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BIOLAW AND BIOETHICS IN SPAIN: FACING NEW CHALLENGES OF SCIENCE

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PREFACE

The general aim of this book is to collect the main research results presented in the *Symposium Biolaw and Bioethics in Spain: facing the challenges of Science*, which was held in the Law School of Seville (Spain) in March 2010. In that scientific event a group of scholars discussed on the lights and shadows surrounding biomedical issues as far as Law was concerned and its implications for legislation at national and European Level. Particularly, it was wanted by organisers, the Research Group *Bioderecho Internacional*[1] and the University of Seville[2] to value the recent normative approaches in Spain on sensitive questions, namely as regards research on human cloning and human cell transfer and reprogramming exclusively for therapeutic reasons, and the new Spanish Law on abortion passed in the early 2010.

Participant in that Symposium developed in their interventions a comparative approach, by taking reference to European Union countries but also considering international agreements binding them. Notably, it was recalled their status of Member States in the European Union and their obligations assumed under the Organisation of the Council of Europe. It was also methodologically assumed by organisers of that Symposium a research technique according to a multidisciplinary, integrative and transversal approach. From a multidisciplinary approach, firstly, considering all branches of Law 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, by which it was defended a holistic vision of these topics and avoiding to fall into a dialectic speech (focusing only the "pros" or the "cons") of such sensitive questions. Finally, it was

[1] www.grupo.us.es/biodeinter

[2] By way of its *Vicerrectorado de Relaciones Institucionales*.

defended a transversal approach because it was considered that there was a global concern, at least at European level, on the considerations surrounding life and death. Any country in Europe is directly and/or indirectly affected by this issue. Coherently, normative approach should be combined and complemented at national and European level.

In Chapter 1, Dr. Daniel GARCÍA SAN JOSÉ presents the special situation of Andalusia, an Autonomous Community in Spain, which is in the group of countries leading at European level the biomedical research on embryo cells reprogramming which seem to overlap the moral and ethical controversy surrounded other research techniques implying the creation-destruction of human embryos[3]. He adverts that there is no European common conception of human life and it could emerge in future some trouble with patenting results of some reprogramming cells techniques. In this sense, he criticised the artificial distinction in Spanish legislation between somatic embryos and human embryos.

The issue of Patent Law is the topic dealt with by Dr. Cecilia GÓMEZ-SALVAGO SÁNCHEZ, Professor of Civil Law in the University of Seville, particularly in the case of patenting biotechnological inventions in Europe. Complementing the approach developed in Chapter 1, the author of this Chapter 2 reaches the conclusion of the necessity of a redefinition of the concept of Human embryos at European level.

Chapter 3 and 4 are dedicated to the Organic Law 2/2010, *on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy* in Spain. Dr. Abraham BARRERO ORTEGA and the Fellow researcher Laura GÓMEZ ABEJA, both from a constitutionally comparative approach, defend the consistency and constitutionality of the bill of this

[3] The Autonomous Community of Andalusia has competence under Spanish Constitution and its *Statute* to develop research on human cells. See Andalusian Law 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 Law 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).

Organic Law passed with a lot of polemic debate in society. Dr. Juan José BONILLA SÁNCHEZ, also from a constitutionalist perspective seems more critical with this Law, especially under the exam of the freedom of conscience of sanitary personnel and their objection of conscience under the situations envisaged by Spanish Legislator as regards interruption of pregnancy by 16-year-old women without the knowledge and consent of their parents or legal representatives.

In Chapter 5, Dr. Antonio RUÍZ DE LA CUESTA, from a perspective of Philosophy of Law, makes a deep reflection on life and death, two sides of the same coin. In the words of his author: "The right to enjoy life more fully and honorably during the vital process that requires the existence of each person is and should be the basis of any democratic and civilized order. The concept of life is a fundamental constitutional right not understood as mere existence, but as a dignified existence in sufficient condition to develop, as far as possible, all the powers of the human person can enjoy. Consequently, not only combated the denials of life in strictly biological dimension, but also all the negatives that prevent the enjoyment of an authentic life and human dignity. Dying with dignity involves building mechanisms that are walkable and manageable, within the limits of possible, the experience of finitude and human expiration".

Authors in this volume want to express their gratitude, firstly, to the University of Seville, and especially to its *Vicerrectorado de Relaciones Institucionales,* for the economic support to this publication; and secondly, to Mr. Francisco ORTIZ, Head Publisher of *Laborum Publishing*, for its commitment with broadening the frontiers of Law to not yet sufficiently explored fields of Life Science.

CHAPTER I. EUROPEAN PLURALISM AND THE REGULATION OF RESEARCH ON HUMAN EMBRYONIC STEM CELLS IN SPAIN: TOO FAR FROM NOWHERE[4]

I.1. Premise and starting point: a variable geometrical context in Europe of research on Human Embryonic Stem cells

There is a constant in any approach from Juridical Sciences to medical advances and no matter how obvious it can be it must always be recalled as a premise: "Science moves faster than Law which is always lagging behind the facts". Consequently, as a caution, we must advert that juridical answers don't come fast and in any case, they are not immutable for a long time.

Having assumed the previous premise, as a starting point in our analysis we must comment the variable geometrical context in Europe as regards regulation in human embryonic stem cells (hESC) research[5]. Geometrical, on the one hand, because it is possible to recognise four

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[5] The *European Group on Ethics in Science and New Technologies to the European Commission*, in its Opinion No 22 (Recommendations on the ethical review of hESC FP7 research projects) of 20 June 2007, evidenced a situation, normatively speaking, of "variable geometrical" among European Union Member States' regulation on human embryonic stem cells (from now on "hESC")

different approaches among European Union Member States on hESC research[6]:

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 be used for that purpose.

Restrictive position (Germany and Italy have stricter hESC research regulations. Scientists in these countries cannot derive new hESC cell lines, but can import them. In Germany, a new discussion has arisen as to whether the 2002 Stem Cell Act regulating the importation of hESC lines should be revised, but no legal proposal has been forthcoming by the date of these Recommendations. 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 to 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* fertilization. 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

[6] *Recommendations on the ethical review of hESC FP7 research projects*, Opinion Nº 22, 2007, pp. 29 and ff., in http://europa.eu/european_group_ethics/publications/docs/opinion_22_final_follow_up_en.pdf

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 geometrical context also, because it seems 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[7].

Such a variable geometrical context in Europe as regards regulation of research on embryonic stem cells may have important effects and juridical consequences[8], particularly as far as commercialisation and patenting in Europe is concerned[9]. 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 furthermore, the Main Board of Appellation ("EBoA") in the European Patent Office showed coincidence in this point it in its decision

[7] 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). 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.

[8] 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,* 14 (2008) 6, p. 859.

[9] 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 of biotechnological inventions (98/44/EC, Official Journal L213, 30/07/1998, pp. 13-21) 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.

of 25 November 2008 in the so called *WARF case*.[10] Under the situation above describes there is a fact which could help to explain it: we miss in Europe a common understanding of human beings, of the beginning of human life and, consequently, of status and rights of embryo as far as its human dignity.

I.2. Waiting for Godot: a different understanding of the beginning of human life and, consequently, of status and rights of Human embryo as regards dignity

It is not a novelty to reads The *European Group on Ethics in Science and New Technologies'* Opinion No 22, on the ethical review of the hESC FP7 research projects, when it seriously concludes 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."[11]

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*[12]. Then, the European Court considered that the issue of when the

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[10] 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). Decision can be obtained in http://www.epo.org/topics/news/2008/20081127.html

[11] *Op. cit.*, p. 38.

[12] 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 …

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."[13]

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)[14]. 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.

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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.

[13] 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.

[14] See paragraphs 45 to 47 in the former and paragraphs 54 to 56 in the latter.

So, the next and envisaged question we need to pose is the following one: at which extent and how this lack of consensus at European level (Council of Europe and European Union) on the nature and status of the embryo may influence in countries like Spain or United Kingdom leading research in hESCs? The answer is that at a large state such lack of consensus may negatively influence in the economy and development of European Societies, like Spanish one, which freely have decided to bet for innovation and hedge technologies as a better way for surmounting the current economic crisis.

I.3. Research on human cloning and cells reprogramming exclusively for therapeutic reasons: the example of Andalusia and Spain

The Autonomous Community of Andalusia (a region of Spain like Catalonia or Basque Country) has been pioneer in Spain enacting a legal framework for research on cloning for therapeutic purposes[15] and particularly, concerning research on cellular reprogramming exclusively for therapeutic purposes with the already cited Law 1/2007 of 16 March, 2007[16]. Such a legislative path has to be understood considering several provisions in the Andalusian *Statute de Autonomy*[17]. Contrary to the

[15] See Law 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.

[16] That is, very soon after 2006 when cells reprogramming was a success. See TAKAHASI, K. and YAMANAKA, S.: "Induction of pluripotent stem cells from mouse embryonic and adult fibroblast cultures by defined factors", *Cell,* 126 (2006), pp. 663-667) up to present with third generation of protein-induced pluripotent stem cells, also called piPS. See a general overview in: STEIN, R.: "Researchers May Have Found Equivalent to Embryonic Stem Cells", *The Washington Post,* 24 July 2009.

[17] It is a kind of Regional Government's Constitution which was newly approved by Organic Law 2/2007 of 19 March, 2007.

option assumed at national level[18], the Autonomic Authorities in Andalusia preferred a concise Law which would be ready to provide immediately legal cover to the research on human cell reprogramming exclusively for therapeutic reasons.

We have already had the opportunity to express our concern that Andalusian Law 1/2007 of 16 March, 2007 of Research on Cellular Reprogramming exclusively for therapeutic reasons would run the risk of being 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 Convention)*[19]. In my opinion, such a risk derives from the ambiguity in expressing the object of the Andalusian Law 1/2007.

Article 1 of Law 1/2007 explains which is the purpose of this Act: Besides the creation of the Committee of Research 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)[20] and f) (providing the definition of somatic pre-embryo)[21] to the light of Par II of the Preamble of this Law[22].

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[18] Law 14/2007 of 3 July, 2007, of Biomedical Research in Spain was approved only three months latter that the Andalusian Law 1/2007 and it is more perfect, legally speaking. Not only for its length, 90 Articles in comparison with 9 in the Andalusian Law, 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.

[19] 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.

[20] 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;

[21] 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 …

In view of Preamble of Law 1/2007, namely, its third paragraph beginning from the end[23], definitions of cell nuclear transfer and of somatic pre-embryo in letters e) and f), respectively, of Article 2 of this Law, seems to be confusing. According to this later 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 oocyte 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 would had been mixed up with reprogramming techniques in order to use the concept of somatic pre-embryo instead of human pre-embryo. So, it would not be formally illegal such techniques although they will be in other context!.

It is easy to find reasons for someone making such mistake of interpretation Law 1/2007: reprogrammed cells were not just functionally

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the nuclear transfer or other similar techniques, from the moment such a technique is applied and up to fourteen days after.

[22] "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 oocyte 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 oocyte. 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."

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

identical to embryonic stem cells (at least this was true in 2007) and although future was blooming considering advances in research 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 adult stem cells and 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 Law 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 oocyte, through nuclear transfer".

Furthermore, Law 14/2007 is being consistent with the Convention for the protection of Human Rights and dignity of the human being with regard to the application of biology and medicine: Convention on Human Rights and Biomedicine (Oviedo Convention), which Article 18.2 stipulates: "The creation of human embryos for research purposes is prohibited". Nevertheless, in the already mentioned Opinion No. 22 of the

European Group on Ethics in Sciences and New Technologies, it could be read in page 32 that Spain allowed the creation for human embryos for research purposes. Are we facing a contradiction with Andalusian and Spanish Laws on biomedical research? It rather seems a case of confusion.

I.4. Human embryos facing somatic embryos: a case of Mr. Jekyll and Mr. Hide?

The case of confusion we have pointed out might be due to the unfortunate wording of Article 33 of Law 14/2007, of Biomedical Research in Spain[24] and according the object of the Andalusian Law 1/2007 how it is prescribed in its Article 1 as allowing to do research on cellular reprogramming exclusively for therapeutic purposes. Reading this provision, one may wonder which are those other purposes referred in Article 4 of Law 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 Law!

Spearing some light into darkness it is necessary to remember that commonly is assumed as the aim of activating oocyte with nuclear transfer of adult somatic reprogrammed cells, not to create human

[24] This provision arises doubts as regard if it is allowed any technique of obtaining human stem cells, including the activation of oocyte 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. To be honest, such confusion should not take place considering the mention made in Article 4 of the Law 1/2007 to Additional protocol to the Oviedo Convention, concerning prohibition of cloning of human beings: "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 Law forbids researching with techniques of cellular reprogramming with somatic cells to generate pre-embryos with reproductive purposes. It is also forbidden researching with these techniques for any other purpose apart from that authorised in this Law."

embryos but embryonic bodies. They are things quite different[25] for most of authors[26] although it is not unanimously accepted[27]. 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*[28], then a dilemma would rise in the Autonomous Community of Andalusia – indirectly also in Spain- since, scientifically speaking, no difference would be pertinent to distinguish a reprogrammed cell to be totipotent which is transferred to a human egg to generate a whole individual. In *Science Daily*[29], last February 12, 2008 it could be read: "University of California –Los Angeles Stem Cell Scientists have reprogrammed human skin cells into cells with the same unlimited properties as embryonic stem cells without using embryos or eggs[30]. Recent works published in 2009 would confirm this point[31].

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[25] HESCs naturally reside within the inner cell mass (embryoblast) of blastocysts, and in the embryoblast, 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 embryoblast to differentiate and form the embryo. IPSCs were injected by micropipette into a trophoblast and the blastocyst was transferred to recipient females. Chimeric living mouse pups were created: mice with iPSCs derivatives incorporated all across their bodies with 10%-90% chimerism. See http://en.wikipedia.org/wiki/Induced_pluripotent_stem_cell visited on 3/2/2010

[26] See, for instance: LÓPEZ MORATALLA, N.: "Clonación terapéutica", *Persona y Bioética,* 8 (2004) 22, in http://biblioteca.unisabana.edu.co/revistas/index.php/personaybioetica/article

[27] See as this regards: ZNIDARSIC, V.: "Biomedical research in Andalusia: a critical approach from Slovenia", *Régimen Jurídico de la Investigación Biomédica en Andalucia (Daniel García San José coord.),* Laborum, Murcia, 2009, pp. 205-206.

[28] We consider here the general sense of totipotency, that is, the ability of a single cell to generate an entire individual. 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* (2007) 1, pp. 153-156.

[29] http://www.sciencedaily.com/releases/2008/02/080211172631.htm

[30] 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 …

It is needless to say that the results of such research techniques foster those in Europe who make opposition to any kind of human stem cell research and defeats Andalusian scientists to see recognised a patent by the European Patent Office. This is so 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[32] as LÓPEZ MORATALLA has recently analysed in Spain[33].

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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,* 10 (2009) 11, p. 743.

[31] See, e.g. the work of Honguan ZHOU, Shili WU, Jin Young JOO, and others, published in *Cell Stem Cell* (2009) 4, pp. 381-384 (http://www.cell.com/cell-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."

[32] It is publicly advertised by private enterprises (for instance www.advancedcell.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

…

We face a European context of incertitude as regards ethical implications of patenting biotechnological inventions implying the use of human embryos[34] and those more suffering it are scientists[35]. It may be clarifying in this sense to evoke those *informing principles* which, according to the *European Group of Ethics in Science and New*

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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."

[33] LÓPEZ MORATALLA, N.: "¿Resucitan al inicio de 2009 las células troncales procedentes de embriones? (Does 2009 mark a revival of embryonic stem cells?)" *Cuadernos de Bioética,* XX (2009) 3, pp. 471-485.

[34] 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 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."

[35] Just to mention some recent articles as this regard: MCLAREN, A.: "A Scientists's View of the Ethics of Human Embryonic Stem Cell Research", *Cell Stem Cell* (2007) 1, 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* (2008) 3, pp. 238-239. LO, B. and PARHAM, L.: "Ethical Issues in Stem Cell Research", *Endocrine Reviews* 30 (2009) 3, pp. 204-213.

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. 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[36]; Secondly, as regards different origins of human stem cells[37]; Thirdly, as far as methods for obtaining stem cells are concerned[38]; 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[39]. This set of *informing principles* surrounding the patentability

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

[37] "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."

[38] "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".

[39] "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."

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 are ethically controverted for a part of the European society if they entail 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 the risks surrounding human reprogramming research currently in process in Andalusia (as in other parts of Spain). There is a clear difference (at least in order to future patenting) between processes for inducing adult stem cells to undergo 'retro differentiation' or 'trans differentiation'[40] from processes to create embryos by transfer of a somatic cell nucleus to an enucleated egg (cloning technique) for derivation of stem cells. Nevertheless, the Andalusian Act seems to allow firstly, the reprogramming of mature somatic adult cells to pluripotent form -and in case Science make it possible, to totipotent form- (Induced Pluripotent Cell or iPS) and secondly, using somatic cell nucleus transfer (SCNT) and cell fusion to cultivate embryonic stem cells (ESC). These adult cells reprogrammed and transferred harder and harder can be distinguished from embryonic stem cells so controversial. This is so at present more than never. As it has been commented worldwide[41], Chinese scientists published last summer two works in the journals *Nature*[42] and *Cell Stem Cell*[43] where they asserted to have created live mice from mature skin

[40] 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.

[41] See, i.e. *The Washington Post*, July 24, 2009.

[42] The work of the team of scientists led by Qi ZHOU of *the Chinese Academy of Sciences* was published in *Nature* 460 (2009) 7254: 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.

[43] 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*, 5 (2009) 2, 135-138: 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.

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 scientific research, there is a fear that it also raises new ethical issues[44]. Particularly worrying is the possibility of making clones selected for specific traits with or without individuals' consent[45]. In any case, many scientists in ant outside Andalusia could still consider necessary –as it is indeed- to evaluate iPS with embryonic stem cells so, controversy would remain for a while[46].

I.5. Conclusion

The nature of the topic dealt with in this Chapter prevents us from presenting definitive concluding remarks. In the way of provisional ideas, summing up the questions analysed above, we can put forward the following:

First. The situation of variable geometrical regulation in Europe as regards research on human embryonic stem cells is a reality with unknown consequences in future for human cellular reprogramming. Although doing research on induced pluripotent stem cells (IPSCs) it seem to have overcome moral objections to nuclear transfer techniques

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[44] 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

[45] In words of Robert LANZA, a stem cell researcher at Advanced Cell Technology in Worcester (United States): "With just a little piece of your skin, or some blood from 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." Interviewed by STEIN, R.: "Researchers May Have Found Equivalent of Embryonic Stem Cells", *The Washington Post*, July 24 2009.

[46] LÓPEZ MORATALLA, N.: "¿Resucitan al inicio del 2009 las células troncales procedentes de embriones?", *op. cit.,* pp. 482-483.

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.

Second. 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. Furthermore, even though what it is at stake in the case of research in Andalusia and Spain 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. Consequently, situation in next future might be particularly worrying in the case of trying to patent at European level the results of research at present done 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 is the so called WARF case concerning patentability of biotechnological inventions implying the use of human embryos. That is, refusing to grant European patent 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.

Third. In order to propose solutions to the problem identified in previous pages any jurist interested in Sciences of Life and, in particular, on embryo research advances, should focus its 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 better as regards biomedical research; namely, human cloning and cell transfer and reprogramming exclusively for therapeutic purposes on a basis of fairness[47]. That is, assuming justice as fairness in the distribution of the

[47] This is the approach suggested by authors like 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,* 90 (2008) 6, pp. 2056-2059. In the same sense: SCLAEGER, Th. M. and other in the editorial of *Drug Discovery Today*, 12 (2007) 7/8, pp. 269-271.

benefits and burdens of public policy in a pluralistic society (in this case, the European society). 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? [48]

Fourth. Juridical research on the existence of such a *corpus iuris* – were to exist- 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 techniques 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 who do research 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 Europe.

[48] *Ibidem,* p.2057. Thus, in opinion of these authors, "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."

CHAPTER II. HUMAN STEM-CELLS RESEARCH. THEIR RELATION WITH PATENT LAW[49]

II.1. Introduction: The direct effects of patents on biotechnological research

The question as whether patents that fall on basic biotechnological tools should or should not be public domain has been raised[50], because many of the most important genetic research act as platforms or launch pads to open areas of investigation. The patents of these basic resources are perceived as a point of deceleration in investigative activity, because of increasing costs that delay the publication of the conclusions and suffocate the collaboration in this area of biomedicine[51]. It is necessary to

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[49] Dr. Cecilia GÓMEZ-SÁNCHEZ SALVAGO. Professor of Civil Law. University of Seville. salvago@us.es This work is the result of a research grant program "Estancias en centros extranjeros y excepcionalmente españoles, de profesores de Universidad e investigadores españoles, incluido el programa Salvador de Madariaga", in the Faculty of Law in University of Trento, in the "Biodiritto" program led by Prof. Carlo CASONATO (Resolution of 17 March 2009 of the Ministry of Universities, BOE, April 2).

[50] Richard GOLD, Yann JOLY, Tomoyhy CAULFIELD: "Genetic Research Tools. The Research Exception and Open Scienze", in *GenEdit,* 2005, Vol III, No.2. From an ethical standpoint see Göran HERMERÉN: "How could the concepts of 'ordre public' and 'morality' be Interpreted? What ethical considerations are relevant in the Patenting of Human DNA?" in *"The ethics of human Patenting genes and stem cells. "Conference Report and Summaries. Held in Copenhagen 28 September 2004,* Organized by The University of Copenhagen. The Danish Council of Ethics Biotika. www.biotik.dk/sw293.asp. (Published by The Danish Council of Ethics)

[51] The negative consequences of patents in biomedical research, see Richard GOLD *et al*, *Genetic Research Tools. The research Exception and open Scienze, op. cit*., pp. 6 and 2. See also Thomas G. JENSEN: "What problems does Patenting pose to fundamental biomedical research-and possible solutions?, i*n The Ethics of Patenting human genes and stem cells." Conference Report and Summaries. Held in Copenhagen 28 September 2004, Organize by* …

sustain non-commercial public investigation[52] and to foment the politics of the sanitary research even though they fall over abnormal illnesses.

From this perspective, the patent system produces two direct effects over biotechnological research: firstly, the difficulty of open access to the research and the technology, and secondly, the increase of sanitation costs[53]. To alleviate them one needs to play a decisive role, for example, the creation of registrations of unmodified stem cells lines, that included information about the embryonic stem cells, germs, and embryonic cells, that guarantee the transparency and facilitate access of the scientific community to the research, and in this way the necessity, world renowned, of public human embryonic stem cell banks[54]. Thirdly, with the ends of assuring that the titles of the patents don't have an abusive use of their rights through the cost of excessive fees, it should be fomented the resource of obligatory licenses, when access to the diagnostic and the treatment are blocked by the inappropriate use of the patents, allowing the equal access to sanitary attention when this process is justified.

The University of Copenhagen. The Danish Council of Ethics Biotika. www.biotik.dk/sw293.asp (Published by The Danish Council of Ethics).

[52] Thomas G. JENSEN, *op. cit*. See section 2 of the summary of the meeting.

[53] In this sense, Opinion No. 16 of the European Group on Ethics (EGE) referred to concerns that the overcharge would prevent access to health care. The EGE considers it essential, in addition to academic exemption, that patents are not too broad, as this could have adverse effects on the objective of supporting innovation in health benefits (EGE 2002, p. 18, section 2.7). See Göran Hermerén, How could the concepts of "ordre public" and "morality" be Interpreted? What ethical considerations are relevant in the Patenting of Human DNA? art. cit.

[54] In Spain the National Stem Cell Bank is attached to the General Office of Research on Cell Therapy and Regenerative Medicine of the Carlos III Health Institute. See http://www.isciii.es/htdocs/terapia/terapia_bancocelular.jsp

II.2. Patent of Human Embryonic Stem cells

II.2.1. The status of the issue: The clause of public order

In the period before the Directive 1998/44/CE about patentability of biotechnological inventions the problem had still not come up. European national regulations in this subject were coordinated by European patent Convention October 5th, 1973, ratified by Spain on July 10th, 1986. New events on biotechnological and genetic engineering were acquiring a growing function in the industrial activities. This placed Europe at a disadvantage in front of the USA and Japan[55].

The first proposition, October 20th, 1988, signaled that live organisms could be patented. Nevertheless, it was criticized ferociously because of the lack of references to the ethical question. After a political battle, the result is a final text of a compromise between the diverse ethical opinions about the way to protect this delicate sector of discoveries and inventions[56].

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[55] We refer in particular to the American patent application for the testing of oncogenes on mice, on 24 June 1985, which was granted on 12 April 1988. See GÓMEZ SEGADE, J. A.: "Decisión de la División de Examen de la Oficina Europea de Patentes de 3 de abril de 1992", in Gómez Segade, *Tecnología y Derecho. Estudios jurídicos del Prof. Dr. H.C., José Antonio Gómez Segade recopilados con ocasión de la conmemoración de los XXV años de cátedra,* Madrid 2001, pp. 723 to 732. See also in the same work by the same author the following articles: "Patentes y bioética en la encrucijada: del onco-ratón al genoma humano" pp. 955-961; "Decisión de la Cámara de Recursos Técnica de la Oficina Europea de Patentes de 3 de octubre de 1990. Patentabilidad de los animales: el ratón transgénico", pp. 689-708. Besides this fact, there were many patent applications on the human genome in the USA and UK. The height of the crisis occurred in 1991 when the U.S. National Institute of Health (Criag Venter) applied for 3.000 patents on gene sequences with no known biological application, which caused the reaction of the UK's Medical Research Council to request, in turn, 1.000 patents.

[56] In this regard, certain statements contained in the preamble may provide guidance to understand the various interests at stake, -the patent holder to profit on the promotion of biotechnology research, and health and welfare of humanity-, and the difficulty of reconciling both of them in the rules of patents.

The Directive 98/44, as the European internal regulations and the European Group of Ethics admit the patentability of the processes surrounding human stem cells, with general requirements (development, the inventive activities, and industrial application). If these requirements are not met the human stem cells cannot be patented. Under the budget if the stem cells have been invented, and not simply discovered or found, nevertheless not all the human embryonic stem cells can be patented[57].

The Directive refers explicitly to the germinal cells in order to exclude them from the patentability, but there is nothing that is written about embryonic stem cells. The question will be then if they can be patented without any ethical obstacle that would stop it[58].

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[57] Article 3: "1. For the purposes of this Directive, inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

Given these requirements, the Preamble 20 says: "Whereas, therefore, it should be made clear that an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment"; and 21: "Whereas such an element isolated from the human body or otherwise produced is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself". Assuming that patent rights do not extend to the human body and its elements in their natural environment, the Preamble reaffirms that (16): "Whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person; whereas it is important to assert the principle that the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented; whereas these principles are in line with the criteria of patentability proper to patent law, whereby a mere discovery cannot be patented".

[58] Geertrui VAN OVERWALLE raises the question. "Patentability of human stem cells and cell lines", in "The Ethics of Patenting human genes and stem cells." Conference Report and Summaries. Held in Copenhagen 28 September 2004, Organized by The University of Copenhagen. The Danish Council of Ethics Biotika. www.biotik.dk/sw293.asp.

The answer needs to be brought forth about Article 6.2 c) Directive 98/44, the public order clause, which excluded the patentability of inventions whose commercial exploitation would be contrary to public order or to the morality, and in particular, the uses of human embryos with commercial or industrial ends. This norm generates transcendent economic consequences in the European economic context, and also brings forth important problems with interpretation[59]. For example, if we make reference to the future acts of economic exploitation of the invention, or if the experimental acts that have preceded the request are understood; if we make reference to the use on the research of excess embryos, or also to the embryos created for the means of the investigation; if it makes sense to distinguish between the ends of the research or the commercialization[60]; without forgetting to remember that complexities of the problem of how to define what an embryo actually is.

Without coming to a finite closure, we can say now that inventions with human embryonic stem cells will be patentable if the employed method doesn't destroy them, in a strict sense, and if the ends are in accordance with the national regulations. So we will continue explaining these specific circumstances.

II.2.2. Relevance of techniques of Embryonic Stem cells research as regards patentability of results

It's a premise in the European context that the method to create the embryonic stem cells cannot destroy the cells, for the patentability of the

[59] Gerard PORTER, Chris DENNIGN, Aurora PLOMER, John SINDEN & Paul TORREMANS: "The patentability of human embryonic stem cell in Europe. Applicants in Europe are left CITH fez options for the patent of hES cell-related technology", in Nature Publishing Group 2006, vol.24, No.6, June 2006. http://www.nature.com/naturebiotechnoloy Just think that as U.S. Patent and trademark Office has granted many patents claiming human embryonic stem cells in their titles (including the patent in the methods of differentiation of such cells), while the European Patent Office (EPO) does not grant patents claiming such cells.

[60] Problems studied by Geertrui VAN OVERWALLE: "Patentability of human stem cells and cell lines", *op.cit*. www.biotik.dk/sw293.asp.

invention[61]. To this effect, it's necessary to question if the term "commercial exploitation" used on art. 6.2 c) of the Directive and in the national patent laws, we make reference only for the future economic uses of the invention, or if the experimental acts that have preceded the request of the patent are understood[62]. The subject has practical transcendences, because if it is the first case, the inventions could be patented when the development of the inventive activity is to be created illegally, although its repetition would not be necessary in order to commercially exploit the invention[63]; in the second case, if the development of the inventive activity were realized contrary to public order it could not be patented.

The question is how far a patent which claims a product, such as an embryonic stem cell line may be withheld if the invention has been obtained through procedures that are contrary to the public order, although the procedure is not the subject of the claim. The EPO has given its answer, including under the blanket of public order (ex Art. 6.2.c) carrying out the invention of the claimed cell line[64]. But the problem is

[61] This has been confirmed by the EPO in the WARF case. Distinctly the office has a very broad concept of embryo and has not clarified the meaning of the term. The procedure for making decisions that this office performs has been criticized. The procedure to certify that inventions do not violate public order or morality has been accused of irregularities; and that they should have been established by a group of experts in the field of ethics that could provide a clear and consistent jurisprudence. Richard GOLD and Alain GALLOCHAT, *op. cit.*, p. 360. Patents are considered by people with little experience, although the topics to be addressed are very important, and can result in denial of the patent.

[62] It follows ROMANDINI: "Comment to the Legge 22 febbraio 2006, n.78 sulle invenzioni biotecnologiche" in Marchetti-Ubertazzi, *Commentario alle leggi brief intellettuale and its owner to concorrenza,* 4th ed., Milano 2007, pp. 1367 et seq., *op. cit.*, p. 1377.

[63] As examples, inventions improved by an illegally derivative of human biological material, violating the rules on informed consent, or through an act of biopiracy.

[64] This is the position of EPO of 25 November 2008, in the case WARF, G0002/06, which claimed a culture of human embryonic cells, which was rejected because the method described enveloped the destruction of embryos. See press release: http://www.epo-org/about-us/press/releases/archieve/2008.html See the comment that STERCKX made, "The Warf / Stem Cells before the EPO Enlarged Boad of Appeal", in *European Intellectual Property Rewiew,* Volume 30, Issue 12, 2008, pp. 535-537. See also on the topic GÓMEZ-SALVAGO SÁNCHEZ: "El marco europeo de la protección juridical de los resultados de la investigación biomedical sobre clonación terapéutica: implicaciones para los investigadores andaluces", in Daniel GARCÍA SAN JOSÉ (ed.) *Régimen jurídico de la investigación* …

that the concept of "public order" does not exist for all the European states, except the preconception that is used by EPO.

An example of a country that adopted this initial positioning was Belgium that with regard to the exemption of public order and morality was not confined to commercial exploitations and extended them to the inventions produced by means contrary to public order or morality[65], however, present legislation in this country has been overtaken by a new one[66].

Another problematic situation arises when the invention has been initiated in accordance with the standards of a system but seeks to extend the exclusivity in the context of other domestic legislation, which is understood in another sense as the clause of "public order" and would cause the rejection of the claimed patent. Let us start with an example. The system in the United Kingdom, which allows the creation of embryos for research (for IVF and nuclear somatic transfer)[67], and derives stem cells from surplus embryos for assisted reproduction, their Patent Office recognizes consistently, that the commercial exploitation of inventions concerning human embryonic pluripotent stem cells is not contrary to public order or morality[68] in the UK. The achieved English patent would be rejected in Italy, because the Italian legislation prohibits the creation of embryos for research, including transfer nuclear somatic stem cells, and

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biomédica en Andalucía. En el marco de la legislación nacional e internacional, ed. Laborum, 2009.

[65] Richard GOLD and Alian GALLOCHAR, *op. cit.*, p. 350. They criticize these authors because they do not seem to fit neither the Directive nor the Trips agreement.

[66] At present, the Law on research on human embryos in vitro (April 2003) expressly permits the derivation of HESTCs coming from the surplus embryos in vitro reproduction and the creation of human embryos for research using SCNT. See the overall picture available at www.stemcellconsortium.org

[67] The Human Fertilization and Embryology (HFE) Act (2008). See http://www.opsi.gov.uk/acts/acts2008/ukpga_20080022_en_1 See also www.dh.gov.uk/en/Publicationsandstatistics/PublicationsLegislation/DH_080205

[68] http://www.ipo.gov.uk/pro_types/pro-patent/p-law/p-pn-stemcells-2009203.htm

cell lines derived from human embryonic cells[69]. The same result would occur if the patent was requested in Austria, which also voted against research with human embryonic stem cells and maintains today the same regulation[70].

The disparity between member countries is a consequence of the freedom that applies to every state in the determination of rules that should govern the field of scientific research on stem cells (Oviedo Convention, art. 18). Consequently, the conflict is served, to be very different regulation of embryonic stem cell research in Europe.

For example, in regard to the creation of embryos for research, it is permitted in the UK (both IVF and nuclear transfer)[71], in Belgium (including SCNT)[72] and in Spain[73]. It is forbidden, however, in Austria[74],

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[69] In the words of the Directive (14) "…patent law cannot serve to replace or render superfluous national, European or international law which may impose restrictions or prohibitions or which concerns the monitoring of research and of the use or commercialization of its results, notably from the point of view of the requirements of public health, safety, environmental protection, animal welfare, the preservation of genetic diversity and compliance with certain ethical standards".

[70] We follow the overall picture provided by the International Consortium of Stem cell networks, available in www.stemcellconsortium.org. In the case of Austria refers to the following address on-line: www.ris.bka.gv.at / Bundesrecht Designed is also used at the following web address: http://www.bionetonline.org/castellano/Content/sc_leg2.htm # Q2 This table has been verified with the legal situation at present (February 2010). Also been taken into account the regulations offered at the following addresses: www.stemcellconsortium.org (last entry 18 September 2008)

[71] The Human Fertilization and Embryology (HFE) Act (2008). See http://www.opsi.gov.uk/acts/acts2008/ukpga_20080022_en_1 You can see also www.dh.gov.uk/en/Publicationsandstatistics/PublicationsLegislation/DH_080205

[72] The Law of 11 May 2003 Concerning research on embryos in vitro states in Article 6: *"Human reproductive cloning is prohibited"*. Article 3 allows research on embryos in vitro for therapeutic purposes as well as for scientific research only where no other method of comparable efficacy is available and under strict conditions, notably if research takes place in laboratories accredited university with local and federal oversight on embryos within their first 14 days of development. Article 4 prohibits the creation of embryos for research purposes, except where supernumerary embryos will not meet research objectives, and subject to the same strict conditions applicable to embryos in vitro under Article 3. See http://unesdoc.unesco.org/images/0013/001342/134277e.pdf

Denmark (including SCNT)[75] and France[76]. It is also prohibited the creation of embryos for research in Germany (including the technique of SCNT)[77] while the investigation is allowed under certain criteria; it is allowed under requisites in Greece (including SCNT), Ireland (including SCNT), Italy (including SCNT), Netherlands and Portugal. Finland has no law allowing or banning the technique of somatic nuclear transfer, but allows the derivation of stem cells from leftover embryos in vitro.

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[73] Art. 33 Law 14/2007, July 3 of Biomedical Research, vetoed the establishment of pre-embryos and human embryos solely for experimental purposes, but allows the use of any technique for obtaining human stem cells for therapeutic or research which does not involve the creation of a pre-embryo or an embryo solely for this purpose, as defined by law, including activation of eggs by nuclear transfer.

[74] In Austria the embryonic stem cell research is not permitted, and is regulated by legislation on assisted reproduction. See the following address: www.ris.bka.gv.at / Bundesrecht

[75] Act on Medically Assisted Procreation 1997, as amended in 2003. See the following address: www.biokemi.org/biozoom/issues/498/articles/2060. They have a Centre for Stem Cell Research, see http://dasc.dk/

[76] France began to legislate before the Directive was adopted, in July 1994 with a law prohibiting patenting the human body or any of its parts, components or products, for reasons of public order and morality. See Richard GOLD and Alain GALLOCHAT: "The European Biotech Directive: Past and Prologue", *op. cit*. p. 340. In vitro fertilization could have only one purpose: to help a couple have a son. Embryos left over were stored in a frozen state for five years for possible later implantation in the uterus of the mother. Parents could also decide to donate to another couple or to have them destroyed. After this period of five years, they had to be destroyed. Currently, the new French law on bioethics passed with the end date of February 6, 2006 continues to prohibit the creation of embryos for research (including the technique of SCNT), while the situation has changed in other ways: allows licenses to import human embryonic stem cell lines, for a period of 5 years. See www.stencellconsortium.org. See also www.agence-biomedecine.fr

[77] Under the terms of paragraph 1 of "Embryo" (Embryo Protection Act) 1991 in Germany any person could be prosecuted if an egg is fertilized for any purpose other than to cause a pregnancy in the same woman who donated the egg. Thus, it was illegal to create an embryo for medical research purposes. Currently research is permitted under HESTCs using criteria set by the German Stem Cell Act of 2002, with the amendments introduced in 2008. Accordingly, only those stem cell lines created before 1 May 2007 may be used for research. It also allows the import of HESC lines.

Regarding the use of embryos for research is allowed in countries like Belgium, France, Spain and the United Kingdom. It is fforbidden, by contrast, in Austria. Finally, the derivation of embryonic stem cells is allowed for surplus embryos from assisted reproduction in Finland[78], Greece, Holland, Sweden, United Kingdom, Belgium, Denmark, France, and Spain. Forbidden, but permitted the importation of cell lines in Germany and Italy.

II.2.3 Significance of research purposes as regards patentability of results

For the purposes of patentability, there is unanimity in the idea that the purpose of the invention must be lawful. The importance of the purpose intended is critical from the standpoint of protecting the results obtained. It now is part of the public policy clause of Art. 6.2.c) of the Directive and has a greater importance.

From the perspective of general interest pursued by the use of embryonic cells, it can improve the health of people (speaking, then, for therapeutic use), or the reproduction of the species (called, in this case, reproductive purposes) when they are intended to be implanted in the uterus for a natural birth). Observing the public policy clause from this point of view, only the first destination is deemed admissible. There is a unanimous rejection of the second destination. Thus, the so-called "cloning" reproduction is considered contrary to human dignity, and as such, contrary to public order and morality. The therapy, however, enjoys in the Directive a broad scope of freedom for each of the Member States designed in its policy, according to internal public order. It is therefore left to each State to decide on stem cell research (given the pluralism of society) with two conditions: where it is permitted, ensure the protection of the embryo, and prohibit the creation of embryos for research

[78] Under the Act, the embryos remaining in the fertilization treatments can be used for research, provided that donors have given their written consent. The embryos are not implanted into an organism and must be destroyed within 14 days after fertilization. The eggs and sperm can be stored in liquid nitrogen for 15 years, for example in cases where a disease at an early stage of adulthood is causing infertility. After the period of 15 years, the eggs and sperm can no longer be used in the investigation and must be destroyed.

purposes[79] because according to the European Group of Ethics, the creation of embryos for research represents a disturbing step in the use of human life like an instrument.

If the optics of the general interest is passed to the particular interest of those who financed the activity, the patent by its very nature is directed at the commercialization of the results. It is undeniable that the interest of funded research activity in a field like biotechnology, which requires large financial resources to invest, is to obtain a monopoly on the patented results and commercially exploit the invention, either directly, or after licensing to a third party - so as to recover the costs invested. In this sense, despite the present economic interests in this area, the public policy clause would prevent the commercialization of the results, which is a political triumph against the big biotech companies, at least for now, as a disincentive to research[80].

The fact of recognizing an area of freedom for each of the Member States to design its internal policy on embryonic stem cell research should not mislead the normative level of research activity with the patentability of the results. In other words, freedom is left to each State to design its policy on stem cells research; another thing is that, although allowed the research, the patentability and the commercialization of the results would be prohibited. The fact that the Directive classifies non-patentable

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[79] The general rule, under which states in Article 15 of the Oviedo Convention of 4 April 1997 for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, is that scientific research in the field of biology and medicine are carried out freely, "subject to the provisions of this Agreement and other legal provisions ensuring the protection of human beings". Art.18 under the heading "Research on embryos in vitro, provides: "1. When experimentation on embryos *in vitro* is permissible under the law, it shall ensure adequate protection of the embryo. 1. It prohibits the creation of human embryos for experimental purposes".

[80] The Warf case drew international attention as it could reduce substantially the opportunities for companies to commercialize stem cell related inventions through patent monopolies. Remarks by Gareth MORGAN, a lawyer specializing in intellectual property from Taylor Wessing LLP (London). Font used: *Biotech Business Week,* July 7, 2008, *"Stem cell research; EPO highest authority to consider stem cell patents",* Section: EXPANDED REPORTING; p.2563. See also *The Scotsman,* May 19, 2008, Monday, 1 Edition. *"Stem cell sector awaits patent ruling",* by Peter Ranscombe Business Reporter. Section: p. 28.

inventions contrary to public order causes not only that national regulations draw up a list of the same classifications, but also a list of prohibited commercial exploitations. In other words: they cannot establish a list of patenting prohibitions for reasons of public order if not accompanied by a sanction of the exploitation of these inventions in their respective territories.

However, some European legal systems distinguish the effects of patenting on the basis that embryonic cells have been created for research purposes or for marketing purposes, accepting the patentability of the former and excluding the latter. Is there any point for distinguishing between commercial or industrial purposes and research purposes, to exclude from patentability the first, and accept patents on embryonic stem cells that are directed to research? Does it make sense to patent a non-market outcome after the invention? What advantage carries patent ownership of the invention if it cannot be marketed for reasons of public policy? In my view, this can only be understood as a key claim to acquire the rights to payment of royalties arising from the ownership of research for when, in the future marketing is allowed.

The Directive 44/98 prohibits the patenting of inventions that have used human embryos for industrial or commercial purposes. In general, the prohibition of patenting may be due to two legislative policy objectives, which I consider necessary to clarify: they can prohibit the patenting of discouraging research and production of a certain field, or leave it to individuals building processes of the invention when they are very cheap, without forcing them to pay royalties. Which one of these objectives should be banned? The answer is none other than the first, discouraging research and production, because it is known that the Directive represented a new configuration of a European patent in ethical issues but it is only the beginning and not the end of the discussions[81]. The public order clause that prohibits the patenting of the human embryos with commercial purposes was established in the Directive to discourage research and production in this area. However, it is not clear that all countries will remain consistent with this legislative policy.

[81] Richard GOLD and Alain GALLOCHAT, *op. cit.*, p. 347

Firstly, the prohibition of the use of human embryos for research or therapeutic purposes doesn't always go together with the prohibition of marketing. Germany, for example, prohibits the derivation of hESCs (except those created before 1 May 2007), but allows the importation (as much as the commercialization) of HESC lines[82], and the same happens in Italy.

Moreover, some jurisdictions that allow the derivation of embryos for scientific purposes and for ethical reasons prohibit the marketing, according with the literal sense of the Directive. Would it make sense then that the results of research could be patented with the means to achieve a monopoly of ownership of research even if the commercialization was prohibited? Of course this does not seem very

[82] In Germany studies in the field of human embryonic stem cell research are regulated by the Embryo Protection Act (EschG) from 1990 and the Stem Cell Act ("Law to Ensure the Protection of Embryos in Connection with the Importation and Use of Human Embryonic Stem Cells" [StZG] from 2002, modified in 2008). According to the Embryo Protection Act, the establishment of human embryonic stem cell (hESC) lines in Germany is prohibited by criminal sanctions. As an exception, hESC lines that were established in foreign countries before 01 May 2008 may be imported to Germany for research purposes (regulated by the Stem Cell Act). Such lines must have been established from "supernumerary" IVF embryos. This means from such embryos that were generated for purposes of reproduction, but no longer can be transferred to a woman. The evaluation is undertaken by an interdisciplinary "Central Ethics Committee for Stem Cell Research (ZES) composed of natural scientists, medical researchers and humanities scholars. It proceeds In accordance with the StZG and the resulting opinions are forwarded to the Robert Koch Institute which makes the final decision concerning the applications. On 10 November 2006 DFG released its statement "Stem Cell Research in Germany - Possibilities and Perspectives" with the aim To improve the basic conditions for stem cell research. On 14 August 2008 the German Parliament modified the stem cell act and made the following changes: - The qualifying date (deadline) for the import of hES cell lines was moved from 01 January 2002 to 01 May 2007, Allowing the import of hESC lines generated before May 2007. - The threat of criminal sanctions for German scientists and the scope of the Stem Cell Act has been limited to activities Carried out in Germany. Since the Stem Cell Act has come into force, 40 research applications (7 April 2009 status) for the importation of hESC lines have been approved (current list at http://www.rki.de). Nine of these hESC applications included the use of which would not have been permitted by the old 2002 version of the Stem Cell Act with the old qualifying date 01. January 2001. DFG is continuing its support for stem cell science. This year there is a joint call between the Chinese NSFC and DFG being evaluated addressing basic principles of stem cell biology. Information obtained from www.stemcellforum.org / about_the_iscf / members / deutsche_forschungsgemeinschaft.cfm

encouraging from the standpoint of investment, but in any case, there are jurisdictions that expressly permit it. Switzerland, for example, where the public order clause does not apply if the exploitation of embryos has research purposes (and expressly recognized this in their patent law)[83]. The patent is excluded only when the operation has commercial or industrial purposes. In my opinion, the commercialization of the invention is a natural element of the patent to recover the costs for investment, so it makes no sense to patent only for the purposes of research[84]. The only consistent explanation I can find is the allowing of patenting of ownership of research, and therefore we have an eye on possible future changes in the rule allowing the marketing of embryos, and eventually, having acquired the rights to payment of royalties for the licensing of exploitation.

II.3. Ethical implications

The real problem as regards the public order clause acting as a limitation for the patentability is to identify what exactly an embryo is.

Obtaining stem cells from human embryos creates the ethical problem that the embryo must be destroyed to extract its inner cell mass, because so far science has failed to obtain cells from the blastocyst without destroying the structure that surrounds it[85]. The problems about what it means to be human in a pluralistic society like Europe are large, as

[83] The possibility of patenting the uses of embryos for research is complemented by an open system of the obtained results to the public, establishing the need to publish the results of research carried out in subordinate employment and public funds.

[84] The distinction between research and marketing does not make sense for EPO. The reason is that just as he holds a patent for a product has the right to third parties shall not use or produce the product without its consent, the claim of the product involves its possible commercial or industrial exploitation, notwithstanding the intent of the patent applicant may be another, like using the product for future research. EPO decision, Case G 0002/06: "... as someone having a patent application with a claim directed to this product has on the grant of the patent the right to exclude others from making or using such product, ... making the commercial or industrial product remains exploitation of the invention even where there is an intention to use that product for further research. ...".

[85] BERIAIN, *La clonación, diez años después,* Granada 2008, *op. cit.*

noted by Geertrui VAN OVERWALLE. Some authors consider that non-viable embryos, which do not lead to a birth, such as those created by parthenogenesis, or by somatic cell nuclear transfer (cloning) are not covered by the exclusion. Others believe that the use of embryos that involves their destruction is contrary to human dignity[86].

There are also those who oppose to the creation of surplus embryos with the means of investigation but don't find a problem using the surplus embryos from *IVF,* or importing cell lines produced in other countries, or simply the extraction, if possible, the cells from the blastocyst for this purpose[87]. The issue is the question. BERIAIN[88], quoting two major supporters of this thesis: United States of America and Germany: "In both cases the moral background becomes the same: it is wrong to destroy embryos to create stem cells, but once they exist, it would be a gross irresponsibility not to benefit from them for the advancement of life sciences. In USA, the ban on embryo experimentation using public funds did not extend to the embryonic cell lines already in existence, nor to those created through private funding. In Germany, meanwhile, though it is forbidden to create embryos for these purposes, it is possible, although subject to many restrictions, to import cell lines obtained in other countries"[89].

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[86] VAN OVERWALLE, G.: "Patentability of human stem cells and cell lines", in *"The Ethics of Patenting human genes and stem cells." Conference Report and Summaries. Held in Copenhagen 28 September 2004, Organized by The University of Copenhagen. The Danish Council of Ethics Biotika.* www.biotik.dk/sw293.asp. p. 21.

[87] BERIAIN, *La clonación, diez años después, op. cit.,* p. 104.

[88] An example: the WARF arguments before the EPO, which stated that the patents that claim the current use of human embryos should be rejected as contrary to morality, but not claiming a product derived from human embryonic cells, although primordial origin wrap isolate the product destroys the embryo.

[89] BERIAIN, *La clonación, diez años después*, *op. cit.*, pp. 106 y 107: The advocates of this hypothesis argue that if a teenager is killed, that should not stop us when we need to use their organs to save other lives, because nobody in their right mind would believe that this will increase violence against adolescents. His view therefore is that one can distinguish between two different acts, destruction of the embryo and the use of their cells, and both are likely to be classified as morally independent.

Opponents to this argument think that the two events are inseparable from a moral standpoint, because they belong to a single set: If one creates embryo cell lines it's only because he wants to use them for research, and vice versa, if one uses these lines, he knows that they have been generated for this purpose. If Germany prohibits the destruction of embryos, but allows the import of lines created in other countries it is because they think that would be enough to continue with their research. In the U.S the possibility of the public research projects to buy cell lines generated with private funding hidden in the investment of the creation of these lines[90].

II.4. Towards a redefinition of Human embryos

On the other hand, new biotechnological inventions have helped to focus the terms of debate, not on whether or not the embryo is a person, but whether the technique is able to generate embryos.

If we look at the Spanish legislation, it's noted that they sought to carefully preserve the traditional biological definition of embryo, considering as such the result of the fertilization. While it's true that opting for the unorthodox way of dividing this figure in two different

[90] On August 9, 2001, President Bush banned the expenditure of public funds for research in HESTCs from that date on the basis that blastocysts have a moral equivalent of people. For Russell KOROBKIN, ("Recent Development in the "Stem Cell Century: Implications for Embryo Research, Egg Donor Compensation, and Stem Cell Patents in Jurimetrics, Vol 49, No .1, 2008, pp. 51-71, *op. cit*. pp. 53, 56) the potential of embryonic stem cell research justifies the investment of public funds, regardless of the consequences that arise for embryos used in the creation of cell lines and the circumstances in which such embryos were created, unable to defend the position that blastocysts have a moral equivalent to that of humans. They have none of the attributes that give people a unique morality. Certainly worth a deference of treatment compared with adult tissues, but not as individuals. At this point, about respect and deference they deserve treatment, the blastocyst, it is worth noting the distinction between reality that destroys human embryos and research using cell lines derived from destroyed embryos. Just as the distinction between research on embryonic stem cell lines when derived from surplus embryos from in vitro fertilization (line respects are accepted), and the creation of embryos solely for research purposes (via less respectful of the blastocyst).

concepts, that of the pre-embryo and the embryo itself[91] Thus the concept is limited to the entity resulting from the merger of male and female gametic material until 56 days later[92].

It has been emphasized the need to promote a new definition of human embryo and characterize them not only by their origin but by their inner qualities, namely its potential to become a person, as has been reflected in some laws, such as Germany, Belgium, the Netherlands, and Japan. Moreover, the prospect of cell structure, as pluripotent or totipotent is the decisive criterion for the purpose of research and patentability in the intellectual property office of the United Kingdom[93].

German law provides in its paragraph 3.4 a definition of embryo: "an embryo is any human totipotent cell that has the ability to divide and become a human individual provided that the required necessary conditions are met"[94]. In Belgium, the embryo is defined as a "cohesive cell or cell system with capacity to develop and lead to a human person"[95]. In the Netherlands as a "cell or group of cells with capacity to develop and become a human being"[96]. In Japan as "a cell - except a germ cell- or cells that can become an individual through their development

[91] BERIAIN, *La clonación. Diez años después, op.cit.*, pp. 108-109.

[92] BERIAIN, "The concept of embryo in the Law 14/2007 of 3 July, biomedical research," in Salome ADROHER, Federico MONTALVO BIOSCA and JÄÄSKELÄINEN (Directors): *Los avances del Derecho ante los avances de la Medicina,* ed. Aranzadi, 2008, pp. 991 and on.

[93] Go to the following address: http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn-stemcells/2009203.htm

[94] Act respecting the protection of the embryo in relation to the importation and use of embryonic stem cells of human origin (Law of stem cells) of 28 June 2002.

[95] See Belgian Chamber of Representatives, *Bill Concerning Research on Embryos in vitro,* December 23, 2002.

[96] See Kingdom of the Netherlands, *Embryo Act,* September 1, 2002.

in vitro of a human or animal, and has not yet begun the formation of the placenta"[97].

In summary, given the need to redefine the concept of embryo, the formula that has more adherences is using the concept of potentiality[98], although, to avoid counter-intuitive (and impractical) ideas that sperm and human eggs are also people[99], it is necessary to distinguish between the ideas of potentiality and possibility, and even, following BERIAIN, going beyond, it is feasible to differentiate, in fact, up to three concepts: active power, passive power and possibility. In this way, and using his words, an embryo *in vitro* has active power because simply it's not necessary to intervene, and it's enough to let nature take its course and develop into a person ...An embryo *in vitro,* in contrast, has only passive power because even if it contains sufficient information to create a human being is not in the right environment to do so. Finally, a embroider body, i.e. the result of failed fertilization, would have neither power nor possibility of creating a human being.

Furthermore, the invention of the technique of somatic nuclear transfer has previously required stating if these nuclei of an egg are human embryos or not. What kind of potential would they have? It appears that the current state of the ontological structure responds to a pluripotent cell, not totipotent, and therefore, "the vast majority of them do not have any potential to develop as individuals"[100]. So, they are not an embryo in a strict sense.

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[97] The author, BERIAIN, *op.cit*.,1005, uses the translation text from the Inter-University Chair BBVA Foundation-Provincial Government of Biscay in Law and Human Genome, Código de Leyes sobre Genética *(II),* Bilbao-Granada, ed. Comares, 2007.

[98] See BERIAIN, La clonación, diez años después, *op.cit*, pp.113 and 117-120 for theories of the supporters of the ontogenesis and epigénesis.

[99] BERIAIN, *op.cit*., pp. 124 and on.

[100] BERIAIN, *op.cit.*, pp. 125-126, and 128. See also Osuna CARRILLO DE ALBORNOZ / Andreu MARTÍNEZ, "Investigación con preembriones. Comentario a los arts. 15 y 16 de la LTRHA", in Corbacho GOMEZ (dir.), Iniesta DELGADO (coord.) Comentarios a la Ley *14/2006 de 26 Mayo de Técnicas de Reproducción Humana Asistida,* Navarra 2007, pp. 483 to 511.

One argument that has been recurrently used against techniques of nuclear stem cell transfers come from the need they have to use vast quantities of human eggs as the only means to create human cell lines. But the problem that arises is that it is too complicated to get the number of eggs needed because the removal from a woman's body is no longer just painful and uncomfortable, but also dangerous[101].

Two possible alternatives are mentioned by BERIAIN: Allow the economic consideration of the eggs (although in his view women would be subjected to unlawful harassment, even if they gave their informed consent).[102] Another alternative would be the use of eggs from other species through the creation of chimeras and hybrids between humans and animals[103]: "The problem with this solution is, however, that in the opinion of many, would be a serious attack on the dignity of the human species as a whole, and would most likely be rejected by the majority. From the opposite point of view however, it is conceivable that prohibiting this kind of research would be, at a time, a serious attack against the principle of beneficence, as it would deprive thousands of people the possibility of benefiting from their results. In another view, a loss of valuable opportunities to improve our understanding of how biological embryo and gamete mechanisms function. These arguments, in fact, have a very substantial importance that made the British government, after announcing its intention to prohibit the application of this kind of technology, to decide to turn back, and finally, to permit this kind of experiment, but subject to strict controls[104].

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[101] BERIAIN, La clonación, diez años después*, op.cit*., pp. 133 and on.

[102] In the U.S., given the narrow legal confines (The Human Cloning Prohibition Act, 2001) the technique could be illegal, regardless of funding source, but the Senate failed to clarify so that there is no federal legislation banning the cloning therapy, although some states have enacted laws expressly prohibiting it. The problem is different: since the technique requires egg donation, experience shows that women are not willing to donate for free, since the law in many of these States consider it unethical to pay for the eggs.

[103] BERIAIN, La clonación, diez años después*, op. cit.,* p.135.

[104] Cfr. http://www.hfea.gov.uk/en/1517.html

With respect to the use of other techniques, we must agree, following BERIAIN that creation of unfertilized egg cells and subsequent destruction for obtaining stem cells does not have any problem from an ethical standpoint[105]. In contrast, ANT, (Altered Nuclear Transfer)[106] to alter the structure of the resulting cell when it was set up as such, what it does is to destroy the once already constituted embryos, rather than avoid that they come to exist[107].

As regards the OAR (Oocyte Assisted Reprogramming)[108], if this technique prevents the embryo from coming into being, the effect caused is to eliminate any potential before the appropriate conditions for the development. This fact removes all reasonable ethical doubt. Finally, the technique of iPS[109] doesn't generate any serious ethical problems, because this technique relies on the alteration of genes in a somatic cell, in a way that it behaves as if it were a pluripotent cell[110].

II.5. Conclusion

In the way of concluding ideas, summing up the questions analysed in this Chapter, we can put forward the following:

First. The disparity of rules and criteria as to what can be patented, and with respect to embryonic stem cell research originates several implications. The first is that notwithstanding that there are alternative routes to European patent application, as demonstrated by the UK - although rarely used, given the irony that the original motivation of the Directive, which was to ensure the hospitality of the laws of European patents for biotechnological inventions from other countries, not only has

[105] BERIAIN, *op. cit*., p. 129. See pp. 48-49 for an explanation of the experiment.

[106] For an explanation of the method, pp. 49-51.

[107] Beriain, op.cit., p. 130.

[108] For a detailed explanation of the method, see pp. 51 and on.

[109] Description of the method on pp. 52 and on.

[110] BERIAIN, *op.cit.*, p. 131.

not been accomplished, but quite the opposite: the patents in USA, Korea, Japan and other countries outside Europe, cannot find a place in Europe. The question then is whether a single system would be desirable for biotechnology patents throughout Europe. Undoubtedly yes, but poor countries' firms in the sector (including Spain), are not in favor because by retaining the power to decide what is patentable and what not in this area, protects their own businesses, which would not be forced to pay large sums for the assignment of licenses for the exploitation of inventions in these areas.

Second. It seems evident the need for common ground for a proper definition of the term "embryo", which is a priority both for the legal practitioners as for researchers. This would clarify further the regime of patentability, which in my opinion, should not be excluded when embryonic stem cells have been created according to a method that has not destroyed embryos strictly, in order to improve the health of population. The patent can be extended to research and/or marketing[111].

Third. The need for an international code of stem cell research is the situation in Europe regarding standards for research on embryos and embryonic stem cells highlighting the great disparity in this field and the result of cultural diversity that exists in Europe. This should lead us to conclude the need to encourage a public debate on these issues. In this sense, it has been highlighted by Professor Bartha Maria KNOPPERS, the need for an international code of stem cell research, to help overcome the ethical barriers in this field of research[112]. Renowned scientists and

[111] One of the challenges posed to the EPO, not explicitly resolved yet, had to do with technological innovations. Methods for generating stem cells from "non-viable" "triploid zygotes", the nuclear transfer technique abnormally creating blastocysts which can not implant in the uterus, but are capable of generating stem cells, or finally, the technique to produce stem cells through biopsy of an embryo in its own right, without interfering with the process their development, in recent years they raised the need to overcome the ethical issues related to stem cell research and whether if the viability of the organism, id est, its potential to develop during pregnancy, is a necessary condition for classification as an embryo for that purpose, or whether the destruction of the embryo in the proper sense is a necessary condition to reject the patent. See "The patentability of human embryonic stem cells in Europe. Applicants in Europe are left with few options for the patent protection of hEScell-related technology", *Nature Biotechnology,* vol. 24, No 6, June 2006.

[112] See the text of the declaration www.stemcellecharter.org

organizations have signed the Charter of stem cells, writing that refers to the Charter of the World Health Organization 1946, which stipulates that "enjoyment of the highest attainable state of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition". To that end, the Stem Cell Charter upholds the following principles:

1. Responsibility to maintain the highest level of scientific quality, safety and ethical probity.
2. Protection of citizens from harm and safeguarding of the public trust and values.
3. Intellectual Freedom to exchange ideas in the spirit of international cooperation.
4. Transparency through the disclosure of results and of possible conflicts of interest.
5. Finally, Integrity in the promotion and advancement of stem cell research and therapy for the betterment of the welfare of all human beings.

CHAPTER III. THE SPANISH LEGAL ABORTION REFORM IN 2010[113]

III.1. Introduction

Comparative Law -and in particular European Legislations- has shown us that there is no unanimity on the constitutional legitimacy of the voluntary interruption of pregnancy. The protection of the antenatal life, in the form of a foetus or embryo understood as a life project, has gone through very different difficulties. However, it must be admitted that nowadays the appropriateness of punishing the voluntary termination of pregnancy and the goodness of legislative solutions which ensure the mother's freedom of choice are being questioned. In any case, a trend towards liberalization regarding abortion within certain limits has been lately observed in the European legislation. A good example of this in our country is the recent discussion on the bill of the Organic Law on sexual and reproductive health and voluntary termination of pregnancy.

In this way, this Chapter has a limited purpose. On the one hand, we shall analyze the European Comparative law's solutions to the matter of the voluntary termination of pregnancy. On the other hand, we shall report the existing solution in the current Spanish law, which is a consequence of the decriminalization of abortion in 1985. All this aims at examining and fitting the constitutionality of the above-mentioned bill. Furthermore, the final purpose of these pages will be to reflect on the constitutionality of the bill, if there is some. However, we would like to anticipate our agreement to the reform, for we believe it is perfectly compatible with the article 15 of the Spanish Constitution, interpreted under the jurisprudence of the Constitutional Court.

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III.2. The voluntary interruption of pregnancy in the European context

III.2.1. Constitutional Views

The voluntary interruption of pregnancy is mentioned in almost no European Constitution. The reasons for this are varied.

Firstly, there is a group of Constitutions which have been valid for a long time (although they might have been amended), that either do not contain a bill of rights (fundamental or constitutional laws regarding the form of the Government) or do not specifically acknowledge the right to life on their dogmatic part. These texts are rooted in the liberal constitutional tradition of the nineteenth century and the first third of the twentieth century, and it is known that the right to life became considered as a constitutional right in the Human Rights International Law and in Europe especially after the Second World War.

A second group of Constitutions, which have been created more recently, and which are rooted in the Social and Democratic State based on the rule of law do explicitly guarantee the right to life, although they do not mention the voluntary interruption of pregnancy or the legal status of the unborn child. The lawmaker does not mention if the respect and the inviolability of life or the universal right to life also refer to the unborn child[114].

The only exception is the Irish Constitution, which ensures the constitutional protection of the unborn child[115]. According to the so-called pro-life amendment ratified by the referendum of 1983, "the State acknowledges the unborn child's right to life and, as long as possible, undertakes to defend and enforce such right while not losing sight of the mother's equal right". It is specifically acknowledged the obligation of

[114] Articles 5.2 of the Constitution of the Republic of Greece, 24 of the Constitution of the Portuguese Republic, 2.2 of the Constitution of the Federal Republic of Germany and 15 of the Spanish Constitution.

[115] Art. 40.3.3º.

public authorities of making laws which respect the antenatal life and protect efficiently the unborn child´s life expectancy, although the pregnant women right to life must be also taken into account. Therefore, the lawmakers will be responsible for evaluating and balancing the existing interests.

The silence in most European Constitutions about abortion could be interpreted as an implicit assertion that there can be no official position or decision from the State regarding an issue which affects the most intimate beliefs of the human being. However, this is not the interpretation which has finally succeeded in nearly all the European jurisdictions, which have understood that, the State might have a legitimate interest in protecting the foetus as a legal right. The Constitutional Court in Germany has a classical point of view on this respect, understanding that Basic Law for the Federal Republic of Germany is referred to every living human being, including the unborn child[116].

Therefore, antenatal life must be defended as an independent right. Thus, the legislation on the interruption of pregnancy is perfectly acceptable, and the lawmaker is empowered to take a formal decision on this matter. This decision might be in any case controlled by the Constitutional Court in order to make a reasonable balance of the conflicting constitutional rights.

III.2.2. Legislative Options

The legislative options regarding abortion could be grouped, at least theoretically, into five models or paradigms.

Firstly, there are some countries which sanction abortion in all cases. In these countries the protection of antenatal life seems to be a right without limits and it prevails over any other legal right. This is the case of Chile, El Salvador or the Dominican Republic.

[116] Judgment of 25/02/1975.

Secondly, there exists the absolute liberalization as an option. In this case, the mother's right to decide whether to have a child or not prevails over the protection of the unborn child under any circumstances. Therefore, the mother's freedom of choice prevails over anything else. However, there is no country in the world where this kind of solution is applied. Although Canada and Puerto Rico have very tolerant legislations, they do not take the woman's right to control her own body to that extreme.

Faced with these two extremist positions, European comparative law has been applying more balanced solutions for decades, trying to reconcile the protection of the unborn child's life with the pregnant woman's autonomy and freedom. Thus, it is created a relationship of conditional primacy among the constitutional conflicting rights and values, taking in consideration the circumstances of each case and the requirements of the principle of proportionality. However, there are different kinds of laws regarding this matter in Europe[117].

Some European countries allow abortion as long as it is performed within a period of time from the beginning of pregnancy. Therefore, abortion is not considered a crime as long as the mother applies for it in the above-mentioned period of time. In that case, as long as the woman respects that time limit, she can decide freely about her pregnancy. Thus, the mother autonomy and freedom prevail over the unborn child's life expectancy during that period. The differences and particularities of the different legislations are related to the period extension, the informative sessions and awareness actions preceding the abortion. For example, in France women are free to decide until the 12th week of pregnancy (the two first weeks from the first day of the missed period are not taken into account, since they are considered as a reasonable period of time when the woman is not certain about her being pregnant or not).

In Holland, where more permissive time limits have been set, women are allowed to abort during the period of time between the conception and the foetal viability, which is the moment when the foetus

[117] MOTILLA DE LA CALLE, A., "La legalización del aborto en el Derecho comparado", *Anuario de Estudios Europeos*, 8, 1992, 133-144.

can survive outside the uterus without medical care. However, first it is necessary to receive psychological advice and wait at least 5 days before performing the abortion. In practice, abortions are done until approximately the 24th week of pregnancy, although this limit is being questioned by a significant part of the Dutch medical community, because according to the current scientific criteria, a foetus can be considered viable before the 24th week of pregnancy. Therefore, some scientists consider convenient to cut the upper limit from 24 to 22 weeks. In any case, abortions after the first quarter must be performed in authorized hospitals.

Those countries which have chosen a system of indications allow abortion when some circumstances concur as provided by law. In principle, abortion is illegal but the law does not sanction this practice if there is a conflict of legal interests. In this way, the protection of antenatal life is sacrificed when some specific rights and values appear and the lawmaker has regulated it.

Basically, in some extreme situations the woman cannot be asked to behave heroically, because that is not the objective of criminal law. There are usually four types of indications:

a) When the pregnancy means a risk for the mother's life or health (therapeutic indication).

b) When there is a chance of physical or mental abnormality in the developing foetus (genetic indication).

c) When the pregnancy is the result of a rap (ethical indication)

d) When the woman or her family's social situation is the cause of the abortion, as abandonment, the inability to take care or educate the child or the number or previous children of the family (socio-economic indication).

The countries´ legislations differ in admitting all these indications or only some of them, or having a time limit or not.

In Ireland and Malta abortion is only legal if the pregnant woman's life is in danger. In Poland it is allowed on the first twelve weeks of pregnancy in case of incest, rape or foetal malformations. However, if

there were some risk for the mother's health, there is no time limit for the abortion.

In Luxembourg the time limit is up to the first twelve weeks of gestation in case of rape or due to socio-economic reasons. From that date, abortion is only allowed if the pregnant woman or foetus´ physical or mental health is in danger. In Finland abortion is allowed if there is some mental or physical risk for the mother (with no time limit), if the foetus has serious malformations (until the 24th week), if the pregnant woman is under 17 years old (until the 20th week) or in case of rape or socio-economic problems (until the 12th week).

In the United Kingdom women can abort until the 24th week of pregnancy in case there was a health risk for the mother or she had social or economical problems.

However, in case of serious risk or foetal malformations, there is no time limit. The last and prevailing solution in Europe is the combination of the time limit system and the system of indications. It is often described as a system of indications respectful with the woman's decision. According to this system, women can freely decide up to a point on time. When that period of time is over, abortion is only permitted in some exceptional circumstances. Also, although there are several legislative options regarding this matter, there exists a prevailing model, which establishes a 12-week time limit combined with indications regarding serious risks for the mother or foetus. Thus, in Portugal the decision can be taken up to the 10th week of gestation. Afterwards, abortion is allowed in case of foetal malformations, when the pregnancy is the result of a crime against sexual freedom or when there is a risk for the mother's mental or physical health. In Italy, the time limit corresponds to the first 90 days of pregnancy. After those days, abortion is only allowed when the mother physical or mental health can be in danger, which also includes congenital malformations in the foetus.

In Germany women can decide freely if they want to have their child until the 12th week of gestation. After the first quarter, abortion is only permitted when the mother's physical or mental health is in danger or when there is no chance for the foetus to live.

In Austria and Belgium the time limit is also 12 weeks. From that moment, the abortion can only be performed when there is a risk for the

pregnant woman's mental or physical health or when the foetus has serious malformations.

In Greece, after the first twelve weeks abortion can only be performed when the woman is under age, when the pregnancy is the result of a rape or incest (until the 19th week) or when foetal malformations are found (Until the 24th week).

In Denmark pregnant women are allowed to abort up to the 12th week from the last day of their period with no restrictions. After those twelve weeks, abortion can only be performed upon permission of the corresponding regional medical council. The council decision may be appealed. However, the council permission is not necessary if foetal malformations are found, if the mother's physical or mental health is in danger or if she is immature or mentally disabled.

In Sweden women decide by themselves up to the 18th week. When that time limit is over, abortion must be authorized by a medical council, which normally occurs when the mother's health is in danger.

The countries with the lowest percentages of abortions (Germany, Holland and Belgium) have, as shown, tolerant legislations. It is not a coincidence that their academic curricula include courses on sexual education.

III.3. Spanish Constitutional Jurisprudence as regards the voluntary interruption of pregnancy

Spain is one of the European countries that use the system of indications. The Organic Law 9/1985, which amends the article 417-bis of the Criminal Code, allowed abortion in three circumstances: when a pregnancy seriously endangers the life, mental or physical health of the woman, when the woman has been raped (up to the first twelve weeks) and in case there was a chance of the child to be born with serious physical or mental disabilities (up to the 22nd week). This kind of legislative option could be described as a general prohibition with exceptions. The Spanish Constitutional Court on the decision 53/1985 ratified the constitutionality of the system of indications in pursuance with the following criteria:

a) The right to life is an essential and fundamental right and also an ontological supposition which allows the people to hold the rest of their rights. Given the importance of this, it requires from the lawmaker to act in the permanent task of configuring the law[118].

b) Life implies a complex biological process which starts at gestation and ends with death. However, it must be admitted that the moment when the unborn child can live independently from the mother has grown in importance119.

c) The unborn child does not hold the right to life but as it is understood as life in development, it is legally protected under article 15 of the Spanish Constitution. Therefore, the Government has two duties with respect to the mother and the unborn child. The first refers to not interrupting or hindering the natural process of gestation. As for the second one, it shall establish a legal system for the defence of life, meaning an efficient protection of it120.

d) The legal protection of the unborn child's life expectancy is not unlimited and it can be sacrificed when there appear some other constitutional rights or values according to the principle of proportionality. The lawmaker must assess the conflicting situations which cannot be observed only from the perspective of the unborn child's life protection. More specifically, criminal lawmaker can legalize abortion when those legal values appear, without that meaning that public authorities do not still have the duty of protecting the developing life121.

That is the case of the *therapeutic*, *ethical* and *genetic* indications. From the constitutional perspective, the lawmaker's decision on partially legalizing abortion cannot be censured when that practice can endanger

[118] Section 3 and 4.

[119] Section 5.

[120] Section 7.

[121] Section 7, 8 and 9.

the woman's physical or mental integrity, or harm the woman's right to be a convinced mother or the fact that appealing to the criminal penalty could make the mother or family behave in a way that exceeds what is normally required from them[122].

Furthermore, in case of the ethical and genetic indications, abortion must be performed within a time limit which is the same in the compared law systems. The time limit for the genetic indication is significantly higher than that of the ethical indication, simply because some diagnosis procedures can be only carried out from the first three months of pregnancy and require a period of observation.

Personally, we believe that the Constitutional Court applies its general criterion regarding the restriction of fundamental rights to the particular case of the right to life. Once the Constitutional Court has clarified in which sense the article 15 of the Spanish Constitution can apply to the unborn child, it then ratifies the thesis regarding the general limitations of the fundamental rights and the necessary requirements so a limit can be considered constitutionally valid. The Constitution protects legal rights, which are rights that the lawmaker has valued as positive because in his/her opinion, they must be especially protected.

There are different rights and interests to be protected and sometimes they come into conflict. The result of this is that limits are set upon a right in order to safeguard other constitutional rights and interests. In particular, when speaking about the protection of the unborn child, some matters cannot be ignored, for example, the free development of personality (article 10), the right to the physical and moral integrity (article 15), the right to the ideological and religious freedom (article 16), the right to the personal and family privacy (article 18.1) and the proportionality of the criminal penalty[123]. The protection of the unborn child can be sacrificed when some justified constitutional interests appear. However, a common requirement for the constitutionality of any measure restricting a fundamental or constitutional right is determined by the strict

[122] Section 11.

[123] Section 9 and 11.

observance of the principle of proportionality[124]. In this regard, in order to check whether a restrictive measure responds to that principle, the three following requirements must be met:

- That the measure is likely to achieve the proposed objective (*judgment of suitability*)
- That there is not any other measure more moderate to achieve that objective with equal efficiency (*judgment of necessity*)
- That it is a balanced measure, which means that it implies more benefits or advantages than prejudices over other rights (*judgment of proportionality in the strict sense*).

According to the decision 53/1985, these conditions appear in the cases of therapeutic, genetic and ethical indications. The three suppositions on the legalization of abortion which are stated on the Organic Law 53/1985, which amends the article 417-bis of the Criminal Code, serve a constitutionally legitimate purpose, without infringing the three requirements arising from the principle of proportionality.

III.4. The reform introduced in 2010 with the Organic Law on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy

The bill of the Organic Law 2/2010 *on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy* means a turnaround in the protection of antenatal life in the Spanish law. It involves the change from a system of indications into a law which combines time limits and indications. Actually, the project upholds the women's right to take a free and informed decision regarding pregnancy and that such decision is respected by others. The lawmaker has found it convenient to establish a 14-week period in which women can freely make a decision on this

[124] GONZÁLEZ BEILFUSS, M., *El principio de proporcionalidad en la jurisprudencia del Tribunal Constitucional*, Aranzadi, Madrid 2003.

regard. The woman will make a decision after having being informed of the aids, benefits and rights which she can have if she decides to continue with her pregnancy. She will also be informed about the medical, psychological and social consequences arising from both options. Also, she will be informed of the right she has to receive guidance before and after the abortion procedure. Furthermore, women shall have a period of reflection of at least three days from the moment that she is informed of the above-mentioned information until the abortion is performed[125]. However, it is possible to abort until the 22nd week of gestation for medical reasons, more specifically when there is a serious risk for the pregnant woman's life or health or there might be some anomalies in the foetus, which must be accredited by a previous medical statement carried out by two specialists different from the one who will perform the abortion[126].

However, in case of death risk for the mother, this statement might not be necessary. Unlike current legislation, a time limit when applying the therapeutic indication is set up. Therefore, in case there appears some risk for the pregnant woman's life or health after the 22nd week, an induced labour shall be convenient since it will reconcile the woman's right to life and physical integrity and the interest on the protection of the unborn child. After the 22nd week of gestation, abortion will only be allowed when the foetus is diagnosed with some anomalies which are incompatible with life (according to this, the conception of antenatal life as a constitutionally protected right shall not be any longer valid) or when is diagnosed with some incurable or serious illness. In these cases, a multidisciplinary medical committee shall authorize the abortion procedure under the current scientific criteria[127]. To end with, the bill establishes a number of actions and measures on the health and educational fields and requires the imposition of penalties in case illegal abortions are performed.

[125] Art. 14.

[126] Art. 15 a) and b).

[127] Art. 15 c).

Nonetheless, the constitutionality of the bill is a controversial question. The main argument against is that time limits contradict the Constitutional Court jurisprudence, since the unborn child's life expectancy cannot depend completely on the mother's freedom. In order to limit the protection of the unborn child, there must be some objective causes, for her only wish is not enough. A system which ignores without any reason the foetus´ life is not acceptable. If the State has the obligation of ensuring the foetus´ life, the legislation which establishes time limits is not compatible with the article 15 of the Spanish Constitution, because it creates a situation of complete lack of protection.

The necessary balance between the life of the unborn child and other constitutional rights and values requires the verification of a supposition of fact and the circumstances which exceptionally allow the sacrifice of the unborn child's life. On the legislation which establishes time limits there is not an external objective element which allows balancing the conflicting values. Therefore, this legislation does not fulfil the requirements established by the Constitution to limit the developing life. To put it in a nutshell, this argument assumes that there is a clear constitutional doctrine which implies the necessity of protecting the unborn child and also implies, in exceptional cases where there is a conflict of interests, the necessity of setting up a system which avoids the complete defencelessness of the unborn. The time limits´ legislation does not meet any of these two requirements which are derived from the article 15 of the Spanish Constitution.

However, we believe that this argument is only a fragmentary vision of the Constitutional Court’s jurisprudence and that it does not make a fair appreciation of the constitutional basis of the legislation on time limits, the significance of the conflict of interests caused by the voluntary interruption of pregnancy and the conditions of the woman's freedom of choice stated on the bill of the Organic Law. These conditions and basis support the constitutionality of the bill from the perspective of the principle of proportionality. The decision of having children and the voluntary interruption of pregnancy are directly linked to the person's dignity, the free development of personality and also are subject to protection through several fundamental rights, especially those which guarantee the moral and physical integrity (article 15), and the family and personal privacy (article 18.1).

The decision of being a mother and when to do it are one of the most private and personal matters of a person's life. According to the Supreme Court of the United States, it is "the most private and personal decision which a person can take in all his/her life"[128]. Thus, it would be part of that "personal and private space free from the knowledge and action of the others and which is necessary in order to have a minimum life quality according to our current culture"[129], as our Constitutional Court states.

More recently, the parliamentary assembly of the Council of Europe has also expressed its agreement on the "freedom of choice for women"[130]. Such decision shall be respected and the governments must guarantee that the voluntary interruption of pregnancy is an accessible and safe practice. Therefore, the State should not interfere more than it is necessary on this regard and should not either create rules based on beliefs about the life sense or the value of life which women do not share.

Thus, the legislation on time limits responds to a constitutionally legitimate purpose. Once this is said, it is obvious that only a law which establishes time limits can achieve this objective, that is, the respect to such an intimate decision and the woman's right to decide freely. According to the Constitutional Court's decision 53/1985, although the system of indications is respectful with the Constitution, it is not the only constitutionally acceptable system. What is more, we believe that the partial legalization of the voluntary interruption of pregnancy is an insufficient legislative option from the perspective of the woman's privacy. The necessity of justifying the interruption of pregnancy through some causes stated on the law does not match with the acknowledgment of a private space reserved for the woman. Therefore, it is obvious the appropriateness and necessity of the legislation on time limits, even more if it is taken into account that generally the decision of aborting is not

[128] Judgment 29/06/1992.

[129] Spanish Constitutional Court, Judgments 73/1982, 231/1988 and 57/1994.

[130] Resolution 1607 (2008).

randomly taken, despite not being present the suppositions related to the current indications.

However, normally it is conditioned by the personal, family and work problems associated to that minimum welfare which everyone has right to. As stated by the State Council on its decision on the bill, "the woman is not supposed to act in a bad faith or randomly when deciding whether or not to continue with her pregnancy". Furthermore, it is not easily conceivable that she may get pregnant wilfully in order to abort or that she aborts thoughtlessly. In case she may choose interrupting her pregnancy (assuming the physical, mental and affection consequences), it will be done considering the most serious causes, at least, subjectively speaking[131]. And subjective questions are the most personal and intimate ones.

III.5. Conclusion

The bill of the Organic law 2/2010 *on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy* declares the woman's freedom of choice within a series of balanced conditions which are provided in the strict sense. Above all, the woman's decision is limited to a period of time shorter than the 22 weeks which the World Health Organization considers as the time when the foetus can live independently from his/her mother and acquires his/her full human individuality (foetal viability). Furthermore, pregnancy can be only interrupted within the first 14 weeks after the woman being informed of the public rights, aids and benefits which she can use. In the words of the State Council, "while the foetus´ guarantees are increased, the mother is entitled to fully exercise her freedom of choice since it is a knowledge-based decision"[132]. Therefore, it is a free and informed choice although it does not promote abortion.

The Government may have a legitimate interest on the protection of the foetus as a legal right. Therefore, the legislation on the voluntary

[131] Opinion of September 17, 2009.

[132] *Ibídem*.

interruption of pregnancy is perfectly acceptable, although it must be respectful with the woman's fundamental rights and not unduly hinder the priority of her decision. The Government's reform is heading in that direction.

CHAPTER IV. THE OBJECTION OF CONSCIENCE OF THE SANITARY PERSONNEL BEFORE THE ADVANCES OF LIFE SCIENCES IN SPAIN[133]

IV.1. Introducing the topic

The denial to accept a medical treatment can come from the proper patient, since it happens in the cases in which the Jehovah's Witnesses are opposed to practice blood transfusions on them, or in the case of the professional of health who has to realize any precise sanitary intervention. These pages are going to deal with the analysis of the second objection, that concerning the active subject of the juridical sanitary relation.

Spanish Constitution of 1978 (from now on "CE") recognizes in Art. 43.1 like a governing principle of the social and economic policy, the right to the protection of the health. Art. 43.2 ads on its own that "it competes to public authorities the organization and monitoring of the public health through preventive measures and necessary services. The law will establish the rights and duties of all in the matter". Hereinafter, art. 51 establish that "public authorities will guarantee the defense of the consumers and users, protecting, by means of effective procedures, the safety, their health and legitimate economic interests".

The right to health is a one of those rights of the personality with legal configuration; which is complementary to the fundamental rights to life and to the physical integrity. It imposes all subjects, public and private, the negative obligation to abstain from committing actions that could injure the above mentioned juridical basic goods of individuals.

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To develop the mentioned right, it was approved Law 14/1986, the 25th April, *General Law on Health*, Boletín Oficial del Estado (BOE) No. 102, of 29th April 1986. It was ratified by Spain the *Agreement of human rights and biomedicine of the Council of Europe*, BOE No. 251, of 20th October 1999, in force in Spain from 1st January 2000, and the Law 41/2002, of 14th November, regulating the autonomy of the patient and the rights and obligations as regards information and clinical documentation, BOE No. 274, of 15th November 2002[134].

The alluded legal dispositions are seen in practice as a bill of rights and duties of the users of the health care, usually exposed in preferential place of the Hospitals, Clinics and Centers of Health[135]. If one detains in further analysis, one will verify that the sanitary personnel, besides taking care of the health of the individual and of the community, respecting the human life and the dignity of the person, it is bound to behave in a particular way and to respect the decisions of the patient. This situation puts in evidence the complexity of the regulation of the medical profession, which not only joins for juridical procedure, but also for ethical, technical and practical rules that derives of *lex artis* professionally[136].

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[134] The juridical frame in which we move to the purposes of this Chapter includes the Spanish Civil Code, the diverse special laws that take as a regular object a specific field or area of the sanitary activity, as the Law 42/1988, of 28th December, on *Donations and Utilization of Embryos and Human Fetuses, their Cells, Tissues and Organs*; the Law 41/2002, of 14th November, *on the Patient*; the Law 9/2003, of 25th April, *on Juridical Regime of the Confined Utilization, Voluntary Liberalization and Marketing of Organisms Modified Genetically*; the Law 44/2003, of 21st November, *on Regulation of the Sanitary Professions*; The Law 45/2003, of 21st November, *on Technologies of Assisted Reproduction* - that modifies the previous Law 35/1988, of 22nd November; finally, the Law 3/2005, of 7th April, which modifies previous Law 3/2001, of 28th March, *Regulatory of the Informed Assent and on the Clinical Records of the Patients*.

[135] www.juntadeandalucia.es/servicioandaluzdesalud/library/plantillas/externa.asp
www.juntadeandalucia.es/servicioandaluzdesalud/contenidos/derechos/derechosydeberes.htm

[136] For example, article 2.6 of the *Ley de la Administración Pública* arranges that "Every professional who intervenes in the welfare activity is forced not only to the correct service of technologies, but to the fulfillment of the duties of information and of clinical documentation, and with regards the adopted decisions free and voluntarily for the patient "

SEOANE RODRÍGUEZ[137], immediately after a report elaborated by an international group of experts under the cover of the *Hastings Center of New York*[138], considers that it has been replaced the traditional paternalism of the Medical Doctor, who usually would adopt decisions without bearing in mind the opinions of his/her patients but only on the basis of benefits which were providing to them from his/her knowledge and experience. That is, it is now that Medical Doctor respects the autonomy of the patient who can decide the therapies on his/her life or health.

Between the duty of the Medical Doctor to try to recover patient's health and the free will of the capable and informed patient to agree or to reject the reasonable treatment, it is placed the objection of conscience of the first one, as a denial to the fulfillment of certain juridical personal obligations that it considers opposite to her religious beliefs, deontology or morals[139]. It is evident that multiple and diverse objections of

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[137] SEOANE RODRÍGUEZ: *The perimeter of the objection of medical conscience*, Indret.com, Barcelona, October, 2009, p. 6.

[138] CALLAHAN, D. (dir.): *Los fines de la medicina. El establecimiento de unas prioridades nevas*, Fundació Víctor Grífols i Lucas, 2004, Barcelona, accessible in http: // www.fundaciongrifols.org/docs/pub11%20esp.pdf. He concludes that the economic, social, scientific changes and axiology demand to adopt a different point of view and to appear again the purposes of the medicine, to adapt them to requirements of our time. The above mentioned ends are four, without hierarchy among them: 1) The prevention of diseases and injuries and the promotion and conservation of the health; 2) the relief of the pain and the suffering caused by the ilnesses; 3) the attention and the treatment of the patients and cares to the incurable ones; 4) the avoidance of the premature death and the search of a calm death.

[139] GOMEZ SANCHEZ: "Reflexiones jurídico-constitucionales sobre la objeción de conciencia y los tratamientos médicos", *Revista de Derecho Político* n º 42, 1997, p. 63. The author holds that four elements constitute the objection of conscience: juridical norm, conscience, conflict between(among) both and manifestation of the affected one.

NAVARRO-VALLS y MARTÍNEZ TORRÓN: "La objeción de conciencia al aborto", en *Libertad ideológica y derecho a no ser discriminado,* Consejo General del Poder Judicial, Madrid, 1996, p. 57. They defend that in the sanitary objection the collision is produced between the right of the pregnant to use a legal mechanism and that of the objector not to being discriminated or burdening by his your conduct. PRIETO SANCHÍS: "Libertad y objeción de conciencia", *Persona y Derecho,* 54/1, 2006, pp. 259-273.

…

conscience can exist (e.g. to compulsory military service, to the practice of abortion, to receiving specific medical treatments, to the payment of taxes, to being elected as member of a Jury, or to receiving certain education) but very few ones have been legally developed[140].

IV.2. Juridical regime and nature.

The Spanish Constitution expressly deal with the objection of conscience to the military service (art. 30.2 CE), as an exception to the obligation, equally constitutional, of defending Spain under art. 30.1 CE - which, at the moment, it is suppressed for her Additional Disposition 13ª of the Law 17/1999, of 18th May, on *the Regime of the Personnel of the Armed Forces*. The objection of conscience is regulated in the Organic Law 22/1998, of 6th July on *the Objection of Conscience and the Social Substitute Service* requiring that the discrepant one realizes an alternative task in benefit of the Community –it is also postponed at present by Regulation 342/2001, of 4th April-.

It seems to me that in this point an attempt of distinction is imposed. Following FERRATER DWELLS, http://www.scribd.com/doc/2538434/Diccionario-de-Filosofia-Jose-Ferrater-Mora ,the bioethical is the science that studies the human conduct in the area of the sciences of the life and of the health, in the light of the values and moral beginning(principles) and the biolaw it is the part of the juridical classification that deals with the exercise of the medicine and with other sanitary or not sanitary professions linked directly with the health.

Morality derives from the Latin *mos-moris*, custom. It is the set of values, principles or procedure of behavior of a group that forms a coherent system in a certain historical epoch and that serves as ideal model of good socially accepted and established conduct. The ethics come from the Greek word *ethos* (Latin person *ethicus*) that we can translate today for character, habit, way of being, conduct. It neither expires nor suggests anything, only it evokes the kindness or evilness of the human acts, about what reasons originate and justify the moral guidelines of an individual or a group.

Deontology comes from the Greek *déon*: owed and *lógos*: agreement and it is the set of principles and ethical rules that, in our case, must inspire and guide the professional conduct of the doctor.

[140] See, for instance, in the judgment of the Spanish Constitutional Court 216/1999, juridical reasoning 3rd dealing with objection of conscience formulated by a candidate for juror in the moment of his incorporation in the list.

Of equal form, the Spanish Constitution allows the clause of conscience of the professionals of the information in its art. 20.1.d), which it has been disciplined by Law 2/1997, of 19th June. But no norm has been applied to the objection of conscience of the sanitary professionals.

It had to be the Constitutional Court, in the foundation 14º of its the judgment 53/1985, of 11th April, solving the unconstitutionality of the Organic Law 9/1985, of 5th July, *on legalization of the therapeutic, ethical and eugenic abortion*, who exhibited that the objection of conscience is one of the powers that form a part of the content of the fundamental right to the ideological and religious freedom recognized in the art. 16.1 in the Spanish Constitution[141].

Later, in its judgment 160/1987 of 27th October, the Constitutional Court started considering the objection as an exception to the fulfillment of certain duties. It is, thus, an autonomous right of constitutional but not

[141] "(...) It is necessary to indicate, as regards the right to the objection of conscience, that it exists and it can be exercised with independence of it having been legally regulated. The objection of conscience forms part of the content of the fundamental right to the ideological and religious freedom recognized in the art. 16.1 of the Constitution and, like this Court has already indicated in diverse occasions, the Constitution is directly applicable, especially as for fundamental rights". See also the judgment 15/1982, of April 23rd, of the same Court.

This first doctrine has been repeated by the Supreme Court in judgments of January 16th and 23rd, 1998, abounding in its direct effect. The judgment 3, of 23rd April, 2005, returning to the classic conception of the objection of conscience and treating to the pharmacist, indicates that the constitutional content of the objection forms a part of the ideological freedom recognized in the article 16.1 of the CE (judgment 53/85), in narrow relation with the dignity of the human person, the free development of the personality (art. 10 of the CE) and the right to the physical and moral integrity (art. 15 of the CE), which does not exclude the reserve of an action in guarantee of this right for those sanitary professionals with competitions as for prescription and dispensation of medicines.

Cfr. PRIETO SANCHIS, AND GASCON ABELLAN: "Los derechos fundamentales, la objeción de conciencia y el Tribunal Constitucional, in *Anuario de Derechos Humanos*, No. 5, 1988; RUIZ MIGUEL: *El aborto: problemas constitucionales*. Centro de Estudios Constitucionales, Madrid, 1990, p. 108; GASCON ABELLAN, M.: *Obediencia al Derecho y objeción de conciencia,* Centro de Estudios Constitucionales, Madrid, 1990 and ESCOBAR ROCA: *La objeción de conciencia en la Constitución española,* Centro de Estudios Constitucionales, Madrid, 1993.

fundamental nature, though related to the religious and ideological freedoms in art. 16. Consequently, it is covered by the resource of protection of fundamental rights. Without its constitutional or legal recognition, objection of conscience might not be exercised and thus, it would not be sufficient to liberate the citizens of constitutional or "sub constitutional" obligations for motives of conscience; otherwise, one would run the risk of trivializing the juridical mandates.

Furthermore, the Constitutional Court stated that the objection of conscience with general character, that is to say, the right to be exempted from the fulfillment of the constitutional or legal duties for turning out to be opposite to own convictions, it is not recognized in our legal system nor in any other legal system, since it would imply the denial of the idea of State (see the judgment 161/1987, of 27th October of the Spanish Constitutional Court, in its Juridical Reasoning 3rd)[142].

The objection of conscience of Medical Doctors, Pharmacists and Nurses is foreseen and ruled in their own rules of professional conduct. Art. 26 of the *Code of Ethics* of 10th November 1999, *on Medical Deontology*, determines that the Medical Doctor, for reasons of conscience, has the right to refuse to advise patients of the methods of regulation and of assistance to reproduction, to practice sterilization or to interrupt a pregnancy. It will report without delay of his abstention and will offer, in his case, the opportune treatment to the problem for those who have consulted him.

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[142]Recently, as for objection of conscience of some parents to their children being taught "Education for the citizenship" in primary and secondary schools, the judgment 1013/2008, of 11th February 2009 of the Spanish Constitutional Court, indicates: "The only situation in which Constitution contemplates the objection of conscience opposite to the exigency of a public duty is that foreseen in its article 30.2. We have to repeat that the doctrine of the Constitutional Court only has allowed, out of this case, the right to protest for motives of conscience of the sanitary personnel that it has to intervene in the practice of the abortion in the modalities in that was legalized… The Spanish Constitutional Jurisprudence, in sum, does not offer base to affirm the existence of a right to the objection of conscience of general scope."

I coincide with MARTIN SANCHEZ, *op. cit.*, "The objection of conscience …It should be recognized as a general right, of fundamental nature".

Medical Doctors will always respect the freedom of the interested persons to looking for the opinion of other Medical Doctors. They also must think that the personnel collaborating with him may have his/her own rights and duties. The Medical Doctors will be able to communicate to Professional Colleges their *objectors of conscience* condition to any effects, especially when the above mentioned condition of objector may create administrative conflict in his/her professional exercise of functions. The College will provide objectors with advice and necessary help.

On December 14th, 2000 the Assembly of Pharmaceutical Colleges in Spain approved the *Code of Ethics and Deontology of the Pharmaceutical Profession*. It's Art. 28 expressly allude to the right of objection in the following terms: "The responsibility and personal freedom of the pharmacist authorizes him/her to exercise this right to the objection of conscience respecting the freedom and the right to the life and to the health of the patient". Art. 33 also say that the Pharmacist will be able to communicate to the Pharmacists' College his/her objector's of conscience condition to any relevant effects. The College will provide him/her with the necessary advice and help.

Art. 22 of the *Deontologist Procedure for the Exercise of the Profession of Nursing in Spain*, approved with obligatory character by Resolution 32/1989 of the General Council of Nursing of Spain, establishes that in conformity with Article 16.1 of the Spanish Constitution, Nurses have in the exercise of their profession, the right to the objection of conscience that will have to be due explicit before every concrete case. The General Council and the Colleges will guard in order to avoid that any nurse could suffer discrimination or prejudice because of the use of this right.

Authors disagree when looking at the objection of sanitary conscience. Some of them consider it as a collision of the rights of the professional with those of the patient. Other authors see it as a case of struggle between two sanitary duties, the juridical one of acting and the mulberry tree of abstaining. They are authors who think of it as a

commitment between a duty and a right, or even as a conflict between values[143].

Here I will support that the deontological rules, in spite of being mulberry moralities, have full juridical efficiency, because it is the proper Law that directly make reference to them in order to fix the content of the rights, duties and responsibilities of the sanitary professional[144]. See, *e.g.*:

a) Article 1.258 of the Civil Code forces to the parts in a contractual relation not to fulfill only the expressly agreed, but also all the

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[143] SIEIRA MUCIENTES: "The objection of sanitary conscience from the constitutional perspective", Presentation of the Congress of Sanitary Law, Spanish Association of Sanitary Law, Madrid, 25-10-1997, pp. 4. The author thinks that a conflict of interests exists between the freedom of conscience and the right not to be discriminated for ideological reasons of the sanitary professional; and the right to the freedom of company in his slope of exercise(fiscal year) of the power of business management, if it is a question of a relation deprived of work, and the principle of hierarchy and the good functioning of the public service, if the professional is in a statutory relation or civil servant of the Sanitary Administration. The sanitary director of public institutions can object as natural person, but not in name of the institution. Also it might be done by the directors of the private or compound centers who have an ideology to safeguard his proper religious identity. And, equally, the pharmacists might object, when there are asked they to provide medicines with micro abortive action. The judge objector to the abortion that meets immersed in a process of integration of the will of the minor that it wants to abort has the right - duty to abstain to save the impartiality in his labor, with base in the reason of abstention of "having direct or indirect interest in the lawsuit or reason".

SEOANE RODRIGUEZ: "La relación clínica en el siglo XXI: cuestiones médicas, éticas y jurídicas", *Derecho y Salud,* 16/1, 2008, pp. 11. He admits that the objection protects in the moral individual integrity, it seeks to guarantee the respect of the above mentioned integrity and of the ideological freedom and of beliefs of the doctor (art. 16 CE). To avoid the arbitrariness and the abuse of the objection of conscience is precise to fulfill certain conditions, between them its individual and exceptional employment and its foundation in personal veracious, authentic reasons of ethical or religious nature and of certain entity.

HERRANZ RODRIGUEZ: *La objeción de conciencia en las profesiones sanitarias,* Scrpta Theologica, Núm. 27, 1995. He holds that the objector reacts against conducts that, though socially allowed, he estimates inadmissible or perverse. He does not try with his action and in an immediate way, to subvert or to change the political, legal or social reigning situation; but it tries itself to excuse, simply, pacifically of certain actions, without, as a result of it, it has to suffer discrimination or resign rights.

[144] See previous footnote No 136.

consequences that, according to his nature, are similar to the good faith, to the use and to the law.

b) Art. 5 i) of the Law 2/1974, of 13th February, of Professional Colleges, exposes that it corresponds to the Professional Colleges to arrange in the area of his competition, the professional activity of the collegiate ones, guarding over the ethics and professional dignity and over the respect due to the rights of the individuals, as well as to exercise the disciplinary faculty in the professional and collegiate order.

Art. 28 of the Law 10/2003, of 6th December, of Professional Colleges of Andalusia, orders that the professional activities will have to develop in conformity with the deontology of the profession.

Under the protection of the above mentioned laws are dictated the Internal Statutes of the Professional Colleges later approved by means of Royal Decree, which its legal nature is out of question[145].

c) Art. 4 of the *Oviedo Convention for the protection of the human rights and the dignity of the human being with regard to the applications of the Biology and the Medicine*, of 4th April 1997, proclaims that "any intervention in the area of the health, included the experimentation, will have to effect inside the respect to the norms and professional obligations, as well as to the applicable policies in every case".

d) Art. 19, b) of the Law 55/2003, of 16th December, on the *Frame Statute of the Personnel in the Health Care Services*, forces them to "to exercise the profession … with observance of the technical, scientific, ethical principles and deontologist that are applicable".

e) Article 4.5. of the Law 44/2003, of 21st November, on *Ordination of the Sanitary Professions*, arranges that the sanitary

[145] By means of Order of May 23rd, 2008, (*Boletín Oficial de la Junta de Andalucía*, BOJA, of 10th June), one proceeds to the adjustment of the Bylaws of the Doctors' Official College of the province of Seville; the Bylaws of the Pharmacists' Real and Illustrious Official College of the Province of Seville was approved on order of 30th December 2005, BOJA 31/01/2006 and the Order of 15th December 2008, approved the Bylaws of the Official College of Infirmary (Nursing) of Seville and arranged its inscription in the Record of Professional Colleges of Andalusia, BOJA of 20th January,2009.

professionals will have as guide of their performance the service to the society, the interest and health of the citizen to whom they give the service, the rigorous fulfillment of their deontologist obligations determined by their own professions in conformity with the in force legislation, and of the criteria of norm-practice or, eventually, the own general uses of their profession.

f) Art. 41.2, of the same legal body, with regard to the rendering of services for foreign account in private centers, prescribes that the sanitary professionals are obliged to exercise the profession, or to develop the set of the functions that have assigned, with loyalty and with observance of the technical, scientific, professional, ethical and deontologists principles that are applicable[146].

[146] Such deontological procedure approved by Professional Colleges enjoy juridical effects if the laws makes direct reference to them (judgements of the Spanish Constitutional Court 89/1989, of 11th May and 194/1998, of 19th October). This Court in its judgment 219/89, of 21st December, affirmed that deontological procedures are not a catalogue of moral duties, but they have consequences of disciplinary type; that establish a series of duties of obliged fulfillment, for what they cannot diminish to advices it brings over of a desirable behavior; and that, according to both, the collegiate tradition and the jurisprudential doctrine of the Spanish Supreme Court, they have a quality of compulsory law for the collegiate ones (Juridical Reasoning No. 5).

As it was indicated in the judgment of 5th December 2006 of the Spanish Supreme Court, the normative sanitary frame, and, therefore, the content of the professional duty that it regulates, does not think of backs to the set of procedure of moral character that it forms the code deontological or of professional conduct. That such rules, for his ethical or moral content, lack in yes same coercive force it does not mean that they do not serve to form juridical principles that they rest on certain values or ethical conceptions, which affect in the medical practice and serve to define the content of the professional duties that must be fulfilled in the sanitary activity. Thus, the procedure of deontology professional and the bylaws of the professional colleges use as guide, and in a decisive, not alone way to fix the protocols of medical action, but specially to value the conduct of the physician and his adequacy to the diligence of a good professional, to the dictations, in sum of *lex artis* ad hoc. There can be known that the system of responsibility for fault rests in an ontological or ethical concept, which is that of the diligence, and that from the General Law of Health and, more recently, from the Law 41/2002, of November 14, of the Patient, one pleads for the integration of such moral principles in the set of rules that regulate the medical activity, and, for ended, for his integration in the compulsory proper content of it.

It is convenient that the Deontology and the Bioethics not only *perfume* the interpretation of the procedure, since they discipline relations man-to-man, but also they *inspire* the legislator, particularly in the matters that concern fundamental rights as the life, the physical and moral integrity, the freedom or the equality. In consequence, the development of one's faculty to differ for reasons of conscience, which integrates the essential content of the fundamental freedoms of conscience and religious, should be done by organic law (under art. 81.1 of the Spanish Constitution and doctrine of the Constitutional Court[147]). Nevertheless, if such regulation is not carried out, it will be always evocable before the ordinary Courts of Justice and before the Constitutional Court, since his level of protection is the reinforced one in art. 53.2 of the Spanish Constitution.

IV.2.1. Subjects

In the Spanish Law the sanitary objection is admissible in three situations: the practice of the abortion, the fulfillment of the previous instructions and the pharmaceutical dispensation[148].

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[147] From an interpretation that must be restrictive, for the exigency of absolute majority for his approval (see the judgments of the Spanish Constitutional Court 160/1987, 127/1994) the Constitutional Court has delimited the notion of development as general regulation of the right or freedom or as ordination of essential aspects of his juridical regime (this way, judgments 93/1988, 173/1998), including likewise the laws that establish restrictions of such rights or freedoms (see also its judgment 101/1991).

As for the rights and freedoms affected, the Spanish Constitutional Court declared itself ready for self-restraint included in the Section 1st of the Chapter II of the Title I of the Constitution (see its judgment 76/1983). That is, as regards the articles 15 to 29 CE.

ROMEO CASABONA: "La objeción de conciencia en la praxis médica", *Libertad ideológica y derecho a no ser discriminado,* Consejo General del Poder Judicial, Madrid, 1996, p. 93. This author indicates that the norm that should regulate the objection will have to refer to the persons who might take refuge in it, acts included in the objection, procedure of his allegation and explicit or implicit repeal and organizational measures to replace the objector.

[148] NAVARRO VALLS AND MARTINEZ TORRON: "La objeción al aborto", *Revista General de Derecho Canónico y Derecho Eclesiástico del Estado,* 9, 2005, p. 2. They understand that, with regard to the right to the objection of conscience of the Judges in the cases of minors' abortions that they differ from his legal representatives, it seems that a …

In general, all the sanitary professionals can object: the graduated in Medicine, Drugstore, Deontology, Veterinary, Psychology, Chemistry, Biology, Biochemistry, as well as other graduated in Sciences of the Health, such as Infirmary, Physical Therapy, Occupational therapy, Chiropody, Optics and Optometry, Dietetics and Human nutrition[149].

In addition it can be done by the Pharmacists, Researchers and Judges, in the terms we will verify soon.

IV.2.2. Sanitary areas where objection of conscience operates

If we attend to *lex artis ad hoc*, to the practice and to the ethics, then, objection of conscience can be exercised as regard actions that could injure the rights to the life, in his beginnings or in his ending, and the rights to the physical integrity and to the moral indemnity.

This way, not only the provocation of abortion, but also the contraception, especially, the post-coital; the voluntary sterilization; the assisted reproduction; the destructive research of human embryos; the selective preconception of sex; the hunger strikers' forced nourishment; the transfusions of blood; the transplant of organs; some interventions of psychosurgery; certain experiments on human beings or animals; the suspension of medical treatments; the participation in the execution of the death penalty; the medical cooperation to the suicide and the euthanasia, among others[150].

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judicial defender would be necessary to designate. The Judge may restraint invoking direct or indirect interest in the lawsuit if reasons of conscience were contaminating him, preventing him from being impartial.

[149] See Arts. 6 and 7 of the Law 44/2003 of 21st November, on *Regulation of the Sanitary Professions*.

[150] ALISENT AND OTHERS: *Ética de la objeción de conciencia.* Fundación de Ciencias de la Salud, Madrid, 2007, studies as field of the objection, the clinical relations. See also SANCHEZ-JACOB: "Objeción de conciencia y su repercusión en la sanidad", *Boletín de Pediatría* 47, No. 199, 2007, http: // www.sccalp.org/bulletins/17, p. 27. He indicates at this regards: the accomplishment of the abortion; the therapeutic cloning; to carry out some transplants; the voluntary sterilization; the limitation of the therapeutic effort; the application …

IV.2.3. Justification of the objection of conscience

One might think that, once certain actions have already been legalized, such as the abortion or the sterilization, it is unjust that the Medical Doctor refuses to accomplish such actions with regards those who request them, even more considering that such actions are freely and subsidizedly offered by sanitary services. Nevertheless, one another could hold that, in an advanced, careful society of the rights and freedoms of his citizens, nobody can legitimately be obliged to execute an action that is contravening seriously his moral conscience. I personally support this second view. In my opinion, It is not difficult to the objector to reject, as part of his professional work, the practice of certain skills on a double basis[151]:

a) Ethical basis, firstly, because such actions objected injure the maximum respect due to the human life. This reason may opposite to all the legal "indications" of the abortion (vital risk for the mother, fetal malformation, consecutive gestation to violation or hypothetical socioeconomic need of the woman), but only the two firsts, therapeutic and eugenic abortion, need genuinely medical knowledge from the objector.

According to the Deontological rules[152], the Medical Doctor is a servant of the human life and of the dignity of the person. He/She only

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of some technologies of assisted reproduction and genetic diagnosis preimplantational; the prescription of emergency contraception (AE); the vaccination; the practice of the circumcision; transfusions of blood, especially in the group of the Jehovah's Witnesses; minors' adoption by homosexuals; and document of previous instructions.

[151] See CEBRIA GARCIA: "La objeción de conciencia al aborto: su encaje constitucional", I3, *Derecho Eclesiático del Estado, Anuario de la Facultad de Derecho de Extremadura* Vol. 21, 2003, pp. 105 to 107 and the doctrine that he mentions.

[152] They enunciate the Hippocratic Oath: "I swear for medical Apollo, for Aesculapius, Hygia and Panacea, swear for all the gods and all the goddesses, taking them as witnesses, to expire faithfully, according to my loyalist to be able and to deal, this oath and commitment: To venerate like my father to whom it taught his this art, to share with him my goods and to attend him in his needs; to consider his children to be my brothers, teaches them this art free if they want to learn it; to communicate the vulgar rules and the secret educations and everything else of the doctrine to my children, and to the children of my teacher and to all the awkward pupils and that have given oath according to custom, but to nobody more. In all …

can practice the abortions legally authorized, upon a free will, and it is his/her duty to provide the sick or healthy embryo fetal with the same assistance that is offered to other patients, including the informed consent of his/her progenitors.

b) Scientist – professional basis, on the second hand, because finishing with a life can be a solution to any but not to all medical problems. This point faces up the so called therapeutic abortion, since experts can offer valid alternatives of treatment that respect the life of those not yet born. In the same form, as regards eugenic abortion, which seeks to eliminate the fetus affected by infections or serious malformations, this scientist basis is valid because it is strange to the medicine the idea of human beings have to be free of blemishes.

I coincide with HERRANZ when he answers those who deny the objection by saying that some professions imply the previous acceptance for their subjects of a certain *status* which determines and limits their freedom of action in certain circumstances. That is to say, assuming this view would suppose that selecting a professional career or the commitments derived from certain working functions demand someone to loose some of their inherent rights as person! Furthermore, the conditions that the sanitary professional must respect are not identical at all time. When he/she began professional career graduated, was it assumed the duty to practice abortions, euthanasia's or to distribute contraceptives? The already above mentioned obligations, existed in the Law, or in the

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that it could and knows, I will use of the dietetic rules to the benefit of the patients and will separate of them any damage and injustice. I will never give anybody mortal medicine, for much that they request me, I nor will take any initiative of this type; neither I will administer abortive any woman. On the contrary, I will live and practice my art of holy and pure form. I will not carve calculations, but I will leave this the surgeons' specialists. In any house that between, I it will do for good of the patients, separating of all voluntary injustice and of all corruption, and principally of any shameful relation with women and boys, already be free or slaves. Everything what sees and hears in the exercise of my profession, and everything what it will know brings over of the life of someone, if it is a thing that it must not be spread, I will keep silent about it and will guard it with inviolable secret. If this oath will expire complete, happy I live and let's gather the fruits of my art and let's be honored by all the men and by the most remote posterity. But if I am a transgressor and perjure, me agree the opposite."

Jurisprudence, or in the Protocols and Rules of *lex artis*, or in the Deontological Codes of Profession?[153]

IV.3. Classes of sanitary objection in Spain

IV.3.1. The objection of conscience to the abortion

According to the Spanish Constitutional Court and the already mentioned Deontological Codes of Medical Doctors, Nurses and Pharmacists, the sanitary professionals can object to the abortion, legalized today in three already above-mentioned suppositions: serious danger for the life or the physical and psychic health of the pregnant woman; when the pregnancy was a consequence of a violation; or in case it was presumed the existence of serious physical or psychic tares in the fetus.

Is it the abortion to be considered a right of the pregnant woman? Thus, is the sanitary professional obliged to practice the abortion in respect of such a right? In order to solve these questions, ORTEGA GUTIERREZ has analyzed the diverse existing positions of Spanish constitutional nature as regards the abortion, summarizing them as follows:

First. The Law simply does not punish any form of the crime; consequently, it does not grant a civil right to the pregnant woman to the abortion nor it impose a duty on the Medical Doctors to practice it. If there is no legal obligation, the objection of conscience would not be necessary.

Second. The right of the pregnant woman for an abortion to be practiced is developed in the Regulation 409/1986, on *Sanitary Accredited Centers and Obligatory Informs for the Legal Practice of the Voluntary Interruption of the Pregnancy*. It is not yet a constitutional duty nor a right for anyone, but just one obligation over the civil servants and labor workers carrying their functions in the Sanitary Administration.

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[153] HERRANZ RODRIGUEZ: *La objeción de conciencia en las profesiones sanitarias, op. cit.,* pp. 120 and 121.

Third. The pregnant woman is a holder of an interest juridically protected which confines the right of the sanitary workers to exercise freedom of conscience under art. 16 CE.

Fourth. The pregnant is a holder of a fundamental right to decide as regards her body according the arts. 10, 17 and 43.1 of the Spanish Constitution[154].

Those legitimized to exercise the right to the objection of conscience opposite to the abortion are Medical Doctor and the personal collaborator - Anesthetists, Matrons, Technical Sanitary Assistants, Nurses-, as well as the Specialists entrusted to express the obligatory informs. Any of them who directly takes part, or cooperates necessarily by means of procedures and activities directed to determining the voluntary interruption of the embarrassment, may exercise objection of conscience to abortion. Can refuse to the practice it both, the material author or dominant operator of the conduct and the mediate author who is served as instrument of the third one who executes it. Furthermore, my view is that they are also objectionable preliminary labors (reports and previous opinions, sedation, placement of routes, shaved, monitoring, control of expansion or alertness of the vital constants), as they are principal and indispensable accessories to reach the result.

On the contrary, it must be understood that it is not covered by the right to the objection of conscience the rest of workers giving their services in a Center credited for the practice of the abortion: watchmen, stretcher-bearers, administrative receptionists, cleansers or cooks.

Authors seem to be divided with regards the possibility for public or private legal person to exercise objection, since they lack an "individual conscience". I understand that if this legal private o public person has juridical personality and capacity different and separated from

[154] ORTEGA GUTIERREZ: "The objection of conscience in the sanitary area", *Revista de Derecho Público*, No 45, 1999, pp. 124 to 126.

its members, then, it can support a proper ideology and refuse in block to carry on with abortive practices[155].

IV.3.2. The objection of conscience to the previous instructions

This kind of objection supposes the rejection for the sanitary personnel that attends patients of the dispositions that one of them has ordered to follow in a future in case he/she is incapacitated to take or to demonstrate decisions on his/her medicals cares, as consequence of a serious physical and/or mental deterioration. The previous instructions are foreseen in the article 11.1 of the Law 41/2002, of November 14th, *Basic of Autonomy of the Patient*.

Most of the Autonomous Communities in Spain have legislated on the so called "vital last will" and have created the corresponding records. Some of them also have recognized expressly the right of the sanitary professionals to formulate objection of conscience respect of the fulfillment of previous instructions (see, e.g. art. 3.3 of the Law 3/2005, of 23rd May, of the Community of Madrid; art. 5.3 of the Decree 168/2004, of 10th September of the Autonomous Community of Valencia, or art. 6 of the Law 1/2006, of 3rd March, of the Autonomous Community of the Balearic Islands)[156].

The 17th, March 2010 the Parliament of Andalusia passed by unanimity the *Law of rights and guarantees of the dignity of the person in the process of the death*, known as "Law of Death in Dignity", that does not regulate the objection of conscience of the sanitary ones. Between its principal aspects, it limits the therapeutic efforts, prohibits the therapeutic cruelty, allows the patients to reject a treatment that prolongs his/her life

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[155] *Ibidem,* pp. 114 and 115. With regard to the ownership of fundamental rights for legal persons and groups without personality: BONILLA SANCHEZ, J.J.: *Personas y derechos de la personalidad,* Reus, Madrid, 2010, especially, pp. 283 to 360.

[156] See GONZALEZ SANCHEZ: "The objection of conscience of the sanitary personnel to the previous instructions for religious motives", in Some controversial questions of the exercise of the fundamental right of religious freedom in Spain / cords. Isidoro MARTIN SANCHEZ, Marcos GONZALEZ SANCHEZ, 2009, pp. 275-295.

in an artificial way and gives coverage to the palliative sedation to relieve the suffering of the patients though it could "shorten his life "[157].

IV.3.3. The pharmaceutical objection of conscience

It is necessary to indicate that according to art. 108 of the Law 25/1990, of 20th December, on medical drugs, it is considered to be a serious infraction the denial to distribute medical drugs "without valid reason". In consequence, this objection would include to the refusal to facilitating certain remedies for professional –its irrelevancy or uselessness -or ethical reasons, e.g. because they may cause effects which can be considered an outrage against the ideology, religion or moral beliefs of the apothecary-.

The Supreme Court of Spain in the judgment of 23rd April, 2005 has affirmed that the constitutional content of the objection of conscience forms a part of the ideological freedom recognized in the article 16.1 of CE. It is in narrow relation with the dignity of the human person, the free development of the personality (art. 10 CE) and the right to the physical and moral integrity (art. 15 CE) and it reserves an action in guarantee of this right for those sanitary professionals competent for prescription and dispensation of medicines.

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[157] According to the journal elpais.com, 17.03.2010, the Andalusian law is the first one of Spain that arranges the rights of the terminal patients and the obligations of the professionals who attend to them. The norm recognizes the right of the Andalusian citizens to declare his vital early will, which will have to be respected as is established in the Statute of Autonomy. The law written with the agreement and the contributions of more than 60 groups, it admits the right to receive, or not if this way it is wished by the patient, clinical veracious and understandable information about his diagnosis, in order to help him in the capture of decisions. Also there develops the right of the patient to receive treatment for the pain, including the palliative sedation and the elegant palliative integrals in his domicile providing that they are not counter indicated. The affected person will be able to reject or to paralyze equally any treatment or intervention, though it could put in danger his life.

In opinion of the journal elmundo.es, 17.02.2010, the People's Party claimed that the right was contemplated to the objection of conscience of the sanitary professional and that the definition of the members of the ethical committees was realized in the proper law and not the regulation, but PSOE (Spanish Socialist Party) and Izquierda Unida (United Left Party) have rejected it. The norm does not regulate the objection of conscience of the medical doctors.

Pharmacists can object to cooperating in the abortion, refusing to the production or direct dispensation of medicaments directly and explicitly abortive, or masked under the name of contraceptives, as the so called "morning-after- pill"; They also can object to provide with contraceptives that in some cases can act like abortive ones, or even to facilitate sanitary products that produce the abortion, such as the DIU, which not only prevents the sperm from reaching the ovum to fertilize it, but also is a barrier for a fertilized ovum sticks fast to the uterus.

Likewise, pharmacists can decline participation in the elaboration or traffic of tranquillizers or anesthetics capable of being used in the processes of euthanasia, or as a medical support to commit suicide[158].

IV.3.4. The objection of others who intervene on the life or integrity of thirds

All those who think that they can injure with their conduct the so called moral rights of the personality of thirds, have right to abstain of any action to this respect[159].

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[158] LOPEZ GUZMÁN: *Objeción de conciencia farmacéutica,* Ediciones Internacionales Universitarias, Barcelona, 1997, pp. 115 to 165. The author thinks that the following suppositions may appear: A) The office pharmacist of drugstore does not need to object when it can replace the objector; it cannot even object when there is danger for the life of the patient or situation of urgency. B) Researcher Pharmacist. It owes originally ethically fundamentally of respect and protection of the life and the health you humanize. In the moment of experimenting with human embryos, to part of having to respect the in force regulation in the matter, can raise his right to the objection of conscience in case in the contract that joins him with the laboratory there were not specified this types of experiments or researches by human embryos. c) The pharmacist of industry who has to make or elaborate abortive products takes part of the same previous solution. D) Respect of the pharmacist who is employed at the Administration, we have to consider the second paragraph of the article 87 of the General Law of Health of 1986: The personnel will be able to be changed of position into imperative needs of the sanitary organization, with respect of all the working conditions and economic inside the Area of Health. E) Pupil of Drugstore who, in accordance with the plans of study, has to realize practices in a drugstore. Here we are not before a supposition of objection of conscience since there is no norm that it forces the pupil to distribute, because it is there to learn.

[159] CEBRIÁ GARCÍA: "La objeción de conciencia al aborto: su encaje constitucional", *op. cit.,* p. 114. He indicates that the objection of conscience can also be invoked by the Judge …

For those who do research on Life Sciences, there is an initiative of the Spanish trade union *Comisiones Obreras*, which incorporates a proposition of law of objection of scientific conscience. According to which it can be kept out of operating anyone that under labor, statutory or civil servant link –including students and scholars-, is tied by activities of researching with eventual adverse consequences for environment, the live beings or the dignity and fundamental rights of a person.

It seems to be included in this kind of objection the genetic manipulations of microorganisms, plants, animals and human beings; its utilization and marketing; the liberation to the environment of organisms modified genetically; the interventions on the alive beings who cause disorders or organic, functional, psychological damages or alterations of conduct; pharmacological procedures or of any other nature; activities of research and development in armament, specially those focused on the development of weapon of massive destruction (nuclear, chemical or biological) and the technological treatments of the information, computer or internet, which concern the intimacy of thirds.

In any educational center, included Universities, it will be necessary to contemplate as optional the assistance to the laboratory practices when carrying on experiments with animals. It will be organized, before the beginning of the academic year, modalities of education that do not foresee activities or interventions of animal experimentation for the overcoming of the tests.

Anytime a request of objection before the Council of objection of conscience in scientific matter is introduced by someone, he or she is free to accomplish the invoked activities. The decisions of the Council would be dictated in 30 days and they are capable of resource of review, which resolution opens the contentious-administrative route[160].

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who must decide on the conflict of interests between the minor that wants to abort and her legal representative. It can abstain from resolving by direct or indirect interest in the matter, under the protection of the art. 219 *Ley Orgánica del Poder Judicial* (Organic law of Judicial Power).

[160] The text is available in http: // www.istas.ccoo.es/descargas/seg19.pdf

…

IV.4. Time and forms of exercising the objection of conscience

Objection of conscience can be invoked at any time, provided it has been communicated to those demanding the sanitary assistance, alternatively to his/her relatives or representatives as soon as possible, in order that they could choose another professional as a substitute. It is not necessary a special form or subsequent requirement of validity or efficiency of any type in order that the declaration of will is operative, though I think that it must be certified in the clinical history to evidential effects of such conduct being legally and ethically endorsed.

Nevertheless the previous considerations, professionals who object in the practice do it in writing to the person in charge of the Sanitary Service or his Professional College and their duties in such a case are determined by the concerned regulatory procedure[161].

The article 24 of the Code of Ethics and Medical Deontology arranges that the medical doctor only will be able to carry out an intervention that tries to modify the human genome with preventive, diagnostic or therapeutic purposes. It prohibits the interventions directed to the modification of genetic characteristics that are not associated with a disease and that try to introduce any modification in the genome of the descendants. Except in the cases that it is necessary to avoid a hereditary serious disease tied to the sex, the doctor will not use technologies of assistance to the procreation to choose the sex of the person that it is going to be born.

[161] The article 9 of the Royal Decree 2409/1986, of 21th November, establishes: The sanitary professionals will inform the solicitants about the medical, psychological and social consequences of the prosecution or interruption of their pregnancy, as far as the existence of measures of social assistance and of familiar orientation that could help them. They will also report on the requirements that, in any case, are reclaimable like the date and the center or establishment in which they can be practiced. Not accomplishment of the practice of the abortion will to be communicated to those interested with immediate character in order patients could with sufficient time go to another medical doctor.

Art. 26.2 of the Code of Ethics and Deontology prescribes that the medical doctor will be able to communicate to Medical Doctors' College his objector's condition of conscience to the effects that he should consider to be proceeding, especially if the above mentioned condition produces to him conflicts of administrative type or in his professional exercise. The College will give him the advice and the necessary help.

It seems to me to be neither suitable nor necessary that objectors' records are created in the sanitary centers, because it supposes elaborating an illicit database to reflect the ideological or religious beliefs of the professionals, which it would attempt also against the articles 16, 2 and 18.1 and 4 of the Spanish Constitution.

IV.4.1. Limits

The first one of them, evidently, is the guarantee of the public order protected by the Law *ex* art. 16. CE[162]. In this sense, art. 3.1. of Law 7/1980, on *Religious freedom* makes concrete the limits of the public order in the safeguard of the safety, of the health and of the public morality.

Following in this point to SIEIRA MUCIENTES, we have to suppose as restrictions to objection of conscience in the sanitary field, the following ones, providing that the businessman could not replace them in the accomplishment of the task controverted[163]:

For the linked labor objector: If in his contract it was stipulated that it had to make abortions or practices tending to the worthy death of the patient, he/she must obey the lawful instructions of the businessman who directs and controls the activity, being based on the freedom of company and on the attention to his organizational needs (art. 20 of the

[162] Only when he has justified himself in sedate judicially the existence of a certain danger for "the safety, the health and the public morality ",it is pertinent to invoke the public order as limit to the exercise of the right to the religious freedom and of worship. In addition, the adopted measure is provided and adapted to the purposes prosecuted (judgments of Spanish Constitutional Court 120/1990, of June 27th, 137/1998, of June 29th, and 141/2000, of May 29th; Judgments of the European Court of Human Rights in the cases Kokkinakis, Hoffman and C.R. c. Switzerland). To the margin of this exceptional supposition, in which necessarily the indicated cautions have to meet, only by means of firm Judgment, and for reference to the practices or activities of the group, there will be able to be considered accredited the existence of conducts opposite to the public order that they authorize to limit lawfully the exercise of the religious freedom and of worship (judgment of Constitutional Court 46/2001, of 15th February, Juridical Reasoning No. 11).

[163] SIEIRA MUCIENTES: *La objeción de conciencia sanitaria,* Dykinson, Madrid, 2000, p. 8.

Spanish *Statute of the Workers* of 1995). If it breaks them and refuses it will be able to be dismissed properly.

For the tied objector civil servant and statutorily linked with the Sanitary Administrations he/she is held by the requirements derived from the principles of hierarchy and of normal functioning of the service of health, that, for the present, they do not include the accomplishment of abortive practices inexcusably (arts. 20 and ff. of the *Juridical Statute of the Medical Personnel of the National Health Service* of 1966[164]).

IV.4.2. Effects

The objection cannot imply discriminatory consequences nor labor, economic or social prejudices for those who exercise it. Otherwise, it would be damaged the fundamental rights recognized in arts. 14 and 16 of the Spanish Constitution. The employer in the field of health services must have foreseen the opportune measures to replace eventual objectors[165].

I have already mentioned that the objector linked by labor relation who promised by contract to realize or to cooperate in abortive or in euthanasia practices cannot later object reasons of conscience for refusing to accomplishing them, and it could deserve to be dismissed properly in case he/she did it. Nevertheless, if the contract signed by him/her did not specify anything in the matter and the worker is dismissed as regards

[164] Art. 27 imposes on him the obligations to give personally his professional services to the protected persons who have to his cargo, when it was needed by the proper interested parties, by other medical doctors of the National Health Service or by the Inspection of Sanitary Services.

[165] According to art. 87.2 of the General Law of Health the sanitary personnel will be able to be changed of working position into imperative needs of the sanitary organization, with respect of all the working conditions and economic inside the area of health. On the other hand, art. 73.2 of the Law 7/2007, of April 12, on the Basic Statute of the Civil servant, prescribes that the Public Administrations will be able to assign to their personnel functions, tasks or responsibilities different from the correspondents to the working place that they had providing that they were adapted to their class, degree or category, when the needs of the service would justify it without wastage in the fee.

objection of consciousness, such measure will be qualified of inappropriate or void.

IV.4.3. Protection

The objection cannot justify that discriminatory measures are adopted against objectors, nor the demand from them of services that replace those which have refused to fulfill. The civil servant objector victimized with acts different to the foreseen ones will be able to contest them in administrative way; contentious- administrative ordinary or special of safeguarding fundamental rights.

Concerning the incidents in a private relationship of employment and with regards the statutory personnel not being civil servant, it will be applied the procedural rules foreseen in the *Law of Labor Procedure*, namely it will be observed the principles and guarantees that inform the labor and summary process of safeguarding of fundamental rights (arts. 175 to 181 of the *Law of Labor Procedure* 2/1995, of 7th April).

Professionals of the health contracted as well civil servants and the individuals in general will always have open the resource to the Constitutional Court for the protection of their freedom of objection of conscience recognized in art. 16 CE.

IV.5. Concluding remarks as regards the objection of the sanitary professionals in Organic Law 2/2010, of March 3, on Sexual and Reproductive Health and Voluntary Interruption of Pregnancy

Last 5th July, 2010 coinciding with the entry into force of new "law of the abortion" in Spain, one could wonder: what juridical nature has the voluntary interruption of the pregnancy for the Spanish Legislator?

Organic Law 2/2010 recognizes expressly the right to the freely determined maternity, as well as the right of all to adopting sovereign decisions concerning their sexual and reproductive life, with the limits

necessary for the respect to the rights of thirds and to the public order guaranteed by the Constitution and the Laws.

This new law grants to every woman, adult and minor[166], the faculty to resolve by her own the interruption of her pregnancy, because only she can have the last word on her body in the exercise of her rights of freedom, intimacy and personal autonomy.

The legislator conceives that the legal authority to abort is inside the right to the free maternity which, in turn, forms a part of the sexual and reproductive choice protected by means of the fundamental rights to the freedom and personal autonomy, to the physical and moral integrity and to the personal and familiar intimacy. In other words, protection is granted to women as regards arts. 15, 16 and 18 of the Spanish Constitution. That is, a protection directly linked to the dignity of the person and to the free development of the personality, which, we remember, is not fundamental rights but constitutional principles called to inspire all of them.

Those not yet born continue without being considered to be capable of showing the fundamental right to the life that the art. 15 CE guarantees. They are just holder of the juridical good "prenatal life" and the obligation for public authorities to protect it can be fulfilled by means of active policies of support to the pregnant women and to the maternity.

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[166] Art. 9.3. c) of the Law 41/2002, *on Basic Regulation of the Autonomy of the Patient and on Rights and Obligations as for Information and Clinical Documentation* arranges that the assent will be granted by representation when the patient minor is not capable intellectually not emotionally of understanding the scope of the intervention. In this case, the assent the legal representative of the minor will give it after having listened to his opinion if it has twelve years. When it is a question of not incapable minors not incapacitated, but emancipated or with sixteen fulfilled years, it is not necessary to give the assent for representation. Nevertheless, in case of action of serious risk, according to the criterion of the medical doctor, the parents will be informed and their opinion will be born in mind for the capture of the corresponding decision.

The Organic Law 2/2010, that we comment, gives new draft to the article 9.4 of the Law 41/2002, allowing that a 16-year-old woman could be informed and consent for herself on the voluntary interruption of her pregnancy, without putting it in knowledge of her legal representatives.

The supposed conflict between the fundamental rights of the woman and the mere interests of the prenatal human being who nests in her abdomen, is resolved by the Spanish Legislator by means of the mechanism of the weighting by which, instead of giving a harmonic and proportionate solution attending to the most disadvantaged, it gives absolute preference to the will of the woman, breaking with it his constitutional obligation to support the *nasciturus*[167].

The Organic Law 2/2010, in consequence, limits itself to specifying the conditions and requirements of the exercise for the mother of her dominion of interrupting freely her pregnancy in the first 14 weeks of gestation.

In what is called "threshold of the fetal viability", around the twenty-second week of pregnancy, the Organic Law 2/2010 allows the medical interruption of the pregnancy for vital or sanitary risk of the pregnant woman, or for eugenics reasons. Beyond the twenty-second week, the abortion can be practiced even by fetal incompatible anomalies by the life, or if there is detected in the fetus an extremely serious and incurable disease.

Abounding in the nature of the interrupting faculty in the woman, part of the essential content of several fundamental rights, the Legislator has to designate to those obliged to make it effective. That is, those are not other different that the public servicemen on Health Administration. The "sanitary service" will be provided to the pregnant woman in public or concerted centers and if it is not possible, in private ones sufficiently accredited. Those working in public health centers will be forced to be

[167] It seems that the legislator is partial to the thesis of the self-consciousness, which is the most extreme, and holds that a distinction exists between "being a person" and "to be biological human". The condition humanizes as such, that is to say, the alone belonging to the human species, it would lack ethical relevancy since it would be a mere "biological information". According to this thought, only in the measure in which an entity is alive, it expresses some type of self-consciousness, deserving to be admitted as "person". Neither in the embryo, nor in the fetus, nor in the newborn child one warns such a self-consciousness, nor psychological continuity exists. For this motive, the suppression of embryos and fetuses, and even that of newborn children with serious deficiencies, would be ethically acceptable. The body is a simple instrument to the service of the mind, where it really takes root in the personality.

formed in sexual and reproductive health, during their studies and along their professional carrier.

New draft is given to art. 145 of the Spanish Penal Code, which continues punishing with prison and incapacitation those who produce the abortion of a woman with her assent, out of the cases allowed by the law or out of an accredited establishment. The pregnant woman who produces her abortion or consents that other person causes it, out of the cases allowed by the law, will be punished by a sentence of fine.

A new article 145 bis is added to the Spanish Penal Code in order to sanction with fine and incapacitation the conducts of those who practice an interruption of the pregnancy inside the cases contemplated by the law, but without fulfilling the requirements demanded in the pregnant woman.

Organic Law 2/2010 keeps silence on the objection of sanitary conscience to the abortion, probably because the Legislator thinks that there cannot be invoked any longer opposite to the express attribution of a fundamental right of the mother of deciding on her body; or because the embryo or fetus, not being a person, holds only a mere interest but not a right[168].

The Latin word *persona*, drift of the Etruscan *phersu* and of the Greek *prósopon,* designated the masks used by an actor in order to the public could differ and recognize the different prominent figures that he

[168] The Council of State in his report to the project of law, of 17th September, 2009 treats the topic of the objection of conscience: "The draft bill submitted to consultation does not regulate the objection of conscience of the sanitary personnel in spite of that the matter that constitutes his object, and especially, the touching thing to the interruption of the pregnancy is, as it indicates the Fiscal Council in her report " one of the most controversial in the public democratic debate [...]On having penetrated the area of the convictions to be inserted in that of the conscience. In relation with the abortion, the Constitutional Court has declared expressly that " the right of objection of conscience exists and can be exercised by independence of which it has been dictated or not such a regulation [...] The objection of conscience forms a part of the content of the fundamental right to the ideological and religious freedom recognized in the article 16.1 of the Constitution. Since it has indicated this court in diverse occasions, the Constitution is directly applicable as for fundamental rights. [...] To this respect, the attention on the existing situation in the compared right, in which practically all the States of our environment have regulated expressly his exercise".

was interpreting. The *Civil Code* appropriated of the concept to mean that the attribution of rights and civil obligations happens to a human being for the Law in the moment in which this one acquires individuality, "becoming detached" of his mother.

It is amazing that to assume the right to the life in the year 2010, the Spanish Legislator continues needing the person's conditions born alive and civil viable according to the scientific, social and juridical reality that was reigning when the *Civil Code* was approved in Spain in 1888.

In 2009 Dr. CONDIC said that the phrase "human being" is very simple, meaning "human-like entity." It's another way of saying that a "human being" is a "human organism." Thus, to determine if a human has come into existence is a simple matter of biology, much easier to resolve than if a human person, which is the subject of human rights, has begun to exist.

When a human being does exist? The answer can be simple: after the union of sperm and egg generates a single cell, single-celled human zygote or embryo. To decide whether the cell is a human being, different from a simple human cell, is necessary to consider the contrasts between a cell and an organism. The key feature of an organism is that all its parts work together in a coordinated manner, as a whole for the benefit of the entity. In the case of single-celled human embryo, the scientific evidence clearly indicates that all parts of a zygote -which brings the mother and the father that brings together- work from the beginning in a highly coordinated manner to promote the life, health and maturation of the embryo.

The single-celled embryo functions as a body to generate the structures and relationships required for its own development programs and this is done from the first moment of the union of sperm and ovum onwards. From the beginning, the embryo serves as an organism and

therefore is a human being whole and complete member of the human species in the first stage of his life[169].

Already I have written in other occasions that the fundamental rights cannot be conceived as opposite realities that tend to enter conflict and that force the legislator or the Constitutional Court to considering and choosing some opposite to others, which are estimated of low range. All the identically protected rights in the Constitution enjoy analogous category and do not contend between themselves. What are faced indeed are the parts of the lithium, because one of them will have trespassed the limits of own rights and would have interfered in others' rights.

The abortion places the mother, holder of the rights to the independent life, to the integrity, to the intimacy and to the freedom of conscience opposite to her child, also carrier of autonomous life, though transitorily subordinated to her. In such a debate the Legislator can never prefer the will of the first over the life of the second, letting him/her undeniably defenseless[170].

In my opinion the denial of the sanitary professional to interrupt the pregnancy for reasons of conscience existed and it will continue existing after the Organic Law 2/2010. It is so because an expert in the matter who may think that inside the woman it develops a human alive being must respect his/her right and fundamental aspiration to continuing living must be opposed to causing his/her death[171]. This will be so even

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[169] Maureen L. CONDIC is Dean of the Westchester Institute for Ethics and the Human Person. See her work "When Does Human Life Begin?: A Scientific Perspective". *Confer* also the link http://www.westchesterinstitute.net

[170] On the solution of conflicts between constitutional goods, more acquaintance has produced to themselves between the freedoms of information and expression and right to the honor, the intimacy and the proper image. See BONILLA SANCHEZ, J.J.: *Persons and rights of the personality*, Reus, Madrid, 2010, especially pp. 70 and ss. and 109 and ss.

[171] ANDORNO, R.: *Bioethical and dignity of the person*, Madrid, Tecnos, 1998, and "The human embryo does it deserve to be protected by the right?", *Cuadernos de Bioética*, Vol. 4, No. 15, 1993, pp. 39-48. This author holds that the Bioethics demands three requirements to denote the personality before the birth: first, the embryo has to be provided with genetic uniqueness, that is to say, he has to be the absolutely original and unique being in the history of the Humanity from the same moment of his existence. The proper body of every person, that is to say, his physical particular and distinctive characteristics, they contribute in a …

though Organic Law 2/2010 thinks that the unborn creature lacks any right to life because, according to the Spanish Civil Code, he/she neither has born, he/she neither has personality nor is capable of rights and civil obligations. It will be so notwithstanding the conduct of the mother is legally covered as correct exercise of the essential content of several fundamental rights[172]. And the reason for such certainty is simple: because the limit to these rights of the mother must be found in the respect to the rights of the others, namely in the right of objection of sanitary conscience.

With such an attitude of rejection, public or private sanitary personnel do not infringe any duty of constitutional or legal nature, of spoiling the gestation, because such a charge is not imposed on them. What they do objecting it is to fulfill a professional oath and a deontological burden legally sanctioned of protecting in due form the human life in any of its stadiums.

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decisive way in the configuration of your self-consciousness, as well as in his effort for differing sufficiently from the others and of having a proper insertion in the society. Secondly, a biological continuity exists between the embryo and the adult who eventually is going to develop. The zygote will take exactly the same genetic information as a fetus, child and adult. In synthesis, if we admit that in the genome all the biological information is contained that gives structure of the new individual and if it is clear that the embryo already possesses this information, a strong argument exists to hold that the embryo and the child in the one that is going to develop are, from an ontological point of view, same and only one human individual. The third argument in favor of the personal status of the embryo is the autonomy of his development. Thanks to the genetic information with which it is provided, the embryo, far from being a mere passive entity, it has an active extraordinary aptitude to develop and to control and coordinate the diverse stages of his process of formation, though this autonomy is relative, to the effect that the embryo is enormously dependent on the mother habitat to survive.

[172] I share the opinion of the Consejo Fiscal (a Spanish Advisory Body at the uppest level as regards legislative proposals) in its report to the project of this law. Thus, I doubt its constitutionality on the grounds of the breach of the State of his obligation to protect the fetus and because a "right is not judicially conceivable to the abortion" as one more measure of planning of the reproduction. The mother cannot be recognized the right to eliminate a human alive, being different and dependent on her. The document is accessible in http://www.abortoinformacionmedica.es/wp-content/uploads/2009/06/15-a-9-anteproyecto-906-consejo-fiscal.pdf.

CHAPTER V. ON LIFE AND DEATH: AN IUSPHILOSOPHYCAL APPROACH[173]

V.1. Introduction

As the Greek philosopher EPICURUS of Samos said, "death is nothing to us, seeing that, when we are, death is not come, and, when death is come, we are not"[174] a thought which would be reinterpreted by Antonio MACHADO with these other words: "death is something that we should not fear because, as long as we are, death is not and when death is, we are not"[175]. We must remember, nevertheless, with José Luis LÓPEZ ARANGUREN, that the stoics already saw death as a part of life, making the former coextensive with the latter[176]. *Quotidie morior* (I die daily), SENECA said[177]; CICERO expressed the same thought: Nascentes Morimur: "in being born we die"[178]. Don Francisco de QUEVEDO would go much further, stating that "cradle" and "grave" are together, because in his opinion "at the same time you begin to be born and to die"[179]. As we can deduce from these conceptions, death must be seen as fully incorporated into life, dissolved in all and every one of its moments ... Because, in the words of the Argentine writer Jorge Luis BORGES, "death is a life lived, life is a death that comes". Back to the thought of

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[174] EPICURUS of Samos: *Letter to Menoeceus*.

[175] MACHADO RUIZ, A.: *Juan de Mairena*, Castalia, Madrid, 1971, pág. 140

[176] LÓPEZ ARANGUREN, J. L.: *Tratado de Ética, Revista de Occidente*, 1ª ed., 1958; 6ª ed. Madrid, 1976, pág. 303.

[177] SENECA, L. A.: *Epistulae ad Lucilium*, 24,20.

[178] CICERO, M.T: *Pro leg*. Man. 4, 16.

[179] QUEVEDO Y VILLEGAS, F.: *La cuna y la sepultura*, Madrid, 1633; in O.C., 6ª ed. by Felicidad Buendía, Aguilar, Madrid, 1974, pages. 1327-1329.

EPICURUS, which remains suggestively present for our analysis, "meditation and the art of living well and dying well are one"[180]. And that is precisely what the following reflections intend.

All of us who meditate on the problems affecting life and death, despite our unavoidable disagreements, sometimes more formal than material, more terminological than semantic or content related- should worry about all development and protection of a dignified human life, whose climax may also be a dignified death, not just think about our actual personal existence or that of our closest relatives in the historical context and cultural space in which we have been allotted to be born or to live, but on a global level for we believe that every human being, whatever their state, their beliefs, race or ethnic origin, has, like all and every one of us, the right to live and die with full dignity.

An iusphilosophycal approach on life and death requires a brief incursion on the conceptual meaning to be given to those words applied to human existence in itself to begin later the analysis of ethical and juridical prescriptivism raised by the enjoyment of a life and death deserving to be called dignified.

Etymologically, the Dictionary of the Spanish Royal Academy of Language (RAE) provides up to twenty main meanings for the word "life" (*vita* in Latin), among which stand out mainly those meaning "internal substantial force or activity, whereby the body which has it works"; "state of activity of every organic being"; "union of soul and body"; "time elapsing from the birth of an animal or plant until its death" ; and, finally, "animation, vitality of one thing or person". Regarding the word "death" (*mors*, in Latin), we found six main meanings among which we can select those that mean "cessation or end of life", "separation of body and soul" in traditional thought, and "destruction, annihilation or ruin".

[180] EPICURUS, *op. cit*., 126

V.2. Reflections on life[181]

Life -as noted by Niceto BLÁZQUEZ[182]- is not a definable concept but a describable one referring to different objects, so we can consider it also as an analogical term. Thus, for example, we may distinguish vegetal, animal and human life; or we may talk about scientific, emotional, political, social, communal, nomadic, sedentary life, etc. Of course, as it is the topic we want to reflect upon, we may also talk about a dignified, humanized life, as opposed to an undignified or dehumanized life, and we may add many more adjectives which would turn the noun "life" into a very ambiguous term. So the *Encyclopedia Britannica*, in its summary section (Micropedia), affirms that life is "a phenomenon almost impossible to define or explain in his last aspects"[183]. What we do agree is that the living being is characterized by an organic body or a vital organism with specific life enabling functions. And in this sense, we may recall that until late XIX Century, it had been taught that the barrier that marked the substantial difference between physics and biology was precisely the barrier of life, or, more precisely, the determinism barrier. So it was said that while the world of the physics was a radically specific and deterministic one, the world of biology, however, the world of the living, was a radically indeterminate and indeterminist world. But as of December 14, 1900, when the scientist Max PLANCK read before the German Physical Society his work *On the Law of Distribution on Energy in the Normal Spectrum*[184], this barrier marked by determinism disappeared. Later, in 1930, Werner HEISENBERG came to show us, in his physical principles of the

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[181] A great number of these thoughts reflect the author's opinions and quotations as expressed in his Works "El derecho a vivir y morir dignamente: su prescriptividad ética y jurídica" published in the volume *Problemas de la eutanasia*, coord. F.J. ANSUÁTEGUI, Dykinson, Madrid, 1998; and "El valor vida humana digna" in the volume *Bioética y derechos humanos: implicaciones sociales y jurídicas*, University of Sevilla Publishing, 2005.

[182] BLAZQUEZ, N.: *Los derechos del hombre*, BAC, Madrid, 1980, pp. 109 and ff.

[183] *Enciclopedia Britannica*, XVth edition, 1943-1973.

[184] PLANCK, M.: *Introducción a la mecánica general*, Ruiz de Lara, Madrid, 1930.

quantum theory, that the world of microphysics, under the principle of indeterminacy or uncertainty, was as much a radically indeterminate world as the world of biology[185]. Thus indeterministic physics appeared whereby from the world of physics to the world of man, there was not but one unbroken line. And this questioned not only causality but, as noted by the anthropologist ADSUARA, the physical, biological and even theological consideration of the world and of life[186]. So when the great physicist Erwin SCHROEDINGER in 1944 asked: "What is life?" he answered as follows: "Life is but a mere physical process of aperiodic crystals"[187]. Consequently, from the world of the electron to the world of man-in a strictly physical level, the problem of what life is would be the object of a deep and decisive question.

For the philosopher Xavier ZUBIRI this barrier that divided the world into two great kingdoms still subsisted, not anymore between the physical and biological worlds, but between the animal world and the human world. Because, in his view, the very word "physical" -as he explained in addressing the problem of essence- "includes both the biological and psychological" adding that "the feelings, insights, passions, acts of will, habits, perceptions, and so on are something physical in the strict sense", considering, later, that "animality and rationality are the moments where what we call a man is fully deployed". In this sense, it could be argued that from the single electron, from the smallest monocellular being to the most perfect anthropoid there is a successive gradation line on what ZUBIRI himself would call the "revitalization of stable matter". "Living matter - the Basque philosopher said- is different from that of non living, but it is a matter as material as any other type of matter that integrates the universe". Insisting on his idea that life is not anymore as some kind of biopsychic force that beings participate in or not, but one being will have more or less life based on these criteria: a certain replication, a certain independence of the environment and some

[185] HEISSENBERG, W.: *The physical principles of the quantum theory*, Dover, New York, 1949.

[186] ADSUARA, E.: *Ciencia y Filosofía: la obra de Xavier Zubiri*, Valencia, 1960.

[187] SCHRÖDINGER, E.: *¿Qué es la vida?*, 4th ed., 1997.

specific control over it, so that the more replication, more independence of the environment, more specific control over the environment, the more life will the living body have. As a conclusion, life will, therefore, this systematic property with the structure of systematic replication, independence and control over the environment. And, of course, he will notice that within the animal world, only in mankind we see the full and formal constitution of a strict individual substantivity; called by ZUBIRI himself an "intelligization of animality" because, by means of intelligence, man is confronted with the environment and himself as "realities" and by it he owns himself as a formally "own" reality[188].

Obviously, the emergence of the human being would mean a decisive event in the history of the vitalization process, as it meant that, at one point in that huge genetic evolution begun almost four billion years ago when early hominids emerge -only five million years ago- the conditions to the progressive production of such an important synthesis between what the classics called the spirit world and the world of matter will exist. This would provide man with his most radical condition, which distinguishes it from other animals: I refer to what ZUBIRI himself in the first part of the quoted work *Sentient intelligence. Intelligence and reality,* called the *sentient intelligence*, considering that "understanding and feeling" were combined in a structural metaphysical unity, as man –as an "open substantivity"- proves to be the only intelligent animal to which things are not merely stimuli he reacts to (as it happens in animals) but realities with which he maintains an twofold attitude: to be with them and before them ("is a sort of retraction in the world but towards the world") answering from his privacy, through his senses, through a visual use of intelligence, as reason is, or by an auditory use of it, such as intuition, giving rise to those two essential manifestations of human behavior: the world of understanding and the world of feeling; the world of logic and the world of sensibility that, as the anthropologist ADSUARA would tell

[188] ZUBIRI, X.: *Naturaleza, Historia, Dios*, Editora Nacional, 1st ed., Madrid, 1944; 9th ed., Alianza Editorial, Madrid, 1987.; *Inteligencia sentiente, Inteligencia y realidad*, Alianza Editorial, Madrid, 1980; 5th ed., 1998. *Sobre la esencia*, 2nd ed. Sociedad de Estudios y Publicaciones, Madrid, 1963, pp. 11-18; 5th ed. Alianza Editorial- Sociedad de Estudios y Publicaciones, Madrid, 1985, pp. 172-173.; *Sobre el hombre*, Alianza Editorial, Madrid, 1986, pp. 52-54 and 462 and ff.

us, conditioned the history of our civilization, the rise and development of those two cultural constructs that were, on one hand, western Greco-Roman culture and, on the other,-Semitic Assyrian oriental culture; cultures that certainly have faced in a very different way feeling and understanding of both life and death. In this regard, studies in 1976 by the French anthropologist THOMAS are interesting, specifically about the different attitudes of Western civilization and black-African civilization on the experiences of life and death[189].

We should, but not leaving the evaluation of these scientific and anthropological speculations that show the interdisciplinary and even transdisciplinary character this subject has focus now upon the importance that the value here called "dignified human life" has in contemporary society. Because, as Erich FROMM notes, men is in a constant need of values to guide his acts and feelings[190], and one of these values -perhaps the most important and motivating one in our time- is the value "life", as an absolute motive of existence itself, as a necessary condition to be able to act, to think, to feel what we are or what we aspire to become. It could be said that this is the heideggerian interpretation of life as a pure possibility, in the sense that, whatever the things that human beings design and decide to make, it all depends on the existence of life. In this regard I recall the great thoughts of the philosopher Emilio LLEDÓ at the *Teatro de la Maestranza* in Seville, when, facing the hard theses that man is a "being for death" (Sein zum Tode) he stated, however, with all due respect to the Freiburg philosopher, that the human being is not at all a "being for death" but a "being for life" (Sein zum Leben).[191]

This echoes ORTEGA's views on human life as a "radical reality" in the sense that all other realities -physical world, psychical world, values world- occur within it and may even be said that only within it they are reality. In the words of ORTEGA Y GASSET, The Theme of our

[189] THOMAS, L.V. : *Anthropologie de la mort*, París, Payot, 1976.

[190] FROMM, E.: *La revolución de la esperanza*, Fondo de Cultura Económica, 1st ed. 1st reimp. Mexico D.F., 1971, p. 92

[191] LLEDÓ, E.: *Discurso en el Teatro de la Maestranza de Sevilla, 28 de febrero de 2003*.

Time ”is to consecrate life, which until now was just a naked fact and as a cosmic chance, making it a principle and a right” so that in his own words: “the theme of our time and the mission of present generation is to make a vigorous try to order the world from the point of view of life”, living it deliberately in an upward direction, with such a subtlety in its estimation that allows us to discover its progressive range within our axiological experience, because we recognize in it a higher value so that any other thing have to be subordinated to it, as life itself, without recourse to considerations from outside life, select and hierarchize values[192].

In this sense, José Luis LÓPEZ ARANGUREN reminded us, in his famous *Treaty on Ethics* that in talking about life as a whole we should not forget the three irreducible dimensions whose physical unity was advocated by ZUBIRI, and which gave the exact profile of life’s reality, that is, duration, futurition and location. “We project in time, as futurition, the moral fate we will shape. In time as a location and “while death arrives”, we are in time to rebuild that moral fate”. So he felt that at the “hour of death” we must difference what it has as a happening -the biological dying- from what it has as a human act -the ultimate act- of the last resort given to man for his own moral building. Until the moment of our death, “there was time” still. Men kept some -many or few- opportunities to change his *ethos*. But from that moment on, the ethos will be defined and finished, the possibilities will be fixed forever, exhausted in the being, coinciding with it so that we begin to be, finally, what we have done of ourselves, what we have wanted to be. Hence his conclusion that “life as such, however serious it is, is not the decisive ethical instance”, but what we have done with it. So, in his view, the main moral task is to “become what one can be with what one is”[193].

Considered from this point of view, life is, therefore, the main reason, the radical foundational value we build our existence on. We should not confuse the significance of human life in a strictly biological sense and its biographical significance, as a singular and unrepeatable

[192] ORTEGA Y GASSET, J.: *El tema de nuestro tiempo*, 2976, pp. 69 and ff.

[193] LÓPEZ ARANGUREN, J.L.: *Ética*, 1976, pp.145-147

existential project, as a most personal creation. As Jesús MOSTERÍN has written, "life in the biological sense is a natural phenomenon, but life in a biography is a work of art. Each one of us is the artist of his life, the author of his biography, the director of his film", concluding that, in his view, "the ideal of a free man (or woman) is to take charge and take responsibility for his life and death"[194]; corroborating thus what ZUBIRI also reminded us when he said that "the structure of the path of life is an unity of nature, freedom and destination" and , therefore, man is an "agent, author and actor of his life, unity displayed in projection, fruition and realization"[195].

For a better understanding of what the right to live and die with dignity means, perhaps we should place ourselves, as a starting point in this positive outlook of love to life, in the sense of a moral construction, that FROMM -facing precisely the antithesis which represents any necrophiliac ethics- would qualify, with a great plasticity, as a biophiliacorientation[196], founded upon what Albert SCHWEITZER considered "the reverence for life". Orientation excellently represented by FROMM himself when he stated that "the person who loves life fully is attracted by the process of life and growth in all areas, attributing to biofiliac the quality of enjoying life and all its manifestations, considering joy as virtuous and sorrow as sinful."[197]

But what we need now is to ensure that these biophiliac values become so highly suggestive that they can act as motivating rules of human behavior, and that they become guiding principles for all tasks and social activities. In this regard, FROMM himself admitted the possibility of establishing objective rules, based on the following premise: it is desirable for a living system to grow and produce the greatest intrinsic and intrinsic harmony, that is, subjectively, the greatest welfare so that the validity of the rules would be given by their advocacy role in prime

[194] MOSTERÍN, J.: "El último capítulo", published in the journal *El País*, 2/2/98, p. 15.

[195] ZUBIRI, X.: *Sobre el hombre*, Alianza Editorial, Madrid, 1986, p. 658.

[196] FROMM, E.: *La revolución de la esperanza, op. cit.*, p. 94.

[197] *Ibídem.*

growth and welfare and the lesser discomfort[198]. In other words, this is so in constitutionalizing the love for life and its development, not only as a value, but as a principle and a rule of conduct[199]. In this sense, MARINA thinks that the constituents of the rights whence all others stem are the following: a) right to a dignified life, b) right to an intelligently free life and c) right to strive for personal happiness[200].

It should be stressed in this regard that life -as told by Benito de CASTRO CID - is a requirement stemming from deep inside the human being, so that their own human rights and fundamental freedoms are the result of the deep human aspiration to live and to live with dignity, protecting in either mediate or immediate way the peaceful and safe enjoyment of their lives and their physical and moral integrity[201], so not only shall the denials of life in a strictly biological sense be fought, from them who kill life, but also all the negations that prevent the enjoyment of an authentic and dignified human life. I remember here, on this purpose, the opinion of LÓPEZ CALERA when he stated that "the denial of life can be synonymous not only to kill, but to prevent an authentic and dignified human life"[202].

In this regard, we should recall the reflections of criminal law expert ROMEO CASABONA, who notes that the right to life should not be confused with life itself, "since the former, subject to the natural biological process and its culmination, which is death, cannot be maintained indefinitely as such and, therefore, the guaranties stemming from that right and its object are constrained by such a natural biological process". As a consequence, the object on which the right to life relates

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[198] FROMM, E.: *El corazón del hombre*, Fondo de Cultura Económica, 2nd ed., Mexico D.F. 1967, pp. 48-49.

[199] *Idem, La revolución de la esperanza*, *op. cit.*, p. 97

[200] MARINA, J. A.: *Ética para náufragos*, Anagrama, Barcelona, 1995, p. 243.

[201] CASTRO CID, B. de: "Dimensión científica de los derechos del hombre", in volume *Los derechos humanos. Significación, estatuto jurídico y sistema*, University of Seville Publishing, No. 38. 1979, pp. 121-126.

[202] LÓPEZ CALERA , N.: *Derecho Natural*, XXI/3,UNED, Madrid, 1980, p. 31.

refers to its preservation from its beginning to its end, so, in his view, "such a right exists only from the moment when life exist and while this life exist" implying the necessity of keeping the necessary conditions that make possible its continuation, its respect and protection[203]. In this sense, MARINA has said even that "life" is not the important ethical value, but the right to life, noting that within it two distinct features are manifest: right and life, with duplicity is present in a single value which explains that life is a radical value, but right is an absolute value. Therefore he concludes stating that "the ethics of survival is to be overcome by an ethics of dignity, where its foundation lies"[204].

The defense of the right to live with dignity implies both a particular state of receptivity, of particular sensitivity for all that help develop that value "dignified human life" in all its fullness and, of course, outright rejection everything radical and supportive of their denial or impairment. Challenging the denying conclusion held by Norberto BOBBIO on a possible absolute foundation of human rights -caused, in the opinion of the Piedmontese iusphilosopher, mainly by their indeterminability, historical relativity, heterogeneity and antinomic contradictions[205]- the, Italian too, philosopher Giuliano PONTA told that human rights to life, health and self autonomy are essential because of the irresistible argument for their rationality, because no rational person can fail to have these basic preferences whose satisfaction is a necessary condition to be able to pursue the satisfaction of any other preference, purpose or value. Likewise, he understood that the variation of the rights and values that, from age to age, are considered fundamental, should not be interpreted as an expression of historical relativism, but as a difficult and complex process of ethical evolution coming, through "moral discoveries," to "moral truths" increasingly well based[206]. And one of

[203] ROMEO CASABONA, C.M.: *El derecho y la bioética ante los límites de la vida humana*, Centro de Estudios Ramón Areces, Madrid, 1986, pp. 27 and ff.

[204] MARINA, J.A., *op.cit.* pp. 230 and ff.

[205] BOBBIO, N.: *El tiempo de los derechos* (translation by R. DE ASÍS), Sistema, Madrid, 1991, pp. 53 and ff.

[206] PONTARA, G.: *Ética y generaciones futuras*, Ariel, Barcelona, 1996; "¿Hay derechos fundamentales?", in *Crisis de la democracia*, Ariel, Barcelona, 1985.

these moral truths, the product of the ethical evolution of mankind, considered by BOBBIO himself as "relevant historical change"[207] - could be the universal acknowledgement of the right to live with dignity, that should seat on the first position in the hierarchy of fundamental rights as the foundation of all others because it allows the greatest realization of other rights. Because, as Eusebio FERNANDEZ also noted - the denial of the right to life and physical integrity "would be in contrast with the testable and verifiable intersubjectively fact that in every known society most people prefer living rather than not living, and they also want a richer and more complex way of life than that provided by the mere physical survival"[208].

Thus, as understood by Luís ZARRALUQUI, "the right to life comes to be understood as the human being's first fundamental right", whose existence is the basic requisite for the concurrence of all others, manifested in these two aspects: positive, as the individual's right to live and have the State to protect his life- and negative -in the sense that no one threatens his life and deprives him of it[209]-; valuation , incidentally, also found at the famous judgment 53/1985 of the Spanish Constitutional Court in deeming the right to life as an "essential and axial fundamental right", as a "logical and ontological prius for the existence of other rights".[210]

BOBBIO wrote in his essay *Present and future of human rights* - while insisting that the important thing "is not founding human rights but protecting them", considering that "they are not for the most part absolute or in any way constitute a homogeneous category"- but he understands, however, as an "absolute value", the status pertaining a handful human rights, valid in all and every situation and for every man without distinction, adding to that that it would be a privileged status stemming

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[207] *Ibidem*, pp. 93-95

[208] FERNÁNDEZ, E.: *Teoría de la justicia y derechos humanos*, Debate, 1984, p. 116.

[209] ZARRALUQUI, L.: *Procreación asistida y derechos fundamentales*, Tecnos, Madrid, 1988, p. 36.

[210] Spanish Constitutional Court, judgment 53/1985.

from a situation seldom verifiable: one where there are "fundamental rights not coming in competition with other fundamental rights"[211]. The human right to the enjoyment of a dignified life should be considered as one of those very few fundamental rights which are at the same time a value and a principle, characterized by their universality and valid in all situations and for all human beings without distinction, so that perhaps it deserves to enjoy the status of "absolute value" which BOBBIO exposed. The clear and convincing claim of unquestionable primacy of this value from all possible fronts and the absolute condemnation of its negation would certainly help raise the levels of humanization needed by our planet s urgently to enable all peoples the enjoyment of the longed universal peace, an indispensable corollary to an existence deserving the label "dignified".

Precisely in his important essay on the interpretation of human rights, PÉREZ LUÑO warns us about the fact that fundamental rights are formulated in constitutional texts as values, as principles and specific rules, being deducted from this interpretative scheme that they work as meta-rules regarding principles, and as rules of the third degree regarding rules or specific provisions, claiming their consideration as "basic ethical and social choices that should preside the political, legal, economic and cultural order", as they represent the system of aware and generalizable preferences expressed in the constitutional process as priorities and foundations of collective coexistence. Therefore he states that the "are directing general ideas support, guide and constrain critically the interpretation and application of every other legal rules."[212]

This shows that, joined with the undoubted prescriptive ethics of values, there is a decisive legal prescriptivism from the moment they are incorporated into the constitutional legal system as legal values, so they must be granted an absolute primacy of hermeneutics because, according to its threefold role, foundational, guiding and critical of the social order, they allow the appraisal and valuation of all rules and regulations that

[211] BOBBIO, N., *op. cit*., pp. 63-84.

[212] PÉREZ LUÑO, A.E.: *Derechos humanos, Estado de Derecho y Constitución*, Tecnos, Madrid, 1984, pp. 286-295.

constitute the legal system as a whole, including even the specific constitutional rules that might enter into conflict with the aforesaid values and that, in this specific hypothesis, could lose their legitimacy, becoming the "unconstitutional constitutional norms" which one could even present an appeal of unconstitutionality against.[213]

Fortunately, there is a broad consensus that the Spanish Constitution, in accordance with the Universal Declaration of Human Rights and other international documents, reflecting the value human life with an undoubtedly ethical and legal prescriptivism, and not only in section 15, when it is stated that "everyone has the right to life and to physical and moral integrity, and under no circumstances may be subjected to torture or to inhuman or degrading punishment or treatment" - but also in other provisions such as sections 43 (protection of health), 45, (enjoyment of the environment and quality of life), 50, 51 and 128 (which strengthen the civil rights on matters affecting their health, safety, life quality and general welfare)[214].

We may deduce from all this that the welfare of citizens, their life quality and, of course, their own right to life and physical and moral integrity include also the assumptions on which, according to section No. 10 of the Spanish Constitution, political and social peace must be based in order to realize the dignity and the free development of their personality. In this sense it is very enlightening RUIZ-GIMÉNEZ's view when he states that the aforesaid constitutional provision "holds a most fundamental rank, with a legitimizing, enlightening and driving efficiency to strengthen institutions, clarify ambiguities, fill gaps and integrate new possibilities in the collective effort towards higher levels of justice and human liberation "[215]. The right to life, therefore, and all that contributes not only to protect but to improve it both qualitatively and quantitatively, is not only a value but a set of principles which focus and specify this

[213] *Ibidem,* p. 287.

[214] Spanish Constitution, 1978.

[215] RUIZ-GIMÉNEZ, J.: "Comentario al artículo 10 de la Constitución Española" in volume *Comentarios a la Constitución Española de 1978*, tomo II, EDERSA, Madrid, 1996, p. 58 and ff.

value, embodied, in turn, in a series of casuistic and specific standards, in other words, linking all public powers together, informing all of their actions, positive legislation and judicial practice, as stated in section 53 of the said Constitution, referring to the guaranties for freedoms and rights.

All this means that -as I already stated in an article on the moral abolition of the death penalty[216]-, if one accepts the hierarchy between values, principles and norms set out above regarding the fundamental right to life, we have at our disposal a hermeneutical tool of extraordinary operative efficiency for the interpretation of extraordinary operational efficiency in interpreting, judging and evaluate critically all public and private activity, so that, while the value "dignified human life" is not expressly set out among the higher principles of Spanish law contained in section 1 of the Constitution, together with freedom, justice, equality and political pluralism, we might well consider it as the a value of this same rank, as we may well understand from the Preamble to the Constitution when it proclaims the will of the Spanish nation to " Promote the progress of culture and of the economy to ensure a dignified quality of life for all", thus promoting the common good of all those who belong to it. We insist that the recognition of this right should bind all public authorities, informing therefore their politics, judicial practice and positive legislation. Because, as it was noted by GARCÍA DE ENTERRÍA[217], values are "the entire base of the legal system, which has to give it its own meaning, which is to preside, therefore, its interpretation and application". And the right to enjoy the fullest and most dignified life in the vital process that existence of everyone means is and should be the foundation of any democratic and civilized legal system. Obviously, if the Spanish Constitution guarantees in its section 9 the principles of legality and normative hierarchy and we interpret strictly and consistently that hierarchical priority that requires absolute respect for the right of everyone to a life qualitatively dignified, no ordinary law could ever proclaim something which breaks such a fundamental right because, as

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[216] RUIZ DE LA CUESTA, A.: "La abolición moral de la pena de muerte: más que abolir deslegitimar", *El Ciervo*, nº.564, Barcelona, March 1998, pp.8-11.

[217] GARCÍA DE ENTERRÍA, E.: *La Constitución como norma y el Tribunal Constitucional*, Cívitas, Madrid, 1981, p. 98.

already stated, it could immediately be unconstitutional be unconstitutional for violation of constitutional values.

A timely and illuminating interpretation of the scope to be given the right to a dignified life applied to a real life sample is present in a sentence given in a Court of Santa Fe de Bogotá, in which the judge speaker, SIERRA BELTRÁN argues as follows: "The concept of life is a fundamental constitutional right not understood as a mere existence, but as a dignified existence with sufficient conditions to develop, as far as possible, all the capabilities the human being can enjoy", adding that it also implies "a right to personal integrity in its fullest sense that, as a prolongation of the earlier right and direct manifestation of the principle of human dignity commands respect for both physical and moral non violence, as well as the right to reasonable greater treatment and lesser possible influence over body and spirit", concluding that when certain anomalies in health –even when they are not illnesses- threaten personal dignity, the patient is entitled to search, by the affordable means, the possibility of a life that, despite the pains, can be carried on with dignity[218].

The projection of the fundamental right to a dignified life in the field of biomedicine is unquestionable and is mirrored, in turn, in the specific recognition of the fundamental right to health that generates commitments and obligations towards its effective protection not only from the State and institutions, but from all citizens towards each other and even from the individual towards himself; obligations, of course, also related to the enjoyment of the environment, food, housing, education, and, broadly, all those services and tools required to ensure the best health or quality of life, that is, of dignity. Health -also understood as a fundamental and chief value- would encompass not only the physical and biological aspects, but also the psycho-affective, intellectual or mental ones, necessary for the person to enjoy a dignified standard and quality of life. The right to health so conceived, as a basic guarantee to ensure that every citizen enjoys a dignified life process, is therefore one of the most important foundations to build a truly democratic and solidarity state of

[218] BELTRÁN SIERRA, A., judgement T-099/99, Santa Fe de Bogotá, 18th February, 1999.

law which obviously intends to go far beyond the postulates defining the liberal State that, in matters relating to health, limited itself to give a merely curative medical attention, at a purely individual level and a very discriminatory one to those who, by virtue of their own economic and contractual capacity and contractual economically, could afford such an assistance. In the solidary State, however, the right to health of every human being is recognized indiscriminately, regardless of their individual economic opportunities, developing a conception of medicine not only as curative but also as preventive, so that public authorities are responsible for ensuring also the collective health of the population through the provision of appropriate social services. But some have talked even about the increasingly pressing need to develop a medicine that still go beyond curative medicine, merely individual, or of preventive medicine, eminently social, one that would be described by some as "improving" medicine, because it does not limit itself to combat and cure the patient ailments or to prevent illnesses that may befall him in the future, but to a medicine that proposes to improve the healthy individual itself, making it even healthier and therefore much happier.

V.3. Reflections on death

At the beginning of these reflections we said that the climax of the enjoyment of a truly dignified human life is a death that also deserves this description. Life's cessation or end must be lived with dignity, that is, as the culmination of a process that must be of an acceptable quality for those who are going to die. So giving the dying a good death ("eu" "thanatos") is without doubt one of the most important challenges to be tackled from the perspective of the dignity of human life -understood not only as a value but as a fundamental right- as its ethical and legal implications should concern us all, not only as professionals or researchers at the theoretical level of legal or biomedical disciplines, but by our unavoidable condition of mortal human beings, aware that sooner or later, at the end of our own personal biography or that of our loved ones, inevitably we will have to face worthily this dramatic situation that awaits us by virtue of our very existence, with the possibility that we may have to adopt, sometimes, committed and hard choices.

Ignacio SOTELO stated that "we have not only the right but the duty to aspire to a good death" ideal that could even become an ethical

imperative, fulfilling the duties imposed by body and spirit in such a way that we do not shorten life unnecessarily, but neither should we try to prolong it artificially because, otherwise, it would be a blatant contradiction or denial of the right to live. In this regard, PECES-BARBA explained us a few years ago that the core of this problem is tied to the scope and meaning of the right to life, and the possibility of making it compatible with the right to a human death, as Javier GAFO would say, or a dignified death[219]. Ignacio BERDUGO believes that reflection on the protected legal good, life, in the context of an individualist social model such as the one reflected in the Spanish Constitution, is based upon "human dignity and rights that are inherent to mankind" so that life, from the perspective of law, is not only a biological fact but also the right to live, to do so with dignity[220]. It is the conclusion drawn from the section 15 of the Constitution when it proclaims that not only all have the right to life, but to their physical and moral integrity, prohibiting torture and cruel, inhuman or degrading treatment in the most absolute terms. A prohibition -as noted by Jesús GONZALEZ PÉREZ- cannot be understood as confined to criminal matters or to the general sanctioning practice, nor to that of the person subject to police action, but having a general application in all kinds of human relationship, as it is becoming a reiterate doctrine of the European Court of Human Rights[221].

Therefore, even in the field of healthcare relationships and the doctor-patient relationship, because, as RODRÍGUEZ MOURULLO understands it - the right to life, understood as the right to personal safety, also encompasses a plurality of rights among which he exposes the right of everyone to physical and mental health, to a bodily and psychical welfare, not to endure the processes of illnesses that eliminate health and not to be forced to feel pain or to suffer. Because, in a world as developed as ours, it should be possible to live and die with the slightest pain and

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[219] PECES-BARBA, G.: "Reflexión moral sobre la eutanasia", published in the journal *ABC*, 16/9/95.

[220] BERDUGO, I.: "Eutanasia, delitos sexuales y libertad de expresión", published in the journal *El País*, 25/2/98, p.28.

[221] GONZÁLEZ PÉREZ, J.: *La dignidad de la persona*, Civitas, Madrid, 1986, p.100.

suffering[222]. However, -as MOSTERÍN explains -often others (legislators, judges, bishops, bureaucrats and cruel and arrogant doctors) with their prejudices "dressed in white coats or black robes" -as Esperanza GUISÁN would say[223]- are those who burst into the filming of the last shots of our own personal biography and "they lengthen it against our will with endless scenes of misery, agony and pain that were not in the original script. They trample on our freedom as authors and turn what could have been an upright work of art complete into a regrettable piece of garbage"[224].

DÍEZ RIPOLLÉS thought, some years ago, that the fact that in such cases (he talked about terminally ill and dying men) very often the wishes of the patient to die peacefully are not obeyed, stemmed from the "absence of an adequate health legislation and an administrative normative system to regulate such situations in the field where they happen more often, i.e. in hospitals". Thus, he warned us on how the art. 10.6 of the General Health Law (then in force) continued being interpreted in its narrowest sense, under which it was stated that the physician's duty was to maintain the patient's life in all circumstances, even against his will, weighing this provision as a slab in the minds of many physicians. Therefore, anticipating with clarity to the law that was not yet enacted, he considered as urgent the existence of "a legal norm that establishes conclusively that every beginning or continuation of a treatment on the health conditions aforesaid had to be preceded by the patient's informed consent"; considering that it involved to ensure the individual with the necessary information to make the decision and guarantee that his will would not be usurped by relatives or by the doctor, and legitimize also the patient vital statements allowing his appointment of legal representatives who can decide on his behalf when needed. All this -RIPOLLÉS DÍEZ concludes- should be accompanied by a specific,

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[222] RODRÍGUEZ MOURULLO, G.: "El derecho a la vida y a la integridad. Prohibición de la tortura", *Revista del Poder Judicial*, especial issue 1, Madrid, 1986, p. 43.

[223] GUISÁN, E.: "La eutanasia y el prejuicio", published in the journal *El País*, 3/3/98., pág. 14

[224] MOSTERÍN, J.: "El último capítulo", published in the journal *El País*, 2/2/98, p. 15.

adequate and reliable verification procedure which must guarantee the necessary legal certainty to all the medical staff intervening. Finally, he proposed the offering of effective alternatives to any eventual objection and exposed the need of facing reality where most patients were uninformed about their actual situation, so that "the possibility of a dignified death depends now on the chances of finding a sensible and responsible professional". The final conclusion summarizing the thought RIPOLLÉS DÍEZ held is that "the technological modern medicine has placed us in new situations, difficult to imagine before, against which many citizens are demanding that the State - the health administration- not only guarantees the right to live, but also the right to die with dignity"[225]. Nevertheless we should not forget that sometimes, as TORRALBA notes[226] - "when a human being wants to put an end to his life because it makes sense no longer, it is not an isolated or autonomous decision, but we all are jointly responsible to the extent that we have not done everything possible, on all levels, to help that person to build a meaning, despite everything". In such cases, rather than ending the problem by annihilating their existence, it is more responsible and supportive (which does not means paternalistic) trying to rebuild, dialogically and solidarily the meaning of it, trying to delve into the roots that have caused this extreme situation and remedy it. That is, expressing our ethical concern for others and for their fulfillment, which is the "core nerve of ethics". Instead, TORRALBA concludes, "indifference respect to the other and disregard is a clear example of the privatization of ethical experience and a clear sign of lack of responsibility".

We must remember, nevertheless, that the value "human life with dignity" also has an unavoidable subjective projection, because together with the parameters from which can be designed by consensus at every historical moment the lesser essential requirements for every human to enjoy a life that would qualify as truly dignified, those other value judgments which everyone project over his own life -and, consequently, over his own death- from his personal watchtower should not be

[225] DIEZ RIPOLLÉS, J.L.,*op. cit*. p. 24

[226] TORRALBA, F.: "Morir dignamente", *Bioética & Debat*, Institut Borja de Bioética, Barcelona, April 1998, pp. 5 and ff.

forgotten, considering whether it is or not worthy of being lived. In this regard, Ignacio SOTELO thought[227] that "as terrible as the situation in which we have been placed by life may be, only each one can judge by himself if it is worth living". And therefore, "what is not in any way thinkable of is, a priori, a fixed set of conditions required from life to be considered unworthy of being lived" since, "from this false objectivity could result in the right of society to kill all disabled people that, under a set of objectively defined conditions, are considered unworthy of life".

This problem worsens significantly when we think about the progressive aging of the population in more developed industrial societies and the increase of degenerating dementia in the elderly. So it becomes necessary "a precise regulation of a right as fundamental as the right to a good death not to be resulting from abuse or harm", having the role of an alibi for a possible murder, because "the good death –as SOTELO himself says- is a gift that others give us to help us to die as aware as possible, together with those who love us" because, as stated by RISLEY and WHITE, in the preamble of *the Humane and Dignified Death Act* in California, written with the collaboration of the Hemlock Society "prolonging the life of a person in the terminal phase of illness can cause inhumane situations and unnecessary pain and suffering, if it does not provide any necessary medical assistance that benefits the patient. Prolonging life against the will of the patient who suffers terrible pains and suffering is cruel and a total disregard for human dignity".

Nevertheless, death does not only concern the dying but us all, because "it can only be within a society where everyone is involved in the death of everyone". This is precisely what SOTELO called the "social dimension of death". Because, in its own words: "dying in a radical solitude, the opposite of a good death, is becoming the fate of contemporary man". And it should be noted that "where this social dimension of death has disappeared, it has evaporated also any solidarity with the living"[228]. Thus, it should be noted that the right to die with dignity, as TORRALBA writes -"asks, firstly, for the social co

[227] SOTELO, I., *op. cit.* p.13.

[228] *Ibidem.*

responsibility to the phenomenon of death and requires a pedagogy of finitude and death, so absent in the formative process of the person"[229]. Moreover, as Victoria CAMPS wrote, "the relief provided by society brings the security that we individually lack", and what the classics of existentialism saw remains true: "none of my acts concerns only me, my options drag and depend from some others, and they are never lonely"[230]. Guaranteeing the right to die with dignity (integrated into the basic right to live with dignity, respecting the superior value "dignified human life" contained in any civilized legal system) requires: a) not applying exceptional measures to artificially prolong the life of an unrecoverable sick person; b) not starting or continuing treatment when the patient is aware and explicitly request it;, and c) applying all kind of measures to mitigate pain, although these by their very nature may well shorten the agony and therefore life in its final moment. In short, this is about -as an editorial article in the journal *El País* noted- ending the fiction of a prolonged artificial life by means of the so called therapeutic aggression, noting the need for "recognition of the personal rights of anyone, who is in a process inevitably fatal, to decide by himself how the transition from life to death must be and to receive the appropriate assistance of medical science for it"[231]- In short, because –as Antonio GALA once wrote regarding this subject- "life is an untransferable right of the living, and death, an untransferable right of those who die. Its compliance should be facilitated then. About the individual, this is the first and highest duty of the community, its first and last declaration of love"[232].

The reductionist and restrictive interpretation of human life to its merely biological and vegetative dimensions, more quantitative than qualitative, hinders the understanding the right to dignified life as a right absolutely compatible with the right to a dignified death, justifying, on the contrary, its contempt by prolonging an unworthy life, or, in other words, being sentenced to an unworthy death. This implies, in turn, the serious

[229] TORRALBA, F., *op. cit.*, p. 6.

[230] CAMPS, V.: ¿Quién decide?, published in the journal *El País*, 29/5/1986, pp.16-17.

[231] Editorial of the journal *El País:* "Derecho a morir", 7/5/89.

[232] GALA, A.: "Eutanasia", published in the journal *El País (semanal)*, 25/6/1989.

consideration of the problem caused by human pain and suffering as factors that undermine the dignity of human life, especially in the final stages of existence, when the conditions are deadly and fatally irreversible. In this sense we cannot remain indifferent to complaints such as that expressed by the writer Ángeles CASO, when she stated that in our country there are many doctors who "refuse to prescribe morphine to patients tortured by unbearable pain, even when their disease is terminally ill. And many private clinics and whole floors in public hospitals where the ideology of the leaders or the fear of possible complications or the simple operation of machinery make the dying are not sedated and have to endure the rigors of hell before the helpless terror of their loved ones"[233].

This can be facilitated also by the fact that, since certain sacrificial moral approaches, of a clearly pagan origins, although collected by individuals and organizations belonging to different faiths, it is still insisted on the sublimation of this suffering as a purifying element and a timely opportunity to develop faith and ensure the heavenly reward; while many contemporary moralists and theologians forcefully repudiate this claim of pain and suffering that evokes the image of a cruel and righteous God who demands human sacrifice to appease His anger. Thus, the Sevillian theologian José María GONZÁLEZ RUÍZ stated that "our theological task for the dying is not the spiritualization or mystification of suffering, nor, even worse, their educational profit ("purgatory on earth"), but rather following in the footsteps of Jesus healing the sick, minimize and eliminate the suffering"[234].

Hence, fortunately, the increasing interest on palliative care shown by medical professionals in palliative care and palliative care for terminally ill patients, sharing the view of Francesc ABEL, physician and Jesuit priest, who claimed that "the real problem is not focused on getting the legislation of euthanasia, but to correct the defects of the health system and encourage all citizens to understand the scope of the duty of

[233] CASO, A.: "El dolor y la moral", published in the journal *El País*, 21/1/1998, p.12.

[234] GONZÁLEZ RUIZ , J. M.: "¿Morir con dignidad?", published in the journal *Sur*, Malaga, 3/3/1998.

human solidarity to overcome in a dignified and human way the mistakes a technological mindset can do in the treatment of terminally ill patients"[235] . Among he rights of the dying that is necessary to defend, CUYÁS made the following summary: a) right not to suffer in vain; b) the right to freedom of conscience; c) the right to know the truth, d) right to decide on itself and everything that relates to him, and e) right to maintain an open dialogue with doctors, family, peers and successors in the workplace[236].

V.4. Final conclusion

In conclusion, the right to a dignified human life, understood as first and superior value of the legal system, located at the top of axiological principles underlying our system of law, also requires that consideration (embedded within it, in strict consistent legislation) the right to die with dignity, that is, to complete our personal life without pain or with minimal pain, with awareness and composure. PERICO wrote that if the expression "right to die with dignity" mean the option to let die in peace, with the exclusion of interventions actually fatal, it is clear that this right exists[237]. In this regard, I fully share the view Francesc TORRALBA defends when he says that every human being has a dignity which is absolute and can not be changed under any circumstances, since it does not depend on his doing but of his being[238]. Therefore, "die with dignity "means the building of mechanisms that make traversable and manageable, within the possible limits, the experience of finitude and human frailty, for it is not necessary to" kill "but to help to die, without imposing an artificial life- no longer is life worth dying for, but rather an undignified death, developing not only palliative medicine, but a new

[235] ABEL, F.: "Eutanasia y muerte digna", published in the magazine *Labor Hospitalaria*, nº 222, Barcelona, 1991, p.367.

[236] CUYÀS, M.: "El encarnizamiento terapéutico y la eutanasia", published in the magazine *Labor Hospitalaria*, nº222, Barcelona, 1991, p.324.

[237] PERICO, G.: "Diritto di morire?", *Agg., sociali*, Roma, 1975. pp. 680 and ff.

[238] TORRALBA, F.: "Morir dignamente", *Bioética & Debat*, Institut Borja de Bioética, Barcelona, Abril, 1998, pp. 1-6.

attitude to the phenomenon of death, facing it as part of our own life, which may also help provide a sense as an "act -as ZUBIRI wrote- Launches man positively from the provisional to the definitive" because if while we live, we are getting provisionally at that last moment of death, the figure achieved and the definition will be obtained not only defining but "definitive." Thus, mankind can pre-live the time and manner of his death, confronting it positively[239].

Fortunately, on March 17th, 2010, the Andalusian Parliament approved the new law of rights, guarantees and dignity in the dying process, in which reasoned preamble explicitly states:

> "All human beings aspire to live in dignity. The legal system is simultaneously concrete and protects this aspiration. But death is also part of life. Dying is the final act of the personal biography of each human being and cannot be separated from that as something different. Therefore, it is the requirement of dignified living and to death. A dignified life requires a dignified death. The right to a dignified human life cannot be cut short by an undignified death. The legal system is therefore also called to realize and protect this ideal of a dignified death."

I sincerely believe that this legal text faithfully synthesizes the nerve center of these reflections about life and death.

[239] ZUBIRI, X.: *Sobre el hombre*, *op. cit.*, pp. 666-668.

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