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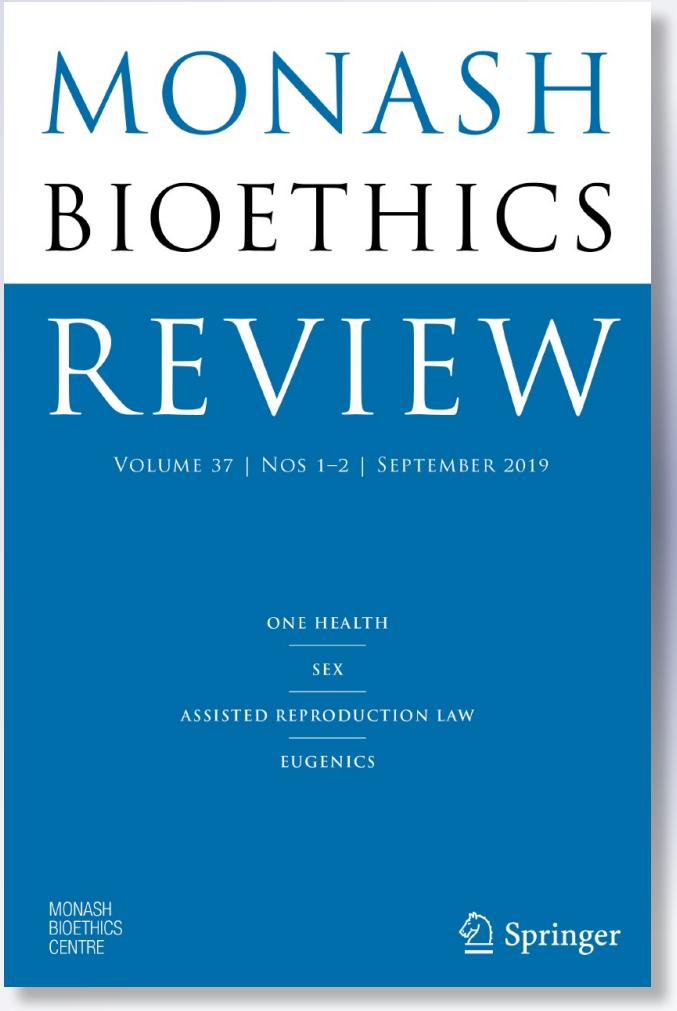
Roberto Cippitani

Monash Bioethics Review

ISSN 1321-2753
Volume 37
Combined 1-2

Monash Bioeth. Rev. (2019) 37:46-67
DOI 10.1007/s40592-018-0088-8



Springer

Monash Bioethics Review (2019) 37:46–67
https://doi.org/10.1007/s40592-018-0088-8

REVIEW ESSAY

Ethical issues and law-making power: how European case law has rewritten Italian law on medically assisted reproduction

Roberto Cippitani[1]

Published online: 19 December 2018

Abstract

The paper relates to the actual extent of the "margin of appreciation" of national law-making power in Europe when it takes ethical issues into consideration. This occurs when the use of technoscience may affect fundamental interests. The discretion of the legislature is limited, particularly by the transnational system arising from the European legal integration within both the European Union and the Council of Europe. The two schemes of integration, although there are differences between them, converge to put national legislation under pressure, particularly when it considers ethical matters. As a matter of fact, ethical issues cannot be approached at the national level alone but must be addressed at least at the continental level. An important role in the work of shaping the ethical rules from a continental perspective is played not by the national legislatures, but by the dialogue between the different levels of the judiciary. This role is inescapable and cannot be replaced by legislation, even if it is approved in a transnational plan. The function of the case law in regulating phenomena with ethical implications is studied, taking into consideration the case of Italian Law no. 40 of 2004 concerning medically assisted reproduction. Over the last 15 years, this law, which is inconsistent with many fundamental ethical principles, but has not been amended by the legislature, has been in the process of being corrected by the dialogue between European and national case law.

Keywords Biolaw · European Law · Impact of Supranational Law on Domestic Legislation · Legal status human embryos · Medically assisted procreation legislation

✉ Roberto Cippitani
roberto.cippitani@unipg.it

[1] Department of Medicine, Jean Monnet Centre of Excellence «Rights And Science», University Degli Studi Di Perugia, Building A, Floor 7th, Piazzale Severi, Sant'andrea delle Fratte, 06132 Perugia, Italy

1 Ethical issues of science and technology in European transnational law

According to European law, scientific research is considered to be a fundamental freedom (see Article 13 of the Charter of Fundamental Rights of the European Union, hereinafter also "EU Charter") (Molina del Pozo and Archontaki 2013). However, this freedom may affect other fundamental rights, as clarified, for example, in the 1997 Oviedo Convention on Biomedicine of the Council of Europe, which states that research activities and professional practice (such as medical activity), although very important for society, could endanger the dignity of individuals if carried out in an inappropriate manner (see, in particular, the preamble of the Convention and Article 1). Within this framework, there is a need to establish "ethical principles" to ensure that the fundamental interests that may be affected by activities such as scientific research or professional activities such as healthcare are protected.[1]

In order to take account of the main issues raised by science, the Council of Europe and the European Union (hereinafter also "EU") are developing a shared system of values. This is a process of cooperation and convergence that can also be observed at the international level, where truly international bioethics have been in the process of being established over the last decades (Andorno 2013). An expression of this process, the EU Charter, is a sort of a "bioethical constitution" which establishes the rights and limits for research and innovation activities (Mathieu 2009, p. 8). As regards the identification of common European values, the preamble of the EU Charter states that its objective is "to strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments". This occurs, as the same paragraph of the preamble emphasises, "by making those rights more visible in a Charter". The EU legislature, as well as the sources of the Council of Europe, realises that the ethical dilemmas of science are challenges that cannot be faced within national borders, as the national legislatures sometimes think. Therefore, European transnational law, rather than the national legal systems, is very much concerned with scientific and technological issues, and above all, with their ethical aspects.

The European Union, which is a supranational legal system that also exercises legislative power through the European Parliament and the Council of Ministers, adopts many legal sources regulating the legal aspects of research and innovation in fields such as the protection of personal data; the use of human tissues; issues concerning the environment; the wellbeing of animals; "double use" technologies;

[1] The expression "ethical principles" is contained, for example, within the legal texts of the European Union regulating the funding for research activities, such as Regulation (EU) 1290/2013 and Regulation (EU) 1290/2013 concerning the Programme "Horizon 2020". Among the ethical principles to be observed by the beneficiaries of EU grants, one can find "the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection" [Article 19, para. 1, Regulation (EU) 1291/2013]; the protection of the human embryo [Article 13 Regulation (EU) 1290/2013]; the wellbeing of animals subject to experimentation [Article 23, para. 10, Regulation (EU) 1290/2013], etc.

security. Also, the Council of Europe, in dealing with the protection of human rights in Europe, elaborates legal instruments concerning the protection of fundamental interests within scientific and medical activities. Above all, the two European regional organisations deal with bioethical issues with the help of their tribunals, the European Court of Human Rights (hereinafter also referred to as the "ECtHR" or the "Court of Strasbourg") and the Court of Justice of the European Union (hereinafter also referred to as the "ECJ" or the "Court of Luxemburg").

Generally speaking, European judges play a very important role in the identification and development of transnational law (Cippitani 2015). In particular, the continuous "dialogue" between continental and national judges leads to a strong implementation of the European system of "ethical principles" even against the national law-making powers.

2 Italian Law 40 of 2004 on medically assisted reproduction

An interesting example of the European way of ensuring the elaboration and implementation of ethical principles in the European legal system, in particular with respect to domestic law, is represented by the case law concerning Italian Law no. 40 of 2004 on medically assisted reproduction (Alpa 2004; Balestra 2004; Bellelli 2004; Carapezza Figlia 2004; Casini et al. 2004; Pocar 2004; Riva 2004; Ruscello 2004).

It is useful to give some information concerning the origins and the content of that law. Italy is among the last of the European countries to regulate a matter that has been addressed in the legislation of other countries since the 1980s[2]: Norway approved a specific law in 1987; the Spanish law concerning the "Tecnicas 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 fertilisation 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 prenatal" ("donation and use of the elements and products of the human body, medically assisted reproduction and prenatal diagnosis"), 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, the Church intervened in this civil political debate, although to a greater extent (Magister 2003; Savi 2006; Valentini 2003). In addition to the political opposition, the legal doctrine promptly criticised the ideological approach of the law (see, for example: Dogliotti and Figone 2004; Sesta 2004), as well as its inconsistency with Constitutional principles, during the period immediately subsequent to its passage

[2] However, since the end of 1950, draft laws on the subject were 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).

(Celotto 2004; Manetti 2004; Pocar 2004). Compared to the legislation of the 1970s concerning family law, 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 in direction (Angelini 2015). However, the critics were not able to galvanise public opinion. As a 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 involved between 3500 and 4500 Italians each year.[3] 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, and the implementing documents (see also the "Guidelines", approved on the ground of Article 7 of the Law by Ministerial Decree of 21 July 2004), contains several controversial 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). 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 fertilisation, two rules were particularly relevant: first, the prohibition of any pre-implant analysis of the embryo, and second, 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 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).

Although during the subsequent years, Law no. 40 has not been even minimally modified by the Italian Parliament, the above-mentioned dispositions have been

[3] 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/.

cancelled or amended. The (apparently) curious fact is that the process of "rewriting" (D'Avack 2010) Law no. 40 has been realised through the interpretations of judges and the case law of the national and European courts. As a matter of fact, more than 30 judgements (at the European and national levels) during the 14 years after the law came into force have deeply modified the Italian legislation on medically assisted reproduction.

3 Identification of the interests to be protected

As mentioned above, in its first article, the Italian law identifies the interests of the persons to be protected, with a particular emphasis on the position of the human embryo. Within the European legal culture, the human embryo is recognised as having a special status, as affirmed by scholars (see Baertschi 2008; for a criticism, see Devolder and Harris 2007); by national institutional documents (see the "Warnock Report", para. 11.17); transnational ethical committees (see Opinion No. 12, para. 2.2. of the European Group on Ethics in Science and New Technologies, hereinafter the 'EGE')[4] and international legal instruments (e.g. Article 18.1 of the Convention of Oviedo of the Council of Europe).[5] The humanity of the embryo has, as its corollary, the respect for human life (EGE Opinion No. 12, para. 2.10) from the beginning, and therefore, from the embryonic stage (see para. 1.26 of EGE Opinion No. 12). Thus, in research and medical activities, the dignity of the embryo must be respected (Andorno 2013, p. 132; Mathieu 1999). Despite the differences in European legislation, some common principles are applicable to activities involving human embryos, especially in the fields of medicine and research (see Opinion No. 15 of 2000 of the EGE, 'Ethical aspects of human stem cell research and use', para. 2.2; see also para. 1.26 of the EGE Opinion No. 12). The respect for human life from the earliest stages of its development inspires some constitutional norms such as those provided by Article 3, para. 2, (b) to (d), of the EU Charter, which prohibits: eugenic practices, in particular, those aimed at the selection of persons; using the human body and its parts as such as a source of financial gain and the reproductive cloning of human beings (see EGE Opinion No. 12, para. 1.21).

However, according to the case law, the approach of Italian Law no. 40/2004 in protecting human embryos does not comply with the above-mentioned European legal framework. As a matter of fact, other important interests are not sufficiently considered by the Italian legislation, although they are recognised by the Italian Constitution. The *Corte Costitutionale* points out the violation of the right to health and to healthcare (see Article 32 Italian Constitution; Article 35 EU Charter) from several viewpoints. For example, Law no. 40/2004, which forbids heterologous

[4] EGE, 'Ethical aspects of research involving human embryo in the context of the 5th Framework Programme', Opinion No. 12, 23 November 1998.

[5] 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), opened for signature on 4 April 1997 in Oviedo.

fertilisation, affects the right to cure infertility. Judgment no. 162/2014 of the Italian Constitutional Court (see para. 7), on the ground of the expansive notion of health within the Statute of the WHO and its case law (judgements nn. 161/1985; 167/1999; 253/2003; 251/2008; 113/2004), considers heterologous procreation to be a lawful act of healthcare. The law also threatened the right to health, creating an obligation for the simultaneous implantation of the fertilised ova and thus prohibiting their cryopreservation. In fact, those provisions were abrogated by the Italian Constitutional Court, which cancelled them with its judgement no. 151 of 2009 (see, in particular, para. 5.2 of the judgement). The latter judgement affirmed the violation of the dignity of the woman and her self-determination (see Articles 2 and 32 of Italian *Costituzione*) if she were forced to undergo the implantation of the ova, as provided by the law.

On the other hand, the European and national judges argued that the Italian law does not take into consideration other fundamental interests specifically recognised by European legal sources. This is the case of the right to become a parent, which was prevented by several dispositions of Law no. 40/2004, such as the prohibition of the analysis of the embryo before its implantation in the uterus[6]; the prohibition of heterologous fertilisation and the restriction of access to medically assisted procreation to fertile couples. The Court of Strasbourg held that the scheme contravenes Article 8 ECHR, which recognises the right to protection of the personal and family life.[7] As a matter of fact, the limitation on the access to techniques for medically assisted procreation, which is not duly justified, constitutes an undue invasion of the personal life of the individuals.[8] For example, the provision of Law no. 40 preventing heterologous fertilisation was cancelled by judgement no. 162/2014 of the Italian *Corte Costituzionale*, which stated, in coherence with the case law of the European Court of Strasbourg, that it is irrational to forbid heterologous fertilisation in all cases, because this would lead to a complete negation of the fundamental right to become parents, especially of persons affected by serious diseases, by preventing such persons from having a child (see para. 13).[9] The protection of the interest to

[6] Regarding the legal implications of a pre-implantation analysis according to Italian and the European case law, see Stefanelli (2016).

[7] This fundamental right includes, among other things, the right to establish and develop relationships with other human beings (see Niemietz v. Germany, 16 December 1992, para. 29, Series A no. 251-B), the right to "personal development" (see Bensaïd v. the United Kingdom, no. 44599/98, para. 47, ECHR 2001-I) and the right to self-determination (see Pretty v. the United Kingdom, no. 2346/02, para. 61, ECHR 2002-III). Aspects such as sexual identity, orientation and life are also considered covered by Article 8 (see, for example, Dudgeon v. the United Kingdom, 22 October 1981, para. 41, Series A no. 45, and Laskey, Jaggard and Brown v. the United Kingdom, 19 February 1997, para. 36, Reports of Judgments and Decisions 1997-I).

[8] See Evans v. the United Kingdom [GC], no. 6339/05, para. 71, ECHR 2007-IV, and A, B and C v. Ireland [GC], no. 25579/05, para. 212, 16 December 2010; R.R. v. Poland, no. 27617/04, para. 181, ECHR 2011. See also ECHR, Dickson v. the United Kingdom [GC], no. 44362/04, para. 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.

[9] Once the Constitutional Court declared the unconstitutionality of the prohibition against heterologous fertilisation, 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 discrimi-

become a parent led to the dismantling of another pillar of Law no. 40/2004, that is, the limitation on access to assisted reproduction of infertile couples. The Tribunal 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 who were fertile, from access to assisted procreation.

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 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 (hereinafter also referred to as the "ECHR"). 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.

4 Freedom of circulation within the European Union and the recognition of personal status

Law no. 40/2004 does not take into consideration other important interests recognised by European law. This is the case of the freedom of the circulation of persons, which 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 and 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 exercise of that right leads to the maintenance of the individual legal qualifications of the persons: their names, their drivers' licences, their professional and academic diplomas and their family status (e.g. spouses, parents, children). EU Member States cannot create barriers to the implementation of a status established by other EU laws through the use of traditional instruments of international private law such as "reciprocity" (see Article 16 of the preliminary

Footnote 9 (continued)
nate against heterologous fertilisation in favour of other techniques by refusing to reimburse the expenses borne by the concerned couples. 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).

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".[10]

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 the recognition of the parentage of same-sex couples. In those cases, Italian judges also correctly applied Constitutional and supranational principles. The Court of Appeals of Bari, on 25 February 2009,[11] 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 UK, 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.[12] More recently, a judgement of the *Corte di Cassazione* (sent. 30 September 2016, no. 19599) recognised the validity in the Italian legal system of the act of birth concerning a child born from two mothers issued in another EU country. 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

[10] ECJ 4 October 2012, C-249/11, Hristo Byankov/Glaven sekretar na Ministerstvo na vatreshnite raboti, para. 40, not yet published; see also ECJ 10 July 2008, C-33/07, Jipa, ECR 2008 p. I-5157, para. 23; Id., 17 November 2011, C-430/10, Gaydarov, para. 33, not yet published. Regarding the limitation on the free movement of persons, see Pizzolo (2013).

[11] In leggiditalia.it.

[12] In 2009, the Tribunal of Rome rejected an action concerning the denial of paternity promoted by the brothers of a man, who was an Italian citizen, and who was married to another man in accordance with UK law. See Garibaldi (2009) and Molaschi (2010).

criminal sanctions provided by Law 40/2004 are not applied (see *Cassazione penale*, sent. 10 March 2016, n. 13525).[13]

Based on the above-mentioned cases, as well as 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, as well as the defence of traditional approaches, often leads to very curious formal solutions. This occurred in the *Conseil d'Etat* in France,[14] 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 homosexual couples are entitled to a "family life" and have the right to "uniform treatment" as that accorded to spouses of different sexes.

Such a formalistic approach was disowned by the European Court of Human Rights in its judgement in Mennesson v. 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, and thus, affected the full exercise of the right to a family life as recognised by Article 8 ECHR.

5 Proportionality and balance between fundamental interests

As stated by the case law, Italian law failed in the identification of the interests to be protected, such as the right to health, to become a parent and to freely circulate. Furthermore, Law no. 40/2004 does not achieve the objective of ensuring an equilibrium between several interests.

First, European and Italian courts consider it unreasonable to treat an embryo (potentially a person) in the same way as a person who is already born or to consider the protection of the embryo on the same level as the protection of women's health (see ECtHR, judg. Costa and Pavan v. Italy, paras. 62 and 63; Corte costituzionale, judg. no. 151/2009, para. 2).[15] Human dignity is a pivotal principle within European

[13] In Foro Italiano, 2016, 5, 2, 286; in Diritto Penale e Processo, 2016, 8, 1085.

[14] Conseil d'État, La révision des lois de bioéthique, Paris, 2009, in legifrance.gouv.fr.

[15] The Court of Strasbourg in Evans v. 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.

(see, for example, the preamble of the EU Charter)[16] and national law, and it is considered to be an "expression of the respect and value to be attributed to each human being on account of his or her humanity" (para. 75).[17] Both persons and embryos deserve respect of their dignity, but in a different way, in accordance with the principle of substantive equality.

Second, any limitation on a fundamental right (such as those to health or to become a parent) should be reasonable and duly justified based on the impossibility of simultaneously protecting other relevant interests (see *Corte costituzionale*, para. 6 of judgement no. 162/2014; see also judgement no. 332 of 2000). As mentioned above, choices such as prohibiting heterologous fertilisation or limiting the access to assisted procreation only to fertile couples were found to be unreasonable, in particular, with respect to the aims of the law. In addition, the European Court of Human Rights, for example, in Costa and Pavan v. Italy, does not consider the idea, affirmed by the Italian Government, that Law no. 40 could prevent "eugenic selection" from being reasonable (see paras. 62 and 63 of the judgement). 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, without sufficient consideration of other fundamental interests (Pardini 2016).

Third, according to the European case law, the law-making power is expected to regulate matters such as medically assisted procreation following the principle of proportionality. This implies that the interference with the individual personal sphere must be "proportionate to the legitimate aim pursued" (see the Lingens judgement of 8 July 1986, Series A no. 103, pp. 25–26, para. 40) and must be "necessary" within "a democratic society", taking into account "not only … the nature of the aim of the restriction but also … the nature of the right involved" (see judgement Gillow v. the United Kingdom, of 24 November 1986, Application no. 9063/80, para. 55).[18] The measures put in place by Law no. 40/2004 have been considered disproportionate from several points of view. The prohibition of pre-implantation analysis, thought to protect the embryo,[19] opened the door to abortion (according to Law no. 194/1977) in case of diseases or malformation of the foetus, as highlighted

[16] With respect to the concept of dignity in the EU Charter, see, among others, Jones (2012); for dignity in bioethics, see Andorno (2009).

[17] See the opinion (submitted on 18 March 2004) by Advocate General Christine Stix-Hackl in the *Omega* case, ECJ judgement 14 October 2004, C-36/02, *Omega Spielhallen- und Automatenaufstellungs-GmbH* v. *Oberbürgermeisterin der Bundesstadt Bonn*, ECR 2004, I-p. I-9609.

[18] The principle of proportionality, in terms of the coherence of the means and the purposes, especially when the law limits a right recognised by the supranational legal system, is also affirmed by the case law of the Court of Justice. See, for example, the judgement *Volker* (ECJ, 9 November 2010, cases C-92/09 and C-93/09, *Volker und Markus Schecke y Eifert*, ECR [2010], p. I-11063, para. 72 and 74); Id., judg. 8 June 2010, C-58/08, *Vodafone* et al., ECR [2010], p. I-p. I-4999, para. 51; Id. judg. 8 April 2014, C-293/12 and C-594/12, Digital Rights Ireland et al., para. 46.

[19] Nevertheless, according to the international instruments, this kind of analysis is considered as legitimate in order to avoid malformations and diseases of the child, see Council of Europe, Explanatory Report to the Convention on Human Rights and Biomedicine, 1997, para. 83. At the national level, only two European countries (Austria and Switzerland) other than Italy have banned the pre-implantation analysis, see ECtHR, judgement Costa and Pavan v. Italy, ref., paras. 29–33.

by the early commentaries on Law no. 40 (Ruscello 2004) and by case law.[20] The Italian Constitutional Court, in its judgement of 5 June 2015, n. 96, declared that there was a clear antinomy in the legislation (a point also underlined by the Strasbourg Court in the judgement in Costa and Pavan v. 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 pathologies leading to anomalies or malformations (see Article 6, para. 1, letter b), of the law 22 May 1978 n. 194). 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. In addition, the Court of Strasbourg (see the judgement in Costa and Pavan v. Italy, para. 57) 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 justifications argued by the Italian Government before the European judge, e.g. in cases in which the foetus was affected by disease, the woman would be able to abort. Also, the obligation for the "single and contemporary implant of the embryos at the maximum of three" in Article 14, para. 2, Law no. 40/2004 was found to be "non-proportional", and thus, illegitimate, by the Constitutional Court in judgement no. 151 of 8 March 2009 based on at least two constitutional principles.[21] 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". Second, 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).

6 Research on human embryos

The judges have analysed an additional aspect of Law 40 not considered rational, which is the prohibition of research activities concerning embryos. 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; Penasa 2011; Veronesi 2007). 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

[20] See the decree of the Tribunal of Cagliari of 5 June 2004 in Famiglia e diritto, 2004, p. 500.

[21] 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.

human embryos, the Court of Florence, in a decree of 12 December 2012,[22] affirmed that the balancing of interests put in place by Law no. 40 was "totally unreasonable", considering that embryos which cannot be implanted for procreation purposes are destined for self-destruction in a 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 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.[23] 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 v. Italy in the Grand Chamber of the European Court of Human Rights.[24] 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.

However, with respect to the issues concerning research on embryos, the dialogue between the national and European judges did not produce a resolution. In particular, the issue was addressed in the judgement of the Grand Chamber of the European Court of Human Rights in the case of Parrillo v. Italy (Application no. 46470/11), adopted on 27 August 2015 (see the commentaries in D'Amico 2015; Poli 2015; Conti 2015a, b). 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). It 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

[22] Tribunal of Florence, 12 December 2012, in Nuova giurisprudenza civile commentata, 2013, I, 589.

[23] 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.

[24] D'Amico (2014) pointed out that the Italian Constitutional Court waited for the judgement of the Court of Strasbourg before taking its decision.

to which there is no consensus within the legislation of the States in the Council of Europe[25]: 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 the 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).[26] 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, para. 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 particularly strange. The case law of the European Court itself, as well as the judgements of the Constitutional Court by other Italian judges, clearly states 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 should not be 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".[27]

[25] See S.H. and Others, cited above, para. 94; Evans, cited above, para. 77; X, Y and Z v. the United Kingdom, 22 April 1997, para. 44, Reports of Judgements and Decisions 1997-II; Fretté v. France, no. 36515/97, para. 41, ECHR 2002-I; Christine Goodwin v. the United Kingdom [GC], no. 28957/95, para. 85, ECHR 2002-VI and A, B and C v. Ireland, cited above, para. 232.

[26] 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).

[27] See the Dissenting Opinion of Judge Sajó, para. 13.

7 The legislature's margin of appreciation in technical and scientific matters

The case law concerning Italian legislation on reproduction leads to the consideration of a very central question: the actual extent of the "margin of appreciation" of the domestic legislature in regulating matters related to science and technology (Penasa 2016a, b). According to the European Court of Strasbourg, in vitro fertilisation treatments are considered 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). In its case law, the European Court of Human Rights usually underlines the absence of homogeneity in the solutions adopted by the Member States of the Convention.[28]

However, the same Court does not exclude its own power to control compliance with the principles of the European Convention. In its judgement no. 162 of 2014 (see among others: Carbone 2014; Casonato 2014; D'Amico 2014; Morrone 2014; Musumeci 2014; Penasa 2014; Pioggia 2014; Rodomonte 2014; Ruggeri 2014; Sorrenti 2014; Tigano 2014; Tripodina 2014; Violini 2014),[29] 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 dignity and to the control of the constitutional judges at the national and European levels. Furthermore, law must be consistent with a specific manifestation of the principles of proportionality and reasonableness, namely with "scientific acceptability" (ECtHR, Costa and Pavan v. Italy, ref.). In scientific matters, the European Court invoked the principle of proportionality when it affirmed, in S.H. v. Austria of 2011,[30] the necessity for an "assessment of the rules governing artificial procreation, taking into account the dynamic developments in science and society" (see paragraph no. 117).[31] In addition, the Court is of the opinion that legislation in this area should emerge from a debate that is not only scientific but also considers broader issues. In Evans v. United Kingdom in 2007, for example, the European Court of Human Rights, considering the Human Fertilisation and Embryology Act 1990, in its definition of the measure of the British legislature's margin of appreciation, held that "the 1990 Act was the culmination of an exceptionally detailed examination of the social, ethical and legal implications of developments in the field of human fertilisation and embryology, and the fruit of much reflection, consultation and debate" (para. 86), and that this was done through

[28] See the judgement ECHR, decision X, Y and Z v. the United Kingdom of 22 April 1997, Reports of Judgements and Decisions 1997-II.

[29] See among others: Carbone (2014), Casonato (2014), D'Amico (2014), Morrone (2014), Musumeci (2014), Penasa (2014), Pioggia (2014), Rodomonte (2014), Ruggeri (2014), Sorrenti (2014), Tigano (2014), Tripodina (2014) and Violini (2014).

[30] See S.H. and Others v. Austria [GC], no. 57813/00, para. 82, ECHR 2011.

[31] See ECtHR, judg. 11 July 2002, *Christine Goodwin v. United Kingdom*, no. 28957/95, para. 74, ECHR 2002-VI; Id. judg. 28 May 2002, Stafford v. United Kingdom [GC], no. 46295/99, para. 68, ECHR 2002-IV.

the integration in the traditional legislative process of technical and independent subjects who supported the legislature with elements of the evaluation of complex issues. In any case, scientific acceptability implies that the domestic law-making power is not entitled to make technical choices, for example, forbidding "certain techniques of artificial procreation that had been developed by medical science but of which they could not avail themselves because of that prohibition" (see S.H. et al. v. Austria, where the European Court analysed Austrian legislation that regulated heterologous fertilisation, allowing only the donation of sperm but not of ova). Otherwise, there would exist an undue "interference by the State with the applicants' rights to respect for their family life". Since its judgement no. 282 of 2002, with regard to questions of constitutionality in relation to legislative intervention in medical and scientific matters, the Italian Constitutional Court has constantly referred to the existence of a principle according to which the legislature cannot act solely on the basis of political discretion, but must take account of the state of scientific and technical knowledge. This is done particularly through the results of the activities of national and supranational bodies (see also the judgement of the *Corte costituzionale* n. 185 of 1998 on the so-called "Di Bella cure").

Italian Law no. 40/2004 did not pass the test of scientific acceptability as elaborated by the Court of Strasbourg. In its judgement no. 162 of 2014 (see among others: Carbone 2014; Casonato 2014; D'Amico 2014; Morrone 2014; Musumeci 2014; Penasa 2014; Pioggia 2014; Rodomonte 2014; Ruggeri 2014; Sorrenti 2014; Tigano 2014; Tripodina 2014; Violini 2014),[32] 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 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 Strasburg, has censured the use of the power of discretion by the Italian legislature. By virtue of this approach, the Italian Constitutional Court, for example, declared article 4, paragraph 3, of Law 40/2004 on medically assisted fertilisation, which prohibited heterologous fertilisation (Judgement No. 162 of 2014), to be unconstitutional. 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 legislature 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. This judgement reiterates that the legislature's intervention in ethically sensitive matters is not merely desirable, but also necessary. However, the Constitutional Court must, even in such cases, exercise control

[32] See among others: Carbone (2014), Casonato (2014), D'Amico (2014), Morrone (2014), Musumeci (2014), Penasa (2014), Pioggia (2014), Rodomonte (2014), Ruggeri (2014), Sorrenti (2014), Tigano (2014), Tripodina (2014) and Violini (2014).

over the constitutionality of the principle of technical-scientific reasonableness. The basic rule in this field is to leave autonomy and responsibility, which must be implemented with respect to the state of knowledge, with scientists and professionals. An example of the application of this approach is Judgement No. 151 of 8 May 2009, which declared another part of Law 40/2004, which established the maximum number of embryos to be implanted in the uterus, to be unconstitutional. The judgement states that a law should not establish a technical rule that derives only from the competence of professionals and from the evolution of technology and science. According to the Italian Constitutional Court, the provision for the creation of no more than three embryos, in the absence of any consideration of the subjective conditions of women, contravenes Article 3 of the Constitution from the point of view of equality and rationality and is contrary to the principle of informed consent provided for in Article 32 of the Italian Constitution. The lack of discretion accorded to doctors affects the fundamental rights, and in particular, subjects both the woman and the embryo to danger:

> 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; 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 on 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".

8 Legislative and judicial approaches to regulating assisted procreation

As mentioned above, for more than a decade, the Italian Parliament and the Italian Government have not formally amended Law no. 40/2004. Only the dialogue between the courts has enabled the law to be consistent with the fundamental principles at the national and supranational levels (Conti 2015a, b). Not all of the outcomes of this jurisprudential conversation are perfect, as highlighted by the case of research on embryos. However, even in that case, the link between the national and supranational case law is evident.

In any case, the question is the legitimacy of this role of the European and national judiciaries in the correction of legislation regarding ethically sensitive matters such as human reproduction. The case of the "rewriting" of Law no. 40/2004 could be considered one example of the so-called "judicial activism" especially of European

judges, which has been criticised by some authors. In many cases, the Court of Justice (Bettati 1989) and the European Court of Human Rights (Mahoney 1998; Letsas 2004) are perceived as seeking to replace the legitimate legislative power (but against this opinion, see: Everling 1983–1984), posing the problem of the "democratic deficit" in the process of legal integration (Busnelli and Calderai 2010). However, the multilevel "dialogue" among judges in Europe is provided by the European Union Treaties, the system of the European Convention on Human Rights and other legal sources. This is the case of the judicial system of the European Union, which is formally composed of the Court of Justice but also of the national judges, which carries out several tasks that are very important for the entire supranational legal order: they can ask the Court of Luxemburg for a preliminary ruling (see Article 267 Treaty on European Union); their case law represents the main reference in order to establish the legal meaning of a national rule[33]; they apply supranational law in the controversies that they decide[34] and they must interpret the national law in the framework of the European Union law,[35] especially taking into consideration the case law of the European Court of Justice.[36] Moreover, the European Court of Human Rights represents the fulcrum of a judicial system which aims at implementing the fundamental rights established by the Convention of Rome ensuring "the observance of the engagements undertaken by the High Contracting Parties in the Convention and the Protocols" (Article 19 European Convention of Human Rights). The Court has the exclusive competence in interpreting the Convention and the legal sources arising from it (Article 32), and its judgements are mandatory for the Member States (see Article 46 of Convention).

In addition, due to the relevance of the fundamental rights in modern law, it is broadly accepted that the international rules in this field and the interpretation given by the international courts also allow domestic judges to implement the international *corpus iuris* of human rights.[37] Also, in intergovernmental regional systems, such as the European Convention on Human Rights, legal doctrine refers to the *Drittwirkung*, that is to say, the direct application of the international corpus of human rights by the national courts to relationships between individuals.[38] The compliance with European rules and principles is a positive obligation of the State, as well as of its powers, in particular, the judicial one (Sanz Caballero 2013). In accordance

[33] See in particular the judgements as follows: ECJ 24 January 2002, C-372/99, *Comission/Italy*, ECR 2002, p.I-819; Id. 8 June 1994, C-382/92, *Comission/United Kingdom,* ECR 1994, p. I-2435, par. 36; Id. 29 May 1997, C-300/95, *Comission/United Kingdom*, ECR 1997, p. I-2649, par. 37.

[34] ECJ 9 March 1978, 106/77, *Amministrazione delle finanze dello Stato/Simmenthal*, ECR 1978, p. 629.

[35] See, for example, ECJ 26 September 1996, C-168/95, *Arcaro*, ECR 1996, p. I-4705, par. 41–43.

[36] See ECJ 6 July 1995, C-62/93, *BP Soupergaz/Greece*, ECR 1995, p. I-1883.

[37] Scott and Stephen (2006) quote the case law of the US Supreme Court, especially the judgement in Sosa v. Alvarez-Machain, 542 U.S. 692 (2004), which supported the idea that the federal courts can use international law; see also Medellin v. Dretke, 544 U.S. 660 (2005); Roper v. Simmons, 543 U.S. 551 (2005).

[38] See, for example, Spielman (1995). In Italy, the legal literature and the case law affirm that the European Convention of Human Rights is directly applicable. See, among others, Nunin (1991). For the case law, see, for example: Corte di Cassazione, 27 May 1975, no. 2129, in *Gius. it*., 1976, I, p. 970; Id. 2 February 2007, no. 2247, in *Nuova giur. civ. comm.*, 2007, p. 1195.

with the framework mentioned above, the national judges, especially the constitutional ones, declare the illegitimacy of norms only if an interpretation consistent with supranational principles is not possible (see the Italian Constitutional Court in Judgement No. 96/2015) (Ferrando 2015).

Therefore, interactions between judges at different levels are correctly designed to influence legislation, especially on issues where the use of technoscience endangers fundamental rights. Obviously, the situation which has occurred regarding Law no. 40 through the extensive intervention of the courts is not desirable from the viewpoint underlined by the European Court of Human Rights that, in sensitive fields such as assisted reproduction, normality should be represented by a pluralistic and open debate within society. 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 technoscience. In some cases, judges have played a substitute role vis-à-vis the legislature, as in the case of the Italian law on medically assisted procreation, where case law repealed the rules of Law 40/2004 or applied them in accordance with constitutional and supranational principles. In other cases, judges have a supporting role for the legislature as technical bodies, ensuring the reasonableness of the law, which, according to the European Court of Human Rights, is the basis for the correct use of the national legislature's margin of appreciation. For example, the French *Conseil d'État* had a remarkable role on the occasion of the last reform of the *lois de bioétique*, Law No. 2011-814 of 7 July 2011 (for a commentary, see Cippitani 2011), through a very detailed report on the coherence of the draft law with the principles developed by transnational and other European countries' jurisprudence.[39] The French legislature obviously did not accept all the suggestions of the Council of State, but it was able to have a precise overview of the issues and principles under discussion. From this point of view, at the national level, judges, especially those in constitutional courts, play a role that is inversely proportional to the follow-up given by the national legislature to these principles. Therefore, in this field, there is a slight approximation of judges to the legal systems where there is a mechanism for debate and reflection on scientific issues. So, it should come as no surprise that the French Constitutional Council, in many of its decisions, does not appear to wish to interfere with the legislative power, due to a very participative legislative process (see, for example, decision 2012-249 on the law on the levy and use of the umbilical cord).

On the other hand, it should be stressed that the role of judges in this area should not be considered as contingent and dependent on the degree of efficiency of the legislature. The function of the judiciary is necessary in elaborating and implementing the ethical directives. As a matter of fact, the elaboration of ethical principles to regulate scientific activity cannot take place only through the legislative power, especially the national legislature. The issue of the ethical limits of science seeks to strike a balance between constitutionally protected fundamental rights (on the one hand, the freedom of research, and on the other hand, dignity and the other fundamental rights). The balance is difficult to achieve, as this is a sector in which

[39] Conseil d'État, *La révision des lois de bioéthique*, Paris, 2009.

philosophical, ideological and political perspectives have an enormous impact, including on the application of legal norms. In a democratic and pluralistic society, a single vision cannot be imposed (Rodotà 1996), but rather, a continuous dialogue between different perspectives even on bioethical issues, albeit in light of the fundamental values, is necessary (Scarpelli 1996). The dialogue concerns a constantly changing technical and scientific field. Therefore, it is not possible to develop permanent or at least lasting solutions to ethical dilemmas. Even a legislature that complies with the scientific reasonableness required by the European Court of Human Rights must regularly update norms, as is the case, for example, with the French bioethics laws, which have been amended regularly since the beginning of the 1990s. However, here too, the speed of technical and scientific change and the plurality of social and legal issues that arise are greater than the capacity to update the legal system.

Another limitation of the legislation is that it refers to a specific geographical area, while ethical problems follow the universal nature of science and technology. An application of this idea is found in the case law of the Court of Justice. In the Brüstle judgement, the Court of Justice states that "although the definition of human embryo is a very sensitive social issue in many Member States, marked by their multiple traditions and value systems, the Court is not called upon, by the present order for reference, to broach questions of a medical or ethical nature, but must restrict itself to a legal interpretation of the relevant provisions with EU law" (para. 30).[40]

Finally, because of the above features, the ethical issues of science are a "complex" (Monnier 2009) matter. If the ethical dilemmas that arise from science were merely complicated, with substantial effort, one could eventually reach solutions. On the other hand, a complex issue does not have a single or a final solution (Morin 1977). In fact, in a complex system, temporary solutions can be developed that serve to find a balance for a given moment; however, they do not eliminate conflict and cannot achieve a balance over the centuries. All of the above leads to the conclusion that the legislative solutions to ethical issues, when properly implemented, are not always the best or cannot be the only ones. To manage the complexity of the ethics of science, an irreplaceable role is carried out by the work of jurists, and especially by the judges, who, acting as "*inter-partes* philosophers" (Palazzo 2008), represent the fulcrum of the dialogue between scientists, public officials and other stakeholders. In fact, jurists are professionals who have specific competence in the application of rules and regulations, but their main function is to mediate conflicts between principles, approaches, ideologies and profiles from different technical perspectives. Judges, in particular, are requested to give very quick answers to problems that are brought to their attention. Therefore, judicial action in the ethical field is necessary to face the challenges that derive from science and technology, seeking an acceptable balance at a specific time, making the connection between different disciplinary points of view and bringing into contact the different legal levels (local, national, supranational, international).

[40] See ECJ, judg. 26 February 2008, C-506/06, Mayr, ERC 2008, p. I-1017, para. 38.

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