

EMBRYO'S RIGHT AND 'FMI' IN EUROPEAN, INTERNATIONAL AND ITALIAN LAW(*)

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Before speaking I would like to thank my dear friend Marco, Annarita and Manuela who helped me in the understanding of the medical and so much technical part that for me, “woman of law”, was not that easy to understand. I would like also to thank the prof. Di Stasi of my university who has written an awesome comment to the two sentences I will talk about and also my professor of thesis, Loris Lonardo, who gave me the passion and the confidence in my writing. Most of all I thank with all my heart my aunt, prof. Maria Antonietta Urciuoli, who has given to me the passion of studying especially law. I would like to have one day her brilliant intelligence and her capacity in writing. Last but not least my boyfriend who is here to sustain me and helped me in every single step. Of course I thank the professor den Exter and Toby to has given me the chance after fascinating me during the congress in Rotterdam to speak here, for my first time, in front of a platea of academics.

There are many different causes of the infertility in a couple of eterosexual people:

1. Man infertility;
2. Impotentia coeundi (Erectile Dysfunction and other causes);
3. Interference pelvis: endometriosis and adhesions syndrome;
4. Tubal pathology;
5. Infertility gamete : anovulation, inability to produce gametes.

Nowadays with a good hormone therapy, a transvaginal ultrasound echography, assessment of sperm capacitation, have been significantly reduced cases of patients undergoing diagnostic laparoscopy.

BMI and changes in lifestyle

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The lifestyle is very important in the evaluation of fertility. We must assess the quality and quantity of physical activity associated with an appropriate BMI (body mass index). It is necessary that there is not excessive thinness or excessive weight because it can lead to a disturbance in the ovulation.

For a BMI > 30 (obese) it is related to a reduced reproductive capacity, an increase of menstrual disorders and infertility type anovulatory. Obesity also is related to a reduced clinical response to fertility treatments. Thanks to a low-calorie diet and changes the weight loss associated with metabolic and clinical improvements.

In parallel with a BMI <18 (underweight) is associated with loss of lean, neuroendocrine stress and dysfunction of the hypothalamic-pituitary-ovarian axis. In these cases no treatment of infertility should be offered up to that BMI is not returned to the lower limit of normal.

Specifically obesity interferes in different ways with the woman's fertility, resulting in:

- Ovulatory dysfunction
- Abnormal response to treatment of ovulation induction and IVF programs
- Abortions
- Pregnancy complicated

The result is a reduced reproductive performance. Weight loss is essential for obese women who wish to conceive, not only before receiving fertility treatment, but before exposure to the risk of pregnancy due to the high incidence of fetal risks associated with maternal obesity, such as fetal abnormalities isolated, fetal deaths, preterm deliveries and early neonatal death. An aggressive approach to reduce weight, including pharmacological strategies and the use of contraception and high doses of folic acid should always be proposed for obese women before a planned parenthood.

Anovulatory infertility

"Anovulatory infertility" it is defined the condition in which there is no rupture of the follicle with subsequent release of an oocyte. Ovulatory disorders account for 20% of the causes of infertility.

It is divided in three groups:

-WHO Group I: failure of hypothalamic-pituitary axis: central anovulation, disorders of the hypothalamus. Part of this group are or people with anorexia, or it is caused by an excessive exercise. Conditions are fairly simple to solve, it allows you to easily get to ovulation.

-WHO Group II: Anovulation normogonadotropica (PCOS) is altered feedback peripheral and this is added (according to some) to the conditions of hyperprolactinemia (“Iperprolattinemic” anovulation). It represents about 80% of all causes of anovulation.

-WHO Group III: ipergonadotropica anovulation (ovarian failure): there is no ovarian tissue with follicles, there is no production of estrogen. This e.g. happens in ovarian dysgenesis and other ovarian pathologies. Only in this case we speak of ovarian failure and could be solved only with a third level of assisted reproduction techniques is that the egg donation.

Ovulation induction

The "induction of ovulation aims to achieve:

- Simple-Ovulation
- Multiple Ovulation: Controlled Ovarian Stimulation (COS) and controlled ovarian hyperstimulation (COH)
- Superovulation: especially in Programs of IVF (In Vitro Fertilization)

While with the anovulatory patient the goal is the single ovulation, in other patients it is to increase the chances of obtaining the pregnancy. This is achieved through:

- the assessment of the number of follicles to take ovulation
- A mechanical nearness of the gamete (essence of seeding).

This technique allows the approach of capacitated sperm with the female gamete, favoring synchronization. However with this technique are reported the maximum the possibilities of success to the minimum natural limit, up to 20%.

The only technique that allows instead to exceed the limit of 20% is natural IVF whose percentage is 50%. (by implanting more than three embryos in the uterine cavity is needed only the step of engraftment).

For assisted reproductive technology superovulation is needed. Today in all assisted reproductive technology are selected follicles that grow; choosing those more mature than

less mature. Today also is allowed even freezing of ova, with good results. You can also preserve the reproductive potential of young women with cancer, not only of reproductive system.

The super ovulation is a different technique from multiple ovulation controlled.

Simple ovulation

Ovulation induction simply involves the use of fertility drugs to stimulate the development of one or more mature follicles in the ovaries . Ovulation signs are simple :

- -Women Who do not develop normally mature oocytes
- -Women Who do not voluntarily release a mature egg each month

It's important that the number of pre-ovulation follicles must not be greater than three, because vice versa, the risk of multiple pregnancies is high.

-I ° step : changing life habits

I ° -II ° step or step therapy itself: in pcs. with insulin resistance can be used metformin (which is a more physiological mechanism and does not require monitoring).

Laparoscopic Ovarian Drilling (LOD)

The LOD is a surgical technique without effective monitoring needs and is recommended for patients who cannot be subjected to continuous ultrasound checks.

The project is to create a hole in the ovarian surface using a monopolar and destroying portions of ovarian tissue.

The result is immediately after the operation a reduction in the proportion of androgens; obviously the effectiveness of the treatment decreases after sometime.

The destruction of ovarian tissue with secondary reduction of the local production of androgens leads to increased rate of spontaneous ovulation and conception and restore menstrual regularity in the 60 % of women, with a great beneficial effect in the long term.

Multiple Ovulation induction

The induction of multiple ovulation can be:

- Controlled Ovarian Stimulation (COS)

- Controlled Ovarian Hyper-stimulation (COH)

Human menopausal gonadotropin (hMG), are extracted from the urine of postmenopausal women and can be used if ovulation or conception does not occur during treatment with CC. The greater risks are multiple pregnancies (10-30%) and ovarian hyper-stimulation syndrome (10-20%). The syndrome can usually be avoided by careful monitoring of the patient and suspending hCG if the ovarian response becomes excessive.

It takes a lot of sensitivity in the use of gonadotropins, there are strict protocols and any changes to the dose of gonadotropins must be adapted according to the response of the patient.

Controlled ovarian stimulation

The objectives of clinical controlled ovarian stimulation depend on the needs of patients :

- -Induction Of multiple follicles from which they can be recovered mature oocytes for use in medically assisted reproduction programs .
- -Induction Of spontaneous ovulation for the maturation of a single follicle which can be followed by a in vivo conception.

Controlled ovarian hyper-stimulation

The controlled ovarian hyper-stimulation (COH) provides for the use of the same drugs used in ovulation but it is intended to bring the development of multiple mature follicles to increase pregnancy rates.

The COH does not correct any specific cause of infertility, but it helps to get more eggs available for intrauterine insemination or in vitro fertilization with or without injection intracytoplasmic sperm. In order to avoid complications it is necessary to regularly check the cycle of COH using blood tests and transvaginal ultrasound in order to reduce the risk of hyper-stimulation syndrome ovarian and increase success rates. Another complication of hyper-stimulation is multiple pregnancy (twins 10%, triple pregnancies 3%). Therefore it is often necessary to stop the treatment if more than three mature follicles are shown on ultrasound.

Intra Uterine Insemination- IUI

This technique is to improve the quality of semen and introduce it, after treatment, in the woman's uterus, thus approaching the male gametes with the female and facilitating their fertilization. The insertion, using special catheters, of the partner's sperm directly within the uterus occurs during the female ovulation. In Italy it was allowed only IUI with the seed of its partners. Before carrying out this method it is necessary to exclude certain diseases of the female genes such as, for instance, an alteration in the tubal function.

The IUI is not effective in cases in which the male presents a very low number of spermatozoa or a serious deterioration of their shape as well as in women with damaged tube.

Superovulation programs IVF

Assisted reproductive technologies procedures

-FIVET: The oocytes are collected and placed in specific culture media. Sperm preparation is added (insemination) and then is evaluated fertilization. The resulting embryos are transferred into the woman about 2-3 days after the pick-up.

- Embryo Transfer: the embryos are placed in the uterus after 2-3 days from the pick-up (for standard IVF). A maximum of three embryos are repositioned, to reduce the possibility of multiple pregnancy, although there are exceptions

- ICSI (Intracytoplasmic sperm injection): A sperm is injected into the cytoplasm of the egg. Suitable for couples who have little or no response IVF, and for men with severe male factor infertility.

The IVF is suggested in cases of

- Male infertility
- Age-related infertility
- Tubal absence or damage
- Repeated failure of IUI
- Preimplantation genetic diagnose

What to do before the IVF:

- No smoking, drugs, alcohol for three months before the IVF cycle
- Do not drink more than two cups of coffee a day

Refrain from any relations 3-4 days before each oocitarario, and after embryo transfer until ready to test for pregnancy.

- Inform the doctor in the presence of fever in the two months prior to IVF
- Avoid smoking, drugs, alcohol in the 3 months prior to the IVF cycle
- Avoid excessive exercise
- Refrain from having sex at least three but no more than 7 days before harvest seminal

First step: ovarian stimulation

Through the use of fertility drugs (FSH, hMG, GnRH agonists and antagonists) the ovaries are stimulated to produce many high-quality oocytes for withdrawal. Oocytes multiple increase the potential for production of multiple embryos, which increases the probability that the next conception. During the 7-14 day period of stimulation, ultrasound and run laboratory tests to monitor the development of follicles

Second step: picking oocyte

When the follicles are ready for picking oocyte, a needle is inserted in the ovary under ultrasound guidance to locate each follicle. The follicular fluid is then collected in a test tube for oocyte retrieval. The procedure takes about 15 minutes.

Third step: collection of semen

Collection of semen during oocyte retrieval. Analysis of semen and selection of high quality cells. Alternatively cryo-preservation of semen.

Fourth step: embryo culture

The semen is joined to the oocytes after oocytarian recovery and it takes five steps.

Fifth step: embryo transfer

One to five days after fertilization, the embryo is transferred into the uterus by inserting a thin catheter in the cervical, specific to the embryo transfer. Multiple embryos are transferred in order to increase the chance of success.

The embryos that are not transferred, can be cryo-preserved and stored in liquid nitrogen for use, if necessary, in subsequent cycles of IVF.

Luteal phase support at the end of treatment

Both in assisted reproduction techniques that insemination must give a luteal supplementation (with progesterone) for aspirating follicles also aspirate cells that should become luteal cells.

Already 12 days after transfer in utero you can have a first reliable evidence of engraftment of performing blood sample dosage bhcg. Only 14 days after the first positive bhcg you can see the room gestational (before you pick up and then you can make withdrawals of urine).

A pregnancy test is scheduled in two weeks after embryo transfer. If the Test result is positive it is needed an echography after two weeks

ICSI

Technique which consists in the microinjection of sperm to single internal mature oocyte. It is the maximum facilitation of a semen inadequate. The induction of Ovulation is the same as the earlier the processing but is different because the eggs are completely stripped before ICSI.

The ICSI is employed for the treatment of infertility by severe male factor, due to:

- Low Sperm motility
- Anomaly Morphology of sperm cells
- Low Or absence of any concentration of sperm in the semen.
- In Case of absence of fertilized oocytes after IVF.

Even when there is azoospermia results can be through ICSI; you can take the precursors of sperm cells in the seminiferous tubules, mature enough to be able to fertilize the egg.

ICSI is performed through several steps:

- 1- Women undergoes fertility treatment to induce ovarian stimulation and follicular maturation.
- 2- Recovery of oocytes and placement in special culture media.
- 3- Once collected, the oocytes are examined under a microscope to assess their quality.
- 4 -Oociti placed in the incubator for 3-6 hours.
 - -Removal Oocytes incubator.

- -Elimination Cells surrounding oocytes in order to assess the maturity oocitaria (ICSI may be performed only on mature oocytes!)
- -The Immature cells are removed from the ground (the next day will be injected in the presence of signs of maturation).

5-The collection of semen to ejaculate can be aspirated from the epididymis (PESA) or testicles (TESA or TESE); It is prepared by special culture media. The preparation can also be obtained from frozen samples.

6-Selection microscopic oocyte.

7-Immobilization of the sperm cell and injected through a fine needle directly into the oocyte cytoplasm. The oocyte is held stationary by applying the opposite side to the injection a small pump that causes a gentle suction. This procedure is repeated for each oocyte. About 5% of the oocytes are damaged by the procedure.

8-The oocytes are examined the next day to look for signs of fertilization (such as in vitro fertilization).

9-The embryos that are formed, grow and divide for more 24-48ore.

10-Not all oocytes will fertilize, and in some embryos will stop the ripening. Can be transferred to a maximum of 3 embryos, the excess will be frozen.

11-Support during the luteal phase

Conclusion

In conclusion of this more technical part of my essay I will summarize assuming that

- The CC is the drug of choice in the patients with chronic anovulation .
- The Changes in lifestyle are recommended for infertile obese women
- The Best strategy in case of resistance to the CC is CC plus metformin combination therapy .
- The LOD followed by three months and only observation , anovulatory patients from further three cycles of CC is a viable option for patients who are well selected .
- The Gonadotropins are the choice for ovulation induction multiple .

- The Assisted reproduction techniques represent a valuable alternative for patients who do not respond to therapy ovulation induction simple or multiple , or in the case of unexplained infertility , tubal / peritoneal or male .

In Italy wasn't possible to do the heterologous FMI because wasn't allowed by the law number 40 of 2004. With a constitutional interpretation done by the judges of the Constitutional Court of Italy the law about FMI has been literally modified with a reformation made by the Court without the normal iter that is previewed by the Constitution passing through the parliamentarian vote. Eleven years after the promulgation of the l. n. 40/2004 the diagnosis preimplantation of the embryo has been authorized by the judge of the Constitutional Court . The fertile couples who were capable of having a children but were carrying a genetic illness couldn't require to do the preimplantation analysis so the Court decided, after a common jurisprudential interpretation in Tribunals, that wasn't mandatory to implant minum three embryos during the FMI (fact that was causing multiple pregnancies and other problems to women) (prohibition eliminated by the sentence of 2009 n. 151 of the Constitutional Court). After sentences before in Milan (2014) and then in Rome (2015) the Court declared the illegality respect the Constitution of that article. In this way they were also attending a previous sentence of the Court of Human Rights of Strasbourg which in 2012 has condemned Italy because they assumed that the l.n. 40/2004 was violating the fundamental rights of every human being and in particular the right of everyone to build a family that is guaranteed by the art. 8 of CEDU. The law concerning the FMI has been destructed by 33 sentences of the Italian Court but still is. Fourth were the prohibition which the Court has cut out from the law. Also the Grande Chambre of the European Court has decided about the use of embryos in the scientific research and the informed consent of the father and the denial of that consent before and after the fertilization. The interdiction of the heterologous fertilization was the only prohibition still standing in Italy together with the impossibility for homosexual couples to accede to the FMI. The secretary of the Luca Coscioni's association, the lawyer Filomena Gallo, has done a truly battle in order to achieve the freedom in the scientific research which is ended thanks to the judges of the Constitutional Court the 9 April of 2015. Regarding the decree to update the guidelines of L. n. 40 / 2004 , which regulates the Medically Assisted Procreation (PMA) to determine whether the Minister has maintained what has been announced, namely granting access to medically assisted fertilization to couples who have need to try to have pregnancy. In particular the legislative decrees 191/2007 and 16/2010 and Agreement State Regions of 15 March 2012 (which applies to

PMA European standards of quality and safety of human cells), and the judge of the Constitutional Court n.151 / 2009 and 162 / 2014 which eliminated, respectively , the maximum number of three embryos to be created and downloaded in a unique, contemporary facility , and a ban on heterologous fertilization. The sentence n. 151/2009 of the Constitutional Court states that " in the field of therapeutic practice, the basic rule should be the autonomy and responsibility of the doctor, who ,with the consent of the patient, makes his professional work necessary choices". The judges of the Constitutional Court in its judgment 162/2014 invite the minister to update the administrative act required by law 40 for what concerns the number of donations for each donor on the French and English model. Why not immediately ensure the real access quickly after one year after the judgment and the total absence of the Ministry for information campaigns for the donation of gametes was asking Filomena Gallo? In the new text of the guidelines are given clinical indications for access to assisted reproduction techniques of heterologous type, while also providing the so-called " double heterologous " - when both members of the couple may receive donated gametes - and the possibility of " egg sharing " and " sperm -sharing " , in the hypothesis that one of the two components of the receiving pair can in turn also be donor gametes to other pairs that access the PMA heterologous. To exclude illegitimate eugenic selection , to couples who access the heterologous FMI it's not allowed to choose specific phenotypic characteristics of the donor but, by the way, in Italy there has never been the choice of the phenotypic characteristics but only in combination depending on the compatibility of health and physical features of the pair. It was written off the list of useful items to mature acceptance aware of the technical proposal. After the establishment of the National Registry of donors, this is the second important step in the upgrade of the entire regulatory framework that regulates the PMA in Italy - said the Minister Lorenzin - update that will be completed in the coming weeks with the decrees on informed consent and so-called " abandoned embryos " , and with the completion of the transposition of European regulations on the donation of gametes. The rapid progress of science, the unstoppable evolution of genetic engineering, the consolidation of prenatal medicine, the anticipation at fertilization interventions, have opened up unimagined horizons in the fight against disease but also raised new and thorny issues concerning the protection of fundamental human rights. In this very sensitive field full of questions, bioethical first biological there is a strong need for certainty, ergo definition. In this regard, it is possible to trace a similarity between our Constitution and supranational sources in the fact that, even in the lack, in terms of content, it does not refer explicitly to the unborn child, although it is allowed a suitable extension to ensure a widespread protection.

Indeed, the absence of explicit references does not legitimize the use of terms only tended to grasp the essence of legal value to be protected, or reduction of protection of a mere object of rights. The specific uniqueness, unity and identity that distinguish from the moment of fertilization the unborn child together with the conviction that, for the purposes of recognition as a human being, what is important is precisely the principle of life, allow you to speak in the specific case of the human person, the latter term has a special significance because they can better than any other to fully express the complexity of belonging to the human race characterized by fullness and perfection details. It should be remembered that many prefer to talk in person or even in the making of foreshadowing of the person. In any case, it does not seem questionable that the unborn child can be contained in the great human family of which, in the first place, art. 1 of the Universal Declaration of Human Rights adopted by the UN General Assembly on 10 December 1948, will ensure dignity and a series of inalienable rights in the hope of a real possibility of peace, justice and equality in the world. From a point of view more detail, the most significant took over the art. 25, paragraph 2, where they are provided care and assistance forms of motherhood and childhood. The Declaration of '48, where human rights constituted a utopia to be pursued and realized, only two years after he joined the art. 1 of the European Convention on Human Rights entitled "Obligation to respect human rights." While the Declaration, however, explicitly refers to every individual, different translation games have brought in the English text of the ECHR to retain the use of the broad term everyone, while the definition appears in French à toute personne, which is matched by the expression "any person" in accordance with the Italian translation, in relation to Articles. 1 and 2. This terminological uncertainty has led the European Commission itself, with interpretation strongly criticized, to affirm in the '80s that cannot carve art. 2 of C.E.D.U. the existence of an absolute right to life of the fetus, especially in contrast to that of the mother. However, this interpretation could be overcome by considering both the Convention closely linked to the Universal Declaration, which expressly is called, is noting the occurrence in 1959 of the Declaration of the Rights of the Child by the UN. We should remember that many prefer to talk about person in fieri or even about the making of foreshadowing of the person. In any case, it does not seem questionable that the unborn child can be contained in the great human family of which, in the first place, art. 1 of the Universal Declaration of Human Rights adopted by the UN General Assembly on 10 December 1948, will ensure dignity and a series of inalienable rights in the hope of a real possibility of peace, justice and equality in the world. From a point of view more detail, the most significant took over the art. 25, paragraph 2, where they are provided care and assistance forms of motherhood and

childhood. The Declaration of '48, where human rights constituted a utopia to be pursued and realized, only two years after was joined by the art. 1 of the European Convention on Human Rights entitled "Obligation to respect human rights". While the Declaration, however, explicitly refers to every individual human being, different translation games have brought in the English text of the ECHR to retain the use of the broad term "everyone", while the definition appeared in French "à toute personne", which is matched by the expression "ogni persona" in accordance with the Italian translation, in relation to Articles 1 and 2. This terminological uncertainty has led the European Commission itself, with an interpretation strongly criticized, to affirm in the '80s that the art. 2 of C.E.D.U cannot presume the existence of an absolute right to life of the fetus, especially in contrast to that of the mother. In any case, the increasing use of techniques of artificial fertilization in vivo and in vitro and fear a drift ethics of scientific progress led the European Parliament, again in 1989, to adopt two resolutions. In the first, on embryo research and the need to protect the human gene, it proclaims the need to protect the zygote and calling on States, in paragraph 32, to legally define the limits of application of research in so that interventions on living human embryos or fetuses are carried out exclusively in diagnosis and therapy, ergo for the child's welfare. One can easily guess that the child in question is none other than the conceived, which concept covers both the embryo and the fetus in fact, the only relevant difference is closely linked to the time factor but either is present that principle of human life which is intrinsically typical of the unborn child. Then, in the first place, it is necessary to mention the article 1 of the Oviedo Convention which commits the signatories to protect "the dignity and identity of all human beings" and to ensure "every individual, without discrimination, respect for their integrity and other rights and fundamental freedoms against the application of biology and medicine. " It 'also significant, the strong recognition in the art. 2 of the primacy of the needs and the "welfare of the human [...] On the 'interest of society or science" as well as a ban on the genetic modification of sperm and eggs for fertilization (art. 13) and every use of techniques of medically assisted procreation for the sole purpose of knowing the sex of the unborn child, "except that in order to avoid a serious hereditary disease linked to sex" (Art. 14). Such provisions projected on the sphere of the subject unborn specific protection, safeguarding its interest in the unrepeatable uniqueness and identity of the person and that is why the second paragraph of art. 18, categorically "is prohibited the creation of human embryos for research purposes" as is expected, however, that where the law allows research on embryos in vitro, it should ensure, in the past, as much as possible an adequate protection. A further ban, place firmly, is that of human cloning inasmuch as the instrumentalization of

human beings through the deliberate creation of genetically identical individuals is considered "contrary to human dignity". Of fundamental importance, also, it is to be considered the Universal Declaration on the Human Genome adopted by UNESCO on 11 November 1997 and approved by the General Assembly of the United Nations in 1998 in which an attempt was made to arrive at a legal definition of the human genome. Main aim of the declaration is to affirm solemnly that "no scientific project in the field of biology and genetics may prevail over the dignity and rights of the person." Fundamental, in the end, is in the European Union the promulgation, in 2000, of the Charter of Fundamental Rights of the European Union, signed in Nice, that art. 1 establishes the principle of super-human dignity, proclaiming inviolable, and art. 2 provides that "everyone has the right to life." Significant in this regard is the recognition, since the preamble, how the EU must put "the person at the heart of its activities" and "the indivisible, universal values of human dignity, freedom, equality and solidarity" which essential basis of the entire system. A careful reading of this legislation in conjunction is a central joint as it allows to establish a series of guiding principles in the field of medicine and biology, such as the prohibition of eugenic practices is, in particular those aiming at the selection people (art. 3, paragraph 2, letter. b) and the reproductive cloning of human beings (art. 3, paragraph 2, letter. d). The main justification for such prohibitions are still traces in axiological priority of the commandment to protect human dignity, which has as its value the values able to inform themselves of the entire legal system as well as a cardinal principle of the system Italian-Community sources. Focusing, then, on Article. 2 of the Charter of Nice is right to note that it is not in any way specify whether life begins at conception but it is not formalized that it begins with the birth. From this finding, it is considered permissible, according to some, in identifying "individual", the Charter gives the right to life, even to the unborn child. The latter refers also the right to physical integrity under article 3 of the Charter of Nice, with some modifications proclaimed 2007 in Strasbourg. The express prohibition, contained therein, of eugenic practices, justification for regarding their conceived as the bearer of legal interests given that most of these practices are intended to affect its genetic heritage. Furthermore, it is given that Article 24 of the Charter of Nice in the child recognizes the holder of subjective legal situations that need special protection because, as stated in the declaration of intent contained in the preamble to the Charter, "the enjoyment of these rights entails responsibilities and duties to others as to the human community and to future generations ", some commentators believe you can extend this provision also conceived not only as part of the human community, but above all, as the embodiment of the respect owed to future generations. Pour conclure, it

seems clear that the best guarantee against the risk of exploitation of prenatal life is the recognition of the unborn child as a human being to whom I extended the super-principle of dignity. Further confirmation of what the effect of Article. 62 of the Constitution for Europe, signed in Rome on Oct. 29 2004, which states that "everyone has the right to life." Finally, we must remember that, following the Treaty of Lisbon, signed on 13 December 2007 but only came into force on Dec. 1, 2009, the Charter of Nice, with appropriate modifications, is, by now, has, by virtue of Article 6.1 of the EU Treaty, the same "legal value as the Treaties" and the Constitution for Europe, signed in Rome in 2004, was for a large part in its main innovations incorporated into the TEU and the TFEU.

In the same direction moves the European Court of Justice, with two interesting decisions on the non-patentability of inventions involving embryos art. 6 n. 2 letter. c) 6 July 1998 Directive 98/44 / EC on the legal protection of biotechnological inventions which states that "are considered unpatentable ... c) uses of human embryos for industrial or commercial purposes". Part of the doctrine rightly points out that this provision should be read in conjunction with art. 5, par. 1 of the directive: "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions". There is therefore a further confirmation that the European legislator has ruled out any possibility of patent infringing the respect due to human dignity. The first of two decisions dated 18 October 2011 in the case *Brustle vs Green Peace* and was adopted in the context of proceedings for cancellation of a German patent on neural progenitor cells and their production from embryonic stem cells and their used for therapeutic purposes. So extremely interesting to the Court, in interpreting the aforementioned article of 6 July 1998 Directive 98/44 / EC on the legal protection of biotechnological inventions, whilst noting the need to define what the 'human embryo, a comparison with scientific knowledge, characterized in each case by a plurality of different views, strongly reiterates the importance of the only legal question and is oriented in favor of an interpretation of the abovementioned legislation dominated first by the teleological criterion. The college makes clear, in fact, of having to obtain the determination of the meaning and scope of the expression "uses of human embryos for industrial or commercial purposes" in the directive, taking into account the context in which it is used and the objects of the discipline or the removal of barriers to trade and to the proper functioning of the internal market. However, despite the clear imprint of mercantilist quest 'last, the judgment in question ends to accommodate distinctly personal approach of the

issue, in line with the increasing openness of Community law to the demands of European constitutionalism. In other words, the tendency, widespread in the Community courts, to ensure that the policy is teleological colors of a precise caliber of value through the proper reference to the fundamental principles of the Union urges the Court to seek to comply with the concept of a human embryo values of human dignity and personal integrity appropriately selected in the 'sphere of the complex regulatory Community as founding values of the system. In this' optical judgment reaches a notion in the broad sense of a human embryo can catch not just any egg from the moment of fertilization but also those obtained through the techniques of parthenogenesis and therapeutic cloning because what is important for granting the quality of human being is the principle of life, that is the beginning of the process of biological development, which is immanent, seamless, the 'need for respect for human dignity. Subsequently, the Grand Chamber of the Court of Justice in December 18, 2014 needed to question again on the issue on the notion of a human embryo in the case International Stem Cell Corporation vs Comptroller General of Patents. While the judgment *Brustle vs Green Peace* 2011, the Court had, as previously argued, extended the concept of a human embryo, in 2014 the same has significantly reduced the scope. This case has to base the refusal of the IPO (Intellectual Property Office) of the UK to recognize two patent applications submitted by International Stem Cell Corporation, a pioneer in the field of biotechnology, which sought to patent a technology of production pluripotent stem cells. In this case, through the parthenogenetic activation of the ovum there is the need of fertilization as the oocyte comes to be stimulated through electrical and chemical techniques thanks to which it can reach the blastocyst stage: never having been fertilized l' oocyte contains only maternal DNA. The IPO had refused recognition right on the basis of the judgment of the Court of Justice of the European Union in 2011, believing that these inventions were to lead to a use involving the destruction of human embryos. On the contrary, the appeal of the International Stem Cell Corporation was based on the assumption that the oocyte "activated" with that kind of peculiar techniques were not then able to develop into a human embryo, since it would be "content" only DNA maternal. The optimization of such value is also the basis of the solution to the problem of qualification of stem cells derived from an embryo at the blastocyst stage or the decision to put a prudent national courts that classification, evoking a dynamic perspective that takes into account the 'scientific evolution . The desire to impress the patent law to the respect for the inviolable rights of 'man inspired, also, the extension being hermeneutics of prohibition in' article 6, No. 2, letter. c.) of the directive applies in all cases the 'application of which is nevertheless capable of affecting the value of

human dignity. Subsequently, the Grand Chamber of the Court of Justice in December 18, 2014 was found to question again on the issue on the notion of a human embryo in the case *International Stem Cell Corporation vs Comptroller General of Patents*. The High Court of Justice has, however, questioned whether human eggs stimulated to divide and develop through parthenogenesis containing only pluripotent cells, ergo not suitable to develop in humans, may or may not be included in the definition of 'human embryo' referred to Directive 98/44 / EC. Precisely for this ruling in 2013 he has applied to the Court of Justice of the European Union. The only point of difference between the two disputes submitted to 'Court's attention a few years later about the amenability to whether "parthenote" in the concept of human embryo. In 2014 there was a revirement respect the judgment of the European Court *Brustle* because we preferred to argue that a parthenote that has no chance of developing into a human being is not syllogistically covered by the term "human embryo". Although it gets better still to British judge that the existence of the intrinsic inability of parthenote to develop into a human being, the college seems to exclude from the notion of human embryo that of "non-fertilized human ovum which through parthenogenesis was induced to divide and develop (...) if, in the light of current knowledge of science, it is free, as such, the inherent capacity to develop into a human being. " It would have been preferable, however, place more emphasis on the fact that, "although the parthenote, according to our current knowledge, not possible in humans, they initially through the same stages of development of a fertilized egg, in particular the division and differentiation cell, and thus constitute human embryos ". However, in order to avoid to address the problem of determining when human life begins, the European Court of Human Rights that, even when he had to make specific reference to the scope of Article 2 of C.E.D.U. "The right to life shall be protected by law ..." merely recognize European States a wide margin of appreciation with regard to legislative policy choices. Even in the earlier case the Court had not taken a clear position because while recognizing, in the name of human dignity, the need for legal protection of the fetus and / or embryo, to the latter's potential to become a person, has failed. However, to identify it as "the person to go secured the right to life under art. 2 of C.E.D.U. ".

In conclusion, the Community Courts, in the fear of diminishing the protection of the human body, thus violating the principle of integrity and dignity contained in the said Directive and, more generally, expressed throughout the Community legal order (art. 3.1 of the Charter and Art. 2 TEU) have opted for a meaning not narrow the human embryo. With this term, in fact, it is intended to refer not only fertilized egg but rather to any oocyte that, a result of

manipulation, is able to develop to give life to an individual. Having built the concept in question, each entity may constitute the beginning of a process of development of a human being signals a strong choice for the protection of the human person, ergo the embryo, its life and its integrity. In strengthening the de facto protection of the initial moment of human life, the judges have marked a turning point, affecting not just the internal reflection on the Member States because they have taken a position as indicated by them scrupulously respectful of the fundamental principles of the Community. In a field significantly delicate and subject to constant new discoveries interwoven into new needs of the human confrontation with continuous and constant with elements meta-juridical increases even more the need for legal certainty. Faced with a confused and sometimes discordant detailed regulations concerning the figure of the unborn is becoming more crucial intervention, not least "creative", the judges not only at Community level but also within each Member State (see the recent activity of the Italian Constitutional Court in the work of re-interpretation of Law 40 of 2004). It warns, however, despite the important supplementary role of the judiciary both Community and national level the prevailing need for crystallization legislation. Moreover, the same Court of Justice of the European Union in *Brustle vs Green Peace* said that "although the definition of the human embryo constitutes a very sensitive social issue in many Member States, marked by the diversity of their values and their traditions, the Court is not required, in the preliminary ruling, to address issues of medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions of the Directive. Beyond profiles directly affect Communitarian legislation, they affect not just the processing formulas elastic variable content (public order, etc.) as the entire apparatus of the categories, conceptual frameworks and cultural patterns internal to the individual Member States. Condition, moreover, the same hermeneutics activity concerning the content and meaning of the domestic law (v. Articles. 54, 101, paragraph 2, and 117, paragraph 1, Cost.). Ultimately, all the data analyzed so far are unanimous in favor of a notion of human embryo intended to guarantee, in an integral way, and from the beginning, the development of the human being and therefore confirming the indissolubility, in axiological terms, between dignity and protection of the person. Donc, the excursus done as far led us to believe in a fully shared conclusion which is more a warning of Zatti to turn to the principles which "land of choice for the equality between men and embryo, and in particular the constitutional statements related to man in his helpless quality of living." Principles among which certainly assumes particular importance the relief recognized fundamental dignity constitutes the very basis of all rights and inviolable value due to each individual as such, therefore also

conceived, since the human person cannot be considered as a simple means but it should be considered only and always as an end.

The modern tools of prenatal diagnosis confirms what mothers have always thought: that children in the womb feel , are connected with their surroundings and above all share the emotions with their mothers : disappointment , depression , anger , fear , affection . Here's how you develop the " proto-conscience " which includes the rudiments of personality of the unborn child. They have turned the spotlight on the fascinating beginning of life , the lost paradise that unites all . And to deepen , but not solve , the old question of the presence of a soul before birth . A change , therefore , is also the social representation of the fetus , the image we have of this stage of life , the expectations of the parents themselves. Current knowledge demolished prejudices and superstitions. But in some cases they have instead confirmed that children in the womb feel , are connected with their surroundings . Since the modern diagnostic tools have allowed us to investigate and explore the womb, to study and monitor it closely, it was discovered as the living fetus, what "evidence", as it develops from the first weeks. They have turned the spotlight on the fascinating beginning of life, the lost paradise that unites us all. And to deepen, but not solve, the old question of the presence of a soul before birth. A change, therefore, is also the social representation of the fetus, the image we have of this stage of life, the expectations of the parents themselves. In fact, research shows that since the first months of gestation when the mother is at peace even the fetus it is, but if he is anxious shake the same way. The mysterious and profound bond between mother and fetus was born well before the birth. Even premature babies express a range of emotions. Observations of behavior in utero, especially between twins, reveal anger, fear, affection. The fetus also reacts to the needles that intrude into the uterus with shock, withdrawal, aggression, feeling real panic. Calms down with the mother's voice, to six months of gestation can move the body to the rhythm of his mother. Nowadays the mother, in addition to nutrients, emotional content goes, directly, to the baby during pregnancy. The way she perceives the environment causes physiological responses in the blood - through the release of signal molecules - that "speak" to the fetus, biochemically inform him of what to expect and how should programming. This means that the mother through the placenta communicates to test small thing, as it is, even what he thinks in a sense, giving you a preview of the environment. In this way the fetus predisposes to adapt to environmental requirements even before birth. Researchers believe prenatal fact that there is connection between what we think the mother during pregnancy and how you feel the unborn child for hormones associated with emotions

that cross the placenta. It seems there is also correlation between emotional life of the pregnant mother and the child's personality. In fact, studies reveal a tendency for anxious mothers to have children, anxious but the topic is controversial. Research suggests that emotional tensions persisted make it difficult to form a strong bond with the child during pregnancy and lead easily to emotional problems in the unborn child. The extreme maternal anxiety is also linked to increased risk of premature birth and low birth weight. Anger and fear incurred hampers the development of the child and his health, emotional tensions chemically impact on the fetus, "scare" his nervous system developing. If Mom is stirred often, the little you get used to feel stressed, to overreact to stimuli, to overload emotionally. In this perspective, "feed" the unborn child that goes beyond pay attention to food. The concept of parenting, "become family" begins at conception, and perhaps even earlier with the ideas and expectations of this event, since the thoughts, feelings and attitudes of parents deeply affect the child's development in the path of growth before and after birth. Enrichment programs, prenatal tested in experimental groups (exposure to music, singing, voice, dance, exercise) confirms that children in the womb are alert, aware, socially oriented and learn from experience. Also a good stimulation, especially through an expressive mother, has positive effects on brain development. The children even in utero feel and know more of what is believed possible. In perfect symbiosis and deep nine months, it seems impossible for the mother to keep something hidden in his small.

Abstract

In Italia non è stato possibile fare l'eterologa FMI perché non è stato consentito dalla legge numero 40 del 2004. Con una interpretazione costituzionale svolta dai giudici della Corte costituzionale d'Italia la legge sul FMI è stata letteralmente modificata con una riforma fatta da parte della Corte, senza l'iter normale che è previsto dalla Costituzione passando attraverso il voto parlamentare. Undici anni dopo la promulgazione della l. n. 40/2004 la diagnosi preimpianto dell'embrione è stata autorizzata dai giudici della Corte costituzionale. Erano quattro i divieti che la Corte ha eliminato dalla legge. Dal momento che gli strumenti diagnostici moderni ci hanno permesso di indagare ed esplorare il grembo materno, di studiare e monitorare da vicino e si è scoperto che il feto "prova" emozioni sin dalle prime settimane. Si sono così accesi i riflettori sul suggestivo inizio della vita, il paradiso perduto che ci unisce tutti. In tal modo si approfondisce ma non si risolve del tutto la vecchia questione della presenza di un'anima prima della nascita. Un cambiamento, quindi, è anche nella rappresentazione sociale del feto, l'immagine che abbiamo di questa fase della vita, le aspettative dei genitori stessi. In realtà, la ricerca dimostra che fin dai primi mesi di gestazione quando la madre è in pace, anche il feto lo è ma se lei è in ansia il bambino lo è allo stesso modo. I bambini anche in utero sentono e sanno di più di ciò che si crede possibile. In perfetta e profonda simbiosi durante i nove mesi, anche se sembra impossibile, fra la madre e il suo piccolo nasce un legame profondo e simbiotico.