JUDGMENT NO. 162 YEAR 2014

In this case the Court heard a referral challenging legislation which prevented couples suffering from absolute and irreversible infertility or sterility from engaging in heterologous medically assisted reproduction. The Court drew on the constitutional right to health of the parents, which it took to include their mental well-being, and held that this right had been infringed in that well-being may be jeopardised by the failure to have children. Since the absolute prohibition imposed by the legislation was not the only way of guaranteeing protection to the other constitutional values affected, it thus ruled unconstitutional the bar on heterologous medically assisted reproduction for couples affected by irreversible sterility or infertility.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Articles 4(3), 9(1) and (3) and 12(1) of Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction), initiated by the *Tribunale di Milano* by the referral order of 8 April 2013, the *Tribunale di Firenze* by the referral order of 29 March 2013 and by the *Tribunale di Catania* by the referral order of 13 April 2013, registered respectively as nos. 135, 213 and 240 in the Register of Orders 2013 and published in the Official Journal of the Republic nos. 24, 41 and 46, first special series 2013.

Considering the entries of appearance by P.E. and another, C.P. and another, V.A. and the cooperative company UMR–Unità di Medicina della Riproduzione, and the interventions by Associazione Luca Coscioni per la libertà di ricerca scientifica [Luca Coscioni Association for Freedom of Scientific Research] and others, the Associazione Vox–Osservatorio italiano sui diritti [Vox Association – Italian Rights Observatory] and the President of the Council of Ministers;

having heard the judge rapporteur Giuseppe Tesauro at the public hearing of 8 April 2014;

having heard Counsel Filomena Gallo and Counsel Gianni Baldini for the Associazione Luca Coscioni per la libertà di ricerca scientifica and others, Counsel

Marilisa D'Amico, Counsel Maria Paola Costantini and Counsel Massimo Clara for P.E. and another, for C.P. and another and for V.A., Counsel Maria Paola Costantini and Counsel Massimo Clara for the cooperative company UMR–Unità di Medicina della Riproduzione and the State Counsel [*Avvocato dello Stato*] Gabriella Palmieri for the President of the Council of Ministers.

[omitted]

Conclusions on points of law

1.– The *Tribunale di Milano*, the *Tribunale di Firenze* and the *Tribunale di Catania* raised, with reference to Article 3 of the Constitution (all three referral orders), Articles 2, 31 and 32 of the Constitution (the first and the third referral orders), and (the first referral order) Articles 29 and 117(1) of the Constitution, in relation to Articles 8 and 14 of the Convention for the Protection of Human Rights and Fundamental Freedoms signed in Rome on 4 November 1950 (hereafter, ECHR), ratified and implemented by Law no. 848 of 4 August 1955, questions concerning the constitutionality of Article 4(3) of Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction) (all referral orders) and Articles 9(1) and (3), limited to the phrase "in breach of the prohibition laid down by Article 4(3)" and 12(1) of the said Law (the first and third referral orders).

Law no. 40 of 2004 lays down provisions on medically assisted reproduction (hereafter, MAR) and allows recourse to MAR "In order to favour the solution to reproductive problems resulting from sterility or human infertility", in accordance with the terms and subject to the arrangements provided for thereunder (Article 1). Article 4(3) of the Law provides that "It is prohibited to use heterologous medically assisted reproduction techniques"; Article 9, laying down the "Prohibition on the denial of paternity and anonymity of the mother", provides first and foremost that "If heterologous medically assisted reproduction techniques are used in breach of the prohibition laid down in Article 4(3), the spouse or cohabitant whose consent may be implied as a result of his actions cannot bring an action seeking to deny paternity in the cases provided for under Article 235(1), no. 1 and no. 2 of the Civil Code or the challenge provided for under Article 263 of the Code" (paragraph 1); secondly, it provides that, "In the event that heterologous techniques are applied in breach of the

prohibition under Article 4(3), the donor of gametes shall not acquire any legal relationship of parentage with the newborn child and cannot exercise any right or be subject to any obligations in respect of the latter" (paragraph 3). Finally, Article 12(1) provides that "Any person who uses in any way the gametes of persons from outside the applicant couple for the purposes of reproduction in breach of the provisions of Article 4(3) shall be punished by an administrative fine of between EUR 300,000 and 600,000".

2.– According to all of the referring courts, Article 4(3) breaches Article 3 of the Constitution in that, since Law no. 40 of 2004 has the purpose of "favour[ing] the solution to reproductive problems resulting from sterility or human infertility", the prohibition imposed by it results in different treatment for couples affected by sterility or infertility issues, in spite of the fact that their circumstances are substantially similar and, therefore, they must have the same entitlement to use the most effective MAR techniques in order to remedy the condition from which they suffer.

In the opinion of the *Tribunale di Milano*, all of the contested provisions also violate Articles 2, 29 and 31 of the Constitution in that – although Article 2 acknowledges and protects the right to establish a family (which is covered by Article 29) – they do not guarantee to couples affected by absolute and irreversible sterility or infertility the fundamental right to the full realisation of private family life and self-determination in that regard which, according to the *Tribunale di Catania*, thereby impairs the right of couples suffering from the more serious illness to establish a family and for them to make autonomous decisions regarding their own lives. For both of the referring courts, the fact that the prohibition under examination does not protect the physical and psychological integrity of such couples and that the general rule for therapeutic practices must be that doctors are vested with autonomy and responsibility for their actions, making the necessary professional choices with the consent of the patient, is claimed to underscore the violation by these provisions of Articles 3 and 32 of the Constitution.

According to the *Tribunale di Catania*, Articles 2 and 31 of the Constitution have been violated on further grounds as the solution to the reproductive problems of the couple may be classified under the fundamental right to maternity/paternity and the contested provisions have struck an unreasonable balance between the right to health of the biological mother and of the genetic mother, the right protected under constitutional

law to establish a family and the rights of the newly born child, also in consideration of the hypothetical status of any psychological suffering caused by the lack of information regarding a person's own genetic origin and the existence of an institute such as adoption, which contemplates atypical parental relations.

Finally, the *Tribunale di Milano* challenges the provisions referred to above, with reference to Article 117(1) of the Constitution, in relation to the combined provisions of Articles 8 and 14 ECHR, presenting in further detail the arguments which, in its opinion, demonstrate such a contrast, having regard also to the judgment of the Grand Chamber of the European Court of Human Rights of 3 November 2011 in *S.H. and others v. Austria*.

3.– As a preliminary matter, it is necessary to reiterate the order read out in the public hearing, which is annexed to this Judgment, concerning the decision to join the proceedings (which related in part to the same provisions, which were challenged in relation to constitutional parameters on grounds and on the basis of arguments that largely coincided) and concerning the admissibility of the intervention in the proceedings before the *Tribunale di Catania* of the *Associazione Vox–Osservatorio italiano sui diritti*, and the intervention within one single submission by *Associazione Luca Coscioni, per la libertà di ricerca scientifica*, *Associazione Amica Cicogna Onlus*, *Associazione Cerco un bimbo* and *Associazione Liberi di decidere*.

According to the settled case law of this Court in fact, only the parties to the main proceedings and third parties vested with a qualified interest that is directly related to the substantive right averred in the proceedings, and not simply governed, in the same manner as any other, by the contested provision or provisions, are entitled to intervene in interlocutory proceedings before the Constitutional Court (see, as representative of the Court's case law, judgments no. 134 and no. 85 of 2013). Thus, as the aforementioned associations are not parties to the main proceedings and are not vested with any such qualified interest, the interventions must be ruled inadmissible. As regards the interventions by the associations referred to above, it must also be reiterated that the fact that they are parties to proceedings different from those in which the referral order was made, in which however an analogous question of constitutionality was raised, is also not sufficient to render them admissible (see *inter alia*, Judgment no. 470 of 2002; Order no. 150 of 2012).

3.1.– The questions of constitutionality under review are a reformulation of questions – in part analogous – raised by the lower courts during the same main proceedings, which were ruled upon by this Court in Order no. 150 of 2012 which – after ruling them admissible – ordered that the proceedings be remitted for a renewed examination in the light of the judgment of the Grand Chamber of the European Court of Human Rights of 3 November 2011 in *S.H. and others v. Austria*.

In complying with that requirement, the *Tribunale di Firenze* and the *Tribunale di Catania* have reformulated the same questions in different terms and provided the arguments which, in their opinion, demonstrate that only the challenges relating to Articles 2, 3, 31 and 32 of the Constitution are still relevant and are not manifestly groundless; thus, they have no longer proposed the questions concerning Article 117(1) of the Constitution in relation to Articles 8 and 14 ECHR. On the other hand, these last questions have been repeated by the *Tribunale di Milano*, which however provided various arguments in support, and it is clear that if the relative arguments are indeed well founded, this will apply exclusively to the merits of the challenges. Therefore, the objection by the State Counsel that the questions are inadmissible on the grounds that they did not comply with the requirements indicated above is not well founded in this regard. The further objection of inadmissibility, arguing that were the challenges to be accepted it would result in an unbridgeable "legislative vacuum", will be examined below along with the review of the merits of the challenges.

3.2.– A question of constitutionality may also be raised during the interim stage, if the court has not ruled on the application (as is the case in the proceedings under examination), or if it has granted the relative measure, provided that its granting does not constitute the full and definitive exercise of the powers vested in the court during that stage (see *inter alia*, Orders no. 3 of 2014 and no. 150 of 2012). The questions are therefore admissible also on this basis.

3.3.– Moreover, the admissibility of the question raised by the *Tribunale di Firenze* is not affected by the failure to challenge Articles 9(1) and (3) and 12(1) of Law no. 40 of 2004, since the provision which the referring court must immediately and directly apply in the main proceedings is only Article 4(3), whilst the failure to consider the other provisions does not impair the accuracy of the account of the reference legislative framework.

It is equally irrelevant that, as has been averred by some of the associations intervening in the proceedings initiated by the *Tribunale di Catania*, the applicant married couple in the respective main proceedings have separated. Irrespective of the issue of proof of such an occurrence, it cannot have any effects on proceedings before the Constitutional Court since, once they have been commenced following a referral order by the referring court, they cannot be influenced by subsequent factual events involving the relationship at issue in the proceedings that gave rise to the referral, as provided for under Article 18 of the supplementary rules on proceedings before the Constitutional Court, in the version approved on 7 October 2008 (see Judgments no. 274 of 2011 and no. 227 of 2010).

3.4.– According to the referring courts moreover, in the cases brought before them for decision, the subjective prerequisites provided for under Article 5 of Law no. 40 of 2004 have been met, but the applicants cannot use homologous MAR with the aim of having a child as one of the members of the couple is affected by an absolute and irreversible reproductive illness entailing sterility or infertility, whilst they could profitably use heterologous MAR.

All referral orders have thus argued in a manner that is not implausible that the questions are relevant, and such relevance obtains, in accordance with the remedy sought, exclusively in relation to the prohibition insofar as it prevents individuals who meet the prerequisites laid down by Article 5 of Law no. 40 of 2004 from using heterologous MAR where the existence of an illness causing irreversible and absolute sterility or infertility has been certified.

Moreover, the questions raised are of an interlocutory nature. In fact, the challenges relate to provisions which the referring courts must apply as a mandatory act in reaching a decision on the claims brought in the main proceedings over whether to recognise the claimant's right to obtain an order requiring the defendants to carry out the action requested, which means that the remedy sought is distinct from the questions of constitutionality raised.

3.5.– Again as a preliminary matter, it needs to be pointed out that no further questions or issues of constitutional law raised by the parties can be taken into account beyond those stated in the referral orders, whether averred by the parties but not endorsed by the referral orders, or whether intended to expand upon or alter *ex post* the

content of the referral orders (on all points, see Judgment no. 275 of 2013, Order no. 10 of 2014).

Moreover, it is for this Court to assess the overall objections and questions comprising the *thema decidendum* and to establish, *inter alia* on procedural economy grounds, the order in which they are to be considered in the judgment, and as the case may be to declare some of them moot where the questions are independent of one another on the grounds that none has preliminary status (see Judgments no. 278 and no. 98 of 2013, no. 293 of 2010).

4.– On the merits, the questions raised with reference to Articles 2, 3, 29, 31 and 32 of the Constitution are well founded as specified below.

5.– The challenges are to be reviewed having regard to all of these parameters considered jointly, as medically assisted reproduction touches upon "various constitutional values" (see Judgment no. 347 of 1998), and consequently Law no. 40 of 2004 impinges upon a range of interests on that level. These interests, considered overall, require "that a balance be struck between them that ensures a minimum level of legislative protection" to each of them (see Judgment no. 45 of 2005), as this Court has already asserted that the very "protection of the embryo is not in any case absolute, but is limited to the need to strike a fair balance with the protection of reproductive needs" (see Judgment no. 151 of 2009).

The questions touch upon ethically sensitive issues, in relation to which the striking of a reasonable balance between countervailing requirements, whilst respecting the dignity of the human person, is "primarily an assessment which falls to the legislator" (see Judgment no. 347 of 1998), although this is without prejudice to its amenability to review in order to verify whether or not an unreasonable balance has been struck between those requirements and the values by which they are inspired. Moreover, the prohibition under examination is not the result of a choice that has become consolidated over time, as it was introduced into our legal system precisely by the contested Article 4(3). Previously, in fact, the application of heterologous fertilisation techniques was "lawful […] and accepted without any subjective or objective limits" and was practised in 75 private clinics in 1997 (Report of the 12th Standing Committee of the Chamber of Deputies presented on 14 July 1998 concerning Bills no. 414, no. 616 and no. 816, tabled during the 12th Legislature). These clinics operated under the terms of the

circulars of the Ministry of Health of 1 March 1985 (Limits applicable to and conditions governing the legitimacy of artificial insemination services under the National Health Service), 27 April 1987 (Measures to prevent the transmission of the HIV virus and other pathogenic agents through human semen used for artificial fertilisation) and 10 April 1992 (Measures to prevent the transmission of the HIV virus and other pathogenic agents in the donation of seminal fluid used for assisted human fertilisation and in the donation of organs, tissue and bone marrow), and the order issued by the Ministry on 5 March 1997 laying down the "Prohibition on the marketing and advertising of gametes and human embryos" (the effect of which was limited in time, although it was subsequently extended for a further ninety days by a subsequent order of 4 June 1997).

The first of these acts prohibited exclusively the possibility of providing heterologous MAR within National Health Service facilities; the second on the other hand stipulated protocols governing the use of semen "for heterologous insemination", thereby laying down rules on the preparation of the register of couples who subjected themselves to that practice and of gamete donors, and the type of assessments to be carried out regarding donors; the third specified further arrangements applicable to the collection, preparation and cryopreservation of donors' seminal liquid, and the screening to which women receiving donations were to be subject "in order to protect the future newly born child"; finally, the fourth prohibited "any form of direct or indirect, immediate or deferred remuneration in cash or in any other form for the provision of gametes, embryos or any other genetic material" and any form of commercial brokerage with a view to such provision, imposing a requirement on clinics practising such techniques to disclose certain data to the Ministry of Health.

Moreover, that prohibition is not imposed by obligations resulting from international law instruments since, as has already been clarified by this Court, its removal does not in any way violate any aspect of the principles laid down by the Oviedo Convention of 4 April 1997 (which only prohibits MAR for selective and eugenic purposes, and still lacks an implementation mechanism) and Additional Protocol no. 168 of 12 January 1998 on the Prohibition of Cloning Human Beings, which was implemented within Italian law by Law no. 145 of 28 March 2001 (Ratification of the Oviedo Convention) (see Judgment no. 49 of 2005).

6.– In the light of this premise, which is appropriate as context for the prohibition under examination, it must be pointed out that, in preventing couples subject to Law no. 40 of 2004 who are absolutely sterile or infertile from using heterologous MAR techniques, such prohibition lacks an adequate foundation in constitutional law.

It must be reiterated first and foremost that the choice by such a couple to become parents and to establish a family including children amounts to an expression of the fundamental and general right of self-determination which, as this Court has previously held, albeit for other purposes and in relation to a different area of law, is protected by Articles 2, 3 and 31 of the Constitution in that it relates to the private sphere and family life. Consequently, any restrictions on that freedom, including in particular the absolute prohibition imposed on its exercise, will only be reasonably and suitably justified if it is impossible to protect interests of equal standing in any other manner (see Judgment no. 332 of 2000). Even for couples who are absolutely sterile or infertile, the decision over whether or not to have a child, which relates to the most intimate and intangible sphere of the human person, must be free from constraint, provided that it does not violate other constitutional values, even when it is exercised following a choice to use this type of heterologous MAR technique, because that choice too is a matter for this intimate and intangible sphere. In this regard it must be recalled that, according to the case law of the Constitutional Court, Law no. 40 of 2004 is aimed at protecting "reproductive requirements", which must be weighed up against other constitutional values, none of which however is provided with absolute protection, as a reasonable balance must be struck between them (see Judgment no. 151 of 2009).

It must also be pointed out that the Constitution does not endorse a concept of family which is inextricably linked to the presence of children (as may be inferred from Judgments no. 189 of 1991 and no. 123 of 1990). Nevertheless, the project of establishing a family including children, irrespective of whether or not they are genetically related, is viewed favourably by the legal order in accordance with constitutional principles, as is demonstrated by the regulations applicable to adoption. In any case, the fact that adoption is intended predominantly to guarantee a family to children (as has been asserted by this Court since Judgment no. 11 of 1981) makes it clear that the issue of genetic origin is not an essential prerequisite for the existence of a family.

The free and voluntary nature of the act that enables a person to become a parent and to establish a family, in the sense specified above, certainly does not imply that the freedom under examination may be exercised without any limits. However, even where these limits are inspired by ethical considerations and convictions, which also need to be taken into account in such a delicate area, as stressed above they cannot consist in an absolute prohibition, unless this is the only way of protecting other interests of constitutional standing.

7.– The legislation under examination also impinges upon the right to health which, according to the settled case law of this Court, must be understood "in the meaning stipulated under Article 32 of the Constitution as including also mental health in addition to physical health" (see Judgment no. 251 of 2008; and by analogy, Judgments no. 113 of 2004; no. 253 of 2003), "which must be protected on an equal footing to physical health" (see Judgment no. 167 of 1999). Moreover, this notion coincides with that endorsed by the World Health Organization, according to which "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being" (Constitution of the World Health Organization, signed in New York on 22 July 1946).

In relation to this issue, the differences between homologous and heterologous MAR are not significant, as the difference between them lies in the fact that the former enables a couple to have a child who is genetically related to both parents. Taking account also of the various manifestations of these techniques, it is certain that the inability to establish a family including children along with one's own partner by recourse to heterologous MAR may have a negative impact – which may even be significant – on the health of the couple, in the manner in which the relative right must be construed as set out above.

In line with this concept of the right to health, it must therefore be reiterated that "according to settled case law, acts of self-determination in relation to one's own body that are directed at the protection of health must be deemed to be lawful" (see Judgment no. 161 of 1985), provided that other constitutional interests are not harmed.

Furthermore, in cases involving illnesses that result in disability – a concept which, on evident solidarity grounds, must be construed broadly – the discretionary power vested in the legislator to enact ordinary legislation specifying the forms of protection

for sufferers is subject to the limit of "respect for an essential core of guarantees for the persons involved" (see Judgments no. 80 of 2010, no. 251 of 2008). Any decisions concerning the merits of therapeutic choices, as regards their appropriateness, cannot result from purely discretionary policy assessments by the legislator, but must take account also of viewpoints based on the study of scientific knowledge and experimental results obtained, acting through institutions and bodies charged with such activities (see Judgment no. 8 of 2011), having regard also to the potential infringement of the right to mental health and the suitability and conduciveness of a particular technique to guarantee protection for that right as required in the light of the notion set out above. It must therefore be reiterated that, "in the area of therapeutic practices, the basic rule must be that doctors are vested with autonomy and responsibility for their actions, making the necessary professional choices with the consent of the patient" (see Judgment no. 151 of 2009), although this is without prejudice to the power of the legislator to enact legislation compatible with the principles of constitutional law. This does not lead to the subjectivisation of the concept of health, nor does it merely accommodate the desire for self-gratification on the part of the couple, distorting the technique for consumerist ends, but rather takes account of the fact that the concept of illness, including mental illness, its impact on the right to health and the existence of therapeutic practices that are capable of protecting it must be determined in the light of assessments which can only be made by medical science, subject to the requirement to ensure that the relative choice does not contrast with interests of equal standing.

8.– Therefore, the contested prohibition impinges upon the constitutional interests referred to. However, this is not sufficient to render it unconstitutional, as for this purpose it is necessary to establish whether its absolute status is the only way of guaranteeing protection to the other constitutional values affected by the technique under examination.

9.– As a preliminary matter, it needs to be pointed out that heterologous MAR aims to promote life and raises problems relating in particular to the period after birth. Since the prohibition has been challenged insofar as it prohibits recourse to that technique in situations involving an illness that is an irreversible cause of absolute sterility or infertility, it must in fact be excluded at root that the technique could be used for illegitimate eugenic goals.

Moreover, according to the widely known results established by medical science, the technique under examination (which must be strictly circumscribed to the donation of gametes and kept separate from other different methods, such as "surrogate pregnancies", which are expressly prohibited under Article 12(6) of Law no. 40 of 2004, the prohibition of which has not been challenged and is not affected in any way and at any point by this ruling, and will hence continue to be valid and effective) does not entail any risk for the health of donors or recipients in excess of the normal level of risk inherent within any therapeutic practice, provided that it is performed within facilities operating subject to strict official controls and in accordance with protocols drawn up by specialist bodies charged with such tasks.

10.– The only interest which contrasts with the aforementioned constitutional interests is therefore that of the person born as a result of heterologous MAR who, according to the State Counsel, would suffer harm both as a result of the psychological risk associated with having non-biological parents, as well as the violation of the right to know his or her own genetic identity. In the opinion of the intervener, the challenges are moreover inadmissible as mentioned above since, were they to be accepted, this would result in an unbridgeable "legislative vacuum" in relation to significant aspects of the applicable legislation, giving rise to "a question relating to policy and legislative technique falling within the competence of the *conditor iuris*", which raises exclusively "political/opportunity choices" falling under the discretionary power reserved to the legislator when enacting ordinary legislation.

This objection highlights the inextricable correlation between aspects relating to the admissibility of the questions and the merits of those questions. For this reason, they must therefore be examined jointly.

The objection that the questions are inadmissible is groundless, although were the questions to be accepted, this would not – as is by contrast asserted by the private parties – bestow renewed validity on the administrative acts referred to above. Considering the contents of the prohibition introduced by Article 4(3) and the fact that it is impossible to classify that rule (and the entire law) exclusively and expressly as a law repealing previously valid legislation, along with the nature of those acts, it is clear that none of the "typical and strictly limited scenarios" involving the revival of validity tolerated under constitutional law obtains (see most recently, Judgment no. 70 of 2013).

11.– In view of the above, it must be reiterated that Law no. 40 of 2004 represents the "first comprehensive body of legislation relating to a delicate sector […] which indubitably affects a variety of significant constitutional interests which, overall, require at the very least that a balance be struck between them that ensures a minimum level of legislative protection" and must be deemed to be "constitutionally necessary" (see Judgment no. 45 of 2005). Nevertheless, the content of this part of the provision is not mandatorily required by the Constitution; in fact, in ruling inadmissible the request for a popular referendum seeking the repeal, *inter alia*, of Article 4(3), it was stressed that were the referendum to be successful, it would not be "liable to remove a minimum level of protection required under constitutional law, which would thus have exempted it from liability to repeal by referendum" (see Judgment no. 49 of 2005).

As regards the "legislative vacuum" prospected by the intervener, referring to the points set out below concerning the existence of any gaps resulting from the acceptance of the questions, it must moreover be recalled that, since Judgment no. 59 of 1958, this Court has asserted that its power "to rule legislation unconstitutional cannot be impeded by any gap in the law which may be caused with regard to the relations at issue; as it is a matter for the legislator […] to remove it with the utmost dispatch and in the most appropriate manner" and has recently reasserted that "when confronted with a violation of the Constitution which cannot be resolved through interpretation – especially where it relates to fundamental rights – the Court is in any case required to provide a remedy" (see Judgment no. 113 of 2011).

In fact, due to the requirement to guarantee the principle of constitutionality, it is essential to assert that the relative review "must cover the legal system as fully as possible" (see Judgment no. 1 of 2014), and it is obviously not conceivable for certain areas to be immune from review. Any other result would in fact cause intolerable harm to the constitutional order considered overall, above all in cases in which the violation of a fundamental freedom has been ascertained, which can never be justified by the failure by the legislator to enact ordinary legislation. Once it has been ascertained that primary legislation breaches constitutional law, this Court cannot therefore avoid its power and duty to remedy the breach and must rule it unconstitutional, whereupon it is then the task of the "legislator to enact appropriate provisions through ordinary legislation" (see Judgment no. 278 of 2013) with the aim of removing any gaps that

cannot be filled by the courts applying the ordinary canons of interpretation, or by the public administration, where this is permitted.

In the present case however, many of the most significant aspects are already regulated by various provisions, also because, mindful of the fact that heterologous MAR is lawful in many European countries, the legislator has subjected it to appropriate regulations as Italian citizens were (and are) able to travel to such countries to take advantage of it, as has actually occurred in a not insignificant number of cases.

11.1.– The fact that the challenges have been held to be well founded does not mean that there is any uncertainty as to the cases in which it is legitimate to use the technique in question. The acceptance of the questions in line with the remedy sought by the referring courts entails that the prohibition under examination is unlawful exclusively with reference to the scenario in which an illness has been certified that is the irreversible cause of absolute sterility or infertility. In particular, according to Articles 1(2) and 4(1) of Law no. 40 of 2004, which clearly relate directly also to heterologous MAR, once the contested prohibition has been ruled unlawful, recourse to that technique must be deemed to be permitted only "where there are no other effective therapeutic methods for removing" the causes of sterility or infertility and their absolute status has been ascertained, which circumstances must be "documented [and certified] by a physician". Moreover, any recourse to this technique must comply with the principles of progressive action and informed consent required under Article 4(2), as is the case for homologous MAR.

There is no gap as regards the subjective prerequisites, as the stated unconstitutionality of the prohibition does not impinge upon that laid down by Article 5(1) of the Law, which is obviously applicable to heterologous MAR (as it already applies to homologous MAR); therefore, this technique can be available exclusively for "married or cohabiting couples of adults of the opposite sex of a potentially fertile age, both of whom are alive". An analogous conclusion must be reached with regard to the rules applicable to consent, as the full regulations laid down by Article 6 of Law no. 40 of 2004 – once the contested prohibition no longer applies in accordance with the limits specified above – evidently also apply to the technique under examination, which represents a particular form of MAR. It is also equally clear that since Article 7 of Law no. 40 of 2004 (which provides the legal basis for the guidelines issued by the Ministry

of Health "indicating medically assisted reproduction procedures and techniques") applies to the directives that must be issued in order to implement the legislation and concerning MAR as a type, of which heterologous MAR is a sub-type, it evidently refers also to the latter, as also do Articles 10 and 11 on the designation of facilities authorised to practice medically assisted reproduction and the documentation of the relative procedures.

In view of the above it may be concluded that the rules laying down prohibitions and sanctions aimed at securing compliance with the rules setting out the subjective prerequisites, the arrangements governing the expression of consent and the medical documentation necessary in order to diagnose the illness and for the technique to be applied, in addition to guaranteeing compliance with the rules governing the manner in which MAR is to be carried out, which also prohibit the marketing of gametes and embryos and surrogate pregnancies (Article 12(2) to (10) of Law no. 40 of 2004), which have not been challenged (and which remain valid and effective), are directly applicable (and not by way of an expansive interpretation) to heterologous techniques, as also are the further provisions except insofar as affected by the rulings of this Court.

The issues on which the intervener has focused, concerning the legal status of the newly born child and the relations with his or her parents, are moreover also governed by the relevant provisions of Law no. 40 of 2004, which are also applicable to children born as a result of heterologous MAR in accordance with ordinary canons of interpretation. The fact that Article 8(1) of that Law contains a broad reference to "children born following the application of medically assisted reproduction techniques", in view of the generic nature of this formulation and the fact that, as specified above, heterologous MAR is a sub-type of a type, means that it is in fact clear that, under that provision, also children born as a result of the application of the latter technique "have the status of children born outside of marriage or children recognised by the couple, which has expressed its desire to use such techniques". Ordinary legislation has moreover taken account of this new concept of paternity, amending Article 231 of the Civil Code which, following the amendment introduced by Article 8 of Legislative Decree no. 154 of 28 December 2013 (Review of the provisions applicable to filiation, pursuant to Article 2 of Law no. 219 of 10 December 2012) provides significantly that "The husband shall be the father of any child conceived or born during the marriage",

thereby replacing the provision as originally worded, according to which "The husband shall be the father of any child conceived during the marriage".

Once the phrase "in breach of the prohibition laid down in Article 4(3)" has been removed from Article 9(1) and (3) of Law no. 40 of 2004 as a result of the acceptance of the questions raised, it will be possible to confirm both that any action seeking to deny paternity (the reference by to Article 235 of the Civil Code following the amendments introduced by Articles 17 and 106 of Legislative Decree no. 154 of 2013 must accordingly now be deemed to relate to Article 243-bis of the Civil Code) and any challenge pursuant to Article 263 of the Civil Code (as amended by Article 28 of Legislative Decree no. 154 of 2013) will be inadmissible, and that birth as a result of heterologous MAR will not result in the establishment of legal relations of parentage between the gametes donor and the newly born child, as the key aspects of the legal status of the latter will thus be regulated.

12.– It is therefore already possible to infer from legislation in force a regulatory framework for heterologous MAR which, with regard to other issues than those considered above, may be inferred using ordinary canons of interpretation from the legislation generally applicable to the donation of tissue and human cells, which lays down general principles, which are applicable notwithstanding the differences between the situations (concerning for example the requirement that donation be free of charge and voluntary, the anonymity of the donor and the requirements of protection from a healthcare point of view covered by Articles 12, 13(1), 14 and 15 of Legislative Decree no. 191 of 6 November 2007 on the "Implementation of Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells"). As regards the number of donations, it will moreover be possible for the guidelines to be updated, also in the light of the law in other European countries (for example in France or the United Kingdom), whilst taking account of the need to permit donations up to a reasonably limited number.

Despite its special configuration in relation to the case under examination, the question of the right to genetic identity is also not new. It has been raised in fact in relation to adoption and legislation has been recently enacted governing the general principle of the right of adoptive parents to access information concerning the identity

of the adoptive child's biological parents along with the procedural arrangements applicable to its exercise (Article 28(4) of Law no. 184 of 4 May 1983 on the "Right of the child to a family", as amended by Article 100(1)(p) of Legislative Decree no. 154 of 2013). In addition, the dogma of secrecy surrounding the identity of the biological parents as an inviolable guarantee of the cohesion of the adoptive family has already been overcome in this area, mindful of the need for a dialectical evaluation of the respective relations (Article 28(5) of Law no. 184 of 1983). This requirement was in fact confirmed by this Court when examining the rule prohibiting access to information where the mother declared at birth that she did not wish her identity to be disclosed; the Court held that that the irreversible nature of the secret caused an irremediable breach of Articles 2 and 3 of the Constitution and thus struck down the provision, ruling that its maintenance was inadmissible and inviting the legislator to introduce appropriate legislation in order to enable the enduring wishes of the biological mother not to disclose her identity to be confirmed, whilst at the same time putting in place rigorous safeguards to protect her right to anonymity (see Judgment no. 278 of 2013).

13.– Given its absolute status, the contested provision is thus the result of an unreasonable balancing of the interests in play, which breaches also the requirement that the law should be reasonable, and cannot be justified even by reference to the need to enact primary or secondary legislation in order to establish certain aspects of the rules on heterologous MAR.

In this regard, it must be recalled that the case law of the Constitutional Court "has inferred from Article 3 of the Constitution a principle of 'rationality' of the law, that does not depend upon any comparison with other legislation and may be discerned in the 'requirement that the legal order adhere to the values of justice and equity' and principles of logical, teleological and historical coherence, which operates as a safeguard against manifest irrationality or inequity within its consequences (see Judgments no. 87 of 2012). When reviewing reasonableness in areas characterised by broad legislative discretion, this Court must satisfy itself that the balance between constitutionally significant interests has not been struck in such a manner as to cause one of these interests to be sacrificed or impaired to an excessive degree, such as to render it incompatible with the requirements of the Constitution. Such assessments must involve "a consideration of the proportionality of the means chosen by the legislator

when exercising its absolute discretion vis-à-vis the objective requirements to be met or the goals it intends to pursue, taking account of the specific circumstances and restrictions that obtain" (see Judgment no. 1130 of 1988). The proportionality test may be used for this purpose, along with the reasonableness test, which "requires an assessment as to whether the provision under review, along with the arrangements stipulated for its application, is necessary and capable of achieving legitimately pursued objectives by requiring that the measure chosen out of those most appropriate imposes the least restriction on the rights in play and burdens that are not disproportionate having regard to the pursuit of those objectives" (see Judgment no. 1 of 2014).

According to these principles, in the light of the stated purpose of Law no. 40 of 2004 of "favour[ing] the solution to reproductive problems resulting from sterility or human infertility" (Article 1(1)), the absolute bar on access to heterologous MAR introduces an evident element of unreasonableness, as the absolute negation of the right to become a parent and to establish a family with children, which impinges upon the right to health in the manner set out above, is imposed against couples suffering from more serious illnesses, in contrast with the rationale of the legislation. It is of no consequence that the comparator situations are not entirely equivalent, both because this is immaterial for the purposes of the rationality of the provision and because "the principle laid down by Article 3 of the Constitution is violated not only when the treatments compared are formally contradictory in view of the fact that the situation is identical, but also when the difference in treatment is irrational according to the rules of practical reason as the respective situations, whilst being different, are reasonably similar" (see Judgment no. 1009 of 1988), as in the case under examination.

The prohibition under examination ultimately causes a violation of the fundamental freedom of the couple to which Law no. 40 of 2004 applies to establish a family with children, whereas its absolute status is not justified by the requirements to protect the newly born child which must be deemed to be secured appropriately by virtue of the arguments set out above regarding some of the most important aspects of his or her legal position, which may already be inferred from applicable legislation.

Finally, whilst it is correctly inspired by the aim of ensuring appropriate protection for the newly born child, the regulation of the effects of heterologous MAR practised outwith our country evidently introduces a further element of irrationality into the

contested legislation. In fact, it leads to an unjustified difference in treatment between couples suffering from more serious illnesses depending upon their financial resources, which are intolerably turned into a prerequisite for the exercise of a fundamental right, as that right is only denied to those who lack the financial resources necessary in order to use that technique in other countries. Moreover, this is not a mere factual inconvenience, but rather the direct effect of the provisions under examination resulting from a manifestly unreasonable balancing of interests. Ultimately, albeit with the objective of ensuring protection to a value of constitutional standing, the contested provisions lay down legislation which does not comply with the requirement of the least possible sacrifice of other interests and values protected under constitutional law, and end up causing a clear and irreversible violation of some of these interests and values, in breach of the constitutional parameters referred to above.

Therefore, Article 4(3) of Law no. 40 of 2004 must be declared unconstitutional insofar as it imposes a prohibition on the recourse to heterologous medically assisted reproduction techniques where an illness has been diagnosed that is the cause of absolute and irreversible sterility or infertility, as also must Article 9(1) and (3) limited to the phrase "in breach of the prohibition laid down by Article 4(3)" and 12(1) of the said Law.

14.– The grounds for challenge raised with reference to Article 117(1) of the Constitution in relation to Articles 8 and 14 ECHR are moot.

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

1) declares that Article 4(3) of Law no. 40 of 19 February 2004 (Provisions on medically assisted reproduction) is unconstitutional insofar as it imposes a prohibition on the recourse to heterologous medically assisted reproduction techniques where an illness has been diagnosed that is the cause of absolute and irreversible sterility or infertility for couples falling under Article 5(1) of the Law;

2) declares that Article 9(1) of Law no. 40 of 2004 is unconstitutional with regard solely to the phrase "in breach of the prohibition laid down in Article 4(3)";

3) declares that Article 9(3) of Law no. 40 of 2004 is unconstitutional with regard solely to the phrase "in breach of the prohibition laid down in Article 4(3)";

4) declares that Article 12(1) of Law no. 40 of 2004 is unconstitutional, within the limits stated in the reasons.