JUDGMENT NO. 84 YEAR 2016

In this case the Court heard a referral order concerning the 2004 Law on medially assisted reproduction, in which it was requested to adopt an expansive ruling to the effect that embryos that were destined to be destroyed as they would not be implanted where affected by disease could be used for scientific research, notwithstanding the statutory prohibition on such usage. The Court noted that there was no pan-European consensus on such a sensitive issue and dismissed the application, holding that "the choice made by the contested legislation is one of such considerable discretion, due to the axiological issues surrounding it, that it is not amenable for review by this Court

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Articles 6(3), last sentence, and 13(1), (2) and (3) of Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction), initiated by the *Tribunale di Firenze* within the civil proceedings pending between C.S.A. and another and Centro di fecondazione assistita "Demetra" srl and another, by the referral order of 7 December 2012, registered as no. 166 in the Register of Orders 2013 and published in the Official Journal of the Republic no. 29, first special series 2013.

Considering the entry of appearance by C.S.A. and another, filed after expiry of the time limit, and the interventions by the *Vox – Osservatorio italiano sui Diritti* [Vox – Italian Rights Observatory] association and the President of the Council of Ministers;

having heard the judge rapporteur Mario Rosario Morelli at the public hearing of 22 March 2016;

having heard Counsel Gianni Baldini for C.S.A. and another, Counsel Massimo Clara for the association *Vox – Osservatorio italiano sui Diritti* and the State Counsel [*Avvocato dello Stato*] Gabriella Palmieri for the President of the Council of Ministers.

[omitted]

Conclusions on points of law

1.− By the referral order mentioned in the headnote, issued during the interim stage of proceedings to protect individual rights as mentioned above, the *Tribunale di Firenze*, sitting as a single judge, raised – in relation to Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction) (which it had been called upon to apply in two respects) – according to the referral order, a "question concerning the constitutionality:

a) of Article 13 […] (absolute prohibition of any clinical or experimental research on embryos other than with the aim of their protection) due to violation of Articles 9, 32 and 33(1) of the Constitution;

b) of Article 6(3), last sentence […] (absolute prohibition on the revocation of consent to MAR following the fertilisation of the egg) due to violation of Articles 2, 13, 32 of the Constitution;

c) of Articles 13(1), (2), (3) and 6(3), last sentence […] on account of their illogical and unreasonable nature, due to violation of Articles 2, 3, 13, 31, 32 and 33(1) of the Constitution".

2.− In reality – as may be inferred from the grounds for challenge (and leaving aside the fact that they do not coincide directly with the operative part) of the order under examination – the referring court does not challenge Article 13 of Law no. 40 of 2004 as a whole, but rather, unequivocally, on the one hand (only) paragraphs 1 to 3 of Article 13 due to violation of Articles 2, 3 (on the basis of the principle of reasonableness), 9, 13, 31, 32 and 33(1) of the Constitution and on the other hand Article 6(3), last sentence, due to violation of Articles 2, 3, 13, 31, 32 and 33(1) of the Constitution.

2.1.− The first question relates to Article 13, with exclusive reference therefore to its first three paragraphs.

The objections formulated against it are in any case directed specifically and exclusively at the provision concerning the "absolute prohibition of any clinical or experimental research on embryos other than with the aim of their protection", and request an expansive ruling enabling the absolute nature of that prohibition to be tempered in the sense that, where it is specifically established that the embryo can no longer be used for reproductive purposes (and is thus destined to be rapidly

"extinguished"), provided that the consent of the parents is obtained, it may be used for other "constitutionally significant" purposes, such as bio-medical scientific research aimed (also) at the protection of health as a fundamental right of the individual and in the interest of society at large.

Regarding the issue of relevance, the referring court considers that the question is essential in order to satisfy the interests actioned in the case before it since – following the cryopreservation by the claimants of nine embryos (of which five were affected by the disease of exostosis and four could not be subjected to biopsy) which, by their express decision, would never be used within the reproductive process – these "excess" embryos would inevitably be destined for self-destruction, whilst the parties would like them to be used for diagnostic medical activities and scientific research in relation to that genetic disease.

As regards the non-manifest groundlessness of the question, the *Tribunale di Firenze* finds that the contested legislation – insofar as it imposes an absolute prohibition on any scientific research on residual embryos from medically assisted reproduction processes (hereafter "MAR") other than with the aim of the embryo's own protection – violates Articles 2, 3, 9, 13, 31, 32 and 33(1) of the Constitution (a reference is made merely *obiter* in the grounds for challenge also to "Articles 1, 5 and 18 of the Oviedo Convention on Biotechnologies"), due to the unreasonable nature of the balance thereby struck between the protection of the embryo and the interest in scientific research in situations (such as that *sub iudice*) involving diseased embryos or embryos the health of which is unknown, where implantation has been refused by the parents, who by contrast wish them to be used for scientific research, considering the alternative of their certain destruction.

2.2.− The second question, as mentioned above, relates to Article 6(3), last sentence, of Law no. 40 of 2004.

According to the referring court's account, the rule laid down in that provision stipulating that consent to the MAR treatment cannot be revoked after the egg has been fertilised amounts to a clear violation of the principle regulating relations between doctor and patient, as the patient is thereby deprived of the possibility to revoke the consent provided to the doctor to carry out acts that will certainly encroach upon his/her physical and mental integrity, having regard also to the particularly delicate stage of the

medical procedure given that the treatment, which is far from having been concluded, is at an intermediate stage which must necessarily be followed by the essential culminating moment of the transfer of the material produced to the uterus. This accordingly results in a violation (also in this respect) of Articles 2, 3, 13, 31, 32 and 33(1) of the Constitution.

In the opinion of the *Tribunale di Firenze* – even though the applicant (following an initial refusal) had decided to undergo MAR treatment using the last embryo (of average quality) out of the total of ten produced by her – also the second question referred is relevant, on the grounds that the interested party has expressed her intention to repeat the MAR treatment (having not previously achieved the desired result), subject however to the proviso that she be able to decide (within that subsequent treatment) whether or not to submit to the transfer into her uterus of the material produced only after the results of the pre-implantation genetic testing of the material have confirmed its quality.

3.− The President of the Council of Ministers, who intervened in the proceedings, asserted through the State Counsel that both questions are inadmissible.

In the alternative, he objected that the challenge relating to Article 13(1) and (3) of Law no. 40 of 2004 is unfounded on the merits.

4.− The application by the married claimants in the proceedings before the referring court for a new time limit to be set following their intervention in these proceedings out of time and the request for leave to intervene made by the association *Vox – Osservatorio italiano dei Diritti* were both ruled inadmissible – as, consequently, the request, filed by both parties, that witnesses be heard – by the order issued by this Court at the hearing of 22 March 2016, which is confirmed herein and which is annexed to this Judgment.

5.− The two questions brought before this Court for review have been raised, as mentioned above, within expedited proceedings; however, this does not stand in the way of their admissibility, as the referring court has not made a definitive ruling on the interim action by the claimants and has not accordingly exercised its full *potestas iudicandi* (on all points, see in particular Judgments no. 96 of 2015, no. 200 and no. 162 of 2014, no. 172 of 2012, no. 151 of 2009).

6.− It is first and foremost necessary to examine the question concerning the constitutionality of Article 6(3), last sentence, of Law no. 40 of 2004.

6.1.− The question is inadmissible due to the merely hypothetical and non-current nature of its relevance.

Indeed, the *Tribunale di Firenze* itself states that, after having initially declared that she did not wish for the only embryo (out of the ten produced) that was certainly not affected by diseases to be implanted in her uterus, the applicant then nonetheless accepted to complete the MAR treatment – and in fact did so, albeit without success.

The doubt regarding the constitutionality of the prohibition on the revocation of consent to implantation after the egg has been fertilised is thus not relevant within the proceedings before the referring court. Furthermore, the conclusion would be no different were it to be argued (as the referring court does) that "The applicants intend to repeat the course of MAR, and it is hence pressingly urgent to resolve any question relating to the expression of consent", given that this future intention does not render "current" the question regarding the revocation of consent within the main proceedings once the interested party has nonetheless consented to the implantation in her uterus of the only embryo (out of those produced) that was not affected by disease, within the context of the course of MAR under discussion here.

6.2.− Besides – after stressing that the requirement laid down by Article 6, "which already in itself lacks any sanction in the event of its violation, was further nuanced by the exception, introduced by the Court in its ruling, from the absolute prohibition on the cryopreservation of embryos in all cases in which the doctor establishes that there would be substantiated risks for the health of the woman in the event of their implantation" − the lower court concedes that the "problematic aspects remaining" in relation to that provision are not specifically relevant for the case at issue in the proceedings since, in its view, they relate in general terms to a "practical-operational aspect" (which, however, is in itself evidently separate from the *quaestio legitimitatis*) and to a "systematic aspect", namely the "aim of ensuring coherence within the system" in relation to which Judgment no. 151 of 2009 ruled manifestly inadmissible – on the grounds that it lacked any relevance – a practically identical question concerning the constitutionality of Article 6(3) of Law no. 40 of 2004.

7.− As regards the objection alleging that Article 13 of Law no. 40 of 2004 is unconstitutional, it is necessary as a preliminary matter to examine the objection raised by the State Counsel that – since the referring court has referred (as alternatives) both to

the provision as a whole and to the first three paragraphs only, “without deciding in favour of one or the other” − the question is inadmissible on the grounds that it was raised “in an uncertain manner […] and in ambiguous terms”.

However, it has already been mentioned above that, according to a systematic reading of the referral order, it is evident without any doubt that the question under examination relates only to the first three paragraphs of Article 13 in that it specifically concerns the “absolute prohibition of any clinical or experimental research on embryos other than with the aim of their protection” provided for thereunder, against which alone, moreover, the objections of the *Tribunale di Firenze* are directed.

This evidently precludes the possibility that the objection is well founded.

8.− On the merits, the *Tribunale di Firenze* asserts – and this is the issue that lies at the heart of the referral order – that this absolute prohibition on experimental research on excess, (albeit) non-implantable, embryos is tantamount to “the complete negation of the individual and collective requirements underlying scientific research activity, precisely in those sectors such as gene therapy and the use of embryonic stem cells, which the medical and scientific community considers to be amongst the most promising for the treatment of numerous serious diseases and, in an entirely irrational manner, to the refusal to strike any balance between these requirements, which are expressions of values protected under constitutional law, and the status of the embryo, in the absence of any balance that reconciles the rule with the fact that it would be pointless to safeguard the latter where it is infected by disease”.

It also asserts that this results in a contrast between this aspect of Article 13 of Law no. 40 of 2004 and the various parameters of constitutional law invoked (Articles 2, 3, 9, 13, 31, 32 and 33(1) of the Constitution).

8.1.− The question, raised in these terms, refers to the conflict – which has serious ethical and legal implications – between the law applicable to science (and the research benefits associated with it) and the rights of the embryo in terms of the protection (weak or strong) due to it on account of and in relation to the (greater or lesser) degree of subjectivity and anthropological dignity recognised to it.

Lawyers, scientists and civil society itself are profoundly divided regarding the solution to the conflict. So too the legislation, the ethical committees and the special commissions of the many countries that have considered the problem and examined the

implications in depth, cannot by any means be said to have converged upon a general consensus.

8.2.− In our legal order, the possibility to create embryos that will not be born – embryos commonly defined as excess or residual – was established on a legal footing by this Court's Judgment no. 151 of 2009, which declared unconstitutional Article 14(2) of Law no. 40 of 2004 insofar as it prohibited the production of more than three embryos whilst in any case requiring that they be destined for one single and simultaneous implantation. As a consequence of this, it departed from the prohibition on cryopreservation enshrined in a general manner in paragraph 1 of the Article due to the need within MAR centres to freeze embryos that are produced but not implanted.

The number of residual embryos that are not transferred, in particular on the grounds that they are diseased, was virtually expanded at a later stage as a consequence and result of the later Judgment no. 96 of 2015. This Judgment – which ruled unconstitutional Articles 1(1) and (2) and 4(1) of Law no. 40 of 2004 insofar as they did not permit the recourse to MAR techniques by fertile couples who are carriers of inheritable genetic diseases that are classified as serious pursuant to Article 6(1)(b) of Law no. 194 of 22 May 1978 (Provisions on the social protection of maternity and the voluntary termination of pregnancy) – allowed for the possibility of diagnosis prior to implantation, in order to avoid the transfer into the uterus of the woman of embryos affected by genetic diseases of this type. Consequently, the prohibition on cryopreservation was also set aside for these embryos.

Finally, by Judgment no. 229 of 2015 relating to a matter of criminal law, whilst declaring unconstitutional Article 13(3)(b) and (4) of Law no. 40 of 2004 (concerning the offence of selection of embryos), in relation (exclusively) to the content of the previous Judgment, no. 96 of 2015, this Court by contrast ruled unfounded a question (which had been raised at the same time within those proceedings) concerning the constitutionality of Article 14(1) and (6) of the same Law, which imposed a criminal prohibition, backed up by sanctions, on the destruction of embryos, including those affected by a genetic disease. The Court reached this conclusion on the grounds that the embryos, "irrespective of their more or less broadly recognisable degree of subjectivity related to the origins of life, can certainly not be reduced to mere biological material", and on the basis of the consideration that "the violation of the protection of the dignity

of the (albeit) diseased embryo that would result from its elimination *tamquam res* has no […] justification in the protection of any other countervailing interest".

8.2.1.− In conclusion, it is clear from the case law referred to that:

the dignity of the embryo, as an entity which holds within itself the genesis of life (albeit at a level of development that has not been pre-defined by the legislator and has still not been unequivocally identified by science), in any case represents a value of constitutional significance "which may be brought under the general principle laid down by Article 2 of the Constitution" (see Judgment no. 229 of 2015);

the protection of the embryo cannot be weakened (where and) due to the sole fact that it is an embryo affected by a genetic malformation, which has been identified as the rationale for the criminal provision (Article 14(1) and (6) of Law no. 40 of 2004) punishing the elimination also of diseased embryos that cannot be implanted (see Judgment no. 229 of 2015);

as for any other constitutional value, also the protection of the embryo has been considered to be open to balancing, in particular with the aim of "protecting the requirements of procreation" and the health of the woman (see Judgment no. 151 of 2009 and no. 96 of 2015).

The referring court thus correctly prefaces that the question "concerning the constitutionally reasonable balance between the protection of the embryo and the interest in scientific research aimed at the protection of (individual and collective) health" raised by it here is "new" for this Court (and has not even been implicitly addressed in its previous rulings).

9.− The prohibition on experimentation with embryos contained in Article 13 of Law no. 40 of 2004 was – as is known – challenged in parallel before the Strasbourg Court on the grounds that it breached Articles 8 and 1, Additional Protocol, of the European Convention for the Protection of Human Rights and Fundamental Freedoms, signed in Rome on 4 November 1950, ratified and implemented by Law no. 848 of 4 August 1955 (ECHR).

The case in question (*Parrillo v. Italy*) has in the meantime been decided by the Grand Chamber, by judgment of 27 August 2015.

In that judgment, the European Court ruled that the party's application was not admissible as regards the alleged violation of Article 1 of the Additional Protocol

(which protects the right of individuals to respect for their possessions). In adopting this ruling it deliberately left to one side the "sensitive and controversial question of when human life begins", concluding by contrast that the consideration that embryos cannot be classified as "possessions" to be decisive and all-embracing ("human embryos cannot be reduced to "possessions" within the meaning of that provision").

It also held (with one dissenting vote) that Article 8 ECHR had not been violated on the grounds that the right invoked by the applicant to donate the embryos (produced by her) for scientific research was not covered by that provision as "it does not concern a particularly important aspect of the applicant's existence and identity".

In the same judgment, the Strasbourg Court nonetheless observed as a premise that the question concerning the donation of embryos not destined for implantation clearly gives rise to sensitive moral and ethical issues and that the comparative law material available demonstrates that, contrary to the assertions of the applicant, there is no broad European consensus on the subject (paragraph 176). In fact, whilst seventeen out of the forty member states in relation to which the Court has information have adopted a non-prohibitive approach in this area (paragraph 177), other countries have enacted laws that expressly prohibit any research into embryonic cells, whereas others permit the research in question subject to strict conditions (paragraph 178). Italy is not therefore the only member state of the Council of Europe to prohibit the donation of human embryos for scientific research (paragraph 179). For these reasons, the Court considers that the Government has not overstepped the wide margin of appreciation enjoyed by it in the present case (paragraph 197).

10.− Accordingly, acting in a manner that did not contrast with ECHR principles (which, moreover, have not been invoked directly in these proceedings), in 2004 the Italian legislator established a link between the protection of the embryo and scientific research in providing (according to the contested Article 13(2) of Law no. 40) that "Clinical and experimental research on each human embryo shall be permitted upon condition that it pursues exclusively therapeutic and diagnostic goals associated with it that are aimed at protecting the health and development of the embryo itself, and provided that no alternative methods are available".

Although the popular referendum to repeal that provision, which was ruled admissible by Judgment no. 46 of 2005 of this Court, was not successful due to the

failure of a majority of voters to participate in the vote, a debate has continued from increasingly divergent positions – within scientific and legal circles, and also within the broader context of civil society – as to whether or not such linkage described above established by the legislation under scrutiny was reasonable, having regard to the range of constitutional principles mentioned in the referral order.

10.1.− From the critical perspective adopted by the referring court – on which basis the court suspects that (the first three paragraphs of) Article 13 of Law no. 40 of 2004 may be unconstitutional – it has moreover been argued on various occasions within the literature and within scientific circles:

that when confronted with the inevitable destruction of embryos that are not implanted (entities which are "in essence" destined for indefinite hibernation, without any reason possibility of coming into the world), the balance should more reasonably be struck in favour of the destination of those embryos to scientific research that may be capable of saving the lives of millions of human beings;

that, within the situation described above, such usage would constitute an expression of respect for human life that was much greater than merely "letting perish", thereby giving a socially useful meaning to the inevitable future destruction of the embryo;

that the subsidiary status sought for the rights of the embryo compared to the requirements of science would classify the issue of excess embryos not destined for implantation within a humanitarian perspective rooted in solidarity, falling within the scope of the principle laid down in Article 2 of the Constitution;

that in any case, living persons could not be the object of experimentation.

10.2.− Conversely, from the opposing side it has been stressed:

that the use and manipulation of human embryos as an object of research would imply their destruction, in evident contrast with the idea that an embryo can be considered as a subject that enjoys from the outset the dignity of a person;

that even in accordance merely with a "precautionary principle", when confronted with the possibility that the embryo is much more than mere biological material, the scientist should decide not to "do nothing", but to "do something else";

that there are in fact alternative outcomes, such as those that direct research towards a technique of regressing adult somatic cells to a stage that is close to the embryonic stage, or otherwise using human stem cells;

that in any case the parents' claim that they be regarded as the "owners" of the embryos that they have generated, as if these were mere biological material and not their children, and that "something" could be given to scientific research – whereas "someone", albeit in embryonic form, cannot be donated – would be legally unacceptable;

that in addition, experimentation is necessarily based on the informed consent of the patient, and therefore research on the embryo would be unlawful given that, were it to be considered a person, it would not be able to take a decision on matters of concern for it, especially when this would entail its destruction;

that in any case, although cryopreservation is not a sufficient measure in order to preserve embryos from their natural destruction, the due respect for life (even if only "in essence") should not enable an equivalence to be established between "to kill" and "to let die".

11.− Thus, confronted with what has been defined as "a tragic choice" between respect for the principle of life (which embraces the embryo, albeit affected by a disease) and the requirements of scientific research – a choice which, as mentioned above, has created such deep divisions on an ethical and scientific level, and for which significantly uniform solutions have not been found, even within European legislation – the reconciliation between opposing interests which may be discerned within the contested provisions pertains to the area of legislation within which the legislator, acting as the interpreter of the general will, is required to strike a balance through legislation between the fundamental values that are in conflict, taking account of the views and calls for action that it considers to be most deeply rooted at any given moment in time within the social conscience.

This has moreover occurred in all European states that, as was recalled by the Strasbourg Court, "have adopted a non-prohibitive approach" towards research into embryonic cells, within which such a possibility has been established only and in all cases through legislation.

Thus, the choice made by the contested legislation is one of such considerable discretion, due to the axiological issues surrounding it, that it is not amenable for review by this Court.

Furthermore, any different weighing of the values in conflict in the sense proposed by the referring court, involving a greater openness to the requirements of society at large as associated with the prospects of scientific research, could not in any case be introduced into the legislative framework through an expansive ruling by this Court (as has been requested by the referring court), given that such a ruling would not be mandatorily required.

In fact, the striking of any other balance between the values in conflict, which the constitutional review seeks to achieve by replacing that adopted by the legislation under review, could not in fact fail to consider (and to engage with) a range of multiple intermediate options, which would also inevitably be reserved to the legislator.

In fact, it is the legislator that must assess the appropriateness (on the basis also of "scientific evidence" and the extent to which it is endorsed on supranational level) concerning *inter alia*: the use for the purposes of research of only embryos affected by disease – and by which diseases – or also those that cannot be discovered through a biopsy; the selection of the specific research objectives and goals that are capable of justifying the "sacrifice" of the embryo; the possibility, and if so the duration, of a prior period of cryopreservation; whether or not it is appropriate (after such a period) to discuss the matter subsequently with the couple, or with the woman, in order to confirm the intention to abandon the embryo and to donate it for experimentation; and the most suitable precautions in order to avoid the "commercialisation" of residual embryos.

12.− The question concerning the constitutionality of Article 13(1) to (3) of Law no. 40 of 2004 is thus in turn inadmissible in relation to both issues raised.

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

1) rules that the question concerning the constitutionality of Article 6(3), last sentence, of Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction), raised with reference to Articles 2, 3, 13, 31, 32 and 33(1) of the

Constitution by the *Tribunale di Firenze* by the referral order mentioned in the headnote, is inadmissible;

2) rules that the question concerning the constitutionality of Article 13(1), (2) and (3) of Law no. 40 of 2004, raised with reference to Articles 2, 3, 9, 13, 31, 32 and 33(1) of the Constitution by the *Tribunale di Firenze* by the referral order mentioned in the headnote, is inadmissible.