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ARTIFICIAL INTELLIGENCE AND MEDICALLY ASSISTED PROCREATION: AN ANALYSIS OF PREIMPLANTATION GENETIC TESTING (PGT) IN THE LIGHT OF BRAZILIAN CRIMINAL LAW

The aim of the present investigation is to analyze the legal limits of preimplantation genetic testing - PGT and their possible criminal implications under Brazilian criminal law. To this end, we will initially address the particularities of these procedures and how artificial intelligence has been applied in order to improve them. Subsequently, we will analyze the legal regime of PGT in Brazil, investigating the requirements and limits imposed by Brazilian legislation on these techniques. At the end of the investigation, we will demonstrate the existence of an undeniable responsibility gap in when it comes to disregarding rules on medically assisted reproduction. However, there may be liability for the disposal of surplus embryos without the parents' consent.

Keywords: *artificial intelligence; medical law; criminal law; Brazilian law; medically assisted procreation; preimplantation genetic testing.*

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Introduction

It is indisputable that artificial intelligence has impacted several sectors of society[1]. Among its main and most promising areas of application, healthcare is certainly one of the most relevant, but also most controversial. Clinical Decision Support Systems, wearable devices and intelligent prosthetics are just some of the current and future examples of the so-called "medicine 4.0"[2].

The present investigation focuses, however, on a more specific - and perhaps more controversial - aspect of this relationship between health and technology: With advances around reproductive medicine and genetics, the so-called "preimplantation genetic testing - PGT" has become more precise, making it possible, with increasing accuracy, to obtain genetic data from the embryo (hereditary diseases, chromosomal anomalies, and even other physical and psychological characteristics)[3]. Therefore, these techniques make it possible to not only eliminate sick embryos, but even select a baby according to the characteristics desired by the parents.

As can be readily seen, however, these are procedures that, although technically viable, raise countless ethical, moral and legal controversies[4]. In view of these considerations, the aim of this investigation is precisely to analyze the legal limits of these procedures and their possible criminal implications[5]. To this end, we will initially address the particularities of the "preimplantation genetic test-

[1] The specificities of this technology in areas such as road traffic, capital markets and access to justice will not be addressed here. For further details, see: Januário, 2020a, 2021, 2023 and 2024.

[2] For a broad analysis of some of these issues, see: Januário, Rodrigues, 2024, Januário, 2020b and 2022.

[3] For Abellán, this is one of the most spectacular advances in recent times in terms of detecting genetic diseases. See: Abellán, 2006: 22.

[4] Silva Sánchez draws attention, for example, to the selective and eugenic nature of these procedures, which lead to the non-implantation of embryos that do not have the desired characteristics. According to the author, their diagnostic nature is also questionable, since they do not lead to any therapeutic option. See details at: Silva Sánchez, 2020: 310. On this issue, see also: Eser, 1998: 221.

[5] As Maria João Antunes rightly points out, the field of medically assisted procreation, precisely because of the diverse approaches it allows - philosophical, moral, ethical, religious, scientific - is "one of the ideal fields for testing the criteria that legitimize penal intervention" [free translation]. See: Antunes, 2010: 82-83.

ing" procedures, in order to provide a precise understanding of how they are performed. We will also discuss how artificial intelligence has been applied to make them more effective. Once this is done, we will analyze the legal regime of PGT in Brazil, investigating the requirements and limits imposed by Brazilian legislation on these techniques.

Based on the conclusions reached in the first two topics, we will answer, at the end of the investigation, the main question of the paper, which is: are there criminal implications for the subjects involved in these procedures? In the present investigation, we will apply the deductive methodology and analyze mainly Brazilian legislation, doctrine and jurisprudence, without prejudice to any brief considerations of comparative law that may be necessary. Furthermore, with regard to materials, we believe that an interdisciplinary approach to the topic in question is imperative, going beyond legal documents and also including medical publications[6].

1. Genetic engineering and preimplantation genetic testing: some necessary definitions, classifications and distinctions

Genetic engineering can be understood as the set of techniques that, aiming to alter structural or functional characteristics of human beings, animals or plants, carry out specific and intentional interventions at the molecular level of DNA or RNA function (genetic insertion, substitution, modification, suppression or inhibition) (Nuffield Council on Bioethics, 2016: 4).

[6] Critically analyzing Portuguese legislation, Faria Costa highlights how the correct assessment of the meaning of some terms used in legislation on medically assisted procreation escapes the hands of the criminal legislator. In this sense: "However, how can an interpreter know what "artificial insemination" or "in vitro fertilization" is? The rule that the perception and awareness of the elements of this crime should be limited to the layman's sphere cannot apply here. More is required. Much more. It must be science and medical thought that defines what "artificial insemination" and "in vitro fertilization" are. Thus, it can be seen that the scope of incrimination is not entirely in the hands of the criminal legislator. Due to the circumstances and the subject matter on which he/she has to legislate, the latter must abdicate his/her constitutional duty - the constitutional duty to define, in homage to the principle of legality, exactly the criminally prohibited behaviors - and within certain limits define the normative contents that incriminate medical science and thought. Which means that - precisely because science is, in its essence and always, innovation, change, correction, and therefore creative fluidity - the incriminating elements "float" as, precisely, the science that determines them "floats", certainly with the advances" [free translation] (Costa, 2009: 119-120).

There are four distinct ways to proceed with gene editing: (i) the introduction of a new gene without interfering with the existing defective gene (gene insertion); (ii) the modification of the defective gene (genetic modification); (iii) the replacement of the defective gene with a normal version (gene replacement); (iv) and the targeted suppression of specific cells or targeted inhibition of gene expression (genetic suppression or inhibition). Furthermore, for us to be within the scope of genetic engineering, there must be the intention to modify the genome (Figueiredo, 2019: 25-26).

Those techniques can be classified as i) *positive gene editing* and ii) *negative gene editing*. The first group includes cases that seek preventive-therapeutic purposes, i.e., the elimination of defective or disease-causing genes, preventing their possible appearance in the future or making the edited organism healthy. Furthermore, the objective may be to provide the individual with certain positive physical or psychological characteristics, even without therapeutic purposes. The second group includes cases in which the objective is to provide the individual with characteristics generally classified as negative, disadvantageous or limiting, such as diseases or disabilities (Figueiredo, 2021: 58-59).

Genome editing can also be classified according to the type of cell line undergoing the intervention (somatic or germline) and the genome that is the target of the intervention (nuclear or mitochondrial DNA) (Figueiredo, 2019: 26).

The admissibility of *negative gene editing* practices has been widely rejected by scholars. As for *positive gene editing* practices, international and supranational regulations point, with rare exceptions, to the exclusive admissibility of gene editing of somatic cells for preventive-therapeutic purposes (also known as "gene therapy"). Gene editing of germ cells for preventive-therapeutic purposes and gene editing for the improvement of human beings have been essentially rejected (Figueiredo, 2021: 59).

Regarding predictive and diagnostic genetics, Figueiredo highlights the current developments in DNA analysis, specifically with regard to the emergence of Next Generation Sequencing Genetic Tests, which are increasingly reliable, accurate and accessible (Figueiredo, 2021: 59).

Despite the relevance of these issues and their possible legal implications, our object of study is restricted to a specific technique applied in the context of in vitro fertilization. *Preimplantation genetic testing* (PGT) consists of genetic

tests performed on embryos up to 3 days old, before transferring them to the woman's body, to find out whether they are possible carriers of genetic characteristics likely to generate hereditary genetic problems and diseases (Reis, 2008: 340; Xavier, 2017: 72).

Although initially applied with families in which a mutation was already known, to avoid the hereditary transmission of a genetic anomaly (linked to the X chromosome) or structural chromosomal anomaly, this technique has been increasingly used to support procreation, aiming to analyze genes and evaluate the quality of embryos produced in vitro (Lopes, Rodrigues, 2016: 128).

As Lopes and Rodrigues explain, "by submitting an embryo to a precautionary genetic examination to search for anomalies, whether of the embryo already in the mother's womb (prenatal diagnosis) or of the embryo that will be implanted in the uterus (pre-implantation diagnosis)", in the event of genetic anomalies, chromosomal or gene pathologies being detected in the embryo, "the possibility is opened up for the parents, given their knowledge of the embryo's genome, to decide not to implant it or, even after implantation, to no longer want its development" (Lopes, Rodrigues, 2016: 128).

In practice, however, in addition to enabling the prior identification of diseased embryos, this technique also makes it possible to perform embryonic genetic selection according to the parents' preferences, i.e., gender and eyes, hair and skin color. Furthermore, the issue regarding the disposal of embryos with the potential for life but which are classified as "unhealthy" is quite questionable. (Cardin, Cazelatto, Oliveira, 2022: 2-5)[7].

More recently, there has been a growing use of artificial intelligence to increase the effectiveness of screening embryos that are more likely to develop fully and healthily (Cardin, Cazelatto, Oliveira, 2022: 6). An example is provided by Meseguer Escriva et al., pointing out the greater accuracy of artificial intelligence models in detecting embryo characteristics related to ploidy, thus facilitating their triage (Meseguer Escriva et al, 2022).

As explained by Jiang et al., although there is a high pregnancy success rate when euploid embryos are screened by PGT-A (approximately 50%), this technique ended up encountering resistance for a number of reasons, such as: i)

[7] For a complete analysis of the dilemmas related to embryo selection, see: Guimarães, 1999: 169ff.

need for invasive biopsy; ii) high financial costs for the tests; iii) clinical delays in the results and difficulties in their interpretation, especially in the presence of embryonic mosaicism, iv) "attrition in freeze-all cycles may occur based on each clinic's biopsy and cryopreservation criteria, eliminating lower quality blastocysts with potential for clinical pregnancy after fresh transfer"; v) when there are a limited number of embryos, sometimes all transferable embryos end up being eliminated by PGT-A, instead of serving only as "a screening tool without diagnostic verification"; vi) finally, as the mere transfer of euploid embryos does not guarantee pregnancy, there is a loss of confidence in this technique on the part of patients (Jiang et al., 2023: 228).

Artificial intelligence is presented precisely as an alternative that seeks to alleviate these problems in the scope in question, as the authors explain:

"Artificial intelligence provides promising options for noninvasive genetic screening for embryo selection, particularly as studies start integrating large, multicenter databases into model training. The power of AI lies in rapid decision making for embryo selection before transfer in the absence of available genetic testing. […] In addition, AI will consolidate resources by providing rapid, digital embryo analysis as compared with the time-consuming, costly, and resource intensive process of PGT-A or alternative noninvasive genetic testing methods, such as spent media testing or blastocoel fluid testing. Integrating reliable, accurate algorithms into microscopy equipment and Embryoscope platforms will be the next key step to allow widespread access to noninvasive genetic testing. As hardware integration is tackled, software development of algorithms that optimize minimal-necessary covariates for ease of use alongside clinical considerations, such as partial aneuploidy and mosaicism, will strengthen the predictive value of AI algorithms among clinical users. Ultimately, AI-based ploidy prediction will work alongside embryologists to reinforce embryo selection before fresh or frozen transfer, aiming to improve clinical pregnancy rates while decreasing cost per cycle" (Jiang et al., 2023: 233-234).

An exemplary AI system in this scope is the so-called ERICA, which acts precisely in anticipating the ploidy potential of blastocysts by extracting texture patterns from static or time-lapse images and subsequent ranking the embryos "based on the identification and scoring of blastocysts using extracted image-based features, and combining them with the metadata for each embryo using a

binary classification model generated by a deep neural network" (Chavez Badiola et al., 2024: 2, 2020). Studies also suggest that, in addition to helping in the decision about whether to transfer embryos, this test has the potential to provide major information regarding the degree of risk of spontaneous abortions (Chavez Badiola et al., 2024).

2. Preimplantation genetic testing according to Brazilian law

Article 225 of the Brazilian Federal Constitution expressly provides for the right of all to an ecologically balanced environment. To ensure the effectiveness of this right, it is the duty of the government, among other measures, to control the production and use of techniques that pose risks to life, quality of life and the environment, as well as to preserve the diversity and integrity of the country's genetic heritage, and to supervise entities dedicated to research and manipulation of genetic material (Brasil, 1988).

The regulation of this constitutional provision is made by Law 11.105 of 2005, which "establishes safety standards and inspection mechanisms for the construction, cultivation, production, handling, transportation, transfer, import, export, storage, research, selling, consumption, release into the environment and disposal of genetically modified organisms - GMOs and their derivatives, with guidelines for encouraging scientific advancement in the area of biosafety and biotechnology, protecting human, animal and plant life and health, and observing the precautionary principle for protecting the environment" [free translation] (Brasil, 2005).

For the purposes of this law, genetic engineering is considered only the activity of producing and manipulating recombinant DNA/RNA molecules, that is, "molecules manipulated outside living cells by modifying segments of natural or synthetic DNA/RNA and which can multiply in a living cell, or even the DNA/RNA molecules resulting from this multiplication; segments of synthetic DNA/RNA equivalent to those of natural DNA/RNA are also considered as such". From this concept comes the definition of genetically modified organism, understood as "an organism whose genetic material - DNA/RNA has been modified by any genetic engineering technique" [free translation] (Brasil, 2005).

It should be noted, however, that the Law expressly excludes from the category of genetically modified organisms those resulting from techniques that "involve the direct introduction, into an organism, of hereditary material, provided that they do not involve the use of recombinant DNA/RNA molecules or genetically modified organisms, including in vitro fertilization, conjugation, transduction, transformation, polyploid induction and any other natural process" [free translation] (Brasil, 2005)[8].

Reinforcing this position, Article 5th of the Law in question expressly provides that: "It is allowed the use of embryonic stem cells obtained from human embryos produced by in vitro fertilization and not used in the respective procedure, for research and therapy purposes, provided the following conditions are met: I - they are nonviable embryos; or II - they are embryos frozen for 3 (three) years or more, on the date of publication of this Law, or that, already frozen on the date of publication of this Law, after completing 3 (three) years, counted from the date of freezing. § 1 In any case, the consent of the parents is required. § 2 Research institutions and health services that carry out research or therapy with human embryonic stem cells must submit their projects for consideration and approval by the respective research ethics committees. § 3 The commercialization of the biological material referred to in this article is prohibited and its practice implies the crime defined in art. 15 of Law n. 9.434, of February 4, 1997" [free translation] (Brasil, 2005).

The prohibitions, therefore, provided for in this Law, are essentially limited to: "I - implementation of a project related to a genetically modified organism without maintaining a record of its individual monitoring; II - genetic engineering in a living organism or the in vitro handling of natural or recombinant DNA/RNA, carried out in disagreement with the standards provided for in this Law; III - genetic engineering in human germ cells, human zygotes and human embryos; IV - human cloning; V - destruction or disposal in the environment of GMOs and their

[8] "The processes excluded from the manipulation category have in common the fact that the forms of modification of genetic material that are allowed are those in which human intervention occurs only as a means of accelerating a causality that already exists, that is, when the genetic material (the molecule) has not undergone previous alteration by the hands of man or those in which the alteration may also occur as a result of chance. This is the hypothesis of mutagenesis, provided for in item I of Article 4th of the Law, in which the modification may occur spontaneously" [free translation] (Minahim, 2020: 294).

derivatives in disagreement with the standards established by CTNBio, by the registration and inspection bodies and entities, referred to in art. 16 of this Law, and those contained in this Law and its regulations; VI - release into the environment of GMOs or their derivatives, within the scope of research activities, without a favorable technical decision by CTNBio and, in cases of commercial release, without a favorable technical opinion by CTNBio, or without licensing by the responsible environmental body or entity, when CTNBio considers the activity to be potentially causing environmental degradation, or without the authorization of the competent environmental body or entity, approval of the National Biosafety Council - CNBS, when the process has been taken up by it, in accordance with this Law and its regulations; VII - the use, commercialization, registration, patenting and licensing of genetic technologies for restricting use" [free translation] (Brasil, 2005).

Therefore, despite its relevance, preimplantation genetic testing is practically not addressed by the Brazilian Biosafety Law, and its regulation is relegated to the medical regulatory body in Brazil. Resolution 2.320/2022 of the Brazilian Federal Council of Medicine is the main regulatory instrument to provide for the ethical guidelines to be adopted by doctors in cases of medically assisted reproduction. Chapter VI sets out the rules for preimplantation genetic testing of embryos, establishing that "assisted reproduction techniques may be applied to the selection of embryos that have undergone diagnosis of genetic alterations that cause diseases - in which case they may be donated for research or discarded, according to the decision of the patient(s) duly documented in a specific informed consent form" [free translation]. Furthermore, they can also be used to type the human leukocyte antigen system of the embryo, aiming at the selection of "HLA-compatible embryos with a sibling already affected by the disease and whose effective treatment is stem cell transplant, in accordance with current legislation" [free translation] (Brasil. Conselho Federal de Medicina, 2022).

However, the resolution expressly provides for that assisted reproduction techniques "cannot be applied with the intention of selecting the sex (presence or absence of the Y chromosome) or any other biological characteristic of the future child, except to avoid diseases in the possible descendant" [free translation] (Brasil. Conselho Federal de Medicina, 2022).

It is therefore observed that there is no room in Brazilian legislation for the application of preimplantation genetic testing for the purpose of choosing the characteristics of the future child, but only for cases involving diseases. Attention is also drawn to the fact that unselected embryos may be sent for research or for disposal, according to the patients' will, and, in any case, there must be free and informed consent.

3. Is there a role for criminal law to play in non-compliance with PGT rules in Brazil?

Chapter VIII of Brazilian Law 11.105/2005 provides for, between Articles 24 and 29, a list of six crimes, with penalties ranging from 1 to 5 years in prison. Among the criminalized behaviors are the use of human embryos in disagreement with the rules set out in Article 5th (Article 24, with a penalty of 1 to 3 years and a fine), the practice of genetic engineering on human germ cells, human zygotes or human embryos (Article 25, with a penalty of 1 to 4 years and a fine) and human cloning (Article 26, with a penalty of 2 to 5 years and a fine) (Brasil, 2005).

It is noted, however, that, in line with the spirit of Law 11.105/2005, the crimes in question are related, in general, to prohibited genetic engineering practices or have genetically modified organisms as their object. An example of this is the crime provided for in Article 27, which provides for a penalty of 1 to 4 years for anyone who disobeys CTNBio rules for the release or disposal of genetically modified organisms into the environment (Brasil, 2005).

There is, therefore, an undeniable gap in criminal liability when it comes to disregarding rules on medically assisted reproduction. Hypothetical cases such as the use of preimplantation genetic testing for the purpose of selecting characteristics of the future child, including gender and physical attributes, would constitute an undeniable ethical violation by the doctors in charge, but not a crime, due to the lack of legal provision in this matter.

With regard, however, to an improper disposal of surplus embryos, there may be room for the application of the crime provided for in Article 24 of Law 11.105/2005 According to this provision, a penalty of 1 to 3 years will be imposed on anyone who uses human embryos in violation of Article 5th. The latter, in

turn, clarifies that surplus embryos may be used in research when they are unviable[9] or have been frozen for more than three years, provided that, in either case, there is consent from the parents. Therefore, if there is no such consent, we may be faced with this crime (Siqueira, Marqueti, 2021: 486).

A highly controversial issue is whether it constitutes a crime when a viable embryo is discarded before the 3-year period, but with the consent of the parents. The basis of this discussion, as Siqueira and Marqueti rightly point out, lies in the dilemma of whether the *Rechtsgut* (legal good) protected by the crime would be "life"[10] or "genetic heritage". We agree with the authors that it seems strange to base the prohibition on the use of an embryo frozen less than 3 years ago on the protection of life, "since there is no apparent reason why the freezing period should determine whether or not it is permitted to attempt against the supposed life of the embryo, considering that embryos frozen more than 10 years ago have already been successfully implanted" [free translation]. Furthermore, it makes no sense to grant parents the right to dispose, with their consent, of the life of the embryo, as suggested in Article 5th, § 1st (Siqueira, Marqueti, 2021: 505, Minahim, 2020: 298).

Therefore, we also agree with the conclusions that the crime in question protects genetic heritage, a *Rechtsgut* of an individual nature, owned by the future parents. That being said, we can also conclude that respect for their autonomy[11] necessarily encompasses their power to dispose of the good. That is the reason why we understand that it is not appropriate to consider the disposal of these embryos before the three-year period as unlawful, when it is the result of the free exercise of the power of disposal of the owners of the good, that is, when the free and informed consent of the parents is present.

[9] "The concept of viability, although not expressed, must be biological, that is, it must be an embryo that does not have the organic conditions to develop in the gestational process to reach other stages of development" [free translation] (Minahim, 2020: 297).

[10] On the relevance of discussions on the protection of the rights of unborn children, see: Pavlović, 2022. On the difficulties in defining what we can understand as life: Ćorić, 2021.

[11] For a detailed analysis of autonomy in its most varied facets, see: Heberling, 2021: 595.

Conclusion

As we have observed throughout the investigation, among the numerous areas of medicine that have been influenced by new technologies and the most recent scientific discoveries, medically assisted procreation is certainly among the most relevant. In this regard, preimplantation genetic testing and especially the application of artificial intelligence to make it more effective are a significant example of how science and technology can work together to ensure the best healthcare for society.

However, it has also been demonstrated that this technique presents undeniable controversies and therefore encounter express limitations and legal requirements. In Brazil, although the Biosafety Law is silent on the matter, Resolution 2.320/2022 of the Federal Council of Medicine allows the use of these tests for the purpose of diagnosing genetic alterations that can cause diseases, with the consequent donation of diseased embryos for research or disposal, in accordance with the free and informed consent of the parents. On the other hand, the use of PGT for the purpose of selecting the gender or other physical characteristics of the future child is expressly prohibited by the resolution.

Despite the relevance of the issue, we identified a clear gap in criminal liability regarding the failure to comply with the rules of medically assisted reproduction, with the use of PGT for purposes other than those provided for in the Resolution not being considered a crime. However, it is possible to consider the disposal or donation of surplus embryos without the free and informed consent of the parents as a crime, in accordance with Article 24 of Law 11.105/2005. In the presence of such consent, we understand that there is no crime, even if the 3-year time period has not been observed.

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