

# THE “CURIOUS CASE” OF ITALIAN LAW No. 40 OF 2004: HOW THE DIALOGUE BETWEEN JUDGES IS MODIFYING THE LEGISLATION ON MEDICALLY-ASSISTED REPRODUCTION

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## ARTICLE INFO

### ABSTRACT

Italian Law no. 40 concerning medically-assisted reproduction was approved on 19 March 2004.

Italy is among the last of the European countries to regulate a matter which has been considered in the legislation of other countries since the 80s of the last century.

Although Law no. 40 has not been modified by the Italian Parliament during the subsequent twelve years, it has been deeply amended by at least 28 judgements issued by Italian courts (the Constitutional Court, as well as the civil, penal and administrative tribunals) and by the European Court of Human Rights, which have progressively dismantled the original text with respect to the following issues: access to assisted reproduction, preimplantation analysis, heterologous fertilisation, etc.

The national and supranational courts have established a very interesting juridical dialogue, which has made Law no. 40 more consistent with the Italian Constitution, as well as with the Convention of Rome, the freedom of movement, and other principles established by the European Union.

The cases addressing Law 40 of 2004 are quite impressive due to the absence of the necessary balance between the different interests in the Italian law-making process, as well as the failure to verify the consistency of the Italian law with supranational principles.

However, this case of Italian law is only an exemplification of how the dialogue among the courts produces the development and application of European law, and how such a dialogue may impact domestic legislation, especially laws regarding very sensitive and delicate issues.

### KEYWORDS

Biolaw. European Law. Impact of supranational law on domestic legislation. Legal status of Human embryos. Medically assisted procreation.

## 1. LAW 40 OF 2004 ON MEDICALLY-ASSISTED REPRODUCTION

On 19 March 2004, the Italian Parliament approved Law no. 40 concerning medically-assisted reproduction<sup>3</sup>.

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<sup>3</sup> Among the early commentaries about Law n. 40 see: RUSCELLO, 2004; CASINI *et al.*, 2004; BELLELLI, 2004; CARAPEZZA FIGLIA, 2004; BALESTRA, 2004; POCAR, 2004; ALPA, 2004; RIVA, 2004.

In pursuance of Article 7 of the Law, the Ministry of Health issued “Guidelines” (Ministerial Decree of 21 July 2004) aimed at implementing several legislative dispositions.

Italy is among the last European countries to regulate a matter that has been addressed in the legislation of other countries since the 80s of the last century<sup>4</sup>: Norway approved a specific law in 1987; the Spanish law concerning the “*Técnicas de reproducción asistida*” was enacted in 1988, as was the Swedish law; Germany approved its *Embryonenschutzgesetz* in 1990; the Austrian legislation related to in vitro fecundation was enacted in 1992; in 1994, France approved law 94, which was devoted to “*don et à l'utilisation des éléments et produits du corps humain, à l'assistance médicale à la procréation et au diagnostic prénatal*”, alongside other legal texts regulating other ethical aspects.

Law no. 40 was strongly promoted by the political majority of that period, which had the open support of the Catholic Church hierarchies; similar to other occasions, they intervened in this civil political debate, although to a greater extent (VALENTINI, 2003; MAGISTER, 2003; SAVI, 2006).

In addition to the political opposition, the legal doctrine promptly criticised the ideological approach of the law (see for example: SESTA, 2004; DOGLIOTTI & FIGONE, 2004), as well as its inconsistency with Constitutional principles during the period immediately subsequent to its passage (MANETTI, 2004; CELOTTO, 2004; POCAR, 2004).

Compared to the legislation of the ‘70s and ‘80s relevant to family matters, which was characterised by the non-interference of the State in people’s personal sphere (see the reform of family law no. 151/1975; law on abortion; law on divorce, etc.), Law 40 represented a strong change of direction (ANGELINI, 2015).

However, the critics were not able to galvanise public opinion. As matter of fact, a subsequent attempt to abrogate the law through a referendum failed because less than the half of the electors voted (according to Article 77 of the Italian Constitution, a referendum is valid only if the majority of electors exercise their right to vote).

Nevertheless, Law 40/2004 produced a true “reproductive tourism” which, according to studies on the phenomenon, has interested between 3500-4500 Italians each year<sup>5</sup>. The freedom of circulation within the European Union allows easy access to medical reproduction techniques available in other European countries.

As a matter of fact, Law 40 contains several disputed dispositions.

Article 1, para. 1 solemnly requires the protection of all “persons” involved in procreation, including the human embryo.

The access to medically-assisted procreation was allowed only for married or stable heterosexual couples who were sterile (Article 5), and only if it were not otherwise possible to remove the impediment to natural procreation (Article 4, para. 1).

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<sup>4</sup> Although since the end of 1950, draft laws on the subject had been submitted. In any case, until the adoption of Law 40/2004, the matter had been regulated in circulars from the Minister of Health (now Health), such as that of 1 March 1985. On the process leading to the approval of Law 40/2004, see CASINI *et al.* (2004).

<sup>5</sup> With respect to the year 2010, see the survey in SHENFIELD *et al.* (2010). In any case, the flow of Italian couples who have gone to other European countries appears to have been constant over the last 10 years. See the reports published at <http://www.osservatorioturismoprocreativo.it/>.

However, Article 4, para. 3, Law no. 40/2004 prohibited access to heterologous techniques for procreation: Only the gametes of the couple were available for the assisted procreation.

With respect to the operations leading to the medical fecundation, two rules were particularly relevant: first, the prohibition of any pre-implant analysis of the embryo, and secondly, the obligation of the physician to provide the “single and contemporary implant of the embryos at the maximum of three”, according to Article 14, para. 2, Law no. 40/2004.

The conservation of the embryos was permitted only in the case of force majeure due to the woman’s health condition and was not allowed beyond the time needed for the implant (Article 14, paras. 1 and 2). On the other hand, the law establishes nothing about the destiny of the embryos when no implantation occurs, and it does not regulate the use of embryos that were produced before the law came into force.

Once requested, the intervention of assisted procreation might be refused based on the will of either of the applicants, but only up to the moment of the fertilisation of the egg (Article 6, para. 3).

To comply with the principle of the respect for embryos, the Italian legislation, in Article 13, prohibits any embryonal experimentation (para. 1), only permitting clinical and experimental research for therapeutic and diagnostic purposes, and only if there are no alternative methods (para. 2). These prohibitions are supported by criminal sanctions (para. 4).

According to Article 8 of Law 40, children who were born following the application of the fecundation technique are considered to be sons/daughters of the persons requiring the assisted procreation. Such a provision could also be applied in cases involving the violation of Law 40, such as, for example, heterologous procreation. As a matter of fact, the donor of a gamete who is external to the couple is not entitled to claim paternity or maternity of the child born from the fecundation (see Article 9).

Although during the subsequent years, Law no. 40 has not been modified by the Italian Parliament, its application has changed dramatically due to non-legislative interventions.

As the subsequent paragraphs will demonstrate, the Italian legislation concerning artificial reproduction seems to have experienced the same destiny as the main character of F. Scott Fitzgerald’s story, Mr. Benjamin Button: Law no. 40/2004 was already old when it was born (from a legal point view) and has experienced rejuvenation (losing its wrinkles) over the years, until it has virtually disappeared.

The process of “rewriting” (D’AVACK, 2010) Italian legislation is not dependent on a mysterious force, as was the case for Mr. Button; rather, it has occurred through the interpretations of judges and the case-law of the Constitutional and European Courts.

As matter of fact, at least 28 judgements during the twelve years after the law came into force have deeply modified the Italian legislation on medically-assisted reproduction.

The present paper tries to describe how it was possible to modify legislation concerning such a sensitive field without any intervention by the law-making power.

## 2. PRE-IMPLANTATION ANALYSIS AND THE PRINCIPLE OF PROPORTIONALITY

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A first important change was made regarding the prohibition of an analysis of the embryo before its implantation in the uterus<sup>6</sup>.

As mentioned above, in order to respect the embryos, the law prohibited their destruction before the implantation.

However, as highlighted by the early commentaries (RUSCELLO, 2004) and by the case-law<sup>7</sup>, an abortion (Law 194/1977) could occur after the implantation of the embryo to interrupt the pregnancy based on disease or malformation.

The disposition has been examined by the European Court of Human Rights.

The Court of Strasbourg held that Article 8 ECHR recognises the right to become or not to become a parent<sup>8</sup>, as well as to access the techniques of medically-assisted procreation<sup>9</sup>.

Meanwhile, European judges consider the use of in vitro fertilisation treatments to be a sensitive moral and ethical issue, and thus, they have allowed the member States to have a wide margin of discretion (see *X, Y and Z v. the United Kingdom*, cited above, § 44); however, the same Court does not exclude its own power to control compliance with the principles of the European Convention, such as proportionality and the need for legislators to take into consideration, as “necessary in a democratic society”, the evolution of science and changes within society.

Decisions concerning the techniques available for medically-assisted procreation are included in the legitimate margin of discretion of each State, as recently stated by the Court in *S.H. v. Austria*. This may be resolved with different approaches, particularly as it is a matter involving sensitive moral and ethical questions (see *S.H. et al. v. Austria*, par. 61).

In particular, in the past, the European Court of Human Rights has underlined the absence of homogeneity in the solutions adopted by the State members of the Convention<sup>10</sup>.

However, the Court has noted the obligation of the States to respect other principles, such as the principle of proportionality (see *S.H. v. Austria*, paragraph no. 117).

With respect to the Italian legislation on medically-assisted procreation, the Court of Strasbourg argued that forbidding pre-implantation diagnosis in order to choose the embryos to be implanted as required by Law 40/2004 is not proportional, based on the (at the very least) odd justification supported by the Italian Government that in cases in which the foetus was affected by disease, the woman would be able to abort (see the

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<sup>6</sup> Regarding the legal implications of a pre-implantation analysis according to Italian and the European case-law, see STEFANELLI (2016).

<sup>7</sup> See the decree of the Tribunal of Cagliari of 5 June 2004 in *Famiglia e diritto* (2004: 500).

<sup>8</sup> See *Evans v. the United Kingdom* [GC], no. 6339/05, § 71, ECHR 2007-IV, and *A, B and C v. Ireland* [GC], no. 25579/05, § 212, 16 December 2010; *R.R. v. Poland*, no. 27617/04, § 181, ECHR 2011.

<sup>9</sup> See ECHR, *Dickson v. the United Kingdom* [GC], no. 44362/04, § 66, ECHR 2007. According to this case-law, the Court of Strasbourg held that it was illegitimate, in accordance with Article 8 ECHR, to fail to provide the applicants - a prisoner and his wife - with facilities for artificial insemination.

<sup>10</sup> See the judgement ECHR, decision *X, Y and Z v. the United Kingdom* of 22 April 1997, Reports of Judgements and Decisions 1997-II.

case of *Costa and Pavan v. Italy*, Application no. 54270/10, of 28 August 2012, in particular para. 57).

The Court stated: “The consequences of such legislation for the right to respect for the applicants’ private and family life are self-evident. In order to protect their right to have a child unaffected by the disease of which they are healthy carriers, the only possibility available to them is to start a pregnancy by natural means and then terminate it if the prenatal test shows that the foetus is unhealthy. In the instant case the applicants have already terminated one pregnancy for that reason, in February 2010” (para. 58).

### 3. THE OBLIGATION TO IMPLANT THE EMBRYOS

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In recent years, the non-proportionality of the Italian legislation on procreation has also been affirmed by the Italian Constitutional Court.

The obligation for the “single and contemporary implant of the embryos at the maximum of three”, according to Article 14, para. 2, Law no. 40/2004 was determined to be illegitimate by the Constitutional Court in judgement no. 151 of 8 March 2009 based on at least three constitutional principles<sup>11</sup>.

First, according to the Court, “[t]he prevision of the creation of a number of embryos [that does] not exceed three, in the absence of any consideration of the subjective conditions of the woman who from time to time is subjected to the procedure of medically-assisted procreation, it is (...) in contrast with Article 3 Const., from the two viewpoints of the principle of reasonableness and that of equality, as the legislator reserves the same treatment to dissimilar situations”.

Secondly, the above-mentioned provision is in conflict with Article 32 of the Constitution, which stipulates the obligation to require informed consent prior to all interventions on the body of a person (v. 6.1 of the judgement).

Thirdly, the obligation to implant a fixed number of embryos must be considered to be “unreasonable”, as the *Corte Costituzionale* affirmed, particularly because such a provision does not allow the physician to decide the number of embryos to be implanted based on the specific situation of the woman (i.e. her age), and technical and scientific evolution (see VACCARI 2009).

The case-law of the *Corte* usually underlines that law-making power is limited by “scientific and experimental knowledge, [which] is constantly evolving and which [is] the base of the medical art: so that, in the field of therapeutic practice, the basic rule is... the autonomy and responsibility of the physician, who, with the consent of the patient, makes the necessary professional choices” (see para. 6.1 of judgement no. 151/2009; see also judgements no. 338/2003 and 282/2002).

The three constitutional principles must be considered as interlinked according to the Court’s argument.

In fact, the lack of discretion accorded to doctors could lead to risks for both the woman and the embryo: “The legislative limit in question ends, then, on the one hand, [in] favour[ing] - making it necessary to resort to the recurrence of said cycles of ovarian stimulation, where the first system does not give rise to any outcome - the increase of the risk of occurrence of diseases that are linked to such hyperstimulation;

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<sup>11</sup> In *Rivista italiana diritto e procedura penale*, 2009, 928 ff.; in *Foro Italiano*, 2009, 9, 1, 2301; in *Famiglia e Diritto*, 2009, 8-9, 761; in *Corriere Giuridico*, 2009, 9, 1213.

on the other hand, [it] determines, in those cases in which...the chances of engraftment [are higher], a different type of injury to the health of the woman and the foetus, in the presence of multiple pregnancies, having regard to the ban on embryonic selective reduction of such pregnancies [in] art. 14, paragraph 4, apart from abortion”.

As there is no longer an obligation to provide contemporary implantation, an exception to the prohibition of cryopreservation was introduced in paragraph 1 of article 14, “as a logical consequence of [the] lapsing, within the limits specified, [of] paragraph 2 - which determines the need for recourse to the freezing technique with regard to the produc[ed] but not implanted embryos [based on] medical choice”.

The 2008 Guidelines of the Ministry of Health had already abolished the prohibition on maintaining the embryos in culture until their extinction. In eliminating the ban, the Ministry had implicitly accepted the possibility of cryopreservation.

An interpretation from the constitutional viewpoint allowed another problematic aspect of the law in question to be resolved: the prohibition of pre-implantation diagnosis.

As a matter of fact, the Constitutional Court, on a first examination concerning Article 13 of Law 40/2004, after the issue of constitutionality was raised by the Court of Cagliari, stated that there was nothing to censor<sup>12</sup>.

This was because the prohibition was not explicitly required by the law, but was introduced by the ministerial guidelines of 2004<sup>13</sup>.

The courts, however, have gradually dismantled the application of that provision.

The Tribunal of Florence, in a 2007 order<sup>14</sup>, argued that the pre-implantation diagnosis banned by the Guidelines, both for eugenic purposes and other aims, did not have an interpretative function, but was innovative. In this sense, the ministerial regulation was in conflict with the hierarchy of sources scheduled by the Constitution and ordinary legislation (in particular, the Tribunal refers to Article 17 Law 400/1988 and Article 5 Annex E of Law 2248/1865). In addition, the Court of Florence emphasised that the absolute prohibition against pre-implantation diagnosis would lead to the violation of the physician’s obligation to provide information according to Article 6 Law 40/2004.

Subsequently, the Administrative Tribunal of Lazio annulled the requirement of the Guidelines that “any investigation in relation to the health of embryos created in vitro, under Article 14, paragraph 5, will be observational” as an unlawful abuse of power<sup>15</sup>.

As stated by the Regional Administrative Court, Article 7 of Law no. 40 empowers the Ministry to adopt procedural rules, but not to interfere in the regulation of the subject of medically-assisted procreation, which was within the competence of the law. The

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<sup>12</sup> Corte costituzionale, order of 9 November 2006, no. 369, in *Foro italiano*, November 2006, c. 6. See BIANCHETTI (2006); PALMERINI (2006). According to the Court of Cagliari, the ban on carrying out a pre-implantation genetic analysis was in contrast with Articles 2 and 32 of the Italian Constitution, because it would not sufficiently guarantee the health of the woman, due to the absence of information on the health of the foetus.

<sup>13</sup> As also argued, the pre-implantation diagnosis was difficult in the application of other dispositions of Law 40/2004 as well, such as the prohibition of cryoconservation and the obligation to implant of all the embryos (see FERRANDO 2009).

<sup>14</sup> See Tribunale of Florence, order of 17 December 2007, in [www.altalex.com](http://www.altalex.com).

<sup>15</sup> TAR (Administrative Regional Tribunal) of Lazio, sect. III quater, judgm. of 21 January 2008, no. 398, in *Guida al diritto*, 2008, part 6, p. 60 ff.



Guidelines, as an administrative act of a regulatory nature, were not able to amend the law.

In the subsequent Guidelines of the Ministry, in 2008, the sentence at issue was stricken, eliminating the stipulation that the investigation must only be “observational” and suppressing the limit of the diagnosis and reaffirming medical discretion.

An order of the Court of Bologna issued on 29 June 2009 (BAC, 2009) authorised preimplantation diagnosis in a case in which the woman was a carrier of muscular dystrophy and was already the mother of a child born in 1999 affected by the same genetic disease. On that occasion, the Court, recalling judgement n. 151/2009 of the Constitutional Court, said that the embryo transfer should take place (Art. 14, paragraph 3), taking into account the health of the woman.

The Court thus stated that the prohibition against preimplantation diagnosis is “unreasonable and inconsistent with the legal system if compared with the widespread practice of prenatal diagnosis, equally invasive of the foetus, dangerous for pregnancy, but perfectly legitimate”. Therefore, the woman's “right to abandon the affected embryo and... only [receive] the transfer of the healthy one” should be recognised.

#### 4. THE PROHIBITION OF HETEROLOGOUS FECUNDATION

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As mentioned above, one of the main provisions of Law 40/2004 was the prohibition of heterologous fertilisation.

Such a prohibition constituted an important difference with respect to the legislation of the other European countries and was not consistent with the opinion of the Court of Strasbourg, which has often included the right to access heterologous insemination techniques within the above-mentioned right to become a partner<sup>16</sup>.

According to the aforementioned judgement (of the Grand Chamber) in *S.H. et al. vs. Austria*<sup>17</sup>, the European Court analysed Austrian legislation that regulated heterologous fertilisation, allowing only the donation of sperm but not of ova.

In that case, the Court argued: “In the Grand Chamber’s view, the legislation in question can be seen as raising an issue as to whether there exists a positive obligation on the State to permit certain forms of artificial procreation using either sperm or ova from a third party. However, the matter can also be seen as an interference by the State with the applicants’ rights to respect for their family life as a result of the prohibition under sections 3(1) and 3(2) of the Artificial Procreation Act of certain techniques of artificial procreation that had been developed by medical science but of which they could not avail themselves because of that prohibition”.

In its judgement no. 162 of 2014<sup>18</sup>, the Italian Constitutional Court implicitly followed this approach, affirming that, with respect to ethically sensitive issues, such as assisted procreation, the identification of the equilibrium between different interests should be a task of the legislative power; however, it must also be subject to the respect for human

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<sup>16</sup> See ECHR, *Dickson v. the United Kingdom* [GC], no. 44362/04, § 66, ECHR 2007-V, in which the Court considered the refusal of the authorities to provide the applicants - a prisoner and his wife - with the facilities for artificial insemination to be a violation of Article 8 of the European Convention.

<sup>17</sup> See *S.H. and Others v. Austria* [GC], no. 57813/00, § 82, ECHR 2011.

<sup>18</sup> See among others: D’AMICO (2014); CARBONE (2014); CASONATO (2014); MORRONE (2014); MUSUMECI (2014); PENASA (2014); PIOGGIA (2014); RODOMONTE (2014); RUGGERI (2014); SORRENTI (2014); TIGANO (2014); TRIPODINA (2014); VIOLINI (2014).

dignity and to the control of the constitutional judges at the national and European levels.

Based on that consideration, the Italian Constitutional Court, based on the principles stated by the Court of Strasbourg, has censured the use of the power of discretion by the Italian legislator.

In particular, the *Corte Costituzionale* stated that it is irrational to forbid heterologous fecundation in all cases, because this would lead to a complete negation of the fundamental right to become parents, especially for persons affected by serious diseases, by preventing them from having a child (see judgement no. 162/2014, para. 13).

As the right to be a parent is constitutionally granted, any limitation of such a right should be reasonable and duly justified based on the impossibility of simultaneously protecting other relevant interests (see para. 6 of judgement no. 162/2014; see also judgement no. 332 of 2000).

Furthermore, the Court argued that the access to reproductive techniques is necessary to enhance the right to the protection of health (see Article 32 Italian Constitution) (VALLINI, 2014) on the ground that such techniques constitute a remedy for reproductive dysfunctions (see paragraph 7 of the judgements). In that respect, the legislator is not allowed to substitute itself for physicians in the identification of better instruments to satisfy the right to the health, as previously stated by the *Corte Costituzionale* in its aforementioned judgement no. 151/2009.

Once the Constitutional Court declared the unconstitutionality of the prohibition against heterologous fecundation, other judges affirmed that right. Thus, the *Consiglio di Stato* (acting as an administrative judge of appeal) affirmed that a health authority (i.e. the Lombardia Region) is not entitled to discriminate against heterologous fecundation in favour of other techniques by refusing to reimburse the expenses borne by the concerned couples<sup>19</sup>. Other forms of discrimination have been condemned by other administrative judges, such as limiting access to heterologous fertilisation based on age (see Administrative Tribunal of Veneto, judgement of 8 May 2015, no. 501 against the regulation of the Veneto Region).

## 5. THE ACCESS TO ASSISTED PROCREATION

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The case-law has led to the dismantling of another pillar of Law no. 40/2004, that is, the limitation of access to assisted reproduction to infertile couples.

The Court of Salerno, in an order of 9 January 2010, upheld the right of both parents carrying a genetic mutation (mutation SMA1 gene, which causes spinal muscular atrophy type 1), who already had a child with the disease who had died, to resort to medically-assisted procreation preceded by pre-implantation diagnosis in order to prevent harm to the foetus.

Furthermore, the Constitutional Court, in its judgement of 5 June 2015, n. 96, declared Law no. 40 unconstitutional to the extent that it excluded couples who were affected by viral diseases but were fertile from access to assisted procreation.

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<sup>19</sup> Consiglio di Stato, Sect. III, judg. 20 July 2016, n. 3297; see also Administrative Tribunal of Lombardia, judgement of 28 October 2015, no. 2271.



In the cases which gave rise to the ruling of the Constitutional Court, two couples had not been allowed access to assisted procreation procedures with pre-implantation diagnosis in order to avoid the risk of transmitting a genetic disease to their children.

The couples therefore brought an action before the Court of Rome, arguing the violation of Articles 2, 3 and 32 of the Italian Constitution, as well as of Articles 8 and 14 of the European Convention of Human Rights.

The Constitutional Court indeed recognised the inconsistency of Law no. 40/2004 from the perspective of access to fertilisation techniques.

As a matter of fact, according to the principle of substantial equality stipulated by Article 3 of the Italian Constitution, the Court affirmed that it is unreasonable to preclude access to the benefits of assisted fertilisation to a fertile couple carrying a transmissible disease.

This is because there was a clear antinomy in the legislation (a point also underlined by the Strasbourg Court in the judgement in *Costa and Pavan vs. Italy*), because the Italian legal system allowed such couples to pursue the goal of procreating a child who does not suffer from a specific hereditary disease through abortion (undeniably the most traumatic means) in the case of a foetus affected by the pathologies leading to anomalies or malformations (see Article 6, para. 1, letter b), of the law 22 May 1978 n. 194).

As the European Court of Human Rights stated in *Costa and Pavan vs. Italy*, the Constitutional Court also pointed out the irrationality of the Italian law, which did not allow (although scientifically possible) the acquisition of “prior” information about the health of the embryo, but permitted the detection of pathologies after the implantation, as well as the subsequent right of women to interrupt the pregnancy.

With respect to Article 32 of the Italian Constitution, the *Corte costituzionale* argued that the violation of women’s right to health was not balanced by an eventual need for the protection of the rights of the unborn child, who would still be exposed to abortion.

The reference to Article 6 letter b) of Law 194/78 on abortion again acknowledges the relevance of the judgement of the physician in all cases in which it is necessary to establish the need for pre-implantation diagnosis, based on the criterion of gravity, which must be determined on the grounds of scientific knowledge. This is necessary to support the right to conscientious and responsible procreation as granted by Law 164/19788.

As a consequence of the above-mentioned interpretation, the selection of embryos in order to avoid of the implantation of embryos affected by genetic disease could not be sanctioned from a criminal point of view (see Articles 13, para. 3, b) and 4 of Law no. 40/2004), as was eventually stated by the Constitutional Court in judgement no. 229 of 2015, following doubts previously expressed by other judges (DE FRANCESCO, 2016).

## 6. RESEARCH ON HUMAN EMBRYOS

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The judges have analysed a further critical aspect of Law 40, that is, the prohibition of research activities concerning embryos.

The issue was addressed in the judgement of the Grand Chamber of the European Court of Human Rights in the case of *Parrillo vs. Italy* (Application no. 46470/11),

adopted on 27 August 2015 (see the commentaries in D'AMICO, 2015; POLI, 2015; CONTI, 2015).

The applicant (the wife of an Italian soldier who had died in a mission in Iraq) brought the action before the European Court in order to declare the illegitimacy of the prohibition in Law 40/2004 of the donation of embryos obtained from in vitro fertilisation for the purpose of scientific research.

The Court recognised 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” (para. 159), and therefore, held that the issue is included under the protection of Article 8 of the Convention of Rome.

However, the right to donate embryos for scientific research should not be considered to be “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” (para 174).

As a consequence, the European judge recognised a wide margin of discretion to the member States regarding that matter (para. 175).

In the Court’s opinion, a broad margin of discretion should also be recognised because the matter of the donation of embryos is a delicate ethical issue, according to which there is no consensus within the legislation of the States in the Council of Europe<sup>20</sup>: Seventeen out of fifty members allow research on human embryonic cell lines; certain States (Andorra, Latvia, Croatia and Malta) expressly prohibit any research on embryonic cells; others allow research on cells imported from abroad (Slovakia, Germany, Austria and Italy). The other States do not have specific legislation concerning the use of human embryos for research.

Therefore, the Court confirmed the power of States “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” (para 180).

The Court of Strasbourg also referred to several European legal sources (both the Council of Europe and the European Union) which have established limits on the research on human embryos in order to “temper excesses in this area” (para. 182)<sup>21</sup>.

<sup>20</sup> See *S.H. and Others*, cited above, § 94; *Evans*, cited above, § 77; *X, Y and Z v. the United Kingdom*, 22 April 1997, § 44, Reports of Judgements 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.

<sup>21</sup> Among other legal sources, Article 27 of the Convention of Oviedo allows national rules providing a wider measure of protection with regard to the application of biology and medicine, as well as Opinion no. 15, adopted on 14 November 2000 by the European Group on Ethics in Science and New Technologies to the European Commission, Resolution 1352 (2003) of the Parliamentary Assembly of the Council of Europe on Human Stem Cell Research and Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products (see paragraph 58, point III letter F and point IV letter B above). Other European dispositions prohibit the creation of human embryos for research purposes (see Article 3 of the EU Charter of Fundamental Rights and Article 18 of the Oviedo Convention) and ban patenting scientific inventions where the process involves the destruction of human embryos (see the judgement of the Court of Justice of the European Union, *Oliver Brüstle v. Greenpeace eV* of 18 October 2011).

The Court, within its wide margin of discretion, argued that the Italian legislative power had created a fair balance 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*, cited above, § 97) (para. 183).

This result was achieved through a parliamentary *iter* which, according to the Italian Government, “had taken account of the different scientific and ethical opinions and questions on the subject”, as well as the fact that the text of the law had been subject to a referendum that had been declared invalid because it had not reached the required threshold of votes cast.

This last argument is very curious.

The case-law of the European Court itself, as well as the judgements of the Constitutional Court and of other Italian judges, clearly state that Law no. 40 does not constitute a good example of a balance between the interests protected at the constitutional and international levels.

It is not clear how this equilibrium was reached in relation to research on human embryos.

As has been argued - within the European Court itself - a simple reference to the parliamentary debate is not sufficient to show why a 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”<sup>22</sup>.

The disequilibrium of the Italian legislation, which is acknowledged in the case-law of the European Court itself, stems from its disproportionate protection of embryos<sup>23</sup>, without sufficient consideration of the other fundamental interests (PARDINI, 2016).

On behalf of such fundamental interests, the national and European judges have censored the Italian legislation: the health of the woman; the right to consent to medical treatment; the right to become parents; the freedom of circulation; the freedom of research and to exercise a professional activity, etc.

The prohibition of research on stem cells from human embryos has also been criticised in some of the legal doctrine (Among others: FERRANDO, 2004; MUSIO, 2004; VERONESI, 2007; PENASA, 2011).

Furthermore, the judgements mentioned above underlined the incoherence of Law 40 with respect to constitutional principles and other laws, such as the legislation concerning abortion.

In relation to the specific issue of research on human embryos, the Court of Florence, in a decree of 12 December 2012<sup>24</sup>, affirmed that the balancing of interests put in place in Law no. 40 was “totally unreasonable”, considering that embryos which cannot be implanted for procreation purposes are destined for self-destruction in few years.

As a matter of fact, Law no. 40 and the above-mentioned judgements will lead to a dramatic increase in the number of embryos which cannot be used and which must be

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<sup>22</sup> See the Dissenting Opinion of Judge Sajó, para. 13. See PENASA (2016).

<sup>23</sup> In other judgements, the opinion of the Court appears different. For example, the Court of Strasbourg in *Evans vs. United Kingdom* affirmed that human embryos are not a legal subject of rights and duties and that both members of a couple have the right to choose the fate of the embryos.

<sup>24</sup> Tribunal of Florence, 12 December 2012, in *Nuova giurisprudenza civile commentata*, 2013, I, 589.

maintained indefinitely at an excessive expense to society (see the Guidelines of the Ministry of Health). In other countries, it is possible to use embryos that are “in [a] state of abandonment” for research purposes<sup>25</sup>.

Law no. 40 does not provide any alternative, and this is contrary to the interests of the Italian Republic in developing research (see Articles 9 and 33 of the Italian Constitution).

On that ground, the Tribunal of Florence remitted the question of constitutionality to the Constitutional Court in its judgement no. 84 of 20 April 2016.

The decision of the *Corte Costituzionale* affirmed that the “tragic choice” between the respect for life at its beginning and scientific research, which is so divisive from an ethical and juridical point of view, should be made by Parliament (see point 11) based on the judgement in *Parrillo vs. Italy* in the Grand Chamber of the European Court of Human Rights<sup>26</sup>.

This certainly does not appear to support a “balance” of interests realised by Law no. 40; rather, it seems to be an invitation to change the legislation in consideration of this matter.

## 7. RECOGNITION OF THE STATUS LAWFULLY ESTABLISHED IN OTHER EU COUNTRIES

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The freedom of circulation of persons within the European Union has inflicted additional blows on the Italian legislation on reproduction.

Such a freedom may be considered as one of the most important fundamental rights recognised by the European Treaties (the Treaty of the European Union, the Treaty of the Functioning of the European Union, the Charter of Fundamental Rights).

That freedom not only allows persons to freely move from one EU country to another, but also to stay in the host country.

The persons also maintain their individual legal qualifications: their names, their drivers’ licences, their professional and academic diplomas, and their family status (e.g. spouses, parents, children).

States cannot create barriers to the implementation of a status established by other EU laws, such as reciprocity (see Article 16 of the preliminary provisions to the *Codice Civile*) or “public order” (see Italy’s Article 16 of Law 218/1995 providing for the reform of the Italian system of private international law).

However, EU law allows the Member States to impose limitations on the free movement of persons (see Article 27, para. 2 Directive 2004/38/EC) for the purpose of “public order”. But the reference to such limitations based on public order “presupposes, in any event, the existence, in addition to the perturbation of the social order which any infringement of the law involves, of a genuine, present and sufficiently serious threat affecting one of the fundamental interests of society”<sup>27</sup>.

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<sup>25</sup> See Articles 2141-5 and 2141-6 of the Code de la Santé Publique in France which provide the “accueil de l’embryon” in case the couple does not want to follow the process of assisted procreation.

<sup>26</sup> D’AMICO (2014) pointed out that the Italian Constitutional Court waited for the judgement of the Court of Strasbourg before taking its decision.

<sup>27</sup> ECJ 4 October 2012, C-249/11, *Hristo Byankov/ Glaven sekretar na Ministerstvo na vatrešnite raboti*, para. 40, not yet published; see also ECJ 10 July 2008, C-33/07, *Jipa*, ECR 2008 p. I-5157, para. 23; Id.,

The question is: What happens if an EU citizen has a family status which is not recognised in another EU country? This question is particularly relevant with respect to the Italian legislation on reproduction, which is among the more restrictive in Europe.

In particular, this problem was posed by Law 40/2004, which prohibited heterologous fertilisation and led to a refusal to recognise the parentage of same-sex couples.

The Italian judges also correctly applied Constitutional and supranational principles in this case.

The Court of Appeals of Bari, on 25 February 2009<sup>28</sup>, declared that the transcription of the parentage of two children born based on a surrogacy is considered to be admissible in Italy, because the two children were citizens of the United Kingdom, and therefore, were EU citizens, and also in furtherance of the best interests of the children.

A decree of 1 July 2011 by the Tribunal of Naples ordered the transcription of a certificate of a child born abroad as a result of the technique of heterologous artificial insemination, because it was not considered to be a violation of public order.

The Court of Appeal of Milan, in an order on 25 July 2016, underlined that decisions concerning the recognition of childhood must be taken only considering the interests of the children, regardless of the prohibitions in the legislation on artificial procreation.

The same principle has been applied by French courts (see the Court of Appeal of Paris, 25 October 2007) and by Spanish practice (see Resolution of the Directorate General of Registries and Notaries, 18 February 2009).

Furthermore, as argued by the legal literature (BILOTTA, 2010), Italian judges have usually recognised the filiation of same-sex couples, which has legally been established by the rules of other EU countries, although in cases not covered by Italian law<sup>29</sup>.

More recently, a judgement of the *Corte di Cassazione* (sent. 30 September 2016, no. 19599) recognised the validity of the act of birth concerning a child born from two mothers issued in another EU country in the Italian legal system.

The lawfulness of a technique of reproduction, in accordance with the legislation of other States, must be considered a situation in which there is an exemption from penal liability, whereby the criminal sanctions provided by Law 40/2004 are not applied (see *Cassazione penale*, sent. 10 March 2016, n. 13525)<sup>30</sup>.

Based on the above-mentioned cases, as well as other many others, when a valid form of parentage is recognised in one EU country, the application of the principles of the substantial definition of family relations, the prohibition against discrimination, the right to free movement, and especially the duty to protect the interests of the child should require full recognition in all other EU States.

The necessity to comply with European principles, along with the defence of traditional approaches, often leads to very curious formal solutions.

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17 November 2011, C-430/10, *Gaydarov*, para. 33, not yet published. Regarding the limitation on the free movement of the persons, see PIZZOLO (2013).

<sup>28</sup> In *leggiditalia.it*.

<sup>29</sup> In 2009, the Tribunal of Rome rejected an action concerning the denial of paternity promoted by the brothers of a man, an Italian citizen, who was married to another man in accordance with UK Law. See GARIBALDI (2009); MOLASCHI (2010).

<sup>30</sup> In *Foro Italiano*, 2016, 5, 2, 286; in *Diritto Penale e Processo*, 2016, 8, 1085.



This occurred in the *Conseil d'État* in France<sup>31</sup>, which, in a case involving a surrogacy performed abroad, suggested the transcription of the paternity, but not the maternity of the “*mère d'intention*”.

However, the *Conseil* proposed that the relationship between mother and son could be indirectly recognised through “delegation” (Article 377 *Code Civil*) or by noting the decision of the foreign administrative authority on the birth certificate in order to demonstrate the linkage in the relations of daily life (for the public administration, schools, etc.).

A similar formal solution was adopted in the judgement of the Italian *Corte di Cassazione* no. 4184 of 15 March 2012, which decided that same-sex marriage is “inexistent” under domestic law; however, using an ambiguous formula, the Court held that cohabiting homosexuals couples are entitled to a “family life” and have the right to “uniform treatment” as that is accorded to spouses of different sexes.

Such a formalistic approach was disowned by the European Court of Human Rights in its recent judgement in *Menesson vs. France* of 26 June 2014 (application no. 65192/11).

The Court of Strasbourg argued that, as the domestic case-law and the opinion of the *Conseil d'État* showed, the absence of the transcription of filiation in the case of surrogacy created an obstacle to and thus affected the full exercise of the right to a family life as recognised by Article 8 ECHR.

## 8. LEGISLATIVE AND JUDICIAL APPROACHES TO REGULATING ASSISTED PROCREATION

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As mentioned above, for more than ten years, the Italian Parliament and the Italian Government have not formally amended Law no. 40.

Only the dialogue between the Courts has enabled the law to be consistent with the basic rules at the national and supranational levels (CONTI, 2015).

Not all of the outcomes of this jurisprudential conversation are perfect, as highlighted by the issue of research on embryos. However, even in that case, the link between the national and supranational case-law is evident.

This mechanism is not “curious”; rather, it is the normal result of the processes of legal integration.

First, family law is today conceived as a matter related to the fundamental rights of persons.

During the second half of the twentieth century, along with the constitutionalisation of human rights, such rights were also internationalised. Indeed, this affirmed the idea that the protection of individual rights is too important to be limited only to national forms of protection<sup>32</sup>; rather, it must be approached from a “global constitutionalism” viewpoint (see, for example: ESPINOZA DE LOS MONTEROS SÁNCHEZ, 2010).

The international legal sources compose a “*corpus iuris* of human rights”, which strongly influences the domestic legal systems, penetrating the national law, especially

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<sup>31</sup> Conseil d'État, *La révision des lois de bioéthique*, Paris, 2009, in [legifrance.gouv.fr](http://legifrance.gouv.fr).

<sup>32</sup> The establishment of the international organisations as an instrument to achieve peace is underlined, for example, in BOBBIO (1984).



through domestic dispositions such as Article 10 of the Italian Constitution (see also Article 10.1 of the Spanish Constitution, and in particular, Article 40.2 concerning the rights of children; see § 25 of the German Fundamental Law).

The legal doctrine has argued that the national courts are allowed to implement the *Drittwirkung* (CASSETTI, 2010), according to which fundamental rights, in particular, as interpreted by the international courts<sup>33</sup>, should be directly applied to relationships between individuals (see SPIELMAN, 1995; NUNIN, 1991).

Secondly, the Italian regulations are subject not only to the international system of human rights, but should be consistent with European law.

The regional integration is not only a kind of international cooperation among States (PIZZOLO, 2010), but also may lead to the progressive establishment of a regional legal system. This is the case for the system for the protection of human rights established by the Council of Europe, and moreover, for the supranational law of the European Union.

In particular, within the regional legal cooperation, the presence of transnational judges has strengthened the integration process. The interpretative strategy implemented by the regional judges, based on a teleological approach, has recognised the existence of a legal system which is prevalent over the domestic ones.

In this respect, the Court of Strasbourg is the main interpreter of the European system of protection of human rights; the Court of Justice recognised the existence of the community legal system in the *Van Gend en Loos* case issued in 1963, at the beginning of the history of European integration<sup>34</sup>, and it has developed it during the last decades.

Indeed, even matters such as family law, which are not subject to exclusive supranational competence, are nevertheless deeply influenced by European legislation.

In this context, the national courts have attempted to make the legislation coherent with both constitutional and supranational principles.

Today, the situation is considerably different from the circumstances under which the 1975 reform of the family law were introduced, when the discussion was focused on the comparison and circulation of the models developed in Europe during the same period<sup>35</sup>.

The compliance with European rules and principles, including family matters, is a positive obligation of the State, as well as of its powers, in particular, the judicial one (SANZ CABALLERO, 2013). Within such integrated legal systems, the application of rules that do not directly refer to family relationships also have a strong impact on them<sup>36</sup>.

As mentioned above, in many cases, the coherence of the Italian legislation with European principles has been established by the courts, through their interpretative instruments, which have been made available both by international and supranational law. The judicial activities have allowed the dynamic and quick adaptation of domestic

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<sup>33</sup> SCOTT & STEPHEN (2006) referred to the case-law of the Supreme Court of the USA, especially the judgement in *Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004), which supported the idea that the federal courts can apply international law; see also *Medellin v. Dretke*, 544 U.S. 660 (2005); *Roper v. Simmons*, 543 U.S. 551 (2005).

<sup>34</sup> ECJ, 5 February 1963, 26-62, *Van Gend en Loos / Administratie der Belastingen*, ECR, 1963, p. 3.

<sup>35</sup> Regarding works concerning the Italian reform of 1975 on Family Law, see, for example, CASSANO (2006).

<sup>36</sup> With respect to the impact of European principles, especially regarding the matter of assisted procreation, see, among others: BERTI DE MARINIS (2014); CASINI & CASINI (2014); D'AMICO (2012:18).

law to transnational principles. However, a judicial adaptation alone does not permit the necessary discussion of sensitive matters, which are subject to different opinions and ideological approaches, such as the legal regulation of family relationships.

Many judgements of the Tribunals have been implementing a constitutional reading of the law.

The Constitutional Court can declare the illegitimacy of the norms only if an interpretation consistent with those principles is not possible (see the Constitutional Court in judgement no. 96/2015) (FERRANDO, 2015).

Obviously, such a situation, which has occurred regarding Law no. 40, through the extensive intervention of the courts, should not be considered desirable in the law-making process, especially in sensitive fields such as assisted reproduction, for which dialogue should represent the main political instrument.

As explained by the case-law of the Court of Strasbourg, the relationship between the judicial and legislative powers should be more well-balanced, especially in matters linked to the ethical and social implications of techno-science.

It is not accidental that the matter of medical reproduction, and in particular, the Italian legislation, provide a good example of the opinions of the European Court of Human Rights.

According to that case-law, legislation concerning science and its implications for society should be the result of substantial debate within society (see *Evans vs. United Kingdom* of 2007<sup>37</sup>).

According to the European Court of Human Rights, the implementation of the law-making power must be based on “scientific acceptability”<sup>38</sup>.

Based on this view, the legislator is not allowed to substitute itself for physicians and other professionals or scientists in identifying better instruments to satisfy fundamental rights such as the right to the health.

In scientific matters, the European Court invoked the principle of proportionality when it affirmed, in *S.H. v. Austria* of 2011, the necessity for an “assessment of the rules governing artificial procreation, taking into account the dynamic developments in science and society noted above” (see paragraph no. 117).

Therefore, a legislative approach to assisted procreation should be possible and opportune, as the experience of other countries has shown<sup>39</sup>.

The French law on bioethics (most recently, *Loi* no. 2011-814 of 7 July 2011) can be used as a counterexample; it was the result of a broad debate involving many components.

At a technical level, the contribution of the *Conseil d'État* was very interesting<sup>40</sup>; it verified the proposed law with specific reference to European and international law through an analysis relative to each provision. This was done in order to measure the compatibility of the draft law with the supranational regulatory environment and to avoid remarks from the judges of Luxembourg to Strasbourg.

<sup>37</sup> ECHR, judg. 10 April 2007, *Evans v. United Kingdom* [GC], no. 6339/05.

<sup>38</sup> ECHR, judg. 28 August 2012, *Costa y Pavan v. Italia*, no. 54270/10.

<sup>39</sup> In the past, the debate on the drafting of law in Italy was more important than today, see, D'ANTONIO (1990); for a comparative standpoint, see LANCHESTER (1990).

<sup>40</sup> Conseil d'État, *La révision des lois de bioéthique*, Paris, 2009, in [legifrance.gouv.fr](http://legifrance.gouv.fr).

Such an examination will not guarantee that the legislative choices will be unexceptionable in every case, but it does reduce the risk that the law, at its birth, may already be legally “old”, that is, disjointed from the constitutional, supranational and international legal context.

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