JUDGMENT NO 161 YEAR 2023

In this case the Constitutional Court considered the question raised by the Ordinary Court of Rome with reference to Articles 2 and 3 of the Constitution on the constitutionality of Article 6(3) of Law No 40/2004 on assisted reproductive technology (ART), which does not provide that a man may withdraw his consent to the implantation of a fertilised embryo into a woman's uterus after the embryo has been fertilised.

The court declared that the question was unfounded.

The fertilised embryo had been cryopreserved for an extended period of time whilst the woman underwent treatment to ensure that her pregnancy could be safely brought to term. In the meantime, however, the relationship between the married couple broke down, following which the husband filed a petition for divorce, and sought to withdraw his consent to ART.

Since Article 6(3) does not provide for such withdrawal of consent, the Court of Rome referred the question to the Constitutional Court.

The ruling by the Constitutional Court states, first and foremost, that the issue falls within so-called "tragic choices" since it is impossible to satisfy all the conflicting interests involved in the case.

The judgment acknowledges that the temporal lag between fertilisation and implantation resulting from cryopreservation of the embryo undoubtedly affects the man's freedom of self-determination. This happens when, due to the passage of time, the *affectio familiaris* on which the couple's project of becoming parents was based and which led the man to give consent to ART has ceased.

However, the Court states that the balancing exercise inherent in Article 6(3) of the Italian law on ART is not unreasonable: the critical element is, indeed, the role played by the man's consent. The centrality of consent in ART means that the man – informed of the possible use of cryopreservation at the time he gave his consent – is aware of the possibility that he might become a father. This makes it difficult to draw a clear-cut line between freedom and responsibility.

Moreover, the man's consent goes beyond the interests inherent in his own individual sphere since it involves other constitutionally relevant interests pertaining both to the woman and the embryo.

Indeed, for the woman access to ART entails the serious burden of allowing her body to be used for medical purposes, with a major physical and emotional investment in becoming a parent, which involves risks, expectations and suffering, and which reaches a turning point when one or more embryos are formed. More specifically, the woman's body and mind are inseparably involved in this process, which culminates in the concrete hope of having a child following the implantation of the embryo into her uterus.

Therefore, if consideration is given to the protection of the mother's physical and psychological health and of the dignity of the cryopreserved embryo, it is not unreasonable to constrain the man's freedom of self-determination with regard to the prospect of becoming a father.

Despite having been introduced in a context in which ART should have been applied without cryopreservation of the embryo, the legal provision is still sufficiently consistent with the new legal context resulting from the rulings of the Constitutional Court which have introduced that option.

The judgment clarifies that the Court is not unaware of the significant consequences that Article 6(3) has on the man, who is thus forced to become the father of a child despite the lack of love for his partner.
Nevertheless, the Court states that it is for the legislature to seek a reasonable point of balance, possibly even a different one.

[omitted]

THE CONSTITUTIONAL COURT

[omitted]

gives the following

JUDGMENT

in proceedings concerning the constitutionality of Article 6(3), last sentence, of Law No 40 of 19 February 2004 (Provisions on assisted reproductive technology), initiated by the Ordinary Court of Rome (*Tribunale ordinario di Roma*), sitting as a single-judge court, within the civil proceedings pending between A.C. and D.R. and another, by referral order of 5 June 2022, registered as No 131 of the 2022 Register of Referral Orders and published in *Official Journal of the Italian Republic* No 46, first special series of 2022.

Considering the entries of appearance by D.R., E.H. spa and A.C., as well as the intervention of the President of the Council of Ministers;

having heard Judge Rapporteur Luca Antonini at the public hearing of 24 May 2023;

having heard Counsel Fabrizio Barberini for D.R., Counsel Francesco Di Mauro for E.H. spa, Counsel Tiziana D'Agostini for A.C. and the State Counsel (*Avvocato dello Stato*) Enrico De Giovanni for the President of the Council of Ministers;

after deliberation in chambers on 24 May 2023.

[omitted]

Conclusions on points of law

1.– By referral order of 5 June 2022 (Register of Referral Orders No 131/2022), the Ordinary Court of Rome, sitting as a single-judge court, questioned the constitutionality of Article 6(3), last sentence, of Law No 40/2004, "at least to the extent that it fails to provide for a time limit for the withdrawal of consent after the oocyte has been fertilised".

2.– After providing that the desire to access assisted reproductive technology (ART) must be expressed jointly in writing by both members of the couple and that "a period not shorter than seven days must pass between the moment of consent and the application of the technique" , the contested Article 6(3), last sentence, provides that such consent "may be withdrawn by each of the persons […] at any time until the oocyte has been fertilised".

3.– The questions originate from the proceedings initiated pursuant to Article 702-*bis* of the Code of Civil Procedure by Ms A.C., who sought an order of specific performance against the private hospital healthcare facility E.H. requiring the implantation of the embryo. Specifically, both she and her husband had consented in September 2017 to the cryopreservation of the embryo within the ambit of an ART procedure at that facility in order to enable a biopsy to be carried out on it.

However, implantation was further postponed on the grounds that the woman's endometrium was not sufficiently thick, and she underwent further specific treatment in November and December of that year. The embryo was not subsequently implanted in her uterus as the husband stopped living in the marital home in January 2018, and the parties formalised their consensual separation in March 2019.

The referral order goes on to state that, in February 2020, Ms A.C. unsuccessfully asked the private hospital to implant the embryo, and that on 24 August 2020 the husband formally withdrew his consent to ART, after applying to the courts for a divorce.

According to the referring court, as that withdrawal of consent occurred after the oocyte had been fertilised, it was not permitted under the contested provision and the question was referred to this Court.

4.– As far as the issue of relevance is concerned, the referring court observes that, having regard to the facts described, the case could not be ruled upon unless a decision is taken concerning the questions of constitutionality raised.

4.1.– As regards the issue of non-manifest unfoundedness, the referring court starts by stating that the provision on the irrevocability of consent was enacted by the legislature within a legislative context in which implantation was to occur "in essence as soon as the embryo had been formed".

However, again according to the referring court, Judgments No151/2009 and No 96/2015 of this Court removed the substantive prohibition on cryopreservation, which means that the provision on the irrevocability of consent now applies within a radically different context. This is because the embryo may be implanted in the uterus even "after a number of years", and hence under radically different circumstances, above all as regards the continuing fulfilment of the prerequisites for access to ART laid down by Law No 40/2004.

In the opinion of the referring court, the contested provision thus interferes with the right to choose whether to become a parent in the event that, in consideration of the passage of time, implantation is requested under "different legal circumstances" from those prevailing at the time of consent.

Thus, since Article 5(1) of Law No 40/2004 allows only "married or cohabiting couples of adults of the opposite sex of a potentially fertile age, both of whom are alive" to access ART, in the event that "the couple's project to become parents is cancelled before implantation", the option of "withdrawal of consent" should still be available.

On the basis of this premise, having established that there is no scope for an "adaptive interpretation", the referring court concludes that, in providing for an effectively absolute preclusion on the ability to withdraw consent after the oocyte has been fertilised, Article 6(3), last sentence, of Law No 40/2004 violates the right to self-determination as regards the decision not to become a parent, as recognised under Article 2 of the Constitution and Article 8 ECHR, and thus also violates Article 117(1) of the Constitution.

The referring court also argues that Articles 3 and 13(1) of the Constitution have been violated in that, in allowing the woman to request implantation even though the man no longer wishes this to occur, the above-mentioned legislation unreasonably forces him "to become a parent against his wishes".

The referring court also argues that Article 3 of the Constitution has also been violated due to the difference in treatment, specifically because the irrevocable nature of consent impinges only on the man's individual freedom. This is because the woman can always refuse to have the fertilised embryo implanted into her uterus, which she could not be forced to tolerate as this would violate her psychological and bodily integrity.

Finally, the contested provision is also claimed to violate Article 32(2) of the Constitution in that it subjects the man to compulsory medical treatment.

[omitted]

8.– The questions raised in relation to Articles 13(1) and 32(2) of the Constitution are inadmissible due to the failure to establish that the questions of constitutionality referred are not manifestly unfounded.

The referring court essentially limits itself to recalling that consent is the "prerequisite that legitimises the medical procedure" and that, since the contested provision disregards consent, it ends up subjecting the man to compulsory medical treatment.

However, the referring court does not propose any specific argument that could explain why the implantation of the embryo, which evidently involves only the woman's body, should entail any medical treatment also for the man or any other form of coerced interference with his body. Moreover, it does not propose any arguments concerning any impact of that treatment on his psychological and physical health.

Accordingly, the violation of the constitutional parameters invoked is asserted in a generic and incontrovertible manner.

9.– As regards the merits, it must first and foremost be noted that the referring court did not err in stating that, following various rulings by this Court, the provision establishing that consent becomes irrevocable after the oocyte has been fertilised applies within a context that is profoundly different from that initially established by Law No 40/2004.

The Law provided in fact that the embryos produced – which could not exceed three in number (Article 14(2)) – had to be implanted in the uterus within the very short space of the few days for which they could survive. The possibility of their cryopreservation, which was prohibited as a general rule (Article 14(1)), thus constituted an exceptional outcome, which was only permitted "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"; moreover, implantation was to occur in any case under all circumstances "as soon as possible" (Article 14(3)).

Within this normative framework, it would have been very difficult for the subjective conditions that had to be met at the time ART was accessed (Article 5(1)) – and, in particular, the fact that the couple was married or cohabiting – to change by the time implantation in the uterus occurred.

The provision establishing the definitive irrevocability of consent after fertilisation followed on from previous provisions setting out a strict framework aimed at guaranteeing the provision of full information to applicants, along with details of their responsibilities, as well as a period of time "not shorter than seven days" during which they could withdraw their consent (Article 6(1), (2) and (3), first and second sentences, and (5)) and featured its own undoubted linear logic: the couple's project of becoming parents could be assumed to remain stable during the very limited number of days between the time when consent was provided and the time when implantation took place.

9.1.– However, this legal framework (within which it was very difficult to anticipate potential conflicts between the various interests at stake) changed as a result of rulings made by this Court that, having established that the legislation as it stood failed to fully protect the woman's psychological and physical integrity, concluded that the strict manner in which Law No 40/2004 imposed a general prohibition on the cryopreservation of embryos was unreasonable.

In particular, Judgment No 151/2009 declared that Article 14(2) was unconstitutional with regard solely to the phrase "for one single and simultaneous implantation, and in any case not more than three", and Article 14(3) "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 jeopardising the health of the woman".

In specifying that "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", that Judgment held that the stipulation of a maximum number of embryos that could be created, coupled with the requirement of one single and simultaneous implantation, on the one hand, entailed "the need for multiple courses of fertility treatment", which involved "an increase in the risks of the emergence of the diseases that are related to hyperstimulation", whilst on the other hand causing "detriment of a different type to 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".

The "logical consequence" of the decision was to create an exception "from the general principle of the prohibition on cryopreservation", given the need "to freeze the embryos produced but not implanted in accordance with the doctor's choice" in order to avoid "jeopardising the health of the woman" (again, Judgment No 151/2009).

Subsequently, by Judgment No 96/2015, this Court issued a ruling concerning provisions (Articles 1(1) and (2) and 4(1)) that precluded access to ART for couples that, despite being fertile, were however carriers of "serious hereditary genetic diseases", duly ascertained by dedicated public facilities, "which are susceptible (according to scientific evidence) to transmitting significant anomalies and malformations to their offspring" and that meet the criteria for seriousness under Article 6(1)(b) of Law No 194 of 22 May 1978 (Rules on the social protection of motherhood and the voluntary termination of pregnancy).

Indeed, the prohibition on access to ART resulting from the provisions referred to above contradicted the rule (laid down by Article 6(1)(b)) that by contrast allowed couples to pursue "their objective of having a child that is unaffected by the specific hereditary disease of which they are carriers through the undeniably more traumatic method of voluntary termination (sometimes more than once) of natural pregnancies".

That prohibition was thus held to violate Article 32 of the Constitution as it did not allow a woman to acquire information "before", which would allow her to avoid making a decision "later" that is significantly more damaging to her health.

The damage thus caused to this right of the woman did not have any "positive counterweight, in terms of balancing, in a need to protect the offspring, which would be, in any case, vulnerable to abortion".

That decision therefore held that the contested legislation amounted to the outcome of an unreasonable balancing of the interests at stake.

As a result of this Judgment, *inter alia*, the prohibition on cryopreservation was *de facto* subject to a further exception since, according to the current state of scientific knowledge, the timescales and procedures for pre-implantation diagnoses are incompatible with the short space of time during which embryos can be implanted without having previously been cryopreserved.

9.2.– Thus, in the wake of this Court's decisions referred to above that sought to give proper importance to the woman's right to psychological and physical health, the relationship of rule and exception between the prohibition on cryopreservation originally imposed by Law No 40/2004 has *de facto* been reversed: cryopreservation has thus become the rule – and with it also "the possibility to create embryos that will not be born"

(Judgment No 84/2016) – whilst recourse to implantation without prior cryopreservation has become the exception.

Even though Article 14(3) still provides that the procedure must be "carried out as soon as possible", there can now be a temporal lag, which may even be significant, between consent to ART and implantation in the uterus. Whereas this was normally intended to occur within the brief period of the first few days following fertilisation, i.e. after the time when the couple's consent became irrevocable, it is now possible for a woman to request the implantation of cryopreserved embryos (having regard to her psychological and physical condition) not only significantly later than that point in time, but even where the subjective circumstances are very different from those that must necessarily have prevailed when the procedures concerned were accessed.

This consideration constitutes the basis for the delicate question that the referring court has placed before this Court.

It is delicate because, in allowing the embryo (or embryos) to be implanted even under circumstances in which, due to the passage of time, the couple's original project has been terminated, the rule that consent becomes irrevocable after the oocyte has been fertilised gives rise to what have been referred to as the "tragic choices" [made by the law] (under different circumstances: Judgments Nos 14/2023 and 118/1996; and in an analogous manner Judgment No 84/2016), in that not all of the conflicting interests at stake can be satisfied.

These are: to protect the woman's psychological and physical health and her self-determination in terms of the decision to become a mother; the man's self-determination in terms of the decision not to become a father; the dignity of the embryo; and the rights of a child born through ART.

This Court has therefore been called upon to assess whether – in providing that consent becomes irrevocable after fertilisation and hence forcing the man to become a father (in the event of successful ART) against his wishes at that later time, which may have changed during the intervening period due to changes to the couple's relationship – the contested provision still, within the systemic context resulting from the rulings within the Court's case law, strikes a balance that is not unreasonable having regard to the aspects raised by the referring court.

10.– The first question to be addressed concerns the violation of the principle of equality, which was raised with regard to the difference in treatment in the sense that the rule establishing the irrevocability of consent in actual fact only sacrifices the man's individual freedom, as the woman can always refuse to have the embryo implanted in her uterus.

The question is unfounded.

The premise to the referring court's interpretation is indeed correct: although the prohibition on the withdrawal of consent applies to "each of the persons" involved, it is beyond doubt that the provision could not be interpreted as allowing coerced implantation against the wishes of the woman.

The implantation of the embryo in the uterus entails genuine medical treatment of a highly invasive nature, which cannot under any circumstances be imposed on the woman, in accordance with the provisions on medical treatment laid down by Article 1(1) and (5) of Law No 219 of 22 December 2017 (Provisions on informed consent and advance healthcare directives), as well as by Article 5 of the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with

regard to the Application of Biology and Medicine, ratified and implemented by Law No 145 of 28 March 2001.

This Court has already held that the prohibition on the destruction of embryos "does not involve […] forced implantation in the woman's uterus" (Judgment No 229/2015).

The woman's circumstances are thus profoundly different from those of the man: as correctly noted by the State Counsel, after fertilisation only she is exposed "to medical action", which she may always "legitimately refuse to undergo", given the "obviously non-coercive status of treatment" on the one hand and the need to protect the woman's psychological and physical health on the other hand.

However, it is precisely this difference in their circumstances that precludes any violation of the principle of equality, as alleged: according to the settled case law of this Court, Article 3 of the Constitution is only violated "where substantially identical situations are governed differently without any justification, and not when situations that are not equivalent are governed differently" (amongst many, Judgments No 71/2021 and 85/2020; see also Judgments Nos 13/2018 and 71/2015), as in the case under examination.

11.– It is now necessary to consider the questions raised with reference to Articles 2 and 3 (with regard to another aspect) of the Constitution, which may be treated together as they concern in essence the unreasonable violation of the man's freedom of self-determination; this is because the irrevocable nature of the consent provided for under the contested Article 6(3), last sentence, forces him – purportedly – "to become a father against his wishes".

11.1.– Also these questions are unfounded since the balancing of the interests that are relevant under constitutional law, which is inherent within the contested provision, does not exceed the threshold of unreasonableness.

This Court is in fact fully aware of the impact that its case law has had on the original framework established by Law No 40/2004, and in particular the expansion mentioned above in the recourse to cryopreservation, with the attendant possibility for a time lag between fertilisation and implantation.

As a result of the contested provision, that time lag undoubtedly impinges upon the man's freedom of self-determination when, due to the passage of time, the emotional bonds on which the couple's project of becoming parents was originally based have broken down. Indeed, as a result of this, the woman's desire to have a child, i.e. to implant the cryo-embryo, interferes with the man's freedom not to have to suffer that decision.

11.2.– These findings cannot however be deemed to be sufficient to render unconstitutional the rule providing that consent becomes irrevocable once provided.

This is due to a variety of reasons.

11.3.– It should be clarified, first and foremost, that the man's self-determination manifests itself within a context in which he has been informed of the possibility of cryopreservation, as allowed under constitutional case law, and thus has consented also to this eventuality.

Article 6 of Law No 40/2004 specifically makes detailed provision concerning the requirement to furnish information before consent is provided, "in order to ensure that consent is informed and is expressed in an informed manner" (paragraph 1, last sentence), also as regards the "legal consequences" resulting from recourse to ART procedures (paragraph 1, first sentence).

That consent must be expressed "jointly in writing to the responsible doctor from the hospital, in accordance with the arrangements set out by decree of the Ministers of

Justice and Health, to be adopted pursuant to Article 17(3) of Law No 400 of 23 August 1988" (paragraph 3, first sentence).

Article 1(1) of Decree No 265 of the Ministry of Justice and of the Minister of Health of 28 December 2016 (Regulations laying down provisions on the expression of consent to access assisted reproductive technology, implementing Article 6(3) of Law No 40 of 19 February 2004) expressly states that the "minimum information necessary for the formation of informed consent" includes the "possibility of cryopreservation of embryos in accordance with the provisions of Article 14 of Law No 40/2004 and Constitutional Court Judgment No 151/2009" (letter (t)) – in addition, obviously, to the ability to withdraw consent only "until the moment of fertilisation" (letter (q)).

Therefore, the information that the doctor is obliged to provide must necessarily cover all consequences of the constraint resulting from the consent provided, and thus both the possibility of a time lag (which may also be significant) between fertilisation and implantation as well as the potential that implantation may occur when the initial preconditions for access to ART have ceased to apply.

11.4.– It must also be clarified that the consent provided pursuant to Article 6 of Law No 40/2004 has a different, and broader, scope than that attributable to the mere notion of "informed consent" to medical treatment as the situation involves an act the goal of which is to create a child.

Within this perspective, as consent constitutes an expression of intention to have a child, it entails a fundamental assumption of responsibility, which performs a key role in the acquisition of parental status.

It is in fact significant that Article 8 provides that "children born following the application of assisted reproductive technology shall have the status of children born into the marriage or of children recognised by the couple that has consented to recourse to the procedures provided for under Article 6", and that Article 9 lays down a twofold prohibition against, on the one hand, challenging paternity in the event of heterologous ART, thereby establishing an "intangible status according to law" (Order No 7/2012), and on the other hand anonymity for the mother.

These provisions highlight the fact that any consent to ART, which becomes irrevocable when the oocyte is fertilised, entails a specific assumption of responsibility in terms of the parent-child relationship, with the result that the child will acquire *status filiationis*, irrespective of any subsequent developments in the couple's relationship.

This implication has considerable significance, so much so that Article 6(5) expressly provides that "upon accessing assisted reproductive technology, the persons requesting it must be clearly informed of the legal consequences set out in Article 8 and Article 9 of this Law, and must sign a document to that effect".

Within the ambit of the specific provisions applicable to ART, the assumption of responsibility by way of consent (Judgment No 230/2020) thus has a core and decisive significance within the legal process that will result in the person becoming a parent, pursuing the aim of "protecting the child's legal status from any changes to a will that, in certain specific cases and under certain conditions set out in a closed list, is relevant for the purpose of its conception" (Judgment No 127/2020).

Ultimately, whilst it may indeed be the case that the provisions concerning the irrevocability of consent establish fertilisation as a point of no return, which may be coldly indifferent to the passage of time and any changes in the couple's relationship with each other, it must also be borne in mind that, owing to the central role of consent within the context of ART, which is in any case guaranteed by law, the man is under all

circumstances aware of the possibility that he might become a father. As such, it is difficult to identify any radical rupture of the link between freedom and responsibility within the scenario objected to by the referring court.

12.– It must be considered above all that the consent provided by the man to ART results in the engagement of other constitutionally significant interests, vested primarily in the woman, alongside those pertaining to the man himself.

12.1.– In accessing ART, the woman is directly involved through her own body in a manner that is incommensurably more significant than the man's involvement.

Specifically, with the aim of realising the joint project of becoming parents the woman is subject first and foremost to demanding cycles of ovarian stimulation, and it cannot be excluded that these may cause illness, including serious illness. It is significant that Ministerial Decree No 265/2016 provides that also "the established or potential risks for the mother and for the unborn child, as apparent within the scientific literature" (Article 1(1)(h)) must be expressly indicated in order to obtain informed consent.

In the event that treatment is successful, under what is certainly the more common scenario involving *in vitro* fertilisation (IVF), an oocyte is retrieved from the woman; this necessarily (and in contrast to the position for the man) involves particularly invasive medical treatment, so much so that it is generally carried out under general anaesthetic.

The oocyte is then fertilised within a very short space of time after its retrieval.

Further pharmacological treatment and analysis, as well as medical interventions, may however be necessary after the embryo has been fertilised (and cryopreserved), as occurred in the case before the referring court in which the claimant underwent specific treatment prior to implantation.

For the woman, access to ART thus entails the serious burden of allowing her body to be used for medical purposes. As such, she makes a major physical and emotional investment in becoming a parent, which entails risks, expectations and suffering, and which reaches a turning point at the time when one or more embryos are formed.

The woman's body and mind are thus inseparably involved in this process, which culminates in the tangible hope of having a child following the implantation of the embryo into her uterus.

By virtue of the expectation established for her by the man's consent to the joint project of becoming parents, the woman has committed to making this physical and emotional investment, which has resulted in the tangible expectation of becoming a mother.

The provision that such consent must be irrevocable thus appears to be necessary in order to safeguard the woman's psychological and physical integrity – since, as noted above, she is involved much more directly than the man – from any negative repercussions that may result for her from the suspension of the process after the point of fertilisation.

This engages the woman's 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" (amongst many, Judgment No 162/2014).

In keeping with the above, the above-mentioned guidelines laid down by the Ministerial Decree of 1 July 2015 provide that "the woman shall always have the right to obtain the implantation of any cryopreserved embryos".

Furthermore, the repercussions referred to above would be even more serious where the woman no longer had any opportunity to embark on ART treatment due to her age

(which has a much greater impact even only in terms of the ability to produce gametes than it does on man) or physical condition – including as a result of the time that has passed since the cryopreservation of the "contested" embryo – which at this stage would entail an absolute preclusion on her freedom of self-determination in relation to reproduction.

12.1.1.– Moreover, precisely the fact that it is the woman's body that is involved has led this Court to conclude that the "political and legislative choice" to leave her as the "sole person responsible to decide whether or not to terminate the pregnancy" is "non-negotiable", holding that the wishes of the embryo's father are not relevant and stating "that this choice cannot be considered to be irrational as it is consistent with the overall legislative architecture, and in particular the fact that the pregnancy impinges upon the physical and psychological health of the woman, if not exclusively then certainly predominantly" (Order No 389/1988).

Mutatis mutandis the findings contained in the above Judgment (because in situations involving *in vitro* fertilisation the woman's body only becomes involved in a similar manner to a natural pregnancy after implantation has occurred), it is nonetheless apparent from it that this Court has allowed the wishes of the man regarding the fate of the embryo to lose all legal significance after the oocyte has been fertilised, even though the respective decision taken by the woman may prevent him from becoming a father. It is important to stress the rationale for this ruling because, as noted above, the woman's body is in any case physically affected also during the procedure necessary for the production of embryos.

12.2.– The considerations pertaining to the dignity of the embryo are complementary to those set out above.

Ruling in line with supranational and ECtHR case law, this Court has clarified that the embryo "holds within itself the genesis of life" (Judgment No 84/2016).

Life must be taken to mean human life, since "that fertilisation is such as to commence the process of development of a human being" (Court of Justice of the European Union, Grand Chamber, judgment of 18 October 2011 in Case C-34/10, *Brüstle v. Greenpeace and V*).

The embryo is in fact generated in the hope that, once it has been transferred into the uterus, it will give rise to a pregnancy and result in birth, and hence "irrespective of their more or less broadly recognisable degree of subjectivity related to the origins of life, can certainly not be reduced to mere biological material" (Judgments Nos 84/2016 and 229/2015; for a similar ruling, see European Court of Human Rights, Grand Chamber, judgment of 27 August 2015 in *Parrillo v. Italy*, which held that: "human embryos cannot be reduced to 'possessions' within the meaning of that provision").

Its "dignity" is therefore "found in the general precept enshrined in Article 2 of the Constitution" and must therefore be protected even in cases involving excess embryos or diseased embryos (Judgment No 229/2015).

It is undoubtedly the case that the protection granted to the embryo is in any case not absolute and moreover "there is no equivalence between the right not only to life but also to [psychological and physical] health of a person who has already been born, such as the mother, and the need to safeguard the embryo, which has not yet become a person" (Judgment No 27/1975).

However, it must also be considered that, to date, constitutional case law has only limited the protection granted to the embryo insofar as "necessary in order to strike a

proper balance with protection for reproductive requirements" (Judgment No 151/2009) and in order to take account of the "woman's right to health" (Judgment No 96/2015).

12.3.– Accordingly, where consideration is given to the need to protect the mother's physical and psychological health, as well as the dignity of the cryopreserved embryo, which may be implanted in the mother's uterus, it is not unreasonable to constrain the man's freedom of self-determination as regards the prospect of becoming a father, with reference to Articles 2 and 3 of the Constitution.

Indeed, ART "aims to promote life" (Judgment No 162/2014) in seeking to support reproduction – that is the birth of a child – and not (only) fertilisation. Accordingly, it is not to be excluded that, even in the event that the couple has become estranged in the meantime, the respective legislation may give priority to the wishes of the woman, who as noted above is heavily involved in both a psychological and a physical sense, where she wishes to implant the embryo, even where a significant period of time has elapsed since cryopreservation.

12.4.– That conclusion is not on the other hand precluded by the consideration that a child born through ART has an undoubted interest in having a stable relationship with its father, which could be hindered by the parents' subsequent separation.

Whereas the ties between the parents may one day come to an end, the bond of filiation on the other hand is indissoluble and is in any case ensured by Articles 8 and 9, recalled above, of Law No 40/2004.

Besides, the fact that the child has a further interest in a family that is not ridden by conflict cannot be stressed so far as to conclude that this amounts to an existential condition that is so decisive as to prefer that the child not be born at all.

12.5.– Finally, the objection made with reference to Article 117(1) of the Constitution, in relation to Article 8 ECHR, regarding the right to respect for private life, which concerns not only decisions to have a child, but also decisions not to have one (amongst many, ECtHR, judgment of 16 January 2018 in *Nedescu v. Romania*) is unfounded.

In the case of *Evans v. United Kingdom*, the facts of which were very similar to those at issue in this case, subject however to the decisive difference that the withdrawal of consent by the man is expressly permitted (and hence cannot give rise to a legitimate expectation for the woman) under British law (as is also the case in other legal systems, such as in France and Austria) until the embryo is implanted, the European Court of Human Rights clarified first and foremost that recourse to *in vitro* fertilisation raises delicate ethical questions and impinges upon areas in which there is no consensus at European level.

It therefore noted the broad margin of appreciation that States must be granted in resolving a dilemma characterised by the fact that – as is stated in the judgment – whatever solution the national authorities might adopt would result in the interests of one or the other parties to the IVF treatment being wholly frustrated, and concluded that there was no reason to believe that the solution adopted by the UK Parliament exceeded the margin of appreciation afforded to it under Article 8 ECHR.

However, it did not conceal the fact that it had "great sympathy for the applicant, who clearly desires a genetically related child above all else" and in its conclusions pointed out that Parliament would have been able to resolve the matter differently (ECtHR, judgment in *Evans v. United Kingdom*).

It must therefore be concluded, in the light of the arguments set out above, that the rule laid down by Article 6(3), last sentence, of Law No 40/2004 that consent becomes

irrevocable after the embryo has been fertilised does not exceed the margin of appreciation afforded to Italy and cannot be deemed to violate Article 117(1) of the Constitution on the grounds that it breaches Article 8 ECHR.

13.– In conclusion, despite having been introduced within a context in which ART was to be completed within one single cycle, i.e. with one single and simultaneous implantation of a limited number of embryos and without in general any recourse to cryopreservation, the rule laid down by the contested provision that consent is irrevocable is still sufficiently consistent also with the new legislative context created by the rulings of this Court.

Moreover, in introducing the possibility of heterologous fertilisation, Judgment No 162/2014 of this Court limited itself to holding, without noting any critical aspects, that "with regard to the rules applicable to consent, […] the full regulations laid down by Article 6 of Law No 40/2004 – 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 ART".

Even though it is binding on the man only, it appears that the contested provision still strikes a balance that is not unreasonable.

This conclusion can be asserted, in summary, on the one hand by virtue of the guarantee of the provision by the man "of consent that is informed and expressed in an informed manner" (Article 6(1) of Law No 40/2004) as regards both the possibility of cryopreservation and the central significance of consent, which aims to reproduce within the context of artificial insemination the irreversible characteristics of the assumption of responsibility within the context of natural fertilisation (Articles 8 and 9 of the Law).

It can also be asserted, on the other hand, for two further reasons.

The first of these is that the irrevocable nature of consent establishes a legitimate expectation for the woman that leads her to undergo the ART procedure, putting her psychological and physical integrity at stake, as has also been stressed by the Supreme Court of Israel, albeit within the context of a different legal system, in a similar case, holding that: "[it] is difficult to assume that she would have agreed to undergo these treatments in the knowledge that her husband could change his mind at any time that he wished" (Supreme Court of Israel, judgment of 12 September 1996, *Nahmani v. Nahmani*, majority opinion, Justice Ts. E. Tal).

The second reason is that it enables the embryo to be implanted.

14.– However, this Court is not unaware of the complex nature of the issue and the consequences that the provision at stake in these proceedings will have in any case for the man, who will end up becoming the father of a child although the conditions under which he had shared the project of becoming a parent no longer obtain.

This is because the legal rule under examination crystallised the consent provided before the family unit fell apart even though, as a matter of fact (in contrast to natural reproduction), it is still possible to prevent embryo previously fertilised and cryopreserved from being implanted.

This Court is mindful of the fact that status as a parent entails a substantial change in a person's rights and obligations, which is liable to affect most practical and emotional aspects of their life.

It is also mindful of the fact that the panorama of comparative law features solutions within both legislation and case law that, in some cases, differ significantly from one another.

Amongst these, merely by way of example, it may be recalled that in the case cited above, the Supreme Court of Israel subjected the possibility of implantation to particular conditions pertaining to parental responsibility (that decision recently served as inspiration for the Constitutional Court of Columbia, in judgment T-357/22 of 13 October 2022 which, in a similar case, enabled the father to be treated in a similar manner to an anonymous donor).

It is clear that the awareness that such cases involve a complex choice, which impinges upon clearly antagonistic interests, has led legal systems to adopt different solutions that reflect the distinguishing features of the constitutional principles at stake within each of them.

15.– However, the fact remains that, under Italian law, the search for a reasonable balance between the various interests at stake, which may potentially differ from the current balance, within cases concerning "ethically sensitive issues" (Judgment No 162/2014) must inevitably fall "primarily to the evaluation of the legislator", "in light of the current views of the societal community" (Judgment No 221/2019), having due regard for human dignity. This is without prejudice to review by this Court of the choices made in order to establish that the balance struck by them is not unreasonable (Judgment No 162/2014).

ON THESE GROUNDS

THE CONSTITUTIONAL COURT

1) *declares* that the questions as to the constitutionality of Article 6(3), last sentence, of Law No 40 of 19 February 2004 (Provisions on assisted reproductive technology), raised with reference to Articles 13(1) and 32(2) of the Constitution by the Ordinary Court of Rome, sitting as a single-judge court, by the relevant referral order, are inadmissible;

2) *declares* that the questions as to the constitutionality of Article 6(3), last sentence, of Law No 40/2004, raised with reference to Articles 2, 3 and 117(1) of the Constitution, the last-mentioned provision in relation to Article 8 of the European Convention on Human Rights, by the Ordinary Court of Rome, sitting as a single-judge court, by the relevant referral order, are unfounded.

Decided in Rome at the seat of the Constitutional Court, Palazzo della Consulta, on 24 May 2023.

Signed:

Silvana SCIARRA, President

Luca ANTONINI, Judge Rapporteur