Corte costituzionale

ORDER NO. 151 OF 2009

Francesco AMIRANTE, President

Alfio FINOCCHIARO, Author of the Judgment

JUDGMENT NO. 151 YEAR 2009

In this case the Court considered a challenge to "law No. 40", which imposed numerous restrictions on fertility treatment including, *inter alia*, a maximum limit of three oocytes, the requirement that they be implanted at the same time, the prohibition on cryopreservation other than in exceptional circumstances, and the inability to withdraw consent to the treatment after the egg has been fertilised. The Court noted that the legislative discretion of Parliament was not absolute, and had to take into account the scientific state of the art. The Court declares the contested provisions unconstitutional due to violation of the principles of reasonableness and equality, as well as of the woman's right to health .

THE CONSTITUTIONAL COURT

composed of: President: Francesco AMIRANTE; Judges: Ugo DE SIERVO, Paolo MADDALENA, Alfio FINOCCHIARO, Alfonso QUARANTA, Franco GALLO, Luigi MAZZELLA, Gaetano SILVESTRI, Sabino CASSESE, Maria Rita SAULLE, Giuseppe TESAURO, Paolo Maria NAPOLITANO, Giuseppe FRIGO, Alessandro CRISCUOLO, Paolo GROSSI,

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 6(3) and Article 14(1), (2), (3) and (4) of law No. 40 of 19 February 2004 (Provisions governing medically assisted reproduction), commenced by the Regional Administrative Tribunal for Lazio by the judgment of 21 January 2008 and the ordinary *Tribunale di Firenze* by the referral orders of 12 July and 26 August 2008, respectively registered as Nos. 159, 323 e 382 in the register of orders 2008 and published in the *Official Journal of the Republic* Nos. 22, 44 and 50, first special series 2008.

Considering the entries of appearance by *Warm* (World Association of Reproductive Medicine), the *Federazione Nazionale dei Centri e dei Movimenti per la vita italiani* [National Federation of Italian Pro-Life Movements and Centres], the *Comitato per la tutela della salute della donna* [Women's Health Protection Committee], C. S. A. and another, C. M. and another, as well as the interventions by the Association *Luca Coscioni per la libertà di ricerca scientifica* [Luca Coscioni for Scientific Freedom and Research] and others and the Association *Cecos Italia*, *S.I.S.Me.R. s.r.l.* (*Società Italiana Studi di Medicina della Riproduzione s.r.l.* [Italian Society for Studies into Reproductive Medicine Ltd.]), the non-profit association *Hera Onlus*, the non-profit association *Sos Infertilità Onlus* [SOS Infertility] and C. M. and another, by the non-profit body *Cittadinanzattiva Toscana Onlus* [Citizens of Tuscany] and by the President of the Council of Ministers;

heaving heard the Judge Rapporteur Alfio Finocchiaro in the public hearing of 31 March 2009;

having heard the barristers Gian Carlo Muccio for *Warm* and for *S.I.S.Me.R. s.r.l.*, Isabella Loiodice and Filippo Vari for the *Comitato per la tutela della salute della donna*, Antonio Baldassarre and Giovanni Giacobbe for the *Federazione Nazionale dei Centri e dei Movimenti per la vita italiani*, Gian Domenico Caiazza for C. S. A. and another, for the association *Luca Coscioni per la libertà di ricerca scientifica* and others and for the association *Cecos Italia*, Ileana Alesso, Massimo Clara, Maria Paola Costantini, Marilisa D'Amico and Sebastiano Papandrea for C. M. and another and for the association *Hera Onlus*, for the association *Sos Infertilità Onlus* and for *Cittadinanzattiva Toscana Onlus* and the *Avvocato dello Stato* Gabriella Palmieri for the President of the Council of Ministers.

The facts of the case

1. – By judgment No. 398 of 21 January 2008 (register of orders No. 159 of 2008) – by which, following remittal of the case by the Council of State, accepting the sixth ground of appeal filed by *Warm* (World Association of Reproductive Medicine), it annulled the

provisions of the guidelines approved by ministerial decree of 21 July 2004 – the Regional Administrative Tribunal for Lazio raised, with reference to Articles 3 and 32 of the Constitution, a question concerning the constitutionality of Article 14(2) and (3) of law No. 40 of 19 February 2004 (Provisions governing medically assisted reproduction), insofar as they require, for the purposes of the provision of fertility treatment, the formation of a limited number of embryos, up to a maximum of three, which must be implanted at the same time, and prohibits the conservation of embryos other than under the limited circumstances contemplated thereunder.

The referring court concludes that the question of constitutionality is relevant in the proceedings before it on the grounds that the although the additional challenge by the same appellant to the aforementioned guidelines – due to violation of Article 32(2) and Articles 2 and 3 of the Constitution, insofar as they do not permit the conservation of embryos for the purposes of implantation other than in entirely exceptional cases and stipulate the formation of a limited number up to a maximum of three, for simultaneous implantation – was made against an act with general content from a secondary source, it in reality impinges upon Article 14(2) and (3) of law No. 40 of 2004, of which the regulative provisions cited are the literal and faithful expression, with the result that the challenge to the provisions contained in the guidelines necessarily involves a consideration of the question concerning the constitutionality of the statutory provision on which it is based.

As regards the issue of non manifest groundlessness, the referring court – considering that the goal pursued by law No. 40 of 2004 as a whole, as may be inferred in particular form Article 1, is that of guaranteeing the rights of all individuals involved in the fertility treatment procedure, including the *conceptus*, and that, pursuant to Article 4(2)(a), when having recourse to the techniques concerned it is necessary to respect the principle that a gradualist approach be adopted in order to avoid interventions with a degree of technical and psychological invasiveness that is more serious (than necessary) for the recipients – considers that, since law No. 40 does not contain a definition of the term "embryo", it is intended to have the broadest meaning possible, that is the situation created starting from the fertilisation of the egg.

Having made these preliminary considerations, the referring court cites Article 14 of law No. 40 of 2004, entitled "Limits to the application of the techniques to embryos", sub-section 2 of which provides that the techniques for the production of embryos "must not create a number of embryos greater than that strictly necessary for one single and simultaneous implantation, and in any case not more than three" whilst sub-section 3 affirms that in the event that "the transfer of the embryos into the uterus is not possible due to serious and documented reasons of *force majeure* relating to the health of the woman which were not foreseeable at the time of fertilisation the cryopreservation of the embryos is permitted until the time they are transferred, which must be carried out as soon as possible".

The lower court holds that the concern expressed by the two provisions cited appears essentially to be that of achieving one single implantation with the main purpose of avoiding cryopreservation, which is however indispensable in cases in which a number of embryos is produced that is greater than that which can actually be implanted, and in any case greater than three: the reason for this provision lies – the referring court notes – in the fact that many embryos may be lost using the technique of cryopreservation.

This legislation appears to the referring court to contrast with Article 3 of the Constitution due to violation of the requirement of reasonableness, and again with Article 3 on equal treatment grounds, in addition to Article 32 of the Constitution, insofar as it permits practices which do not adequately balance the protection of the health of the woman with that of the embryo.

Indeed, the referring court observes, to accept – as Article 14(2) of law No. 40 of 2004 does – the possibility of an implantation of more than one embryo (up to a maximum of three), in the awareness that some of them may be lost, means admitting that in order to have a tangible expectation of becoming pregnant it is necessary to carry out an implantation of more than one embryo and moreover accept that one or more of these embryos, alongside that which results in a pregnancy, may be lost.

In the situations described above, the law permits protection of the embryo to be diminished in order to leave space to the goal pursued, which is that of permitting the resource to a fertility treatment technique guaranteed by concrete hopes of success.

However, although the purpose of the law is that of striking an appropriate balance between the protection of the embryo and that of the need for reproduction, a provision which requires the production of embryos of a number such as to render the performance of one single implantation possible, and in any case with no more than three, is claimed to be unreasonable, as also is the substantial prohibition on cryopreservation, which is permitted only in cases of *force majeure* relating to the health of the woman arising after the fertilisation.

Law No. 40 of 2004 should not have precluded the possibility of permitting the many variables which apply to matters of assisted reproduction from being taken into account, such as for example the health and age of the interested woman and the possibility that she may produce embryos that are not strong, thereby referring not to those which are capable of producing a "better race" – an idea expressly and correctly prohibited by law No. 40 of 2004 – but simply those which may prove to be most appropriate for achieving the result of pregnancy and reproduction.

Moreover, the provision for the possibility of varying between one and three the embryos for implantation, in accordance with Article 14(2) of law No. 40 of 2004, is not capable of resolving this issue since that provision is intended to ensure concrete possibilities of pregnancy for persons of average physical condition, whilst it does not provide the same likelihood for women who are not young or those who are not able to produce three embryos of good quality in the terms specified above at the same time. The difference in treatment accordingly consists in this fact, since different situations are subject to the same treatment predetermined by the law.

The prior determination of the number of embryos which may be produced and subsequently implanted, imposed by the provision in a categorical manner and regardless of any concrete evaluation by the patient's doctor of the person who intends to subject herself

to the fertility treatment procedure, does not respect this balancing of interests which law No. 40 of 2004 appears to seek to pursue.

The referring court moreover complains of the violation of the right to health, enshrined by Article 32 of the Constitution. In fact, the restriction of the number of embryos which may be produced and at the same time implanted and the prohibition on the cryopreservation of the same – other than in the restricted circumstance described above – means that in the eventuality, which is far from improbable, that an attempt were not to be successful, it would be necessary to subject the woman to subsequent fertility treatment, namely a medical practice which brings with it the risk of ovarian hyperstimulation syndrome, and the foundation for which lies in the law and not any requirements of a medical nature. Leaving aside any evaluation of the consequences in physical and psychological terms for the patient who is subject to it, this practice is claimed to contrast with the very same principles which inspire the law under examination, and in particular that of the "lower invasiveness" expressly enunciated by Article 4(2)(a).

1.1. – *Warm*, a party in proceedings before the lower court, entered an appearance in the proceedings before the Court, requesting the Court to make a declaration of unconstitutionality as requested by the referring court, submitting arguments in line with those contained in the writ commencing the proceedings before the Constitutional Court.

In particular, with regard to the alleged violation by the contested provisions of Article 32 of the Constitution, it is argued in the entry of appearance that the limit imposed by law No. 40 of 2004 of insemination with three oocytes stands in contrast with the requirement to protect the health of the woman, unreasonably reducing the possibilities of success of the fertility treatment, preventing the biologist from electing the embryos most suitable for development into a foetus from those formed, and from freezing those in excess for a future transfer, and requiring the woman to subject herself to renewed ovarian stimulation treatment and to extract the oocytes through surgery. On the other hand, the opposite risk is pointed out in the entry of appearance, namely that of successful fertilisation, with the possible emergence of a multiple pregnancy which, in turn, entails risks for the health of the woman and the *conceptus*.

On the other hand, Warm emphasises that the legislation concerned eliminates the ability of the doctor to make a discretionary assessment – as the only person capable of striking the best balance between the risks and benefits for the woman and the embryo, at the time when providing fertility treatment – in violation of Article 3 of the Constitution, due to the discrimination imposed between women in good health, for whom it is more likely that the embryos will be successfully inseminated, and those who are not on the grounds of their age or physical condition.

Finally, *Warm* claims that the contested provisions are internally unreasonable, on the grounds of teleological inconsistency, since the means provided are inconsistent with the *ratio legis*; this is because, in permitting the formation and simultaneous single implantation – due to the prohibition on cryopreservation – of the maximum number of three embryos, the provisions concerned accept, and indeed hope, that only one of them will be successfully inseminated, with the resulting loss of the others, thereby departing from the obligation to protect the rights of all subjects involved in the procedure.

The fact that the arrangements are unreasonable is also clear from the comparison with the provisions regulating abortions, since the protection of the embryo, which is the guiding inspiration behind the prohibition on cryopreservation and elimination contained in Article 14 of law No. 40 of 2004, disappears once the insemination has been successfully concluded, since abortion is thereafter permitted up until the ninetieth day of pregnancy.

Finally, the provision for the maximum number of three implantable embryos is claimed to be irrational on the grounds that it lacks any medical or scientific basis.

The association also requests a declaration that Article 14(1) of law No. 40 of 2004 is unconstitutional, which lays down the prohibition on the elimination and cryopreservation of embryos the continuing applicability of which, should the question concerning the constitutionality of Article 14(2) and (3) be accepted, would result in an extension of the prohibitions, without accepting any possibility of derogation.

1.2. – Appearances were also entered in proceedings before the Court by the *Federazione Nazionale dei Centri e dei Movimenti per la vita italiani* and the *Comitato per la tutela*

della salute della donna – which had intervened *ad opponendum* in the main proceedings – both arguing that the question should be ruled inadmissible or groundless.

The former averred that the question was inadmissible due to irrelevancy on the grounds that the referring regional administrative tribunal did not rule on the lack of a direct interest of *Warm* in the proceedings, having mistakenly concluded that a definitive judgment had been reached on this question, as stipulated by the Council of State on appeal. The referring court moreover failed to take into consideration certain grounds contained in the application by *Warm* which had been rejected in the above judgment and were not re-proposed.

On the merits, the Federation argues that the maximum limit of three embryos was stipulated by law No. 40 of 2004 for the purposes of protecting the health of the woman and the embryos, taking into account the difficulties associated with multiple pregnancies. Essentially, law No. 40 strikes a reasonable balance between the interest of the couple in becoming parents and the right to life of the *conceptus*, expressly asserted by Article 1 of the same law. Moreover, also the protection of the health of the woman would be better guaranteed by a "soft" stimulation rather than a strong stimulation, carried out with a view to have available an abundant number of oocytes. Finally, also the discretionary choice of the doctor should comply with the rules resulting from the requirement to protect fundamental human rights.

The *Comitato per la tutela della salute della donna* averred in turn that the question was inadmissible on the grounds that it was raised by a judgment rather than a referral order, in violation of the procedural rules governing proceedings before the Constitutional Court. The referring regional administrative tribunal – it is pointed out in the written statement – on the one hand raised the question of constitutionality, whilst on the other partially resolved the case by decision appealable before the Council of State.

Another ground for the inadmissibility of the question is outlined in the change of the legislative framework due to the intervention of new guidelines in the area of fertility treatment, laid down by ministerial decree of 11 April 2008, which would have resulted in the discontinuation of the administrative proceedings, and thereby also put an end to the proceedings before the Constitutional Court.

On the merits, the Committee averred that the question was groundless, arguing that the weakening of the embryo's right to life was not a matter within the purview of ordinary legislation, having regard the the constitutional foundation of that right, and that moreover the limitation to three of the maximum number of implantable embryos corresponded to the maximum number of embryos likely, according to medical science, to give rise to a pregnancy.

1.3. – The President of the Council of Ministers intervened in the proceedings, represented and advised by the *Avvocatura Generale dello Stato*, arguing in turn that the question was inadmissible on the grounds that it was raised by a judgment, and on the merits that it was groundless. In this regard, the intervener observes that the challenge amounts to a criticism of the discretionary choices of Parliament, which by contrast, in its view, struck a reasonable balance between the interest of the woman in the successful outcome to the fertility treatment procedure and the protection of the embryo.

1.4. – Interventions were also made by the association *Luca Coscioni per la libertà di ricerca scientifica*, the association *Cecos Italia* and S.I.S. Me.R. s.r.l., which argued for a declaration that the provisions challenged by the regional administrative tribunal were unconstitutional, on grounds which mirrored the contents of the measure referring the question.

1.5. – The parties that had entered appearances – *Warm* and the *Federazione Nazionale dei Centri e dei Movimenti per la Vita italiani* (which also questioned the satisfaction of the requirement of the interlocutory nature of the question raised) and the *Comitato per la tutela della salute della donna* – accordingly submitted written statements, arguing for their respective conclusions. The latter in particular pointed out that, notwithstanding the referral of the case file to the Court, proceedings before the lower court had continued, since the court had met in chambers following an application for correction of a material error filed by *Warm*, extending its challenge also to Article 14(1) of law No. 40 of 2004, and issuing a judgment (No. 7956 of 2008), by which the Regional Administrative Tribunal for TAR Lazio provided an authentic interpretation of the previous decision by which it had raised the question of constitutionality under examination. In the alternative, the Committee

requested the Court to remit the case to the lower court in order to permit it to reconsider the relevance of the question in the light of the supervening decree of the Minister of Health of 11 April 2008 which adopted the new guidelines on fertility treatment, and to assess the supervening irrelevance of the question due to the repeal of the previous guidelines.

Written statements were also filed by the *Avvocatura Generale dello Stato*, which argued that the question was inadmissible and groundless, the association *Cecos Italia* and the Luca Coscioni association, as well as the non-profit associations *Amica Cicogna Onlus* [Stork Friend], *Madre Provetta Onlus* [Mother Test-tube], *Cerco un bimbo* [Looking for a Child], *L'altra Cicogna Onlus* [The Other Stork] and the association www.unbambino.it, which on the other hand argued in favour of a declaration of unconstitutionality.

1.6. – Shortly before today's public hearing, the representative of *Warm* filed a written statement containing an analysis of the data from the European Register for treatment carried out in 2005, recently published by the European Society of Human Reproduction and Embryology (ESHRE), which highlight the detriment to the health of both the woman and the embryo which the application of law No. 40 of 2004 entails, with particular reference to the prohibition on forming more than three embryos and the accompanying obligation to transfer all of them, without any possibility of cryopreservation.

The *Federazione Nazionale dei Centri e dei Movimenti per la vita italiani* filed a written statement, which reiterated the conclusions already submitted, placing particular emphasis on the failure to challenge Article 1 of law No. 40 which, by defining the *conceptus* as the subject vested with rights, constitutes the basis for the entire legislative framework, and pointed out that the objective, mandatory under constitutional law, of preventing as far as possible the destruction of human embryos without preventing the fertility treatment procedure is pursued by Parliament through reasonable policy choices.

The written statement also points to the fact that “sweet” [sic.] stimulation, which is sufficient in order to produce a limited number of oocytes such as to permit the formation of a maximum number of three embryos, provides protection against the risks for the woman's health associated with hyperstimulation.

As far as the legislative differences between law No. 194 of 22 May 1978 (Provisions on the social protection of maternity and the voluntary termination of pregnancy) and law No. 40 of 2004 are concerned, the intervener Federation points out that it is mistaken to compare the situation of a women whose health is in danger due to an unwanted pregnancy and that of a couple who has requested the application of the fertility treatment procedure, taking into account also the need to prevent the recourse to illegal abortions in the former case.

Ultimately, it is pointed out in the written statement, since the start of life occurs with the formation of the embryo, *in vitro* reproduction is strongly desired and the decision to use it is the result of a determination, the maturity and resoluteness of which is controlled also by the healthcare facilities through the preliminary interview provided for under Article 6 of the law under examination. The decision of a couple which requests fertility treatment is also a form of taking responsibility for the new human being.

The *Comitato per la tutela della salute della donna* also filed a written statement in which it reiterates the grounds of inadmissibility already submitted and, on the merits, argues that the question raised by the Regional Administrative Tribunal for Lazio is groundless, highlighting the balancing of the rights of all subjects involved in the fertility treatment covered by law No. 40 of 2004 and emphasising the data contained in the last report of the Minister of Health to Parliament on the state of implementation of the law, in which it is observed that after the entry into force of the law, which limits the number of embryos which may be created for each course of artificial procreation, a dramatic fall in complications from ovarian hyperstimulation occurred.

It is pointed out in the written statement that it was the scientific and technological community itself that was calling for a limitation – often to even lower than three embryos – in order to guarantee a successful outcome to the implantation. In this regard, the statement refers to the guidelines elaborated by the Human Fertilisation and Embryology Authority (HFEA), which oversees the application of fertility treatment techniques in the United Kingdom, according to which it is appropriate to transfer no more than two embryos

in normal circumstances, and at most three embryos only in cases involving women older than forty.

As regards the question of the irrevocable nature of consent to implant the embryos, since the implantation cannot be coerced and the violation of the obligation does not entail penalties against the woman, it is asserted in the written statement that the only reason which might lead the woman to change her mind after having decided to subject herself to fertility treatment techniques is the desire to use fertility treatment in order to select the best embryos, discarding the others. Essentially, in placing the question before the Constitutional Court, the introduction of eugenics is being requested which, amongst other things, would result in complete deregulation in the sector of artificial reproduction.

2. – By the referral order issued on 12 July 2008 (No. 323 of 2008), the ordinary *Tribunale di Firenze* raised a question concerning the constitutionality of Article 14(1) and (2) of law No. 40 of 2004, due to violation of Articles 3 and 32(1) and (2) of the Constitution, insofar as they impose the prohibition on the cryopreservation of excess embryos, the requirement for the creation of a maximum of three embryos as well as the single and simultaneous implantation of the same; and Article 6(3), last part, of the same law due to violation of Article 32(2) of the Constitution where it provides that the woman may not withdraw her consent to the implantation in her uterus of the embryos created.

It is stated in the referral order that, after having obtained on an urgent basis authorisation from the court to carry out a pre-implantation genetic diagnosis with cryopreservation of the remaining embryos affected by the disease exostosis, from which the woman suffered, C.S.A. and P.G. had obtained medical reports which stated that the provision for the predetermined procedures for implementing fertility treatment specified under Article 14(2) of law No. 40 of 2004 were unreasonable and unfair in this specific case, taking into account the health of the applicant and a probability of creating unhealthy embryos equal to fifty percent which meant that, in the case before the court, the number of embryos necessary to ensure an adequate chance of success was equal to six.

Following the refusal by the managers of the Centre which the couple approached, justified by the fact that the request would have violated Article 14 of law No. 40, the two applied to

the courts for an interim ruling, requesting amongst other things the court to authorise the Centre to produce a number of embryos adequate to offset the "generic" and "diagnostic risk" of this specific case, not less than six units, also claiming that Article 14(1) and (2) of law No. 40 of 2004 were unconstitutional.

The court seized, having held that it was admissible to raise the question of constitutionality in interim proceedings, found that the arrangements put in place by the law, with regard to the obligation to create a maximum number of three embryos for implantation in one single and simultaneous process and the resulting prohibition on the cryopreservation of the embryos (so-called excess embryos), creates serious harm to the health of the woman and, at the same time, does not guarantee the goal which the law itself posits as its policy aim ("to favour the solution to reproductive problems resulting form sterility or human infertility...": Article 1 of law No. 40 of 2004), providing contradictory and non optimal solutions. In fact – the lower court observes – in the event that treatment is unsuccessful, the law imposes the requirement to carry out multiple ovarian stimulations, since it provides that each course of production and implantation shall be exhaustive, since it does not permit the cryopreservation of embryos for subsequent implantation, thereby entailing serious problems for the health of the woman who must subject herself to multiple courses of hormone treatment, with certified medical consequences.

This means that the provisions violate Article 32(1) of the Constitution with regard to the woman's right to health, even when balanced against that of the embryo required pursuant to Article 1 of law No. 40 of 2004 given that, leaving aside the legal definition of the concept of the *conceptus*, it must in the opinion of the lower court be concluded that the right of the person prevails over that which is not yet a person.

The provisions are also claimed to violate the principle of reasonableness, an expression of the principle of substantive equality laid down by Article 3 of the Constitution, since they treat in a uniform manner individual situations which are entirely dissimilar and which require a different approach to treatment. To reduce fertility treatment to one single model, valid for all specific situations which come to the attention of doctors, would be equivalent to obliterating completely the results of scientific study, which indicate that a range of

factors related to the parents have an impact on the choice of treatment to be followed, which must therefore be left (as moreover all medical treatment, subject always to the requirement of informed consent) to the discretion of the doctor, who is the repository of the technical knowledge of the specific case.

The technique chosen – the referring court argues – is unreasonable due to its requirement for one single possibility of implantation with a maximum number of three embryos, with no provision for any evaluation of the various factors which may apply to the specific individual case and which may condition the outcome (age, illness, type of sterility, etc.) and entail a further danger for the health of the woman and of the foetus resulting form the increase in multiple births.

The referring court also argues that Article 32(2) of the Constitution has been violated, which prohibits compulsory medical treatment unless imposed by law and provided that it respect human dignity. The prior determination of one single treatment protocol, not tailored to the therapeutic needs of the individual person and the consent of the same, is claimed to result in the subjection of the person to undesired medical treatment that is not directed at the protection of that person's health or the health of the public at large. The only exception to the mandatory nature of the implantation which law No. 40 contemplates is contained in Article 14(2), where the transfer into the uterus is suspended where the mother is suffering from an illness that was not foreseeable at the time of fertilisation and only for the period necessary in order to recover from the illness. This also entails, according to the lower court, a violation of Article 32(2) of the Constitution by the provision laid down by Article 6 of law No. 40 of 2004, insofar as it sanctions the irrevocable nature of consent to receive fertility treatment from the time when the egg is fertilised, with reference to the position of the women into whom the embryo must be implanted.

2.1. – C.S.A. and P.G., the private parties in the interim proceedings, entered appearances in the proceedings before the Court, requesting that the contested provisions be ruled unconstitutional.

2.2. – The President of the Council of Ministers intervened, represented and advised by the *Avvocatura Generale dello Stato*, arguing that the question was inadmissible on the grounds that it was raised during the course of interim proceedings and, on the merits, claiming that it was groundless since it fell within Parliament's sphere of legislative discretion.

2.3. – The association *Sos Infertilità Onlus* also intervened, claiming that it has the right to present its arguments to the Court since a declaration of unconstitutionality, if any, would have a direct affect on the activity of the association which, under the terms of its statute, has as its goal the treatment and assistance of infertile couples, and arguing that the contested provisions were unconstitutional, due to violation of Articles 3, 31 and 32 of the Constitution.

2.4. – Similar arguments were submitted by M.C. and G.R., who intervened on the basis of their conviction that they had the right to present their arguments in the proceedings, since any declaration of unconstitutionality would have a direct impact on their situation and on the proceedings commenced by them before the ordinary *Tribunale di Firenze* seeking the granting of an urgent measure in relation to which a question of constitutionality was raised (order No. 382 of 2008), as well as by the association *Hera Onlus*, the goals specified under the statute of which include the support and protection for infertile couples.

2.5. – Finally, the association *Luca Coscioni per la libertà di ricerca scientifica*, as well as the associations *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and the association www.unbambino.it intervened beyond the applicable time limits, arguing in favour of a declaration of unconstitutionality.

2.6. – Shortly before the public hearing, the representative of C.S.A. and P.G. filed a written statement, reaffirming the claims already submitted. The written statement points out in particular, on the one hand, the fact that the balance between the woman's interest in the protection of her health and that of the protection of the embryo is struck by law No. 40 of 2004 in a manner which contradicts the framework of constitutional values as interpreted in the case law of the Constitutional Court since judgment No. 27 of 1975, and on the other hand that there is a contradiction between the objectives pursued by the law under

examination and the solutions made available for this purpose which risks compromising the final result of the solution of reproductive problems resulting from sterility or infertility. In fact, the choice in favour of a single and inderogable therapeutic model, defined in mandatory terms under legislation and not tailored to the therapeutic needs of the individual person, results – according to the written statement – in a complete insensitivity to the requirements raised in individual cases, which means that the legislation is unsuitable to achieve the goals which the law itself posits, including the protection of the embryo. The healthcare professional, who is required to adopt a uniform protocol irrespective of the circumstances of the specific case, is deprived of all technical autonomy in providing the therapeutic solution adequate to the pathology which he is called to treat, in contrast also with the principles and mandatory standards for the professional as well as good medical practice, and therefore with the code of medical practice.

It is also emphasised in the written statement that the case law of the Constitutional Court has repeatedly considered the appropriateness of general and principled choices, predetermined on a mandatory basis by Parliament, to regulate matters relating to questions of status and fundamental rights pertaining to the private sphere of the individual, ruling that solutions which fail to take into consideration the specific circumstances of the individual case are unreasonable. In this regard, reference is made to the case law on adoption, with reference to the exception to the maximum age difference between the adoptive parent and the adoptive child.

A further element of unreasonableness within the contested legislation is stated to lie within the changed legislative context (as a result of certain decisions of the merits courts and the approval of the new guidelines issued concerning assisted reproduction by the Minister of Health by the ministerial decree of 11 April 2008) regarding the admissibility of pre-implant diagnosis. It is claimed that this diagnosis would not have any practical utility were the couple not bound in any case by the obligation for one single and simultaneous implantation of not more than three embryos and the prohibition on cryopreservation.

Finally, the written statement also sets out the reasons why it is necessary to subject to constitutional review – as the referring court has done – also Article 6(3) of law No. 40 of

2004, with regard to the part concerning the irrevocable nature of the consent to implantation once fertilisation has occurred, due to requirements of systematic consistency with a legislative framework which could in any case be affected by internal discrepancy were the challenge limited only to Article 14(1) and (2). On this point, it is argued in particular that, even though the provision concerned posits a rule that is not backed up by any specific sanction in the event that it is violated by the patient, nevertheless, within the context of the ambiguity within the law, any choice regarding the decision to adopt coercive measures in order to ensure respect for the command violated would end up being left to the body charged with its interpretation.

2.7. – Finally, written statements were filed on behalf of the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and the association www.unbambino.it.

3. – The ordinary *Tribunale di Firenze* raised, by referral order of 26 August 2008 (No. 382 of 2008), a question concerning the constitutionality of Article 14(2) of law No. 40 of 2004, limited to the words "for one single and simultaneous implantation, and in any case not more than three", due to violation of Articles 2, 3 and 32 of the Constitution; of Article 14(3) of the same law, limited to the words "When the transfer of the embryos into the uterus is not possible", "of *force majeure*", "which were not foreseeable at the time of fertilisation" and "until the time they are transferred, which must be carried out as soon as possible", due to violation of Articles 2, 3, 13 and 32 of the Constitution; of Article 6(3) of law No. 40 of 2004, insofar as it does not contain at the end, the words "and by the woman, also subsequently", due to violation of Articles 2, 3, 13 and 32 of the Constitution; and of Article 14(4), due to violation of Articles 2, 3, 13 and 32 of the Constitution.

The question was raised during proceedings involving an application pursuant to Article 700 of the Code of Civil Procedure by two infertile spouses affected by genetic diseases who, after having repeatedly but unsuccessfully attempted fertility treatment, requested on an urgent basis the issue of an order permitting them to carry out so-called *in vitro* fertilisation, following pre-implantation diagnosis, and that the embryos created on the basis of the instructions given by the patient by transferred into the uterus of Mrs C.,

applying the procedures dictated by medical science in order to ensure the greatest chance of success of the technique, in consideration of the age and state of health of the patient, taking into account also the risk of dangerous multiple pregnancies, and providing also for the cryopreservation for future implantation of the suitable embryos which it was not possible to transfer immediately.

The referring court, having excluded the possibility of a constitutionally informed interpretation of the provisions concerned, due to the unequivocal nature of the legislation, ruled that the question was relevant in the proceedings before it on the grounds that the provisions of law No. 40 of 2004 constitute a clear obstacle to the acceptance of the requests made by the applicants. In this regard, having found that these requests were based on the legitimacy of so-called pre-implant diagnosis – which, according to the lower court, was to be regarded as perfectly lawful, with efficacy *erga omnes*, after judgment No. 398 of the Regional Administrative Tribunal for Lazio of 21 January 2008, and after the issue of the new guidelines on the application of law No. 40 of 2004 – the lower court observes that in order No. 369 of 2006 this Court ruled manifestly inadmissible the question concerning the constitutionality of Article 13 of law No. 40 of 2004, insofar as it prohibited the subjection of the embryo, prior to implantation, to diagnoses in order to ascertain eventual diseases, on the grounds that it was necessary to verify the constitutionality also of other articles contained in law No. 40 (specifically, the provisions on the "revocable nature of consent until the egg is fertilised", the "prohibition on the creation of a number of embryos greater than that necessary for one single implantation, which is therefore mandatory for all embryos", and the "prohibition on cryopreservation and the elimination of embryos"), which had not been contested. The lower court concludes that it is meaningless to assert the right of the applicants to carry out pre-implant diagnosis where they have not been released from the obligation for a single and simultaneous implantation of no more than three embryos, from the prohibition on cryopreservation of the same other than under the inflexible circumstances specified under Article 14(3) of the law, and from the irrevocable nature of the consent to treatment for medically assisted reproduction once the egg has been fertilised. The questions raised are, according to the referring court, relevant also in view of

the *periculum in mora*, since the time-scale necessary in order to issue an ordinary judgment (certainly longer than interim proceedings *ante causam*) constitute a factor that is in itself liable to be detrimental to the requirement of protection.

Regarding the question of non-manifest groundlessness, the lower court considers that insofar as Article 14(2) imposes the creation of no more than three embryos with a view to their single and simultaneous implantation, it violates the constitutional principles laid down by Articles 2, 3 and 32 of the Constitution, insofar as it results in the repeated subjection of the woman to treatment which, being invasive and having a low level of efficacy, violates the principle of respect for human dignity, with disregard for the provisions of Article 2 of the Constitution. The provision under examination moreover ends up causing disparities in treatment between situations which are not identical and require different treatment, in violation of the principle of substantive equality laid down by Article 3 of the Constitution, as well as violating the fundamental right to health proclaimed by Article 32 of the Constitution, resulting in a significant risk that the woman will be repeatedly subjected to treatment with a high level of dangerousness for her physical and psychological well-being.

The lower court asks, once the so-called pre-implant diagnosis has been admitted, what should be the fate of the prohibition on the cryopreservation and elimination of the embryos, the *raison d'être* for which was certainly more consistent with the previous prohibition, which imposed the sequence creation-transfer-implantation of the embryo, within a context where the woman who has received fertility treatment cannot withdraw her consent, entirely to the benefit of a situation which the law itself defines “protection of the embryo”.

According to the referring court moreover, the absolute freedom to produce an excess number of embryos would in turn result in a situation whereby, in spite of the fact that it occurs subject to the reasonable legislative prerequisites laid down by Articles 1, 4 and 5 of the law, still risks being a precursor for problems that are not free from implications of an ethical and legal nature, but also from operational and financial consequences (simply where it is considered, for example, that the guidelines, both in their original version as

well as the current version, specify that "the embryos which may be considered to have been abandoned shall be frozen centrally at the expense of the state"): therefore, the question concerning the constitutionality of Article 14 of law No. 40 of 2004 is limited as indicated above.

In addition to the above, a further challenge is made to Article 6(3) of law No. 40 which, as a corollary to the previous provisions, provides that the consent to undergo fertility treatment may not be withdrawn by any of the individuals indicated under the same sub-section after the egg has been fertilised. The constitutional principles relevant are also in this case Articles 2, 13 and 32 (the latter to its full extent) of the Constitution, to which must be added Article 3 of the Constitution with the indication, as *tertium comparationis*, of sub-section 4 which expressly grants at all times the doctor responsible for the facilities the power to decide whether or not to carry out the fertility treatment on medical grounds, and such grounds cannot fail to include also those more specifically relating to the physical and psychological well-being of the woman.

A ruling on Article 6(3) of law No. 40 of 2004 is requested in order to give consistency to a legislative scheme which, were the challenge limited (for the reasons indicated above) only to Article 14(2) and (3), would in any case remain affected by an internal discrepancy (highlighted by the Constitutional Court in order No. 369 of 2006, also with reference to the provision now at issue). If the legislative system requested results from a ruling that pre-implant diagnosis is lawful and the ruling of unconstitutionality requested is characterised by the superior status recognised to the health of the woman (enshrined by law No. 194 of 1978 on the voluntary termination of pregnancy and which cannot be frustrated by legislation such as that under examination), it is therefore a necessary consequence that, for requirements of systematic consistency, only the woman be entitled to withdraw her consent to fertility treatment.

The above is confirmed by the clear provision (albeit not of legislative status) contained in each of the versions of the guidelines (section "cryopreservation of embryos: procedures and time-limits") according to which "the woman always has the right to obtain the transfer of the frozen embryos".

Finally, the question concerning the constitutionality of Article 14(4) of law No. 40 of 2004 is raised, due to violation of Articles 2, 3, 13 and 32 of the Constitution.

According to the referring court, the provision in question is not immediately clear: in particular, it is not clear whether it is a provision on the voluntary termination of pregnancy (as would be suggested by the recourse to the term "pregnancies" and the reference to law No. 194 of 1978) – in the sense therefore that it does not prevent a voluntary termination of pregnancy relating only to some of the embryos involved (as a remedy *ex post* to unwanted multiple pregnancies resulting from fertility treatment) – or (as would be suggested by the initial phrase "for the purposes of this law on medically assisted reproduction") a specification of the prohibition on the cryopreservation or elimination of embryos pursuant to Article 14(1). The applicants have correctly pointed out – the lower court observes – that the prohibition is justified where, having made the choice to produce more than one embryo (two or at most three, according to the contested scheme), it is then decided to implant a lower number, in violation of the rule on their single and simultaneous transfer. If on the other hand the rule on the production of no more than three embryos, their single and simultaneous implantation and the strict prohibition on cryopreservation, were no longer to apply, the prohibition on the reduction of the number of embryos would no longer be meaningful either.

One justification for the provision could remain through the reference to the provisions on the voluntary termination of pregnancy, but at this point it would amount to superfluous and excessive reference, since Article 14(1) is already sufficient (possibility of elimination of embryos in the cases provided for under law No. 194 of 1978).

The referring court asks finally whether this solution would not run the risk of a eugenic trend, and in particular a "negative eugenics", understood as that intended to ensure that people who suffer from hereditary diseases are not born, pursuing the goal of "improving" the human race.

Another no less important doubt is whether couples who are *not* sterile or infertile, but who have a strong risk of transmitting genetic diseases, really end up receiving, due to the fact that they cannot have fertility treatment and with reference to this pre-implant diagnosis

and the ability to select the embryo, less favourable treatment than couples, again with a strong risk of transmitting genetic diseases but who *are* sterile or infertile, who by contrast could have recourse to all of the above, in the event that the questions of constitutionality raised were accepted.

On this point moreover, the lower court points out that, given the prevalence of the women's right to health over any possible subjective situation of the embryo, the risk of "negative eugenics" ends up being a false problem, which is unresolved – and in fact aggravated – by requiring a woman who has already been subject to ovarian stimulation and the implanting operation to terminate her pregnancy, whether voluntarily or not.

3.1. – C.M. and G.R., the parties to the merits proceedings, entered appearances in the proceedings before the Court.

3.2. – The President of the Council of Ministers intervened, represented and advised by the *Avvocatura Generale dello Stato*, arguing that the question was inadmissible and groundless, on the basis of arguments similar to those submitted regarding the proceedings commenced by referral order No. 323 of 2008.

3.3. – Interventions were also made by the non-profit associations Hera O.N.L.U.S., *Sos Infertilità Onlus* and *Cittadinanzattiva Toscana Onlus*, the associations *Cecos Italia* and *Luca Coscioni per la libertà di ricerca scientifica*, as well as the non-profit associations *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and the association www.unbambino.it, each of which adhered to the request that the contested provisions be declared unconstitutional.

3.4. – Shortly before the date scheduled for the public hearing, the *Avvocatura Generale dello Stato* filed written statements in the proceedings commenced by referral orders No. 323 and 382 of 2008, reiterating the arguments submitted.

The state representative restated, and expanded on, the objection that the questions were inadmissible on the grounds that they were raised during the course of interim proceedings, pointing out that the content of the measure requested would end up having irreversible effects, with implications on the relevance of the questions. Concluding, the *Avvocatura Generale* emphasises the fact that the questions are not of an interlocutory nature, since a

judgment accepting them, if issued, would give concrete form to the protection requested before the referring court.

The questions are also claimed to be inadmissible on the grounds that they relate to a sector, the legal regulation of which calls for a careful and prudent weighing up of the interests in play through a delicate process involving the balancing of values, within the ambit of a discretionary political evaluation reserved to Parliament.

It is argued in the written statement that the reasoning of the referring court suffers from a basic fault, consisting in the fact that the question raised regarding Article 14(2) and (3) of law No. 40, as motivated by the court itself, does not impinge upon the prohibition of a general nature on the cryopreservation and elimination of the embryos contained in sub-section 1 of that article, with the result that it would not make sense to request the removal of the exception to the rule stating the prohibition contained in sub-section 3.

A further ground for inadmissibility may be found in the referring court's intention to call into question the scheme of the entire law. Here again, the grounds for unconstitutionality, if ascertained, would also affect other provisions of law No. 40. Finally, the referring court is claimed to be raising a question of a merely interpretative nature.

On the merits, the questions are argued to be groundless. On the basis that Article 14(2) of the law adopts the indications contained in the Resolution on artificial insemination approved by the European Parliament on 16 March 1989 and follows the approach chosen by the German Parliament, the *Avvocatura dello Stato* claims that the referral orders consist in a criticism of the discretionary choices of Parliament, which weighed up the interest of the woman in the successful outcome of the assisted reproduction against that of protecting the embryo. The reasonableness of the numerical limit contained in Article 14(2) is consistent, according to the intervener, with the conclusions of science and the techniques intended to guarantee the successful outcome of the implantation. The written statement contains data from the *Istituto superiore della Sanità* [National Health Board] which indicates that, following the entry into force of law No. 40, the facilities, the couples treated and the number of pregnancies have increased, and that the high number of triplet

pregnancies in Italy is not a direct consequence of the legislative provisions, but must be associated with the manner in which the procedure is implemented in particular cases.

Finally, the written statement argues that the irrevocable nature of consent to implantation, stipulated pursuant to Article 6(3), cannot be regarded as equivalent to a compulsory form of treatment, which by contrast covers those therapeutic or diagnostic activities aimed at preventing or curing diseases in the interest of the individual concerned, alongside the public health interest. Moreover, the irrevocable nature of consent is not accompanied by procedures for compulsory implementation.

Written statements were filed on behalf of M.C. and G.R., as well as the non-profit associations *Hera O.N.L.U.S.*, *Sos Infertilità Onlus*, and *Cittadinanzattiva Toscana O.N.L.U.S.* and the association *Luca Coscioni, per la libertà di ricerca scientifica*.

Conclusions on points of law

1. – The Regional Administrative Tribunal for Lazio (referral order No. 159 of 2008) questions, by a judgment, with reference to Articles 3 and 32 of the Constitution, the constitutionality of Article 14(2) and (3) of law No. 40 of 19 February 2004 (Provisions governing medically assisted reproduction), insofar as insofar as they provide, for the purposes of the application of the procedure for fertility treatment, for the formation of a limited number of embryos, up to a maximum of three, for simultaneous implantation, permitting the cryopreservation of the embryos until the time they are transferred, which must be carried out as soon as possible, only due to serious and documented reasons of *force majeure* relating to the health of the woman.

The ordinary *Tribunale di Firenze* (referral order No. 323 of 2008) suspects, with reference to the same constitutional principles, that Article 14(1) and (2) of law No. 40 of 2004 are unconstitutional insofar as they impose a prohibition on the cryopreservation of excess embryos, the mandatory requirement to create a maximum of three embryos and a single and simultaneous implantation of the embryos, which may in any case not be greater than three, because the prior determination of a uniform healthcare protocol would entail

subjecting the woman to undesired treatment not directed at the protection of her own health, nor that of the general public.

The court also questions the constitutionality of Article 6(3), last part, of the same law, where it provides that the woman may not withdraw her consent to the implantation in her uterus of the embryos created, due to violation of Article 32(2) of the Constitution, which prohibits compulsory medical treatment unless imposed by law and provided that it respect human dignity.

The ordinary *Tribunale di Firenze* (referral order No. 382 of 2008) challenges Article 14(2) of law No. 40 of 2004, limited to the words "for one single and simultaneous implantation, and in any case not more than three", due to violation of Articles 2, 3 and 32 of the Constitution; Article 14(3) of the same law, limited to the words "When the transfer of the embryos into the uterus is not possible", "of *force majeure*", "which were not foreseeable at the time of fertilisation" and "until the time they are transferred, which must be carried out as soon as possible", due to violation of Articles 2, 3, 13 and 32 of the Constitution; Article 14(4) of law No. 40, due to violation of Articles 2, 3, 13 and 32 of the Constitution, on the grounds that this provision results in the repeated subjection of the woman to treatment which, being invasive and having a low level of efficacy, violates the principle of respect for human dignity; creates disparities in treatment between situations which are not identical and require different treatment, in contrast with the principle of substantive equality laid down by Article 3 of the Constitution, as well as violating the fundamental right to health due to the significant risk that the woman will be repeatedly subject to treatment with a high level of dangerousness for her physical and psychological well-being.

Finally, the court also challenges Article 6(3) of law No. 40, insofar as it does not contain, at the end, the words "and by the woman, also subsequently", due to violation of Articles 2, 3, 13 and 32 of the Constitution.

2. – The three measures adopted by the lower courts raise questions which largely overlap and this means that it is appropriate to join the cases for treatment together and decision with a single judgment.

3. – As a preliminary matter, the Court confirms the order issued during today's public hearing, and attached to this judgment, by which it ruled inadmissible the interventions by the associations *Cecos Italia*, *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it, as well as *S.I.S.Me.R. s.r.l.* (*Società Italiana Studi di Medicina della Riproduzione s.r.l.*) in the proceedings commenced by referral order No. 159 of 2008; the interventions by the non-profit associations *Sos Infertilità Onlus* and *Hera Onlus*, as well as C.M. and G.R. in the proceedings commenced by referral order No. 323 of 2008; the interventions by the non-profit associations *Hera Onlus*, *Sos Infertilità Onlus* and *Cittadinanzattiva Toscana Onlus*, the association *Cecos Italia*, as well as the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it in the proceedings commenced by referral order No. 382 of 2008. This order was issued in accordance with the settled position under constitutional case law, according to which interventions in interlocutory constitutionality proceedings by subjects which are not parties to the proceedings before the lower court, and which are not vested with a qualified interest directly pertinent to the substantive relationship at issue in the proceedings are not admissible (see *inter alia*, judgment No. 96 of 2008, and orders No. 393 of 2008 and No. 414 of 2007).

4. – It is now necessary to examine the objections of inadmissibility raised by the parties in relation to the various referral measures.

4.1. – The objection of inadmissibility raised by the *Avvocatura Generale dello Stato* and by the *Comitato per la tutela della salute della donna* on the grounds that the Regional Administrative Tribunal for Lazio raised the questions by judgment rather than by referral order, in breach of the provisions regulating proceedings before the Constitutional Court, is groundless.

This Court has in fact asserted – and the principle must be restated in this case – that “this fact does not mean that the question is inadmissible given that, as may be inferred from a reading of the decision, when referring the question of constitutionality the lower court

ordered the suspension of the main proceedings and the transmission of the case file to the registry of the Constitutional Court, which means that this decision – even if it states that it is a 'judgment' – must be recognised as having the status of a 'referral order' that substantively complies with the provisions of Article 23 of law No. 87 of 1953" (judgment No. 452 of 1997).

4.2. – Another objection of inadmissibility is filed, again with reference to the question raised by the Regional Administrative Tribunal, by the *Federazione Nazionale dei Centri e dei Movimenti per la vita italiani*, with regard to the issue of relevance on the grounds that the lower court did not rule on the lack of direct interest of *Warm* (World Association of Reproductive Medicine), an applicant in the proceedings before the lower court, having erroneously held that a judgment had been in relation to that question, as established by the Council of State on appeal.

This objection too should not be accepted, since the Regional Administrative Tribunal did not implausibly assert that there was no scope for review of the issue of the standing to sue of *Warm*, since a definitive ruling had been made on this issue, as may be inferred from the judgment ordering remittal from the Council of State.

4.3. – The further objection of inadmissibility, raised by the *Comitato per la tutela della salute della donna* following the change in the legislative framework as a result of the issue of the new guidelines on fertility treatment, contained in the ministerial decree of 11 April 2008, which would have resulted in the termination of the administrative proceedings and, along with them, would have put an end to the constitutionality proceedings, is also groundless.

It is in fact sufficient to point out the fact that the 2004 guidelines applied up until the time when they were replaced and, therefore, whilst the administrative proceedings were pending, and the guidelines subsequently issued cannot have any impact on any of the questions raised.

4.4. – In the written statements filed by the *Comitato per la tutela della salute della donna* and the *Federazione nazionale dei centri e dei Movimenti per la vita italiani* it was averred that the question raised by the Regional Administrative Tribunal was inadmissible on the

grounds that it failed to satisfy the requirement that it be an interlocutory issue, since the subject matter of the main proceedings would end up substantially coinciding with that of the constitutionality proceedings.

Also this objection is groundless.

When determining the admissibility of a question of constitutionality raised during the course of proceedings before a court, it is necessary *inter alia* that it relate to a provision with the force of law which the referring court is required to apply, as a necessary step in the resolution of the dispute at issue in the main proceedings. In the case before the Court, there is no doubt that were the questions raised concerning Article 14(2) and (3) of law No. 40 of 2004 to be accepted, this would have a tangible effect on the proceedings before the lower court, consisting in the acceptance of the claims made by the private parties, since the challenges brought against the contested secondary legislation would have to be accepted (see the similar finding, regarding this principle, judgments Nos. 303 and 50 of 2007).

4.5. – With regard to the questions raised by referral orders No. 323 and No. 382 of 2008 by the ordinary *Tribunale di Firenze*, the state representative claims that they are inadmissible on the grounds that they were raised during interim proceedings, arguing first that the contents of the measure requested would end up producing irreversible effects, with implications on the significance of the questions, whilst also emphasising the fact that the questions are not of an interlocutory nature, since any judgment which accepted them would have the effect of granting the protection requested before the referring court.

The objection is groundless.

The case law of this court accepts the possibility that questions of constitutionality may be raised during interim proceedings, both where the court does not accept the application as well as when it grants the relative measure, provided that the granting of the measure does not entail the definitive exhaustion of the power to issue an interim ruling which the court exercises in those proceedings (judgment No. 161 of 2008 and orders No. 393 of 2008 and No. 25 of 2006).

In the case before the Court, the interim proceedings are still in progress and the lower courts have not exhausted their own *potestas iudicandi*: their entitlement to raise the

questions of the constitutionality of the provisions which they are called upon to apply during that stage is therefore not open to challenge (judgment No. 161 of 2008).

5. – The question concerning the constitutionality of Article 14(1) of law No. 40 of 2004 was raised, with reference to Articles 3 and 32(1) and (2) of the Constitution, by the ordinary *Tribunale di Firenze* by referral order of 12 July 2008 (No. 323 of 2008): it is manifestly inadmissible due to the failure to give reasons in support of its relevance.

5.1. – Article 14(2) and (3) of law No. 40 are challenged by the Regional Administrative Tribunal for Lazio and by the ordinary *Tribunale di Firenze* by referral order of 26 August 2008, according to arguments which are substantively similar, whilst the ordinary *Tribunale di Firenze* challenged, by referral order of 12 July 2008 – in addition to sub-section 1 – sub-section 2 of Article 14, but not sub-section 3.

The question raised by the Regional Administrative Tribunal for Lazio concerns Article 14(2) and (3) of law No. 40 insofar as it requires the creation of a number of embryos for implantation which may in no case be greater than three and the simultaneous implantation of the same, and also prohibits the cryopreservation of embryos other than under the limited circumstances provided for thereunder. The referring court suspects that the contested provisions violate Articles 3 and 32 of the Constitution. As regards the number of embryos, it argues, first and foremost, that legislation which on the one hand asserts that it is informed by the goal of promoting solutions to reproductive problems resulting from sterility or infertility, whilst on the other hand imposing the aforementioned numerical limit on the production of embryos, disregarding any concrete evaluations by the doctor of the person who intends to subject herself to the fertility treatment procedure, and taking care only to avoid the recourse to cryopreservation, which could result in the loss of the embryos, thereby also risking the meaningless sacrifice of the embryos produced, is inherently unreasonable. Therefore, the provision under examination does not respect that balancing of interests which law No. 40 of 2004 appears to seek to pursue.

On the other hand, according to the Regional Administrative Tribunal, this limitation results in a unjustified difference in treatment, depending on the different physical conditions of the women who undergo fertility treatment.

Finally, the violation of Article 32 of the Constitution is identified in the fact that the contested legislation results in the need for subsequent ovarian stimulation treatment in the not unlikely eventuality of an unsuccessful outcome to the first attempted implantation, which contrasts precisely with the principle that treatment should be less invasive which is expressly asserted in Article 4(2)(a) of the law as one of the principles which must inform the technique concerned.

5.2. – By the referral order of 12 July 2008 (No. 323 of 2008), the ordinary *Tribunale di Firenze* raised a question concerning the constitutionality of Article 14(2) of law No. 40 of 2004, due to violation of Articles 3 and 32(1) and (2) of the Constitution, insofar as it imposes the obligation to create a maximum number of three embryos as well as the single and simultaneous implantation of the same. The question was raised during the course of the same proceedings when issuing an order authorising pre-implant diagnosis, following which the applicants had obtained medical reports specifying a fifty percent possibility that embryos might be created affected by diseases, with the result that, in the case before the court, the number of embryos necessary to ensure an adequate likelihood of success was equal to six.

Article 32(1) of the Constitution is suspected to have been violated with regard to the woman's right to health which should, albeit balanced against that of the embryo required pursuant to Article 1 of law No. 40 of 2004, be considered to be predominant over the right of whoever has not yet become a person: where the treatment is unsuccessful, the law imposes a requirement to carry out various courses of ovarian stimulation, since it does not permit the cryopreservation of the embryos for subsequent implantations and causing serious problems for the woman who must undergo hormone treatment several times, with certified medical consequences.

It is also considered that the principle of reasonableness has been violated due to the identical treatment of individual situations which are entirely dissimilar and which would require a different approach to treatment, completely disregarding scientific research which indicates how a range of factors relating to the parents have an impact on the choice of treatment to be provided, which must therefore be left (as moreover all medical treatment,

subject always to the requirement of informed consent) to the discretion of the doctor, who is the repository of the technical knowledge of the specific case.

Article 32(2) of the Constitution, which prohibits compulsory medical treatment unless imposed by law and provided that it respect human dignity, is claimed to have been violated due to the prior determination of one single treatment protocol, not tailored to the therapeutic needs of the individual person and the consent of the same and which results in the subjection of the person to undesired medical treatment that is not directed at the protection of that person's health or the health of the public at large.

5.3. – Finally, by the referral order issued on 26 August 2008 (No. 382 of 2008), the ordinary *Tribunale di Firenze* suspects that Article 14(2) violates Article 2 of the Constitution by requiring the creation of no more than three embryos for one single and simultaneous implantation, resulting in the repeated subjection of the woman to treatment which, being invasive and having a low level of efficacy, violates the principle of respect for human dignity; causes disparities in treatment between situations which are not identical and require different treatment, in violation of the principle of substantive equality laid down by Article 3 of the Constitution; and violates the fundamental right to health proclaimed by Article 32 of the Constitution, resulting in a significant risk that the woman will be repeatedly subjected to highly dangerous treatment. However, in order to avoid granting the absolute freedom to produce an excess number of embryos, which would raise problems of an ethical and religious nature, the Court is requested do make a declaration of unconstitutionality within the limits specified above (limited to the words "for one single and simultaneous implantation, and in any case not more than three").

5.4. – Article 14(3) is also challenged on the basis of the same constitutional principles (with regard to Article 32 of the Constitution, given also of the need to avoid a situation where the woman, who is required to accept the implantation of embryos affected by serious diseases, must first start a pregnancy and later terminate it, either voluntarily or not, causing serious harm to her physical and psychological well-being), limited to the words "When the transfer of the embryos into the uterus is not possible", "of *force majeure*", "which were not foreseeable at the time of fertilisation", and "until the time they are

transferred, which must be carried out as soon as possible". The action proposed is thereby intended to prevent the emergence of paradoxical situations, such as those highlighted in the referral order (in the example provided, a supervening and sudden febrile illness could give rise to cryopreservation, whereas a pre-existing serious genetically transmittable disease would not). Moreover, by implying that a person may be treated without her consent and without any overriding reasons of general interest or to protect public health and safety in accordance with an express legislative provision, Article 14(3) is also stated to violate Articles 13 and 32(2) of the Constitution.

The state representative has countered these observations with the argument that Parliament struck a reasonable balance between the interest of the woman and the protection of the embryo, that the limit of three embryos protects the health of the woman and of the embryos, that law No. 40 of 2004 strikes a balance between the interest of the couple and the right of the *conceptus*, that the health of the woman is better guaranteed by a "soft" stimulation, that the limitation to three of the maximum number of embryos which may be implanted corresponds to the maximum number of embryos likely, according to medical science, to result in pregnancy.

6. – The questions concerning the constitutionality of Article 14(2) and (3) raised are well founded, within the limits set out below.

6.1. – It should be noted at the outset that the law under examination contains – as pointed out by some of the referring courts – a limit on the protection provided to the embryo, since even where the number of embryos produced is limited to only three, it is in any case accepted that some of them may not result in pregnancy, since the specification of the maximum number of embryos which may be implanted accepts that risk, thereby permitting a weakening of the protection of the embryo with the goal of ensuring the tangible expectation of pregnancy, in accordance with the goals proclaimed by the law. Therefore, the protection of the embryo is not at all absolute, but is limited by the need to strike a correct balance with the protection of the requirements of reproduction.

In view of the above, the Court finds that the prohibition laid down by Article 14(2) results – by precluding any possibility of creating a number of embryos greater than that strictly

necessary for one single and simultaneous implantation, and in any case greater than three – in the need for multiple courses of fertility treatment (in contrast also with the principle, expressed in Article 4(2), that a gradualist approach be adopted and that the technique of assisted reproduction be as little invasive as possible), since the three embryos produced, if they are indeed three, will not always be capable of giving rise to a pregnancy. The chances of success vary in fact in line both with the characteristics of the embryos, the individual conditions of the women who undergo fertility treatment, as well finally as their age, with the likelihood of a pregnancy progressively falling for older women.

The legislative limit under examination therefore ends up on the one hand – by rendering necessary the repetition of courses of ovarian stimulation where the first implantation does not produce any results – favouring an increase in the risks of the emergence of the diseases that are related to hyperstimulation; on the other hand, in situations where the likelihood of successful insemination is greater, it causes a detriment of a different type of the health of the woman and the foetus in cases involving a multiple pregnancy, having regard to the prohibition on the selective reduction of embryos for such pregnancies, pursuant to Article 14(4), other than by way of abortion. This is because the legislative provision does not leave the doctor any possibility to make an assessment, on the basis of the most up to date and accredited technical and scientific knowledge, of the individual case under treatment, with the resulting specification on a case by case basis of the numerical limit of embryos for implantation which is considered appropriate in order to ensure that a serious attempt at assisted reproduction is made, and reducing to a minimum conceivable the health risk to the woman and the foetus.

In this regard, it is important to point out that the case law of the Constitutional Court has repeatedly emphasised the limits placed by scientific and experimental knowledge on legislative discretion, which are continuously developing and on which the medical state of the art is based: this means that, in matters concerning clinical practice, the basic rule must be the autonomy and responsibility of the doctor who, with the consent of the patient, makes the necessary professional choices (judgments No. 338 of 2003 and No. 282 of 2002).

The provision for the creation of a number of embryos not greater than three, in the absence of any consideration of the individual conditions of the woman who may from time to time undergo fertility treatment, ultimately violates Article 3 of the Constitution on the dual grounds of reasonableness and equality, since Parliament requires that dissimilar situations be treated identically; as well as Article 32 of the Constitution, due to the detriment caused to the health of the woman – and as the case may be, as seen above, of the foetus – related to that treatment.

The Court therefore finds that Article 14(2) of law No. 40 of 2004 is unconstitutional, limited to the words "for one single and simultaneous implantation, and in any case not more than three".

The decision to declare the contested provisions unconstitutional thereby upholds the principle according to which the techniques of reproduction must not create a number of embryos greater than that which is strictly necessary in accordance with evaluations reserved in the specific case to the doctor, but strikes down the provision requiring one single and simultaneous implantation and imposing a maximum number to the embryos for implantation, thereby eliminating both the unreasonableness of the treatment of different situations in an identical manner, as well as the need for the woman to undergo, if necessary, another course of ovarian stimulation, which it is possible may infringe her right to health.

The conclusions reached, which introduce an exception from the general principle of the prohibition on cryopreservation contained in Article 14(1), as the logical consequence of the striking down, within the limits indicated, of sub-section 2 – according to which it is necessary to freeze the embryos produced but not implanted in accordance with the doctor's choice – moreover means that the Court must declare unconstitutional sub-section 3, insofar as it does not provide that the transfer of the embryos, which must be carried out as soon as possible, under the terms of that provision, must be carried out without jeopardising the health of the woman.

7. – The question concerning the constitutionality of Article 14(4) of law No. 40, raised with reference to Articles 2, 3, 13 and 32 of the Constitution by the ordinary *Tribunale di*

Firenze by referral order No. 382 of 2008 is manifestly inadmissible due to the failure to give reasons in support of its relevance in the proceedings before the lower court.

8. – The question concerning the constitutionality of Article 6(3) of law No. 40, insofar as it does not permit, after the egg has been fertilised, the withdrawal of the consent to receive fertility treatment, for which both of the referral orders of the ordinary *Tribunale di Firenze* request a declaration of unconstitutionality with the sole goal of giving coherence to the system, is also inadmissible, again due to its failure to satisfy the prerequisite of relevance.

ON THOSE GROUNDS

THE CONSTITUTIONAL COURT

hereby;

declares that Article 14(2) of law No. 40 of 19 February 2004 (Provisions governing medically assisted reproduction) is unconstitutional, limited to the words "for one single and simultaneous implantation, and in any case not more than three";

declares that Article 14(3) of law No. 40 of 2004 is unconstitutional is unconstitutional insofar as it does not provide that the transfer of embryos, which according to that provision must be carried out as soon as possible, is to be carried out without without jeopardising the health of the woman;

rules that the question concerning the constitutionality of Article 14(1) of law No. 40 of 2004, raised with reference to Articles 3 and 32(1) and (2) of the Constitution by the ordinary *Tribunale di Firenze* by referral order No. 323 of 2008, is manifestly inadmissible;

rules that the questions concerning the constitutionality of Article 6(3) of law No. 40 of 2004, raised with reference to Articles 3 and 32 of the Constitution by the ordinary *Tribunale di Firenze* by referral order No. 323 of 2008 and, with reference to Articles 2, 3, 13 and 32 of the Constitution, by the same court by referral order No. 382 of 2008, are manifestly inadmissible;

declares that the question concerning the constitutionality of Article 14(4) of law No. 40 of 2004, raised with reference to Articles 2, 3, 13 and 32 of the Constitution by the ordinary *Tribunale di Firenze* by referral order No. 382 of 2008, is manifestly inadmissible.

Decided in Rome, at the seat of the Constitutional Court, *Palazzo della Consulta*, on 1 April 2009.

Signed:

Francesco AMIRANTE, President

Alfio FINOCCHIARO, Author of the Judgment

Giuseppe DI PAOLA, Registrar

Filed in the Court Registry on 8 May 2009.

The Director of the Registry

Signed: DI PAOLA

Appendix:

read out in the hearing of 31 March 2009

ORDER

Whereas:

in the constitutionality proceedings commenced pursuant to the referral by the Regional Administrative Tribunal for Lazio (Register of Orders No. 159 of 2008) the association *Cecos Italia*, the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it, as well as S.LS.Me.R. s.r.l. – *Società Italiana Studi di Medicina della Riproduzione s.r.l.* intervened, none of which was a party to the proceedings before the lower court;

in the proceedings commenced pursuant to the referral order by the *Tribunale di Firenze* (Register of Orders No. 323 of 2008) the association *Sos Infertilità Onlus*, the association *Hera Onlus*, as well as C.M. and G.R. intervened, none of which was a party to the proceedings before the lower court;

in the proceedings commenced pursuant to the referral order of the *Tribunale di Firenze* (Register of Orders No. 382 of 2008) the association *Hera Onlus*, the Association *Sos Infertilità Onlus*, the association *Cittadinanzattiva Toscana Onlus*, the Association *Cecos Italia*, as well as the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it intervened, none of which was a party to the proceedings before the lower court;

according to the settled case law of this Court, interventions may be made in interlocutory constitutionality proceedings only by the parties to the main proceedings and third parties with a qualified interest directly pertinent to the substantive relationship averred in the proceedings and not simply regulated, on the same basis as any other, by the contested provision (see *inter alia*, judgment No. 96 of 2008; orders No. 393 of 2008, No. 414 of 2007, and the order read out in the hearing of 26 February 2008);

the inadmissibility of the intervention is not altered by the fact that proceedings similar to the main case are pending, since the admissibility of that intervention would be at odds with the interlocutory nature of constitutionality proceedings, on the grounds that those parties would have access to the proceedings without a prior verification of the relevance and non manifest groundlessness of the question by the lower court (judgment No. 220 of 2007; order No. 393 of 2008, cited above, and the orders read out in the public hearings of 3 July 2007 and 19 June 2007).

on those grounds

THE CONSTITUTIONAL COURT

rules inadmissible the interventions by the association *Cecos Italia*, the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it, as well as *S.I.S.Me.R. s.r.l. – Società Italiana Studi di Medicina della Riproduzione s.r.l.* in the proceedings commenced pursuant to the referral order No. 159 of 2008; the interventions by the association *Sos Infertilità Onlus*, the association *Hera Onlus* as well as C.M. and G.R. in the proceedings commenced pursuant to the referral order No. 323 of 2008; the interventions by the association *Hera Onlus*, the association *Sos Infertilità Onlus*, the association *Cittadinanzattiva Toscana Onlus*, the association *Cecos Italia*, as well as the associations *Luca Coscioni per la libertà di ricerca scientifica*, *Amica Cicogna Onlus*, *Madre Provetta Onlus*, *Cerco un bimbo*, *L'altra Cicogna Onlus* and www.unbambino.it, in the proceedings commenced pursuant to the referral order No. 382 of 2008.

Signed: Francesco Amirante, President