

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

GRAND CHAMBER

CASE OF PARRILLO v. ITALY

(Application no. 46470/11)

JUDGMENT

STRASBOURG

27 August 2015

This judgment is final.

In the case of Parrillo v. Italy,

The European Court of Human Rights, sitting as a Grand Chamber composed of:

Dean Spielmann, *President*,
Josep Casadevall,
Guido Raimondi,
Mark Villiger,
Isabelle Berro,
Ineta Ziemele,
George Nicolaou,
András Sajó,
Ann Power-Forde,
Nebojša Vučinić,
Ganna Yudkivska,
Vincent A. De Gaetano,
Julia Laffranque,
Paulo Pinto de Albuquerque,
Helen Keller,
Faris Vehabović,
Dmitry Dedov, *judges*,

and Johan Callewaert, *Deputy Grand Chamber Registrar*,

Having deliberated in private on 18 June 2014 and 22 April 2015,

Delivers the following judgment, which was adopted on the last-mentioned date:

PROCEDURE

1. The case originated in an application (no. 46470/11) against the Italian Republic lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by an Italian national, Ms Adelina Parrillo ("the applicant"), on 26 July 2011.

2. The applicant was represented by Mr N. Paoletti, Ms C. Sartori and Ms N. Paoletti, lawyers practising in Rome. The Italian Government ("the Government") were represented by their co-Agents, Ms P. Accardo and Mr G. Mauro Pellegrini.

3. The applicant alleged, in particular, that the ban (under section 13 of Law no. 40 of 19 February 2004) on donating to scientific research embryos conceived through medically assisted reproduction was incompatible with her right to respect for her private life and her right to the peaceful enjoyment of her possessions guaranteed under Article 8 of the Convention and Article 1 of Protocol No. 1. She also complained of a violation of

freedom of expression guaranteed under Article 10 of the Convention, of which scientific research was, in her submission, a fundamental aspect.

4. The application was allocated to the Second Section of the Court (Rule 52 § 1 of the Rules of Court).

5. On 28 May 2013 notice of the complaints under Article 8 of the Convention and Article 1 of Protocol No. 1 was given to the Government and the remainder of the application was declared inadmissible.

6. On 28 January 2014 a Chamber of the Second Section composed of Işıl Karakaş, President, Guido Raimondi, Peer Lorenzen, Dragoljub Popović, András Sajó, Nebojša Vučinić and Paulo Pinto de Albuquerque, judges, and Stanley Naismith, Section Registrar, relinquished jurisdiction in favour of the Grand Chamber, neither of the parties having objected to relinquishment (Article 30 of the Convention and Rule 72).

7. The composition of the Grand Chamber was determined in accordance with Article 26 §§ 4 and 5 of the Convention and Rule 24.

8. The applicant and the Government each filed observations on the admissibility and merits of the application.

9. The European Center for Law and Justice, the associations Movimento per la vita, Scienza e vita, Forum delle associazioni familiari, Luca Coscioni, Amica Cicogna Onlus, L'Altra Cicogna Onlus, Cerco Un Bimbo, VOX – Osservatorio italiano sui Diritti, SIFES (Society of Fertility, Sterility and Reproductive Medicine) and Cittadinanzattiva and forty-six members of the Italian Parliament were given leave to intervene in the written procedure (Article 36 § 2 of the Convention and Rule 44 § 3).

10. A hearing took place in public in the Human Rights Building, Strasbourg, on 18 June 2014 (Rule 59 § 3).

There appeared before the Court:

(a) *for the Government*

Ms P. ACCARDO,
Mr G. MAURO PELLEGRINI, *Co-Agents*,
Ms A. MORRESI, member of the National Bioethics Committee and professor of physical chemistry at the Department of Chemistry, Biology and Biotechnology, Perugia University,
Ms D. FEHILY, inspector and technical adviser at the National Transplantation Centre, Rome *Advisers*;

(b) *for the applicant*

Mr N. PAOLETTI,
Ms C. SARTORI,
Ms N. PAOLETTI, *Counsel*;

Mr M. DE LUCA, professor of biochemistry and Director
of the Centre for Regenerative Medicine
"Stefano Ferrari", University of Modena
and Reggio Emilia *Adviser*.

The Court heard addresses by Ms Accardo, Ms Morresi, Mr Paoletti, Mr De Luca and Ms Sartori, and answers to questions by judges from Ms Accardo, Mr Mauro Pellegrini, Mr De Luca, Ms Paoletti and Mr Paoletti.

THE FACTS

I. THE CIRCUMSTANCES OF THE CASE

11. The applicant was born in 1954 and lives in Rome.

12. In 2002 she had recourse to assisted reproduction techniques, undergoing *in vitro* fertilisation (IVF) treatment with her partner at the Centre for reproductive medicine at the European Hospital ("the centre") in Rome. The five embryos obtained from the IVF treatment were placed in cryopreservation.

13. Before the embryos could be implanted the applicant's partner died, on 12 November 2003, in a bomb attack in Nasiriya (Iraq) while he was reporting on the war.

14. After deciding not to have the embryos implanted, the applicant sought to donate them to scientific research and thus contribute to promoting advances in treatment for diseases that are difficult to cure.

15. According to the information provided at the hearing before the Grand Chamber, the applicant made a number of unsuccessful verbal requests for release of the embryos at the centre where they were being stored.

16. In a letter of 14 December 2011, the applicant asked the Director of the centre to release the five cryopreserved embryos so that they could be used for stem-cell research. The Director refused to comply with her request on the ground that this type of research was banned and punishable as a criminal offence in Italy under section 13 of Law no. 40 of 19 February 2004 ("Law no. 40/2004").

17. The embryos in question are currently stored in the cryogenic storage bank at the centre where the IVF treatment was carried out.

II. RELEVANT DOMESTIC LAW AND PRACTICE

A. Law no. 40 of 19 February 2004, in force since 10 March 2004 ("Rules governing medically assisted fertilisation")

Section 1 – Purpose

"(1) In order to remedy reproductive problems arising as a result of human sterility or infertility, recourse may be had to medically assisted reproduction in the conditions and in accordance with the procedures provided for by this Law, which guarantees the rights of all the persons concerned, including those of the subject thus conceived."

Section 5 – Conditions of access

"... [only] couples [composed of persons] who have reached the age of majority, are of opposite sex, are married or cohabiting, are of reproductive age and living may have recourse to assisted reproduction techniques."

Section 13 – Experiments on human embryos

"(1) It is forbidden to experiment on a human embryo.

(2) Clinical and experimental research on a human embryo shall be authorised only on condition that it is performed exclusively for therapeutic or diagnostic purposes with the aim of protecting the health and development of the embryo and that no alternative methods exist.

...

(4) Anyone who infringes the prohibition provided for in subsection 1 shall be liable to a term of imprisonment ranging from two to six years and to a fine of 50,000 to 150,000 euros. ...

(5) Any health professional convicted of an offence provided for in this section shall be debarred from practising medicine for one to three years."

Section 14 – Limits on application of technology to embryos

"(1) The cryopreservation or destruction of embryos is forbidden, without prejudice to the provisions of Law no. 194 of 22 May 1978 [rules on social protection of maternity and voluntary termination of pregnancy].

(2) Embryo production techniques shall not result in the creation of a higher number of embryos than that strictly required for a single and simultaneous implantation and in no circumstances shall more than three embryos be created.

(3) Where the embryos cannot be implanted into the uterus for reasons of serious and proven *force majeure* affecting the state of health of the woman concerned which were unforeseeable at the time of fertilisation, cryopreservation of the embryos shall be authorised until the date of transfer, which shall be effected as soon as possible."

18. By judgment no. 151 of 1 April 2009 (see paragraphs 29-31 below), the Constitutional Court declared unconstitutional the provision in section 14(2) of Law no. 40/2004 according to which embryo production techniques must not result in the creation of a higher number of embryos than that strictly required for "a single and simultaneous implantation and in

no circumstances shall more than three embryos be created". It also declared section 14(3) unconstitutional on the ground that it did not provide that the transfer of the embryos should be performed without jeopardising the woman's health.

B. Opinion of the National Bioethics Committee on adoption for birth ("ADP") (18 November 2005)

19. Following the enactment of Law no. 40/2004, the National Bioethics Committee examined the issue of the fate of abandoned cryopreserved embryos, the Law making no specific provision in this regard but implicitly banning the use of surplus embryos for scientific research.

20. In that connection the Committee issued an opinion in favour of "adoption for birth", a practice enabling a couple or a woman to adopt surplus embryos for implantation and thus allowing the embryos in question to be used for the purposes of bringing them to life and starting a family.

C. Ministry of Health decree of 11 April 2008 ("Explanatory notes on assisted reproduction")

> "... Cryopreservation of embryos: ... There are two categories of embryos amenable to cryopreservation: the first is embryos that are awaiting implantation, including those that were cryopreserved prior to the entry into force of Law no. 40 of 2004; the second is embryos that have been certified as abandoned ..."

D. Final report of the "Study Commission on embryos" of 8 January 2010

21. By a decree of 25 June 2009, the Ministry of Health appointed a Study Commission on embryos stored in cryopreserved form in assisted reproduction centres. The following is a passage from the final report by that Commission, adopted by a majority on 8 January 2010.

> "The legal ban on the destruction of embryos is to be understood as prohibiting the interruption of cryopreservation other than in two cases: where the thawed embryo can be implanted in the uterus of the mother or another woman willing to have it implanted; or where natural death or permanent loss of viability as an organism can be medically certified. In the light of current [scientific] knowledge, the viability of an embryo cannot be certified unless it has been thawed, thus creating the paradoxical situation in which, once thawed, an embryo cannot be frozen a second time and if it is not immediately implanted into the uterus death will inevitably ensue. Hence, a tutiorist prospect of frozen embryos being stored for an indeterminate period. However, it can be assumed that advances in scientific research will make it possible to determine the criteria and methods for diagnosing death, or in any event loss of viability, of cryopreserved embryos. It will thus be possible to overcome the present – and legally inevitable – paradox of potentially indefinite cryopreservation. Pending those results, [it should be reaffirmed that] the explicit ban under section 14 of

Law no. 40 of 2004 on the destruction of embryos, including therefore frozen embryos, cannot be ignored. That is not all, for as regards the fate of surplus embryos, the authors of Law no. 40 opted for their storage and not their destruction, thus establishing as a principle that they should be kept alive even where their fate is uncertain."

E. The Constitution of the Italian Republic

22. The relevant Articles of the Constitution provide as follows.

Article 9

"The Republic promotes the development of culture and of scientific and technical research. ..."

Article 32

"The Republic safeguards health as a fundamental right of the individual and as a collective interest. ..."

Article 117

"Legislative power is exercised by the State and the Regions in compliance with the Constitution and the constraints deriving from the Community legal order and international obligations. ..."

F. Constitutional Court judgments nos. 348 and 349 of 24 October 2007

23. These judgments address questions raised by the Court of Cassation and an appellate court regarding the compatibility of Legislative Decree no. 333 of 11 July 1992 on the criteria for calculating expropriation compensation with the Constitution and with Article 6 § 1 of the Convention and Article 1 of Protocol No. 1. They take account of the Court's Grand Chamber judgment in *Scordino v. Italy (no. 1)* [GC], no. 36813/97, ECHR 2006-V.

24. In these judgments, after reiterating the legislature's obligation to comply with international obligations (Article 117 of the Constitution), the Constitutional Court defined the place assigned to the European Convention on Human Rights in the Italian legal system, stating that it was of intermediate rank between an ordinary law and the Constitution. The Constitutional Court also stated that the courts below had to interpret rules of domestic law in a manner compliant with the Convention and the Court's case-law (judgment no. 349, point 6.2, see paragraph 26 below) and that, where such an interpretation was impossible or the courts below doubted the compatibility of the domestic law with the Convention, they had to raise a question of constitutionality before the Constitutional Court.

25. The relevant passages of judgment no. 348 of 24 October 2007 read as follows.

"4.2. ... It is necessary to define the rank and role of the provisions of the European Convention on Human Rights with a view to determining, in the light of [Article 117 of the Constitution], their impact on the Italian legal order. ...

4.3. While on the one hand [these provisions] complement the protection of fundamental rights, and therefore supplement the values and fundamental principles protected by the Italian Constitution itself, on the other hand they maintain their formal status as simple sources of ordinary legislation. ...

Today the Constitutional Court is called upon to clarify the normative and institutional question [referred to above], which has significant practical implications for the everyday work of legal practitioners. ...

The ordinary courts do not have the power to set aside ordinary legislation conflicting with the European Convention on Human Rights, since the alleged incompatibility between the two raises a question of constitutionality regarding a possible violation of Article 117 § 1 of the Constitution and [thus] falls within the exclusive jurisdiction of the Constitutional Court. ...

4.5. ... The principle enshrined in Article 117 § 1 of the Constitution will only become operative in practice if 'the international law obligations' binding on the legislative powers of the State and the Regions are duly specified. ...

4.6. Compared with other international law treaties, the European Convention on Human Rights has the particular feature of having instituted the jurisdiction of a court, the European Court of Human Rights, which is assigned the role of interpreting the provisions of the Convention. Article 32 § 1 [of the Convention] provides: 'The jurisdiction of the Court shall extend to all matters concerning the interpretation and application of the Convention and the Protocols thereto which are referred to it as provided in Articles 33, 34, 46 and 47.'

Since legal provisions acquire meaning [*vivono*] through the interpretation which is given to them by legal practitioners, and in the first place the courts, the natural consequence of Article 32 § 1 of the Convention is that the international law obligations undertaken by Italy in signing and ratifying the European Convention on Human Rights include the duty to bring its own legislation into line with the provisions of the Convention in accordance with the meaning attributed to these by the [European] Court [of Human Rights], which was specifically set up to interpret and apply those provisions. It is therefore not correct to speak of a jurisdictional competence that operates in addition to that of the Italian courts, but rather of a pre-eminent interpretative role which the signatory States have recognised in the European Court, thus contributing to clarifying their international law obligations in that particular area.

4.7. It should not be inferred from the foregoing that the provisions of the European Convention on Human Rights, as interpreted by the Strasbourg Court, have the force of constitutional law and thus escape scrutiny by this court of their constitutional legitimacy. It is precisely because the provisions in question supplement constitutional principles, while remaining of lower rank, that it is necessary that they be in conformity with the Constitution. ...

Since, as stated above, the provisions of the European Convention on Human Rights acquire meaning through the interpretation given to them by the European Court, scrutiny of their constitutionality must give consideration to the norms that result from

that interpretation, and not the provisions considered in themselves. Moreover, the judgments of the Strasbourg Court are not unconditionally binding for the purposes of reviewing the constitutionality of national laws. This review must always be a balancing exercise between the constraints arising from international law obligations, as imposed by Article 117 § 1 of the Constitution, and the constitutionally protected interests enshrined in other Articles of the Constitution. ...

5. In the light of the methodological principles set out above, the constitutional review requested by the referring court must be carried out in such a way as to ascertain: (a) whether there is actually a conflict that cannot be resolved through interpretation between the domestic provision in question and the provisions of the European Convention on Human Rights, as interpreted by the European Court and regarded as a source supplementing the constitutional principle contained in Article 117 § 1, and (b) whether the provisions of the European Convention on Human Rights integrating that principle, and understood according to their interpretation by the [European] Court, are compatible with the Italian constitutional order. ..."

26. The relevant parts of judgment no. 349 of 24 October 2007 read as follows.

"6.2. ... [The principle laid down] in Article 117 § 1 of the Constitution [does not mean] that the provisions laid down in international agreements and implemented by ordinary legislation, as is the case for the provisions of the European Convention on Human Rights, must be regarded as having constitutional status. As the constitutional principle in issue imposes a duty on the legislature to comply with those provisions, any national provision incompatible with the European Convention on Human Rights and thus with the 'international law obligations' referred to in Article 117 § 1 would *ipso facto* violate this constitutional principle. Article 117 § 1 ultimately creates a reference to Convention provisions which may be relevant in a particular case, giving life [*dà vita*] and substantive content to the international law obligations evoked generally and to the [underlying constitutional] principle, such as to be generally classified as 'interposed provisions', and which in turn are reviewed in terms of their compatibility with the Constitution, as will be discussed below.

It follows that it is a matter for the ordinary courts to interpret national law in conformity with the international legal provision in question ... Where this is not possible, or where the court doubts the compatibility of the national law with the 'interposed' Convention provision, it must raise a question of constitutionality before the Constitutional Court in the light of Article 117 § 1 of the Constitution ...

Regarding the European Convention on Human Rights, consideration must be given to its special nature compared with other international agreements since it goes further than simply listing reciprocal rights and duties of the signatory States. The latter have created a system for the uniform protection of fundamental rights. The application and interpretation of that system is naturally in the first instance a matter for the courts of the member States, which are the ordinary courts in relation to Convention law. Definitive uniformity in application is on the other hand guaranteed by the centralised interpretation of the European Convention on Human Rights – a task assigned to the European Court of Human Rights in Strasbourg, which has the last word and the jurisdiction of which 'shall extend to all matters concerning the interpretation and application of the Convention and the Protocols thereto which are referred to it as provided [therein]' (Article 32 § 1 of the Convention). ...

The Constitutional Court and the Strasbourg Court ultimately have different roles, even though both share the same objective of protecting as effectively as possible fundamental rights. The interpretation of the Rome Convention and of the Protocols is a matter for the Strasbourg Court, which guarantees the application of a uniform level of protection throughout the member States.

However, where a question is raised before the Constitutional Court regarding the constitutionality of a national provision in the light of Article 117 § 1 of the Constitution in respect of an incompatibility – insurmountable through interpretation – with one or more provisions of the European Convention on Human Rights, it is incumbent on this Court to determine whether there actually is an incompatibility and [where one is found to exist] to verify whether the actual provisions of the European Convention on Human Rights, as interpreted by the Strasbourg Court, guarantee a protection of fundamental rights that is at least equivalent to the level guaranteed by the Italian Constitution.

This does not require an assessment of the interpretation by the Strasbourg Court of a provision of the European Convention on Human Rights ... but verification as to whether that provision, as interpreted by the court expressly charged with that task by the member States, is compatible with the relevant constitutional provisions. Accordingly, a correct balance will be struck between the duty imposed by the Constitution to guarantee respect for international obligations and the need to prevent this resulting in a breach of the Constitution itself."

G. The case-law of the Constitutional Court

1. Constitutional Court Order no. 369 of 24 October 2006

27. In this Order the Constitutional Court declared inadmissible a question of constitutionality raised by the Cagliari Court in respect of section 13 of Law no. 40/2004, which bans the use of pre-implantation diagnosis.

28. In ruling thus the Constitutional Court observed that the court referring the question for a preliminary ruling had confined itself to raising the question of the constitutionality of section 13 alone of Law no. 40/2004 whereas, according to the terms of the application for a preliminary ruling, other provisions of the same Law also had the effect of banning pre-implantation diagnosis, particularly section 14(3).

2. Constitutional Court judgment no. 151 of 1 April 2009

29. This judgment concerns the constitutionality of the provisions of section 14(2) and section 14(3) of Law no. 40/2004, which provide for the creation of a limited number of embryos (maximum of three) and the obligation to implant them simultaneously and also prohibit the cryopreservation of surplus embryos.

30. The Constitutional Court held that the subsections in question were unconstitutional because they jeopardised women's health by obliging them to undergo several cycles of ovarian stimulation and also to expose

themselves to the risk of multiple pregnancies on account of the prohibition on selective abortion.

31. The judgment does not make any reference to the European Convention on Human Rights. Nor was the Convention cited by the referring courts (Lazio Regional Administrative Court and Florence Court).

3. Constitutional Court Order no. 97 of 8 March 2010

32. In this Order the Constitutional Court declared inadmissible the questions of constitutionality that the Milan Court had raised before it, as those questions had already been dealt with in its judgment no. 151/2009.

4. Constitutional Court Order no. 150 of 22 May 2012

33. In this Order, which referred to *S.H. and Others v. Austria* ([GC], no. 57813/00, ECHR 2011), the Constitutional Court remitted to the lower court the case brought before it concerning the ban on heterologous fertilisation laid down in Law no. 40/2004.

5. Constitutional Court judgment no. 162 of 10 June 2014

34. This judgment concerns the constitutionality of the blanket ban on access to heterologous fertilisation in the event of medically established sterility or infertility, as provided for in Law no. 40/2004.

35. Three courts of ordinary jurisdiction had sought a preliminary ruling from the Constitutional Court regarding the question whether the Law in issue was compatible with Articles 2 (inviolable rights), 3 (principle of equality), 29 (rights of the family), 31 (State's obligations to protect rights of the family) and 32 (right to health) of the Constitution. One of those courts – the Milan Court – had also asked the Constitutional Court to rule on the compatibility of the Law in issue with Articles 8 and 14 of the Convention.

36. The Constitutional Court ruled the relevant legislative provisions unconstitutional.

37. It held in particular that the choice of the applicants in the proceedings to become parents and found a family with children was an aspect of their freedom of self-determination regarding the sphere of their private and family life which attracted the protection of Articles 2, 3 and 31 of the Constitution. It also observed that persons who were totally sterile or infertile had a right to protection of their health (Article 32 of the Constitution).

38. It found that, while the rights in question could be the subject of restrictions based on ethical considerations, those restrictions could not amount to a blanket ban unless it were otherwise impossible to protect other constitutionally guaranteed freedoms.

39. With regard to the compatibility of the legislative provisions in issue with Articles 8 and 14 of the Convention, the Constitutional Court confined itself to observing that the questions in that regard had been covered in the conclusions it had reached on the constitutionality of the provisions in issue (see above).

H. Orders of the domestic courts regarding access to pre-implantation diagnosis

1. Cagliari Court Order of 22 September 2007

40. In this Order the Cagliari Court observed that the claimants had first instituted urgent proceedings in the context of which a question of constitutionality had been raised. It added that this question had then been declared inadmissible by Order no. 369 of the Constitutional Court adopted on 24 October 2006 (see paragraphs 27-28 above), which had therefore not provided any guidance regarding the interpretation to be given to domestic law in the light of the Constitution.

41. With regard to the civil proceedings brought before it, the court pointed out that there was no explicit ban under domestic law on access to pre-implantation diagnosis, and that interpreting the Law in such a way as to construe that a ban existed would have been contrary to the claimants' right to be duly informed of the medical treatment that they sought to undergo.

42. Furthermore, it noted that a ban on pre-implantation diagnosis had been introduced subsequently by secondary legislation, namely, Ministry of Health Decree no. 15165 of 21 July 2004 (particularly the part providing that "tests to determine the state of health of embryos created *in vitro*, within the meaning of section 14(5) [of Law no. 40 of 2004], cannot be carried out for purposes other than observation of those embryos ("*dovrà essere di tipo osservazionale*"). It held that this was contrary to the principle of legality and the Council of Europe's Oviedo Convention.

43. It observed, lastly, that interpreting Law no. 40/2004 so as to allow access to pre-implantation diagnosis was consonant with the right to health accorded to the mother. Consequently, it granted the claimants access to pre-implantation diagnosis.

2. Florence Court Order of 17 December 2007

44. In this Order the Florence Court referred to the Order of the Cagliari Court cited above and stated that it agreed with its interpretation of the domestic law. Accordingly, it granted the claimants access to pre-implantation diagnosis.

3. Bologna Court Order of 29 June 2009

45. In this Order the Bologna Court granted the claimants access to pre-implantation diagnosis, stating that this was consonant with the protection of women's health recognised by the Constitutional Court's interpretation of domestic law in its judgment no. 151 of 1 April 2009 (see paragraphs 29-31 above).

4. Salerno Court Order of 9 January 2010

46. In this Order, adopted following urgent proceedings, the Salerno Court referred to the new developments introduced by Ministry of Health Decree no. 31639 of 11 April 2008, namely the fact that tests to determine the state of health of embryos created *in vitro* were no longer limited to observation of those embryos and that access to assisted reproduction was authorised for couples where the man was a carrier of sexually transmitted viral diseases.

47. It concluded that pre-implantation diagnosis had to be regarded as just one of the antenatal treatment techniques designed to determine the state of health of the embryo.

48. Consequently, it authorised pre-implantation diagnosis of the claimants' embryo *in vitro*.

5. Cagliari Court Order of 9 November 2012

49. In this Order the Cagliari Court referred to the reasoning in the above-cited Orders. It indicated, further, that judgments nos. 348 and 349 delivered by the Constitutional Court on 24 October 2007 showed that interpreting the law with a view to guaranteeing access to pre-implantation diagnosis was compatible with the European Convention on Human Rights, especially having regard to the judgment delivered by the Strasbourg Court in *Costa and Pavan v. Italy* (no. 54270/10, 28 August 2012).

6. Rome Court Order of 15 January 2014

50. In this Order the court raised the question of the constitutionality of sections 1(1) and (2) and 4(1) of Law no. 40/2004, which prohibit couples who are neither sterile nor infertile from using assisted reproduction techniques with a view to obtaining a pre-implantation diagnosis. The court also considered the matter from the standpoint of Articles 8 and 14 of the Convention.

51. While having regard to the judgment in *Costa and Pavan* (cited above), it found that the Law should not be interpreted extensively, since it did expressly provide that access to assisted reproduction techniques was reserved to sterile or infertile couples.

I. Question of the constitutionality of section 13 of Law no. 40/2004 raised by the Florence Court

52. In a decision of 7 December 2012, the Florence Court raised the question of the constitutionality of the ban under section 13 of Law no. 40/2004 on donating surplus embryos to scientific research with regard to Articles 9 and 32 of the Constitution, which guarantee freedom of scientific research and the right to health respectively.

53. On 19 March 2014 the President of the Constitutional Court adjourned its examination of the case pending the decision of the Grand Chamber in the present application, *Parrillo v. Italy* (no. 46470/11).

III. COUNCIL OF EUROPE DOCUMENTS

A. Recommendation 1046 (1986) of the Parliamentary Assembly of the Council of Europe on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes

"...

6. Aware that the progress [of medical science and technology] has made the legal position of the embryo and foetus particularly precarious, and that their legal status is at present not defined by law;

7. Aware that adequate provisions governing the use of living or dead embryos and foetuses do not at present exist;

8. Convinced that, in view of scientific progress which makes it possible to intervene in developing human life from the moment of fertilisation, it is urgent to define the extent of its legal protection;

9. Having regard to the variety of ethical opinions on the question of using the embryo or the foetus or their tissues, and to the conflicts between values which arise;

10. Considering that human embryos and foetuses must be treated in all circumstances with the respect due to human dignity, and that use of materials and tissues therefrom must be strictly limited and regulated ... to purposes which are clearly therapeutic and for which no other means exist;

...

13. Stressing the need for European co-operation,

14. [The Parliamentary Assembly r]ecommends that the Committee of Ministers:

a. call on the governments of the member states:

...

14.1.2. to limit the use of human embryos and foetuses and materials and tissues therefrom in an industrial context to purposes which are strictly therapeutic and for which no other means exist, according to the principles set out in the appendix, and to bring their legislation into line with these principles or to enact rules in accordance

therewith which should inter alia specify the conditions in which removal and use may be undertaken for a diagnostic or therapeutic purpose;

14.1.3. to forbid any creation of human embryos by fertilisation in vitro for the purposes of research during their life or after death;

14.1.4. to forbid anything that could be considered as undesirable use or deviations of these techniques, including:

...

research on viable human embryos;

experimentation on living human embryos, whether viable or not;

...”

B. Recommendation 1100 (1989) of the Parliamentary Assembly of the Council of Europe on the use of human embryos and foetuses in scientific research

“...

7. Considering that the human embryo, though displaying successive phases in its development ... displays also a progressive differentiation as an organism and none the less maintains a continuous biological and genetic identity;

8. Recalling the need for European co-operation and for the widest possible regulation in order to overcome the contradictions, risks and foreseeable shortcomings of exclusively national standards in these fields,

...”

54. The relevant passages of the Appendix to that Recommendation read as follows.

“B. On live pre-implantation embryos:

4. In accordance with Recommendations 934 (1982) and 1046 (1986), investigations of viable embryos in vitro shall only be permitted:

for applied purposes of a diagnostic nature or for preventive or therapeutic purposes;

if their non-pathological genetic heritage is not interfered with.

5. ... research on living embryos must be prohibited, particularly:

if the embryo is viable;

if it is possible to use an animal model;

if not foreseen within the framework of projects duly presented to and authorised by the appropriate public health or scientific authority or, by delegation, to and by the relevant national multidisciplinary committee;

if not within the time-limits laid down by the authorities mentioned above.

...

H. Donation of human embryological material

20. The donation of human embryological material shall be authorised solely for scientific research on diagnostic, prevention or therapeutic purposes. Its sale shall be prohibited.

21. The intentional creation and/or keeping alive of embryos or foetuses whether in vitro or in utero for any scientific research purpose, for instance to obtain genetic material, cells, tissues or organs therefrom, shall be prohibited.

22. The donation and use of human embryological material shall be conditional on the freely given written consent of the donor parents.

23. The donation of organs shall be devoid of any commercial aspect. The purchase or sale of embryos or foetuses or parts thereof by their donor parents or other parties, and their importation or exportation, shall also be prohibited.

24. The donation and use of human embryological material for the manufacture of dangerous and exterminatory biological weapons shall be forbidden.

25. For the whole of this recommendation, 'viable' embryos shall be understood to mean embryos which are free of biological characteristics likely to prevent their development; however, the non-viability of human embryos and foetuses shall be determined solely by objective biological criteria based on the embryo's intrinsic defects."

C. 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: Convention on Human Rights and Biomedicine (Oviedo Convention) of 4 April 1997

Article 2 – Primacy of the human being

"The interests and welfare of the human being shall prevail over the sole interest of society or science."

Article 18 – Research on embryos *in vitro*

"1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.

2. The creation of human embryos for research purposes is prohibited."

Article 27 – Wider protection

"None of the provisions of this Convention shall be interpreted as limiting or otherwise affecting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine than is stipulated in this Convention."

D. Additional Protocol to the Convention on Human Rights and Biomedicine concerning Biomedical Research, of 25 January 2005

Article 2 – Scope

"1. This Protocol covers the full range of research activities in the health field involving interventions on human beings.

2. This Protocol does not apply to research on embryos *in vitro*. It does apply to research on foetuses and embryos *in vivo*.

..."

E. Report by the Working Party on the Protection of the Human Embryo and Fetus of the Steering Committee on Bioethics, published on 19 June 2003 – Conclusion

"This report aimed at giving an overview of current positions found in Europe regarding the protection of the human embryo *in vitro* and the arguments supporting them.

It shows a broad consensus on the need for the protection of the embryo *in vitro*. However, the definition of the status of the embryo remains an area where fundamental differences are encountered, based on strong arguments. These differences largely form the basis of most divergences around the other issues related to the protection of the embryo *in vitro*.

Nevertheless, even if agreement cannot be reached on the status of the embryo, the possibility of re-examining certain issues in the light of the latest developments in the biomedical field and related potential therapeutic advances could be considered. In this context, while acknowledging and respecting the fundamental choices made by the different countries, it seems possible and desirable with regard to the need to protect the embryo *in vitro* on which all countries have agreed that common approaches be identified to ensure proper conditions for the application of procedures involving the creation and use of embryos *in vitro*. The purpose of this report is to aid reflection towards that objective."

F. Resolution 1352 (2003) of the Parliamentary Assembly of the Council of Europe on human stem cell research

"...

3. Human stem cells may be derived from a growing number of tissues and fluids from humans of any age and are not limited to embryonic sources.

...

5. The harvesting of embryonic stem cells for the time being necessitates the destruction of human embryos.

...

7. The Assembly points out that a number of embryonic human stem cell lines suitable for scientific research are already available worldwide.

...

10. The destruction of human beings for research purposes is against the right to life of all humans and against the moral ban on any instrumentalisation of humans.

11. Therefore the Assembly calls on member states:

11.1. to promote stem cell research as long as it respects the life of human beings in all states of their development;

11.2. to encourage scientific techniques that are not socially and ethically divisive in order to advance the use of cell pluripotency and develop new methods in regenerative medicine;

11.3. to sign and ratify the Oviedo Convention to make effective the prohibition of the production of human embryos for research;

11.4. to promote common European basic research programmes in the field of adult stem cells;

11.5. to ensure that, in countries where it is allowed, any research on stem cells involving the destruction of human embryos is duly authorised and monitored by the appropriate national bodies;

11.6. to respect the decision of countries not to take part in international research programmes which are against ethical values enshrined in national legislation and not to expect such countries to contribute either directly or indirectly to such research;

11.7. to give priority to the ethical aspects of research over those of a purely utilitarian and financial nature;

11.8. to promote the establishment of bodies where scientists and representatives from civil society can discuss different kinds of projects on human stem cell research with a view to strengthening transparency and democratic accountability."

G. Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin, adopted by the Committee of Ministers on 15 March 2006

55. This Recommendation, which does not apply to embryonic and foetal tissues (see Article 2, paragraph 3), aims to protect the fundamental rights of persons whose biological material might be used for a research project after having been removed and stored (i) for a specific research project prior to adoption of the Recommendation; (ii) for future unspecified research; or (iii) as residual material originally removed for clinical or forensic purposes. This Recommendation seeks, *inter alia*, to promote the establishment of practice guidelines on the part of the member States and to reduce to a minimum the risks related to research activities for the private life of the persons concerned. It also lays down rules about obtaining and collecting biological materials.

H. Resolution 1934 (2013) of the Parliamentary Assembly of the Council of Europe on ethics in science and technology

"...

2. ... [T]he Assembly holds that more concerted ethical consideration should be given – at national, supraregional and global levels – to the goals and purposes pursued by science and technology, to the instruments and methods they employ, to their possible consequences and side effects, and to the overall system of rules and behaviour within which they operate.

3. The Assembly believes that having a permanent structure for ethical reflection at the global level would make it possible to address ethical issues as a 'moving target', rather than fixing an 'ethical code', and enable a periodic re-questioning of even basic assumptions, such as the definition of 'human identity' or 'human dignity'.

4. The Assembly welcomes the initiative of UNESCO in setting up the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST) with a view to engaging in ongoing ethical reflection and exploring the possibilities of drafting and periodically reviewing a set of fundamental ethical principles based on the Universal Declaration of Human Rights. It believes that the Council of Europe should contribute to this process.

5. In this respect, the Assembly recommends that the Secretary General of the Council of Europe consider establishing a flexible and informal structure for ethical reflection, through co-operation between relevant Assembly committees and members of relevant expert committees, including the Committee on Bioethics (DH-BIO), with a view to identifying emerging ethical issues and main ethical principles that could guide political and legal action in Europe.

6. To reinforce the common European framework of ethics in science and technology, the Assembly recommends that member States, which have not yet done so, sign and ratify the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164, 'Oviedo Convention') and its protocols and fully engage in the work of the Committee on Bioethics.

...

10. The Assembly invites the European Union and UNESCO to co-operate with the Council of Europe to reinforce the common European framework of ethics in science and technology and, to this end:

10.1 create European and regional platforms to regularly exchange experiences and best practice covering all fields of science and technology, using the experience acquired in the framework of the European Conference of National Ethics Committees (COMETH) initiated by the Council of Europe, and more recently the Forum of National Ethics Councils (NEC Forum) funded by the European Commission, and the meetings of the Council of Europe Committee on Bioethics;

10.2 draft and periodically review a set of fundamental ethical principles to be applied to all fields of science and technology;

10.3 provide further guidance to help member States harmonise ethical rules and monitoring procedures, building on the positive impact of ethical requirements under the European Commission's Seventh Framework Programme for Research and Technological Development (2007-2013) (FP7)."

IV. RELEVANT EUROPEAN UNION LAW AND MATERIALS

A. European Group on Ethics in Science and New Technologies (EGE) to the European Commission

56. Set up by the European Commission in 1991, the EGE is an independent body composed of experts whose task is to advise the European

Commission on ethical questions relating to science and new technologies. The EGE has provided two opinions on the use of embryos *in vitro* for research purposes.

1. Opinion no. 12: Ethical aspects of research involving the use of human embryo in the context of the 5th Framework Programme, 23 November 1998

57. This opinion was published at the request of the European Commission following the proposal of the European Parliament to exclude research projects that resulted in the destruction of human embryos from Community funding in the context of the 5th Framework Programme. The relevant passages read as follows.

> "2.6 ... [I]n the scope of European research programmes, the question of research on the human embryo has to be approached, not only with regard to the respect for fundamental ethical principles, common to all Member States, but equally taking into consideration diverse philosophical and ethical conceptions, expressed through the practices and the national regulations in force in this field.
>
> ...
>
> 2.8 In the light of the aforementioned principles and specifications, the Group considers that according to the ethical dimension of the Community's Fifth Framework Programme Community funding should not a priori exclude human embryo research which is the object of different ethical choices in different countries ..."

2. Opinion no. 15: Ethical aspects of human stem cell research and use, 14 November 2000

58. The relevant parts of this opinion read as follows.

> "2.3. **Pluralism and European ethics**
>
> ... In the context of European pluralism, it is up to each Member State to forbid or authorise embryo research. In the latter case, respect for human dignity requires regulation of embryo research and the provision of guarantees against risks of arbitrary experimentation and instrumentalisation of human embryos.
>
> 2.5. **Ethical Acceptability of the field of the research concerned**
>
> The Group notes that in some countries embryo research is forbidden. But when this research is allowed, with the purpose of improving treatment for infertility, it is hard to see any specific argument which would prohibit extending the scope of such research in order to develop new treatments to cure severe diseases or injuries. As in the case of research on infertility, stem cell research aims to alleviate severe human suffering. In any case, the embryos that have been used for research are required to be destroyed. Consequently, there is no argument for excluding funding of this kind of research from the Framework Programme of research of the European Union if it complies with ethical and legal requirements as defined in this programme."

B. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004

"...

(7) The regulation of advanced therapy medicinal products at Community level should not interfere with decisions made by Member States on whether to allow the use of any specific type of human cells, such as embryonic stem cells, or animal cells. It should also not affect the application of national legislation prohibiting or restricting the sale, supply or use of medicinal products containing, consisting of or derived from these cells."

C. Judgment of the Court of Justice of the European Union (CJEU) of 18 October 2011 (C-34/10 *Oliver Brüstle v. Greenpeace eV*)

59. In this judgment, delivered following a referral for a preliminary ruling from the German Federal Court of Justice (*Bundesgerichtshof*), the CJEU ruled on the interpretation to be given to Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

60. In issue was the part of the Directive which, tempering the principle that the use of human embryos for industrial or commercial purposes could not be patented, specified that this exclusion from patentability did not affect "inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it".

61. The CJEU observed that the purpose of the Directive in question was not to regulate the use of human embryos in the context of scientific research. It was limited to the patentability of biotechnological inventions. The CJEU then considered that inventions involving the use of human embryos continued to be excluded from patentability even where they purported to serve scientific research (those purposes being indistinguishable, where patents were concerned, from other industrial and commercial aims). The CJEU indicated at the same time that this exclusion did not affect inventions for therapeutic or diagnostic purposes which were applied to the human embryo and were useful to it.

D. European Union funding of research and technological development

62. Since 1984 the European Union has provided funding for scientific research through framework programmes covering periods spanning several years.

63. The relevant parts of Decision No 1982/2006/EC of 18 December 2006 concerning the Seventh Framework Programme of the European

Community for research, technological development and demonstration activities (2007-2013) read as follows.

Article 6 – Ethical principles

"1. All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.

2. The following fields of research shall not be financed under this Framework Programme:

– research activity aiming at human cloning for reproductive purposes,

– research activity intended to modify the genetic heritage of human beings which could make such changes heritable,

– research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

3. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member State(s) involved.

..."

64. The relevant parts of Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC read as follows.

Article 19 – Ethical principles

"1. All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights and its Supplementary Protocols.

...

3. The following fields of research shall not be financed:

(a) research activity aiming at human cloning for reproductive purposes;

(b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable;

(c) research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

4. Research on human stem cells, both adult and embryonic, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

..."

E. Communication from the European Commission on the European Citizens' Initiative "One of Us" COM(2014) 355 final (Brussels, 28 May 2014)

65. On 10 April 2014 the citizens' initiative "One of Us" had proposed legislative amendments to exclude from European funding scientific projects involving the destruction of human embryos.

66. In its Communication of 28 May 2014, the European Commission stated that it could not uphold the request on the ground that its proposal to fund the projects in question took account of ethical considerations, potential health benefits and support at European Union level for stem-cell research.

V. RELEVANT INTERNATIONAL LAW MATERIALS

A. Report of the Unesco International Bioethics Committee (IBC) on the ethical aspects of human embryonic stem cell research (6 April 2001)

67. The relevant parts of the conclusions of this report read as follows.

> "A. The IBC recognises that human embryonic stem cell research is a subject on which it is desirable for a debate to occur at national level to identify which position on this issue is to be adopted, including abstaining from this research. It urges that debates be conducted at appropriate national regulatory levels, enabling expression of a range of views, and whenever possible allowing a consensus to be reached on the limits of the permissible in this important new therapeutic research field. There should be an on-going process of education and information in this area. States should take appropriate measures to initiate an on-going dialogue within society on the ethical issues raised by such research, involving all actors concerned.
>
> B. Whatever form of research involving embryos is allowed, steps should be taken to ensure that such research be carried out within the framework of a State-sponsored regulatory system that would give due weight to ethical considerations, and set up appropriate guidelines. When authorisation of donations of supernumerary pre-implantation embryos from IVF treatments for therapeutic embryonic stem cell research is under consideration, particular attention should be given to the dignity and rights of both parental donors of embryos. Thus, it is essential that the donation be made only after the donors should have been given full information as to the implications of the research and have given their prior, free and informed consent. The purposes for which such research is carried out, and the way of its performance, should be subject to assessment by the appropriate ethics committees, which should be independent of the researchers involved. This assessment should include ex post facto ethical evaluation of such research."

B. Judgment of the Inter-American Court of Human Rights in *Artavia Murillo et al. (*in vitro *fertilization) v. Costa Rica* (preliminary objections, merits, reparations and costs), judgment of 28 November 2012, Series C No. 257

68. In this case the Inter-American Court gave a ruling on the ban on carrying out *in vitro* fertilisation in Costa Rica. It held, *inter alia*, that an embryo could not be regarded as a "person" within the meaning of Article 4 § 1 of the American Convention on Human Rights (protecting the right to life), "conception" occurring only from the moment the embryo was implanted in the uterus.

VI. COMPARATIVE LAW MATERIALS

69. According to the information available to the Court on the legislation of forty member States[1] regarding the use of human embryos for scientific research, three countries (Belgium, Sweden and the United Kingdom) allow scientific research on human embryos and the creation of embryos for that purpose.

70. The creation of embryos for scientific research is banned in fourteen countries[2]. However, research using surplus embryos is generally allowed in those countries, subject to certain conditions.

71. Like Italy, three member States (Slovakia, Germany and Austria) prohibit scientific research on embryos in principle, and permit it in very restricted cases, such as for the protection of the health of the embryo or where the research is carried out on cell lines imported from abroad.

72. In Slovakia any research on embryos is strictly forbidden, other than research for medical purposes for the benefit of the health of the persons directly participating in the research in question.

73. In Germany the importation and use for research purposes of embryonic cells is in principle banned by law and authorised only exceptionally and subject to strict conditions.

74. In Austria the law provides that "viable cells" cannot be used for purposes other than *in vitro* fertilisation. However, the concept of "viable

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1. Andorra, Armenia, Austria, Azerbaijan, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Finland, France, Georgia, Germany, Greece, Hungary, Ireland, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Republic of Moldova, Monaco, the Netherlands, Poland, Portugal, Romania, Russia, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, the former Yugoslav Republic of Macedonia, Turkey, the United Kingdom and Ukraine.

2. Bulgaria, Czech Republic, Estonia, Finland, France, Greece, Hungary, the Netherlands, Portugal, Serbia, Slovenia, Spain, Switzerland and the former Yugoslav Republic of Macedonia.

cells" is not defined in the law. According to practice and legal commentary, the statutory ban concerns only "totipotent" embryonic cells[3].

75. In four countries (Andorra, Latvia, Croatia and Malta) the law expressly prohibits any research on embryonic stem cells.

76. In sixteen countries (Armenia, Azerbaijan, Bosnia and Herzegovina, Georgia, Ireland, Liechtenstein, Lithuania, Luxembourg, the Republic of Moldova, Monaco, Poland, Romania, Russia, San Marino, Turkey and Ukraine) the matter is not regulated. Some of these States take a rather restrictive approach in practice (for example, Turkey and Ukraine), while others have a rather non-prohibitive practice (for example, Russia).

THE LAW

77. The Court notes at the outset that the Government raised a number of objections to the admissibility of the present application. They submitted that the applicant had not exhausted the domestic remedies available to her in domestic law; that she had failed to lodge her application within the six-month time-limit provided for in Article 35 § 1 of the Convention; and that she did not have victim status. The Court will examine these objections below before analysing the other aspects of the application.

I. NON-EXHAUSTION OF DOMESTIC REMEDIES

A. The Government's submissions

78. The Government submitted that the applicant could complain of the prohibition on donating her embryos to scientific research before an ordinary civil court on the ground that the ban was contrary to the Italian Constitution and the Convention. In support of that submission, they cited a number of domestic decisions in which the national courts had interpreted Law no. 40/2004 in the light of the Constitution and the European Convention on Human Rights, in particular regarding access to pre-implantation diagnosis (Orders of the Cagliari Court of 22 September 2007 and 9 November 2012 and those adopted by the Florence, Bologna and Salerno Courts on 17 December 2007, 29 June 2009 and 9 January 2010 respectively, see paragraphs 40-49 above).

79. According to the Government, the court in question would then have had to interpret the Law prohibiting the donation of embryos in the light of

3. Embryonic cells not yet differentiated and each of which, in isolation, has the potential to give rise to an entire organism (*Larousse* Medical Dictionary).

the Convention, as required by Constitutional Court judgments nos. 348 and 349 of 24 October 2007.

80. If the court had considered that there was an insurmountable conflict between its interpretation of the Law and the rights asserted by the claimant it would have had to submit a question of constitutionality to the Constitutional Court. That court would then have examined the issue of compatibility with human rights on the merits and would have been able to annul the domestic provisions with retroactive and *erga omnes* effect.

81. Moreover, several cases concerning the constitutionality of Law no. 40/2004 had already been brought before the Constitutional Court. A number of decisions had been delivered in that regard, particularly Constitutional Court Orders nos. 369, 97 and 150 (adopted on 24 October 2006, 8 March 2010 and 22 May 2012 respectively), judgment no. 151 delivered on 1 April 2009, a decision of the Florence Court of 7 December 2012 and an Order of the Rome Court adopted on 15 January 2014 (see paragraphs 27-33 and 50-53 above).

82. In the Government's submission, the applicant had also breached the principle of subsidiarity laid down in Protocol No. 15 of 24 June 2013 because she had failed to use domestic remedies before lodging her complaints with the Court.

83. Lastly, a question of constitutionality concerning an identical case to the present one had been raised by the Florence Court before the Constitutional Court (see paragraphs 52-53 above). If the Constitutional Court's decision were to go against the claimant, the latter would still be able to lodge an application with the Court.

B. The applicant's submissions

84. The applicant submitted that any action in the ordinary courts would have been bound to fail because domestic law imposed a blanket ban on donating embryos to scientific research.

85. She also submitted that a constitutional remedy could not be regarded as a remedy that had to be used for the purposes of Article 35 § 1 of the Convention, since the Italian legal system did not provide for direct application to the Constitutional Court.

86. Lastly, she indicated that on 19 March 2014 the President of the Constitutional Court had adjourned its examination of the question raised by the Florence Court to which the Government referred pending the Grand Chamber's decision in the present case.

C. The Court's assessment

87. The Court reiterates first of all that under Article 35 § 1 it may only deal with a matter after all domestic remedies have been exhausted.

Applicants must have provided the domestic courts with the opportunity, in principle intended to be afforded to Contracting States, of preventing or putting right the violations alleged against them. That rule is based on the assumption that there is an effective remedy available in the domestic system in respect of the alleged breach. The only remedies which Article 35 § 1 requires to be exhausted are those that relate to the breach alleged and are available and sufficient. The existence of such remedies must be sufficiently certain not only in theory but also in practice, failing which they will lack the requisite accessibility and effectiveness: it falls to the respondent State to establish that these conditions are satisfied (see, among many other authorities, *McFarlane v. Ireland* [GC], no. 31333/06, § 107, 10 September 2010; *Mifsud v. France* (dec.) [GC], no. 57220/00, § 15, ECHR 2002-VIII; *Leandro Da Silva v. Luxembourg*, no. 30273/07, §§ 40 and 42, 11 February 2010; and *Vučković and Others v. Serbia* (preliminary objection) [GC], nos. 17153/11 and 29 others, §§ 69-77, 25 March 2014).

88. In the instant case, relying on the system of constitutional review instituted by Constitutional Court judgments nos. 348 and 349 of 24 October 2007, the Government submitted that the remedies available to the applicant in domestic law had not been exhausted. They cited examples of decisions on the merits and decisions of the Constitutional Court concerning Law no. 40/2004.

89. The Court observes at the outset that, in the above-mentioned judgments nos. 348 and 349, the Constitutional Court defined the place assigned to the Convention in the Italian legal system, considering that it was of intermediate rank between an ordinary law and the Constitution. It also found that it was incumbent on the judges of the ordinary courts to interpret domestic law in a manner compliant with the Convention and the Court's case-law. It stated that, where such an interpretation was impossible or the ordinary court had doubts as to the compatibility of domestic law with the Convention, it was bound to raise a question of constitutionality before it.

90. The Court also reiterates that in the absence of a specifically introduced remedy, the development and availability of a remedy said to exist, and its scope and application, must be justified by the Government with reference to the domestic courts' case-law (see, *mutatis mutandis*, *Melnītis v. Latvia*, no. 30779/05, § 50, 28 February 2012; *McFarlane*, cited above, §§ 115-27; *Costa and Pavan v. Italy*, no. 54270/10, § 37, 28 August 2012; and *Vallianatos and Others v. Greece* [GC], nos. 29381/09 and 32684/09, §§ 52-58, 7 November 2013).

91. In the instant case the Court observes that the Government referred to a number of cases concerning Law no. 40/2004 but did not provide any examples of domestic decisions in which the question of donating surplus embryos to research was determined. Moreover, the Court cannot properly

criticise the applicant for failing to lodge an application for a measure prohibited by law.

92. With regard to the Government's submission that, since the adoption of judgments nos. 348 and 349, the ordinary courts are obliged to interpret the Law giving rise to the prohibition in the light of the Convention and Strasbourg case-law whereas they were not formerly bound by such an obligation, a number of considerations lead the Court to conclude that this statement is not actually being followed, by established judicial practice, in, among others, the sphere of assisted reproduction.

93. The Court notes first of all that in a similar case to the present one, which concerned the ban on donating surplus embryos to scientific research, the Florence Court decided, on 7 December 2012, to raise before the Constitutional Court the question of the constitutionality of section 13 of Law no. 40/2004 with regard to Articles 9 and 32 of the Constitution, which guarantee the freedom of scientific research and the right to health respectively (see paragraph 22 above). The Court observes, however, that the lower court did not raise any question regarding the compatibility of the ban in question with the rights guaranteed by the Convention.

94. It notes, secondly, that, barring a few exceptions, the decisions of the lower courts and of the Constitutional Court regarding Law no. 40/2004 cited by the Government (see paragraphs 78 and 81 above) do not refer to the Convention. This is the case regarding Orders nos. 369/2006 and 97/2010 of the Constitutional Court and its judgment no. 151/2009, the Orders of the Cagliari, Florence, Bologna and Salerno Courts adopted on 22 September 2007, 17 December 2007, 29 June 2009 and 9 January 2010 respectively, and of the decision of the Florence Court of 7 December 2012.

95. Admittedly, in Order no. 150 of 22 May 2012, in which it remitted to the lower court a case concerning the ban on heterologous fertilisation, the Constitutional Court did refer, *inter alia*, to Articles 8 and 14 of the Convention. The Court cannot fail to observe, however, that in its judgment no. 162 of 10 June 2014 in the same case the Constitutional Court examined the prohibition in question only in the light of the Articles of the Constitution that were in issue (namely, Articles 2, 31 and 32). With regard to Articles 8 and 14 of the Convention, invoked by only one of the three lower courts (see paragraph 35 above), it merely observed that the questions raised under those provisions were covered by the conclusions it had reached regarding the constitutionality issue (see paragraph 39 above).

96. Accordingly, the Orders of the Cagliari Court (of 9 November 2012) and the Rome Court (of 15 January 2014) were the only two exceptions to the failure to take account of the Convention and its case-law. Having regard to the Court's conclusions in *Costa and Pavan* (cited above), the Cagliari Court authorised access by the claimants to pre-implantation diagnosis and the Rome Court raised a question of constitutionality on that point before the Constitutional Court. The fact remains that these are just

two isolated cases out of the eleven referred to by the Government, which concern a different subject from the one in issue here and one in respect of which the Court has already ruled.

97. Furthermore, as the compatibility of section 13 of Law no. 40/2004 with the rights guaranteed by the Convention is a new issue, the Court is not convinced that the possibility open to the applicant to bring her complaints before an ordinary court constitutes an effective remedy.

98. Judgments nos. 348 and 349 themselves clarify the difference between the respective roles of the Strasbourg Court and the Constitutional Court, finding that the former has the task of interpreting the Convention while the latter must determine whether there is a conflict between a particular domestic provision and the rights guaranteed by the Convention, *inter alia*, in the light of the interpretation provided by the European Court of Human Rights (see paragraph 26 above).

99. Moreover, the decision taken on 19 March 2014 by the President of the Constitutional Court to adjourn its examination of the question raised on 7 December 2012 by the Florence Court pending a ruling by the Court in the instant case (see paragraph 53 above) is consonant with this approach.

100. In this context the Court observes that, in a recent judgment (no. 49, deposited on 26 March 2015) in which it analysed, *inter alia*, the place of the Convention and the Court's case-law in the domestic legal order, the Constitutional Court indicated that the ordinary courts were only bound to comply with the Court's case-law where it was "well established" or expressed in a "pilot judgment".

101. In any event the Court has observed on many occasions that, in the Italian legal system, litigants are not entitled to apply directly to the Constitutional Court. Only a court which is hearing the merits of a case has the possibility of making a reference to the Constitutional Court, at the request of a party or of its own motion. Accordingly, such an application cannot be a remedy whose exhaustion is required under the Convention (see, among other authorities, *Brozicek v. Italy*, 19 December 1989, § 34, Series A no. 167; *Immobiliare Saffi v. Italy* [GC], no. 22774/93, § 42, ECHR 1999-V; *C.G.I.L. and Cofferati v. Italy*, no. 46967/07, § 48, 24 February 2009; *Scoppola v. Italy (no. 2)* [GC], no. 10249/03, § 75, 17 September 2009; and *M.C. and Others v. Italy*, no. 5376/11, § 47, 3 September 2013). However, the Commission and the Court have held, with regard to other member States, that direct application to the Constitutional Court was a domestic remedy that had to be used (see, for example, *W. v. Germany*, no. 10785/84, Commission decision of 18 July 1986, Decisions and Reports (DR) 48, p. 102, at p. 105; *Union Alimentaria Sanders S.A. v. Spain*, no. 11681/85, Commission decision of 11 December 1987, DR 54, p. 101, at 107; *S.B. and Others v. Belgium* (dec.), no. 63403/00, 6 April 2004; and *Grišankova and Grišankovs v. Latvia* (dec.), no. 36117/02, ECHR 2003-II).

102. Having regard to the foregoing, the Court cannot consider that the system requiring domestic provisions to be interpreted in the light of the Convention established by judgments nos. 348 and 349 constitutes a turning point capable of refuting that conclusion (see, by converse implication, the recent decisions of the Court acknowledging the effectiveness of applications to the Turkish Constitutional Court following the creation of a system of direct application to that court: *Hasan Uzun v. Turkey* (dec.), no. 10755/13, §§ 25-27, 30 April 2013, and *Koçintar v. Turkey* (dec.), no. 77429/12, 1 July 2014).

103. The principles established in judgments nos. 348 and 349 of 24 October 2007 are to be welcomed, particularly regarding the place assigned to the Convention in the Italian legal system and the encouragement given to the national judicial authorities to interpret domestic standards and the Constitution in the light of the Convention and the Court's case-law. The Court also notes that, in areas other than assisted reproduction, there have been many decisions in which the Constitutional Court has ruled a domestic provision unconstitutional on the basis, *inter alia*, of its incompatibility with the rights guaranteed under the Convention and the Court's case-law (see, for example, judgment no. 39 of 5 March 2008 regarding legal incapacities following bankruptcy, judgment no. 93 of 17 March 2010 on the public nature of hearings in proceedings for enforcement of interim measures, and judgment no. 210 of 3 July 2013 concerning the retrospective application of criminal law).

104. However, it should first be noted that the Italian system provides only for indirect application by individuals to the Constitutional Court. Furthermore, the Government have not shown, backed up by established case-law and practice, that, where the donation of embryos to research is concerned, an action by the applicant before the ordinary courts combined with the duty on those courts to raise a question of constitutionality before the Constitutional Court in the light of the Convention amounted to an effective remedy in the present case that the applicant should have used.

105. Having regard to the foregoing and to the fact that the Constitutional Court decided to suspend its examination of a similar case pending the Court's decision in the instant case, the objection raised by the Government must be rejected.

II. COMPLIANCE WITH THE SIX-MONTH TIME-LIMIT

A. The Government's submissions

106. At the hearing the Government objected that the application had been lodged out of time, submitting that the Law banning embryo donations for scientific research had come into force on 10 March 2004 and that the applicant had not sought release of her embryos for the purpose of donating

them until 14 December 2011, in a letter sent on that date to the centre for reproductive medicine where the embryos were cryopreserved.

B. The applicant's submissions

107. The applicant replied to this objection during the hearing, submitting that she had indeed made a written request to the centre for reproductive medicine for release of her embryos on 14 December 2011, but had earlier made other identical requests verbally.

108. At all events the applicant maintained that any request to the centre for reproductive medicine was bound to fail, since the applicable Law categorically prohibited the donation of embryos to scientific research.

C. The Court's assessment

109. The Court has already acknowledged that where an interference with the right relied on by an applicant emanates directly from legislation, the very maintenance in force of the impugned legislation may constitute a continuing interference with the right in question (see, for example, *Dudgeon v. the United Kingdom*, 22 October 1981, § 41, Series A no. 45, and *Norris v. Ireland*, 26 October 1988, § 38, Series A no. 142, in which the applicants, who were homosexuals, complained that laws making homosexual practices criminal offences infringed their right to respect for their private life).

110. The Court has recently proceeded on that basis in *Vallianatos and Others* (cited above, § 54), in which the applicants complained of a continuing violation of Articles 14 and 8 of the Convention on account of their inability, as same-sex couples, to enter into a "civil union", whereas different-sex couples were legally able to do so. Further, in *S.A.S. v. France* ([GC], no. 43835/11, § 110, ECHR 2014), which concerned the statutory ban on wearing clothing designed to conceal one's face in public places, the Court observed that the applicant's situation was similar to that of the applicants in *Dudgeon* and *Norris* (both cited above), in which it had found a continuing interference with the exercise of the rights protected by Article 8 of the Convention.

111. The Court acknowledges that in the above-cited cases the effect of the legislative measures complained of on the daily lives of the applicants was more substantial and more direct than in the present case. Nevertheless, the statutory ban on donating embryos to scientific research in issue here does undeniably have an impact on the applicant's private life. That impact, which results from the biological link between the applicant and her embryos and the plan to start a family that was at the origin of their creation, is a direct result of the entry into force of Law no. 40/2004 and constitutes a continuing situation in that it has continuously affected the applicant since

then (see the final report of the Study Commission on embryos of 8 January 2010, which refers to potentially indefinite cryopreservation of frozen embryos, paragraph 21 above).

112. In this type of case, according to the Court's case-law, the six-month period does not start to run until the situation complained of has come to an end (see, among other authorities, *Çınar v. Turkey*, no. 17864/91, Commission decision of 5 September 1994, DR 79-B). Consequently, the Court does not accept the Government's argument that the time period runs from the date on which the Law in issue came into force.

113. Moreover, the Government's submission is tantamount to considering that the applicant wanted to donate her embryos from the date on which the Law in issue came into force, which is not a matter that is open to speculation by the Court.

114. The objection on the ground of delay in lodging the application, raised by the Government under Article 35 § 1 of the Convention, cannot therefore be upheld.

III. THE APPLICANT'S VICTIM STATUS

A. The Government's submissions

115. The Government also objected on the ground that the applicant did not have victim status, submitting that, during the period from 12 November 2003 – the date of her partner's death – to 10 March 2004, when Law no. 40/2004 came into force, the applicant could have donated her embryos to research since there were no regulations governing the matter at that time and a donation of that sort was therefore not prohibited.

B. The applicant's submissions

116. The applicant submitted at the hearing that a very short period of time had elapsed between the date of her partner's death and the date when the Law came into force – approximately four months – and that she had not been able to make a clear decision during that time as to what she wanted to do with the embryos obtained from the IVF treatment she had undergone.

C. The Court's assessment

117. The Court reiterates that where an interference with an applicant's private life emanates directly from legislation, the maintenance in force of the impugned legislation constitutes a continuing interference with the exercise of the right in question. In the personal circumstances of the

applicant, the very existence of this legislation continuously and directly affects her private life (see *Dudgeon*, § 41, and *Norris*, § 34, both cited above).

118. In the instant case the applicant has been unable to donate her embryos to research since Law no. 40/2004 came into force (see also paragraph 113 above). As the situation has remained unchanged since then, the fact that the applicant wanted to donate her embryos to research at the time of lodging her application is sufficient for the Court to find that she has victim status. Furthermore, with regard to the Government's argument that the applicant could have donated her embryos to scientific research during the period between her partner's death and the entry into force of the Law, the Court takes note of the information submitted by the applicant according to which, during the short period referred to above, she had not been able to make a clear decision concerning the fate of the embryos.

119. The Government's objection on the ground of the applicant's lack of victim status must therefore be dismissed.

IV. ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

120. Relying on Article 8 of the Convention, the applicant alleged that the ban under section 13 of Law no. 40/2004 on donating embryos to scientific research resulted in a violation of her right to respect for her private life. The relevant parts of Article 8 provide:

> "1. Everyone has the right to respect for his private ... life ...
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

A. The parties' submissions

1. The Government's submissions

121. The Government submitted at the outset that the question whether human embryos could be donated to scientific research did not fall within the concept of "right to respect for private life".

122. At the hearing the Government contended that Article 8 of the Convention could have applied only "indirectly" in the present case, that is, only if the applicant had wanted to start a family by having her embryos implanted and had been prevented from doing so by the application of Law no. 40/2004.

123. In any event they maintained that the alleged interference with the applicant's private life was in accordance with the law and pursued the legitimate aim of protecting the embryo's potential for life.

124. With regard to the proportionality of the impugned measure, the Government confined themselves in their written observations to referring to the arguments they had submitted under Article 1 of Protocol No. 1. However, at the hearing the Government submitted that the Italian legislation was not inconsistent, arguing that the applicant had wrongly affirmed that cryopreserved embryos could not develop into human lives. In that connection they submitted that, if properly carried out, cryopreservation was not limited in duration and that there were currently no scientific means by which the viability of a cryopreserved embryo could be determined without thawing it.

125. The Government also submitted that Italian law, which allowed abortion, was not incompatible with the ban on donating embryos to research, since in the event of an abortion the protection of the life of the foetus clearly had to be weighed against the situation and interests of the mother.

126. During the hearing they also observed that embryos were definitely protected under European law. In their submission, the Council of Europe Convention on Human Rights and Biomedicine (Oviedo Convention) of 4 April 1997 certainly did not require States to authorise destructive scientific research on embryos, since, in their submission, the choice as regards carrying out such research fell within the wide margin of appreciation of the States in this sphere.

127. They went on to observe that the preparatory works to Law no. 40/2004 showed that it was the end-product of a substantial amount of work that had taken account of a range of scientific and ethical opinions and questions on the subject. Moreover, the Law in question had been the subject of several referendums, regarding, *inter alia*, maintaining section 13, which had been declared invalid because the required threshold of votes had not been reached.

128. Furthermore, while acknowledging that Italian scientific research used embryonic cell lines imported from abroad and resulting from the destruction of the original embryos, they pointed out that the production of these cell lines was not carried out at the request of Italian laboratories and observed that there were approximately 300 embryonic cell lines in the world that were made available to the entire scientific community. In that connection they pointed out that the deliberate destruction of a human embryo could not be compared with the use of cell lines from human embryos that had already been destroyed.

129. With regard to European Union funding for scientific research, the Government submitted that the Seventh Framework Programme for research, technological development and demonstration activities and the

Horizon 2020 Framework Programme for Research and Innovation (see paragraphs 63-64 above) did not provide for funding of projects involving the destruction of embryos, whether these had been created in Europe or imported from third countries.

130. They observed, lastly, that in its opinion of 18 November 2005 on adoption for birth (see paragraphs 19-20 above), the National Bioethics Committee had already tackled the subject of the fate of surplus embryos with a view to finding solutions that would respect their lives.

131. In their view, this solution could now become a reality having regard to judgment no. 162 of 10 June 2014 in which the Constitutional Court had declared the ban on heterologous fertilisation unconstitutional, thus allowing the use of surplus embryos from an *in vitro* fertilisation for non-destructive purposes, in accordance with the objective pursued by Italian legislation in this area.

2. The applicant's submissions

132. The applicant affirmed at the outset that according to the Court's case-law "private life" was a broad concept (she referred to *Pretty v. the United Kingdom*, no. 2346/02, § 61, ECHR 2002-III, and *Evans v. the United Kingdom* [GC], no. 6339/05, § 71, ECHR 2007-I).

133. She went on to submit that she had lost her partner in tragic circumstances, which was why she had not been able to start a family as she had wished. At the hearing she explained that only four months had elapsed between her partner's death and the Law's entry into force, so she had not had the necessary time to reflect on her plans to start a family, and that in any event the implantation of embryos *post mortem* was illegal.

134. Accordingly, she considered that the State also required her to witness the destruction of her embryos rather than allowing her to donate them to research, which would pursue a noble cause and be a source of comfort to her after the painful events that had occurred in her life. In those circumstances she submitted that her right to her private life was in issue.

135. She also maintained that the ban on donating embryos was completely illogical, since the only alternative offered by the system was the death of the embryos. At the hearing she pointed to the inconsistencies in the Italian legal system, submitting that the embryo's right to life relied on by the Government was irreconcilable with the possibility available to women to abort up until the third month of pregnancy and with the use by Italian laboratories of embryonic cell lines obtained from the destruction of embryos created abroad.

136. Furthermore, she considered that the possibility of donating embryos not destined for implantation also fulfilled a public interest since research on induced pluripotent stem cells had not yet replaced research on stem cells, which was why the latter continued to feature among the most

promising research methods, particularly regarding the treatment of certain incurable diseases.

137. She also submitted that the State did not have a wide margin of appreciation in the present case, particularly given the existing European consensus regarding the possibility of donating to scientific research embryos that were not destined to be implanted.

138. At the hearing she referred to the judgment of 18 October 2011 of the Court of Justice of the European Union in *Oliver Brüstle v. Greenpeace eV* (see paragraphs 59-61 above). Noting that this judgment was limited to prohibiting the patentability of inventions involving the destruction of human embryos, she inferred that the inventions themselves – and the prior research – were not banned at European level.

139. Lastly, she submitted that the Communication from the European Commission on the European Citizens' Initiative "One of Us" of 28 May 2014 (see paragraphs 65-66 above) confirmed that the funding of research on embryonic human stem cells was permitted.

3. Observations of the third-party interveners

(a) The European Centre for Law and Justice (ECLJ)

140. The ECLJ submitted that in the present case the interests of science – to which the applicant attached importance – did not take precedence over the respect due to the embryo, in line with the principle of the "primacy of the human being" enshrined in Article 2 of the Oviedo Convention.

141. It also observed that in all the cases raising questions related to assisted reproduction that had been brought before the Court the interference with the applicants' private and family life stemmed from a law that prevented the couple or the mother from having a child. The situation was different here in that the applicant had decided not to have the embryos implanted even though at the time she had undergone the IVF treatment there had been no law prohibiting gestation *post mortem*.

142. Lastly, referring to *S.H. and Others v. Austria* and *Evans*, both cited above, it observed that the member States were afforded a wide margin of appreciation in this area.

(b) The associations Movimento per la vita, Scienza e vita and Forum delle associazioni familiari, represented by Mr Casini

143. These associations submitted that destructive experiments on human embryos, which were "subjects", were banned by law and that the Oviedo Convention did not impose any obligation to authorise such experiments.

144. They also observed that the member States enjoyed a wide margin of appreciation in this area.

(c) The associations Luca Coscioni, Amica Cicogna Onlus, L'Altra Cicogna Onlus and Cerco Un Bimbo and forty-six members of the Italian Parliament, represented by Ms Gallo

145. These third-party interveners submitted that the concept of "private life" was an evolving one, that it was not susceptible to exhaustive definition, and that the applicant claimed, *inter alia*, the right to respect for her choice to donate her own biological matter to research, namely, embryos that were no longer destined for a parental project and were in any event bound for destruction.

146. They added that the interference in question was not justified by the purpose relied on, since Italian law did not afford absolute protection to the embryo's life.

(d) The associations VOX – Osservatorio italiano sui Diritti, SIFES (Society of Fertility, Sterility and Reproductive Medicine) and Cittadinanzattiva, represented by Ms D'Amico, Ms Costantini, Mr Clara, Ms Ragni and Ms Liberali

147. These associations pointed out that section 13 of Law no. 40/2004 curtailed the freedom of individuals to decide the fate of their own embryos, which had to be cryopreserved indefinitely, thus incurring substantial costs.

148. According to them, cryopreservation was not in any way useful to embryos destined to die, nor to couples, who were not generally keen to use embryos that had been cryopreserved for a long time for implantation, as the "quality" of these embryos diminished over time. Cryopreservation was just as useless for the medical centres where the embryos were stored.

B. The Court's assessment

1. Applicability to the present case of Article 8 of the Convention and admissibility of the complaint raised by the applicant

149. In the present case the Court is called upon for the first time to rule on the question whether the "right to respect for private life" guaranteed by Article 8 of the Convention can encompass the right invoked before it by the applicant to make use of embryos obtained from *in vitro* fertilisation for the purposes of donating them to scientific research.

150. The Government submitted that the provision in question could have applied only indirectly in the instant case and exclusively under its "family life" aspect, that is, only if the applicant had wanted to start a family by means of cryopreservation and the subsequent implantation of her embryos and had been prevented from doing so by the application of Law no. 40/2004.

151. However, the applicant indicated in the application form (see paragraph 14 above) and repeated at the hearing (see paragraph 116 above) that, since the death of her partner, she was no longer intending to start a

family. Moreover, she did not at any time allege before the Court that there had been a violation of her right to respect for her family life under Article 8 of the Convention.

152. In reality the subject matter of the case brought before the Court concerns the restriction of the right asserted by the applicant to decide the fate of her embryos, a right which at the very most relates to "private life".

153. Like the applicant, the Court observes at the outset that, according to its case-law, the concept of "private life" within the meaning of Article 8 of the Convention is a broad one not susceptible to exhaustive definition and embraces, among other things, a right to self-determination (see *Pretty*, cited above, § 61). The concept also incorporates the right to respect for both the decisions to become and not to become a parent (see *Evans*, cited above, § 71, and *A, B and C v. Ireland* [GC], no. 25579/05, § 212, ECHR 2010).

154. In the cases examined by the Court that have raised the particular question of the fate of embryos obtained from assisted reproduction, the Court has had regard to the parties' freedom of choice.

155. In *Evans*, when analysing the balance to be struck between the conflicting rights that the parties to *in vitro* fertilisation may rely on under Article 8 of the Convention, the Grand Chamber "[did] not consider that the applicant's right to respect for the decision to become a parent in the genetic sense should be accorded greater weight than [her ex-partner]'s right to respect for his decision not to have a genetically related child with her" (see *Evans*, cited above, § 90).

156. Furthermore, in *Knecht v. Romania* (no. 10048/10, 2 October 2012), where the applicant complained, *inter alia*, of the refusal of the national authorities to authorise the transfer of her embryos from the medical centre where they were being stored to a specialised clinic of her choice, the Court held that Article 8 was applicable only from the standpoint of respect for the applicant's private life (ibid., § 55) even though the applicant had also alleged an infringement of her right to respect for her family life (ibid., § 51).

157. With regard to domestic law, the Court observes that, as submitted by the Government at the hearing, judgment no. 162 of 10 June 2014 in which the Constitutional Court declared unconstitutional the ban on heterologous fertilisation (see paragraphs 34-39 above) should now allow "adoption for birth", a practice which consists in a couple or a woman adopting surplus embryos in order to have them implanted, and had been envisaged by the National Bioethics Committee in 2005. Furthermore, the Court notes that in the judgment in question the Constitutional Court found that the applicants' choice to become parents and found a family with children was an aspect of "their freedom of self-determination regarding the sphere of their private and family life" (see paragraph 37 above). This means that the Italian legal system also attaches importance to the freedom

of choice of parties to *in vitro* fertilisation regarding the fate of embryos not destined for implantation.

158. In the instant case the Court must also have regard to the link existing between the person who has undergone *in vitro* fertilisation and the embryos thus conceived, which link is due to the fact that the embryos contain the genetic material of the person in question and accordingly represent a constituent part of that person's genetic material and biological identity.

159. The Court concludes that the applicant's ability to exercise a conscious and considered choice regarding the fate of her embryos concerns an intimate aspect of her personal life and accordingly relates to her right to self-determination. Article 8 of the Convention, from the standpoint of the right to respect for private life, is therefore applicable in the present case.

160. The Court observes, lastly, that this complaint is not manifestly ill-founded within the meaning of Article 35 § 3 (a) of the Convention and cannot be declared inadmissible on any other grounds. It must therefore be declared admissible.

2. Merits of the complaint raised by the applicant

(a) Whether there has been an "interference" "in accordance with the law"

161. Like the parties, the Court considers that the ban under section 13 of Law no. 40/2004 on donating to scientific research embryos obtained from an *in vitro* fertilisation and not destined for implantation constitutes an interference with the applicant's right to respect for her private life. It points out in this connection that at the time when the applicant had recourse to *in vitro* fertilisation there were no legal provisions regulating the donation of non-implanted embryos obtained by that technique. Consequently, until the Law came into force the applicant was not in any way prevented from donating her embryos to scientific research.

(b) The legitimacy of the aim pursued

162. During the hearing the Government submitted that the objective pursued by the measure complained of was to protect the "embryo's potential for life".

163. The Court reiterates that the enumeration of the exceptions to the individual's right to respect for his private life, as listed in Article 8 § 2, is exhaustive and that their definition is restrictive. For it to be compatible with the Convention, a limitation of this freedom must, in particular, pursue an aim that can be linked to one of those listed in this provision (see *S.A.S. v. France,* cited above, § 113).

164. The Court observes that neither in their written observations nor in the reply to the question asked at the hearing did the Government refer to the provisions of paragraph 2 of Article 8 of the Convention.

165. However, in their written observations on Article 8 of the Convention the Government referred to the considerations they had set out regarding Article 1 of Protocol No. 1 (see paragraph 124 above) according to which, in the Italian legal system, the human embryo is considered as a subject of law entitled to the respect due to human dignity (see paragraph 200 below).

166. The Court also notes that, similarly, two third-party interveners (the ECLJ and the associations Movimento per la vita, Scienza e vita and Forum delle associazioni familiari) submitted that the human embryo had the status of "subject" (see paragraphs 140 and 143 above).

167. The Court acknowledges that the "protection of the embryo's potential for life" may be linked to the aim of protecting morals and the rights and freedoms of others, in the terms in which this concept is meant by the Government (see also *Costa and Pavan*, cited above, §§ 45 and 59). However, this does not involve any assessment by the Court as to whether the word "others" extends to human embryos (see *A, B and C v. Ireland*, cited above, § 228).

(c) Necessity of the measure in a democratic society

(i) The principles established in the Court's case-law regarding assisted reproduction

168. The Court reiterates that in determining whether an impugned measure was "necessary in a democratic society", it will consider whether, in the light of the case as a whole, the reasons adduced to justify that measure were relevant and sufficient for the purposes of paragraph 2 of Article 8 (see, among many other authorities, *S.H. and Others v. Austria*, cited above, § 91; *Olsson v. Sweden (no. 1)*, 24 March 1988, § 68, Series A no. 130; *K. and T. v. Finland* [GC], no. 25702/94, § 154, ECHR 2001-VII; *Kutzner v. Germany*, no. 46544/99, § 65, ECHR 2002-I; and *P., C. and S. v. the United Kingdom*, no. 56547/00, § 114, ECHR 2002-VI).

169. Furthermore, a number of factors must be taken into account when determining the breadth of the margin of appreciation to be enjoyed by the State in any case under Article 8. Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will usually be restricted (see *Evans*, cited above, § 77, and the other authorities cited therein, and *Dickson v. the United Kingdom* [GC], no. 44362/04, § 78, ECHR 2007-V). Where, however, there is no consensus within the member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin will be wider (see *S.H. and Others v. Austria*, cited above, § 94; *Evans*, cited above, § 77; *X, Y and Z v. the United Kingdom*, 22 April 1997, § 44, *Reports of Judgments and Decisions* 1997-II; *Fretté v. France*,

no. 36515/97, § 41, ECHR 2002-I; *Christine Goodwin v. the United Kingdom* [GC], no. 28957/95, § 85, ECHR 2002-VI; and *A, B and C v. Ireland*, cited above, § 232).

170. The Court has also observed that in any event "the solutions reached by the legislature are not beyond [its] scrutiny. It falls to the Court to examine carefully the arguments taken into consideration during the legislative process and leading to the choices that have been made by the legislature and to determine whether a fair balance has been struck between the competing interests of the State and those directly affected by those legislative choices" (see *S.H. and Others v. Austria*, cited above, § 97).

171. In the above-mentioned case the Court also observed that the Austrian Parliament had not yet "undertaken a thorough assessment of the rules governing artificial procreation, taking into account the dynamic developments in science and society" and pointed out that "this area, in which the law appear[ed] to be continuously evolving and which [was] subject to a particularly dynamic development in science and law, need[ed] to be kept under review by the Contracting States" (see *S.H. and Others v. Austria*, cited above, §§ 117-18).

172. In *Costa and Pavan* (cited above, § 64), the Court held that Italian legislation on pre-implantation diagnosis lacked consistency in that it did not permit implantation to be limited to the embryos not affected by the disease of which the individuals concerned were healthy carriers but did allow the applicant to abort a foetus which would have been born with the disease in question.

173. It also considered that it was not its task to substitute its own judgment for that of the national authorities in choosing the most appropriate regulations governing assisted reproduction, observing in particular that the use of *in vitro* fertilisation techniques raised sensitive moral and ethical questions in an area that was constantly evolving (see *Knecht*, cited above, § 59).

(ii) Application of the above-mentioned principles to the present case

174. The Court observes at the outset that, unlike the above-cited cases, the instant case does not concern prospective parenthood. Accordingly, while it is of course important, the right invoked by the applicant to donate embryos to scientific research is not one of the core rights attracting the protection of Article 8 of the Convention, as it does not concern a particularly important aspect of the applicant's existence and identity.

175. Consequently, and having regard to the principles established in its case-law, the Court considers that the respondent State should be afforded a wide margin of appreciation in the present case.

176. Furthermore, it observes that the question of the donation of embryos not destined for implantation clearly raises "delicate moral and ethical questions" (see *Evans*; *S.H. and Others v. Austria*; and *Knecht*, all

cited above) and that the comparative law materials available to the Court (see paragraphs 69-76 above) show that, contrary to the applicant's affirmations, there is no European consensus on the subject (see paragraph 137 above).

177. Admittedly, certain member States have adopted a non-prohibitive approach in this area: seventeen of the forty member States about which the Court has information allow research on human embryonic cell lines. In some other States there are no regulations, but the relevant practices are non-prohibitive.

178. However, certain States (Andorra, Latvia, Croatia and Malta) have enacted legislation expressly prohibiting any research on embryonic cells. Others allow research of this type only subject to strict conditions, requiring for example that the purpose be to protect the embryo's health or that the research use cells imported from abroad (this is the case in Slovakia, Germany, Austria and Italy).

179. Italy is therefore not the only member State of the Council of Europe which bans the donation of human embryos to scientific research.

180. Furthermore, the above-cited Council of Europe and European Union materials confirm that the domestic authorities enjoy a broad margin of discretion to enact restrictive legislation where the destruction of human embryos is at stake, having regard, *inter alia*, to the ethical and moral questions inherent in the concept of the beginning of human life and the plurality of existing views on the subject among the different member States.

181. An example of this is the Oviedo Convention, Article 27 of which provides that none of its provisions should be interpreted as limiting the possibility for a Party to grant a wider measure of protection with regard to the application of biology and medicine. Opinion no. 15, adopted on 14 November 2000 by the European Group on Ethics in Science and New Technologies to the European Commission (see paragraph 58 above), Resolution 1352 (2003) of the Parliamentary Assembly of the Council of Europe on human stem cell research (see Part III, point F above) and Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products (see Part IV, point B above) contain similar provisions.

182. The limits imposed at European level aim rather to temper excesses in this area. This is the case for example of the ban on creating human embryos for scientific research provided for in Article 18 of the Oviedo Convention, or the ban on patenting scientific inventions where the process involves the destruction of human embryos (see the judgment of the Court of Justice of the European Union in *Oliver Brüstle v. Greenpeace eV* of 18 October 2011).

183. That being said, the State's margin of appreciation is not unlimited and it is the Court's task to examine the arguments to which the legislature

has had regard in reaching the solutions it has retained and to determine whether a fair balance has been struck between the interests of the State and those of the individuals directly affected by the solutions in question (see *Evans*, cited above, § 86, and *S.H. and Others v. Austria*, cited above, § 97).

184. The Court notes in this context that, relying on documents relating to the preparatory works to Law no. 40/2004, the Government submitted at the hearing that the drafting of the Law had given rise to discussions that had taken account of the different scientific and ethical opinions and questions on the subject (see paragraph 127 above).

185. It can be seen from a report by the XIIth Standing Committee submitted to Parliament on 26 March 2002 that doctors, specialists and associations working in the field of assisted reproduction had contributed to the discussions and that the liveliest part of these had in general concerned the sphere of individual freedoms, pitting the advocates of a secular conception of the State against those in favour of a denominational approach.

186. Furthermore, during the discussions of 19 January 2004, Law no. 40/2004 had also been criticised on the ground, among others, that recognition of the embryo as a legal subject under section 1 of the Law gave rise, according to some, to a series of prohibitions, such as the use of heterologous fertilisation and the use of cryopreserved embryos not destined for implantation for scientific research.

187. Like the Government, the Court reiterates that Law no. 40/2004 was the subject of several referendums that were declared invalid for failure to reach the required threshold of votes cast. In order to promote the development of scientific research in Italy in the area of diseases that are difficult to cure, one such referendum proposed to repeal the part of section 13 that made authorisation to carry out scientific research on embryos conditional on protecting their health and development.

188. The Court therefore observes that, during the drafting process of the Law in question the legislature had already taken account of the different interests at stake, particularly the State's interest in protecting the embryo and that of the persons concerned in exercising their right to individual self-determination in the form of donating their embryos to research.

189. The Court notes the applicant's allegation that Italian legislation on medically assisted reproduction is inconsistent, in support of her submission that the interference complained of is disproportionate.

190. In her written observations and at the hearing, the applicant observed that it was difficult to reconcile the protection of the embryo advocated by the Government with a woman's legal ability to terminate a pregnancy on therapeutic grounds up until the third month and also the use by Italian researchers of embryonic cell lines obtained from embryos that had been destroyed abroad.

191. The Court's task is not to review the consistency of the Italian legislation in the abstract. In order to be relevant for the purposes of the Court's analysis, the inconsistencies complained of by the applicant must relate to the subject of the complaint that she raises before the Court, namely, the restriction of her right to self-determination regarding the fate of her embryos (see, *mutatis mutandis*, *Olsson*, cited above, § 54, and *Knecht*, cited above, § 59).

192. With regard to the research carried out in Italy on imported embryonic cell lines taken from embryos that had been destroyed abroad, the Court observes that, while the right asserted by the applicant to decide the fate of her embryos relates to her wish to contribute to scientific research, that cannot however be seen as a circumstance directly affecting the applicant.

193. Furthermore, the Court takes note of the information provided by the Government during the hearing, according to which the embryonic cell lines used in Italian laboratories for research purposes are never produced at the request of the Italian authorities.

194. It agrees with the Government that the deliberate and active destruction of a human embryo cannot be compared with the use of cell lines obtained from human embryos destroyed at an earlier stage.

195. It concludes from the foregoing that, even supposing that there are inconsistencies in the legislation as alleged by the applicant, these are not capable of directly affecting the right invoked by her in the instant case.

196. Lastly, the Court observes that in this case the choice to donate the embryos in question to scientific research emanates from the applicant alone, since her partner is dead. The Court does not have any evidence that her partner, who had the same interest in the embryos in question as the applicant at the time of fertilisation, would have made the same choice. Moreover, there are no regulations governing this situation at domestic level.

197. For the reasons outlined above, the Court considers that the Government have not overstepped the wide margin of appreciation enjoyed by them in the present case and that the ban in question was "necessary in a democratic society" within the meaning of Article 8 § 2 of the Convention.

198. There has therefore been no violation of the applicant's right to respect for her private life under Article 8 of the Convention.

V. ALLEGED VIOLATION OF ARTICLE 1 OF PROTOCOL No. 1

199. Relying on Article 1 of Protocol No. 1, the applicant complained that she was unable to donate her embryos and was obliged to keep them in a state of cryopreservation until their death. Article 1 of Protocol No. 1 provides:

"Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties."

A. The parties' submissions

1. The Government's submissions

200. The Government submitted at the outset that the human embryo could not be regarded as a "thing" and that it was in any event unacceptable to assign an economic value to it. They observed that in the Italian legal system the human embryo was considered as a subject of law entitled to the respect due to human dignity.

201. They also submitted that the Court afforded member States a wide margin of appreciation regarding the determination of the beginning of human life (they referred to *Evans*, cited above, § 81), particularly in areas such as this, where complex moral and ethical questions were in issue that were not the subject of a consensus among the member States of the Council of Europe.

202. They concluded that there had been no violation of Article 1 of Protocol No. 1 in the present case.

2. The applicant's submissions

203. The applicant submitted that embryos conceived by *in vitro* fertilisation could not be regarded as "individuals" because if they were not implanted they were not destined to develop into foetuses and be born. She concluded that, from a legal point of view, they were "possessions".

204. In the circumstances she considered that she had a right of ownership of her embryos and that the State had imposed restrictions on that right that were not justified on any public-interest grounds. In her view, the protection of the embryos' potential for life could not reasonably be invoked in that regard since they were destined to be eliminated.

3. Observations of the third parties

(a) The European Centre for Law and Justice (ECLJ)

205. The ECLJ submitted that embryos could not be regarded as "things" and accordingly could not be deliberately destroyed. It also argued that the concept of "possession" had an inherently economic connotation which had to be ruled out in the case of human embryos.

206. Referring to *Vo v. France* ([GC], no. 53924/00, § 82, ECHR 2004-VIII), it pointed out, lastly, that the Court allowed States to determine in their domestic legal order "when the right to life begins" and that it afforded them a wide margin of appreciation in this area (see *A, B and C v. Ireland*, cited above, § 237).

(b) The associations Movimento per la vita, Scienza e vita and Forum delle associazioni familiari, represented by Mr Casini

207. These third-party interveners submitted that the human embryo could never be regarded as a "thing".

208. They submitted, further, that Italian legislation on the subject was consistent. While they acknowledged that abortion on therapeutic grounds was legal, they observed that this was not because the embryo could be regarded as a "thing" but because account was taken of the different interests involved, particularly those of the mother.

(c) The associations Luca Coscioni, Amica Cicogna Onlus, L'Altra Cicogna Onlus and Cerco Un Bimbo and forty-six members of the Italian Parliament, represented by Ms Gallo

209. Ms Gallo reiterated the arguments submitted by the applicant concerning the status of the embryo.

(d) The associations VOX – Osservatorio italiano sui Diritti, SIFES (Society of Fertility, Sterility and Reproductive Medicine) and Cittadinanzattiva, represented by Ms D'Amico, Ms Costantini, Mr Clara, Ms Ragni and Ms Liberali

210. These third-party interveners did not submit any observations under Article 1 of Protocol No. 1.

B. The Court's assessment

1. The principles established in the Court's case-law

211. The Court reiterates that the concept of "possessions" within the meaning of Article 1 of Protocol No. 1 has an autonomous meaning which is not limited to ownership of material goods and is independent from the formal classification in domestic law: certain other rights and interests constituting assets can also be regarded as "property rights", and thus as "possessions" for the purposes of this provision. In each case the issue that needs to be examined is whether the circumstances of the case, considered as a whole, conferred on the applicant title to a substantive interest protected by Article 1 of Protocol No. 1 (see *Iatridis v. Greece* [GC], no. 31107/96, § 54, ECHR 1999-II; *Beyeler v. Italy* [GC], no. 33202/96, § 100, ECHR 2000-I; and *Broniowski v. Poland* [GC], no. 31443/96, § 129, ECHR 2004-V).

212. Article 1 of Protocol No. 1 applies only to a person's existing possessions. Future income cannot be considered to constitute a "possession" unless it has already been earned or is definitely payable. Further, the hope that a long-extinguished property right may be revived cannot be regarded as a "possession"; nor can a conditional claim which has lapsed as a result of a failure to fulfil the condition (see *Gratzinger and Gratzingerova v. the Czech Republic* (dec.), no. 39794/98, § 69, ECHR 2002-VII).

213. However, in certain circumstances a "legitimate expectation" of obtaining an asset may also enjoy the protection of Article 1 of Protocol No. 1. Thus, where a proprietary interest is in the nature of a claim, the person in whom it is vested may be regarded as having a legitimate expectation if there is a sufficient basis for the interest in national law, for example where there is settled case-law of the domestic courts confirming its existence (see *Kopecký v. Slovakia* [GC], no. 44912/98, § 52, ECHR 2004-IX).

2. Application of the above principles to the present case

214. The Court notes that the present case raises the preliminary question of the applicability of Article 1 of Protocol No. 1 to the facts of the instant case. It notes that the parties have diametrically opposed views on this matter, especially regarding the status of the human embryo *in vitro*.

215. It considers, however, that it is not necessary to examine here the sensitive and controversial question of when human life begins as Article 2 of the Convention is not in issue in the instant case. With regard to Article 1 of Protocol No. 1, the Court considers that it does not apply to the present case. Having regard to the economic and pecuniary scope of that Article, human embryos cannot be reduced to "possessions" within the meaning of that provision.

216. As Article 1 of Protocol No. 1 is not applicable in the instant case, this part of the application must be rejected as incompatible *ratione materiae* with the provisions of the Convention, in accordance with Article 35 §§ 3 and 4 thereof.

FOR THESE REASONS, THE COURT

1. *Rejects*, unanimously, the objection raised by the Government on the ground of non-exhaustion of domestic remedies;

2. *Rejects*, by a majority, the objection raised by the Government on the ground of delay in lodging the application;

3. *Rejects*, by a majority, the objection raised by the Government on the ground that the applicant lacks victim status;

4. *Declares*, by a majority, the application admissible regarding the complaint based on Article 8 of the Convention;

5. *Declares*, unanimously, the application inadmissible regarding the complaint based on Article 1 of Protocol No. 1;

6. *Holds*, by sixteen votes to one, that there has been no violation of Article 8 of the Convention.

Done in English and in French, and delivered at a public hearing in the Human Rights Building, Strasbourg, on 27 August 2015.

Johan Callewaert	Dean Spielmann
Deputy Registrar	President

In accordance with Article 45 § 2 of the Convention and Rule 74 § 2 of the Rules of Court, the following separate opinions are annexed to this judgment:

(a) concurring opinion of Judge Pinto de Albuquerque;

(b) concurring opinion of Judge Dedov;

(c) joint partly concurring opinion of Judges Casadevall, Raimondi, Berro, Nicolaou and Dedov;

(d) joint partly dissenting opinion of Judges Casadevall, Ziemele, Power-Forde, De Gaetano and Yudkivska;

(e) partly dissenting opinion of Judge Nicolaou;

(f) dissenting opinion of Judge Sajó.

D.S.
J.C.

CONCURRING OPINION OF JUDGE PINTO DE ALBUQUERQUE

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I. Introduction

1. I have no objections to the admissibility and inadmissibility decisions of the majority of the Grand Chamber[1]. However, I cannot follow their reasoning on the substantive issue at stake, namely the use of cryopreserved embryos for stem-cell research. I nevertheless voted, without hesitation, with the majority for a finding of no violation of Article 8 of the European Convention on Human Rights ("the Convention").

II. Human embryo research in international law

A. United Nations standards

(i) The Universal Declaration on the Human Genome and Human Rights

2. As can be seen from Article 6 § 1 of the International Covenant on Civil and Political Rights and from the ninth paragraph of the Preamble to the Convention on the Rights of the Child, international law is not indifferent to the need to protect potential human life. But Article 15 § 3 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966 also obliges the States Parties "to respect the freedom indispensable for scientific research". Yet this scientific freedom may be restricted in order to promote the "general welfare in a democratic society" (Article 4 of the ICESCR). The protection of unborn human life as an indispensable social value in a democratic society, which concerns the welfare not only of present but also future generations, falls squarely within the restriction clause of Article 4 of the ICESCR, read in the light of the developments of international law in the second half of the twentieth century.

In fact, the United Nations have taken significant steps towards acknowledging the human dignity of embryos by protecting them in the context of scientific research and human experimentation, starting with the adoption of the Universal Declaration on the Human Genome and Human Rights by the General Conference of the United Nations Educational, Scientific and Cultural Organisation (Unesco) in 1997[2], endorsed by the

1. In my view, the non-exhaustion of domestic remedies is the only problematic issue, but this objection was properly dismissed in view of the explicit position of the Italian Constitutional Court, which has adjourned its examination of a case raising the same legal question, pending the decision of the Grand Chamber in the present case (see paragraph 53 of the present judgment).

United Nations General Assembly in 1998[3]. The Declaration provides that the human genome underlies recognition of the inherent dignity and diversity of the human family. Everyone has a right to respect for their dignity and their rights, regardless of their genetic characteristics. That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity. The human genome, which by its nature evolves, is subject to mutations. It contains potentialities that are expressed differently according to each individual's natural and social environment. The human genome in its natural state must not give rise to financial gains. The Declaration further states that no research or research applications concerning the human genome, in particular in the fields of biology, genetics and medicine, should prevail over the respect for the human rights, fundamental freedoms and human dignity of individuals or groups of people. Practices that are contrary to human dignity, such as reproductive cloning of human beings, are not permitted.

(ii) The International Ethical Guidelines for Biomedical Research Involving Human Subjects

3. In 2002 the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), updated the International Ethical Guidelines for Biomedical Research Involving Human Subjects, which concern the application of three basic ethical principles, namely, respect for persons, beneficence and justice, to research involving human subjects[4]. Accordingly, they provide that biomedical research involving human subjects can be ethically justifiable only if it is carried out in ways that respect and protect, and are fair to, the subjects of that research and are morally acceptable within the communities in which the research is carried out[5].

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2. Unesco General Conference 29 C/Resolution 17, Unesco GC, 29th session (11 November 1997), adopted unanimously and by acclamation. See also the Guidelines for the Implementation of the Universal Declaration on the Human Genome and Human Rights annexed to 30 C/Resolution 23 (16 November 1999). These Resolutions had already been anticipated by the World Medical Association Declaration on Ethical Principles for Medical Research Involving Human Subjects, which will be dealt with later on in this opinion.

3. UN General Assembly Resolution A/RES/53/152, 9 December 1998, adopted without a vote.

4. The Council for International Organizations of Medical Sciences (CIOMS) is an international, non-governmental, non-profit organisation established jointly by the WHO and Unesco in 1949. Like those of 1982 and 1993, the 2002 CIOMS Guidelines are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects.

(iii) The International Declaration on Human Genetic Data

4. The International Declaration on Human Genetic Data was adopted by the General Conference of Unesco in October 2003[6]. The purposes of the declaration are to ensure the respect for human dignity and protection of human rights and fundamental freedoms in the collection, processing, use and storage of human genetic data, human proteomic data and of the biological samples from which they are derived, in keeping with the requirements of equality and justice. The Declaration provides that each individual has a characteristic genetic make-up. Nevertheless, a person's identity should not be reduced to his or her genetic characteristics. Human genetic data and human proteomic data may be collected, processed, used and stored only for the purposes of medical and other scientific research or any other purpose consistent with the Universal Declaration on the Human Genome and Human Rights and international human rights law.

(iv) The United Nations Declaration on Human Cloning

5. The United Nations Declaration on Human Cloning was adopted by the United Nations General Assembly in March 2005[7]. The Declaration calls upon member States to adopt all measures necessary to adequately protect human life in the application of life sciences, to prohibit all forms of human cloning in as much as they are incompatible with human dignity and the protection of human life, and to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity.

(v) The Universal Declaration on Bioethics and Human Rights

6. The Universal Declaration on Bioethics and Human Rights was adopted by acclamation by the General Conference of Unesco in October 2005[8]. The Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings. It

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5. See also the WHO publication "Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants", 2011. In 2003 the WHO had already approved the Guideline for Obtaining Informed Consent for the Procurement and Use of Human Tissues, Cells and Fluids in Research, in order to assist researchers in dealing with the ethical issues relating to how clinical research materials should be obtained, used and eventually disposed of, as well as informed consent. The guideline also applies to previously collected human biological materials stored in repositories. It provides that monetary payment or other inducement for donating embryonic tissue for research is expressly prohibited.

6. Unesco General Conference Resolution 32 C/15, Unesco GC, 32nd session (2003).

7. United Nations General Assembly Resolution 280, Fifty-ninth session (March 23, 2005), UN Doc A/RES/59/280. The declaration was passed with 84 countries voting in its favour, 34 countries voting against it, and 37 countries abstaining.

8. Unesco General Conference, 33rd session (2005).

stresses the need for scientific research to occur within the framework of ethical principles and to respect human dignity, human rights and fundamental freedoms. The interests and welfare of the individual should have priority over the sole interest of science or society. In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to affected individuals should be maximised and any possible harm to such individuals should be minimised. The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably. No individual or group should be discriminated against or stigmatised, in violation of human dignity, human rights and fundamental freedoms. The impact of life sciences on future generations, including on their genetic constitution, must be given due regard.

(vi) Opinions of the Unesco International Bioethics Committee

7. The Unesco International Bioethics Committee (IBC) outlined its position in regard to embryonic stem cells in a report entitled "The Use of Embryonic Stem Cells In Therapeutic Research: Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research", in 2001[9]. For the purposes of the report, the human embryo is examined in its early stages of development and before implantation in the uterus. If research is allowed on human embryos with the purpose of deriving embryonic stem cells, then it must be subjected to strict supervision and severe basic constraints, including full consent on the part of the donors and justification in terms of the benefit to humanity. Research for non-medical purposes would be clearly unethical, as would research which goes beyond the very early stages of embryonic development. The medical applications of the research must be well-identified therapeutic applications and not trivial or cosmetic non-medical desires, nor *a fortiori* for eugenic enhancement. Under no circumstances should human embryo donation be a commercial transaction, and steps should be taken to discourage financial incentives.

Human embryonic stem-cell research – and embryo research in general – is a matter on which each community will have to decide itself. Steps should be taken to ensure that such research be carried out within the framework of a State-sponsored regulatory system that would give due weight to ethical considerations, and set up appropriate guidelines. When authorisation of donations of supernumerary pre-implantation embryos from *in vitro* fertilisation (IVF) treatments for therapeutic embryonic stem-cell

9. Unesco International Bioethics Committee, "The Use of Embryonic Stem Cells In Therapeutic Research: Report of the IBC on the Ethical Aspects of Human Embryonic Stem Cell Research", BIO-7/00/GT-1/2(Rev.3), 6 April 2001. The IBC is a body, created in 1993 and made up of thirty-six independent experts, that follows progress in the life sciences.

research is under consideration, attention should be given to the dignity and rights of both parental donors of embryos. Thus, it is essential that the donation be made only after the donors have been given full information as to the implications of the research and have given free and informed consent. Alternative technologies for obtaining human stem-cell lines, from genetically compatible sources for therapeutic research on transplantation, should be considered. In all aspects of research involving human embryos, particular importance should be given to respect for human dignity and the principles set out in the Universal Declaration of Human Rights of 1948 and the Universal Declaration on the Human Genome and Human Rights of 1997.

8. In 2003, in its "Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention"[10], the IBC affirmed that the destruction of embryos for non-medical reasons or termination of pregnancies because of a specific gender were not "counterbalanced" by preventing subsequent suffering from a severe disease. Germ-line intervention was aimed at correcting a specific genetic abnormality in germ cells or early-stage embryos or involved the introduction of genes that may confer additional traits to the embryo. The IBC highlighted that, in regard to germ-line intervention, the distinction between "therapeutic purposes" and "enhancement of normal characteristics" was not clear. It reiterated that "germ-line interventions could be contrary to human dignity".

9. In the "Report of IBC on Human Cloning and International Governance"[11], the IBC noted that the terms "reproductive cloning" and "therapeutic cloning" introduced into bioethical debates did not adequately describe the technical procedures used. New scientific developments such as induced pluripotent stem cells opened new possibilities of research and, in the medium term, of therapeutic applications.

10. In a report entitled "Advice of the IBC on the Patentability of the Human Genome"[12], the IBC acknowledged that allowing the patenting of the human genome could inhibit research and monopolise scientific knowledge, and was of the view that there were strong ethical grounds for excluding the human genome from patentability.

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10. Unesco International Bioethics Committee, Report of the IBC on Pre-implantation Genetic Diagnosis and Germ-line Intervention, SHS-EST/02/CIB-9/2(Rev.3), 24 April 2003.

11. Unesco International Bioethics Committee, Report of IBC on Human Cloning and International Governance, SHS/EST/CIB-16/09/CONF.503/2 Rev.2, June 2009.

12. Unesco International Bioethics Committee, Advice of the IBC on the Patentability of the Human Genome, Eighth session of Unesco (IBC), Paris, 12-14 September 2001.

B. Universal professional standards

(i) The World Medical Association Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects

11. The World Medical Association approved the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data. Approved in 1964 and last amended in 2013, the Declaration provides that the primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and to improve preventive, diagnostic and therapeutic interventions. Even the best-proven interventions must be continually evaluated by further research for their safety, effectiveness, efficiency, accessibility and quality. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights. That goal can never take precedence over the rights and interests of individual research subjects. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm. They should receive specifically considered protection. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices or interventions that result from the research.

(ii) The International Society for Stem Cell Research Guidelines for the Conduct of Human Embryonic Stem Cell Research

12. The 2006 Guidelines of the International Society for Stem Cell Research are meant to emphasise the responsibility of scientists to ensure that human stem-cell research is carried out according to rigorous standards of research ethics, and to encourage uniform research practices that should be followed by all human stem-cell scientists globally. The guidelines focus on issues unique to stem-cell research that involve pre-implantation stages of human development, research on the derivation or use of human pluripotent stem-cell lines, and on the range of experiments where such cells might be incorporated into animal hosts.

All experiments pertinent to human embryonic stem-cell research that involve pre-implantation stages of human development, human embryos or embryonic cells, or that entail incorporating human totipotent or pluripotent cells into animal chimeras, must be subject to review and approval. Furthermore, all such experiments must be subjected to ongoing monitoring

by a special oversight mechanism or body. Investigators should seek approval through a process of Stem Cell Research Oversight.

Forms of research that should not be pursued because of broad international consensus that such experiments lack a compelling scientific rationale or raise strong ethical concerns include: *in vitro* culture of any post-fertilisation human embryos or organised cellular structures that might manifest human organismal potential, regardless of the derivation method, for longer than fourteen days or until formation of the primitive streak begins, whichever occurs first; research in which any products of research involving human totipotent or pluripotent cells are implanted into a human or non-human primate uterus; and research in which animal chimeras incorporating human cells, with the potential to form gametes, are bred to each other.

C. Inter-American standards

13. Article 1 of the 1948 American Declaration on the Rights and Duties of Man provides that "[e]very human being has the right to life, liberty, and the security of his person". The drafters of the American Declaration specifically rejected a proposal for the Declaration to state that the right to life starts at conception[13].

Article 4 § 1 of the 1969 American Convention on Human Rights states: "Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception." However, the Inter-American Commission on Human Rights (IACHR) has examined the preparatory works and determined that the American Convention language recognising a right to life, "in general, from the moment of conception" was not intended to confer an absolute right to life before birth[14]. In *Artavia Murillo et al.*[15], the Inter-American Court of Human Rights decided that the respondent State had based its ban on *in vitro* fertilisation on an absolute protection of the embryo that, by failing to take other competing rights into account, had involved an arbitrary and excessive interference in private and family life. In contrast, the impact on the protection of prenatal life was very slight because the risk of embryonic loss was present both in IVF and in natural pregnancy. Moreover, the interference had discriminatory effects for those persons whose only possible treatment for infertility was *in vitro* fertilisation. The Inter-American Court also concluded that the human embryo prior to

13. Resolution no. 23/81, OEA/Ser. L/V/II.54, Doc. 9 Rev. 1, § 18 (b), 6 March 1981.
14. *Baby Boy v. the United States*, Resolution No. 23/81 of the IACHR, 6 March 1981.
15. *Artavia Murillo et al. ("*in vitro *fertilization") v. Costa Rica* (preliminary objections, merits, reparations and costs), judgment of 28 November 2012, Series C No. 257, paragraphs 315-16.

implantation could not be understood to be a person for the purposes of Article 4 § 1 of the American Convention.

D. African standards

14. Article 4 of the African Charter on Human and Peoples' Rights adopted in 1981 states that "[h]uman beings are inviolable. Every human being shall be entitled to respect for his life and the integrity of his person". The drafters of the African Charter specifically rejected language protecting the right to life from the moment of conception[16].

The Organisation of African Unity, now the African Union, passed the Resolution of Bioethics in 1996[17]. The African Union supported the principles of inviolability of the human body, the genetic heritage of the human species and the non-subjection of the human body, its components, and particularly the human genes and the sequences thereof, to commercial and property rights. It pledged to supervise research facilities on embryos.

15. In 2008 the Unesco Cairo office organised an "Expert Meeting of Ethical and Legal Issues in Human Embryo Research" aimed at addressing the issue of embryonic research, in partnership with the WHO and the Islamic Educational, Scientific and Cultural Organization. The recommendations included in the final report of the meeting are "intended to fit within the distinctive religious and social cultures and values of the Eastern Mediterranean and the Arab region". The report recommends that where research and/or biological materials are allowed to be imported from other countries, care should be taken to ensure that their procurement and creation do not contradict ethical or religious values or traditions. The purpose of ethically appropriate, cost-beneficial research should be defined considering such purposes as the study of human genetics and infertility treatment. Research that a country may consider unacceptable should include reproductive cloning, germ-line therapy, and germ-line genetic manipulation. Countries should create or review provisions on issues such as the use of surplus embryos from IVF for research, research cloning, and tissue typing (HLA) of embryonic, foetal or other cells for treatment of a child already born. Countries should consider the forms of embryonic stem-cell research that require special oversight, what agency should conduct the oversight and what body should be accountable. Countries should monitor and exchange information that would reduce or eliminate the need for embryonic stem-cell research, such as the development of induced pluripotent stem cells and cell lines that are safe for use in humans.

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16. Draft African Charter on Human and Peoples' Rights, Article 17, O.A.U. Doc. CAB/LEG/67/1 (1979).
17. Resolution AHG/Res.254 (XXXII).

E. European standards

(i) The European Union standards

16. Article 3 of the Charter of Fundamental Rights states:

> "1. Everyone has the right to respect for his or her physical and mental integrity.
>
> 2. In the fields of medicine and biology, the following must be respected in particular:
>
> – the free and informed consent of the person concerned, according to the procedures laid down by law,
>
> – the prohibition of eugenic practices, in particular those aiming at the selection of persons,
>
> – the prohibition on making the human body and its parts as such a source of financial gain, the prohibition of the reproductive cloning of human beings."[18]

17. Directive 98/44/EC of 6 July 1998 of the European Parliament and of the Council on the legal protection of biotechnological inventions aims at enhancing the European Union's competitiveness in the global market, protects the intellectual property of major industries, and sustains innovative techno-scientific research, but also aims to respect the fundamental principles safeguarding the dignity and integrity of the person, while asserting the principle that "the human body, at any stage in its formation or development, including germ cells, and the simple discovery of one of its elements or one of its products, including the sequence or partial sequence of a human gene, cannot be patented".

Notwithstanding the fact that it does not provide a legal definition of the term "human embryo", the Directive lays down rules on the use of human embryos for scientific purposes, by providing that "[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation." More specifically, processes for cloning human beings, for modifying the germ-line genetic identity of human beings, and uses of human embryos for industrial or commercial purposes, among others, are not patentable. It follows that the European Union expressly considers the

18. The Commentary of the Charter, written by the EU Network of Independent Experts on Fundamental Rights, explains that Article 3 (paragraph 2) was drafted with the purpose of limiting certain practices in the fields of medicine and biology. Furthermore, it states that the four principles guaranteed therein are not exhaustive and that they should be read in line with the provisions 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 (Oviedo Convention).

use of human embryos for industrial or commercial purposes to be contrary to the minimum requirement set by respect for *ordre public* or morality[19].

18. In October 2011 the Court of Justice of the European Union (CJEU) provided further clarification on the use of human embryos for scientific purposes in *Oliver Brüstle v. Greenpeace eV* (C-34/10). Regarding the interpretation of the term "human embryo", the CJEU acknowledged that the term entailed a broad concept that "must be understood in a wide sense." On that ground the Grand Chamber of the CJEU concluded that the term was intended to refer to any human ovum as soon as it has been fertilised, since that moment was crucial to the commencement of the development of the human being. That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell had been transplanted and a non-fertilised human ovum whose division and further development had been stimulated by parthenogenesis. The Grand Chamber ruled that the use of embryos for the purpose of scientific research was not patentable. However, it recognised the patentability of the use of embryos for therapeutic or diagnostic purposes when applied to a human embryo and useful to the embryo itself. Lastly, the Court established that patentability was also excluded when the implementation of an invention required prior destruction of the human embryo or their use as base material, whatever the stage at which that took place and even if the description of the technical teaching claimed did not refer to the use of human embryos. Since the embryo enjoyed human dignity from the moment of fertilisation, it was not possible to distinguish different phases of development from the time of fertilisation that would justify a lesser degree of protection of the embryo over a certain period of time. Being an "autonomous concept of European law", the human embryo benefited from mandatory legal protection afforded by virtue of respect for its inherent human dignity, which precluded the possibility that member States of the Union would deprive the human embryo of its protection or provide a lesser degree of protection than that asserted by the crystal-clear decision of the judges of the CJEU.

19. The European Group on Ethics in Science and New Technologies to the European Commission (EGE) issued its first opinion on the use of embryonic cells for research in a report, entitled "Ethical Aspects of Research Involving the Use of Human Embryos in the Context of the Fifth Framework Program", in 1998[20]. It noted that, despite fundamental

19. See also the European Union policies on funding research and technological development cited in paragraphs 62 to 64 of the present judgment. The practice has been that projects which include research activities that destroy human embryos, including for the procurement of stem cells, are excluded.

differences in viewpoints, the common values and principles on the topic included respect for human life, relief from human suffering, the need to guarantee the quality and safety of medical treatment, freedom of research and the informed consent of the women or couples concerned. With regard to IVF treatment, the opinion acknowledged that IVF technology usually gave rise to spare embryos, and where cryopreservation was not possible, the only two options were research (leading to destruction) and destruction. As such, the Group concluded that "funding should not *a priori* exclude human embryo research which [was] the object of different ethical choices in different countries but that this funding should, nevertheless, only be granted under the strict conditions set out in the following paragraphs. ...".

20. In 2000 the EGE issued a second opinion supplementing its earlier one with a report, entitled "Ethical Aspects of Human Stem Cell Research and Use"[21]. In the context of European pluralism, it is up to each member State to forbid or authorise embryo research. In the latter case, respect for human dignity requires regulation of embryo research and the provision of guarantees against risks of arbitrary experimentation and instrumentalisation of human embryos. The creation of embryos with gametes donated for the purpose of stem-cell procurement is ethically unacceptable when spare embryos represent a ready alternative source. Remote therapeutic perspectives must be balanced against considerations related to the risks of trivialising the use of embryos and exerting pressure on women, as sources of oocytes, and increasing the possibility of their instrumentalisation. Free and informed consent is required not only from the recipient. The donor should be informed of the possible use of her embryonic cells for the specific purpose in question before requesting consent. The potential for coercive pressure should not be underestimated when there are financial incentives involved. Embryos must not be bought or sold, nor even offered for sale. Measures should be taken to prevent such commercialisation.

21. In 2002 the EGE issued an opinion regarding the patentability of human embryonic stem cells[22]. With regard to the applicability of patents, the EGE concluded that isolated stem cells which had not been modified did not, as a product, fulfil the legal requirements – especially with regard to industrial applications – to be regarded as patentable. When unmodified stem-cell lines were established, they could hardly be considered a

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20. EGE Opinion no. 12, Ethical aspects of research involving the use of human embryos in the context of the 5th framework programme, 23 November 1998. The EGE is an independent body that advises the European Commission on ethical issues in science and new technologies in connection with legislation and policy.

21. EGE Opinion no. 15, Ethical aspects of human stem cell research and use, 14 November 2000.

22. EGE Opinion no. 16, ethical aspects of patenting inventions involving human stem cells, 7 May 2002.

patentable product. To patent such unmodified stem-cell lines would also lead to patents that were too broad in scope. Only stem-cell lines which had been modified by *in vitro* treatments or genetically modified so that they had acquired characteristics for specific industrial application fulfilled the legal requirement for patentability. As to processes involving human stem cells, whatever their source, there was no specific ethical obstacle in so far as they fulfilled the three requirements of patentability.

22. In 2007 the EGE made recommendations on the ethical review of funding for research projects concerning embryonic stem cells, recognising the need to promote research, serve the public interest, promote international cooperation, respect member State autonomy and embed ethics within research initiatives[23]. The report stated that embryonic stem-cell lines had to result from non-implanted IVF embryos, and that if any alternatives to these types of stem cells should be found their use should be maximised. In addition, it stressed that donors' rights had to be protected and safeguarded in terms of health, informed consent, data protection and free donation. The EGE concluded that the use of human embryos to generate stem cells "should be minimised as much as possible in the EU".

(ii) Council of Europe standards

23. The Council of Europe first dealt with the issue of the use of human embryos for scientific purposes in Recommendation 1046 (1986) of the Parliamentary Assembly of the Council of Europe (PACE) on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes. The Assembly considered that human embryos and foetuses must be treated in all circumstances with the respect due to human dignity and that use of materials and tissues therefrom must be strictly limited and regulated to purposes which were clearly therapeutic and for which no other means existed. Consequently, it called on the governments of the member States to: limit the use of human embryos and foetuses and materials and tissues therefrom in an industrial context to purposes which were strictly therapeutic and for which no other means existed; forbid any creation of human embryos by IVF for the purposes of research during their life or after death; and forbid anything that could be considered to be an undesirable use or deviations from these techniques, including research on viable human embryos and experimentation on living human embryos, whether viable or not[24].

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23. EGE Opinion no. 22, Recommendations on the ethical review of hESC FP7 research projects, 20 June 2007.

24. The point of departure of the Assembly was that "from the moment of fertilisation of the ovule, human life develops in a continuous pattern, and that it is not possible to make a clear-cut distinction during the first phases (embryonic) of its development". In its Recommendation 874 (1979) on a European Charter on the Rights of the Child, the

PACE Recommendation 1100 (1989) on the use of human embryos and foetuses in scientific research emphasised that the human embryo, though displaying successive phases in its development, "none the less maintain[ed] a continuous biological and genetic identity". Thus, it prohibited the intentional creation and/or keeping alive of embryos or foetuses, whether *in vitro* or *in utero*, for any scientific research purpose, for instance to obtain genetic material, cells, tissues or organs therefrom.

PACE Resolution 1352 (2003) on human stem cell research emphasised that "[t]he destruction of human beings for research purposes [was] against the right to life of all humans and against the moral ban on any instrumentalisation of humans" and thus called on member States to promote stem-cell research as long as it respected the life of human beings in all states of their development[25].

24. Article 18 of the Oviedo Convention reads as follows.

> "1. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.
>
> 2. The creation of human embryos for research purposes is prohibited.[26]"

This provision affirms the application of the subsidiarity principle by establishing that the primary legal parameter to consider is the domestic law of the member State concerned. However, paragraph 1 establishes a mandatory legal status that must be secured to the embryo, which must benefit from "adequate protection". Thus, the use of embryos for scientific purposes must not be assessed on a casuistic basis, but subjected to a principled evaluation of the "adequateness" of the protection provided to the embryo, according to the European legal parameter. The drafters of the Oviedo Convention gave a clear indication to that effect in paragraph 2 of Article 18, which expressly prohibits the creation of human embryos with the aim of applying them in research, and in Article 14, which prohibits sex selection[27]. Moreover, that principled evaluation is guaranteed by the United

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Assembly had already asserted "the rights of every child to life from the moment of conception".

25. See also Resolution 1934 (2013) on ethics in science and technology.

26. The Oviedo Convention (ETS no. 164) was adopted on 4 April 1997 in Oviedo, Spain, and came into force on 1 December 1999. Hitherto it has been ratified by twenty-nine States. The Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (ETS no. 168) was adopted on 12 January 1998 and came into force on 1 March 2001. The Additional Protocol on Human Rights and Biomedicine, concerning Biomedical Research (ETS no. 195), which was adopted on 25 January 2005 and came into force on 1 September 2007, covers the full range of research activities in the health field involving interventions on human beings, including on foetuses and embryos *in vivo*.

27. It should be pointed out that Article 14 is one of the absolute provisions of the Oviedo Convention, as can be seen from Article 26 § 2.

Nations Declaration on Human Cloning, which calls upon member States to adopt all measures necessary to "adequately" protect human life in the application of life sciences.

Complementing the European Convention on Human Rights in the field of biomedicine and genetic science, the Oviedo Convention aims to establish European standards in this field[28]. Two consequences derive from this. Firstly, the European Court of Human Rights ("the Court") is the ultimate interpreter and guarantor of the rights, freedoms and obligations set out in the Oviedo Convention (Article 29 of this Convention) and hence of the "adequateness" of the protection provided to the embryo, especially vis-à-vis genetic engineering techniques contrary to human dignity. The above-mentioned problem that the distinction between "therapeutic" techniques and techniques aiming at the "enhancement of normal characteristics" is not always clear only increases the need for careful oversight by the Court.

Secondly, the ratification of the Oviedo Convention and its Protocols by a large number of States is a strong indication that a growing European consensus has been built around the provisions of this Convention and its Protocols. This consensus is strengthened by the above-mentioned Resolutions and PACE Recommendations, the Charter of Fundamental Rights of the European Union and its additional legislative and jurisprudential framework, namely, Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 and the crucial *Oliver Brüstle* judgment, which all reflect the worldwide trend of international law towards acknowledging legal protection of the human embryo. In the light of all these materials, if a margin of appreciation is to be afforded to member States of the Council of Europe on issues related to a human being's existence and identity, and particularly scientific research on the human embryo, that margin should be a narrow one[29].

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28. See paragraphs 8-20 and 165 of the Explanatory Report to the Oviedo Convention.

29. To this extent I fully share the Grand Chamber's conclusion that the Oviedo Convention is a sign of the narrowing of the Council of Europe member States' margin of appreciation (see paragraph 182 of the present judgment). In *Evans v. the United Kingdom* ([GC], no. 6339/05, ECHR 2007-I), which also concerned the fate of frozen human embryos, the parties and the Court agreed that Article 8 was applicable and that the case concerned the applicant's right to respect for her private life. According to the powerful joint dissenting opinion of Judges Türmen, Tsatsa-Nikolovska, Spielmann and Ziemele, "[a] sensitive case like this cannot be decided on a simplistic, mechanical basis, namely, that there is no consensus in Europe, therefore the Government have a wide margin of appreciation; the legislation falls within the margin of appreciation … that margin of appreciation should not prevent the Court from exercising its control, in particular in relation to the question whether a fair balance between all competing interests has been struck at the domestic level. The Court should not use the margin of appreciation principle as a merely pragmatic substitute for a thought-out approach to the problem of proper scope of review". An identical comment could be made in *Parrillo*.

Inspired by a similar clause contained in Article 53 of the European Convention on Human Rights, Article 27 of the Oviedo Convention provides for the possibility of a wider measure of protection of human life by national law. However, this should not be interpreted as affording a "broad" margin of appreciation. The two issues should not be confused, as the majority seem to do in paragraph 181 of the present judgment. It is one thing for the possibility of national legislation to provide broader protection to human life, human beings, foetuses and embryos, as provided for by Article 27 of the Oviedo Convention[30], and quite another to accept a "broad" margin of appreciation in this field, which could eventually be used, or rather, misused to enact legislation diminishing the protection of human beings, foetuses and embryos[31].

25. Consequently, a positive obligation on the State to protect the embryo and other forms of prenatal human life, both *in vitro* and *in utero*, must be derived from both Articles 2 and 8 of the Convention. This positive obligation includes: firstly, the obligation to promote the natural development of embryos; secondly, the obligation to promote scientific research for the benefit of the individual embryo subject to it; thirdly, the obligation to define the exceptional cases where embryos and embryonic stem lines may be used and how; and, fourthly, the obligation to punish under criminal law the use of embryos outside the lawful exceptions.

26. Some argue that this is an evolving domain and that the Court should therefore not compromise itself by establishing any definitive scientific position that might change in the future. This is a double-edged argument. It can serve to limit the Court's interference with the State's margin of appreciation, but it can also be used to expand the Court's oversight of the State's interference with unborn life. Precisely because this domain may evolve in a manner seriously dangerous to humankind, as we have seen in the past, attentive scrutiny of the States' narrow margin of appreciation, and

30. See paragraphs 161 to 162 of the Explanatory Report to the Oviedo Convention. In the case of a conflict between the freedom of research and the protection due to embryos, States parties may go beyond the mandatory "adequate" protection due to the latter, and adopt more prohibitive policies.

31. It is worthwhile pointing out that PACE Recommendation 934 (1982) on genetic engineering had already called for States "to provide for explicit recognition in the European Convention on Human Rights of the right to a genetic inheritance which has not been artificially interfered with, except in accordance with certain principles which are recognised as being fully compatible with respect for human rights (as, for example, in the field of therapeutic applications)". In fact, the Convention is not indifferent to the creation and instrumentalisation of embryos for scientific experimentation, the creation of hybrids or human cloning. These are essential questions pertaining to the protection of what ontologically can be defined as a form of human life, and are certainly within the remit of the Convention. I do not see how we can accept a wide margin of appreciation under the Convention if a Contracting Party wants, for example, to pursue a eugenic or racist pre-natal policy.

potentially preventive intervention by this Court, is an absolute requirement today. Otherwise the Court would be giving up the most basic of its tasks, namely protecting human beings from any form of instrumentalisation.

III. The position of the parties

A. Purposeless nature of the legal restriction in Italy

27. The applicant considers that donating "her" five cryopreserved embryos that are not destined for implantation pertains to her "private life" within the meaning of Article 8 of the Convention and fulfils a public interest, since it provides researchers with stem cells much needed for research on incurable diseases[32]. On the basis of the above-mentioned interpretation of Article 8 of the Convention, in conjunction with Article 18 of the Oviedo Convention, the Government's argument that section 13 of Law no. 40 of 19 February 2004 pursues the legitimate aim of protecting the embryo's potential for life is acceptable. In that light, scientific research on a human embryo, authorised for therapeutic and diagnostic purposes with the aim of protecting the health and development of that embryo when no alternative methods exist, is an admissible exception to the prohibition of scientific research on human embryos.

28. To the applicant's argument that the death of the five cryopreserved embryos is inevitable under Italy's current legal framework, since implantation of embryos *post mortem* is prohibited, as is their donation for scientific research, the Government rightly reply that cryopreservation is of unlimited duration. Frozen embryos can be stored indefinitely. Furthermore, the use of cryopreserved embryos for non-destructive purposes, such as heterologous fertilisation, is now possible in the Italian legal order, in view of the Italian Constitutional Court's judgment no. 162 of 2014.

B. Contradictory nature of the applicable Italian legal framework

29. To the applicant's argument that the Italian legal framework, which allows for the importation and use of stem-cell lines from previously destroyed human embryos, is inconsistent, the Government convincingly reply that the production of embryonic cell lines abroad is not carried out at the request of the Italian laboratories and is not incompatible with the

32. The applicant's position is in fact contradictory because she also claims that she has a property right over her embryos. It is unacceptable to invoke at the same time a right to property and a right to privacy with regard to the human embryos "owned". Unless the implication was that using and disposing of human beings – in the instant case human embryos – would be a form of maintaining a relationship with them.

prohibition in Italy of such destruction. Lastly, in abortion cases the mother's interests have to be weighed against those of the foetus under Italian law, which was not the case here.

C. Non-prohibitive European consensus

30. To the applicant's European consensus argument, the Government oppose their wide margin of appreciation, denying the existence of such a consensus on the basis of the fact that the Oviedo Convention does not require destructive scientific research on embryos, the European Union funding programme for scientific research does not provide for funding of projects involving the destruction of embryos and the *Oliver Brüstle* judgment (cited above) prohibited the patentability of inventions involving the destruction of human embryos. As argued above, the international materials referred to by the Government support the contention of a narrow margin of appreciation, precisely with a view to protecting the embryo.

IV. The position of the majority

31. The majority's reasoning is both contradictory in terms of logic and scientifically inadmissible. It is contradictory in terms of logic because they admit, on the one hand, that the embryo is an "other" for the purposes of Article 8 § 2 of the Convention, since the protection of the embryo's potential for life may be linked to the aim of protecting the "rights and freedoms of others" (see paragraph 167 of the present judgment)[33]. On the

33. This is not a new statement of principle by the Court, as can be seen from paragraph 59 of *Costa and Pavan v. Italy* (no. 54270/10, 28 August 2012). In the very exceptional human circumstances of that case, I voted for the *Costa and Pavan* findings and naturally I subscribe to the principle stated in paragraph 59. But I must also clarify today that it was not the intention of the Second Chamber to create a new Convention right to become the parent of a healthy child and therefore an unfettered negative "right to self-determination" consisting in disposing of non-implanted embryos. Neither explicitly nor implicitly was such a right established in that judgment. The judgment was determined by the principle of necessity, in so far as the test of the less intrusive measure envisages minimal impairment of the competing interests by asking whether there is an equally effective but less intrusive means available to further the same social need. In doing so, the Court also acknowledged the relevance of the precautionary principle in assessing interventions in the medical sphere, which aims at avoiding more severe interventions in favour of less severe ones at all stages of human life (on the precautionary principle in the Italian legal order, see the opinion of the *Comitato nazionale per la bioetica* (Italian National Bioethics Committee), entitled "Precautionary principle: bioethical philosophical and legal aspects", of 8 June 2004). Although paragraph 65 of *Costa and Pavan* uses the word "right", this unfortunate *maladresse de plume* should not be taken literally, since the same judgment also refers, in paragraph 57, to the parents' "desire" to have a healthy child. The circumstances of *Costa*

other hand, however, the same majority affirm that this acknowledgment does not involve any assessment by the Court as to whether the word "others" extends to human embryos. The patent logical contradiction between the two statements is so obvious that it is irremediable. The only possible reading of this contradiction is that the majority were so divided that they could not decide whether the statement of principle in paragraph 59 of *Costa and Pavan* should prevail over the opposite statement of principle in paragraph 228 of *A, B and C v. Ireland* ([GC], no. 25579/05, ECHR 2010). With some effort, one could argue that the order of the statements is indicative of a certain prevalence of the former over the latter.

In this context, it is crucially important to note that the Grand Chamber did not cite paragraph 56 from *Evans* (cited above) in which the Court had stated that "the embryos created by the applicant and J. [did] not have a right to life within the meaning of Article 2 of the Convention", nor the Chamber judgment in that case (*Evans v. the United Kingdom*, no. 6339/05, § 46, 7 March 2006), nor even the classic statement of principle in *Vo v. France* ([GC], no. 53924/00, § 82, ECHR 2004-VIII). This omission is noteworthy. Not only does it reflect the Grand Chamber's uneasiness with the *Evans* anti-life principle, but it furthermore consolidates the opposite principle set out in paragraph 59 of *Costa and Pavan* that the embryo is an "other", a subject with a legal status that could and should be weighed against the legal status of the progenitors, which is absolutely in line with the position of the Italian Constitutional Court on the embryo's right to life protected by Article 2 of the Italian Constitution[34].

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and Pavan are in no way similar to the present case, and can certainly not be used to ground an unfettered "negative right" to decide the fate of non-implanted embryos.

34. See the clear reasoning of judgment no. 27 of 18 February 1975 (*Ritiene la Corte che la tutela del concepito - che già viene in rilievo nel diritto civile (artt. 320, 339, 687 c.c.) - abbia fondamento costituzionale. L'art. 31, secondo comma, della Costituzione impone espressamente la "protezione della maternità" e, più in generale, l'art. 2 Cost. riconosce e garantisce i diritti inviolabili dell'uomo, fra i quali non può non collocarsi, sia pure con le particolari caratteristiche sue proprie, la situazione giuridica del concepito*) and judgment no. 35 of 30 January 1997 (*il diritto alla vita, inteso nella sua estensione più lata, sia da iscriversi tra i diritti inviolabili, e cioè tra quei diritti che occupano nell'ordinamento una posizione, per dir così, privilegiata, in quanto appartengono - per usare l'espressione della sentenza n. 1146 del 1988 – "all'essenza dei valori supremi sui quali si fonda la Costituzione italiana"*), and the opinions of the *Comitato nazionale per la bioetica* (Italian National Bioethics Committee) of: 22 June 1996 (Identity and status of the human embryo); 27 October 2000 (Therapeutic use of stem cells); 11 April 2003 (Research using human embryos and stem cells); 16 July 2004 (The use for research purposes of H1 and H9 cell lines deriving from human embryos); 15 July 2005 (Bioethical considerations concerning the so-called "ootid"); 18 November 2005 (Adoption for birth of cryopreserved embryos deriving from medically assisted procreation); 26 October 2007 (The fate of embryos resulting from medically assisted procreation and not complying with the conditions for implantation); and 26 June 2009 (Chimeras and hybrids, with special attention to cytoplasmic hybrids).

32. For that same reason, I also cannot accept the interpretation of the right of self-determination to found a family, referred to by the Italian Constitutional Court in judgment no. 162 of 10 June 2014, in such a way as to include a "negative right" consisting in the disposing of non-implanted embryos. The reasoning in paragraph 157 of the present judgment is thus based on a rhetorical "fallacy of the undistributed middle", according to which the majority assume that because they share a common property two separate categories are connected. In other words, in interpreting judgment no. 162, the majority assume that because the right to become a parent is an aspect of a person's private life, as is the right to have IVF treatment, both of these rights are unfettered in so far as they are rights to "self-determination", thus forgetting that the exercise of "self-determination" of the progenitors in the latter case may impinge upon the existence of another human life: that of the non-implanted embryo. As the Italian Constitutional Court itself said in that judgment, "*[l]a libertà e volontarietà dell'atto che consente di diventare genitori e di formare una famiglia nel senso sopra precisato, di sicuro non implica che la libertà in esame possa esplicarsi senza limiti*" (the freedom and voluntariness of the act which permits a person to become a parent and form a family within the meaning defined above certainly does not mean that the freedom in question can be interpreted as having no limits). In sum, the Constitutional Court's reasoning in judgment no. 162 does not lend support to an unlimited "right to self-determination" or "freedom of choice of parties to IVF regarding the fate of embryos not destined for implantation". It is wrong to interpret the Constitutional Court's reasoning in favour of "adoption for birth" – that is, in favour of the embryo's life – as allowing parties to IVF to destroy the resulting embryos.

33. The majority's reasoning is also scientifically inadmissible because it accepts that "the embryos contain the genetic material of the person in question and accordingly represent a constituent part of that person's genetic material and biological identity" (see paragraph 158 of the present judgment). The majority clearly overlook the fact that the embryo is a different biological identity from the person who has undergone IVF, although the embryo does contain that person's genetic material. The statement in paragraph 158 is unacceptable, both in ontological and biological terms. The majority forget that human dignity makes it imperative to respect "the uniqueness and diversity" of each human being, as the Universal Declaration on the Human Genome and Human Rights puts it. In other words, every human being is far more than a unique combination of genetic information that is transmitted by his or her progenitors.

34. The lack of clarity in the majority's reasoning is also reflected in the definition of the applicable margin of appreciation theory. In paragraph 169 of the present judgment, they acknowledge that the margin allowed to States is "restricted" in issues related to "an individual's existence or identity", but

they also accept that "where the case raises sensitive moral or ethical issues", the margin will be wider. Again, this makes no sense to me. Issues related to the individual's existence or identity, namely to the beginning and end of human life, are *per se* heavily influenced by ethical and moral considerations. I would even go so far as to say that most of the human rights contained in the Convention and its Protocols are intrinsically attached to ethical and moral questions that have been the subject of debate for many years. Thus, the intrinsically moral or ethical nature of a legal issue under the scrutiny of the Court should not be a factor limiting the latter's competence or determining the margin of appreciation to be afforded to States. The argument regarding the sensitive ethical or moral nature of the issue at stake is hence irrelevant in establishing the width of the margin of appreciation[35].

35. To this, the majority add, in paragraph 174 of the present judgment, that the applicant's relationship with "her" embryos "does not concern a particularly important aspect of the applicant's existence and identity". Once more, the majority contradict themselves. In paragraph 158, they say that the embryos represent a "constituent part" of the genetic material of the applicant and of her biological identity, but in paragraph 174, they contradict that statement and conclude that the protection of a "constituent part" of the applicant's biological identity is not one of the core rights of Article 8. It is beyond my understanding that the majority can, in their own logic, maintain that the core rights of Article 8 do not include the protection of a "constituent part" of the applicant's identity.

36. Having accepted that the margin of appreciation was not unlimited, the majority promise an analysis of the "arguments to which the legislature has had regard in reaching the solutions it has retained" (see paragraph 183 of the present judgment). Unfortunately, no such analysis was done. In the subsequent paragraphs the majority merely address, and then superficially, the procedure for domestic approval of the impugned legislation, referring to the "discussions that had taken account of the different scientific and ethical opinions and questions on the subject" (see paragraph 184), to a parliamentary report on the various contributions of "doctors, specialists and associations working in the field of assisted reproduction" (see paragraph 185), to some criticisms made during the debate of 19 January 2004 (see paragraph 186), and to several referendums on the legislation (see paragraph 187). The conclusion that "during the drafting process of the Law in question the legislature had already taken account of the different

35. Hence I cannot accept the reasoning in paragraphs 176 and 180 of the present judgment, which, while referring to *Evans* (cited above), *S.H. and Others v. Austria* (cited above) and *Knecht v. Romania*, no. 10048/10, 2 October 2012, concludes that "the ethical and moral questions inherent in the concept of the beginning of human life" are indicative of a "broad margin of discretion".

interests at stake" (see paragraph 188) is disappointing. It adds nothing to the substantive assessment of the question at stake.

37. After devoting nine paragraphs to the width of the margin of appreciation (see paragraphs 174-82) and six paragraphs to the domestic procedure for approving the Law (see paragraphs 183-88), the judgment finally addresses, in paragraphs 189 to 195, the core of the applicant's arguments, namely, the alleged contradictions in the Italian legal framework. Here the majority clearly align themselves with the Government. Without delving into much detail, the important statements made in paragraphs 193 to 194 are nevertheless a clear signal to the Contracting Parties that the Court does not oppose the policy of importing and using stem-cell lines obtained from human embryos destroyed outside the European legal space, as long as they are not produced at the request of the Contracting Parties.

V. Application of the Court's standards

38. The inadequacy of the majority's reasoning should not detract from the essential point. In spite of the hesitations and contradictions in the majority's reasoning, they reiterated the *Costa and Pavan* principle that embryos are "others" for the purposes of the Convention and, in the light of this principle, accepted that their protection justified the prohibition of human embryo research and embryonic stem cell research subject to two exceptions:

(a) scientific research on a human embryo is permissible if it has therapeutic and diagnostic purposes with the aim of protecting the health and development of the embryo and no alternative methods exist;

(b) embryonic stem-cell research is permissible on condition that it is performed exclusively with stem-cell lines obtained from human embryos destroyed outside the European legal space without any intervention of the Contracting Parties.

39. Since the embryo is not a thing or a "possession", as the Court rightly states in paragraph 215 of the present judgment, it is an "other" with whom the person who has undergone IVF has a potential parental relationship. In so far as the embryo has a unique biological identity, but shares genetic material with the progenitors, the private nature of the relationship between these human beings is unquestionable. This is why Article 8 comes into play[36].

40. For the majority, the Italian legislation does not overstep the wide margin of appreciation of the respondent State (see paragraph 197 of the present judgment). To my mind, the first exception does not go beyond the

36. The same conclusion can be drawn from *S.H. and Others v. Austria*, cited above, § 82.

narrow limits of the State's margin of appreciation in issues related to the existence and identity of human beings. Moreover, it is also in line with the aim of the Oviedo Convention, which must be perceived today as complementing the European Convention on Human Rights in the field of biomedicine and genetic science. In spite of the fact that the Italian State has not yet ratified the Oviedo Convention, it has complied with its concern to protect human life, human beings, foetuses and embryos, the Convention's protection of the embryo as an "other", a subject with a legal status, the Universal Declaration on the Human Genome and Human Rights prohibition of discrimination based on genetic characteristics and the overarching principle in the Declaration of Helsinki that medical research on a vulnerable group is only justified if the research responds to their health needs or priorities, which – at its deepest level – cannot but encompass the most vulnerable members of all humanity: embryos.

41. The situation is more delicate in the case of the second exception. In view of the intention of the Grand Chamber to guarantee the "right" of the embryo as an "other" throughout the European legal space, and having regard to the basic principles of legal reasoning, that exception must be interpreted narrowly. The second exception entails, logically, three consequences. Firstly, a Contracting Party to the Convention cannot use, nor permit the use in its territory of cell lines obtained from embryos destroyed outside the European legal space at that Party's initiative. Secondly, a Contracting Party cannot use, nor permit the use in its territory of cell lines obtained from embryos destroyed in the territory of another Contracting Party. Thirdly, a Contracting Party cannot use, nor permit the use in its territory of cell lines obtained from embryos destroyed outside the European legal space at the initiative of another Contracting Party.

42. Only this strict interpretation of the second exception will safeguard its application in the context of Article 8 § 2 of the Convention. Otherwise, the use, or permission of use, in a Contracting Party's territory of cell lines obtained from embryos destroyed outside the European legal space at the initiative of that Party or any other Party to the Convention would allow the outsourcing of the Convention violation. Furthermore, the use or permission of use in a Contracting Party's territory of cell lines obtained from embryos destroyed in the territory of another Contracting Party would render the former complicit in the latter's violation of the Convention. Neither of these situations is tolerable in the light of the rules governing the international responsibility of the States read in conjunction with the Contracting Parties' Convention obligations[37].

37. Article 16 of the 2001 Draft Articles on Responsibility of States for Internationally Wrongful Acts could be relied on here.

VI. Conclusion

43. Unborn human life is no different in essence from born life. Human embryos must be treated in all circumstances with the respect due to human dignity. Scientific research applications concerning the human genome, in particular in the field of genetics, do not prevail over the respect for human dignity. Scientific progress must not be built upon disrespect for ontological human nature. The scientific goal of saving human lives does not justify means that are intrinsically destructive of that life.

The beginning and end of human life are not questions of policy subject to the discretion of the member States of the Council of Europe. The "adequacy" of the protection provided to the embryo by the Contracting Parties to the Convention is subject to close scrutiny by the Court, since States have a narrow margin of appreciation with regard to fundamental issues related to the human being's existence and identity. In Europe, an insurmountable limit to our possibilities of experimenting with human life is established by the Convention. Thus, it is incompatible with the Convention to produce or use living human embryos for the preparation of embryonic stem cells, or to produce cloned human embryos and then destroy them in order to produce embryonic stem cells. In the European legal space, scientific research on human embryos and embryonic stem-cell lines is allowed only in the two exceptional cases referred to above.

CONCURRING OPINION OF JUDGE DEDOV

1. The Court has not found a violation of Article 8 of the Convention. Whilst I agree with this conclusion, I believe that this case could have been much more valuable for the Court's case-law regarding the beginning of life.

2. The Court noted that the present case, unlike previous cases, did not concern the applicant's choice to become a parent, and that this weakened her position. The Court analysed the competing interests, namely, the State's wide margin of appreciation regarding the protection of embryos and the applicant's right to self-determination.

3. The Government raised the issue of the "embryo's potential for life" in support of the legitimacy of the aim of the interference. Such an important aim, which cannot be reduced to a question of the margin of appreciation, presumes that the embryo's existence is a condition for a human being's development. Since the right to life is at stake, it completely changes the judicial approach in accordance with the Court's role in interpreting the Convention, including the positive obligation of the State to safeguard the beginning of life.

4. The principle of respect for the embryo's right to life means that the judicial decision cannot be limited by reference to the margin of appreciation. Otherwise, the Court would also have to find no violation in the opposite situation: where an applicant opposed the donation of embryos to scientists, which may be permitted, or not prohibited, by a State.

5. In my view, the embryo's right to life is a key criterion for reaching the right decision. I am sure that if this criterion had been applied, many previous cases, such as *Evans v. the United Kingdom* ([GC], no. 6339/05, ECHR 2007-I), *Vo v. France* ([GC], no. 53924/00, ECHR 2004-VIII) and *S.H. and Others v. Austria* ([GC], no. 57813/00, ECHR 2011), would have been decided in favour of the applicants, who indeed wanted to become parents and, as a result, save the embryo's life.

6. There are plenty of sources to support this view. They have been submitted to the Court by the third parties and European institutions. These sources include, *inter alia*, the Communication from the European Commission on the European Citizens' Initiative "One of us" COM(2014) 355 final (Brussels, 28 May 2014), the Grand Chamber judgment of the Court of Justice of the European Union of 18 October 2011, C-34/10 *Oliver Brüstle v. Greenpeace eV*, and Regulation 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020). In particular, Parliamentary Assembly of the Council of Europe (PACE) Recommendation 874 (1979) on a European Charter on the Rights of the Child asserted "[t]he rights of every child to life from the moment of conception". I regret that I cannot agree with the conclusion of the Inter-

American Court of Human Rights in *Artavia Murillo et al. (*in vitro *fertilization) v. Costa Rica* (preliminary objections, merits, reparations and costs), judgment of 28 November 2012, Series C No. 257 that "conception" occurs only after implantation of the embryo in the uterus. From the point of view of humanity, I prefer the Government's view that, for the sake of preservation of the embryo's potential, it is vital to implant it if another woman would like to become a mother by that method.

7. I ought also to mention PACE Resolution 1352 (2003) on human stem cell research, which is even more specific: "[t]he destruction of human beings for research purposes is against the right to life of all humans ..." (see paragraph 10 of the Resolution). Moreover, thanks to the European Citizens' Initiative "One of Us", the embryo's right to life has been expressly acknowledged by millions of European citizens, and the initiative was supported by the EU governing bodies. Nevertheless, the Court is still silent on the subject. That ambiguity, which has continued from case to case, ultimately affected the applicant and her legal representatives, who were not sure which Article of the Convention should be applied in the present case, or which right should be protected: the right to private life or the property right.

8. I am not convinced that the margin of appreciation or the lack of consensus should prevent the Court from reaching such a conclusion. Since the right to life is absolute, and is one of the fundamental rights, neither the margin of appreciation nor sovereignty nor consensus is a relevant factor. A margin of appreciation is required only to determine which measures are necessary to protect a fundamental value (for example, public expenditure or a time-limit on the cryopreservation of embryos). The embryo's life cannot be sacrificed for the purpose of inter-State competition in biomedicine.

9. The right to life is absolute, and this fundamental tenet makes it unnecessary to explain why a murderer, a disabled person, an abandoned child or an embryo should be kept alive. We do not need to evaluate their usefulness for society, but we remain hopeful regarding their potential. The embryo's right to life cannot be called into question by the fact that, until implantation, its potential for development is something that can be maintained artificially, because any such new technology is a natural development created by human beings.

10. Even though the right to life is absolute, one might reflect on the consequences of this approach, and I would like to express some thoughts on this. Firstly, the applicant's right to self-determination would not be affected if the embryo were donated to another woman anonymously. Secondly, research would be directed (and is already being directed) in another way with a view to reprogramming adult cells into stem cells or to recombining the DNA, if necessary, in particular to cultivate a new organ for a diseased person from his or her own stem cells.

11. The impugned decision of the Government to maintain the embryo's life is not an extraordinary measure. The same approach is adopted in any other society which already spends public funds on supporting disabled persons or others who cannot take care of themselves. Moreover, since sperm and egg banks exist, it would not be a problem to create a bank of embryos (gametes). Ultimately, a donation – in the present case an automatic donation which some may regard as interference – is ethically acceptable if it is necessary to save a person's life.

12. The absolute nature of the right to life reconciles any ethical, moral, religious, scientific, social or other opinions. The one single ethical issue I would recognise in the development of biomedicine is the maternity/paternity issue in the context of donorship. As explained by the Government, the only means of maintaining the embryo's potential is to implant the embryo in the uterus of another woman (unable to conceive) who would like to have a child. In such a situation the applicant's status as a donor should be recognised automatically. The legal status of donor resolves ethical problems, as motherhood, in terms of family relations, differs from the mere similarity of genetic material. In *S.H. and Others v. Austria*, cited above, the Court found no violation of the applicants' rights by the respondent State as a result of the prohibition of donations of reproductive material from third persons other than either of the parents of the future child. In the opposite situation, such as in the present case, the Court has again found no violation. This has happened because the relevant principles (right to life) were not applied by the Court, and the *S.H. and Others v. Austria* case was therefore unfortunate. The present judgment makes the outcome of future cases relating to biomedicine unpredictable.

13. The role of the Court is to determine fundamental values and prevailing interests in order to examine each particular case on its merits. Accordingly, the Court cannot but conclude that the right to life as one of the fundamental rights and freedoms is at stake in the present case.

14. Since new biotechnology objectively expands our perception of the forms and conditions of human existence, I am not aware of any objective obstacles to the legal recognition of this achievement, as soon as possible, as it is well known that any delay in such recognition at national and international level is potentially life-threatening and arbitrary.

JOINT PARTLY CONCURRING OPINION OF JUDGES CASADEVALL, RAIMONDI, BERRO, NICOLAOU AND DEDOV

(Translation)

1. We do not entirely share the reasoning of the Grand Chamber regarding the rejection of the objection raised by the Government on the ground of non-exhaustion of domestic remedies.

2. We had initially been satisfied by the Government's analysis. In their submission, while it was true that the question of constitutionality could only be raised by the court and not by the parties – whose power was limited to requesting the court to exercise that option – and was therefore not a remedy that *in principle* had to be used for the purposes of Article 35 of the Convention, that was not true in the light of the precedent established by the famous "twin" judgments of the Constitutional Court nos. 348 and 349 of 24 October 2007, which concerned the eventuality of a conflict between Italian legislation and the Convention as interpreted by the Court.

3. The Government pointed out – correctly in our opinion – that if the lower court had considered that there was an insurmountable conflict between its interpretation of the legislation and the rights asserted by the claimant it would have had to raise a question of constitutionality. The Constitutional Court would then have examined the issue of compatibility with human rights on the merits and would have been able to set aside the domestic provisions with retroactive and *erga omnes* effect.

4. According to the precedent deriving from these two judgments of 2007, the ordinary courts now have two alternatives when examining the question of compatibility of domestic law with the Convention. Either they succeed, with all the technical means available to them, in construing domestic law in a manner compliant with the Convention as interpreted by the Court, or they *must* refer the question to the Constitutional Court, which will then set the relevant domestic legal provision aside unless it finds that there is a conflict between the Convention and the Constitution. This is an alternative in the strict sense of the term (*tertium non datur*).

5. In this context the Court's traditional case-law, cited in paragraph 101 of the present judgment, should not apply in the present case. According to that case-law, based on the lack of direct access by litigants to the Italian Constitutional Court in accordance with the rule that only a court hearing the merits of a case has the possibility of referring a question to the Constitutional Court (at the request of a party or of its own motion), that request cannot be regarded as a remedy that has to be used in order to comply with the Convention requirements.

6. However, where a potential applicant challenges the compatibility of domestic legislation with the Convention we are no longer in the classic

situation where the ordinary courts alone are master of the decision whether or not to apply to the Constitutional Court. In those circumstances, which are those of the present case, the traditional case-law is no longer relevant. If the ordinary court is placed by a potential applicant in the position of having to assess the compatibility of a domestic law with the Convention, it may of course interpret the domestic law in a manner compliant with the Convention. However, if it does not succeed in doing so it will have no choice: it will *have to* refer the question – provided of course that it is relevant for the outcome of the dispute – to the Constitutional Court.

7. In that situation, a potential applicant who has not obtained from the lower court an interpretation of the domestic legislation in a manner compliant with the Convention *has the right* to have the matter adjudicated by the Constitutional Court, with one proviso that we will examine below and is applicable in the present case.

8. Our only reason for ultimately deciding to join the majority decision rejecting that objection in the present case is the development that has occurred in the Italian Constitutional Court's case-law in the form of judgment no. 49, deposited on 26 March 2015. In that judgment the Constitutional Court analysed, *inter alia*, the place of the Convention and the Court's case-law in the domestic legal order, indicating in that regard that the ordinary courts were only bound to comply with the Court's case-law where it was "well established" or expressed in a "pilot judgment". Where a new question arises, as is undeniably the case here, the position adopted by the Constitutional Court means that a potential applicant cannot be deemed to be obliged to apply to the domestic courts before lodging an application with the Court.

9. That said, we observe that the reasoning of the present judgment – from which we must, partially, depart for the reasons outlined above – refers to judgment no. 49/2015 of the Italian Constitutional Court (see paragraph 100 of the present judgment) and that this reference gives the judgment an eclectic flavour. We see an opening here with regard to the traditional case-law.

10. The weight given to that decision in the reasoning of the present judgment paves the way, in our opinion, towards a departure from the Court's traditional case-law – within the limits permitted by the precedent of the Italian Constitutional Court of course – which may lead it to consider that even where legislation is directly at the root of the alleged violation a potential applicant must *in principle* first apply to the domestic courts in so far as the very substance of the precedent established in Constitutional Court judgments nos. 348 and 349 delivered in 2007, and attenuated by judgment no. 49 delivered by that court in 2015, is not called into question.

JOINT PARTLY DISSENTING OPINION OF JUDGES CASADEVALL, ZIEMELE, POWER-FORDE, DE GAETANO AND YUDKIVSKA

1. The applicant alleges that the prohibition under Italian law on donating embryos conceived through medically assisted reproduction to scientific research is incompatible with her right to respect for private life. The Court has ruled that her ability to exercise a conscious and considered choice regarding "the fate of her embryos" concerns an intimate aspect of her personal life and, accordingly, relates to her right to "self-determination" (see paragraph 159 of the present judgment). On this basis, it concludes that Article 8 of the Convention is applicable. It proceeds to find no violation because, *inter alia*, the ban was "necessary in a democratic society" to protect the rights and freedoms of others within the meaning of Article 8 § 2 of the Convention.

2. Whilst we have voted for no violation of Article 8 of the Convention, there is a significant difference between our reason for so doing and the reasons outlined in the present judgment. We part company with the majority long before it reaches its assessment of the proportionality of the prohibition in question. We consider that the applicant's complaint is incompatible *ratione materiae* with the provisions of the Convention in accordance with Article 35 §§ 3 and 4 thereof.

3. To date, both the former Commission and the Court have considered many sensitive cases which have posed fundamental questions concerning either potential, early, embryonic or foetal human life and/or its interconnection with the personal rights of others[1]. Whilst the Court has found that matters related to procreation – and, in particular, to the decision of becoming or not becoming a parent – constitute an aspect of a person's private life[2], it has refrained from pronouncing on the fundamental question as to when "protected life" under the Convention begins. It has, therefore, avoided making any ruling on the status of the human embryo, as such.

4. As the judgment confirms, the applicant, in reality, has asserted the right "***to make use of embryos***" (see paragraph 149 of the present judgment) or, to put it another way, the right "***to decide the fate***" of embryos (see paragraph 152) which were created through *in vitro* fertilisation. The Court has now ruled, for the first time, that such matters as "*deciding the fate of*"

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1. See, for example, *Vo v. France* [GC], no. 53924/00, § 75 and 80, ECHR 2004-VIII; *Evans v. the United Kingdom* [GC], no. 6339/05, ECHR 2007-I; *Dickson v. the United Kingdom* [GC], no. 44362/04, ECHR 2007-V; *Brüggemann and Scheuten v. Germany*, no. 6959/75, Commission's report of 12 July 1977, Decisions and Reports (DR) 10, p. 100; *H. v. Norway*, no. 17004/90, Commission decision of 19 May 1992, DR 73, p. 155.

2. See, for example, *Dickson,* cited above, *Evans*, cited above, and *S.H. and Others v. Austria* [GC], no. 57813/00, ECHR 2011.

or "*making use of*" human embryos fall within an individual's right to respect for *private life* (see paragraph 152). Accordingly, the present judgment marks a critical turning point in the Court's jurisprudence. It makes a far-reaching and, in our view, unacceptable pronouncement on the status of the human embryo.

5. The majority's finding is disconcerting not only in terms of the utilitarian overtones used when speaking of the human embryo but also because of the disturbing rationale that forms the basis of its pronouncement. The majority's reason for finding that a choice concerning "the fate of the embryo" falls within the scope of the applicant's private life is "*the link existing between the person who has undergone* in vitro *fertilisation and the embryos thus conceived*". This link, the majority assert, is due to the fact that "***the embryos*** *contain the genetic material of the person in question and accordingly* ***represent a constituent part of that person's*** *genetic material and biological* ***identity***" (see paragraph 158 of the present judgment) (emphasis added).

6. To find that the embryo is "a constituent part" of the applicant's identity is a far-reaching finding indeed. Unlike the majority, we do not consider that embryos can be reduced to constituent parts of anyone else's identity – biological or otherwise. Whilst sharing the genetic make-up of its biological "parents", an embryo is, at the same time, a separate and distinct entity albeit at the very earliest stages of human development. If a human embryo is no more than a constituent part of another person's identity then why the abundance of international reports, recommendations, conventions and protocols that relate to its protection? These instruments reflect the broad general acceptance within the human community that embryos are more than simply "things". They are, as the Parliamentary Assembly of the Council of Europe has put it (in paragraph 10 of Recommendation 1046 (1986)), entities that "*must be treated in all circumstances with the respect due to human dignity*" (see part III, Council of Europe documents, section A, of the present judgment).

7. In adopting the approach it has taken in this case, the Court has endorsed a positivist and reductionist view of the human embryo. It has classified it as "*a constituent part*" of another person's genetic material and biological identity and has thus decided that its fate and the "use" to which it may be put is a matter that falls within that other person's right to respect for private life. Embryos, like all other human entities, inevitably, share the genetic DNA of their biological "parents". The mere sharing of genetic material is an unsafe and arbitrary basis for determining that the fate of one human entity falls within the scope of another person's right to self-determination.

8. Regrettably, the muddled reasoning of the majority that is evident on the question of admissibility persists when it comes to the merits (see paragraph 167 of the present judgment). In assessing the proportionality of

the ban in question the Court considers that it may be linked to the aim of protecting "the rights and freedoms of others", but this, the majority quickly asserts, does not involve any assessment as to whether the word "others" extends to human embryos!

9. In our view, and consistent with the Court's case-law to date, it would have been preferable to find that since prospective parenthood is not an issue in this case, the applicant's right to "*self*-determination" as an aspect of her private life simply does not arise. Her submission that the donation of embryos would confer upon her a certain "noble feeling" is noted, but the Convention, of course, is concerned exclusively with the protection of fundamental human rights rather than with the fostering of feelings of one kind or another. Her asserted right to "*make use of the embryos*" for scientific research is not a right within the scope of Article 8 of the Convention. Accordingly, in our view, this part of the application should have been rejected as incompatible *ratione materiae* with the provisions of the Convention, in accordance with Article 35 §§ 3 and 4 thereof.

PARTLY DISSENTING OPINION OF JUDGE NICOLAOU

1. In my opinion, the application should have been dismissed as having been lodged out of time.

2. Article 35 § 1 provides that the Court may only deal with a matter if it is brought before it within a period of six months from the date on which the final decision is taken. The starting point is not always apparent, however. It may be that it is not marked by a decision or is otherwise unclear. Continuing situations in which Convention rights are infringed may present particular difficulty as to when time begins to run. Our case-law provides guidance on how to approach such cases. In *Varnava and Others v. Turkey* ([GC], nos. 16064/90 and 8 others, §§ 159 and 161, ECHR 2009), it was stated in general terms that the time-limit does not apply to continuing situations. That is not quite accurate for, as subsequently explained in that judgment, in such situations the ongoing breach simply means a renewal of the start of the period each day, so the time-limit does in principle apply. When continuing situations cease, time begins to run uninterrupted for the whole six-month period. The difficulty in some cases lies in ascertaining the moment in time at which the situation has come to an end. As pointed out in *Varnava* (cited above, § 161), not all continuing situations are the same since the nature of the situation may be such that the passage of time affects what is at stake. It may, therefore, be necessary to examine how a situation has developed in order to assess the significance of events or the prospects of achieving a solution and to judge what would be reasonable by way of a starting point in the particular circumstances of the case. The Court takes a broad and practical view of such matters.

3. The majority take the view that the present case is one of a continuing situation of an unlimited duration, co-extensive with the existence of Law no. 40 of 19 February 2004, which came into force on 10 March 2004. My own view is that the applicant was not entitled to wait *ad infinitum* before seeking redress.

4. The facts presented by the applicant are sketchy. Sometime in 2002 five embryos, which were obtained as a result of *in vitro* fertilisation treatment of the applicant and her partner, were placed in cryopreservation for the purpose of implantation at a future time. Before the end of the following year the applicant's partner was killed in Iraq while reporting on the war. After that, at an unspecified time, the applicant decided not to have the embryos implanted. Subsequently, she made a number of unsuccessful oral requests that the embryos be released for use in scientific research. The number of requests and the times at which they were made have not been specified. It can be assumed that they were all made after Law no. 40 had come into force, for previously there had been no impediment to donating the embryos, for whatever purpose. Furthermore, it remains unexplained why the applicant did not bring the matter to Strasbourg earlier, namely,

soon after the new Law came into force, and instead waited for more than seven years before doing so.

5. It must have been clear to the applicant that under the new Law her requests could not be granted. This Law provides, in so far as relevant, as follows.

Section 13 – Experiments on human embryos

"(1) It is forbidden to experiment on a human embryo.

(2) Clinical and experimental research on a human embryo shall be authorised only on condition that it is performed exclusively for therapeutic or diagnostic purposes with the aim of protecting the health and development of the embryo and that no alternative methods exist."

6. Under section 13(5) of that Law, infringement of the prohibition entails severe sanctions, including imprisonment for up to six years.

7. There are of course instances where legislative provisions do indeed give rise to a continuing interference with the exercise of Convention rights under either Article 8 or Article 14 taken together with Article 8, of a kind that is not attenuated and does not cease over time unless the cause is removed. The majority cite *Dudgeon v. the United Kingdom*, 22 October 1981, § 41, Series A no. 45; *Norris v. Ireland*, 26 October 1988, § 38, Series A no. 142; *Vallianatos and Others v. Greece* [GC], nos. 29381/09 and 32684/09, § 54, 7 November 2013; and *S.A.S. v .France* [GC], no. 43835/11, § 110, ECHR 2014, and these are not the only cases on the subject. The majority acknowledge that in those cases the effect of the impugned legislation on the daily lives of the complainants "was more substantial and more direct than in the present case" (see paragraph 111 of the present judgment). They do not, however, attach importance to a difference which I, for my part, consider crucially important. In those cases the legislative provisions complained of had, in one way or another, a tremendous practical impact on the daily lives of the complainants, with decisive and far-reaching effects on how they conducted themselves and organised their affairs. There are no such issues in the present case. The majority content themselves merely with the fact that there is a "biological link between the applicant and her embryos and the plan to start a family that was at the origin of their creation" (ibid.), notwithstanding that, in regard to the second proposition, the plan to start a family by using the embryos was abandoned early on and has not been a live issue in the case. They conclude that the prohibition in question "does undeniably have an impact on the applicant's private life" (ibid.).

8. In the admissibility decision on the six-month time-limit (see *Parrillo v. Italy* (dec.), no. 43028/05, 3 November 2015), the majority go no further than I have already stated. Admissibility is premised on the view, which I do not share, that the new Law has an unending impact on the applicant's life. Subsequently, however, in the present judgment, the majority explain

what they see as the particular nature, and therefore force, of that impact. Paragraphs 158 and 159 read as follows:

> "158. In the instant case the Court must also have regard to the link existing between the person who has undergone *in vitro* fertilisation and the embryos thus conceived, which link is due to the fact that the embryos contain the genetic material of the person in question and accordingly represent a constituent part of that person's genetic material and biological identity.
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> 159. The Court concludes that the applicant's ability to exercise a conscious and considered choice regarding the fate of her embryos concerns an intimate aspect of her personal life and accordingly relates to her right to self-determination. Article 8 of the Convention, from the standpoint of the right to respect for private life, is therefore applicable in the present case."

9. I find myself at a considerable distance from the majority's position that the matter in question relates to the applicant's right to self-determination.

In fact it seems to me, with very great respect, that later on the majority also distance themselves from that initial position. It is interesting to note in this regard that when dealing with the specifics of the case the majority say, at paragraph 174 of the present judgment, that

> "... the instant case does not concern prospective parenthood. Accordingly, while it is of course important, the right invoked by the applicant to donate embryos to scientific research is not one of the core rights attracting the protection of Article 8 of the Convention, as it does not concern a particularly important aspect of the applicant's existence and identity."

10. I agree with that. Further down, at paragraph 192, the majority observe that

> "... while the right asserted by the applicant to decide the fate of her embryos relates to her wish to contribute to scientific research, that cannot however be seen as a circumstance directly affecting the applicant."

11. Again, I agree. Unlike in the relevant cases cited above, where reliance was placed on the fact that the applicants were directly affected by the impugned legislation, in the present case the applicant was not directly affected. What she contemplated doing – namely, donating the embryos for research – did not directly affect her in her private life. I fail to understand why the majority, examining the applicant's arguments in the light of the various aspects of the new Law, could not conclude from the very beginning, as they do in paragraph 195, that whatever inconsistencies may or may not be found in the new Law, "... these are not capable of directly affecting the right invoked by her in the instant case".

12. This conclusion is entirely in line with what I have already explained as the determinative difference between the present case and the above-cited judgments in *Dudgeon*, *Norris*, *Vallianatos and Others* and *S.A.S. v. France*.

13. My own opinion that the application should have been declared inadmissible for exceeding the time-limit is based on what I consider to be the rather tenuous nature of the link between the applicant and the frozen embryos. It seems to me that although there is indeed a meaningful link, since the embryos emanated from the genetic material of the applicant and her partner, and this link brings the matter within the ambit of Article 8, it does so only at the periphery and amounts to no more than the possibility, on the part of the applicant, of expressing a wish concerning their fate. On receiving a negative response, and as there was no adequate domestic remedy to be exhausted, the limitation period should have started running at that point for the purpose of subjecting the relevant legislative restriction to review under the Convention.

14. Having regard to the position set out above, it cannot be said that that aspect of Article 8 gives the applicant a right which lasts for an indefinite period of time. The new Law came into force about four months after her circumstances had dramatically changed and, if the six-month time-limit is added onto that, one would be tempted to think there was enough time for her to decide whether she wished to have a say in the matter. It is also possible, however, to approach the question more broadly and, on the basis of a continuing situation created by the new Law, examine what may have been a reasonable time frame within which a person in the applicant's position, in the sad circumstances in which she found herself, could have sufficiently reflected and acted. What I certainly cannot accept is that the applicant was entitled to unlimited time for setting in motion the Strasbourg machinery of human rights protection.

DISSENTING OPINION OF JUDGE SAJÓ

To my regret, I cannot share the views expressed by the majority. I therefore respectfully dissent, for the reasons explained below.

Applicability of Article 8 of the Convention to the present case

Error! Bookmark not defined.. In the present case the Court concludes that "the applicant's ability to exercise a conscious and considered choice regarding the fate of her embryos concerns an intimate aspect of her personal life and accordingly relates to her right to self-determination" (see paragraph 159 of the present judgment). I could not agree more, except to say that this not only "relates" to the right of self-determination but is an exercise of that right, which is the crux of the right to private life. The applicant's right to self-determination reflects her right to personal autonomy and freedom of choice (see *S.H. and Others v. Austria* [GC], no. 57813/00, § 80, ECHR 2011; *McDonald v. the United Kingdom*, no. 4241/12, §§ 46-47, 20 May 2014; and *Pretty v. the United Kingdom*, no. 2346/02, § 61, ECHR 2002-III). Here, the applicant's choice (a right) was to donate her embryos to the advancement of life-saving science rather than allow them to lose viability over time[1]. The nature of the right at stake in this case is the applicant's freedom of choice. This case is not about the rights of parenthood or even the possible rights of a foetus; the applicant's right here is to act as a free and autonomous individual with regard to her genetic footprint.

2. According to the Court's case-law, "[t]he Court's task is not to review the relevant law and practice *in abstracto*, but to determine whether the manner in which they affected the applicant gave rise to a violation of the Convention" (see *N.C. v. Italy* [GC], no. 24952/94, § 56, ECHR 2002-X). The issue is not the use of embryos in research as regulated by Italian law but the way the general measure affected embryos which had been created and cryopreserved before any restriction was in force. This case is about a very specific situation: what happens when legislation intervenes and impedes the exercise of that pre-existing right in regard to pre-existing embryos? The embryo would have the potential to develop into a human being, but this remains merely a potential as it cannot happen without the consent of the donor(s), as discussed in *Evans v. the United Kingdom* [GC], no. 6339/05, ECHR 2007-I.

1. This does not imply that the cells at issue are a part of her "biological identity" as the judgment describes it, but rather that the applicant has a right to primary control over her genetic footprint.

The applicant decided not to give her consent. Certainly, a law which required the applicant to use the embryos herself would violate her right to determine whether or not to become a parent. A law which required the applicant to allow her embryos to be "adopted" by a third party would likewise violate her fundamental right not to be compelled into parenthood[2]. There is only one option left under Italian law: indefinite cryopreservation of the non-implanted embryos[3].

3. I do not consider that the applicant's "right to choose" (as a matter of self-determination) is "a particularly important facet of an individual's existence or identity" (see pargraph 169 of the present judgment). While the point is debatable, I accept that there is no European consensus[4] concerning the fate of cryopreserved embryos and will not discuss whether the experience of seven or four countries is sufficient to draw that conclusion (although the comparative data provided by the Court do not reflect the practice of the countries in regard to embryos that had been created for reproductive purposes before the imposition of a ban on research, and only a few countries prohibit all research on embryonic stem cells). It follows that the State has a wide margin of appreciation to restrict the right.

Whether there has been an "interference" "<u>in accordance with the law</u>"

4. The Court acknowledges that there has been an interference with the applicant's right to private life under Article 8. However, it is important to emphasise that at the time that the applicant chose to undergo *in vitro*

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2. See *Evans*, cited above. Of course *Evans* is only partially relevant to this case, as the applicant's rights in the present case do not involve parenthood.

3. Although the applicant is not currently paying for the storage of these embryos, according to her, there is no legal provision which would prevent the medical storage service from charging her. The Government have not contested that submission.

4. It will remain a mystery to me why the *lack* of a European consensus on the existence of a right is so often interpreted <u>against</u> the existence of a right, where such a right can be deduced from the autonomous concept of a Convention right, for example also in the light of international-law developments and social realities. If the exercise of a freedom has been found to be permissible in at least some countries, then this should create a presumption in <u>favour</u> of that Convention right if this is otherwise compatible with a reasonable interpretation of the meaning and scope of the right. This does not of course rule out the possibility that there may be good reasons in another country for restricting that right. Or are we saying that the recognition of the broader scope of a right in a number of countries is arbitrary and irrelevant?
With its controversial margin of appreciation doctrine, as it is understood by the Court, the State is exempted from the duty to provide a substantive justification for the existence of an imperative need to interfere. Reference to the lack of European consensus as a decisive indicator of the absence of a certain meaning or scope of a Convention right disregards the Preamble to the Convention, which refers to the "further realisation of human rights" as one of the methods for pursuing the aim of the Convention.

fertilisation (IVF), there was no law in place in Italy regarding the fate of surplus embryos. As the Grand Chamber has already held, the phrase "in accordance with the law" requires that "domestic law must be sufficiently foreseeable in its terms to give individuals an adequate indication as to the circumstances in which and the conditions on which the authorities are entitled to resort to measures affecting their rights under the Convention" (see *Fernández Martínez v. Spain* [GC], no. 56030/07, § 117, ECHR 2014). The applicant was facing a situation in which she had no real choice but to see her embryos being stored in cryopreservation indefinitely by the State. This had not been foreseeable when she chose to undergo IVF. She could not possibly have known that she would have only four months after the death of her partner to decide what to do with the embryos before that decision was removed from her control by the new legislation. It is noteworthy that the law does not contain any specific rule as to the fate of embryos which were being cryopreserved before the entry into force of that law.

The legitimacy of the aim pursued

5. In the present case the Government have not provided any clear reasons for the aims of the interference. These aims were reconstructed (with some effort) by the Court and then accepted by it. In the absence of any justification by the Government for the aim of the interference, the majority supply two possible justifications: the protection of morals and the protection of the rights of others. As to the protection of morals, the Court does not provide information about public morals in Italy, where the impugned practice was legal for many years[5]. The Government did not refer to the protection of morals and the Court does not explain where the moral interest lies; nor does it take into consideration any specific moral interest in the proportionality analysis.

6. As to the rights of others, "[t]he Court acknowledges that the 'protection of the embryo's potential for life' may be linked to the aim of protecting morals and the rights and freedoms of others" (see paragraph 167 of the present judgment)[6]. Who are these others? Is the embryo "another",

5. Of course this is not the duty of the Court. It is the Government who should know and explain what the aim of the legislation is. At least during the last stage of the debate the proponents of the law expressly denied that the law served some kind of moral purpose. Giuseppe Fioroni, Member of Parliament, stated that the law did not serve Catholic morals, but natural law (19 January 2004).
http://legxiv.camera.it/_dati/leg14/lavori/stenografici/framedinam.asp?sedpag=sed408/s000r.htm

6. The Court draws on the Government's written submissions under Article 1 of Protocol No. 1, whose applicability in this case has been rejected. It was only in the oral address that

that is, a person? There is no answer, except that the embryo is described in Law no. 40/2004 as a "subject" having rights. That they do not fall under the category of possessions does not transform embryos into human beings or rights-holders[7]. The fact that there is a State interest in protecting potential life cannot be equated with a right of a person.

7. The Court finds that a right of others is present because "the potential for life" may be linked to that alleged right. I hope I am mistaken, but I fear that we face a risk here of loosening the standard applicable to the list of permissible aims for the restriction of rights. So far, the Court has consistently held that the list of exceptions to the individual's Convention rights is exhaustive and that their definition is restrictive (see, among other authorities, *Svyato-Mykhaylivska Parafiya v. Ukraine*, no. 77703/01, § 132, 14 June 2007, and *Nolan and K. v. Russia*, no. 2512/04, § 73, 12 February 2009). This is essential to any serious protection of rights. Unfortunately, in *S.A.S. v. France* [GC], no. 43835/11, § 113, ECHR 2014, it was held that "to be compatible with the Convention, a limitation of this freedom must, in particular, pursue an aim that can be linked to one of those listed in [Article 9 § 2 of the Convention]. The same approach applies in respect of Article 8 of the Convention." From the position that there "can be a link" to those exhaustively listed exceptions, we now move to the position where a link may exist if this is not ruled out as unreasonably speculative ("there may be", rather than "there can be" a link).

Failure to undertake a serious scrutiny of a State's purported aim in imposing the restriction will undermine the potential for rights to be protected from any proportionality analysis. The scrutiny of the aim of a measure is part of the supervisory role of the Court (see *Handyside v. the United Kingdom*, 7 December 1976, § 49, Series A no. 24). If we wish to apply the margin of appreciation doctrine, we could say that in matters of economic policy there is little scope for such an analysis, given the cognitive advantage the national legislation or national authorities enjoy or that, "[b]ecause of their direct knowledge of their society and its needs, the national authorities are in principle better placed than the international judge to appreciate what is 'in the public interest'" (see *James and Others v. the United Kingdom,* 21 February 1986, § 46, Series A no. 98). This reasoning cannot be applied without additional and convincing reasons to areas where

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a submission was made that the law served to protect the "embryo's potential for life," but this was not made in the context of Article 8, § 2 of the Convention.

7. Organs, for example, are not treated as pure possessions, but that does not confer on them the status of "human being". The legal status of biological material is not obvious and must be clarified before any assumptions can be made about rights.

In Italian legal theory a "subject" is a point of reference for legal relations, not a person. All persons are subjects but not all subjects are persons ("*Ogni persona è soggetto, non ogni soggetto è persona*"), Cass., 24 July 1989, no. 3498, in *Foro it*., 1990, I, c. 1617.

the issue is not the general "public interest" in economic or social policies but morals, health policy or science[8].

8. The judgment accepts, without further reflection, the strength of the State's interest in banning all uses of IVF embryos apart from implantation. However, in *S.A.S. v. France* (cited above) it is noted that "the Court's practice is to be quite succinct when it verifies the existence of a legitimate aim within the meaning of the second paragraphs of Articles 8 to 11 of the Convention" (ibid., § 114). Nevertheless, the Grand Chamber went on to explain in *S.A.S. v. France* (ibid.) that, particularly when the Government's objectives are subject to dispute, (as is the case in the present context, see paragraphs 135-37 of the present judgment), the Court will undertake a thorough examination of the link between the measure and the objective. In the present case, the link was taken for granted without any enquiry being made of, or justification sought from, the Government.

Necessary in a democratic society

9. The Court has affirmed that, even where there is a broad margin of appreciation under Article 8, the Government must still adduce "relevant and sufficient reasons" justifying the interference (see *Zaieţ v. Romania*, no. 44958/05, § 50, 24 March 2015; *Hanzelkovi v. the Czech Republic*, no. 43643/10, § 72, 11 December 2014; *Winterstein and Others v. France*, no. 27013/07, § 147, 17 October 2013; and *S. and Marper v. the United Kingdom* [GC], nos. 30562/04 and 30566/04, § 101, ECHR 2008)[9]. Regarding general measures that interfere with a right under Article 8, the Court has held as follows: "First, the Court may assess the substantive merits of the Government's decision, to ensure that it is compatible with Article 8. Secondly, it may scrutinise the decision-making process to ensure that due weight has been accorded to the interests of the individual" (see *Hatton and Others v. the United Kingdom* [GC], no. 36022/97, § 99, ECHR 2003-VIII).

10. A measure of interference that serves the above aim is a general one. The Court has held that in order to determine the proportionality of a general measure, the Court must primarily assess the legislative choices underlying it (see *James and Others*, cited above, § 36). The quality of the parliamentary and judicial review of the necessity of the measure is of particular importance in this respect, including to the operation of the relevant margin of appreciation (see *Animal Defenders International v. the United Kingdom* [GC], no. 48876/08, § 108, ECHR 2013).

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8. *James and Others* (cited above) granted only a "certain margin of appreciation", which over the years has "developed" into a "wide" margin of appreciation.

9. See also the case-law cited in paragraph 168 of the present judgment.

11. The legislative history of Law no. 40/2004 indicates that for decades the matter was not regulated in Italy owing to ongoing disagreement in society and among professional experts. The divisions continued during years of parliamentary debate. Opponents of the proposed ban[10] claimed that it reflected a specific ideological conviction, while its supporters claimed that it served the protection of life and the family, and was a solution that followed natural law, not the dictates of the Catholic religion. The divisions continued right up to the final debate[11].

12. The Government failed to provide evidence of a thorough parliamentary discussion of the fate of embryos already in cryopreservation at the time of entry into force of the new Law[12]. Moreover, the Law was enacted by a majority, amidst serious disagreement[13]. The Italian parliamentary debate therefore differed from that considered in *Animal Defenders International*, cited above, where, among other things, there was cross-party support in Parliament. There is also no evidence that the applicant's rights or personal situation were taken into account; the Law contains a blanket ban that deprives the applicant of her right to freedom of choice. Contrary to the situation in *Animal Defenders International*, there could not be a domestic proportionality analysis in her case. Not only does this general ban disregard the applicant's right to self-determination with respect to an important private decision, it does so in an absolute and unforeseeable manner. The Law contains no transitional rules which would have enabled the proper authority to take into consideration the specific situation of the applicant, whose embryos obtained from the IVF treatment were placed in cryopreservation in 2002 and whose husband passed away in 2003, four months before the Law came into force.

13. In contrast to the clearly articulated moral interest presented by the applicant, and the strong social interest in the scientific research at stake, which lends considerable weight to the otherwise "not particularly

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10. Key provisions of the law had already been found to be unconstitutional or in violation of the Convention (see paragraphs 27-39 of the present judgment, and *Costa and Pavan v. Italy* (no. 54270/10, 28 August 2012)).

11. "*Tutti (sia il rapporto Warnock sia gli scienziati che hanno partecipato alle varie audizioni di Camera e Senato) hanno dichiarato: sì, è vita, però...*" "All (both the Warnock Report and the scientists who participated in the different hearings of the Chamber and the Senate) have declared: yes, life, but…", Deputy Maria Burani Procaccini, in defence of the Draft (19 January 2004) http://legxiv.camera.it/_dati/leg14/lavori/stenografici/framedinam.asp?sedpag=sed408/s000r.htm.

12. The Law did not in any way envisage what would happen to pre-existing surplus embryos. It was only the National Bioethics Committee that decided *ex post facto* (18 November 2005), on uncertain legal grounds, that adoption for birth was permissible (see paragraphs 19-20 of the present judgment).

13. 25% of the electorate participated in the invalid referendum on the Law in 2005, with 88% in favour of a partial repeal.

important right" of the applicant, the majority simply observe that the Italian legislature carried out a thorough examination of this issue prior to drafting Law no. 40/2004 (see paragraph 184 of the present judgment). As mentioned above, the conditions required in that regard established in *Hatton and Others* and *Animal Defenders International* (both cited above) are not satisfied. In the absence of clear reasons arising from the parliamentary debate, it is only when the Government provide sufficient clarity that the Court can properly inquire into why the blanket ban on donation is necessary when weighed against the applicant's personal choice. The Court's citation from the preparatory works does not explain why a ban on donation is necessary for Italy's purported moral preference in favour of embryos in the circumstances of the present case. Since the Government cannot force a person to use her embryos to create a human being without her consent, a blanket ban on all other life-promoting uses (such as medical research) is not only overly restrictive of the individual's freedom of self-determination, it also disregards the constitutional values recognised in Article 33 of the Italian Constitution[14] and the value system of the Convention, which recognises the interest of Article 10 in scientific research (see *Mustafa Erdoğan and Others v. Turkey*, nos. 346/04 and 39779/04, §§ 40-41, 27 May 2014). More importantly, the protection of life cannot be relied on, not only because the meaning and weight of that argument remain contested in regard to the applicant's embryos but also because those embryos, notwithstanding their potential for life, have no chance of becoming human beings. As to embryos in general in Italy, the duty to protect the potential of the non-viable embryo cannot exist in absolute form in Italian law given that even a viable foetus can be aborted[15].

14. The applicant in this case faced an impossible and unforeseeable choice. At best, the choices open to her were to use the embryos herself, or allow another couple to use them, or to let her biological material languish indefinitely until such (unknown and unknowable) time as the embryos lost viability or could be used for a procreative purpose contrary to her clearly expressed wishes.

15. Given the applicant's age, it would not be possible for her to use all five embryos herself. Additionally, according to expert testimony presented at the hearing before the Court and not contested by the Government, in

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14. "The Republic guarantees freedom of the arts and sciences, which may be freely taught." The Government did not provide evidence that the constitutional values of science were put in the balance in Parliament, and only made submissions about the use of pluripotent cells in research.

15. Commentators were quick to point out the internal inconsistencies in the Law. See *Carlo Casonato, Legge 40 e principio di non contraddizione: una valutazione d'impatto normativo. Collana Quaderni del Dipartimento di Scienze Giuridiche dell'Università di Trento,* vol. no. 47, Università di Trento, 2005.

practice, her embryos could not now be used by another couple because of the age of the embryos and because they were not subjected to the proper tests at the time of their creation. Therefore, these embryos will not in fact be used to create a human life because they will never be implanted into a uterus[16]. This medical reality is not contested by the Government.

16. Most importantly, the applicant has made a clear choice not to allow her embryos to be used for procreation.

17. The applicant's interest in donating her embryos to scientific research, rather than allowing them to remain unused, is a deeply personal and moral decision. This choice is driven by her desire to honour her late partner and to further invaluable medical research with the potential to save lives[17]. According to expert testimony presented at the hearing (and to many other international medical and scientific sources), research deriving from embryonic stem cells is currently being used in clinical trials for spinal cord injuries, Parkinson's disease and other diseases that are currently incurable or difficult to cure. Countries which allow such research have developed sophisticated forms of informed consent and controls to ensure that the embryos are used in ethical ways[18]. Such research uses the pluripotent (undifferentiated) cells created through the IVF procedure to develop a greater understanding of human development and discover new ways of treating diseases that have been devastating and incurable for many people around the world[19]. The cells created through IVF are unique and valuable biological material, which the applicant wishes to put to use, rather than leave to lose viability as they remain frozen indefinitely.

18. Whether or not the Government's desire to protect the potential for life outweighs the applicant's interest in using her own genetic material to contribute to life-saving science is a question that cannot be dismissed out of hand. The judgment in this case lacks any sort of proportionality analysis and does not consider the important third-party interest in the health benefits arising from scientific discovery. By simply stating that there is no European consensus on whether embryos left over from IVF procedures should be used in scientific research, the Court departs from its well-established standards. There is of course a margin of appreciation regarding this issue, but that does not mean that the law may operate in whatever

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16. Perhaps, then, the Government expect that humanity will develop the scientific ability to grow a human being from an *in vitro* embryo without the use of a uterus?

17. A choice that is at least as closely linked to the preservation and protection of life as that of the current legislation.

18. See the Stanford Medical School report at: http://med.stanford.edu/news/all-news/2011/04/new-approach-to-ivf-embryo-donations-lets-people-weigh-decision.html.

19. See, for example, the testimony of Professor de Luca in *Patient Handbook on Stem Cell Therapies*, published by the International Society for Stem Cell Research: www.closerlookatstemcells.org/docs/default-source/patient-resources/patient-handbook---english.pdf; and National Institutes of Health: www.nih.gov.

manner a government sees fit. The measure must still be proportionate to the interference with the applicant's rights.

19. In order for an interference to be proportionate the Government must provide legitimate (relevant and sufficient) reasons. Even assuming, in view of *Evans* (cited above, § 81), that there is a wide margin of appreciation in IVF cases, "since the use of IVF treatment gives rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments"[20], the interference still cannot be arbitrary. In Italy both abortion and research on foreign stem-cell lines are permitted. The Law disregards the interest in preventing actual human suffering through scientific research in the name of the protection of a potential for life which, moreover, cannot ever materialise in the circumstances of the case. I cannot see why preponderant weight is attached to the potential for life when Italian law does allow the abortion of a viable foetus, and in the particular circumstances of the present case, that potential cannot materialise, in the absence of the consent of the applicant. This attitude and the related explanation are not only inconsistent but plainly irrational and as such cannot be sufficient justification for the proportionality of the measure.

20. I do not think that fast-moving science and technology is of relevance here, unless science will one day enable the production of babies outside the uterus and outside the human body, and there will be a moral consensus that in such cases the embryo has the right to become a homunculus (ectogenesis), irrespective of the wish of the donors. I cannot imagine that such considerations are applicable in the present case, notwithstanding the efforts to create an artificial womb.