order to establish a common legal framework for researching and experimenting on human embryonic stem cells[261].

4.2. The reports of European Committees of Bioethics

Another way of looking at this question is to point out that the role of the Ethics Committees working inside the Council of Europe has been also remarkable. This is the case, for instance, of the *Director Committee of Bioethics* –previously denominated as the *ad hoc Committee of Experts on Bioethics* (CAHBI) under the direction of the Committee of Ministers of the Council of Europe[262]. In this sense it can also be mentioned the *European Conference of National Committees of Ethics* (COMETH)[263] which also under the auspicious of the Council of Europe has promoted the cooperation of national ethics

261 Even though the continuous calls of the Parliamentary Assembly to the Committee of Ministers for promoting such common legal framework. See, for instance, point 9. A of Recommendation 1100 (1989) on the use of human embryos and foetuses in scientific research, which on its own, recalls similar previous Recommendations 934 (1982) and 1046 (1986); points 12 and 13 of Recommendation 1240 (1994) on the protection of material of human origin, available in *Texts of the Council of Europe on Bioethical Matters,* Vol. II, *op. cit.*, pp. 20 and 39.

262 www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/CDBI.

263 www.coe.int/T/E/Legal_Affairs/Legal_co-operation/Bioethics/COMETH.

structures from member States in order to share experience and information. The truth, however, is that it has been in the context of the European Union where the most relevant Committee of Bioethics has developed its functions: the *European Group on Ethics in Science and New Technologies*[264] whose precedents were the *Biotechnology Steering Committee*, whose aim was to coordinate policy relating to the development of biotechnology, and the *Biotechnology Interservice Committees*, intended to consider the development of regulations for commercial applications and the evaluation of risks[265].

The European Commission of the European Union decided to incorporate ethics in the decision process concerning the European policies of research and technological development in November, 1991. To this aim, the European Commission created the *Group of Advisers for the Ethics of Biotechnology*. On 16th December 1997, the European Commission decided to replace it for the current *European Group on Ethics for Sciences and New Technologies* and at the same time extended its mandate to any matter where Science and Technology would be applicable for a period of four years successively renewed.

It should be mentioned in passing that the *European Group on Ethics for Sciences and New Technologies* submitted to the European Commission its Opinion No. 15 *On Ethical aspects of human stem cell research and use*, on 14th November 2000, where it recalled the fundamental ethical principles applicable to such research as they had already been recognised in previous Opinions: the principle of respect for human dignity; the principle of individual autonomy (entailing the giving of informed consent and respect for privacy and confidentiality of personal data); the principle of justice and of beneficence (namely with regard to the improvement and protection of health); the principle of freedom of research (which is to be balanced against other fundamental principles); the principle of proportionality (including that research methods

264 http://ec.europa.eu/european_group_ethics/htm

265 Muñoz, Emilio, *Bioethics in Europe. Modern Science and Bioethics, op. cit.,* p. 17.

are necessary to the aims pursued and that no alternative more acceptable methods are available); and the precautionary principle (by which is important to take into account the potential long-term consequences of stem cells research and use for individuals and the society.[266]

Generally speaking, ethics committees' review of scientists' research is increasingly being contested by the own researchers on the grounds that it adds considerably to the burden and cost of research administration, it slows research down, and it deters some research altogether[267]. This is particularly worrying in the relatively new field of human bio monitoring[268] where -as it has been complained of- they are being simply restricted and prevented for the wrong reasons. According to these complaints,

> "Indeed, whilst in general there is a willingness to be in compliance with what can reasonably be expected from ethically correct conduct research, researchers are faced with a labyrinth of rules and guidelines, often open for interpretation, this leaves them worried about the fact that the legitimacy of the research which is ongoing might be challenged."[269]

---

266 Pages 15 and 16 of the Opinion No. 15 of the EGE of 14th November 2000, on Ethical Aspects of Human Stem Cells Research and Use.

267 MACNEILL, Paul Ulhas, "Regulating Experimentation in Research and Medical Practice", in *A Companion to Bioethics, op. cit.,* p. 477. As observes this author, researchers (at least in the United States) complain of an enormous effort expended by many people in reviewing research proposals, "most of which entails very little risk of harm, and there is little or no gain for all this effort in terms of actually avoiding harm." *Ibídem.*

268 As is described by DUMEZ, human bio monitoring is a useful tool to assess human exposures to environmental agents and their health effects, based on sampling and analysis of an individual's tissue and fluid. Biomarkers indicate steps in a series of events leading to diseases that may result from exposure to (toxic) pollutants or harmful agents. Because many significant diseases develop over longer period of time, methods for detecting early markers that can predict risks are important for disease prevention. DUMEZ, Brigit et al., "Research on ethics in two large Human Bio monitoring Projects ECNIS and New Generis: a bottom up approach", *Environmental Health,* 2008, 7 (Supple. 1). Available at: http://www.ehjournal.net/content/7/S1/S7

269 *Ibídem*.

Critical views to research ethics committees could also be approached from another angle in relation to its constitution, mostly made up of researchers and physician who can be biased in favour of research[270]. In this connection, professor Plomer has even gone as far as to criticize the institutional role of the European Group on Ethics in Science and New Technologies focusing on its appointment and composition. Looking at its controversial Opinion No. 22 on the ethical review and funding of stem cell research under the FP7 Programme, this author maintains that the European Group on Ethics in Science and New Technologies must change the appointment of its members in order to ensure this ethical committee being free from religious or other partial affiliations. Specifically, in her opinion, it should be replaced the existing permanent committee structure with a rolling *ad hoc* committee whose membership would vary in accordance with the terms of the inquiry to ensure a better match between the expertise of members and the terms of inquiry for each task[271]. It should be pointed out, as another important fact, that the European Group on Ethics for Science and New Technologies could be better employed in developing European Guidelines for Ethics suitable for new international research networks funded by European programmes. The current situation -commonly criticized by European researchers- is that of the necessity "for each participating member State to obtain ethical approval individually whereas the ideal situation would be that international ethical approval was able to apply."[272] It is evident that this would require a European Union level Ethics Committees or the European Group on Ethics in Science and New Technologies changing its role.

At the end of the day, it must be acknowledged that the role and

---

270 Luna, Florencia and Macklin, Ruth, "Research Involving Human Beings", in *A Companion to Bioethics, op. cit.,* p. 467.

271 Plomer, Aurora, "The European Group on Ethics: Law, Politics and the Limits of Moral Integration in Europe", *op. cit.,* pp. 839-859.

272 Sepai, Ovnair et al., "Human bio monitoring data interpretation and ethics; obstacles or surmountable challenges?", *Environmental Health,* 2008, 7 (Supple 1) S13, available at: http://www.ehjournal.net/content/7/S1/S13

power of the European Group on Ethics in Science and New Technologies is a secondary effect of a legislative void existing in Europe (and in the rest of the world) during years. My personal opinion on the matter is that bioethical principles in hand of ethics committees should not be viewed as rigid rules or prohibitions but providing a vocabulary and useful 'warrants' during argumentation[273]. In practice, however, bioethical principles have assumed a specific characteristic of a set of surrogate laws:

> "The statement of a principle or the enunciation of a behaviour code are frequently given the same absolute and peremptory connotation as a law, although they are proclaimed by committees and bodies that are not part of the nation's lawmaking institutions, by bodies that are often private but which have a marked vocation to use prescriptive language"[274]

For this reason, many authors as professor Mazzoni prevent us from listening to these chants of sirens. Just as this author maintains,

> "In these cases the indication of a code of conduct formulated in a law-type language may sound like a law, but actually, is no more than a recommendation which should be taken as a guideline, as a suggested protocol, emanating from a judgment of an ethical nature, which is very different from the meaning and importance of a juridical regulation, an encoded law."[275]

---

273 This is so especially considering that bioethical principles often conflict, none of them is pre-eminent; they offer guidance but no absolutes. Harrison, Myron, "Applying bioethical principles to human monitoring", *op. cit.,* available at http://www.ehjournal.net/content/7/S1/S8

274 Mazzoni, Cosimo M. (Ed.), *A Legal Framework for Bioethics, op. cit.,* p. 6.

275 *Ibidem.*

4.3. A principle-based European approach to regulate the research on human cloning and human embryonic stem cells

What should be established at the very outset is that a principle-based approach must, at a minimum, hold that some general moral norms or action guides are central in moral reasoning[276]. Then, moral dilemmas and conflicts could be resolved by balancing these moral norms[277]. Lastly, the adoption of recognized and accepted principles of individual and collective ethics is to be confirmed by their inclusion in a legal system, in the form of binding and compulsory rules calling for a specific code of conduct[278].

Even a superficial look at this issue reveals that more than at universal level[279], it is at regional level where we can identify inferring principles of international Bio law[280]. The existence in Europe of principles concerning the research on human cloning and embryonic stem cells is evident. This has been possible –as already stated- mainly thanks to the Council of Europe working on the topic during years[281].

---

276 Childress, James F., "A Principle-based Approach", in *A Companion to Bioethics, op. cit.,* p. 67.

277 *Ibidem.* p. 71. In four possible ways: a) using maxims or rules of thumb as merely illuminative; b) balancing prima facie binding principles and rules; c) ranking principles in lexical or serial order; and d) adhering to absolute principles and rules.

278 Mazzoni, Cossimo M. (Ed.), *A Legal Framework for Bioethics, op. cit.,* p. 6.

279 The Council for International Organizations of Medical Sciences considered in a document published in 2002 that three principles: respect for persons, beneficence and justice, were widely accepted as stipulating the requirements of ethics in research involving human beings. IOMS, *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* Gèneve, 2002.

280 Inferring principles in the meaning already analysed in the last epigraph of Chapter 1.

281 The European Community has also made efforts to establish the bioethical foundations of policies and regulations to help define and control the possible risk of commercial applications of new technologies, in particular, those related to genetic engineering and the environmental release of modified organisms. Muñoz, Emilio, *Bioethics in Europe. Modern Science and Bioethics, op. cit*, p. 16.

These principles deal with the process and object of biomedical research but they also concern the juridical protection by patent laws of the results of such research. Speaking purely personally, the importance of these principles is due to the fact that they could be seen as the minimum standards common to the countries integrating the big Europe. That is, those States of the European Union and those States of the Council of Europe as well. It is not an overstatement to say that these common standards accepted by different countries of Eurasia, from Iceland to Russian Federation, could help the international community of States as a whole to get inspiration for achieving the necessary consensus for a regulation of controversial bioethical issues at universal level[282]. It would be particularly relevant for achieving an agreement commitment on setting down the common standards on human cloning, on the regime of biotechnological patents and on the commercialization of genetically modified organisms. It would be claimed that these principles can work for the international community in a similar way as they have done in Europe fulfilling a legal void in this issues. In this connection, professor Mazzoni draws the attention to the fact that, one only need to think of the role and of the lawmaking activity undertaken by the European Union in recent years to realise that the production of laws to foster a unified interpretation of the bioethical issues have been scarce or even worse with

282 In my view, the lack of consensus at global level is due to different reasons but it seems particularly relevant that the discussion around this topic has been reduced to confronting two opposite and unreconciling positions. On the one hand it is the extreme position of those who defend radical freedom of scientists. Close to them, there are those who believe in the freedom of marketing eventual results attained by those scientists. On the other hand it is the extreme position of those who defend, from ethical and religious basis, the inalienable human rights, the first of which is the right to life. This right is recognised in a very wide sense because they aim to protect the life in any form and not only the life of born people. Close to them are those more moderate who are afraid of endangering human dignity and other fundamental freedom by way of a free regime for researching on human cloning and human embryonic stem cells.

> "(Texts) dominated by the need to reach a compromise between the opposite viewpoints, to the extent that the texts produced are almost ineffective as far as proclaiming general principles is concerned, and equally inefficient in making recommendations to the legislative bodies of the Member States"[283]

Noticing the situation of *variable geometry* in Europe as regards regulation of researching in human embryonic stem cells which has been analyzed in previous Chapter, the above considerations give us to understand these common European standards even of more relevance as an example for a global approach in the Organisation of United Nations or in wherever else pertinent place. The main conclusion I pretend to reach with this analysis is the existence in Europe –at large- of common standards concerning the research on human cloning and embryonic stem cells from a comprehensive approach. Namely, they are principles dealing with the process and object of biomedical research[284] and concerning the juridical protection by patent laws of the results of such research as well. Basically here the question is simple: what can and can not be patented concerning biotechnological inventions dealing with human beings? The answer however is complex as competing interests are at stake[285].

---

283 Mazzoni, Cosimo M. (Ed.), *A Legal Framework for Bioethics, op. cit.,* p. 7. Facing this disappointing legislative environment in European Union, Professor Mazzoni's conclusion is to be expected: "The diversity of the current legislative context in the Member States of the European Union does not allow us to be optimistic as far as achieving a speedy legislative harmonization is concerned."

284 What can be researched? In which way? Under which guarantees and safeguards? With which limits and for which purposes? Are only some of the main questions these principles seek to resolve.

285 In general, the extension of patent monopoly to biotechnology may conflict with a) the preservation of biological and genetic diversity existing in nature; b) the need of greater fairness in the industry/agriculture and North/South relations; c) the right of the individual-and of the future generations- that human genetic characteristics are not tempered with. See Ricolfi, Marco, "Bioethics Markets and Morals: The Case of Biotechnological Patents", in *A Legal Framework for Bioethics, op. cit.,* p. 134.

4.3.1. Principles directly applicable to the research and experimentation on human cloning and human embryonic stem cells

Let's start by considering the inferring principles of International bio law in Europe which are directly applicable to the research and experimentation on human cloning and human embryonic stem cells. The analysis of the documents emanated since the 80's from the Parliamentary Assembly and Committee of Ministers of the Council of Europe, the Conventions adopted in the frame of this Organisation and the reports provided by several European Consulting Committees on Bioethics, like the European Group on Ethics in Science and New Technologies, all together gives us to recognize the following seven inferring bioethical principles in Europe:

a) The *principle of human integrity and protection of the dignity and identity of the human being* in biomedical research which entails that any intervention on human beings, in the realisation of genetic analysis, and in the treatment of personal genetic data and of biological samples of human origin is to be used for research purposes[286].

286 See at this regards, Principle 2.1 of Recommendation No. R(90)3 of the Committee of Ministers to Member States concerning medical research on human beings; Epigraph fourth of Point 1 "Democracy and Human Rights" of the Final Declaration resulting from the Second Summit of the Council of Europe, held in Strasbourg the 11th October 1997; Paragraphs 10 and 17 of the Preamble of the Convention on Human Rights and Biomedicine (ETS 164) and its articles 1 and 2; Article 1 of the Additional Protocol to the Convention on Human Rights and Biomedicine on the prohibition of cloning human beings (ETS No. 168); Paragraphs 3 and 12 of the Preamble and Articles 1 and 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning Transplantation of organs and tissues of human origin (ETS No. 186); Paragraphs 3 and 8 of Preamble and Articles 1 and 3 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research (CETS No. 195); Points 4.i) and 10 of Recommendation 934 (1982) of the Parliamentary Assembly on genetic engineering; Point 1 of Recommendation 1240 (1994) of the Parliamentary Assembly on the protection and patentability of material of human origin;

b) The *principle of the free autonomy* of a person as a basis for specific rights granted by consent and for this being given after reception of full understandable information[287].

c) The *principle of not discrimination and confidentiality* by anyone who in the exercise of his/her functions accesses to personal data of others[288].

d) The *principle of gratuity* of donations of biological material[289].

Point 4 of the Opinion No. 252 (2004) of the Parliamentary Assembly on the draft additional protocol to the Convention on Human Rights and Biomedicine on biomedical research; Paragraph 5 of Resolution No. 3 on human rights and scientific progress in the fields of biology, medicine and biochemistry, adopted in the European Ministerial Conference on Human Rights held in Vienna on 19-20 March 1995.

287 See at this regards, Principles 3 and 6 of the Recommendation R (90) 3 of the Committee of Ministers to the member States concerning medical research on human beings; In the Convention on Human Rights and Biomedicine (ETS No. 164), Chapter II, Articles 5 to 9, 16 in its epigraphs iv and v, and Article 22: Articles 12 and 13 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186); Articles 13 and 14 (Chapter VI) and Articles 25 to 27 (Chapter VIII) of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research (CETS No. 195); Point 4.iv) of Recommendation 934 (1982) of the Parliamentary Assembly on genetic engineering; Articles 9 to 13 and 16 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes.

288 See at this regards, Articles 3 and 10 of the Convention on Human Rights and Biomedicine (ETS No.164); Article 23 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186); Article 25 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research (CETS No. 195); Point 7.d) of the Recommendation 934 (1982) of the Parliamentary Assembly on genetic engineering; Article 4 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (CETS No. 203).

289 See at this regards, Article 21 of the Convention on Human Rights and Biomedicine (ETS No. 164); Article 21 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of

e) The *principle of due diligence* by fixing quality and security standards which include the origin of human cells and tissues and the strict respect of the precautionary principle to prevent and avoid risks for life and health[290].

f) The *principle of freedom of research and production of scientific results* to be balanced with other fundamental interests at presence and always under independent supervision which takes into consideration also ethic issues[291]. Finally,

---

organs and tissues of human origin (ETS No. 186); Point 2 of the Recommendation 1240 (1994) of the Parliamentary Assembly on the protection and patentability of material of human origin.

290 See at this regards, Principles 2.2, 12 and 14 of Recommendation R (90) 3 of the Committee of Ministers to member States concerning medical research on human beings; Articles 4, 16.i and ii of the Convention on Human Rights and Biomedicine (ETS No. 164); Article 11 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning transplantation of organs and tissues of human origin (ETS No. 186); Paragraphs 9 and 10 of Preamble and Articles 5,6,17, 21 to 24, 29 and 31 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research (CETS No. 195); Point 4.v) of Recommendation 934 (1982) of the Parliamentary Assembly on genetic engineering; Article 6 of Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (CETS No. 203).

291 See at this regards, Principle 15 of Recommendation R (90) 3 of the Committee of Ministers to member States concerning medical research on human beings; Articles 15 and 16.iii of the Convention on Human Rights and Biomedicine (ETS No. 164); Articles 7 and 9 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning biomedical research (CETS No. 195); Point 3.iii of the Recommendation 934 (1982) of the Parliamentary Assembly on genetic engineering; Point 4 of the Recommendation 1046 (1986) of the Parliamentary Assembly on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes; paragraphs 1.3 and 4 of the Recommendation 1100 (1989) of the Parliamentary Assembly on the use of human embryos and foetuses in scientific research; Point 12 of the Recommendation 1425 (1999) of the Parliamentary Assembly on biotechnology and intellectual property; Point 10.v) of the Resolution 1352 (2003) of the Parliamentary Assembly on human stem cells research; Points 2 and 3 of the Opinion No. 252 (2004) of

g) the *principle of gradual conception of the human life protection* according to which, it is absolutely forbidden to create human pre-embryos and embryos exclusively for research purposes but it is allowed using whatever else techniques to obtain human embryonic stem cells with therapeutic or research purposes provided these alternative techniques do not entail the creation of a pre-embryo or an embryo to that aim[292].

4.3.2. Principles ruling the patentability of results of research on Human embryos

Ethical questions regarding embryo research would also raise questions regarding the moral permissibility of patenting the results of such research. Surprisingly, a broadly consequentiality approach which considers the positive consequences of patenting, particularly in terms of human welfare[293], has been challenged on the same moral grounds to emphasize its eventual negative aspects. As Holtug has stated,

---

the Parliamentary Assembly on the draft additional protocol to the Convention on Human Rights and Biomedicine on biomedical research; Article 7 of the Additional Protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes (CETS No. 203)

292 See at this regards, Article 18 of the Convention on Human Rights and Biomedicine (ETS No. 164); Point 14.A ii) and iii) of the Recommendation 1046 (1986) of the Parliamentary Assembly on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes; Paragraph 6 of Recommendation 1100 (1989) of the Parliamentary Assembly on the use of human embryos and foetuses in scientific research; Points 5, 10 and 11.vi) of the Resolution 1352 (2003) of the Parliamentary Assembly on Human stem cells research; Point 7 of the Opinion No. 252 (2004) on the draft additional protocol to the Convention on Human Rights and Biomedicine on biomedical research.

293 Holtug, Nils, "Creating and Patenting New Life Forms", in *A Companion to Bioethics, op. cit.,* p. 236. He defines "welfarist" as the claim that (1) the moral value of an act should be based exclusively on how good an outcome it brings about, and (2) the goodness of an outcome is a function only of the welfare it contains.

> "For welfarist, the question of patents is quite complex. On the one hand, patents stimulate important research. On the other hand, patents may tend to increase prices on therapeutic drugs and other important products. And they may negatively affect the way in which we relate to life, both our own and that of animals, by increasingly commercializing it"[294]

To the light of the previous considerations analyzed in epigraph 2 of Chapter 3, it seems to me pertinent to clarify which European informing principles are also applicable to biotechnological patents in order to clarify which patents can be considered as being respectful of public moral and of the principle of human dignity. These principles would be particularly relevant considering that the patentability of inventions in Europe is ruled by different premises than those accepted in United States[295].

It is evident that we face a European context of incertitude as regards ethical implications of patenting biotechnological inventions implying the use of human embryos[296] and those who particularly

---

294 Holtug, Nils, "Creating and Patenting New Life Forms", *op. cit.,* p. 243.

295 One of the main differences between both patent regimes is that in Europe patent of biotechnological inventions are not allowed if it is estimated that they are in conflict with the public order or morality of one of the European countries. The concept of public order (*ordre public*) implies the respect of human dignity which is in the root of human rights, as it is redacted in Article 1 of the Charter of Fundamental Rights of the European Union. The European Convention of Patents of 1973 (Munich Convention) makes a reference to the public order in Article 53 and the Directive 98/44 of 6 July 1998 also makes mentions to morality and public order in Article 6.

296 It is relevant at this point to pay attention to the fact that even inside the European Group of Ethics for Sciences and New Technologies to the European Commission was impossible to reach a *consensus* on this topic when Opinion No. 16 *on the ethical aspects of patenting inventions involving human stem cells* was redacted. It was needed to include the dissident opinion of Professor Günter Virt: "Human embryonic stem cells are excluded from patentability because we cannot get embryonic stem cell lines without destroying an embryo and that means without use of embryos. This use as material contradicts the dignity of an embryo as a human being with the derived right to life. If

suffer from that situation are scientists[297]. In the referred Opinion No. 16, the European Group on Ethics in Science and New Technologies enounced some guidelines on the issue of patenting biotechnological inventions which latter were closely followed by the European Patent Office in its decision in the so called *WARF case*. We can see, then that it may be clarifying in this sense to evoke those informing principles which, according to the European Group of Ethics in Science and New Technologies, would help to competent authorities of European Union countries in order to grant or to refuse granting authorisation for such kind of patents[298]:

1. Isolated stem cells which have not been modified do not, as product, fulfil the legal requirements, especially with regards to industrial applications, to be seen as patentable. In addition, such isolat-

---

the condition for patentability is the industrial and commercial use and if the use of human embryos for industrial and commercial purposes is not patentable, then every exception, which cannot exclude industrial and commercial purposes, is against the ethical sense of the directive. Patenting is an incentive. Patentability of human embryonic stem cells and stem cell lines would push research towards embryonic stem cells and thus undermine the priority of research using non embryonic stem cells. Despite the relatively clear regulations in the directive this incentive for research will lead to forms of "bypasses" which makes it impossible to guarantee an ethically tolerable situation in the field of patentability."

297 Just to mention some recent articles as this regard: Mclaren, A.: "A Scientist's View of the Ethics of Human Embryonic Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 23-26. Sugarman, J. and Siegel, A.: "How to Determine Whether Existing Human Embryonic Stem Cell Lines Can be Used Ethically", *Cell Stem Cell* 3, 2008, pp. 238-239. LO, B. and Parham, L.: "Ethical Issues in Stem Cell Research", *Endocrine Reviews* Vol. 30, No. 3, 2009, pp. 204-213.

298 To be as clear as possible these principles are pre-grouped in four items: Firstly, concerning the content of patents and regarding patentability of processes which imply human stem cells notwithstanding its source; Secondly, as regards different origins of human stem cells; Thirdly, as far as methods for obtaining stem cells are concerned; Finally, regarding the protection of donors, the eventual economic and social consequences and the philosophical implications of the system of patents when it is applied to stem cells.

ed cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body.

2. When unmodified stem cell lines are established, they can hardly be considered as a patentable product. Such unmodified stem cell lines do not have indeed a specific use but a very large range of potential not yet described uses. Therefore, to patent such unmodified stem cell lines would also lead to too broad patents. Thus, only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial applications, fulfil the legal requirements for patentability.

3. Application for a patent involving human stem cells should declare which is the source of the stem cells and, considering the strong ethical concerns about the use of human embryos, processes which would lead to uses of human embryos for industrial or commercial purposes are contrary to "ordre public" and morality and not patentable.

4. When the donated cells may become part of a patent application, donors should be informed of the possibility of patenting and they are entitled to refuse such use. Apart from justified compensation, donors ought not to get a reward which could infringe the principle of non-commercialisation of the human body. These ethical requirements should apply as far as possible to imported stem cells[299].

5. Concerning ethical aspects of patents involving human embryonic stem cells, political and legal decisions may change the self understanding of what it means to be a human being in a given epoch and society. Furthermore, the questions of the dignity and the moral status of the embryo remain indeed highly controversial in a pluralistic society as the European Union. Those who are opposed to human embryo research, cannot, a fortiori, consider any patenting in that field. Among those who consider research on embryos ethically acceptable, some may feel great reluctance towards patenting the resulting inventions, while others consider patenting inventions derived

299 *Ibídem,* p. 17.

from embryo research as acceptable, especially given the potential medical benefits[300].

What conclusions can be drawn from this set of informing principles surrounding the patentability of biotechnological inventions implying the use of human embryos may be translated into a golden rule: it should be advisable not to authorise patents in processes implying techniques of nuclear transfer (human cloning) which is ethically controversial for a part of the European society if entails the destruction of the human embryo. As it has already been stated, this golden rule was fully assumed by EBoA of the European Patent Office in 2008 in the so called *WARF case* and my personal view is that nothing suggests a change in future.

4.4. Concluding observations

As the principal ideas of issues dealt with in this Chapter it can be mentioned the following:

1. The different normativity as regards research on human cloning and human embryos in Europe is appalling. More than a matter of different speeds in regulating this field, it would better seem a picture of European States running away in different directions. The lack of consensus in this topic is more than evident due to the irreducible ethical-moral considerations underlying this kind of research. Facing this lack of consensus, the main merit of the Council of Europe has been to work for many years, since the early 80's, to make way for a commitment of minimum common standards throughout the formulation, explicit or implicitly, of inferring principles in Europe for the research on human cloning and human embryonic stem cells, which could be valid both, as regards the object and process of researching and concerning the patentability of inventions resulting of that research.

2. It must also be said that at European level it seems to consolidate the conviction among States that biomedical research focused on hu-

300 *Ibídem*, p. 13.

man embryonic stem cells, demands an agreement on a set of inferring principles. These principles, once consolidated, are to be respected by all States, particularly by those leading this kind of research willingly or forced by the peculiarities of the European regime of patents. Such principles are the following ones, to the light of the workings of the Council of Europe and, up to a point, also of the European Union: a) principle of human integrity and protection of the dignity and identity of the human being in biomedical research which entails that any intervention on human beings, in the realisation of genetic analysis, and in the treatment of personal genetic data and of biological samples of human origin to be used for research purposes; b) principle of the free autonomy of a person as a basis for specific rights granted by consent and for this being given after reception of full understandable information; c) principle of not discrimination and confidentiality by anyone who in the exercise of his/her functions accesses to personal data of others; d) principle of gratuity of donations of biological material; e) principle of due diligence by fixing quality and security standards which include the origin of human cells and tissues and the strict respect of the precautionary principle to prevent and avoid risks for life and health; f) principle of freedom of research and production of scientific results to be balanced with other fundamental interests at presence and always under independent supervision which takes into consideration also ethic issues; g) principle of gradual conception of the human life protection.

3. What final conclusions can be drawn from the set of informing principles surrounding the patentability of biotechnological inventions implying the use of human embryos which were asserted in the referred Opinion No. 16 of the European Group on Ethics in Science and New Technologies, may be translated into a golden rule: it should be advisable not to authorise patents in processes implying techniques of nuclear transfer (human cloning) which is ethically controversial for a part of the European society if entails the destruction of the human embryo. As it has already been stated, this golden rule was fully assumed by EBoA of the European Patent Office in 2008 in the so called *WARF case* and my personal view is that nothing suggests a change in future.

PART III

NEW CHALENGES AHEAD FOR INTERNATIONAL BIO LAW

CHAPTER 5

THE BLOOMING PROMISES OF RESEARCH ON HUMAN CELLS REPROGRAMMING: THE CASES OF SPAIN AND ANDALUSIA[301]

5.1. Introduction

Andalusia has a specific situation in Spain[302], in the group of countries leading at European level the biomedical research on embryo cells reprogramming. These new techniques of researching seem to overlap the moral and ethical controversy surrounded other research techniques implying the creation-destruction of human embryos, since it is a matter of somatic embryos and not of human embryos what it is at stake. Nevertheless as it has been proved in Chapter 3, there is no European common conception of human life and it could emerge in future some trouble with patenting results of reprogramming cells techniques. In this sense, the case *WARF* resolved last 25 November 2008 by the Enlarged Board of Appeal of the European Patent Office has raised questions to be considered

301 This Chapter is a revised version of the Article published in the *Law and Human Genome Review* in June 2010, titled "Research on Human Cells Reprogramming in Andalusia (Spain): Quo vadis Europe?"

302 I mean, considering the Autonomous Community of Andalusia has competence under Spanish Constitution and its *Statute* to develop research on human cells. See Andalusian Act 1/2007, of 16 March 2007, of researching in cellular reprogramming exclusively for therapeutic purposes in Andalusia, BOE No. 89, 13 April 2007, pp. 16299 to 16302 (it can be consulted into English in http://www.grupo.us.es/biodeinter) At national level, Biomedical research is regulated in Spanish Act 14/2007, 3 July 2007, of biomedical research in Spain, BOE No. 159, 4 July 2007 (it can be consulted into English in http://www.catedraderechoygenomahumano.es/revista.asp).

by countries like Spain using cellular reprogramming as research and therapy techniques.

5.2. Biomedical research in Andalusia (Spain): human cells reprogramming through nuclear transfer exclusively for therapeutic purposes

The Autonomous Community of Andalusia has been pioneer in Spain enacting a legal framework for researching on cloning for therapeutic purposes[303] and particularly, concerning research on cellular reprogramming exclusively for therapeutic purposes with the already cited Act 1/2007 of 16 March, 2007[304]. Such a legislative path has to be understood considering several provisions in the Andalusian *Estatuto de Autonomía,* a kind of Regional Government's Constitution[305]. It is precisely according to these provisions concerning research in the Andalusian *Estatuto de Autonomía*[306] that it was approved Act

303 See Act 7/2003 of 20 October, 2003, by which was regulated Research in Andalusia with human pre-embryos non valid for IVF. BOJA (Official Journal of Andalusia) No. 210, 21 October, 2003.

304 Since 2006 (see TAKAHASI, K. and YAMANAKA, S., "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors", *Cell,* 2006, No. 126, pp. 663-667) up to present with third generation of protein-induced pluripotent stem cells, also called piPS. See: STEIN, R., "Researchers May Have Found Equivalent to Embryonic Stem Cells", *The Washington Post,* 24 July, 2009.

305 Approved by Organic Law 2/2007 of 19 March, 2007.

306 Article 10.3.11 of the Statute de Autonomía for Andalusia asserts as one of the main basic objectives of this Autonomous Community the industrial and technologic development based on innovation, scientific research, public and private initiatives, energetic sufficiency and evaluation of quality as the basis for harmonious development of Andalusia. Art. 37.1.13 in the Statute also envisages the encouragement of the capacity to star projects, research and innovation as one of the ruling principles in the public policies in Andalusia. Articles 54 and 55 are also relevant. The former stipulates that the autonomic competences of Andalusia cover up to "a) fixing proper lines of researching

16/2007 of 3 December, 2007, concerning the Science and Knowledge in Andalusia[307]. As regards specific biomedical research in Andalusia, these legal initiatives, though recent ones, are nevertheless old fashioned. It is true that Science moves faster than Law, which is always lagging behind the facts. In the case of Andalusia, this is especially true due to the specific intention of Regional Legislators to provide legal framework mainly for the researching already started in Andalusia by Dr. Bernat Soria with three germinal cell lines brought to him from the Karolinska Institute of Sweden in 2003.

Thus, contrary to the option assumed at national level[308], the Autonomic Authorities in Andalusia preferred a concise Act ready to provide immediately legal cover to the research on human cell reprogramming exclusively for therapeutic reasons. To mention only some examples to support this assessment, Act 14/2007 of Biomedical Research in Spain regulates vital aspects of researching in this field, such as compensation for damages and its assurance to persons as a consequence of their participation in this kind of researching, in Article 18; It contemplates specific situations such as research during pregnancy and lactation or as regards protection of persons without the capacity to provide their consent, in Articles 19 to 21; Act 14/2007 also regulates the creation of a Guarantees Commission for the creation of Bio banks in Articles 63 to 71; It stipulates in extent a regime of infractions, sanctions and compensations for damages in Title IV, Articles 72 to 76. It is also remarkable from Act 14/2007 to have included a

---

and the control and evaluation of projects; b) the organisation, functioning, control, monitoring and accreditation of research centres in Andalusia (…)" The latter provision asserts that it is to the Autonomous Community of Andalusia to do research for therapeutic purposes, notwithstanding general coordination at state level by Central Government of Spain.

307 BOE No. 20, 23 January, 2008, pp. 4455-4467.

308 Act 14/2007 of 3 July, 2007, of Biomedical Research in Spain was approved only three months latter that the Andalusian Act 1/2007 and it is more perfect, juridically speaking. Not only for its length, 90 Articles in comparison with 9 in the Andalusian Act, but also for it having been conceived as a norm of reference in this field, and so, covering as much present and envisaged questions as possible.

clause in Article 89 which, in my opinion, it is unduly absent in the Andalusian Act 1/2007, considering that concern is shared at national and regional level for transfer of knowledge and thus, patenting the results of biomedical research[309].

The comparison between both norms on human cells research at national and regional level, proves the so different approach followed by Legislator in the case of Andalusia Community. It could have no major consequences normally but indeed it can since some questions not covered in the Andalusian Act which have been dealt with in the national Act, may have negative influence in biomedical research in Andalusia. As a matter of example, Article 78.1.d) of Act 14/2007 provides as competence of the *Spanish Committee on Bioethics* to: "(…) d) Represent Spain in the supranational and international forums and Organisations that deal with Bioethics." As it is evident, there is no mention to the possibility for Autonomous Communities like Andalusia to express their opinion –if only indirectly- or its right to be informed of issues internationally discussed by Government of Spain, even though these issues may include some issues of its exclusive competence[310]. Another evidence of eventual negative implications for biomedical research in Andalusia is the risk of intrusion of Central Authorities into the competences of Regional Government by way of the previous and favourable report of the *Guarantees Commission for the Donation and use of Human Cells and Tissues* for those research projects which deal, in whole or in part, with matters listed in the Act 14/2007 (practically all possible

309 "Art. 89. (…) 4. Likewise, measures shall be taken that contribute to promote adequate returns to the National Health System in relation to the investments undertaken in the ambit of biomedical research."

310 The belief of a long-life "political marriage" between Central and Regional Governments in late recent years might explain why the Andalusian Authorities would seem not worried at this point. In my opinion, in case a political change happens, Act 1/2007 should have included –on the basis of Articles 54.3 and 45.3 of Andalusian *Estatuto de Autonomía*- that "Andalusia express its will and determination to participate in collaboration with the *Spanish Committee on Bioethics* in the supranational and international forums and Organisations that deal with Bioethics."

matters concerning human stem cells). Article 37 of Act 14/2007 is clear when establish a relation of hierarchy of the *Guarantees Commission for the Donation and Use of Human Cells and Tissues* over any other commission which could be created in the Autonomous Communities of Spain[311]. Furthermore, Article 17 of this Act includes a specific mandate to competent Autonomic commission to temporary suspension of the authorised research in the cases where the requisites provided by this Act are not met and when it is necessary to protect the rights of citizens. Temporary suspension of a research project authorised in Andalusia under Act 1/2007 of researching in cellular reprogramming for therapeutic purposes could be ordered, for instance, when the undertaking of such research would entail an invasive procedure in human beings and there were no assurance of the general and special damages that could be derived for the person in whom it would had been carried out. Andalusian Act 1/2007 does not require such assurance but Article 18 of Act 14/2007 does.

Furthermore, we have already had the opportunity to express our concern that Andalusian Act 1/2007 of 16 March, 2007 of Researching on Cellular Reprogramming exclusively for therapeutic reasons would run the risk to be perceived as a potentially illegal Act in comparison to Spanish Law on Biomedical Research and considering international obligations assumed by Spain under the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (the Oviedo

311 Article 37. Creation of the Commission. 1. A Guarantees Commission for the Donation and Use of Human Cells and Tissues is created as the association composed of several persons, assigned to the Institute of Health Carlos III, of a permanent and consultative nature, aimed at providing counsel and guidance on the research and experimentation with human embryonic biological samples and to contribute to the updating and dissemination of the scientific and technical knowledge in this matter. 2. *The counterpart commissions that are created in the Autonomous Communities shall be considered as commissions to provide support and reference to the Guarantees Commission for the Donation and Use of Human Cells and Tissues and shall collaborate with it in the exercise of its functions.*" (Cursive is added).

Convention)[312]. In my opinion, such a risk derives from the ambiguity in expressing the object of the Andalusian Act 1/2007.

Article 1 of Act 1/2007 explains which is the purpose of this Act: Besides the creation of the Committee of Researching on Cellular Reprogramming, it is aimed "To regulate the research in the Autonomous Community of Andalusia through the use of techniques of cellular reprogramming in human somatic cells, in order to change them into pluripotent stem cells with exclusive therapeutic purposes." The risk pointed out emerges of reading this provision together with Article 2 "Definitions", namely, letters d)[313] and f) (providing the definition of somatic pre-embryo)[314] to the light of Par II of the Preamble of this Act[315].

In the Preamble of Act 1/2007, third paragraph beginning from the end[316], and on the other hand, definitions of cell nuclear transfer

312 Signed in Oviedo the 4th April, 1997. BOE No. 251 of 20th October, 1999. i.e. my work: *Bioderecho en Andalucía,* Centro de Estudios Andaluces, 2009.

313 According to this Article 2.d) cellular reprogramming is a technique by which a differentiated adult cell is forced to go back in its evolutionary process up to change into a pluripotent cell which can later change into different kinds of cells, tissues or even organs;

314 By which "Somatic pre-embryo" is considered a group o cells resulting from successive division of the cellular form created throughout techniques of cellular reprogramming, like the nuclear transfer or other similar techniques, from the moment such a technique is applied and up to fourteen days after.

315 "Among the techniques of cellular reprogramming it has achieved a notable development for its feasibility and reproductive capacity the so called nuclear transfer. This technique consists of the transfer of the nucleus of a somatic cell to the cytoplasm of an ovocite previously enucleated. The process generates, under some circumstances, a reprogramming of the nucleus of the somatic cell which assumes the features of a pluripotent cell and its immediate division in successive stages, similarly to a pre-embryo in stage of blastocyst. From that point on, it is possible to get stem cells with the genetic features of the somatic cells whose nucleus was inserted into the ovocite. The differentiation of these stem cells in different cellular lines could allow in future, just in case research progresses duly, to using these cells or tissues for replacing those ones irreversibly damaged by a degenerative illness by working with a cell from the same person."

316 "The Autonomic Commission on Ethic and Medical Research in Andalusia redacted an opinion favourable to the biomedical research by way of nuclear

and of somatic pre-embryo in letters e) and f), respectively, of Article 2 of this Act, should be confusing. According to this provision, cell nuclear transfer is a technique of cellular reprogramming consisting of the transfer of the nucleus of a somatic cell to the cytoplasm of an ovocite previously enucleated. Similarly, a somatic pre-embryo would be a group of cells resulting from successive division of the cellular form created throughout techniques of cellular reprogramming, like the nuclear transfer or other similar techniques, from the moment such a technique is applied and up to fourteen days after. In my opinion, letter e) read together with Preamble could be easily misunderstood as if it was considering human cloning for therapeutic purpose and, given the fact that creation of pre-embryos and embryos for research purposes is prohibited in Spain, the cell nuclear transfer technique is mixed up with reprogramming techniques in order to use the concept of somatic pre-embryo instead of human pre-embryo.

It is easy to find reasons for someone making such mistake of interpretation of Andalusian Act 1/2007: reprogrammed cells were not just functionally identical to embryonic stem cells (at least this was true in 2007) and although future was blooming considering advances in researching on induced pluripotent stem cells (iPSCs) any scientist in the world would agree in the necessity of keeping on working on embryonic stem cells –no matter they are ethically sensible- as well as with adult stem cells[317] although they inner limitations[318], with foetal

transfer with therapeutic purposes, where it was asked from the Andalusian Government for the development of the regulatory normatively for being possible these techniques of researching."

317 As one of the possible advantages of adult cells it must be considered that if replacement tissues could be developed from a person's own adult stem cells, there would not be a concern about an immune reaction, whereas there would be such a concern in case of replacement of tissues developed from embryonic stem cells. Lindsay, Ronald A., *Future Bioethics, op. cit.,* p. 233.

318 As Ronald Lindsay has written, one problem with adult stem cells is that they lack a key protein that maintains the pluripotency of embryonic stem cells and they do not appear to have the same potential to proliferate under research conditions as embryonic stem cells. Lindsay, Ronald A., *Future Bioethics, op. cit.,* p. 232.

cells[319] and with reprogrammed adult cells because it still remains unclear which of them will eventually prove most effective. Maybe all of them would be required depending on the therapy and patient targeted. Obviously, Andalusian Legislator has no intention of making anything illegal. The Act 14/2007 of 3 July, 2007 of Biomedical Research in Spain, remembers in paragraph 3 of it Preamble that:

> "The Law expressly prohibits the creation of human pre-embryos and embryos exclusively for the purpose of experimentation, in accordance with the gradualist perspective on the protection of human life set out by our Constitutional Court in rulings such as 53/1985, 212/1996 and 116/1999, but allows the use of any technique for the obtaining of embryonic stem cells for therapeutic or research purposes that does not entail the creation of a pre-embryo or of an embryo exclusively for this purpose and in the terms provided in this Laws".

Such a prohibition is included in Article 33, in Title IV "On the obtaining and use of cells and tissues of human embryonic origin and other similar cells" when it says:

> "1. The creation of human pre-embryos and embryos exclusively for experimentation purposes is prohibited. 2. The use of any technique for obtaining human stem cells for therapeutic or research purposes is allowed, always when it does not entail the creation of a pre-embryo or an embryo exclusively for this purpose, in the terms provided in this Law, including the activation of ovocite, through nuclear transfer".

Furthermore, Act 14/2007 is being consistent with the Conven-

319 As it occurs with adult cells, most foetal cells seem to be limited in their ability to be transformed into different cell types. However, foetal cells that are shed in the amniotic fluid that surrounds the developing foetus have been proved, under some circumstances, to have the capacity of pluripotency. They also have in common with embryonic stem cell the ability to proliferate in cultures. LINDSAY, Ronald A., *Future Bioethics, op. cit.,* p. 233.

tion 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 Convention), which Article 18.2 stipulates: "The creation of human embryos for research purposes is prohibited".

Besides, the risk of confusion we have pointed out might be due to the unfortunate wording of Article 33 of Act 14/2007, of Biomedical Research in Spain. This provision arises doubts as regard if it is allowed any technique of obtaining human stem cells, including the activation of ovocite by way of nuclear transfer for therapeutic and research purposes or if, on the contrary, the right meaning of such provision is to allow the obtaining of human stem cells providing no pre-embryo or embryo is created, including in such prohibition the activation of ovocite by way of nuclear transfer of somatic cells. It is a real risk in my opinion and, in this sense, only is needed to recall the Opinion No. 22 of the *European Group on Ethics in Science and New Technologies to the European Commission*, where Spain was referred as a country allowing the creation of human embryos exclusively for researching purposes, like United Kingdom and Sweden.[320] To be honest, such confusion should not take place considering the mention made in Article 4 of the Act 1/2007 to Additional protocol to the Oviedo Convention, concerning prohibition of cloning of human beings[321]:

> "According to Additional Protocol to the Convention of 4 April, 1997 for the protection of human rights and dignity of the human being with respect to applications of biology and medicine, by which it is forbidden cloning human beings, this Act forbids researching with techniques of cellular reprogramming with somatic cells to generate pre-embryos with reproductive purposes.

---

320 *Recommendations on the Ethical Review of hESC FP7 Research projects, op. cit.,* p. 32.

321 Some authors also consider the prohibition of crating human pre-embryo is not only for reproductive but also for therapeutic purposes. See: Znidarsic, V., "Biomedical research in Andalusia: a critical approach from Slovenia", Chapter VI in *Régimen Jurídico de la investigación biomédica en Andalucía,* Daniel García San José (Coord.) Ed. Laborum, 2009, p. 206.

It is also forbidden researching with these techniques for any other purpose apart from that authorised in this Act."

Risk of confusion, nevertheless is still present because if the object of the Andalusian Act 1/2007 is prescribed in Article 1 as allowing to do research on cellular reprogramming exclusively for therapeutic purposes, one may wonder which are those other purposes referred in Article 4 of Act 1/2007? As far as reaches our knowledge, human cloning may be reproductive or for therapeutic purposes, so hardly can we understand Article 4 *in fine* since it could imply that it is also forbidding techniques of cellular reprogramming with somatic cells to generate pre-embryos for research purposes, which in fact could be thought to be authorised according to Article 2 and Preamble of the same Act!

5.3. Somatic embryos versus human embryos. A revival of Dr. Jekyll and Mr Hide?

It is true that the aim of activating ovocite with nuclear transfer of adult somatic reprogrammed cells is not to create human embryos but an embryonic body, something different. HESCs naturally reside within the inner cell mass (embryo blast) of blastocyst, and in the embryo blast, differentiate into the embryo while the blastocyst's shell (trophoblast) differentiates into extra embryonic tissues. The hollow trophoblast is unable to form a living embryo and thus it is necessary for the embryonic stem cells within the embryo blast to differentiate and form the embryo. IPSCs were injected by micropipette into a trophoblast and the blastocyst was transferred to recipient females. Chimerical living mouse pups were created: mice with iPSCs derivatives incorporated all across their bodies with 10%-90% chimeras.[322] This is so understood by most of authors[323] but not

322 See http://en.wikipedia.org/wiki/Induced_pluripotent_stem_cell

323 See, for instance, López Moratalla, N., "Clonación terapéutica", *Persona y Bioética,* Vol. 8, No. 22, 2004. Available at: http://biblioteca.unisabana.edu.co/revistas/index.php/personaybioetica/article

unanimously[324]. However, if Science keeps advancing at present rate making possible to create human pre-embryos and embryos with the technique of nuclear transfer of adult reprogrammed cells which would be *totipotent* and not only *pluripotent*, then a dilemma would rise in the Autonomous Community of Andalusia –indirectly also in Spain-. We consider here the general sense of totipotency, that is, the ability of a single cell to generate an entire individual[325]. In such case, Autonomic commissions and committees with competence in this field, namely the Committee of Researching in Cellular Reprogramming could make a literal interpretation of Act 1/2007 and consider that nuclear transfer of adult somatic reprogrammed cells are authorised even in case of human pre-embryo (still called somatic pre-embryo) is created exclusively for therapeutic purpose. That is, not just to germinate specific lines of stem cells but any human body cell and thus, ready to derive in chimerical embryos, as it has already successfully happened in China in 2009 with chimerical mice. Were this to be happen, a situation of illegality would rise by comparison with Act 14/2007 of Biomedical Research in Spain (Preamble and Article 33) and it would generate the international responsibility of Spain for violation of obligations assumed under the Article 18 of the Oviedo Convention.

It is needless to say that the results of such research techniques hardly would see recognised a patent by the European Patent Office according to the ruling of its Enlarged Board of Appeal in the so called *WARF case* in 25 November 2008. Such a refusal for granting the European patent would be based on being morally unacceptable in some European societies and, specially, due to the fact that there no exists other means of obtaining similar results but being ethically less controversial[326].

---

324 See as this regards, Znidarsic, V., "Biomedical research in Andalusia: a critical approach from Slovenia", *op. cit.,* pp. 205-206.

325 See Testa, G., Borghese, L., Steinbeck, J. A. and Brüstle, O., "Breakdown of the Potentiality Principle and Its Impact on Global Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 153-156.

326 It is publicly advertised by private enterprises (for instance www.advanced-

In *Science Daily*[327], last February 12, 2008 it could be read: "University of California –Los Angeles Stem Cell Scientists has reprogrammed human skin cells into cells with the same unlimited properties as embryonic stem cells without using embryos or eggs[328]. Recent works published in 2009 would confirm this point[329].

---

cell.com) some of the technologies that support their research on cellular reprogramming: somatic cell nuclear transfer, chromatin transfer and fusion technologies. From the three techniques seems to be particularly interesting the third one. In their own words: "Our fusion technologies involve the fusion of the cytoplasm of one cell into another. In the same manner that the cytoplasm of an egg cell is capable of transforming any cell back to an embryonic state, the fusion of the cytoplasm of other cell types, including differentiated cell types (such as blood cells) is capable of reprogramming another cell type (such as a skin cell)… They also have the potential to fuse the cytoplasm of undifferentiated cells, such as embryonic stem cells, with somatic cells to transport the somatic cell DNA back to pluripotency. We believe that the fusion technology we are developing can be developed into as broad and powerful a technique as SCNT, producing histocompatible, youthful stem cells that are multy and potentially even pluripotent. If successfully developed, this technology may also provide a pathway that does not utilize human egg cells which would reduce the cost of the procedure, increase the number of patients that could benefit from its implementation and bypass many of the ethical issues associated with technologies based upon or using eggs and embryos, because it does not require the creation or destruction of embryos."

327 http://www.sciencedaily.com/releases/2008/02/080211172631.htm.

328 As it can be read in this piece of news, the UCLA study confirms the work first reported in late November 2008 of researcher Shinya Yamanaka at Kyoto University and James Thomson at the University of Wisconsin. Taken together, the three studies demonstrate that human iPS cells can be easily created by different laboratories and are likely to mark a milestone in stem cell-based regenerative medicine. *Besides these new techniques to develop stem cells could potentially replace a controversial method used to reprogram cells, somatic cell nuclear transfer (SCNT), sometimes referred to as therapeutic cloning.* (Cursive is added). To further reading on ethics opposition to using human eggs: DICKENSON, D., "Good Science and good ethics: why we should discourage payment for eggs for stem cell research", *Nature Review Genetics,* Vol. 10, No. 11, 2009, p. 743.

329 See, e.g. the work of Honguan Zhou, Shili Wu, Jin Young Joo, and others, published in *Cell Stem Cell* 4, May 8, 2009, pp. 381-384 (http://www.cell.com/cell-

We face a European context of incertitude as regards ethical implications of patenting biotechnological inventions implying the use of human embryos[330] and those more suffering it are scientists[331]. It may be clarifying in this sense to evoke one of those informing principles which, according to the *European Group of Ethics in Science and New Technologies to European Commission,* would help to competent authorities of European Union countries in order to grant or to refuse granting authorisation for such kind of patents[332]:

---

stem-cell/supplemental/S1934-5909(09)00159-3 In this study scientists have demonstrated that somatic cells (in the case, murine fibroblasts) can be fully reprogrammed into pluripotent stem cells by direct delivery of recombinant reprogramming proteins. This protein transduction method represent –in the words of its authors- a significant advance in generating iPSCs in comparison with previous iPSCs methods: "First, it effectively eliminates any risk of modifying the target cell genome by exogenous genetic sequence, which are associated with all previous iPSCs methods, and consequently offers a method for generating safer iPSCs. Second, the protein transduction method provides a substantially simpler and faster approach than the currently most advanced genetic method, which requires time-consuming sequential selection of potentially integration-free iPSCs. And finally, given the robustness and wide availability of large-scale recombinant protein production, this demonstrated completely chemically defined reprogramming regime could potentially enable broader and more economical application of reprogramming methodology."

330 It is relevant at this point to pay attention to the fact that even inside the European Group of Ethics for Sciences and New Technologies to the European Commission was impossible to reach a *consensus* on this topic when Opinion No. 16 *on the ethical aspects of patenting inventions involving human stem cells* was redacted. It was needed to include the dissident opinion of Professor Günter Virt, as already commented in epigraph 3 of chapter 4.

331 Just to mention some recent articles as this regard: Mclaren, A., "A Scientist's View of the Ethics of Human Embryonic Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 23-26. Sugarman, J. and Siegel, A., "How to Determine Whether Existing Human Embryonic Stem Cell Lines Can be Used Ethically", *Cell Stem Cell* 3, 2008, pp. 238-239. Lo, B. and Parham, L., "Ethical Issues in Stem Cell Research", *Endocrine Reviews* Vol. 30, No. 3, 2009, pp. 204-213.

332 To be as clear as possible these principles are pre-grouped in four items: Firstly, concerning the content of patents and regarding patentability of processes which imply human stem cells notwithstanding its source; Secondly, as

> "(…) 5. Concerning ethical aspects of patents involving human embryonic stem cells, political and legal decisions may change the self understanding of what it means to be a human being in a given epoch and society. Furthermore, the questions of the dignity and the moral status of the embryo remain indeed highly controversial in a pluralistic society as the European Union. Those who are opposed to human embryo research, cannot, a fortiori, consider any patenting in that field. Among those who consider research on embryos ethically acceptable, some may feel great reluctance towards patenting the resulting inventions, while others consider patenting inventions derived from embryo research as acceptable, especially given the potential medical benefits."[333]

This informing principles surrounding the patentability of biotechnological inventions implying the use of human embryos may be translated into a golden rule: it should be advisable not to authorise patents in processes implying techniques of nuclear transfer (human cloning) which is ethically controversial for a part of the European society if entails the destruction of the human embryo. This golden rule was fully assumed by the European Patent Office in 2008 in the so called *WARF case* and nothing suggests a change in future.

So the question to be finally resolved concerns to what is authorized under the Andalusian Act. As a jurist I recognise my lack of deep knowledge in this scientific field but, like the European Group on Ethics in Science and New Technologies has commented in its Opinion No 16 of 7 May 2002, on Ethical aspects of patenting inventions involving human stem cells, there is a clear difference (at least in order to future patenting) between processes for inducing adult stem cells to undergo 'retro differentiation' or 'Tran differen-

---

regards different origins of human stem cells; Thirdly, as far as methods for obtaining stem cells are concerned; Finally, regarding the protection of donors, the eventual economic and social consequences and the philosophical implications of the system of patents when it is applied to stem cells.

333 *Ibídem*, p. 13.

tiation'[334] from processes to create embryos by transfer of a somatic cell nucleus to an enucleated egg (cloning technique) for derivation of stem cells. Thus, according to the Andalusian Act, it seems to be allowed to reprogram mature somatic adult cells to pluripotent form (Induced Pluripotent Cell or IPS) and then, using somatic cell nucleus transfer (SCNT) and cell fusion to cultivate embryonic stem cells (ESC). These adult cells reprogrammed and transferred hardly can be distinguished from embryonic stem cells so controversial. This is so at present more than never. As it has been commented worldwide[335], Chinese scientists published last summer two works in the journals *Nature*[336] and *Cell Stem Cell*[337] where they asserted to have created live mice from mature skin cells that had reverted to an embryonic-like state. No doubt that such scientific success could overlap controversy surrounding embryonic stem cells, and although in Andalusia the clause "exclusively for therapeutic purposes" could seem a limit for researching of scientists, there is a fear that it also raises new ethical issues[338]. Particularly worrying is the possibility of making clones selected for specific traits with or without individuals' consent[339].

---

334 Trans differentiation is the induction of adult stem cells to differentiate into cells of a tissue type different from that normally associated with the particular stem cells. *Op. cit.*, p. 11.

335 See, i.e. *The Washington Post*, July 24, 2009.

336 The work of the team of scientists led by Qi ZHOU of *the Chinese Academy of Sciences* was published in *Nature* vol. 460, No. 7254, July 23, 2009: 37 iPS cell lines created, three of which produced 27 live offspring, the first of which they named Tiny. One of the offspring, a 7-week-old male, went on to impregnate a female and produced young of its own.

337 The work of the team of researchers led by Shaorong GAO of *the National Institute of Biological Sciences in Beijing* appeared published in *Cell Stem Cell*, Vol. 5, Issue 2, 135-138, 23 July 2009: five iPS cell lines, one of which was able to produce embryos that survived until birth. Four animals were born but only one lived to adulthood.

338 See: HENDERSON, M., "New artificial stem cells have their own ethical issues", *The Times on line,* July 24, 2009. http://wwwtimesonline.co.uk/tol/news/science/article6725335.ece.

339 In words of Robert LANZA, a stem cell researcher at Advanced Cell Technology in Worcester, Mass.: "With just a little piece of your skin, or some blood from

As a matter of proposing solutions to the problem identified in previous pages any jurist interested in Sciences of Life and, in particular, on embryo research advances, should focus attention in identifying a common normative framework (a *corpus iuris)* not as far as the conception of human life or the status of embryo, but only as regards biomedical research; namely, human cloning and cell transfer and reprogramming exclusively for therapeutic purposes on a basis of fairness[340]. That is, assuming justice as fairness in the distribution of the benefits and burdens of public policy in a pluralistic society (in this case, the European society)[341].

---

the hospital, anyone could have your child –even an ex-girlfriend or neighbour… This isn't rocket science; with a little practice, any IVF clinic in the world could probably figure out how to get it to work. In addition, researchers could genetically engineer traits into the cells before using them to create embryos for designer babies. For instance, the technology already exists to genetically increase the muscle mass in animals by knocking out a gene known as mystain, and could be used by a couple who wants a great child athlete." Quoted in: Stein, R.: "Researchers May Have Found Equivalent of Embryonic Stem Cells", *op. cit.*

340 Chevernak, F. A. and Mccullough, L. B., "How physicians and scientists can respond responsibly and effectively to religiously based opposition to human embryonic stem cell research", *Fertility and Sterility,* Vol. 90, No. 6, 2008, pp. 2056-2059. In the same sense: Sclaeger, Th. M. and other in the editorial of *Drug Discovery Today*, Vol. 12, Numbers 7/8, 2007, pp. 269-271.

341 Chevernak, F. A. and Mccullough, L. B., "How physicians and scientists can respond responsibly and effectively to religiously based opposition to human embryonic stem cell research", *op. cit.,* p. 2057. In opinion of these authors, four questions would implement the requirements of fairness: 1. What is the nature of the burden of those who object to a public policy supporting biomedical research? 2. What is the burden of mortality, morbidity, lost functional status, and care giving of the current standard of medical care that might be reduced by the research? 3. What is the opportunity for those who will be burdened to have access to the clinical benefits of the research? 4. When different groups are significantly burdened but in different ways, whose burden should be judged as more serious, far-reaching, and irreversible? Thus, in their view: "Fairness does not oblige physicians and scientists to agree with the judgment that hESC research is morally burdensome, but does oblige them to take this moral burden very seriously. Physicians and scientists should not express disrespect, or worse, contempt, for opponents

Juridical research on the existence of such a *corpus iuris* –were to exists- should pay attention to a couple of questions. Firstly, as far as regulation on what can or cannot be object of research and by which means and procedures. Secondly, as far as legal protection of results of such research by way of patents. Once we have identified this European *corpus iuris* concerning biomedical research it will be useful to establish confining parameters (like a frame) of any national legislation in Europe in this field, by fixing the margin of how much discretional can be national authorities and private entities as well. It will also help for guaranteeing rights and freedoms of citizens and for providing security for those researching on human embryos. To sum up, the result of this juridical work would provide security of the legality of human cloning research and cell reprogramming techniques with nuclear transfer in Andalusia and Spain.

5.4. Concluding observations

The nature of topic dealt with in this Chapter, would prevent us from presenting definitive concluding remarks. As a matter of provisional ideas summing up questions analysed in previous pages we can advance the following:

1. The situation of variable geometry in Europe as regards regulation at national and supranational level of researching in human embryonic stem cells is a reality with unknown consequences in future for researching on cellular reprogramming. Although researching with induced pluripotent stem cells (IPSCs) seem to overlap moral objections to nuclear transfer techniques which imply destroying early-stage embryos, the key stone of the matter is the lack of a European common conception of human life and concerning the beginning of human life.

---

or attempt to define their objection away. Physicians and scientists should, however, insist that other, clinically relevant, burdens must be identified, and the opportunity for offsetting or compensating benefits must be addressed."

2. Bearing in mind that Science advances faster than Law, which is always lagging behind the facts, it is reasonable to think that there is a risk that the distinction between somatic embryos and human embryos, in cellular reprogramming or in human cloning for therapeutic purposes respectively, will be weaker and weaker in next future. The recent works of two Chinese scientist teams published in 2009 in *Nature* and in *Cell Stem Cell* noticing to have created live mice from mature skin cells that they had reverted to an embryonic-like state, should be seen as an evidence of such a risk.

3. The situation we envisage in next future is particularly worrying in the case of research at present done in Andalusia because we have tried to prove the inconsistence of the wording of the Andalusian Act 1/2007 of researching on cellular reprogramming exclusively for therapeutic purposes, and considering the guidelines provided by the European Group of Ethics in Science and New Technologies to the European Commission and the ruling of the Enlarged Board of Appeal of the European Patent Office is the so called WARF case concerning patentability of biotechnological inventions implying the use of human embryos.

4. Jurists interested in Sciences of Life and, in particular, on embryo research advances, should focus attention in identifying a European common normative framework (a *corpus iuris)* on a basis of fairness, not as far as the conception of human life or concerning the status of embryo, but as regards biomedical research on human cloning and on cellular transfer and reprogramming exclusively for therapeutic purposes. That is, assuming justice as fairness in the distribution of the benefits and burdens of public policy in a pluralistic society like the European society.

5. According to Article 2 of Act 1/2007, cellular reprogramming techniques in Andalusia imply the nuclear transfer of somatic reprogrammed cells. That is, the same technique used in cloning the sheep Dolly and that for which a European patent was not granted in 2008 in the so called *WARF case* although what it is at stake is a somatic embryo and not properly a human embryo, as it had been normally considered up to now. Science makes possible cellular reprogramming techniques

without being necessary the method of somatic nuclear transfer. From a scientist basis, there is no problem in assuming the necessity of keeping on working on embryonic stem cells –even if it is ethically sensible- as well on adult stem cells and on reprogrammed adult cells, because it still remains unclear which of them will eventually prove most effective. Unfortunately or not, it is not only a concern of scientists alone but also of society at large. Then, Law makes appearance, even with the best of intentions, to provide complexity to the matter. In the end is a question of political choice, where Law does not reach and thus, the only thing we can do is to exclaim: *Quo vadis Europe?*

CHAPTER 6

WAITING FOR GODOT AND FOR LEGAL REGULATION OF IRREDUCIBLE BIOETHICAL PROBLEMS. THE JUDICIAL APPROACH OR THE IMPORTANCE OF BEING EARNEST

6.1. Introduction

As an starting point for this final Chapter, it can be assumed that legislations which form public policy should be on a broadly utilitarian weighing-up of harms and benefits, a kind of cost-benefit analysis, although these utilitarian arguments will not be enough to convince all[342]. There are even authors who emphasize utilitarian view as a morally binding obligation for all humankind and all societies to pursue promising therapeutic research[343].

The situation of variable geometry in Europe as regards regulation at national and international level of researching in human embryonic stem cells is a reality with unknown consequences in future for researching on cellular reprogramming. Although researching with induced pluripotent stem cells seems to overlap moral objections to

342 Warnock, Mary and Braude, Peter, "Research Using Preimplantation Human Embryos", *op. cit.,* p. 490. For those against research with human embryos discussion ends up in the fact they are human (they belong to no other species of animal) and alive. Taking the life of another human being is then wrong whatever its stage of development and aims pursued. Others, like Irving and Harris claim that to turn our backs on the research that might save so many lives "is literally to acquiesce to participation in the sacrifice of those lives." Irving, Louise and Harris, John, "Biobanking", in *The Oxford Handbook of Bioethics, op. cit.,* p. 256.

343 Irving, Louise and Harris, John, "Biobanking", in *The Oxford Handbook of Bioethics, op. cit.,* p. 255.

nuclear transfer techniques which imply destroying early-stage embryos, the key stone of the matter is the lack of a European common conception of human life and concerning the beginning of human life.

It is reasonable to think that there is a risk that the distinction between somatic and human embryos, depending on cellular reprogramming or human cloning techniques, will be weaker and weaker in future. Furthermore, even though what it is at stake is a somatic embryo and not properly a human embryo, Science makes possible cellular reprogramming techniques without being necessary the method of somatic nuclear transfer, as it is applied in Spain and in Andalusia. Consequently, situation in next future might be particularly worrying in the case of trying to patent at European level the inventions resulting from research currently developed in Spain and in Andalusia, considering the guidelines provided by the European Group of Ethics in Science and New Technologies to the European Commission and the ruling of the Enlarged Board of Appeal of the European Patent Office in the so called WARF case concerning patentability of biotechnological inventions implying the use of human embryos. That is, refusing to grant European patents protection for any controverted technique considered contrary to public morals and human dignity of any European society were to be proved the existence of less controverted techniques.

As a matter of proposing solutions to the problems identified in previous pages, it could be claimed that any jurist interested in Sciences of Life and, in particular, on embryo research advances, should focus attention in identifying a common normative framework (a *corpus iuris)* not as far as the conception of human life or the status of embryo, but rather as regards biomedical research on a basis of fairness[344]. That is, assuming justice as fairness in the distribution of the

344 Chevernak, F. A. and Mccullough, L. B., "How physicians and scientists can respond responsibly and effectively to religiously based opposition to human embryonic stem cell research", *op. cit.,* pp. 2056-2059. In the same sense: Sclaeger, Th. M. and others in the editorial of *Drug Discovery Today*, *op. cit.*, pp. 269-271.

benefits and burdens of public policy in a pluralistic society (in this case, the European society)[345].

In opinion of authors like Chevernak and Mccullough, four questions would help to implement the requirements of fairness: 1. what is the nature of the burden of those who object to a public policy supporting biomedical research? 2. What is the burden of mortality, morbidity, lost functional status, and care giving of the current standard of medical care that might be reduced by the research? 3. What is the opportunity for those who will be burdened to have access to the clinical benefits of the research? 4. When different groups are significantly burdened but in different ways, whose burden should be judged as more serious, far-reaching, and irreversible? Thus, in their view:

> "Fairness does not oblige physicians and scientists to agree with the judgment that hESC research is morally burdensome, but does oblige them to take this moral burden very seriously. Physicians and scientists should not express disrespect, or worse, contempt, for opponents or attempt to define their objection away. Physicians and scientists should, however, insist that other, clinically relevant, burdens must be identified, and the opportunity for offsetting or compensating benefits must be addressed."[346]

It will be interesting to see whether such a *corpus iuris* pay attention to a couple of questions. Firstly, as far as regulation on what can or cannot be object of research and by which means and procedures. Secondly, as far as legal protection of results of such research by way of patents. Once we have identified this European *corpus iuris* concerning biomedical research it will be useful to establish confining parameters (like a frame) of any national legislation in Europe in this field, by fixing the margin of how much discretional can be national authorities and private entities as well. It will also help for guaran-

---

345 Chevernak, F. A. and Mccullough, L. B., "How physicians and scientists can respond responsibly and effectively to religiously based opposition to human embryonic stem cell research", *op. cit.,* p. 2057.

346 *Ibidem.*

teeing rights and freedoms of citizens and for providing security for those researching on human embryos. To sum up, the result of this juridical work would provide security of the legality of human cloning research and cell reprogramming techniques with nuclear transfer in Andalusia and Spain. This has been the fundamental argument for our approach in previous Chapters, particularly in Chapter 4.

At the end of the day, however, it must be acknowledged that the chances of translating those inferring bioethical principles into European regulations are less than expected and, in any case, it will take time. My personal opinion on the matter is that alternative approaches are ready to be taken into account. My preference is to assume the doctrine of balancing different interests as it is understood and applied by the European Court of Human Rights in its case-law. The doctrine of balancing different interests implies, as Professor Pérez Luño has written, that in case of convergence among different fundamental rights, if it impossible to preserve all of them, then it will be necessary to use generic categories to establish a hierarchy among them. Thus, the proportionality of restriction according the legitimate aim pursued, the necessity of choosing that restriction less grievous for fundamental rights or that respectful of their essential content[347].

I fully agree with Professor Ruíz de la Cuesta when he applies this doctrine -originally thought for the collision of fundamental rights –to the ethical dilemma of the human embryonic cells and research. In his opinion, human life is present in a human pre-embryo and in an embryo as well. Although in that stage this human being lacks the properties to determine its individuality and can not be recognized as a person, at least, human life is in presence, as it is also in a born person who, in addition, has full recognition of its personal dignity. Consequently, in his opinion, in case of conflict between both human lifes, that in a human pre-embryo or embryo and that in a born person, for instance, with a seriously ill, there should be out of question the prevailing life of the latter over the former when, for

347 Pérez Luño, A. E., *Derechos Humanos, Estado de Derecho y Constitución,* 8th edition, Mergablum, Sevilla, 2005, p. 302.

example in the technique of the genetic pre implantation diagnostic, the sake of the latter would imply the death of the former[348].

6.2. The European Court of Human Rights' management of a fair balance between legitimate competing interests at stake

The European Convention for the Protection of Human Rights and Fundamental Freedoms (hereafter "the Convention") stems from 4th November, 1950. Signed in Rome within the framework of the Council of Europe, it enshrines essentially classical rights and freedoms. Since then, other rights have been added via different Protocols (number 1, 4, 6, 7, 12 and 13) but no mention of any right to health nor to any freedom of research (let alone to do research on living embryos) can be found in them. As a matter of fact, it has been maintained that the decision by the Convention drafters to guarantee civil and political rights instead of social, economic or even the so called rights "of the solidarity", was due to their desire, according to the Preamble of this Treaty,

> "To take the first steps for the collective enforcement of certains of the rights stated in the Universal Declaration."[349]

We must not lose sight of the hard fact that the Convention is not a mere instrument enunciating human rights but one of the few international documents making provision for the control of respect of the rights it guarantees. In effect, the Convention grants individuals direct access to the review system subjected to thorough reforms, the latest one by the Fourteenth Protocol to the Convention, which

348 Ruíz de la Cuesta, Antonio, "De las cuestiones bioéticas al bioderecho en las ciencias de la vida", pp. 29-80 in *Régimen Jurídico de la investigación biomédica en Andalucía,* Daniel García San José (Coord.) Ed. Laborum, 2009.

349 Carrillo Salcedo, Juan Antonio, *El Convenio Europeo de Derechos Humanos*, 2003, Tecnos, Madrid, p. 19.

entered into force on June 1st 2010[350]. This way, individuals can apply directly to the European Court of Human Rights (thereafter "the European Court") even against the State under their jurisdiction they are whenever they consider themselves to be the victim of a breach of any right and freedom guaranteed in the Convention.

It was Paul Mahoney, former Registrar of the European Court, who referred to judicial activism and judicial self-restraint in this judicial body as both sides of the same coin[351]. In my view, it would be more accurate to describe it graphically as a moving pendulum in action. On the one hand the *doctrine of margin of appreciation*[352] pushes the Strasbourg judges towards a judicial self-restraint in order to respect the pluralism of European countries and the particular way the accomplish their obligations under the Convention. On the other hand, there is a force pulling this pendulum towards a judicial activism in favour of individuals. This is due to the fact that the Convention is a living instrument of open textured language- containing standards rather than detailed rules- to be interpreted in the context of the present-day society. In the own European Court's words:

> "In interpreting the Convention regard must be had to its special character as a treaty for the collective enforcement of human rights and fundamental freedoms (…) Thus, the object and purpose of the Convention as an instrument for the protection of individual human beings require that its provisions be interpreted and applied so as to make its safeguards practical and effective (…) In addition, any interpretation of the rights and freedoms guaranteed has to be consistent with 'the general spirit

350 CETS No. 194, Protocol No. 14 to the Convention for the Protection of Human Rights and Fundamental Freedoms, amending the control system of the Convention.

351 Mahoney, Paul, "Judicial activism and judicial self-restraint in the European Court of Human Rights: two sides of the same coin", *Human Rights Law Journal*, 1990, Vol. 11, No. 1-2, pp. 57-88.

352 It is an original formula of the European Court which is not found at any other international court of human rights.

> of the Convention, an instrument designed to maintain and promote the ideals and values of a democratic society' (...)"[353].

Rather than a principle derived from the Convention itself, it seems clear that the margin of appreciation doctrine should be better seen as a voluntary concession made by the European Court in the exercise of judicial restraint[354]. Why the European Court would concede to the Contracting States in this terrain is, in my opinion, closely linked to the fact that under the Convention scheme of human rights protection there is a shared responsibility for enforcement of rights and freedoms by Contracting States and the European Court. In this way, sometimes the facts of the case involves a problem or situation which requires an European approach and consequently, the supervising control by the European Court is strict. In these cases the margin of appreciation is limited and irrelevant as the Court looks to standardize rather than harmonize the Contracting States' approaches on that particular point[355]. In many other cases, on the contrary, the European Court is respectful of national traditions and permits corresponding States a wide margin of appreciation to tackle the enforcement of rights and freedoms guaranteed in the Convention. In this way, the European Court would look for harmonization instead of standardization[356].

---

353 Paragraph 87 of the European Court's judgment of 26 June 1989 in the *case of Soering v. The United Kingdom*.

354 Mahoney, Paul, "The Doctrine of the Margin of Appreciation under the European Convention on Human Rights: Its Legitimacy in Theory and Application in Practice", *Human Rights Law Journal*, 1998, Vol. 19, No. 1, p. 4.

355 See, for example, the importance given to the role of the press in a democratic society, as a watch-dog informing on issues of general concern, which permit a narrow margin of appreciation to States when interfering in the freedom of expression of journalists.

356 See, for instance the wide margin of appreciation given to national authorities to regulate affairs concerning public morals, as there is not an unique European conception of what is morally acceptable, and to deal with controversial issues, such as the change in the civil status of transsexuals.

6.3. The doctrine of the margin of appreciation and the principle of proportionality as a paradigm to follow at universal level

The doctrine of the margin of appreciation is consistently applied in the supervisory work of the European Court regarding the engagements of the Contracting States[357]. However, the twin concepts of *proportionality* and *a fair balance between the interests at stake*, have been used by the European Court in many judgments as a factor to control the margin of appreciation at the disposal of Contracting States to deal with the Convention obligations and to determine if there was or was not a breach of some of the rights set out in the Convention.

The *test of proportionality* would aim to verify whether two requirements have been accomplished: firstly, the means chosen by the national authorities must be proportionate to the legitimate aim pursued; secondly, the respect of a fair balance between the different competing interests at stake should be assured. In practice, this second requirement implies two things: on the one hand, the requirement of not imposing restrictions (in those articles which permit them) other than which are strictly necessary[358]; on the other hand, there must not exist other less severe means for applicants' rights to achieve the legitimate aims pursued with the interference. Otherwise, were such less grievous means to exist and were not to be used,

357 On the origins and early judicial construction of the margin of appreciation doctrine see, *inter alia*, Macdonald, R.st.J., "The Margin of Appreciation", *The European System for the Protection of Human Rights,* Macdonald, R.st.J., Matscher, F., Petzold, H., Martinus Nijhoff Publishers, Dordrecht, 1993, pp. 83-124. Picheral, C. and Olinga, A.-D., "La théorie de la marge d'appréciation dans la jurisprudence récente de la Cour Européenne des droits de l'homme", *Revue Trimestrielle des Droits de l'Homme*, 1995, nº 24, pp. 567-604.

358 See, e.g., the European Court's judgments of 8 July 1986, *case of Lingens v. Austria*, paragraph 76, and judgment of 23 April 1992, *case of Castells v. Spain*, paragraph 46.

the European Court would have to qualify that interference as not proportionate and, consequently, as an unnecessary measure in a democratic society.

This is as a consequence of having distinguished between two levels of proportionality. In the first one, proportionality lies between the legitimate aim or the interference and the means by which this is carried out. At this stage, national margin of appreciation is relevant in the European supervision as it is proved by the mere exigency of "relevant" reason for the interference. In the second level of proportionality -specifically described as "a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights"[359]- under scrutiny is the contrast between the general interest and the harm suffered by the individual from the point of view of his fundamental rights. This time relevant reasons are not enough for national authorities to justify their interference in conventional rights and freedoms. They will need to provide "sufficient" reasons, which would imply, in practice, the lack of other less grievous means by which the legitimate aim could be reached in the present case.

The key seems to be how to predict in a consistent way what reasons provided by national authorities should be "relevant" or "sufficient". According to European Court's case law, whenever an intimate aspect of the individuals' rights is at stake (such, for example, intimacy as regards to private life), reasons must be particularly convincing and a rather narrow margin of appreciation if left to Contracting States in the matter. In this way, the European Court can easily develop at the same time, both "harmonizing" and "providing uniformity" logics according to its own judicial policy options in managing the obligations assumed by States as dissimilar as San Marino and Russia.

When applying the principle of proportionality[360], the European

359 Paragraph 89 of the European Court's judgment of 26 June 1989, *case of Soering v. United Kingdom*.

360 For a specific approach to the application of this principle in the reasoning of the European Court, see García San José, Daniel, *The Environmental Dimension of the European Convention of Human Rights, op. cit.* For a general

Court usually asks itself about the extent of the margin of appreciation that, in the concrete circumstances of the case, should be permitted to the corresponding State in order to value the necessity of a restriction in the exercise of European Convention rights. In the first instance it is the national authorities of the Contracting States in the Convention who must assure the effective protection of these rights and freedoms for any person under its jurisdiction. Consequently, thanks to their permanent and direct contact with the "living forces" in the country, national authorities should be granted a margin of appreciation, e.g., to consider that determinate measures, and not others, are the most convenient to achieve the legitimate aim pursued. In general, the greater the margin of national appreciation is, the easier it will be for national authorities to justify the inexistence of other less severe means for individuals' rights, consequently being judged proportionate by the European Court.

In any case, the margin of national appreciation is by no means limitless[361]. Its extent depends on a series of factors which can be present or absent in any particular case and, furthermore, according to the importance that such circumstances may have for the European Court in that case. The analysis of the European Court's case law proves the fact that it is possible to distinguish between these factors, some of them inducing the European Court to admit a wide margin of appreciation whereas others would seem to make it assume a narrow margin. The former would include the positive nature of the obligation on the defendant State, the fair balance to be struck between the general interest and the interest of the individual suffering the interference in his rights, the differing material and formal peculiarities of the judicial systems of the Contracting States, the legitimate aim justifying the interference and, finally, the context of the case.

---

analysis, see: García San José, Daniel: *Los derechos y libertades en la sociedad europea del siglo XXI*, University of Seville Publishing, 2001, pp. 74-91.

361 See, e.g., the European Court's judgment of 7 December 1976 in the *case of Handyside v. UK*, paragraph 48; judgment of 24 May 1988 in the *case of Müller v. Suitzerland*, paragraph 35, and judgment of 29 of October 1992, paragraph 68, in the *case of Open Door Well Women v. UK*.

Examples of the latter are the existence or not of European consensus in the matter under discussion, the teleological interpretation of the Convention, the importance for the individuals of the right affected by the interference and the model of democratic society considered under the Convention. These factors are combined randomly by the European Court in every case judged, consequently, not always producing the same result on the grounds of a judicial policy option[362].

Thus, it is to be noticed the *sui generis* approach followed by the European Court on Human Rights to manage the European pluralism which characterises the contracting States –by inventing the doctrine of margin of appreciation- and their international obligations under the European System for Protection of Human Rights –through a two-level of principle of proportionality which permits harder or softer supervision at convenience. *On* the first level, proportionality is established between the legitimate aim for the interference and the means by which this is carried out. To this aim, national margin of appreciation is relevant for the European Court as it is proved by the fact that it would merely demand a "relevant" reason for the interference. Nevertheless, on the second level of proportionality, in order to ascertain if a fair balance between the demands of the general interest of the community and the requirements of the protection of the individual's fundamental rights has been assured[363], the European Court would apply a narrow interpretation on the general interest and on the harm suffered by the individual from the point of view of his fundamental rights. Here, relevant reasons would not be enough for allowing national authorities to justify themselves when interfering in conventional rights and freedoms. They would also need to provide "sufficient" reasons, implying in practice, and the lack of other less grievous means by which the legitimate aim could be reached in the present case.

362 As far as the environmental case-law, see *infra* epigraph 7.1. For an analysis of the interaction of these factors, see: García San José, Daniel, *Los derechos y libertades fundamentales en la sociedad europea del siglo xxi*, *op. cit.*, pp. 108 to 139.

363 Paragraph 89 of the European Court's judgment of 26 June 1989, *case of Soering v. the United Kingdom*.

6.4. Concluding observations

This brief analysis of the management by the European Court of the European pluralism while, at the same time, develop the function of securing the effectiveness of human rights and freedoms in the European countries having signed the Convention, may be shocking for the readers. Mainly, because, it could be claimed that it does not match very well with the European Court's approach to the main controversial bioethical issues, such as the consideration of human embryos and foetuses. As we have seen it in Chapter 3 when commenting the judgments of this Court in the *cases Vo* and *Evans*. It is true and the only thing to say here is that for many authors, me included, the European Court should have followed a different path by interpreting the Convention under the present living conditions, and up the most, redressing the balance from an excessive margin of appreciation in this issue towards a principle of proportionality which makes real the protection of rights and freedoms under the Convention. It is not a problem the Convention was drafted and signed in 1950, when bioethical issues were not as compelling as they are nowadays. The real point is that, in my opinion, the European Court seems to have found the perfect equilibrium for managing really hard issues: pluralism is Europe is to be respected in a way that it allows to recognise when it is necessary a European paradigm of democratic society. Consequently, some times it will be prevalent the differences of any particular European democracy whereas, other times, it will be necessary to stress the uniform European view on an issue. Both approaches are not incompatible but, indeed necessary for the progress of the European society and of the European societies which integrate it.

I honestly feel that in this book we have seen irreducible bioethical controversial with consequences not only for those living in the world of ideas and feelings but, especially, for those suffering in the real world of pain and cry. Legislators, both at national and international level, cannot obviate the beliefs and moral feelings of a part of their societies when they decide to regulate human embryo research. How-

ever, it is not a valid option not to do anything, that is, not to legislate at all in order to protect these feelings. It is also a bad solution, in my opinion, to put in the same balance different interests at stake when in the final analysis, it cannot be any doubt that their weights are different. One could claim that legislator seem guided more often than not for their fear of loosing votes in next elections if they take polemic decisions. Thus, the best polemic decisions are those which never are taken. All this may well be true, but there is a chance of changing things. It would be naïve to suppose that things can change by themselves, as the time goes by, and at the same time scientific advances come into a society as deep as to make it change. The truth is, however, that Science and technical advances move faster than Law which is always lagging the facts.

My personal opinion on the matter is that if we can act now, then we must act now. The international judicial protection in Europe of many human rights, such as the right to live with dignity, the right not to suffer ill treatment as many other protected under the European Convention of Human Rights may be not as perfect solution as to prepare an Additional Protocol specifically protecting the right to health. However, the lack of political will in many States in order to regulate at European level bioethical issues, gives us to think it as the less bad solution. At least, judges in the European Court do not need to think in their re-election as most of politicians do. The *ratio decidendi* developed by the European Court of Human Rights managing the European pluralism and the effective secure of most human rights and freedoms in Europe proves, in my opinion, than a fair balance is possible at international level in establishing an universal regulation of human embryo research for the general sake of the humanity. For us and for those who will come to replace us.

FINAL OBSERVATIONS

Everything that has been said in previous pages illustrates the following conclusions:

1. New and critical approaches to Bioethics have been claimed for in order to meet the complex emerging challenges to healthcare, medicine, the body and society. These critical views have let open the door to a "New Deal" for Bioethics, which in some way resembles a return to its origins as a discipline of study – a science of survival- thanks to the idea of Global Bioethics. It is on the grounds of Global Bioethics that International Law is increasingly concerned as it could be claimed the international obligations among States to preserve environment or to implement the human right to health worldwide through a universal regulation on human embryo research.

2. As the main contribution of International Law to Global Bioethics it must be referred the issue of enforcement through obligations flowing from human rights as specified in many binding instruments for States. It should be pointed out, however, that International Law only has the potentiality to provide this enforcement if political will of States is accompanied. In a claim for a worldwide respect of the human right to health, there are self-interested reasons as well as an issue related to international peace and security. International Law approach to Bioethics is also needed in its very essence. Being true that it is universally accepted the necessity to develop a response to the new technologies advances and discoveries in Life Sciences, the universality of answers, however, can be challenged. It could be claimed that in order to achieve bioethical principles common to all

peoples and cultures represented in the Organisation of the United Nations, it would be preferred a transculturalism dialogue among nations in the world, for which it is firstly required a common language at present only successfully provided by International Law. An universal regulation of bioethics and, specifically of human embryo research settled down upon principles and values which are able to be shared and assumed by a large number of states of the international community is possible although not easy. It is possible, firstly, for instance, considering human embryo research as a common concern of the international community as a whole, eventually in two ways: affirming general principles to be accomplished individually by any state in the world, or settling down an international regime with its own mechanisms and institution for implementing this objective regime.

3. Human embryo research is a blooming business not only for pharmaceuticals but also for Governments up to the point it is talked about "bio economy". In this connection, for many authors in the Global Bioethics new stream, there is an inner contradiction in the regime of patents and the TRIPS Agreements which supports it, and the values endorsed in the Human Genome Declaration. Assuming that the human genome is to be considered as a resource apart from state sovereignty and private actors, according to the main international instruments, as a consequence, any human embryo research should be for the benefit of mankind as a whole, and not for a part of the international community in a similar way to the legal status of the seabed and ocean floor beyond the limits of national jurisdiction, as envisaged in Part XI of the International Convention on the Law of the Sea. The failure of Part XI of this Convention has led some authors to assert that common heritage of humankind should not any longer be considered as traditionally but as a new reading of principle of sovereignty which have been conditioning International Law since XVII Century up to present date. Sovereignty should be read, according to these authors, in a functional way. In this sense, Article 15.1 of the Universal Declaration on Bioethics and Human Rights envisages that "benefits resulting from any scientific research and its applica-

tions should be shared with society as a whole within the international community, in particular with developing countries." This provision of procedural nature must be read together with Article 16 (protection of future generations) and Article 17 (protection of the environment, the biosphere and biodiversity) of the same Declaration.

4. Be as it may, it can indeed be proved that the stately consensual basis is now considered not only upon an individual basis –as traditionally- but upon a collective consensual basis, facing global threats which are of *general interest* rather than of *common interest*. That is, issues which are of more relevance for the international community of States as a whole than for the States integrating such international community. The fundamental argument for our approach is that the legitimacy of this new normative order, still in progress, is on the grounds of the perception of global threats as issues of general interest of the international community of States as a whole, and on a collective consensual basis which will be prevalent over the individual consensual basis considering inferring principles of International Law such as the principle of necessity. Thus, the common sense and the "but of course" test proposed by Professor Franck would imply that when global concerns only can be addressed through multilateral approaches, then the unilateral position of one single State or a little group of States can not be an obstacle. In other words, their unilateral reluctance can not be relevant any longer in this issue.

The snag about this argument is that it must be resolved how to distinguish a real situation demanding a multilateral approach from a situation some ones pretend to consider as such. My own point of view is that the human embryo research is one of these issues demanding a multilateral regulation from International Law. Ethical controversial surrounding this issue- including Global Bioethics and their claims for a worldwide effectively protection of a human right to health- compel us to adopt such a multilateral approach. To be honest, hardly can I think other peremptory issue affecting the human being as species which would merit such multilateral approach more than this one.

5. Any international regulation of embryo research will be condi-

tioned by the dialectic discussion confronting those who defend freedom for scientific cloning research, and those others who oppose any research on embryos and the application of technical developments on human beings.

Two set of questions arise up in connection with human embryo research from the point of view of International Law: firstly, it is the possibility of establishing an international regulation on the principle of human dignity and the moral consideration of human embryos. Secondly, it is the question of fundamental human rights which could be affected by any international legal frame regulating human embryo research. In the development of these issues the guiding questions to be answered will be the following ones: What is the limit under the human dignity principle to the human embryo research? How fundamental human rights can be protected against the risks of the human embryo research? What is the fair balance to be struck facing other compelling human rights such as the right to health?

6. It is an open question whether there is an universally shared conception of human dignity to be fully respected in decisions or practices taken or carried out by those to whom this Declaration is addressed, namely but not only, States. Another question deals with a particular person's fundamental right to the enjoyment of the highest attainable standard of health which could require research on embryos. Would this fundamental right prevail over any ban on this kind of research by national authorities if they consider is in the context of their national society as being contrary to human dignity?

As it would be expected, no further agreement is found concerning the first question, probably due to the Human Rights' speech was politically used during the Cold War by both -Western democracies and by Soviet Union and other allies –to emphasize civil and political rights versus economic and social rights.The Universal Declaration on Human Cloning, adopted by the General Assembly of the United Nations on 8th March 2005, also let open the question revealing that the lack of consensus of the international community of States on this point could be considered as insurmountable. At European level, the controversy is inevitable since although fundamental rights, be-

ing the first of them the right to life, are only enjoyable by any born person, the principle of human dignity can be considered also in connection with human embryos.

7. Undoubtedly, in the human cloning research enter into consideration ethical questions as it happens in any scientific development having social consequences. Thus, it is important to strike a balance between what a society can do and what it should or should not to do. Research on human cloning risks not only the trivialization of human life and be contrary to human dignity in the sense that human beings can be considered as commodities and artefacts. This research may also endanger the respect of some fundamental rights such as the right to life, to psychical and physical integrity, to genetic privacy and to not suffer discrimination. The risk of breaching these rights, nevertheless, should not prevent us from the chances and benefits these techniques offer in finding out a cure for some severe illnesses. In this sense, it should be observed that the enjoyment of the highest attainable standard of health is also a fundamental right to be preserved.

8. The right to health care forms a part of a broaden family of positive "welfare" rights, like a right to education or the right to housing. It includes care that effectively promotes normal functioning by reducing the impact of disease and disability, thus protecting the range of opportunities that would otherwise be open to us. It is interesting to note how this right finds further ground as a special case of a right to equality of opportunity in the sense that disease and disability restrict the range of opportunities that would otherwise be open to individuals. However, any State assumes an own understanding of an "adequate standard of living for health and well-being." If one starts from that principle, then it is evident that there one of the main obstacles to the universal implementation of a human right to health is the scope of the Governments' obligations.

9. Considering States' obligations of result regarding the right to health seems totally convincing. It could be claimed as a consequence that patients around the world -when they apply scientists to engage in genetic research invoking their right to health- must find out a positive attitude from the International Legislator –the own States-

regulating those scientists' research. Since 2001 the United Nations has been considering the elaboration of an international convention on the cloning of human beings. At present, clearly there is consensus in the international community to ban reproductive cloning but not as far therapeutic cloning as it proves the Resolution 59/280, which endorses the United Nations Declaration on Human Cloning, adopted on 8 March 2005. The no definition of human dignity lets open the door to States forbidding both, reproductive and therapeutically cloning, whereas other States would only ban on reproductive cloning. Such situation is in contradiction with steps made by the international community of States as a whole towards a universally protected human right to health. The particular position of many States also would entail their international responsibility for breaching obligations they freely assumed under the Convention on Economic, Social and Cultural Rights.

10. The jurisprudence of the European Courts of Justice directly has contributed to confirm the European pluralism as regards the beginning of human life and the concept of human being. Indirectly, it also has served to settle down the limits of biomedical research on human beings as it is reflected in the European regime of patents when dealing with biomedical patents implying human embryos. The *European Group on Ethics in Science and New Technologies* expressed the view in its Opinion No 22, on the ethical review of the hESC FP7 research projects, that "as far as human embryo stem cells research is concerned, there is no consensus on its social acceptability in the European Union, and divergent views co-exist. A debate on the best model (e.g. "minimal consensus" or "subsidiary" model) to regulate hESCs research at European Union level is therefore taking place within and across several European Union member States." *Nihil nobit sub solis*. The European Court of Human Rights, ruling as a Grand Chamber, said something very similar in the *case of VO v. France* some years before. The European Court considered that the issue of when the right to life begins is a question to be decided at national level: firstly, because the issue has not been decided within the majority of the States which had ratified the Convention, in par-

ticular in France, where this question has been the subject of public debate; and, secondly, because there is no European consensus on the scientific and legal definition of the beginning of life. It asserted that "At European level, there is no consensus on the nature and status of the embryo and/or foetus. At best, it can be regarded as common ground between States that the embryo/foetus belonged to the human race, its potential and capacity to become a person requires protection in the name of human dignity, without making it a person with the right to life for the purpose of Article 2."

11. The decision on appeal of the European Patent Office in the so called *WARF Case*, of 25 November 2008, is due to the principle of the gradual conception of the human life protection and the prohibition in Europe of destroying human embryos to get human embryonic stem cells. In its proper measure, the EPO decision is showing that it is not allowed to patent at European level the process of creation of a human embryo specifically to the purposes of experimentation and research. Although this may be allowed in United States with private founds, in Europe such a research firstly would contravene Article 18 of the European Convention on Human Rights and Biomedicine (Oviedo Convention), and secondly, such a research implying the creation-destruction of human embryos finds out a solid opposition in part of the European Society under moral grounds, and ready to invoke Article 6 of the European Directive on patentability of biotechnological inventions and Article 53 a) of the EPC, as it is remarked by the EGE in its Opinion No. 16 of 7 May, 2002 on the Ethical Aspects of Patenting Inventions involving Human Stem Cells.

12. Recently, Opinion No. 19 of the European Group on Ethics in Science and New Technologies, of 16th March 2004, *Concerning some aspects of cord blood banking, and particularly, commercial cord blood banks* is quite illustrative of the European dilemma in this point placed at local level of some countries like Spain. The recent efforts by private firms to store the blood from umbilical cord of newborn children for one's own use (autologous transplantation) or for the use of close relatives (allogenic transplantation), have raised questions whether private or public, for-profit or non-profit cord banks should

be allowed. Questions, which seem far of being out of controversy for the while.

13. The different normativity as regards research on human cloning and human embryos in Europe is appalling. More than a matter of different speeds in regulating this field, it would better seem a picture of European States running away in different directions. The lack of consensus in this topic is more than evident due to the irreducible ethical-moral considerations underlying this kind of research. Facing this lack of consensus, the main merit of the Council of Europe has been to work for many years, since the early 80's, to make way for a commitment of minimum common standards throughout the formulation, explicit or implicitly, of inferring principles in Europe for the research on human cloning and human embryonic stem cells, which could be valid both, as regards the object and process of researching and concerning the patentability of inventions resulting of that research.

14. At European level it seems to consolidate the conviction among States that biomedical research focused on human embryonic stem cells, demands an agreement on a set of inferring principles. These principles, once consolidated, are to be respected by all States, particularly by those leading this kind of research willingly or forced by the peculiarities of the European regime of patents. Such principles are the following ones, to the light of the workings of the Council of Europe and, up to a point, also of the European Union: a) principle of human integrity and protection of the dignity and identity of the human being in biomedical research which entails that any intervention on human beings, in the realisation of genetic analysis, and in the treatment of personal genetic data and of biological samples of human origin to be used for research purposes; b) principle of the free autonomy of a person as a basis for specific rights granted by consent and for this being given after reception of full understandable information; c) principle of not discrimination and confidentiality by anyone who in the exercise of his/her functions accesses to personal data of others; d) principle of gratuity of donations of biological material; e) principle of due diligence by fixing quality and security standards

which include the origin of human cells and tissues and the strict respect of the precautionary principle to prevent and avoid risks for life and health; f) principle of freedom of research and production of scientific results to be balanced with other fundamental interests at presence and always under independent supervision which takes into consideration also ethic issues; g) principle of gradual conception of the human life protection.

15. What can be drawn from the set of informing principles surrounding the patentability of biotechnological inventions implying the use of human embryos which were asserted in the referred Opinion No. 16 of the European Group on Ethics in Science and New Technologies, may be translated into a golden rule: it should be advisable not to authorise patents in processes implying techniques of nuclear transfer (human cloning) which is ethically controversial for a part of the European society if entails the destruction of the human embryo. As it has already been stated, this golden rule was fully assumed by EBOA of the European Patent Office in 2008 in the so called *WARF case* and my personal view is that nothing suggests a change in future.

16. The situation of variable geometry in Europe as regards regulation at national and supranational level of researching in human embryonic stem cells is a reality with unknown consequences in future for researching on cellular reprogramming. Although researching with induced pluripotent stem cells (IPSCs) seem to overlap moral objections to nuclear transfer techniques which imply destroying early-stage embryos, the key stone of the matter is the lack of a European common conception of human life and concerning the beginning of human life.

Bearing in mind that Science advances faster than Law, which is always lagging behind the facts, it is reasonable to think that there is a risk that the distinction between somatic embryos and human embryos, in cellular reprogramming or in human cloning for therapeutic purposes respectively, will be weaker and weaker in next future. The recent works of two Chinese scientist teams published in 2009 in *Nature* and in *Cell Stem Cell* noticing to have created live mice from

mature skin cells that they had reverted to an embryonic-like state, should be seen as an evidence of such a risk.

17. The situation we envisage in next future is particularly worrying in the case of research at present done in Andalusia because we have tried to prove the inconsistence of the wording of the Andalusian Act 1/2007 of researching on cellular reprogramming exclusively for therapeutic purposes, and considering the guidelines provided by the European Group of Ethics in Science and New Technologies to the European Commission and the ruling of the Enlarged Board of Appeal of the European Patent Office is the so called WARF case concerning patentability of biotechnological inventions implying the use of human embryos.

18. Jurists interested in Sciences of Life and, in particular, on embryo research advances, should focus attention in identifying a European common normative framework (a *corpus iuris)* on a basis of fairness, not as far as the conception of human life or concerning the status of embryo, but as regards biomedical research on human cloning and on cellular transfer and reprogramming exclusively for therapeutic purposes. That is, assuming justice as fairness in the distribution of the benefits and burdens of public policy in a pluralistic society like the European society.

19. According to Article 2 of Act 1/2007, cellular reprogramming techniques in Andalusia imply the nuclear transfer of somatic reprogrammed cells. That is, the same technique used in cloning the sheep Dolly and that for which a European patent was not granted in 2008 in the so called *WARF case* although what it is at stake is a somatic embryo and not properly a human embryo, as it had been normally considered up to now. Science makes possible cellular reprogramming techniques without being necessary the method of somatic nuclear transfer. From a scientist basis, there is no problem in assuming the necessity of keeping on working on embryonic stem cells –even if it is ethically sensible- as well on adult stem cells and on reprogrammed adult cells, because it still remains unclear which of them will eventually prove most effective. Unfortunately or not, it is not only a concern of scientists alone but also of society at large. Then, Law makes

appearance, even with the best of intentions, to provide complexity to the matter. In the end is a question of political choice, where Law does not reach and thus, the only thing we can do is to exclaim: *Quo vadis Europe?*

20. A brief analysis of the management by the European Court of the European pluralism while, at the same time, develop the function of securing the effectiveness of human rights and freedoms in the European countries having signed the Convention, may be shocking for the readers. Mainly, because, it could be claimed that it does not match very well with the European Court's approach to the main controversial bioethical issues, such as the consideration of human embryos and foetuses. As we have seen it in Chapter 3 when commenting the judgments of this Court in the *cases Vo* and *Evans*. It is true and the only thing to say here is that for many authors, me included, the European Court should have followed a different path by interpreting the Convention under the present living conditions, and up the most, redressing the balance from an excessive margin of appreciation in this issue towards a principle of proportionality which makes real the protection of rights and freedoms under the Convention. It is not a problem the Convention was drafted and signed in 1950, when bioethical issues were not as compelling as they are nowadays. The real point is that, in my opinion, the European Court seems to have found the perfect equilibrium for managing really hard issues: pluralism is Europe is to be respected in a way that it allows to recognise when it is necessary a European paradigm of democratic society. Consequently, some times it will be prevalent the differences of any particular European democracy whereas, other times, it will be necessary to stress the uniform European view on an issue. Both approaches are not incompatible but, indeed necessary for the progress of the European society and of the European societies which integrate it.

21. I honestly feel that in this book we have seen irreducible bioethical controversial with consequences not only for those living in the world of ideas and feelings but, especially, for those suffering in the real world of pain and cry. Legislators, both at national and interna-

tional level, cannot obviate the beliefs and moral feelings of a part of their societies when they decide to regulate human embryo research. However, it is not a valid option not to do anything, that is, not to legislate, in order to protect these feelings. It is also a bad solution, in my opinion, to put in the same balance different interests at stake when in the final analysis, it cannot be any doubt that their weights are different. One could claim that legislator seem guided more often than not for their fear of loosing votes in next elections if they take polemic decisions. Thus, the best polemic decisions are those which never are taken. All this may well be true, but there is a chance of changing things. It would be naïve to suppose that things can change by themselves, as the time goes by, and at the same time scientific advances come into a society as deep as to make it change. The truth is, however, that Science and technical advances move faster than Law which is always lagging the facts.

22. My personal opinion on the matter is that if we can act now, then we must act now. The international judicial protection in Europe of many human rights, such as the right to live with dignity, the right not to suffer ill treatment as many other protected under the European Convention of Human Rights may be not as perfect solution as to prepare an Additional Protocol specifically protecting the right to health. However, the lack of political will in many States in order to regulate at European level bioethical issues, gives us to think it as the less bad solution. At least, judges in the European Court do not need to think in their re-election as most of politicians do. The *ratio decidendi* developed by the European Court of Human Rights managing the European pluralism and the effective secure of most human rights and freedoms in Europe proves, in my opinion, than a fair balance is possible at international level in establishing an universal regulation of human embryo research for the general sake of the humanity. For us and for those who will come to replace us.

REFERENCES (INCLUDING BIBLIOGRAPHY)

Abellán-García Sánchez, Fernando, "El estatuto jurídico del embrión en España: de la ley de reproducción de 1988 a la clonación terapéutica de nuestros días", *Law and Human Genome Review,* 28/2008, pp. 59-83.

Alkorta Idiakez, Itziar, "Human Tissue and Cells Regulation in Spain: looking at Europe to solve inner contradictions?" *Law and the Human Genome Review,* 29/2008, pp. 25-43.

Álvarez-Díaz, Jorge Alberto, "El estatuto biológico del embrión humano. Nuevas repercusiones bioéticas y biojurídicas", *Law and Human Genome Review,* 28/2008, pp. 195-211.

Annas, George, "Bioterrorism, Public Health and Civil Liberties", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 788-792.

—, "The man on the moon, immortality and other millennial myths: the prospects and perils of human genetic engineering", *Emory Law Journal,* 2000, Vol. 49, No. 3, pp. 753-782.

—, "Genism, racism and the prospect of genetic genocide", 2001. At http://www.thehumanfuture.org/commentaries/annas_genism.html

Aparisi Miralles, Ángela, "Bioética, bioderecho y biojurídica", *Anuario de Filosofía del Derecho,* 2007, No. 24, pp. 63-84.

Bandrés Moya, Fernando, et al., "Implicaciones éticas y legales de la investigación biomédica", *Medicina Clínica (Barc)* 2008, 131 (Supl. 5) pp. 87-90.

Barbera, Joseph, et al., "Large-Scale Quarantine Following Biological Terrorism in the United States: Scientific Examination, Logistic and Legal Limits and Possible Consequences", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 775-783.

Barrero Ortega, Abraham, "Reflexiones constitucionales a propósito de la investigación biomédica en Andalucía", pp. 81-94 in *Régimen Jurídico de la investigación biomédica en Andalucía.* Daniel García San José (Coord.) Ed. Laborum, 2009.

Barrero Ortega, Abraham and Gómez Abeja, Laura, "The Spanish Legal Abortion Reform in 2010", Chapter III in *Biolaw and Bioethics in Spain. Facing New Challenges of Science,* Daniel García San José (Dir.). Laborum, 2010, Murcia, pp. 71-90.

Baylis, F. and Robert, J. S., "The inevitability of genetic enhancement technologies", *Bioethics,* 2004, Vol. 18, pp. 1-26.

Bauer, Susanne, "Societal and ethical issues in human bio monitoring –a view from science studies", *Environmental Health,* 2008, 7 (Supple 1) S 10. In www.ehjournal.net/content/7/S1/S10.

Beauchamp, T., and Walters, L., (eds.), *Contemporary Issues in Bioethics,* Woodworth Publishing Company, Belmont, 1994.

Bell, D., "Human Cloning and International Human Rights Law", *The Sydney Law Review,* 1999,Vol. 21, No. 2, pp. 202-230.

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979, usa.

Benatar, Salomon R., "Global health ethics and cross-cultural considerations in bioethics", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 341-349.

Benítez Ortúzar, Ignacio, "Investigación con células madre. Legislación y problemas éticos", *Estudios jurídico-penales sobre genética y biomedicina,* 2006, Dykinson, Madrid, pp. 69-92.

—, "El ordenamiento jurídico ante la clonación de células humanas", *Cuadernos de política criminal,* 2003, No. 79, pp. 47-70.

Bernat, Erwin, "Marketing of Human Organs?", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 161-172.

Beyleveld, Deryck and Brownsword, Roger, *Human dignity in bioethics and biolaw,* Oxford University Press, 2001.

Bonilla Sánchez, Juan José, "The objection of conscience of the sanitary personnel before the advances of Life Sciences in Spain", Chapter iv in *Biolaw and Bioethics in Spain. Facing New Challenges of Science,* Daniel García San José (Dir.). Laborum, 2010, Murcia, pp. 91-132.

Bonnicksen, Andrea, "Therapeutic Cloning: Politics and Policy", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 441-470.

Bovenberg, Jasper A., "Mining the Common Heritage of our dna: Lessons learned from Grotius and Pardo", *Duke Law & Technology Review,* 2006, 8. Available at: http://www.law.duke.edu/journals/dltr/articles/pdf/2006DLTR0008.pdf

Brock, Dan W., "Cloning Human Beings: an Assessment of the Ethical Issues. Pro and Con", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp.593-602.

Buchanan, Allen E., "The right to a Decent Minimum of Health Care", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 59-63.

Bustreo, Flavia and Doebbler, Curtis F. J., "Making health an imperative of foreign policy: the value of a human rights approach", *Health and Human Rights,* Vol. 12, No. 1, 2010, pp. 47-59.

Byk, Christian, "Pre implantation genetic diagnosis: an ambiguous legal status for an ambiguous medical and social practice", *Law and Human Genome Review,* 28/2008, pp. 85-113.

—, "International Law and Life Sciences: a new battlefield of power or a new temple for justice and peace?", *Journal International de Bioéthique,* 2004, 5 (2-3), pp. 151-162.

—, "Juridical Policies and Bioethics: the three pillars of biomedical legislative wisdom", *Eubios Journal of Asian and International Bioethics,* 1995, Vol. 5, pp. 57-59.

Carrillo Salcedo, Juan Antonio, *El Convenio Europeo de Derechos Humanos*, 2003, Tecnos, Madrid

Casonato, Carlo, Penasa, Simone, Rao, Radhika, "The Law on somatic cell nuclear transfer: comparing the Andalusian Statute", pp. 209-242, in *Régimen Jurídico de la investigación biomédica en Andalucía.* Daniel García San José (Coord.) Ed. Laborum, 2009.

Chadwick, Ruth, "Genetic testing and screening", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 160-165.

—, "Gene Therapy", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 207-215.

Chervenak, F. A. and Mccullough, L. B.: "How physicians and scientists can respond responsibly and effectively to religiously based opposition to human embryonic stem cell research?", *Fertility and Sterility,* Vol. 90, No. 6, 2008, pp. 2056-2059.

Childress, James F., "A Principle-based Approach", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 67-76.

Cohen-Kohler, Jillian Clare and Illingworth, Patricia, "Access to medicines and the role of corporate social responsibility: the need to craft a global pharmaceutical system with integrity", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 359-368.

Commission on Human Rights, *Resolution 2004/26 of 16 April 2004 (E/CN.4/2004/L. 11/Add.3) Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria.*

Commission on Human Security, *Human Security Now* Report, New York, 2003.

Committee on Economic, Social and Cultural Rights, *General Comment No 14, The Right to the Highest Attainable Standard of Health*, un Doc. E/C.12/2000/4.

Council of Europe, *Texts of the Council of Europe on Bioethical Matters,* Vol. i, Council of Europe, Strasbourg, 2005.

—, *Texts of the Council of Europe on Bioethical Matters,* Vol. II, Council of Europe, Strasbourg, 2005.

Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* Gèneve, 2002.

Daniels, Norman, "Is there a Right to Health Care and, if so, What Does It Encompass?", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 362-372.

Deane, Christine, "The public perception of biotechnology", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 409-414.

De Miguel Beriain, Íñigo, "El embrión humano después de Dolly: Nuevas pautas para nuevos tiempos", *Law and Human Genome Review,* 29/2008, pp. 45-65.

Delbruck, J., "Structural Changes in the International System and Its

Legal Order: International Law in the Era of Globalization", *SZIER (Swiss Journal of International Law),* 2001, Vol. 11, No. 1, pp. 1-36.

Dickenson, D.: "Good Science and good ethics: why we should discourage payment for eggs for stem cell research", *Nature Review Genetics,* Vol. 10, No. 11, 2009, p. 743. Http://www.nature.com/nrg/journal/v10/n11/full/nrg2684.html

Druml, Ch.: "Stem Cell Research: Towards Greater Unity in Europe?", *Cell,* No. 139, 2009, pp. 649-651.

Dumez, Birgit, et al., "Research on ethics in two large Human Bio monitoring Projects ecnis and Ner Generis: a bottom up approach", *Environmental Health,* 2008, 7 (Supple 1) S7 www.ehjournal.net/content/7/S1/S7

Dupuy, Pierre-Marie, *Droit International Public,* 8. Ed., Dalloz, Paris.

Durán Costell, Elvira, "Ethical issues in the face of advances in biotechnology", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 415-420.

Ekdahl, K., "Ethical Issues from the ecdc Perspective. Bioethical Implications of Globalisation Processes", *Workshop on Globalisation and New Epidemics: Ethics, Security and Policy Making,* European Commission, Brussels, 2006.

Eser, Albin and Koch, Hans-Georg, "La investigación con células embrionarias humanas. Fundamentos y límites penales", *Law and Human Genome Review,* 20/2004, pp. 37-63.

European Commission, *Preparing Europe for a New Renaissance. A Strategic View of the European Research Area,* Brussels, 2009.

European Group on Ethics in Science and New Technologies to the European Commission, Opinion No. 25 of 17 November 2009 on Ethics of synthetic biology. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm.

—, Opinion No 22 (Recommendations on the ethical review of hesc fp7 research projects) of 20 June 2007. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm.

—, Opinion No. 19of 16th March 2004, concerning some aspects of cord blood banking, and particularly, commercial cord blood banks, Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm.

—, Opinion No. 16 of 7 May, 2002, on Ethical aspects of patenting inventions involving Human stem cells. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm.

—, Opinion No. 15 14th November 2000, on Ethical Aspects of Human Stem Cells Research and Use. Available at: http://ec.europa.eu/european_group_ethics/avis/index_en.htm.

Faden, Ruth R. and Beauchamp, Tom L., "The concept of Informed Consent", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 145-149.

Flores Trejo, Fernando, "El Bioderecho: Nueva Rama Científica Interdisciplinaria", *Revista de la Facultad de Derecho de México,* No. Extra 1, 2005, pp. 133-145.

Fox, Michael W., *Bringing Life to Ethics,* State University of New York Press, 2001, New York.

Friedmann, Theodore, "Principles for Human Gene Therapy Studies", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 522-525.

Franck, Thomas, "Non-Treaty Law-Making: When, Where and How?", in Wolfrum, Rudiger and Röben, V. (eds.), *Developments of International Law in Treaty Making,* Springer, Berlin, 2005, pp. 417-436.

Gao, Sh. And others: "iPS Cells can Support Full-Term Development of Tetraploid Blastocyst-Complemented Embryos", *Cell Stem Cell*, Vol. 5, Issue 2, pp. 135-138.

García San José, D.: *Bioderecho en Andalucía*, Centro de Estudios Andaluces, Seville, 2009.

—, *El Derecho Internacional Poscontemporáneo,* Tirant Lo Blanch, Valencia, 2008.

—, *The Environmental Dimension of the European Convention of Human Rights,* Council of Europe Publishing, Strasbourg, 2005.

—, "De vuelta con las Células Madre: el Marco Europeo de la Clonación Humana y los Bancos de Cordones Umbilicales", *Revista de Derecho Comunitario Europeo,* 2006, pp. 481-516.

—, "Claves para un régimen internacional de la clonación humana", *Anuario Mexicano de Derecho Internacional,* 2005, pp. 153-171.

—, "Marco normativo andaluz y nuevas demandas sociales sobre investigación en transferencia y reprogramación celular: un estudio comparado con la normativa nacional y europea", pp. 129-158, in *Régimen Jurídico de la investigación biomédica en Andalucía*. Daniel García San José (Coord.) Ed. Laborum, 2009.

—, "Aproximación al marco legal común europeo relativo a la investigación

sobre clonación humana", *Anuario Mexicano de Derecho Internacional,* x, 2010, pp. 567-590.

—, "Research on Human Cells Reprogramming in Andalusia (Spain): Quo vadis Europe?", *Law and the Human Genome Review,* 2010, (in press)

—, "European pluralism and the regulation of research on Human Embryonic Stem cells in Spain: too far from nowhere", Chapter I in *Biolaw and Bioethics in Spain. Facing New Challenges of Science,* Daniel García San José (Dir.). Laborum, 2010, Murcia, pp. 15-40.

—, *Los derechos y libertades en la sociedad europea del siglo XXI*, University of Seville Publishing, Seville, 2001.

Gbadegesin, Segun, "Culture and Bioethics", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 24-35.

Gillon, Raanan, "Human Reproductive Cloning: A look at the Arguments Against it and a Rejection of Most of Them", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 621-632.

Gillon, Raanan and Sokol, Daniel K., "Confidentiality", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 513-519.

Godoy Vázquez, M. Olaya, "El marco jurídico de la investigación y experimentación con células madre embrionarias", *Anuario de la Facultad de Derecho de Ourense,* 2004, pp. 221-232.

Gómez-Salvago Sánchez, Cecilia, "El marco europeo de la protección jurídica de los resultados de la investigación biomédica sobre clonación terapéutica: implicaciones para los investigadores andaluces", pp. 95-128, in *Régimen Jurídico de la investigación biomédica en Andalucía.* Daniel García San José (Coord.) Ed. Laborum, 2009.

—, "Human Stem-cells research. Their relation with Patent Law", Chapter II in *Biolaw and Bioethics in Spain. Facing New Challenges of Science,* Daniel García San José (Dir.), Laborum, 2010, Murcia, pp. 41-70.

González Morán, Luís, "Bioética y Bioderecho: un diálogo necesario", *Institut Borja de Bioética,* No. 50, 2007, pp. 10-16.

Goodwin, Michele, "Bio law: A few thoughts about altruism and markets", *Kansas Journal of Law & Public Policy,* Vol. XVIII: 2, 2009, pp. 208-214.

Gostin, Lawrence O., "Law and Ethics in a Public Health Emergency", in

Contemporary issues in bioethics, Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 784-787.

Goudsmit, Frank, et al., "Global perspectives on the Life Sciences Industry", *The Journal of Biolaw & Business,* Vol. 9, No. 3, 2006, pp. 3-7.

Green, Ronald M., "Embryo and foetal research", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 231-240.

Greenlee, S., "Dolly's Legacy to Human Cloning: International Legal Responses and Potential Human Rights Violations", *Wisconsin International Law Journal,* 2000, Vol. 18, No. 2, pp. 537-554.

Greenwood, Heather L. and Daar, Abdallah S., "Regenerative medicine", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 153-159.

Gregory, Eric, "Religion and Bioethics", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 46-55.

Grisolía, Santiago, "Biotechnology in the Third Millennium", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 31-64.

Gugerell, Christian, "Legal protection of genetic discoveries and patentability of manipulated living organisms. The European Patent Office in Munich", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 385-400.

Hansmann, Henry, "Markets for Human Organs", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 145-160.

Harrison, Myron, "Applying bioethical principles to human bio monitoring", *Environmental Health,* 2008, 7 (Supple. 1) S8, available at: http://www.ehjournal.net/content/7/S1/S8

Hartman, Barry M. and Naidu, B. David, "Nanotechnology: An Update on Business Opportunities and Regulatory Challenges", *The Journal of Biolaw & Business,* Vol. 10, No. 1, 2007, pp. 25-28.

Hawkins, A., "Protecting Human Dignity and Individuality: The Need for Uniformity in International Cloning Legislation", *The Transnational Lawyer,* 2001, Vol. 14, pp. 243-294.

Henderson, Donald A., "The Looming Threat of Bioterrorism", in *Con-*

temporary issues in bioethics, Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 761-767.

Henderson, M.: "New artificial stem cells have their own ethical issues", *The Times on line,* July 24, 2009. http://wwwtimesonline.co.uk/tol/news/science/article6725335.ece

—, "Stem cells without genetic defects heralded as breakthrough", *The Times on line,* June 1, 2009. http://wwwtimesonline.co.uk/tol/news/science/article6402006.ece

Hinricher, J., "The Law-Making of the International Telecommunications Union (ITU). Providing a New Source of International Law?", *Heidelberg Journal of International Law,* 2004, No. 64, pp. 489-501.

Hirtzlin, Isabelle, et al., "An empirical survey on bio banking of human genetic material and data in six eu countries", *European Journal of Human Genetics,* 2003, 11, pp. 475-488.

Holm, Soren, "Policy-Making in Pluralistic Societies", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 153-174.

Holtug, Nils, "Creating and Patenting New Life Forms", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 235-244.

Human Genome Organization (hugo) Ethics Committee, Statement on Gene Therapy Research, April 2001. Available at http://www.hugo-international.org/img/gene_2001.pdf.

International Law Association, International Law on Biotechnology Committee (Prof. Thomas Cottier, Chair),

—, Conference Report Toronto (2006).

—, Conference Report Rio (2008).

—, Draft Committee Report The Hague (2010).
Available at: http://www.ila-hq.org/en/committees/index.cfm/cid/1016.

Irving, Louise and Harris, John, "Bio banking", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 240-257.

Joseph, Sarah, "Pharmaceutical Corporations and Access to Drugs: the ´Fourth Wave of Corporate Human Rights Scrutiny", *Human Rights Quarterly* 25 (2003) 425-452.

Jusdado Ruíz-Capillas, Miguel Ángel, "La controversia en la investi-

gación con células madre embrionarias", *Anuario de Derechos Humanos,* Vol. 9, 2008, pp. 403-430.

Kahn, Jeffrey and Mastroianni, Anna, "The implications of Public Health for Bioethics", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 671-695.

Kinderlerer, Julian and Milius, Djims, "The Patent System, Biotechnology and Synthetic Biology", Annex I to European Group of Ethics for Science and New Technologies Opinion No. 25 *Ethics of Synthetic Biology*, 2010.

Klabbers, Jean, *An Introduction to the Institutional International Law,* Cambridge University press, Cambridge, 2002.

Kluge, Eike-Henner, "Human Genome Research and the Law: The Ethical Basis of International Regulation", *Jahrbuch für Recht un Ethik,* 1999, No. 7, pp. 159-178.

Knoppers, Bertha Maria and Saginur, Madeleine, "Bio-banking", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 166-173.

Kuhse, Helga and Singer, Peter, "What is Bioethics? A Historical Introduction", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 3-12.

Lee, M. Silver, "U.S. Dream child or nightmare scenario?", *UNESCO The Courier,* September 1999. Available at: http://www.unesco.org/courier/1999_09/UK/dossier/intro02.htm.

Lee, Stacey B., "Informed consent: enforcing pharmaceutical companies' obligations abroad", *Health and Human Rights,* Vol. 12, No. 1, 2010, pp. 15-28.

Lemmens, Trudo and Luther, Lori, "Financial conflict of interest in medical research", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp.222-230.

Lenoir, N., "Universal Declaration on Human Genome and Human Rights: The First Legal and Ethical Framework at the Global Level", *Columbia Human Rights Law Review,* 1999, Vol. 30, No. 3, pp. 537-587.

Lindsay, Ronald A., *Future bioethics,* 2008, Prometheus Books, New York.

Lo, B. and Perham, L.: "Ethical Issues in Stem Cell Research", *Endocrine Reviews,* Vol. 30, No. 3, 2009, pp. 204-213.

López Moratalla, N.: "Clonación terapéutica", *Persona y Bioética,* Vol. 8,

No. 22, 2004, in http://biblioteca.unisabana.edu.co/revistas/index.php/personaybioetica/article.

—, "Resucitan al inicio del 2009 las células troncales procedentes de embriones", *Cuadernos de Bioética,* XX, 2009, No. 3, pp. 471-485.

—, "¿Clones humanos?", *Cuadernos de Bioética* Vol. 15, No. 55, 2004, pp. 385-404.

Lowry, Christopher and Schüklenk, Udo, "Global Health Responsibilities", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 393-403.

Luna, Florencia, "Research in Developing Countries", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 621-647.

Luna, Florencia and Macklin, Ruth, "Research involving Human Beings", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 457-468.

Macdonald, R.st.J., "The Margin of Appreciation", *The European System for the Protection of Human Rights,* Macdonald, R.st.J., Matscher, F., Petzold, H., Martinus Nijhoff Publishers, Dordrecht, 1993, pp. 83-124.

Macklin, Ruth, "Global Health", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 696-720.

Macneill, Paul Ulhas, "Regulating Experimentation in Research and medical Practice", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 469-486.

Mahoney, Paul, "Judicial activism and judicial self-restraint in the European Court of Human Rights: two sides of the same coin", *Human Rights Law Journal*, 1990, Vol. 11, No. 1-2, pp. 57-88.

Mantovani, Ferrando, "The use of gametes, embryos and foetuses in genetic research and for cosmetic and industrial purposes", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 271-284.

Martens, P., «L'irrésistible ascension du principe de proportionnalité», *Présence du droit public et des droits de l'homme. Mélanges offerts à Jacques Velu (I)*. Bruylant, Bruxelles, 1992, pp. 49-68.

Martínez Sánchez, Isidoro, "Bioderecho y Religión en España: el aborto y la reproducción asistida", *Derecho y Religión,* No. 2, 2007, pp. 141-184.

Martyn, S. R., "Human Cloning: The Role of Law", *University of Toledo Law Review,* 2001, Vol. 32, No. 3, pp. 375-386.

Mazzoni, Cosimo Marco, "Bioethics Needs Legal Regulation", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 3-10.

—, "Gift Ethics and Organ Donation", Ibídem, pp. 173-180.

McCall Smith, Alexander and Revel, Michael, *The use of embryonic stem cells in therapeutic research*, unesco, International Bioethics Committee, 2001, Paris.

McGee, Glenn and Caplan, Arthur L., "The Ethics and Politics of Small Sacrifices in Stem Cell Research", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp.646-648.

Mclaren, A.: "A Scientist's View of the Ethics of Human Embryonic Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 23-26.

Meier, Benjamin Mason and FOX, Ashley M., "International Obligations through collective rights: moving from foreign health assistance to global health governance", *Health and Human Rights,* Vol. 12, No. 1, 2010, pp. 61-72.

Menikoff, Jerry, *Law and Bioethics. An Introduction.* Georgetown University Press, Washington D.C., 2001.

Meslin, Eric M. and Dickens, Bernard M., "Research ethics", in *The Cambridge Textbook of Bioethics,* Singer, Peter A. and Viens, A. M. (eds.), Cambridge University Press, 2008, pp. 187-193.

Mon Post, M., "Human Cloning: New Hope, New Implications", *Temple International and Comparative Law Journal,* 2001, Vol. 15, No. 1, pp. 171-193.

Moreno, Jonathan D., "Bioethics and Bioterrorism", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 721-733.

—, "Ethics Committees and Ethics Consultants", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 573-583.

Munson, Ronald, "Organ Transplantation", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 211-233.

Muñoz, Emilio, *Bioethics in Europe. Modern Science and Bioethics,* csic, 1992, Madrid.

Murray, Stuart J., "The Perils of Scientific Obedience: Bioethics under the

Spectre of Biofascism", in *Critical Intervention in the Ethics of Healthcare,* Murray, Stuart J. and Holmes, Dave (eds.), Ashgate, Farnham, 2009, pp. 97-114.

Murray, Thomas H., "Enhancement", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 491-515.

Nelkin, Dorothy, "Bioethics and Law", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 119-130.

Nielsen, Linda, "From Bioethics to Biolaw", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 39-52.

Nippert, I.: "The pros and cons of human therapeutic cloning in the public debate", *Journal of Biotechnology* 98 (2002), pp. 53-60.

Nys, Herman, "Human gene therapy", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 93-116.

—, "Embryo research", *Ibídem,* pp. 257-270.

Nys, Herman and Fobelets, Geraldine, "The regulation of bio banks in Spain", *Law and Human Genome Review,* 29/2008, pp. 169-188.

Parens, Erik, "The Goodness of Fragility: On the Prospect of Genetic Technologies Aimed at the Enhancement of Human Capabilities", in *Contemporary issues in bioethics,* Beauchamp, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 548-562.

Pence, Gregory, "Cloning", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 193-204.

Picheral, C. and Olinga, A.-D., "La théorie de la marge d'appréciation dans la jurisprudence récente de la Cour Européenne des droits de l'homme", *Revue Trimestrielle des Droits de l'Homme*, 1995, nº 24, pp. 567-604.

Plomer, A.: "The European Group on Ethics: Law; politics and the limits of moral integration in Europe", *European Law Journal,* 2008, Vol. 14, Issue 6, pp. 839-859.

Potter, Van Renssealer, "Bioethics, Science of Survival", *Biology and medicine,* 1970, Vo. 14, pp. 127-153.

Pureza, José Manuel, *El Patrimonio común de la Humanidad,* Trotta, Madrid, 2002.

Quintana, Octavi, "International bioethics? The role of the Council of Europe", *Journal of medical ethics,* 1993, 19, pp. 5-6.

Requena Casanova, M., "Nota sobre la ratificación por España del Convenio para la protección de los derechos humanos y la dignidad del ser humano con respecto a las aplicaciones de la biología y la medicina", *Revista Española de Derecho Internacional,* 1999, Vol. li, No. 2, pp. 794-799.

Richards, Janet R., "A World of Transferable Parts", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 375-390.

Ricolfi, Marco, "Bioethics, Markets and Morals. The Case of Biotechnological Patents", in *A Legal Framework for Bioethics,* Mazzoni, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 131-144.

Robertson, Ann, "Biotechnology and the Governance of Life: The Case of Pre-Implantation Genetic Diagnosis", in *Critical Intervention in the Ethics of Healthcare,* Murray, Stuart J. and Holmes, Dave (eds.), Ashgate, Farnham, 2009, pp. 61-80.

Romeo Casabona, Carlos María, *Implicaciones jurídicas de la utilización de muestras biológicas y biobancos en investigación científica,* Bilbao, 2007. http://www.catedraderechoygenomahumano.es.

—, "Genetics and the Law", in *Biotechnology, Law and Bioethics. Comparative Perspectives,* Romeo Casabona, Carlos M. (ed.), Bruylant, Bruxelles, 1999, pp. 31-64.

Ruíz de la Cuesta, Antonio, "De las cuestiones bioéticas al bioderecho en las ciencias de la vida", pp. 29-80 in *Régimen Jurídico de la investigación biomédica en Andalucía,* Daniel García San José (Coord.) Ed. Laborum, 2009.

—, "On Life and Death: an iusphilosophycal approach", Chapter V in *Biolaw and Bioethics in Spain. Facing New Challenges of Science,* Daniel García San José (Dir.). Laborum, 2010, Murcia, pp. 133-166.

Sándor, J., "Human rights and bioethics: competitors or allies? The role of International Law in shaping the contours of a new discipline", *Medical Law,* 2008, 27 (1), pp. 15-28.

Savulescu, Julian, "Genetic Interventions and the Ethics of Enhancement of Human Beings", in *The Oxford Handbook of Bioethics,* Steinbock, Bonnie (ed.), Oxford University Press, 2007, pp. 516-535.

—, "Genetic Enhancement", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 216-234.

Schlaeger, Th. M., Lensch, M. W. and Taylor, P. L.: "Science aside:

the trajectory of embryonic stem cell research in the USA", *Drug Discovery Today,* Vol. 12, Numbers 7/8, 2007, pp. 269-271.

SELGELID, Michael J., "Infectious Disease", in *A companion to Bioethics,* KUHSE, Helga and SINGER, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 430-440.

SENIOR, K.: "Extending the ethical boundaries of stem cell research", *TRENDS in Molecular Medicine,* Vol. 7, No. 1, 2001, pp. 5-6.

SEPAI, Ovnair, et al., "Human bio monitoring data interpretation and ethics; obstacles or surmountable challenges?". Available at: www.ehjournal.net/content/7/S1/S13.

SIOTA ÁLVAREZ, Mónica, "La importancia de la bioética y de los comités de ética en la creación del Bioderecho", *Anuario de la Facultad de Derecho de Ourense,* 2002, pp. 479-499.

SOMMERVILLE, Ann, "Public health ethics", in *The Cambridge Textbook of Bioethics,* SINGER, Peter A. and VIENS, A. M. (eds.), Cambridge University Press, 2008, pp. 266-273.

SORIA ESCOMS, Bernat, "Usos terapéuticos de las células madre de origen embrionario", *Estudios de Derecho Judicial,* 2002 (40), pp. 13-24.

SOUTO PAZ, José Antonio, "Objeción de conciencia y bioderecho", *Estudios en homenaje al Profesor Martínez Valls,* 2000, Vol. 2, pp. 687-698.

SPENCER, Robert C. and LIGHTFOOT, Nigel F., "Preparedness and Response to Bioterrorism", in *Contemporary issues in bioethics,* BEAUCHAMP, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 768-774.

SPICKER, Stuart F., "The Resurgence of Biomedical Research Ethics. From Research Risks to Risks to Research", *Law and Human Genome Review,* 17/2002, pp. 23-27.

SREENIVASAN, Gopal, "Global health and non-ideal justice", in *The Cambridge Textbook of Bioethics,* SINGER, Peter A. and VIENS, A. M. (eds.), Cambridge University Press, 2008, pp. 369-378.

STEIN, R.: "Researchers May Have Found Equivalent to Embryonic Stem Cells", *The Washington Post,* 24 July, 2009.

STEINBOCK, Bonnie, "Moral Status, Moral Value and Human Embryos: Implications for Stem Cell Research", in *The Oxford Handbook of Bioethics,* STEINBOCK, Bonnie (ed.), Oxford University Press, 2007, pp. 416-440.

SUGARMAN, J. and SIEGEL, A.: "How to Determine Whether Existing Human Embryonic Stem Cell Lines Can be Used Ethically?", *Cell Stem Cell* 3, 2008, pp. 238-239.

Takahasi, K. and Yamanaka, S.: "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors", *Cell,* 2006, No. 126, pp. 663-667.

Talavera, Pedro, "Células madre embrionarias: enigma terapéutico, dilema ético y negocio de alta rentabilidad", in *Biotecnología y Posthumanismo,* Ballesteros, Jesús and Fernández, Encarnación (coords.) Thomson-Aranzadi, Navarra, 2007, pp. 217-282.

Testa, G., Borghese, L., Steinbeck, J. A. and Brüstle, O.: "Breakdown of the Potentiality Principle and Its Impact on Global Stem Cell Research", *Cell Stem Cell* 1, 2007, pp. 153-156.

Toebes, Brigit, "Towards an improved understanding of the international human right to health", *Human Rights Quarterly*, Vol. 21, 1999, pp. 661-679.

Tomuschat, Christian, "The Complementarity of International Treaty Law, Customary Law and Non-Customary Law making", in Wolfrum, Rudiger and Röben, V. (eds.), *Developments of International Law in Treaty Making,* Springer, Berlin, 2005, pp. 409-416.

Tooley, Michael, "Personhood", in *A companion to Bioethics,* Kuhse, Helga and Singer, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 129-139.

Torres Cazorla, M. Isabel, "Las implicaciones de los avances científicos en el campo jurídico y la necesidad de proteger los derechos humanos", *Revista electrónica de Geriatría,* www.geriatrianet.com, Vol. 12, No.2, 2000.

—, "El derecho 'a no ser informado' en el Convenio sobre Biomedicina y sus Protocolos Adicionales: últimos avances de la mano del Protocolo relativo a los tests genéticos con fines médicos", in *La Obra Jurídica del Consejo de Europa,* (Fernández Sánchez, P. A., ed.) Seville, 2010, pp. 549-564.

Torres Fernández, M. Elena, "La donación de órganos o tejidos de donante vivo por personas incapaces de consentir a la luz del Convenio relativo a los derechos humanos y la biomedicina y su protocolo adicional", *Estudios jurídico-penales sobre genética y biomedicina,* 2006, Dykinson, Madrid, pp. 382-407.

unesco, Universal Declaration on the Human Genome and Human Rights, Gen. Conf. Res. 29 C/Res.16, adopted by the un General Assembly, G. A. Res. 152, un gaor, 53rd Sess., un Doc. A/RES/53/152 (1999).

—, Universal Declaration on Bioethics and Human Rights, Adopted by acclamation on 19 October 2005 by the General Conference of UNESCO.

VAN DER BURG, Wibren, "Law and Bioethics", in *A companion to Bioethics,* KUHSE, Helga and SINGER, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 56-64.

VEATCH, Robert M., "Justice, The Basic Social Contract and Health Care", in *Contemporary issues in bioethics,* BEAUCHAMP, Tom L. (ed.), 6th edition, Thomson Wadsworth, 2003, Belmont, pp. 53-58.

VOLK, M. L., and UBEL, P. A., "A Gift of Life: Ethical and Practical Problems with Conditional and Directed Donation", *Transplantation,* 2008, Vol. 85, No. 11, pp. 1542-1544.

WARNOCK, Mary and BRAUDE, Peter, "Research Using Preimplantation Human Embryos", in *A companion to Bioethics,* KUHSE, Helga and SINGER, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 487-494.

World Health Organisation's Commission on Intellectual Property Rights, Innovation and Health, *Report on Public Health, Innovation and Intellectual Property Rights,* Gèneve, 2006.

WRIGHT, Linda, ROSS, Kelley and DAAR, Abdallah, S., "Organ transplantation", in *The Cambridge Textbook of Bioethics,* SINGER, Peter A. and VIENS, A. M. (eds.), Cambridge University Press, 2008, pp. 145-152.

YAMIN, Alicia E., "Our place in the world: conceptualizing obligations beyond borders in human rights-based approaches to health", *Health and Human Rights,* Vol. 12, No. 1, 2010, pp. 3-14.

YOUNG, Robert, "Informed Consent and Patient Autonomy", in *A companion to Bioethics,* KUHSE, Helga and SINGER, Peter (eds.) 2nd edition, Wiley-Blackwell, Oxford, 2009, pp. 530-540.

ZATTI, Paolo, "Towards a Law for Bioethics", in *A Legal Framework for Bioethics,* MAZZONI, Cossimo M. (ed.), Kluwer, 1998, The Hague, pp. 53-66.

ZHOU, H., WU, Sh., JOO, J. Y., and others: "Generation of Induced Ploripotent Stem Cells Using Recombinant Proteins", *Cell Stem Cell* 4, 2009, pp. 381-384.

ZHOU, Q. And others: "iPS cells procedure viable mice through Tetraploid complementation", *Nature*, vol. 460, No. 7254, 23 July, 2009.

ZNIDARSIC, V.: "Biomedical research in Andalusia: a critical approach from Slovenia", Chapter VI, pp. 159-208 in *Régimen Jurídico de la investigación biomédica en Andalucía,* Daniel GARCÍA SAN JOSÉ (Coord.) Ed. Laborum, 2009.