JUDGMENT NO. 96 YEAR 2015

In this case the Court heard two referrals questioning Article 1, paragraphs 1 and 2, and Article 4, paragraph 1, of Law no. 40 of 19 February 2004 (Rules on medically assisted procreation), which permitted access to medically assisted procreation (PAM) only in cases of certified and incurable sterility or infertility of a couple. The referrals dealt with two, nearly identical claims brought by fertile couples who were carriers of serious genetic diseases, and who had, in the past, ended natural pregnancies by means of abortion upon discovering that they had conceived offspring affected by the respective diseases. Both couples wanted recourse to PAM methods with preimplantation diagnosis to select embryos unaffected by their respective diseases. The referrals alleged contradiction with Articles 2, 3, 32, and 117 (with reference to ECHR Articles 8 and 14) of the Constitution. The Court held, preliminarily, that the cases were appropriately referred, since an expansive Constitutional interpretation of the provisions was not possible in light of their literal content, and application of international law in place of domestic law is not within the powers and duties of ordinary judges; it further held the questions to be founded on the basis of the claimed violations of Articles 3 and 32 of the Constitution. The Court declared the questioned provisions to be unconstitutional, finding that there was an unavoidable element of unreasonableness in prohibiting fertile couples who were carriers of genetic diseases from having access to PAM methods in light of their Constitutional right to a healthy child, also reflected in Article 6, paragraph 1, letter *b*) of Law no. 194 of 22 May 1978 (Rules on the social protection of motherhood and the voluntary termination of pregnancy), which allows couples to pursue their goal of having a healthy child by means of therapeutic abortion to eliminate natural pregnancies affected by anomalies and malformations meeting a normative threshold for seriousness. The Court declared that the provisions, therefore, amounted to an unreasonable balancing of the interests involved, since any offspring affected by the relevant genetic diseases would be, in any case, legally exposed to abortion. The Court also found a violation of a woman's right to health enshrined in Article 32 of the Constitution, in that the provisions deprived certain women of the means to avoid resorting to the traumatic method of voluntary abortion in order to obtain the objective of a healthy child, by preventing her from having access to anterior means that the Court considered less dangerous to her mental and physical health.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 1, paragraphs 1 and 2, and Article 4, paragraph 1, of Law no. 40 of 19 February 2004 (Rules on medically assisted procreation), initiated by the *Tribunale Ordinario* of Rome with two referral orders of 15 January and 28 February 2014, registered as nos. 69 and 86 of the Register of Referral Orders 2014 and published in the Official Journal of the Republic nos. 21 and 24, first special series of 2014.

Considering the entries of appearance of P.M.C. et al., of M.V. et al., and of the "Associazione Luca Coscioni, per la libertà di ricerca scientifica" et al.;

having heard from judge rapporteur Mario Rosario Morelli;

having heard from Counsel, Filomena Gallo and Gianni Baldini on behalf of P.M.C. et al, M.V. et al., and the "Associazione Luca Coscioni, per la libertà di ricerca scientifica" et al.

[omitted]

Conclusions on points of law

1. - Article 1, paragraphs 1 and 2, and Article 4, paragraph 1, of Law no. 40 of 19 February 2004 (Rules on medically assisted procreation) provide, respectively, that, "[i]n order to facilitate resolution of reproductive problems stemming from human sterility or infertility, the use of medically assisted procreation is allowed, under the conditions and in the manner prescribed by this Law, which guarantees the rights of all stakeholders, including the unborn;" "[t]he use of medically assisted procreation is allowed if there are no other effective treatment methods available to cure the causes of the sterility or infertility;" and "[t]he use of techniques of assisted reproduction is allowed only when it is found impossible to otherwise cure the causes that impede procreation and is, in any case, limited to cases of unexplained sterility or infertility documented by medical certification and to cases of sterility or infertility proven and established by medical certification."

2. – The *Tribunale Ordinario* of Rome alleges that the cited provisions – to the extent that they do not allow fertile couples who are carriers of transmittable genetic diseases to have recourse to methods of medically assisted procreation [hereinafter "MAP"] – violate Articles 2, 3, and 32 of the Constitution, as well as Article 117, first paragraph, of the Constitution, in reference to Articles 8 and 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, and ratified and executed with Law no. 848 of 4 August 1955 [hereinafter "ECHR"].

3. – The question was raised with two referral orders of identical content, based on two precautionary proceedings brought by two (fertile) married couples, both of which had terminated, via therapeutic abortion, earlier, spontaneous pregnancies, due to the risk of

transmitting hereditary genetic diseases to their children (respectively, Becker's muscular dystrophy in the first case and a chromosomal mutation in the second), and who, therefore, asked to be urgently admitted to PAM procedures, with preimplantation genetic diagnosis, having the sole purpose of selecting an embryo that is not affected by that particular form of disease.

4. – Having ruled out, as a preliminary matter, the possibility of not applying the allegedly unconstitutional provisions due to inconsistency with the ECHR (despite the intervening 28 August 2012 decision of the Strasbourg Court, which, in the analogous case of *Costa and Pavan v. Italy*, "denounced the inconsistency of the Italian legislative system, which […] does not allow couples who are carriers of genetic diseases to have access to 'P.A.M.'"), and considering the impossibility of a constitutional interpretation of the provisions that conforms to the proposal advanced by the claimants, the referring judge held that the limitation imposed by the 2004 legislator on the access to PAM methods, consisting in the requirement that the couple be sterile or infertile, was relevant to the decision of whether the provisions complied with the cited constitutional parameters.

5. – According to the referral, the challenged provisions are in contradiction with:

- Article 2 of the Constitution, as they cause a violation of inalienable rights of the person, i.e. "the couple's right to a 'healthy' child and the right to self-determination in procreative choices," which, under the challenged ban on their access to PAM procedures, irremediably occurs to couples that are neither sterile nor infertile, but are carriers of genetic disease;

- Article 3 of the Constitution, "understood as a principle of reasonableness, a corollary of the principle of equality, in that it entails the paradoxical, unreasonable, and inconsistent consequence of forcing these couples, who desire to have a child free from disease the effects of which they well know, to have natural pregnancies and resort to the tragic choice of therapeutic abortion of the fetus, permitted under Law no. 194 of 22 May 1978;"

- Article 3 of the Constitution again, on the grounds that the aforementioned ban discriminates between fertile couples who are carriers of genetic diseases and couples in which the man has a viral sexually transmitted disease, whose right to resort to PAM methods was recognized by decree of the Ministry of Health on 11 April 2008 (Guidelines on medically assisted procreation);

- Article 32 of the Constitution, as a violation of a woman's right to health results, based on the claim that she, in order to exercise her choice to have a child unaffected by genetic disease, would be forced to undergo natural pregnancy and then resort to abortion (upon verifying that the genetic disease had been transmitted), with the concomitant, concrete increase in risks to her physical health and psychological wellbeing, "in the absence of an adequate balancing of the protection of the woman's health with that of the embryo;"

- Article 117, first paragraph, of the Constitution, with reference to ECHR Articles 8 (Right to respect for private and family life) and 14 (Prohibition of discrimination): concerning the first, because the "unreasonableness" of the ban on access to PAM imposed on [fertile] couples who are carriers of genetic diseases, "which has the de facto result of encouraging recourse to the abortion of the fetus," would involve undue interference in that couple's family life; and, concerning the second, because of the discrimination highlighted in the claim made under Article 3 of the Constitution.

6. – The question, as it has been presented, is admissible, even if raised in the context of *ante causam* expedited proceedings, the referring court not having yet pronounced a definitive holding on the claimants' precautionary motion, and not having, therefore, executed its *potestas iudicandi* (among many, see Judgments nos. 200 and 162 of 2014, 172 of 2012, and 151 of 2009).

7. – Due to the suspected conflict between the above-cited Article 1, paragraphs 1 and 2, and Article 4, paragraph 1, of Law no. 40 of 2004 with Articles 8 and 14 of the ECHR, the referring judge correctly referred the case to this Court, since he is not permitted to directly apply treaty laws in place of national ones that may be incompatible with them, since, unlike Community law, the ECHR does not create a supranational legal order, but constitutes a model of international treaty law, suitable to bind the State, but that does not produce direct effects in the internal legal order (Judgments nos. 349 and 348 of 2007, and later judgments consistent with them). This placement of the ECHR within the system of sources was left unaltered even after the reference made to it under Art. 6(3) of the Treaty on the European Union (TEU), as modified by the Lisbon Treaty, signed on 13 December 2007, ratified and executed with Law no. 130 of 2 August 2008, which entered into force on 1 December 2009.

Indeed, this Court has already had the occasion to clarify that "it cannot be inferred, from qualifying the fundamental rights that are the object of the ECHR's provision as general principles of Community law, that the parameter found under Article 11 of the Constitution is determined in reference to the ECHR. Nor, relatedly, can the ordinary judge be inferred to have the power/duty to not apply internal rules that are inconsistent with the Convention" (Judgments nos. 303 of 2011 and 349 of 2007). For this reason, "the principles in question are relevant solely in relation to situations to which Community law (now Union law) is applicable" (Judgments nos. 210 of 2013, 303 of 2011, and 80 of 2011), and seeing as the situations, objects of the cases before the referring court, are not traceable to Community law, there was, therefore, no room for a potential non-application of the national rules by the referring *Tribunale*, which must also be considered limited to cases in which the relevant Community law is endowed with direct effects.

8. – The same *Tribunale* was also correct in ruling out the possibility of developing a corrective interpretation of the challenged provisions, to extend access to PAM methods, including in favour of the claimant couples, given the unequivocal and inevitable literal content of the provision under which recourse to such methods "is in any case reserved to cases of sterility or infertility."

The relevance of the question being so supported, its resolution is, therefore, contingent upon whether or not the question raised by the claimants in the main precautionary proceedings is founded.

9. – On the merits, the question is founded, based on the claim – which absorbs every other challenge – concerning the violations effectively caused by the challenged provisions of Articles 3 and 32 of the Constitution.

In the first place, there is an unavoidable element of unreasonableness in the indiscriminate ban placed by the challenged provisions on access to PAM, with preimplantation genetic diagnosis, by fertile couples affected (even as healthy carriers) by serious hereditary genetic diseases, which are susceptible (according to scientific evidence) to transmitting significant anomalies and malformations to their offspring. This is unreasonable in that, in clear legal contradiction (which was also highlighted by the Strasbourg Court in the above-cited *Costa and Pavan v. Italy*), our legal order, in any case, permits these couples to pursue their objective of having a child that is unaffected by the specific hereditary disease of which they are carriers through the undeniably more traumatic method of voluntary termination (sometimes more than once) of natural pregnancies – as permitted under Article 6, paragraph 1, letter *b*) of Law no. 194 of 22 May 1978 (Rules on the social protection of motherhood and the voluntary termination of pregnancy) – when, through now-routine prenatal examinations, "pathological processes relating to serious abnormalities or malformations of the fetus, which seriously endanger the woman's physical or mental health, have been diagnosed."

To wit, the regulatory system originating under the challenged provisions does not allow (even though it is scientifically possible) a woman to acquire information *before*, which would allow her to avoid making a decision *later* that is significantly more damaging to her health.

Therefore, Article 32 of the Constitution, of which the provision under review runs afoul, is also violated, for the absence of respect for the woman's right to health. In addition, the damage thus caused to this right has no positive counterweight, in terms of balancing, in a need to protect the offspring, which would be, in any case, vulnerable to abortion.

The challenged regulation, therefore, amounts to the outcome of an unreasonable balancing of the interests at stake, in violation, too, of the criterion of reasonableness of the legal order – and violates the right to health of fertile women who are carriers (themselves, or the other partner in the couple) of serious hereditary genetic diseases – to the extent that it does not allow for, and therefore forbids that, under the framework of the law under review, couples affected by such pathologies, properly diagnosed in order to meet the demands of caution, by the dedicated, specialized public institution, can have recourse to PAM methods. The examination would be done for the sole purpose of making a prior identification of embryos who have not received the pathology from their parent that carries with it the danger of relevant anomalies or malformations (if not untimely death) to the offspring, as in the same "normative

threshold of seriousness" already established by Article 6, paragraph 1, letter *b*) of Law no. 194 of 1978.

10. – It being established that, by reason of the absolute quality of the aforementioned prohibition, the provisions at issue contrast with constitutional parameters, "this Court cannot therefore avoid its power and duty to remedy the breach and must rule it unconstitutional" (Judgment no. 162 of 2014), and it then falls to the legislator to introduce appropriate provisions for the purpose of making the intended identification (even periodically, on the basis of technical and scientific advancements) of the diseases that may justify access to PAM by fertile couples and the related diagnostic procedures (including for purposes of preliminary subjection to preimplantation genetic diagnosis) and of appropriate measures providing forms of authorization and regulation of institutions qualified to perform them (potentially also validating the practices already established for the purpose by the majority of European legal systems, in which this form of medical practice is allowed). This clearly does not fall within the power of this Court, and is reserved to legislative discretion.

ON THESE GROUNDS
THE CONSTITUTIONAL COURT

having joined the judgments,

declares Article 1, paragraphs 1 and 2, and Article 4, paragraph 1, of Law no. 40 of 19 February 2004 (Rules on medically assisted procreation) to be unconstitutional, to the extent to which they do not allow fertile couples who are carriers of genetic diseases that meet the criteria for seriousness under Article 6, paragraph 1, letter *b*) of Law no. 194 of 22 May 1978 (Rules on the social protection of motherhood and the voluntary termination of pregnancy), diagnosed by the appropriate public institutions, to have access to methods of medically assisted procreation.

Decided in Rome, at the seat of the Constitutional Court, *Palazzo della Consulta*, on 14 May 2015.