FERTILISATION IN ARTIFICIAL WOMB

LEGAL AND BIOETHICAL ISSUES

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ABSTRACT:

In the paper, the authors² present legal and bioethical issues related to the fertilization outside the human body, particularly, to the producing and applying an artificial womb for this purpose. Considering these issues appears to be necessary to create proper legislation that will provide a legal basis for the given issue.

KEY WORDS: Artificial; womb; fertilisation; fetus; embryo

1. Introduction

According to the myth, in the evening, Zeus, Hermes and Poseidon found a grange on their way and they asked for shelter in there. The poor farmer hosted them and gave them to eat and to drink. To thank him for his generosity, the gods revealed their identity and, since he sacrifices his only bull for them, they offered him a favour. He told them about the promise to not marry another woman he had done to his recently dead wife. But his wish is not to have a new wife, but a child (*nec coniunx et pater esse volo*), so he asked for the birth of a son. The gods took the bull's hide and urinate into it; then they asked the farmer to bury it in his garden and to dig it up nine moths later. The peasant did so and in the end, he found a beautiful and strong child wrapped in the leather. He called him Urion, *ab urina*, and later on the name changed to Orion³.

The growth of an organism in an artificial environment outside the body in which it would normally be found is called *ectogenesis*. This term was coined in 1923 by the British scientist Haldane in his *Daedalus*⁴. Haldane wrote imagining how a 2070 college student would describe the evolution of this technique.

"It was in 1951 that Dupont and Schwarz produced the first ectogenetic child. [...] France was the first country to adopt ectogenesis officially, and by 1968 was producing 60,000 children annually by this method. [...]"⁵.

Ectogenesis attracts the attention from many scholars. In 1931, Aldous Huxley⁶ wrote about a fictional world in which ectogenesis represents the first step of a eugenic program of social re-

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² The paper represents the fruit of joint reflections by the authors. Paragraphs 1, 2 and 4 have been written by George G. Tumanishvili, paragraph 3 by Marco Poli. The conclusions have been written by both authors.

³ P. Ovid Naso, *Fasti*, trans. George Frazer (Cambridge: Harvard University Press, 1959), book 5, 188-259.

⁴ J.B.S. Haldane, *Daedalus, or Science and the Future, a paper read to the Heretics, Cambridge*, on Feb. 4th, 1923.

⁵ Haldane, *Daedalus*.

organization. In his novel, he describes how, at the Central London Hatchery, artificially fertilised ova were placed into incubators where they remain a different amount of time, according to the cast he or she belongs to. Children destined to work in chemical factories are treated so they can tolerate lead and calcium and "a special mechanism kept [embryonic rocket-plane engineers' containers] in constant rotation 'to improve their sense of balance'"

Huxley's work has left a so deep mark that "the mere mention of it evokes a whole complex of hostile attitudes towards science. It has become a kind of byword for a society in which the values (or non-values) of scientific technology are dominant, and which has therefore reduced man to a species of machine".

Despite many scholars' essays discussing Medically Assisted Procreation (MAP), only a few studies addressed ectogenesis ethical and legal implication. According to Gelfand, "this is both surprising and troubling given that it is likely that an artificial womb designed for human use will be developed in the near future, and the moral and social implications of ectogenesis are complex and far-reaching". The impact of ectogenesis on social relationships and values imagined in fictional worlds since then is huge. Human life and laws ruling many aspects of it would be deeply affected by an effectively performing artificial womb: the opportunity to consider a pregnancy in which the human body is not involved would inevitably face those cultural, ethical, social and (sometimes) religious framework on which national legislation are built on.

This article is going to focus on ectogenesis implications, both from the embryo and the mother/father (Parent(s) point of view. In doing so, a definition and description of the artificial womb technology will be provided stressing out the scientific development and the scope of ectogenesis. Defined the state of the art, this work will describe two categories of potential artificial womb use: *ex vivo* pregnancies and *in utero* pregnancies. According to these categories, the article analyzes legal implications related to potential sex selection techniques.

2. Artificial womb

2.a. Artificial womb and its purpose

Ectogenesis is defined as the "development of a mammalian embryo in an artificial environment". The artificial environment involved in this technique is the artificial womb, that is the device that holds the embryo during the pregnancy. In this period, "the artificial womb would supply nutrients and oxygen to an incubated fetus and would be capable of disposing of "waste materials". This would, therefore, necessitate an artificial placenta for mediating the necessary exchanges between fetal circulation and the system that would replace the maternal flow". Indeed, an artificial womb needs several components in order to achieve its purpose: a "shell" to house the embryo, amniotic fluid to surround it and a regulatory system to provide the right amount of oxygen, nutrients and hormones.

Medically speaking, ectogenesis is already partially a reality. Indeed, the period in which the fetus has to be inside of the womb to successfully develop is becoming smaller and smaller. Thinking at

⁶ Aldous Huxley, Brave New World, New York: Harper Perennial Modern Classics, 2010.

⁷ Huxley, Brave New World, 35.

⁸ Peter Firchow, "Science and Coscience in Huxley's Brave New World", *Contemporary Literature* 16, n. 3 (1975), 301

⁹ Scott Gelfald, "Introduction", in *In Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction*, ed. Scott Gelfand and John R. Shook, (Amsterdam-NY: Rodopi B.V., 2006),

¹⁰ Webster's 3rd New International Dictionary (3rd ed. 1961).

¹¹ Carlo Bulletti *et al*, "The Artificial Womb", *Annals of the New York Academy Science* 1221 (2011), 124.

the beginning of the pregnancy, thanks to in vitro fertilization (IVF), conception can occur in the laboratory and then the embryo can be kept alive for two of three days before placing it in the womb. At the other end, extremely premature babies born before the 25th weeks' have up to 50% probability of survival¹². This gap of a little more of five months in which the natural womb is essential is likely to be narrowed because of the doctors' attempts to save premature children. Moving from this considerations, res ipsa loquitur: saving premature born babies is the first purpose of an artificial womb.

Freeing pregnancy from a natural uterus, ectogenesis could be regarded as an instrument to overcome gender inequalities¹³: thanks to this technique, women could avoid the biological burden of the gestation and all the health, pain and work implication related to the pregnancy (see 3.a).

Artificial womb could also represent the turning point in the surrogacy debate: "The medical case for ectogenesis, then, would consist of the medical case for surrogate motherhood coupled with the claim that ectogenesis should be chosen in preference to surrogacy" 14. The reason for this preference is linked to the "carrier's" artificial and strictly controlled nature. In this sense, artificial womb might be favoured for several reasons: avoiding the risk of women exploitation, reducing costs of the procedure (once it becomes a standard one), staying out of any battle over custody.

For the sake of completeness, we mention another argumentation for ectogenesis, it is that embryos could be grown to guarantee tissues to mature humans 15. Indeed, using in transplantation fetuses' cells, the risk of immunological rejection is very low. However, even if transplantation of fetal tissues has received great worldwide attention during 1980's and 1990's this artificial womb's implication has to be considered obsolete. The same purpose is now achieved with embryonic stem cells. These cells are derived from a pre-implantation blastocyst at 5-7 days post-fertilization and they possess qualities such as "pluripotency and a seemingly limitless capacity to proliferate in vitro in their undifferentiated state" ¹⁷. Embryonic stem cells derived from a not-implanted embryo. rather than from a fetus, so artificial womb is not implicated in this process.

So, freeing human beings from what we have considered biological and factual burdens, ectogenesis seems to be the key to a new procreative anthropocentric era, imposing to investigate potential self-determination rights' balances.

2.b. The Historical Perspective

This is not the first time that the possibility of ectogenesis has received attention. Firstly, in 1920's, the idea of ectogenesis was generated and circulated in intellectual circles, generating little or no interest in the average person. This changed in 1970's and 1980's when ectogenesis became of public interest. Not only the cultural élite, but also a wider public took part in the debate over the linkage between sexuality and reproduction. According to Firestone, independently of the level reached in political and social equality, nothing would change for women as long as natural

¹² Imad T. Jarjour, "Neurodevelopmental Outcome After Extreme Prematurity: A Review of the Literature". Pediatric Neurology 52, n. 2 (2015), 143.

¹³ See Shulamith Firestone, *The Dialectic of Sex* (New York: Bantam Books, 1970).

¹⁴ Peter Singer and Deane Wells, "Ectogenesis." In Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction, edited by Scott Gelfand and John R. Shook (Amsterdam-NY: Rodopi B.V., 2006), 11.

¹⁵ Singer, "Ectogenesis", 15.

¹⁶ M.Terese Verklan, "The ethical use of fetal tissue for transplantation and research", Journal of Advanced Nursing 18, n. 8 (1992), 1172.

¹⁷ Steinhoff, Gustav, ed. Human Embryonic Stem Cell, in Regenerative Medicine: from Protocol to Patient. Berlin: Springer International Publishing, 2016 (Springer International Publishing, 2016), 27.

reproduction remains rule¹⁸. However, not all feminists supported ectogenesis: according to them, artificial reproduction was a repudiation of women's body and women themselves. Specifically, O'Brien¹⁹ theorized a women's *reproductive consciousness* in contrast with a men's *alienated reproductive consciousness*²⁰: this dissimilarity and the correlated uncertain connection of the man with the child are the reason why men are seeking the control women's reproductive power²¹.

In the today debate, the majority of the population thinks that artificial womb is not the instrument of a misogynistic plot²². This is due to the certainty that women can have control over the artificial reproduction (ectogenesis) as well as over the natural one. Furthermore, compared to previous debates, what changed the most in the today-scenario is the science involvement: ectogenesis is believed to be more a science fact than a science fiction.

Recent success in ectogenical research have been already mentioned, but it is not an isolated incident: these research teams are not the first, nor the last, scientists to attempt Promethean research. In 1944, Dr John Rock made the first successful in vitro fertilization²³; then, Dr L.B. Shettles²⁴ succeeded in maintaining embryos to the blastocyst stage for 3 days. Attempts to support the implantation of human embryos outside of the women body were firstly performed in 1982 in Italy by Dr Bulletti and continued in New York City in 1983²⁵.

Referring to the artificial womb's components, the *shell* to hold the developing embryo have been realized both out of artificial materials and out of human endometrial cells grown on a scaffolding shaped like a uterus²⁶. In addition, the amniotic fluid – which serves to protect the embryo from the outside injuries, promote musculoskeletal development and maintain a constant temperature, has been used in both experiments with animals and humans²⁷. There is also the need for a device through which the embryo can receive oxygen, nutrients and hormones. One noticeable example of this kind of equipment is the ECMO, an extracorporeal membrane oxygenator that delivers blood flow and oxygen to the embryo; it also works as a dialysis machine. In this sense, in Japan, in 1996, Dr Kuwabara reported attempts at preserving a developing goat in an artificial womb, provided with amniotic fluid and blood supply, for three weeks ²⁸. Then, many attempts have been performed, culminating in the 2016 goal in which researchers broke the record for keeping human embryos alive in an artificial environment. Researchers in the US and the UK have been able to keep embryos alive and active outside of the human body, completely independent of a woman's

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¹⁸ Firestone, *The Dialectic of Sex*. Firestone argued that the joy of giving birth is a mere patrirchal myth; childbirth is "like shitting a pumpkin".

¹⁹ Mary O'Brien, *The politics of reproduction* (London:Routledge and Kegan Paul, 1981)

²⁰ Talking about *alienation*, O'Brien means that men sense their control over whether human life goes on and whether, in particular, their own genetic offspring lives on.

²¹ See inter alia Adrienne Rich, Of Woman Born: Motherhood as Experience and Institution (New York: Norton, 1986); Gena Corea, The Mother Machine: reproductive technologies from artificial insemination to artificial wombs (New York: Harper & Row, 1985).

²² Rosemarie Tong, "Out of Body Gestation: in whose best interest?", *Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction*, ed. Scott Gelfand and John R. Shook (Amsterdam-NY: Rodopi B.V. ed., 2006), 11

²³ Miriam F. Menkin and John Rock, "In vitro fertilization and cleavage of human ovarian eggs". *American Journal of Obstetrice and Gynecology* 55, n. 3 (1948), 440.

²⁴ Landrum B. Shettles, "Selection of Biology: Studies on living human ova." *Transaction of the N. Y. Academy of Science* 17, n. 2 (1954), 99; and Landrum B. Shettles, "The living human ovum." *American Journal of Obstetrics and Gynecol*ogy 76, n. 2(1958), 365.

²⁵ Carlo Bulletti *et al*, "Extracorporeal perfusion of the human uterus", *American Journal of Obstetrice and Gynecology* 154, n.3 (1986), 683.

²⁶ See Francesca Dolendo, "Baby Machines: The Birth of the Artificial Womb", *Triple Helix* 2, n. 4 (2006).

²⁷ Jonathan Knight, "Artificial womb: An Out of Body Experience". *Nature* 419 (2002), 106.

²⁸ Bulletti, "The Artificial womb".

womb. ²⁹⁻³⁰. For the first time, human embryos were grown for 13 days in an artificial womb. Then, researchers had to stop the experiment because "for ethical reasons, [scientists] are obliged to stop [...] cultures at day 14 of development or before the primitive streak formation"³¹.

3. Artificial womb legal implications

The Roman law principle according to which *mater semper certa est* has always been considered the basis for creating the status/relationship of mother and child. Leaving out – for simplicity – the adoption case, according to many³² national laws, motherhood is founded on the fact of birth: the legal mother is the woman who has given birth to the child. Indeed, legal mother corresponds to the biological one; in the case of egg donation, the biological element is not relevant³³. Removing the woman in labour from the reproductive scenario, ectogenesis will inevitably undermine this conception. Following paragraphs will discuss the artificial womb's legal implication in relation to maternal, paternal and embryo interests.

3.a. Maternal and Paternal Interests

The artificial womb is considered a medical device aimed to overcome various biological limits linked to the reproductive field. Do these limits constitute an injustice? Do the State have the duty to actively remove these limits? Does the artificial womb – as a fertility treatment – have to be provided in the healthcare system?

About the distribution of sources, Dworkin³⁴ stressed the importance of a fair equality and the central role of justice in health care. In this sense, natural inequalities may generate a *prima facie* right to restitution. Focusing on the fertility ground, Burley tried to answer the question "who should bear the cost of fertility treatments?"³⁵. Burley observes, on the one hand, that infertility may generate a *prima facie* right to restitution, so the infertile could seek for compensation; but, on the other hand, he noticed that having children could be regarded as being merely an expensive

²⁹ Ian Sample, "Researchers break record for keeping lab-grown human embryos alive", Guardian (2016).

³⁰ Alessia Deglincerti *et al.*, "Self-organization of the in vitro attached human embryo", Nature 533 (2016), 251.

³¹ Marta N. Shahbazi *et al.*, "Self-organization of the human embryo in the absence of maternal tissues." *Natural Cell Biology* 18 (2016), 706.

³² See CZECH REPUBLIC: according to §775 Obč.Z. a mother is a woman who has given birth to a child ("matkou dítěte je žena, která je porodila"). ITALY: Article 267 c.c. maternity is demonstrated by proving the identity of the person who is assumed to be the child with the person who was given birth by the woman who is alleged to be the mother ("la maternita' e' dimostrata provando la identità di colui che si pretende essere figlio e di colui che fu partorito dalla donna, la quale si assume essere madre"). FRANCE: Article 310-3 Code civil, filiation is proved by the act of birth of the child, by the act of recognition or by a statutory declaration which affirms the status (la filiation se prouve par l'acte de naissance de l'enfant, par l'acte de reconnaissance ou par l'acte de notoriété constatant la possession d'état).

³³ see e.g. ITALY: Tribunal of Rome, *Ordinanza* 8th August 2014 and Ord. 22nd April 2015. The two couples involved in this case had used homologous fertilization in vitro and were awaiting the implantation of the embryos produced. During the operation, the healthcare staff mixed up the test tubes and implanted the two embryos in the wrong womb. In its judgment, the Tribunal of Rome affirmed that, coherently to what Article 269 CC affirms, gametes' genetical origin is not relevant to determine motherhood: the mother is the woman who have given birth to the child. CZECH REPUBLIC: Z. Králíčková, *New Family Law in Czech Republic: Back to Traditions and Towards Modern Trends*, in The International Survey of Family Law, 71, 84 (2014).

³⁴ R. Dworkin, *Justice in the Distribution of Health Care*, 38 McGill Law Journal 833, 836 (1993)

³⁵ Justine C. Burley, "The Price of Eggs: Who Should Bear the Cost of Fertility Treatments?" In *The future of Human Reproduction*, ed. John Harris and Søren Holm (Oxford: Clarendon Press, 1998), 127

taste, so it does not necessarily constitute grounds for compensation. To overcome this impasse, quoting Dworking, she stressed that if people's tastes are *involuntary* acquired and they are related to their conception of the 'good life', then restitution is possible but not necessarily warranted. Indeed, if individuals "could be offered the means of removing or relieving the desire or taste for X in a way that did not encompass the provision of X, but they chose to retain the desire, they would *not* be eligible for compensation" Infertile couples who have a strong desire for children don't want to receive treatment aimed at removing the desire: they want the provision of children themselves. According to what we said so far, in this case, state funding for fertility is not justified.

Then, Burley approached the problem from a different angle: people who cannot have children do not choose their infertility, nor do they construe *childlessness* as part of their conception of good life. They are victims of cruel fate and, because of that, they may merit compensation. Thus, for Burley, since persons' inability (infertility) to pursue their life goals (having a child) is not the result of a voluntary choice, fertility treatments can be fitted into Dworkin's framework as a form of redistributive justice. It has to be noticed that Burley's argument doesn't prove anything but a prima facie right to restitution. Facing limited State budget, the question of who have the right to have the *care* remains. Dworkin recommend a 'quasi veil of ignorance' method in which, "[n]o one would be in a position to say, of himself or anyone else, that that person is more or less likely to contract sickle-cell anaemia, or diabetes, or to be the victim of violence in the street, than any other person"³⁷. In this kind of hypothetical scenario, Burley suggests that, since reproduction central role is socially recognized, "[i]t is plausible to insist that individuals in the aggregate would stipulate infertility as one handicap they were particularly concerned to receive compensation for"³⁸.

Artificial womb as remedy for gender inequalities

As we have seen, natural inequalities can be argued to constitute *prima facie* grounds for restitution. Moving from this starting point, Smajdor adds another element. She says that the fact that, unlike men, women have to gestate and give birth in order to have a child is a *prima facie* injustice that could be overcome by the development of ectogenesis.

Applying the 'veil of ignorance' method, she tries to imagine which criteria individuals might use in their analysis about this topic. First of all, she moves from Burley considerations: the probability of having a particular condition is considered a significant factor, as well as some social tendencies do, such as the desire for genetical linked descendants. Then she added her own 'ingredients'.

Even though Dworkin does not recognise freedom from pain as a good, he assumes that freedom from pain is likely to be very important. Indeed, in his analysis, he distinguishes well-being in two categories: *volitional well-being*, that is improved when someone achieve what he/she wants; and *critical well-being*, that is improved when the person achieve what he/she should want, "that is the achievements or experiences that it would make his life a worse one *not* to want" In this scenario, the *freedom from pain and sexual or other frustration* would constitute a third category of well-being, but it can figure within the two named categories. Even if avoiding pain counts in volitional interest, it counts as well as part of critical interest. Because of that, since gestation and childbirth are very likely to be associated with pain and suffering, Smajdor suggest that this factor is likely to be considered by people from behind the veil.

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³⁶ A. Smajdor, The Moral Imperative for Ectogenesis, 16 Cambridge Quarterly of Healthcare and Ethics, 336, 337 (2007)

³⁷ Dworkin, "Justice in the Distribution of Health Care", 889.

³⁸ Burley, "The Price of Eggs", 142.

Ronald Dworkin, "Foundations of Liberal Equality",in *Equal Freedom: Selected Tanner Lectures on Human Values*, ed. Stephen L. Darwall (Ann Arbor: University of Michigan Press 1995), 230
 Dworkin, "Foundations of Liberal Equality", 230, footnote 33.

Moreover, if we consider a 'behind the veil' scenario in which people do not know to which gender they will belong, people have to be conscious that they have 50% of probability to face those problems linked to pregnancy. Still focusing on the criteria to elect for the provision of such a compensation, Smajdor highlights that the women's desire to reproduce as men do - "without risking their physical and mental health, economic and social well-being". — is recognizable as a health-oriented need, rather than an expensive taste. In fact, we have to keep in mind that 15% of all pregnant women develop potentially life-threatening complications.

Furthermore, even if the "yuck factor" linked to artificial womb would prevail on all the other "behind the veil" arguments and someone might argue that problems related to pregnancy are recoverable or at least medically manageable and that some women enjoy the experience of being pregnant 's, Smajdor's demand for reproductive freedom and self-determination sounds reasonable. Supporting this view, Burley's 'bungee jumpers metaphor' make it clear the difference between option luck (non compensable) and brute luck (compensable). Suppose that a person who suffer detached retinas and a healthy one go bungee jumping: the first one does not have a claim for compensation, because he voluntary underwent under the risk. According to Smajdor, pregnancy is the bungee jumping and "there might be greater scope for ectogenesis to be prioritized due in part to the pain and trauma that even the best-managed childbirth entails" so that women can consciously choose to jump or not.

So far, we analysed the artificial womb's impact on gender inequalities linked to the pregnancy, but, for the sake of intellectual honesty, we have to briefly expose our doubts on the decisiveness of this argumentation in the whole cultural landscape. Indeed, even though it seems to be the key for a new reproductive gender equality, ectogenesis is not solving the problem of who is entitled to be the caregiver after the childbirth. Murphy emphasises that pregnancy prepares women for motherhood in some way, suggesting that gestational mothers are the best one to take care of children⁴⁶. This common and questionable⁴⁷ assumption shows that the cultural problem on the woman's role still exists and, to turning upside down what Firestone said, nothing would change for women as long as they are still asked to play the part of 'angel of the hearth'.

- One parent case

Just as some women might wish to be free from the burden of pregnancy indispensability, as the same men might wish to do so. Nowadays, in many countries, single women have access to IVF, so they can start a one-parent family. In the previous paragraph, the artificial womb impact on women reproductive freedom has been analysed, stressing ectogenesis central role in reproductive self-determination. This paragraph will analyse artificial womb implication from the single-man point of view.

We can imagine a man with a strong desire for biological offspring. He is not biologically meant to gestate and give birth, so he will not succeed in passing on his genes unless a woman carries a child genetically related to him. Within a fertile straight couple or a lesbian one, the woman involved in this scenario is the female partner or wife; for infertile straight couples and (in some lawscapes)

⁴⁵ Smajdor, "The Moral Imperative for Ectogenesis", 340-1.

⁴¹ Smajdor, "The Moral Imperative for Ectogenesis", 340.

 $^{^{\}rm 42}$ World Health Organization. Managing complications in pregnancy and childbirth, V (Geneva, Switzerland: World Health Organization, 2003).

⁴³ See T. Murphy, "Research priorities and future of pregnancies", *Cambridge Quarterly of Healthcare Ethics*, 21 (2011).

⁴⁴ Burley, "The Price of Eggs", 136.

⁴⁶ Murphy, "Research priorities and future of pregnancies".

 $^{^{47}}$ See A. Mullin, Reconceiving preganancy and childcare (Cambridge: Cambridge University Press, 2005).

same-sex ones (two men), the woman is a surrogate mother. More and more single women are starting a single-parent family ⁴⁸.

Being a single man with a strong desire for paternity could be considered as a deficit in personal resources? Applying to this topic Smajdor's reasoning, the fact that women do not have to be in a couple to have a genetically related child, whereas men do, is natural inequality and so it is the candidate for redistributive justice. Single men do not choose the inability to gestate themselves and the fact of not having a partner; and as we have previously seen, the deficit in personal resources which is not the result of a personal choice and that inhibits the person's capacity to pursue his life goals constitutes the basis for compensation. Access to motherhood has been granted to women in a relationship, single ones and infertile ones: mainly referring to the last two mentioned categories, for the sake of equal treatment, according to men the same treatment appears fair.

Would the artificial womb for single men succeed the veil-of-ignorance test? Reasonably the freedom to be fully developed as a human person, that is, in this case, the freedom to pursue paternity goal, can be included within the Dworkin's *freedom from pain and sexual or other frustration*. Even the Smajdor's gender-blind behind the veil scenario would reasonably give something to think about.

Nevertheless, the "yuck factor" would play the main role in here. Indeed, if on the one hand, biotechnologies are considered an advantage for someone, on the other hand, they are considered as dangerous by others: those technologies are alternatively presented as a Pandora's vase or a cornucopia 49. The artificial womb for single men, as well as surrogacy for male gay couples, is criticized by ecocentrism supporters because it is considered an expression of an anthropocentric approach 50. Scepticism on ectogenesis as an alternative to natural pregnancy has already been stressed in the previous paragraph, and it is even stronger if this technology is referred to single men. This approach considerably distances itself from the natural procreative course, and because of that, it raises many doubts. For this very reason, even though artificial womb might be reasonably considered as an instrument to achieve complete equality, it will not probably pass the veil-of-ignorance test.

Contractual agreement between intentional parents

Modern cases support the idea that marital and procreative decisions fall within a constitutionally protected zone of privacy. Because of the privatization process concerning family law, more and more relevance has been given to individuals' self-determination. For this reason, it is possible to imagine a scenario in which genetic mother and father could define their rights over an embryo in an artificial womb trough a contract. The aim of a contract is to enforce promises and to protect parties' expectations: this is due to the fact that unplanned factors can complicate even the best-laid plan.

Trying to find it out a possible discipline, it has to be stressed that, in several countries, "protecting the unborn" laws are in force with the aim of defending life before birth, which is perceived as inviolable⁵¹. Protecting these lives is an *ordre public* matter, so the margin of self-determination

⁴⁸ Maria Salomon et al., "Setting up a networking platform for single women using donor semen", in Abstracts of the 31st Annual Meeting of the European Society of Human Reproduction and Embryology (2015).

⁴⁹ This methaphor in Mariachiara Tallachini, "Biotecnologie e diritto", in Mariachiara Tallachini and Fabio Terragni, Le biotecnologie. Aspetti etici, sociali e ambientali, (Milan: Mondadori, 2004), 104-106.

⁵⁰ See Stéphane Bauzon, "Dal Rischio alla Precauzione: il caso delle biotecnologie" in *La Persona Biogiuridica* (Turin: Giappichelli: 2005).

⁵¹ See Diya Uberoi and Maria de Bruyn, "Human rights versus legal control over women's reproductive self-determination", Health and Human Rights 15, n. 1 (2013).

accorded to future parents depends on the space that *ordre public* itself has left to private choice. Indeed, if a contract is illegal on grounds of *public policy*, it is void *ab initio* and it is unenforceable⁵².

It seems reasonable that the rules governing those contracts will be those used by IVF clinics, rather than the one used for surrogacy. This is due to the great differences between ectogenesis and surrogacy: firstly, the latter involves a third party carrier; secondly, surrogacy contracts enforceability is centred around the right of the surrogate mother in not being forced to sever her rights to the children.

Regarding the content of the contract between future parents, it would probably concern the end of the artificial pregnancy. In this sense, there are two possible contracts: one affirming that the pregnancy has to continue until the end under any circumstances; and the other authorizing termination. This second contract leads to the problem of identifying who can end the gestation: potentially the parties might opt for a *mutual consent* model or for a *unilateral termination* one.

Artificial womb contracts allowing unilateral termination are likely to be unenforced because they "represent a more extreme version of contracts concerning frozen embryos, which are still often declared unenforceable"⁵³.

The mutual consent type of contract is meant to allow the termination of pregnancy when both parties *mutually consent* to discontinue the pregnancy. In such a scenario, if both parties agree on the termination, regarding the enforcement, the only aspect of determining is the lawfulness or not of the action. If only one person wants to discontinue the pregnancy, probably courts would apply

National Assembly, Constitution of the REPUBLIC OF ECUADOR. Article 45 (2008). Available at: http://pdba.georgetown.edu/Constitutions/Ecuador/english08. html; M. Szabó, "Constitutional reforms in HUNGARY, 2011-12" (presentation at The 12th Conference of the Asian Ombudsman Association, Tokyo, *JAPAN*, December 6, 2011). Available at http://www.google.com/url?sa=t&rct= j&q=hungary%20constitutional%20reform%202011&soure=web&cd=5&sqi=2&ved=0CDwQFjAE &url=http%3A%2F%2Fwww.aoa2011.go.jp%2Fcommon%2Fpdf%2F02session%2FSession2_Hung ary.ppt&ei=p17TvDXEIXrtgflqM3PBg&usg=AFQjCNGQ0pd2jk0BF1fRGtQ3Bx7H2SErnA&sig2=_ BUoass3PfAa44TePB8DAQ; M. Cosgrove, "MEXICO high court allows state anti-abortion 29, amendment." Jurist Legal News & Research (September 2011). http://jurist.org/paperchase/2011/09/mexico-high-courtallowsstateantiabortionamendment.php; Congress of the Republic, Political Constitution of PERU, Art. 2 (2006). Available at http://www.congreso.gob.pe/_ingles/CONSTITUTION_29_08_08.pdf; J. P. Enrile, An Act to Uphold the Human Rights and Promote the Welfare of the Unborn Child, Amending for the Purpose Articles 256, 257, 258, and 259 of the Revised Penal Code, and for Other Purposes; 2010. Available http://alfi.org.ph/2011/wp-(MANILA, Senate). at content/uploads/2011/02/3eSB2497-Protection-of-the-Unborn-child-Ponce-Enrile.pdf; R.Wicker, S91 Life at conception act. Washington, DC, United States Senate (2011). Available at http://www.opencongress.org/bill/112-s91/text.

⁵² For France, see Eva Steiner, "Surrogacy Agreements in French Law", *The International and Comparative Law Quarterly* 41, n. 4, 866-875 (1992). Contracts against *ordre public* are null (*nullité absolue*). According to the Cour de Cassation, in the Alma Mater case the Cour said: "ces conventions [i.e. surrogacy arrangements] contreviennent au principe d'ordre public de l'indisponibilité de l'état des personnes". In the adoption case it said: "la convention par laquelle une femme s'engage, fut-ce titre gratuit, i concevoir et i porter un enfant pour l'abandonner i sa naissance contrevient tant au principe d'ordre public de l'indisponibilité du corps humain qu'i celui de l'indisponibilité de l'état des personnes".

U.K. see Cheshire, Fifoot and Furmston, *Law of Contract*, (Oxford: Oxford University Press, 16th ed.: 2012), 460. "Contracts against public policy are not illegal, in the sense that a contract to do a prohibited or immoral act is illegal. They are not 'unenforceable', in the sense that a contract within the Statute of Frauds in unenforceable for want of writing. These covenants lie somewhere in between. They are invalid and unenforceable".

⁵³ Jessica H. Schultz, "Development of Ectogenesis: How Will Artificial Wombs Affect the Legal Status of a Feto or Embryo?", Chicago-Kent Law Review 84 (2010).

the rules used for frozen embryo cases⁵⁴, enforcing prior agreements between the parties, that in this case is the agreement about the need for a mutual consent. In such a sphere, the dominant framework recognises the personal autonomy central role and turns on the intent of the parties; "[n]ot surprisingly, this emphasis on individual choice places a "virtual veto power" in the hands who want to avoid reproduction" However, it has to be noticed that, regarding enforceability, artificial womb disputes are different from the IVF one: if a court does not enforce an artificial womb contract, the court is choosing to let a potential life to grow; otherwise, if the court enforces an artificial womb contract, the court is actually preventing a developing life from continuing.

- Contract between intentional parents and the service provider

An ectogenesis scenario involves someone (a couple or a single person) who wants to have a baby and a clinic, which performs the artificial womb technique. To resolve any conflict between these two parties, the key is – again – a contract, but which one? There are many options such as service contracts, at-will employment ones, adoption ones and sale of goods ones; but not all of these frameworks are appropriate in such agreements.

Firstly, we will focus on the at-will employment contract. The clinic may be considered an employee because it is hired to provide the gestation through the artificial womb to the intended parents, such as a day labourer provide his physical labour to the employer. However, this kind of contract is characterized by the fact that both the employer and the employee can terminate their working relationship whenever and for whatever reason. This factor makes an at-will employment contract inappropriate for an artificial womb contract: neither the intended parents nor the clinic can terminate their relationship at will.

Secondly, it is impossible to imagine an adoption. Intended parents provide their gametes to a clinic that gestate the embryo in an artificial womb. It would sound hysterical to consider the clinic as the natural mother of the child, and it would seem simply crazy to consider so an artificial womb, that is a machine. Just notice that even for surrogacy contracts, the adoption contract has been considered inappropriate, because of the lack of genetic ties⁵⁶.

Thirdly, according to the US Uniform Commercial Code, the definition of "goods" includes "the unborn young of animals and growing corps"⁵⁷. Even tough this provision seems to allow the sale of a human embryo or fetus as a good, it has to be noticed that these are not a *res*. Many courts held that embryos and fetuses are neither a person nor a property, they have to be considered as a *tertium genus* between *res* and *persona*. For this reason, the goods contract model is inadequate.

Finally, service contract refers to an agreement between the independent contractor and the employer: the first party agrees to supply time, effort and expertise in exchange for compensation. As an example, consider the contract between parents and a childcare provider running a day-care centre: he/she is paid for taking care of the children. As the same, the clinic (herein after, the 'service provider') assume the duty to take care of the embryo inside the artificial womb. The service provider receives a compensation for developing the embryo and then the fetus. In a scenario in which there is more than one provider, probably, still paying the mere rent of the machine, intended parents can safely remove the artificial womb from the provider and turn to another one. About surrogacy in California, Berys argue that usually service providers' activities are "regulated by state law that dictates the level of care to be taken. In contrast, because gestational

⁵⁴ See the leading case Davis v. Davis 842 S.W.2d 588, 597 (Tenn. 1992).

⁵⁵ Olivia Lin, "Rehabilitating Bioethics: Recontextualizing in vitro Fertilization Outside Contractual Autonomy", *Duke Law Journal* 54(2004), 485-500

⁵⁶ See e.g. Jonson v. Calvert, 851 P.2d 776, 778 (Cal. 1993),

⁵⁷ U.C.C. §2-105 (1998)

⁵⁸ See Roe v. Wade, 410 U.S. 113, 162 (US) and Constitutional Court, judgment 27/1975 (Italy).

⁵⁹ Flavia Berys, "Interpreting a Rent-a-Womb Contract: How California Courts Should Proceed When Gestational Surrogacy Arrangements Go Sour", *California Western Law Review* 42 (2006).

surrogacy has not yet been written into legislation, there is no official standard established for the level of care to be exercised when gestating a fetus for another person" 60. This argument is unconvincing for ectogenesis. Artificial womb contracts are related to a futuristic technology, so, once it comes true, the legislator may reasonably rule it in detail. Then, she points out that service contract does not fit for surrogacy because "the surrogate is not only providing the service of physical care for the baby, but she is also earning her fee by handing the child over after its birth. In comparison, in a service contract, the fee is directly tied to the service itself, and not necessarily to the status of a product or good"61. Moreover, Anderson draws attention to the fact that "commercial surrogate contracts objectionably commodify children because they regard parental rights over children, not as trusts, to be allocated in the best interests of the child, but as like property rights, to be allocated at the will of the parents."62. Mutatis mutandis, these reasonings are relevant also for the ectogenesis sphere. First of all, Anderson's argumentation is based on a childbirth-centric conception of motherhood. According to her, the surrogate has parental rights on the baby because of the delivery. We argue that the surrogate is not a pregnant woman who, for various reasons, is seeking for adoptive parents for her baby. The surrogate is a woman that has accepted to gestate someone else's baby, and naturally, the gestation itself culminate in the childbirth. Applying this approach to an artificial pregnancy would lead, ab absurdo, to recognize a corporative motherhood, for the provider, or an artificial one, for the machine. It is obvious that in such a scenario the mater semper certa est rule does not apply on a delivery basis: for this reason, parents are the ones who provide genetic materials. For this reason, the artificial womb contract does not include any transfer of the parental right, because intended parents are legal parents yet. The agreement is that is the service provider develop the commissioning couple's embryo, they will pay a certain amount of money. In the end, the service contract seems to be appropriate for artificial-gestational agreements.

III.b. for fetus or embryo

Ectogenesis also imposes an analysis from the embryo and fetus' point of view, rather than solely investigate the fully developed humans' one, as we did so far. Unlike IVF embryos, the ones used for the ectogenic purpose are expected to develop. Indeed, IVF is a reproductive technology connected to conception, not gestation; so, if the embryo is not implanted in a uterus, it will naturally die within fourteen days. Embryos implanted in an artificial womb are instead supposed to fully develop without time limits. Moreover, if on the one hand IVF embryos in a petri dish are a mass of undifferentiated cells, on the other hand, in vitro fetus (here in after i.v. fetus)⁶³ develops human organs, assuming a human shape. As already mentioned, ectogenesis raises legal, moral and ethical dilemmas: central to these dilemmas is the question as to what an i.v. fetus is.

First of all, some terminological punctuations have to be done. We use the term "fetus", rather than "embryo", relying on the Code of Federal Regulation (CFR) definition: "[f]etus means the product of conception from implantation until delivery".⁶⁴. Even if the medical definition of fetus relates to the period of development from eight weeks to birth, the CFR's definition highlights a relevant aspect: the fact that human embryos obtain different moral protection depending on whether they are implanted in a womb or not. In fact, if an embryo in a petri dish may be exposed to intrusive experiments, on the other hand, an *in vivo* one is generally not exposed to harmful research because

⁶⁰ Berys, "Interpreting a Rent-a-Womb Contract", 341

⁶¹ Berys, "Interpreting a Rent-a-Womb Contract", 342.

⁶² Elizabeth S. Anderson, "Why Commercial Surrogate Motherhood Unethically Commodifies Women and Children: Reply to McLachlan and Swales", Health Care Analysis 8 (2000).

⁶³ Raskin and Mazor define 'in vitro fetus' the fetus that's growing in an artificial womb. Joyce M. Raskin and Nadav A. Mazor, "The Artificial Womb and Human Subject Research", in S. Gelfand, J.R. Shook, Ectogenesis: Artificial Womb Technology and the Future of Human Reproduction" (Amsterdam-NY: Rodopi B.V. ed., 2006), 159

⁶⁴ CFR 45 §46.202(c)

it is gestated in a living human body. According to Raskin and Mazor⁶⁵, the fetus benefits from the mother full moral status, because the pregnant woman and the fetus are physically inseparable. Even if it is not medically accurate, the term 'fetus' gives the idea of the higher moral/legal status of the implanted embryo, contributing in a terminological way to stress out the difference between IVF embryos and i.v. fetuses.

An i.v. fetus is different from any of the unborn entities we know. Thus, answering the ontological question about its nature is very important. Relatively to embryos and fetuses, the literature expressed three beliefs on this point: person, property and subjects entitled to special respect. According to the western legal tradition on this point, the fetus is not a person because of the differences linked to the early-life stage; nor a property, because they are not subject to property rights, e.g. it can not be alienated. The special respect view is the more persuasive because it enhances the fetus' potential to become a person, but it also recognizes that the fetus is not a person yet.

"The mere existence of an embryo in a womb adds value to its moral status" 66, but what if the womb is an artificial one? If the fetus' higher status depends on the fact that it is embedded within the carrier body, does the artificial nature of the artificial womb have any consequence on the IV fetus status? The independent nature of gestation imposes to reflect on two main aspects: viability and birth.

Many courts and several states legislatures use the concept of viability to describe the point of development of the fetus at which the fetus comes within the ambit of state interest, permitting the state to regulate and even ban abortion. The fetus becomes viable when it is "potentially able to live outside the mother's womb, albeit with artificial aid". The IV fetus might be considered viable from the moment of implantation because since that moment the fetus lives outside the mother's womb with artificial aid.

This leads to many relevant implications, such as the one related to abortion. If the IV fetus is viable since the beginning, this means that it cannot be aborted at all. This not only contrasts with the right to privacy but also it evidently contrasts with the right to equal treatment. In this kind of scenario, women involved in a natural pregnancy have their rights to dignity and autonomy in decision-making respected, but, on the contrary, women who resort to artificial womb do not have the same treatment.

Regarding birth, the traditional moment in which it occurs is marked by the act of departing the womb. In the case of i.v. fetuses, this definition would lead to some anomalous situations. Think at the case in which an extremely premature baby was born and, in order to save his or her life, he or she is put in an artificial womb, until the end of the pregnancy. When was the baby born: departing from the mother's womb or from the artificial one? Is he or she born twice?

Raskin and Mazor described a situation in which

"a prematurely born neonate maintained on a life support system is considered born, whereas an in vitro fetus at the same stage of development and sustained in the same manner is not "born" yet.

Does this mean that in terms of human subject research regulation the in vitro fetus should receive more protection due to the fact that it exists outside of a physical body, and thus "on its own" as a living human? Moreover, considering that the in vitro fetus is no longer protected by the natural shield of a female womb, it is further exposed to the scientific hunger for research than the in vivo

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⁶⁵ Raskin, "The Artificial Womb and Human Subject Research", 165.

⁶⁶ Raskin, "The Artificial Womb and Human Subject Research", 164.

⁶⁷ Roe v. Wade, IX B.

fetus. Does this make the in vitro fetus a distinct member of a much more vulnerable class of beings that require extended protection?" ⁶⁸

In this regard, we argue that this inconsistency can be easily overcome considering the mother's womb and the artificial one at the same level. In this way, the naturally gestated fetus and the i.v. one receives the same protection.

Generally, both the viability and birth implications might find a solution considering a fetus a fetus, regardless of its nature and of its method of gestation. Equalizing the two kinds of wombs would inevitably lead to an equal moral value for fetuses so that they would be in the same category for the purpose of protection.

4. Sex selection

Mostly in the common thought, ectogenesis is usually linked to positive eugenics, understood as breeding the 'best' human traits to benefit future generations. The ability to externally observe the growing fetus and to actively control its development in various ways scares people: such a massive technical competence understandably might lead to fear a slippery slope mechanism.

In this sense, one possible implication is linked to sex selection. In many parts of the word, parents demonstrate a gender bias, preferring sons⁶⁹. In the July 2010 issue of the Atlantic "The End of Men"⁷⁰, Hanna Rosin highlighted girl preference emerged in relation to sex-selection practices performed in the US⁷¹. This paragraph is meant to hypothesise artificial womb's implications in this area and their legal implications.

As already mentioned, there are two categories of artificial womb use:

- a) *ex vivo* pregnancies: the embryo is conceived with IVF techniques and it is directly implanted into the artificial womb for the entire gestation;
- b) *in utero* pregnancies: the embryo starts the pregnancy as a natural one; then the partially developed fetus is extracted by a surgeon from the woman's womb and it is inserted into an artificial womb for the rest of the gestation.

In this scenario, methods od sex selection vary in the timing of the necessary intervention.

"One of these methods (MicroSort) involves pre-conception selection of the sex of the sperm. A second method (pre-implantation genetic diagnosis; PGD) uses post-conception but the pre-implantation selection of the embryo. Finally, several older methods (amniocentesis, chorionic villi sampling, ultrasound, or blood tests) use post-implantation screening and rely on abortion of an already well-established fetus" ⁷².

Because of the timing, techniques occurring before implantation (MicroSort and PGD) may only apply only to *ex-vivo* pregnancies, unlike the post-implantation ones that apply to both pregnancies.

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⁶⁸ Raskin, "The Artificial Womb and Human Subject Research", 166.

⁶⁹ V. Bhaskar, "Sex Selection and Gender Balance", *American Economic Journal* 3(2011), 214-244. "This phenomenon is especially prevalent in South and East Asia. In Northern India, it is common to celebrate the birth of a boy and bemoan that of a girl. [...] In Dharmapuri district of Tamil Nadu, India, infant girls were often fed uncooked rice, as a way of inducing rapid death. In Punjab (northern India), the caste of Bedi Sikhs have traditionally been known as kudi-maar – 'girl-killer'" ⁷⁰ Hanna Rosin, The End of Men, The Atlantic, July 2010.

⁷¹ See Rajani Bhatia, "Constructing Gender from the Inside Out: Sex-Selection Practices in the United States", *Feminist Studies* 36, n.2 (2010). In her article, she argue "that recent sex-selection practices involving new technolo gies in the United States do mark a significant socio-cultural-technical shift that feminists should be paying attention to – even if they do not portend the hyperbolic *end of men*".

⁷² Vardit Risper-Chaim, "Contemporary Muftis between Bioethics and Social Reality: Selection of the Sex of a Fetus as Paradigm", *The Journal of Religious Ethics* 36, n.1 (2008), 60.

Genetic screening technique, in the form of Preimplantation Genetic Diagnosis (PGD), was developed for couples at risk of transmitting a genetic disease to their children. It was meant to detect specific genetic or chromosomal abnormalities, but PGD can be used to discover other genetical information, such as the sex of the unborn. PGD is used in conjunction with IVF, so to give the opportunity to perform a genetic screening of the embryo before it is implanted. If this technique would be used without any restriction, future parents could have access to a certain amount of genic information – also the sex of the unborn-baby– and they could decide to implant only embryos of their favourite sex.

MicroSort allows pre-conception sex selection by sorting male from female sperm. Ejaculated sperm is sorted into predominately male or female sperm. The sperm of the desired sex is then used to inseminate the woman, avoiding in such way abortion and even elimination of embryos.

Nowadays, "sex screening" is usually strictly ruled. It is allowed only to prevent genetic diseases in which sex has a relevant role. Opening to a PGD indiscriminate use, would lead to several questions such as: is it ethical to use PGD to discover the sex of the unborn baby and, because of this information, decide to continue the pregnancy or to abort? Is it sex selection part of women right to free choice and control over their reproduction?

Thanks to the other methods previously mentioned, the sex of the unborn child will be discovered later in the pregnancy.

"One method is a blood test that can determine the sex of the fetus after only five weeks of pregnancy. [...] Amniocentesis is a well-established and accurate method to verify the sex of the fetus. Unfortunately, it must be performed beginning at week fifteen of pregnancy. [...] A similar test, chorionic villi sampling, is done at ten to twelve weeks. Ultrasound scanning can also reveal the sex of the fetus and is a noninvasive method, but it is not one hundred percent reliable" 73.

In all these cases, if the detected sex is the undesired one, abortion is the only option. According to the international trend, normally, Voluntary Interruption of Pregnancy is allowed within the 10th week. These techniques arise new problems concerning the best standard to perform an abortion for artificial womb.

Without getting bogged down in the details of every method, it has to be noticed that there is two kind of sex selections: sex selection *for medical reasons*, aimed to avoid genetic diseases; and *elective* sex selection, aimed to have a child of a specific gender without medical reasons.

Elective sex-selection techniques involve ethical, cultural and legal dilemmas. First of all, this kind of approach indirectly legitimises a gender-based discrimination. As they say these days, white-western-straight-men are more likely to be taken on for managerial roles and have higher incomes. Not expressing a preference for a specific biological sex, but letting future parents free to decide, the legitimization of these techniques would be formally neutral; but in such a scenario it is obvious which sex would be the chosen one. Because of that, permission of elective sex selection legitimises the preference and the liked discrimination according to which it is better to have a baby boy, rather than a girl.

Last, but not least, to elective gender selection is linked the slippery slope fear. A U.K. -based bioethics group, Human Genetics Alert, writes: "If we allow sex selection it will be impossible to oppose 'choice' of any other characteristics, such as appearance, height, intelligence, et cetera"⁷⁴.

⁷³ Risper-Chaim, "Contemporary Muftis between Bioethics and Social Reality", 61.

⁷⁴ Marcy Darnovsky, "Revisiting Sex Selection: The Growing Popularity of New Sex Selection Methods Revives an Old Debate" Genewatch 17, n. 1 (2004), 4.

The shadow of past atrocities⁷⁵ is still influencing our approach to procreative research and technique. Can the law forget them?

Conclusion

Because of its nature, the artificial womb is a controversial topic. It involves birth, death, parenthood, family, sex and freedom. It involves many aspects of human beings' identity, it contests those cultural archetypes which define primary interpersonal relationships (sexual, emotional and family ones) and it moves deep structures of our personal nature.

The uncontrollable quickness of scientific discoveries brought to a cultural shock. It was the shock "of individuals facing the possibility of making choices about their own existence and the shock of societies facing newly broadened horizons. It was a shock to political frameworks, which had to deal with ethical dilemmas and with the uncontrollable quickness of new scientific discoveries. Finally, it was a shock to lawyers because scientific progress changed the basis of their *toolkits*"⁷⁶.

In such a scenario, the need of rules emerges. Embracing ethical pluralism, the law will be responsible for encouraging or restraining scientific technology.

Following the biolaw approach, this paper stressed out the artificial womb's fundamental role in overcoming biological gender inequalities. If ectogenesis becomes reality, it would contribute to the debate over fetuses, such as its moral status and the parenthood rights over an i.v. fetus. Moreover, the contractual regulation would lead to new questions about these agreements limits and the in utero viability.

Law appears to be at a crossroad: on the one hand, because of the fear of betraying nature, the contrast to the new paradigm; on the other, embracing and actively managing the change, so to avoid injustices during the transitional period. If the law approaches ectogenesis with the aim of maximising the social good, maintaining the health and preventing sufferings, as Daedalus, it will hit the target.

It is important the technological progress be aimed at providing an improvement to people's life. In the given case it is also important to consider all the issues including philosophical, medical and bioethical ones, also good and bad sides of it, so to speak. Following considering these issues development and implementation of the appropriate domestic legislation must be provided by every country for issues discussed in the paper not to be in a legal vacuum.

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⁷⁵ See the Nuremberg Code, aimed to provide ethical principles for human experimentation. It is the result of the subsequent Nuremberg trials at the end of the Second World War.

⁷⁶ C. Piciocchi, Bioethics and Law: Between Values and Rules, 12 Indiana Journal of Global Legal Studies 2, 471, (2005).

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