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**The Italian Law on assisted reproductive technologies n. 40 of 2004 facing the European Court of Human Rights: the case of Costa and Pavan v. Italy.**

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**Abstract:**

This article will describe the current legal framework on assisted reproduction technology (ART) regulation in Italy, taking into account recent case-law derived from the implementation of the Law 40 of 2004 on ART. Special attention will be devoted to the case of Costa and Pavan v. Italy, recently decided by the Tenth Session of the European Court of Human Rights (ECtHR). In that decision, the European Court declared the incompatibility of the ban to pre-implantation genetic diagnosis introduced by the abovementioned Italian law on ART. The case will be analysed from a dual perspective. On the one hand, it will be considered in the light of the ECtHR case-law, in order to derive systematic aspects of continuity or discontinuity between the former and the latter. On the other hand, the case will be considered in the light of its concrete and prospective impact on the Italian legal approach to ART regulation, considering especially the direct and indirect influence of the case: e.g., its possible utilisation by Italian judges when they are called upon to implement Law 40.

**Keywords:** ART regulation – embryo – European Court of Human Rights – preimplantation genetic diagnosis – right to procreate

**Summary:** *1. Introduction. 2. The Italian legal approach to ART regulation: Law 40/2004 and its enforcement. 2.1. The regulation of PGD: How contradictory rules (inevitably) generate creative case-law. 2.2. The normative journey towards the judicial rewriting of the PGD regulation. The Italian case-law on PGD. 3. The European Court of Human Rights case-law on the beginning of life and ART regulation: Towards the consolidation of a common understanding of the role of law? 3.1. The right to procreate and have access to ART: within or beyond article 8 of ECHR? 3.2. The margin of appreciation within the medical sector: consensus or clear trend of legislations? The exceptionalism of the regulation of beginning of life. 3.3. The scrutiny of the concrete exercise of the margin of appreciation: From deference to strict scrutiny? The reasoning of the ECtHR in Costa and Pavan v. Italy. 4. Conclusion. The impact of the decision on the Italian legal system: a prospective and actual foresight.*

## 1. Introduction.

The case represents the more recent (but probably not the last) stage of the judicial journey of the Italian law on ART, which is being substantially re-written by the multilevel judicial system (national judges; Constitutional Court; European Court<sup>1</sup>). The article is structured in two main sections. The first part will describe the case of the Italian couple that appealed to the European Court of Human Rights, in order to state the incompatibility of law 40 with article 8 and 14 of the European Convention of Human Rights (ECHR). It will be linked with the legal and judicial developments characterising the Italian legal framework, as they are fundamental in order to understand the potential relevance of the case being examined. In the second part of the article, the analysis will focus on the recent case-law of the ECtHR with regard to legal issues related to the beginning of life. More concretely, in the last decade, ECtHR has been called upon to decide many relevant cases<sup>2</sup> dealing with: the protection (and the very existence) of a right to procreate and its expression by means of assisted reproductive technologies; the duty of Contracting States to guarantee the exercise of such rights and the concurring margin of appreciation to be recognised to them when regulating ethically and socially sensitive issues such as those related to the beginning of life. Special attention will be given to the case of *Costa and Pavan v. Italy*.

## 2. The Italian legal approach to ART regulation: Law 40/2004 and its enforcement.

Law 40/2004 is characterised by a strict approach, which has been defined as ‘value oriented’<sup>3</sup>. It is the result of a Parliamentary debate in which the goal of protecting the embryo must prevail on all other relevant rights and interests involved<sup>4</sup>. Embryo protection can be considered as the *fil rouge* connecting the different chapters of the law, together with the intention of guaranteeing a traditional concept of family and biological familial relationships. They both characterise the structure of the law, starting from the purposes which legitimate the access to ART (art. 1), towards the regulation of the concrete implementation of medical techniques (art. 14), passing through the regulation of research and experimentation with embryos (art. 13)<sup>5</sup>. All these issues directly affect the discussed

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<sup>1</sup> See E. Dolcini, *La lunga marcia della fecondazione assistita. La legge 40/2004 tra Corte costituzionale, Corte EDU e giudice ordinario*, in *Rivista italiana di diritto e procedura penale*, 2, 2011, 428 ff.

<sup>2</sup> See section 3 of the article.

<sup>3</sup> I recently proposed a classification grounded on the concrete characters of both law-making and law-enforcement of national regulations on ART: see S. Penasa, *Regulating ART: The Rise of a (Common?) ‘Procedure-Oriented’ Approach Within EU*, in *Global Jurist*, 12, 1, 2012.

<sup>4</sup> Nevertheless, see the decision of the Italian Constitutional Court n. 151 of 2009, that provides an interpretation according to which the protection entitled to the embryo by the Law 40 must not be intended as absolute, as it is concurrent with other constitutional goods and interests (firstly, the health of the woman involved in ART).

<sup>5</sup> According to R. Deech and A. Smajdor, *From IVF to Immortality - Controversy in the Era of Reproductive Technology*, 2007, p. 209, «in effect, the law introduces a set of prohibitions rather than constructing a general

case. Costa and Pavan, an Italian married couple, are immune carriers of cystic fibrosis. Therefore, they risk transmitting the disease to their child, which is particularly serious and potentially fatal, as previously occurred in 2006. They aim at having access to ART, in order to benefit from preimplantation genetic diagnosis (PGD) and select an embryo that does not carry the disease. Precisely at this stage, the couple clashed with the Law 40. According to article 1 of the law, the access to ART is allowed exclusively for facilitating the resolution of reproductive problems resulting from human sterility or infertility. Unlike many other national experiences<sup>6</sup>, Italian regulation does not consider the case of genetically transmittable diseases, which is excluded from the reasons allowing access to ART. This is a purely discretionary and political choice provided by legislature, which in turn conditions other legal options enforced by Law 40, such as the admissibility of the PGD and the selection of embryos. Only an exception to this general criterion is provided, significantly not directly by the law, but through a secondary regulation entitled to give effectiveness to the more technical content of the law. Reference goes to the Guidelines on ART provided by the Ministry of Health in 2008, on the ground of article 7 of Law 40, which states that the Ministry of Health, by consulting the *Consiglio Superiore di sanità*, is entitled to approve guidelines on regulation of the procedures and techniques of medically assisted procreation<sup>7</sup>. According to the Guidelines, access to ART is allowed also when the risk of transmitting sexual diseases – such as HIV and hepatitis B (HBV) and C (HCV) virus – *de facto* represents an obstacle for procreation, by imposing precautions which necessarily result in a condition of infertility. Also in this case, the perspective is ‘fertility oriented’, in the sense that the exception is legitimated by the condition of substantial infertility of the couple and not directly by the aim of impeding the transmission of diseases through access to ART.

The appellants do not fall in the abovementioned category of people, as they are not substantially infertile: their condition is not related to sexually transmissible diseases, but rather to genetically transmissible one. This is a clear tilt of the Italian regulation, which will be analysed in depth below<sup>8</sup>.

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regulatory framework for the conduct of assisted reproduction and/or research».

<sup>6</sup> The Spanish regulation is a relevant example: article 1 of the Law 14/2006 on ART states that the law aims at regulating ART also when they are applied for preventing and treating genetic diseases, when sufficient diagnostic and therapeutic guarantees exist and they are properly authorised according to the law.

<sup>7</sup> According to the law, the guidelines bind all authorised structures and must be periodically updated, at least every three years, according to technical and scientific development that may occur.

<sup>8</sup> As broadly known, the concept of ‘regulatory tilt’ is utilised by R. Brownsword, *Rights, regulation, and the technological revolution*, Oxford University Press, 2008, p. 28. See also M.E.A. Goodwin, E.J. Koops, R.E. Leenes (eds.), *Dimensions of technology regulation*. Wolf Legal Publishers, 2010, particularly B.J. Koops, *Ten Dimension of Technology Revolution – Finding Your Bearings in the Research Space of an Emerging Discipline*, pp. 311-326.

## *2.1. The regulation of PGD: How contradictory rules (inevitably) generate creative case-law.*

It is worth emphasising how this approach characterises the entire legal structure of Law 40. Starting from the purposes of the law, Italian legislature builds a legal architecture in which the PGD is not formally regulated and the implementation of ART is strictly regulated by the law. Therefore, both the couples and professionals healthcare operate in a context characterised by legal uncertainty, as the law contains provisions open to different – and opposite – interpretation. Within the legal texture, contradictory rules coexist. Article 14 states that the couple are informed about the number and, upon request, the health condition of the produced embryos before their transfer to the woman's womb. On this ground, it might be possible to assume that the enforcement of a diagnostic technique – such as the PGD – is consistent with and functional to the aim of granting comprehensive information to the involved couple. From this perspective, the PGD may be permissible, as a functional activity to the effective exercise of a right entitled directly by Law 40 (to be informed about the health condition of embryos). However, at the same time article 13 (dedicated to the “experimentation on human embryos”) clearly prohibits any experimentation and research on human embryos. The only exception to this absolute ban is represented by the research that pursues therapeutic and diagnostic purposes in the light of health and development of the embryo on which it is performed, and when any other alternative methods are not available. In any case, the law prohibits any form of selection of embryos or gametes for eugenic purposes (art. 13) and also the selection (or manipulation) of embryos aimed at altering the embryo's gene pool, except when it has therapeutic and diagnostic purposes. Accordingly, this regulatory asset seems to forbid the activity to which the PGD is functional: to select, among the created embryos, those that do not carry genetically transmissible diseases. Therefore, on the one hand the couple has the right to be informed on the health conditions of the embryos; on the other, it is unclear whether the technique which is functional to its effective enforcement – PGD – is allowed by the law, also in the light of both its own purposes and a very strict/prohibitionist structure. The uncertainty is further increased by a concurrent prohibition provided by article 14.1. According to this article, both embryos cryopreservation and elimination are absolutely forbidden. It entails that all created embryos for reproductive purposes must be simultaneously transferred to the womb, in order to avoid the risk of the embryo's destruction or loss (art. 14.2)<sup>9</sup>.

Therefore, the regulatory tilt achieves its acme when interpreters and judges are called to guarantee the consistency and coherence of all these concomitant provisions. At this stage, a dichotomy between the law on the books and the law in action emerges, when we consider the judicial

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<sup>9</sup> The duty to produce no more than three embryos and contemporaneously transfer all the created embryos have been quashed by the Constitutional Court in the aforementioned decision 151/2009, which has also relaxed the absolute ban of embryo's cryopreservation.

enforcement of the Italian regulation in the context of PGD. It has been said that Italian law on ART is subject to a re-writing process by part of the judiciary, when considering the large amount of decisions pertaining to its provisions<sup>10</sup>. Certainly, the issue of PGD represents a paradigmatic example of this highly critical and controversial trend. Facing an unclear legal framework, Italian couples started to sue against the law 40, in order to have access to ART and then to PGD. Judicial reaction represents a normative journey characterised by different intermediate stopovers, within which the Costa and Pavan case represents the latest but probably not the last one.

## *2.2. The normative journey towards the judicial rewriting of the PGD regulation. The Italian case-law on PGD.*

At a first stage, the judiciary adopted a very strict interpretation, according to which the PGD – in the light of both the letter of the law and legislature purposes – must be forbidden. According to the Tribunal of Catania (2004)<sup>11</sup>, the selection of embryos not affected by genetically transmissible diseases and the concomitant cryopreservation of unhealthy embryos, are expressly forbidden by article 14.1 of the law 40. This, on the ground of the unambiguous intention of the legislature to limit the access to ART exclusively to the certification of a condition of sterility or infertility. Indirectly, the purpose of avoiding the transmission of genetic diseases from the parents to the embryos does not allow couples to have access to ART and therefore to PGD. Another judge, stating that it is not possible to achieve an interpretation allowing PGD, confirmed this interpretation<sup>12</sup>. The same judge considered unconstitutional the ban of PGD, when the latter is aimed at preventing the transmission of a genetic disease. According to the judge, Law 40 must be considered inconsistent with the Italian Constitution when it does not allow detecting, through the PGD, if the embryos are affected by parents' genetic disease, and it causes a serious and actual risk for woman's health. Furthermore, if the legal order recognises the right of the parents to be informed about the health of the foetus during the pregnancy, it is not possible to deny a similar right with regard to ART. Otherwise, the equality clause provided by article 3 of the Italian Constitution is violated, as similar situations are treated differently without any reasonable and justified reason<sup>13</sup>.

This is the first turning point of the judicial development with regard to admissibility of PGD

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<sup>10</sup> G. Ferrando, *La riscrittura costituzionale e giurisprudenziale della legge sulla procreazione assistita*, in *Famiglia e diritto*, 5, 2011, p. 520.

<sup>11</sup> Tribunal of Catania, I Section, Order, 3<sup>rd</sup> May, 2004.

<sup>12</sup> Tribunal of Cagliari, Order, 29<sup>th</sup> June, 2004.

<sup>13</sup> See S. Penasa, *The issue of constitutional law legitimacy on 'human assisted reproduction' between reasonableness of the choices and effectiveness of the protection of all involved subjects*, in *Revista de Derecho y Genoma Humano*, 25, 2006, pp. 117-137.

according to Law 40. The Italian Constitutional Court was called at checking the constitutionality of PGD ban provided by the law, on the ground of the abovementioned reasoning. Significantly enough, the Court “decided not to decide”<sup>14</sup>. It dismissed the case on procedural grounds, stating that – according to the same appellant judge's reasoning – the ban of PGD derives from the whole structure of the law and its own fundamental principles, and not merely from article 13. Therefore, the judge failed in proposing appeal, as it would have to refer also to other articles, which are not part of the constitutional adjudication. Interestingly, the Constitutional Court does not take stand with regard to the admissibility of PGD. It merely follows the reasoning of the appealing judge, showing its supposed inconsistency; it is also worth noting that the Court should have bypassed the described argumentative gap, by applying the traditional mechanism of the derived unconstitutionality, according to which the Court can declare unconstitutional also provisions not directly assumed by de the a quo judge, but linked to the one expressly object of the scrutiny<sup>15</sup>.

The static and cautious approach of the Constitutional Court provoked the reaction of ordinary judges, and indirectly opened the second stage of the judicial journey of Law 40. Starting from the decision of the Court, hence, ordinary judges changed their approach. Even if the text of the law was unvaried, judges started to enforce what had previously been considered impossible: an interpretation consistent with the Constitution, according to which PGD must be considered allowed by the law, even if under specific conditions and requirements. Therefore, departing from an approach that was very deferential to the supposed intent of legislature based on the letter of the law, interpreters started to move towards a more dynamic and open approach, based on a systematic and evolutionary interpretation. The shift was radical, but necessary in order to guarantee the consistency of the law with constitutional principles and rights: the equality principle and the right to health of the woman, and – from a more general perspective – the coherence and reasonableness of the whole legal framework, when comparing ART and the abortion regulation. Significantly, the European Court of Human Rights has been called upon, in the *Costa and Pavan v. Italy* case, to rule precisely on these two aspects: on the one hand, the compatibility of Law 40 with article 8 of ECHR, stating the right to respect private and family life; on the other hand, the equality clause provided by article 14 ECHR, prohibiting any discrimination based on sex and personal conditions. From that time on, a process of gradual but continuous development related to the PGD admissibility started. The shift characterising Italian case-law on PGD is particularly relevant for showing the progressive gap/deviation between the text of law 40 and its concrete enforcement. Furthermore, it performs a decisive role within the ECtHR reasoning in the commented case,

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<sup>14</sup> Constitutional Court, Order, n. 369/2006. See L. Trucco, *Procreazione assistita: la Consulta questa volta, decide (almeno in parte) di decidere*, in *Giurisprudenza italiana*, 2, 2010, p. 281-289.

<sup>15</sup> See M. D'Amico, *Il giudice costituzionale e l'alibi del processo*, in *Giurisprudenza costituzionale*, 6, 2006, pp. 3859 ff.

particularly with regard to the issue concerning the violation of article 14. We will see that the European Court does not take into account the whole case-law in that context, limiting its own arguments to a specific decision<sup>16</sup>, without being able to appreciate the decisive evolution within the Italian case-law towards a comprehensive admissibility of PGD. This approach has inevitably conditioned the pronouncement, as we will see in section three. Accordingly, it may open the door for a new conclusion on whether the Italian Government will decide to appeal the decision before the Grand Chamber of ECtHR<sup>17</sup>.

The first step of the judicial reaction to the Italian Constitutional Court's decision was the decision of the Tribunal of Cagliari in 2007<sup>18</sup>. The judge points out that, due to the coexistence of concurrent provisions and the absence of a stated rule on PGD, opposite interpretations have been proposed: respectively, allowing and banning PGD. According to the judge, the approach which allows PGD must be preferred, on the ground of an interpretation consistent with the Italian Constitution, when a set of conditions – interestingly, not provided directly by the law but derived from the text by judicial reasoning – are fulfilled: 1. PGD is requested by those subjects who, according to article 14.5, are allowed to be informed about the number and health conditions of created embryos; 2. PGD is carried out on embryos created for reproductive purposes, in order to be transferred to the woman's womb; 3. PGD is functional in detecting possible diseases and guaranteeing the couple adequate information about the health condition of the created embryos. This approach was confirmed by the Tribunal of Florence (2007), which went a step further in building a regulatory framework for PGD. The Tribunal stated that not only the law does not provide for the ban of PGD, but it even entails this technique. These decisions have set the theoretical ground for a further development of the case-law, precisely with regard to the concrete scope of application of both PGD and access to ART. As stressed above, the issue of the right to have access to ART is interconnected with the admissibility of PGD, as the limit imposed on the former – in order to exclude the purpose of avoiding the risk of transmission of genetic diseases – inevitably conditions the availability of the latter.

On this ground, the Tribunal of Salerno stated in 2010 the right of a couple carrying a genetically transmissible severe disease to have access to both ART and PGD, even if they are not affected by sterility or infertility. The decision seems to really go beyond both the text and the general purposes of Law 40. As stressed before, the law allows the access to ART exclusively in order to overcome sterility and infertility, thus excluding the purpose of avoiding transmission of genetic diseases. Nevertheless, the Tribunal suggests a reconstruction of the whole legal structure based on the

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<sup>16</sup> Precisely the Order of the Tribunal of Salerno (2010), which allows a fertile couple carrying a genetic disease to have access to ART (see below).

<sup>17</sup> On 28<sup>th</sup> of November 2012, the Italian Government appealed the ECtHR decision, which will be accordingly evaluated by the Grand Chamber.

<sup>18</sup> Tribunal of Cagliari, 24<sup>th</sup> September 2007.

enlargement of the subjects entitled to access ART, based on the identification of a right of the woman to have a child. According to the judge's reasoning, this right derives directly from article two of the Italian Constitution, which protects inviolable human rights: it would encompass also the right of reproductive self-determination, which will be unreasonably violated by an interpretation impeding access to ART for fertile couples carrying genetic diseases<sup>19</sup>. Once the purposes for accessing ART have been broadened, the admissibility of PGD becomes a consequence of the goal of preventing transmission of genetic diseases. Therefore, according to the Tribunal, the PGD is functional in satisfying the interest of the couple in having adequate information on the health of embryo.

When considered from a comparative perspective, the Italian exceptionalism becomes clearly evident. It encompasses not only the fact that – within the European context – Italy is one of the last legal systems in which PGD is not allowed expressly by law<sup>20</sup>. Beyond that, and more significantly, the Italian approach is characterised by the reversal of traditional roles and functions between the legislature and the judiciary. If in most European countries has intervened for regulating PGD, legislature, although according to different timing and methods and requirements<sup>21</sup>, Italian legislature declined to formally introduce a rule on this issue. In this way, it leaves both the subjects directly involved (the woman, the couple, physicians<sup>22</sup>) and the interpreters (firstly the judges<sup>23</sup>, but also scholars) in a condition of legal uncertainty, which inevitably leads to contradictory and controversial decisions and theoretical understanding, as the analysis of the Italian case-law has revealed. Exceptionalism reveals itself also with regard to the functional and logical relationship between two interrelated issues: on the one hand, conditions legitimising the access to ART; on the other hand, the admissibility of PGD, which should logically follow – as a consequence – the former. Within the Italian legal framework, the functional and logical connection has been reversed, by means of the intervention of the judiciary which has tried to restore both consistency and reasonableness of the legislative structure: facing a legislative gap with reference to the PGD, the judiciary deeply stresses the existing rules on the conditions for accessing ART. The final result, even if satisfactory in principle, inevitably entails a regulatory tilt which goes to increase legal uncertainty – as a general binding rule is still lacking – and stress on the principle of separation of

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<sup>19</sup> The Tribunal refers to the right to have a healthy child, grounded on article 2 of the Italian Constitution. We will see in section 3 that also the ECtHR addresses the issue of the existence of such a right, based on article 8 of the ECHR.

<sup>20</sup> As recognised by the same ECtHR in the case *Costa and Pavan*, «*oltre l'Italie, ne concerne que deux des trente-deux Etats ayant fait l'objet d'examen, à savoir l'Autriche et la Suisse*» (point 70).

<sup>21</sup> France, Spain, UK and Germany.

<sup>22</sup> See A. Molinelli, A. Bonsignore, V. Darretta, P. Anserini, *Results and unsolved problems following the amendment to the Italian Law on assisted reproduction brought about by the Constitutional Court*, in *European Journal of Obstetrics & Gynecology and Reproductive Biology*, vol. 162, 1, 2012, pp. 1-4, in which the Authors study the impact of the Italian Constitutional Court modifications on assisted reproduction from both a gynaecological and medico-legal point of view.

<sup>23</sup> From this perspective, see I. Pellizzone, *Fecondazione assistita e interpretazione conforme a costituzione. Quando il fine non giustifica i mezzi*, in *giurisprudenza costituzionale*, 1, 2008, pp. 552 ff.

powers<sup>24</sup>.

As anticipated above, the physiological divergence between the law on the books and the law in action becomes a pathological fracture within the Italian legal system when regulating ART and PGD. Whether the former is functional to adapt the legal framework to the development – highly relevant within the biomedical context – of the reality to be regulated, the latter provokes paradoxical and unacceptable consequences, such as the complete bypass of the written rule characterising a specific regulation<sup>25</sup>. It is important to stress that concerns do not affect the purpose of the judicial action, which clearly aims at restoring both consistency and legitimacy of the legislative framework. More precisely, the way followed to achieve the goal may be debatable: in any case, it is a consequence of an inadequate and incoherent legislative apparatus which unreasonably put pressure on the judiciary<sup>26</sup>.

Within this regulatory framework, the continuous reference to the judiciary seems unavoidable: it inevitably leads to an on-going process of legal rewriting which involves also constitutional adjudication and the international judicial context. As we will see in section 3, different normative levels (national, international and supranational) reciprocally interact, developing a 'normative chain reaction' within which also the case *Costa and Pavan v. Italy* can be encompassed.

### *3. The European Court of Human Rights case-law on the beginning of life and ART regulation: Towards the consolidation of a common understanding of the role of law?*

Preliminarily, a brief description of the concrete case is due. The appellants are an Italian couple that are both immune healthy carriers of cystic fibrosis, a rare genetic disease which can be transferred to the child and commonly have a fatal outcome. The couple experienced previous pregnancy in 2006 and the newborn child was affected by the disease. In 2010, in order to avoid the risk of transmitting the disease, they requested an antenatal diagnosis, which testified that the foetus was affected by cystic fibrosis. Eventually, they opted for interrupting the pregnancy, according to Law 194 of 1978<sup>27</sup>. Facing this dramatic background and aiming at preventing fatal outcomes, the couple finally would like to access ART in order to perform a PGD. As mentioned above, Italian Law 40/2004 on the one hand limits the subjects who are allowed to have access to ART to infertile

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<sup>24</sup> See C. Tripodina, *Sul come scansare la briglia delle leggi. Ovvero, la legge sulla procreazione assistita secondo il giudice di Salerno*, in [www.costituzionalismo.it](http://www.costituzionalismo.it), 2011.

<sup>25</sup> See S. Agosta, *Preimplantation Diagnosis of the Embryo: Legislative Inflexibility in vitro and Attempts at Greater Flexibility in vivo*, in R. Bin, S. Lorenzon, N. Lucchi (eds.), *Biotech Innovations and Fundamental Rights*, Springer, 2012, p. 180.

<sup>26</sup> Within this regulatory framework, the judiciary “suffers” the pressure deriving not exclusively from the concrete case to be decided, but also from what should represent a regulatory tool instead of a regulatory obstacle: the legislative source.

<sup>27</sup> The Italian Law 194/1978, on social protection of motherhood and abortion (“*Norme per la tutela sociale della maternità e sull’interruzione volontaria della gravidanza*”).

or sterile couples, formally excluding the ones who carry genetic diseases. On the other hand, it lacks a specific provision on PGD, opening to concurring and opposite judicial interpretations which leave couples (and physicians and medical centres) in a condition of legal uncertainty. Therefore, the couple – without previously referring to Italian judges<sup>28</sup> – opted for standing before the ECtHR, in order to understand if a strict interpretation of Law 40, according to which only infertile couple are allowed to access ART and accordingly PGD is forbidden, is consistent with both articles 8 and 14 of ECHR.

### *3.1. The right to procreate and have access to ART: within or beyond article 8 of ECHR?*

As is broadly known, article 8 states that everyone has the right to respect for his private and family life. This provision has been repeatedly interpreted by the ECtHR in a broad sense, in order to include interests and personal conditions related to contexts other than the strict familial and private environment. Also the sexual and reproductive context has been considered in order to understand if – and how – it may benefit from the protection provided by article 8. ECtHR has been called upon in a number of cases to decide about the compatibility of national laws regulating reproductive and sexual issues with article 8. Therefore, the Court must approach the issue of whether the right to procreate falls within article 8 as an expression of private and family life<sup>29</sup>. On this regard, the European Court has structured and consolidated a case-law according to which the notion of “private life” is a broad one, and encompasses also the right to personal development (case *Bensaïd v. United Kingdom*, n. 44599/98, point 47, 2001-I) and the right to self-determination (*Pretty v. United Kingdom*, n. 2346/02, point 61, 2002-III). Within this legal context, also the right to respect for the decisions both to have and not to have a child must be considered relevant *Evans v. the United Kingdom* [GC], no. 6339/05, point 71, ECHR 2007-IV, e *A, B and C v. Ireland* [GC], no. 25579/05, point 212, 16 December 2010), together with «the right to respect for their decision to become genetic parents» (*Dickson v. the United Kingdom* [GC], no. 44362/04, point 66, ECHR 2007-XIII). On this ground, the Court has also faced the issue of the existence of the right to procreate. On this regard, two decisions are particularly relevant. On the one hand, the Dickson case, in which the ECtHR stated that «article 8 was applicable in that the refusal of artificial insemination facilities at issue concerned their private and family lives which notions incorporate

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<sup>28</sup> Therefore, the requirement of previous fulfilment of internal remedies comes into view. The ECtHR recognised the absence, within the Italian legal framework, of an effective remedy, which legitimates couple to directly stand before the European Court. This point represents the object of the Italian Government's appeal against the commented decision.

<sup>29</sup> Referred to the approach of the ECtHR on biomedical and technological issues, see T. Murphy, G. Ó Cuinn, *Works in Progress: New Technologies and the European Court of Human Rights*, in *Human Rights Law Review*, vol. 10, n. 4, 2010, pp. 601 ss.

the right to respect for their decision to become genetic parents»<sup>30</sup>. Therefore, the access to ART seems to fall within the scope of article 8. On the other hand, the Court confirmed this approach in the S.H. and others v. Austria case (2011). The Grand Chamber, although it reverses the first instance decision<sup>31</sup>, agrees with the theoretical background proposed by the First Section. According to the Grand Chamber, «the right of a couple to conceive a child and to make use of medically assisted procreation for that purpose is also protected by Article 8, as such a choice is an expression of private and family life» (point 82). Therefore, the right to access ART seems to be also guaranteed, in order to effectively exercise the right to conceive. Significantly, even when the Court dismisses the appellants' request, it nevertheless agrees with the described approach, favourable to recognising conventional relevance to the right to procreate<sup>32</sup> and to have access to ART<sup>33</sup>.

With regard to the first issue, the Tenth Section of ECtHR follows, in the case of Costa and Pavan, the line drawn by the ECtHR case-law. Furthermore, it seems to go a step further in the concrete determination of individual interests falling within the scope of article 8. According to the Court's reasoning, the couple does not have exclusively the right to access ART, but also the appellant's desire to procreate a child not suffering a genetic disease of which the parents are carriers must fall within the protection guaranteed by article 8 ECHR (point 57). It must be underlined that the Court refers to a «*désir des requérants de procréer un enfant qui ne soit pas atteint par la maladie génétique dont ils sont porteurs sains*». Anyway, the qualification of the couple's interest in terms of a “desire” instead of a “right” seems to have no effect in terms of protection provided by article 8 in the concrete case as interpreted by the ECtHR. Therefore, if we assume a pragmatic approach which goes beyond the formal definition of a personal interest, it is possible to conclude that, despite the term used by the judges, the situation of the appellants effectively falls within the scope and protection provided by article 8 of ECHR, and it must be considered by national legislatures when regulating ART.

A process of progressive broadening of the scope of application of article 8 is clearly detectable within the ECtHR case-law. This process follows scientific development in the context of reproductive rights: in this sense, when ART have become an ordinary technique for favouring procreation, it starts to be considered an alternative way to exercise the personal right to procreate, which must be taken into account by both national legislatures and ECtHR. The commented

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<sup>30</sup> See *Dickson v. the United Kingdom* [GC], no. 44362/04, § 66, ECHR 2007-XIII. In the case of *Dickson v. the United Kingdom*, which concerned the refusal to provide the applicants – a prisoner and his wife – with facilities for artificial insemination.

<sup>31</sup> Decision S.H. and others v. Austria of the Grand Chamber, 3<sup>rd</sup> November 2011.

<sup>32</sup> Even when it defines it as “desire”, as it happened in the case Costa and Pavan.

<sup>33</sup> See M. Eijkholt, *The right to found a family as a stillborn right to procreate?*, in *Medical Law Review*, vol. 18, n. 2, 2010, pp. 138 ss.

decision perfectly fits within this approach, as the Court not only broadens the implementation of article 8, according to scientific and medical development, in order to encompass new techniques able to effectively guarantee the exercise of a right to procreate. But it also draws a distinction between the right to a healthy child («*droit à avoir un enfant sain*», point 53) and the right appealed to by the couple to have access to ART and then PGD, in order to procreate a child not carrying a specific genetic disease (cystic fibrosis). The Court reveals a possible ‘labelling game’, aimed at confusing the legitimate interest in not transmitting a specific genetic disease, by means of the available medical techniques, with the demand for a healthy child, which is effectively unachievable according to the current scientific development and inappropriate from a legal perspective. The Court clearly draws the distinction, which is also a concrete line between admitted and not admitted purposes of PGD, between the detection of a specific disease and a general survey by means of PGD. According to the Court, the couple aims at achieving the first goal, as the required PGD is not oriented at excluding other factors which could impair the child’s health: the PGD exclusively aims at detecting a «*maladie génétique spécifique d’une particulière gravité [...] et incurable au moment du diagnostic*»<sup>34</sup>. According to a strict interpretation proposed to the Court by both the appellants and the Italian Government, the Italian law on ART does not allow this kind of technique. This is a key element of the whole case. By suggesting this interpretation, both the appellants and the Italian Government orient the reasoning of the ECtHR with regard to at least two issues.

On the one hand, the European Court agrees in considering the absence of an effective remedy within the Italian legal system, as – according to the appellants’ arguments – the law absolutely prohibits the access to PGD (point 36). Therefore, lacking an internal specific remedy, it is up to the national Government to prove, on the ground of a consolidate case-law, the development, availability and concrete enforcement of an effective remedy allowing the couple to benefit of a PGD. The same Government expressly recognises that PGD is absolutely forbidden by the law 40/2004: according to the Court, «*on ne saurait reprocher valablement aux requérants de ne pas avoir introduit une demande visant l’obtention d’une mesure qui, le Gouvernement le reconnaît explicitement (...), est interdite de manière absolue par la loi*». It is important to note that the interpretation made by the ECtHR, on the ground of the allegation made by the appellants and the Government, seems to not consider the national case-law analysed in section 2. The Court states that PGD is absolutely forbidden within the Italian legal system, as it considers exclusively the decision of the Tribunal of Salerno<sup>35</sup>: once this decision is taken alone, without mentioning the

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<sup>34</sup> Paragraph 54. Significantly, the Court in drawing this distinction, which is based on medical and scientific evidence, refers to the Opinion of the Committee on Bioethics of the Council of Europe on “preimplantation and antenatal diagnosis”, published in November, 2010 (see point 25).

<sup>35</sup> See above.

whole case-law which is clearly oriented at authorising PGD, the ECtHR can not do anything but consider the latter as an «isolated decision», which cannot be decisive in showing the existence of an effective remedy<sup>36</sup>.

On the other hand, the strict interpretation of law 40/2004, based on an incomplete selection of relevant decisions at the national level, is decisive for dismissing the issue raised with regard to the supposed violation of article 14 ECHR. No discrimination has been produced by national regulation between different categories of persons, as «*l'interdiction d'accéder au diagnostic en question touchant toute catégorie de personnes*»<sup>37</sup>: this is the result of parties' allegation<sup>38</sup>. Once more, the case-law resulting from the enforcement of the law is not taken into account. In the case of appeal by the Italian Government, this may be a relevant factor in order to overturn the decision on the violation of article 14: once assumed that PGD is allowed – even though by an interpretation consistent with the constitution – for infertile couples, the evaluation of the Court may be different. It represents further evidence of the condition of legal uncertainty provoked by a legislation which does not expressly take position on a relevant – ethically and socially sensitive – issue: it substantially delegates to judges – at different levels – the function of identifying a reasonable balancing between the constitutional goods involved and giving protection to a legitimate interest of the couple, which falls within the protection guaranteed by article 8 ECHR.

### *3.2. The margin of appreciation within the medical sector: consensus or clear trend of legislations? The exceptionalism of the regulation of beginning of life.*

It leads to a further issue, connected with the existence of a right to procreate also by means of ART: the limits that national legislatures encounter when regulating ART and their concrete enforcement. The second paragraph of article 8 does not exclude a limitation of such a right (or desire), when and if it respects the conditions provided by the Convention<sup>39</sup>. The issue of the margin of appreciation to be recognised to national legislatures characterises also the case-law

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<sup>36</sup> Paragraph 38.

<sup>37</sup> Paragraph 76.

<sup>38</sup> According to the ECtHR “ *Le Gouvernement fait valoir que le droit italien interdit l'accès au D.P.I. à toute catégorie de personnes, le décret ministériel du 11 avril 2008 s'étant limité à permettre aux couples dont l'homme est affecté par des maladies virales transmissibles sexuellement d'accéder à la fécondation artificielle dans le but d'éviter le risque de transmission de pathologies sexuellement transmissibles à la mère et à l'enfant dérivant de la procréation par les voies naturelles. Les techniques de la procréation assistée ne seraient utilisées dans ce contexte qu'afin d'épurer le sperme de sa composante infectieuse. A la différence du D.P.I., il s'agit donc d'un stade précédant celui de la fécondation de l'embryon. Les requérants n'opposent pas d'arguments spécifiques à cette analyse*” (points 73-74).

<sup>39</sup> As broadly known, paragraph 2 of article 8 ECHR states that «There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others».

relating to the beginning of life and concretely the access to ART<sup>40</sup>. The Costa and Pavan case, although it does not expressly refer to the theory of consensus<sup>41</sup>, seems to follow the line of reasoning consolidated within the ECtHR case-law. Anyway, the latter is far from being considered coherent and linear. Significantly, the theory of consensus and its concrete implementation have been qualified as ‘elusive’<sup>42</sup>, as it is not clear both on which criteria it is grounded – quantitative and/or qualitative – and how they connect with the concrete regulated issues<sup>43</sup>, and where the actual border lies between consensus and a «clear common trend in the legislation of Contracting states»<sup>44</sup>. In S.H. and others v. Austria, the Grand Chamber strives to clarify the distinction, which is decisive when evaluating the compatibility of national legislation with paragraph 2 of article 8. The Court seems to adopt a quantitative approach, by stating that the clear convergence between States detectable on the relevant context would still not consolidate enough to refer to the theory of consensus. Accordingly, it is not sufficient for limiting the margin of appreciation: the Court faces a «settled and long-standing principles established in the law of the member States but rather reflects a stage of development within a particularly dynamic field of law and does not decisively narrow the margin of appreciation of the State»<sup>45</sup>.

The different relevance of quantitative and qualitative criteria emerges from other ECtHR decisions, which confirm the wavering nature of its own case-law in this context. In the Goodwin case, differently from S.H. and others v. Austria, the Court seems to settle for a trend within national legislations, by stating that «the Court accordingly attaches less importance to the lack of evidence of a common European approach to the resolution of the legal and practical problems posed, than to the clear and uncontested evidence of a continuing international trend in favour not only of increased social acceptance of transsexuals but of legal recognition of the new sexual identity of post-operative transsexual» (point 85)<sup>46</sup>. The case A., B. and C. v. Ireland represent a turning point between the quantitative and qualitative approach to the theory of consensus<sup>47</sup>. The issue tackled by the ECtHR consists in the following question: is the consensus able to limit the national margin of

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<sup>40</sup> On the theory of margin of appreciation, see Y. Arai-Takahashi, *The Margin of Appreciation Doctrine and the Principle of Proportionality in the Jurisprudence of the ECHR*, Intersentia, 2002.

<sup>41</sup> It merely refers to «*éléments de droit comparé*» (point 29-33).

<sup>42</sup> A. L. Lecis, *Consenso europeo, chi è costui? L'individuazione del consensus standard da parte della Corte Edu tra interpretazione evolutiva e margine d'apprezzamento*, in [www.diritticomparati.it](http://www.diritticomparati.it), November 2011; see also J. Gerards, *Pluralism, Deference and the Margin of Appreciation Doctrine*, in *European Law Journal*, vol. 17, n. 1, 2011, pp. 107 ss.

<sup>43</sup> The more it raises ethical and social concerns, the more the margin must be broaden, even when a consensus among the States can be detected (see the case A., B. and C. v. Ireland).

<sup>44</sup> See S.H. and others v. Austria, both the sixth ECtHR Section and the Grand Chamber (point 96).

<sup>45</sup> See S.H. and others v. Austria, Grand Chamber (point 96).

<sup>46</sup> K. Dzehtsiarou, *European Consensus and the Evolutive Interpretation of the European Convention on Human Rights*, in *German Law Review*, vol. 12, n. 10, 2011, p. 1736.

<sup>47</sup> See L. Busatta, *La sentenza A, B e C c. Irlanda: la complessa questione dell'aborto tra margine d'apprezzamento, consenso e (un possibile) monito*, in *Diritto pubblico comparato ed europeo*, 2011; S. McGuinness, *A, B, and C to D (for delegation!)*, in *Medical Law Review*, 19, 2011, pp. 476-491; E. Wicks, *A, B, C v Ireland: Abortion Law under the European Convention on Human Rights*, in *Human Rights Law Review*, vol. 11, n. 3, 2011, pp. 556-566.

appreciation when it acts on ethically and socially very sensitive issues such as abortion (and ART)? The Court proposes a contextual interpretation of the theory of consensus: a mechanical relationship between consensus and margin of appreciation may be excluded, when the concrete context raises fundamental ethical and social concerns. Therefore, even quantitatively recognising the existence of a consensus among the States in favour of the admissibility – even if regulated and conditioned – of abortion, this data cannot be considered in itself a decisive factor when qualitatively detecting the concrete extension of the margin of appreciation to be recognised in the field to the Contracting States<sup>48</sup>: when a social and ethical sensitive issue is dealt with, the consensus in itself is not sufficient for defining the concrete discretionary power of each Contracting State<sup>49</sup>. In order to conclude the digression within the ECtHR case-law and approach directly the Costa and Pavan case, the last relevant decision is the abovementioned S.H. and others v. Austria. It is possible to derive from the reasoning a set of criteria which seem to orient the ECtHR when checking the concrete exercise of legislative power in limiting the rights protected by article 8: a) «Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will normally be restricted»; b) nonetheless, «where (...) there is no consensus within the member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it (...) the margin will be wider»; c) the latter must be considered «particularly where the case raises sensitive moral or ethical issues»; d) «By reason of their direct and continuous contact with the vital forces of their countries, the State authorities are, in principle, in a better position than the international judge to give an opinion, not only on the “exact content of the requirements of morals” in their country, but also on the necessity of a restriction intended to meet them»<sup>50</sup>.

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<sup>48</sup> According to the Court, even if it appears from the national laws referred to that most Contracting Parties may in their legislation have resolved those conflicting rights and interests in favour of greater legal access to abortion, this consensus cannot be a decisive factor in the Court's examination of whether the impugned prohibition on abortion in Ireland for health and well-being reasons struck a fair balance between the conflicting rights and interests, notwithstanding an evolutive interpretation of the Convention (*Tyrer v. the United Kingdom*, § 31; and *Vo v. France* [GC], § 82)», paragraph 237.

<sup>49</sup> P. Gallagher, *The European Convention on Human Rights and the Margin of Appreciation*, in *UCD Working Papers in Law, Criminology & Socio-Legal Studies Research Paper*, n. 52, 2012, , p. 11.

<sup>50</sup> Paragraph 94.

### *3.3. The scrutiny of the concrete exercise of the margin of appreciation: From deference to strict scrutiny? The reasoning of the ECtHR in Costa and Pavan v. Italy.*

Moving to the case *Costa and Pavan v. Italy*, a shift in the evaluation of the margin of appreciation is clearly detectable, as expressly recognised also by the European Court<sup>51</sup>. After having grounded on article 8 ECHR a right to access ART in order to avoid the risk of transmitting a genetic disease to the child, the Court goes further in considering if the prohibition provided by national law with regard to PGD is compatible with the second paragraph of article 8. More precisely, the Court reiterates on the one hand that, within the Italian legal system, access to ART is limited to infertile/sterile couples, with the exclusion of fertile couples carrying transmissible genetic diseases (point 58); on the other hand, it confirms the absolute ban of PGD, according to which all categories of persons are excluded from having access to this technique.

The parameter taken into account by the Court is the compatibility of the regulation with a democratic society<sup>52</sup>. According to the appellants, the prohibition is not incompatible with article 8 in itself, but when considered in conjunction with the whole legal framework in which it is inserted, in particular the regulation of abortion. More concretely, the question refers to the proportionality and coherence of the prohibition, when considering that the legal system considers legitimate the antenatal diagnosis, in order to detect potential diseases of the foetus (point 60). The Court plainly dismisses the Italian Government's allegations<sup>53</sup>, and focuses on the systematic coherence of the regulation: the Italian legal system reveals itself to be incoherent, as while prohibiting that the transfer is limited exclusively to those embryos not carrying the disease that affects the appellants, it authorises abortion of a foetus affected by the same pathology. It inevitably impacts on the right to respect the couple's private life. The Court refers to the right to procreate a child not affected by the disease which the appellants are carrying, that has to be considered part of the protection guaranteed by article 8 ECHR. In this way, the content of article 8 has been further broadened. Once such a right has been recognised, the Court considers incoherent that the only way to guarantee it is abortion grounded on an antenatal diagnosis (point 65). This regulatory framework inevitably provokes negative consequences on the health of the woman, as she is aware that, due to the prohibition of PGD, the choice will be only between procreating a sick child and performing a therapeutic abortion (point 66).

At this stage, a significant development within the ECtHR approach to the theory of the margin of national appreciation seems to be evident. Although the Court refers explicitly to the recent case-

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<sup>51</sup> See paragraph 69.

<sup>52</sup> According to paragraph 2 of article 8 ECHR.

<sup>53</sup> The Government alleged three objections, according to which the ban of PGD aims at protection the health of both the «*enfant et de la femme*», the dignity and freedom of conscience of physicians and lastly avoiding the risk of «*derives eugéniques*» (point 61).

law in the field of ART (precisely to the decision of the Grand Chamber in the S.H. and others v. Austria case), in which – as mentioned above – a broad national margin of appreciation has been recognised<sup>54</sup>, the perspective from which the Court moves for checking the concrete enforcement of the national discretionary power relevantly differs. Where the Grand Chamber in S.H. and other v. Austria<sup>55</sup> substantially declines to check the proportionality of the concrete balancing provided by national regulation, by referring to the absence of a clear consensus among the Contracting States<sup>56</sup>, the Tenth Section moves a step forward: it ploughs through the door of the scrutiny of the legislative discretionary choices at a national level, by checking the proportionality of the measure not per se, but in the light of the whole regulatory context, in which abortion is authorised on the same factual grounds. The perspective is clearly different: in the S.H. case the target is directly the compatibility of the ban of gametes donation for reproductive purposes with article 8 ECHR; in the commented case the scrutiny refers to the external coherence of the prohibition of PGD, in order to check its proportionality and consistency within a more general legal framework. The incompatibility with article 8 is declined in terms of systematic incoherence of the Italian legal system, which leads to a lack of proportionality of the interference in the private life of the appellants<sup>57</sup>. In this decision, therefore, the Court does not limit its scrutiny according to a deferential approach based on both the absence of a clear consensus among the Contracting States and the substantial presumption of compatibility of legislative choices; it moves forward, towards a more strict scrutiny which goes to verify the concrete content of the regulation, evaluating its effective proportionality and systematic coherence<sup>58</sup>.

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<sup>54</sup> The Court states that «*La Grande Chambre a établi que, en matière de fécondation hétérologue, compte tenu de l'évolution de la branche en examen, la marge d'appréciation de l'Etat ne pouvait pas être restreinte de manière décisive.*

*Tout en reconnaissant que la question de l'accès au D.P.I. suscite de délicates interrogations d'ordre moral et éthique, la Cour relève que le choix opéré par le législateur en la matière n'échappe pas au contrôle de la Cour (voir, mutatis mutandis, S.H., précité, § 97)».*

<sup>55</sup> Although the Court states that it is called upon to evaluate «*carefully the arguments taken into consideration during the legislative process and leading to the choices that have been made by the legislature and to determine whether a fair balance has been struck between the competing interests of the State and those directly affected by those legislative choices*» (point 97).

<sup>56</sup> However, the central question in terms of Article 8 of the Convention is not whether a different solution might have been adopted by the legislature that would arguably have struck a fairer balance, but whether, in striking the balance at the point at which it did, the Austrian legislature exceeded the margin of appreciation afforded to it under that Article (see *Evans*, cited above, § 91). In determining this question, the Court attaches some importance to the fact that, as noted above, there is no sufficiently established European consensus as to whether ova donation for *in vitro* fertilisation should be allowed.

<sup>57</sup> Point 71.

<sup>58</sup> Also in the first decision on the S.H. and other v. Austria, the ECtHR Section assumed a similar approach, which was been reverted by the Grand Chamber («*a complete ban on the medical technique at issue would not be proportionate unless, after careful reflection, it was deemed to be the only means of effectively preventing serious repercussions*» (point 76).

*4. Conclusion. The impact of the decision on the Italian legal system: a prospective and actual foresight.*

Conclusively, it seems appropriate to briefly analyse the impact that the decision may have on the Italian regulation of ART, with regard to the specific issue of PGD admissibility. One preliminary caution must be underlined: the commented decision has a temporary effect, as the Italian Government has appealed the decision before the Grand Chamber. The S.H. case is paradigmatic in showing that, particularly in a highly sensitive context such as the biomedical one, a decision done by a Section of the ECtHR can be easily overturned in a second phase, according to a different understanding of the concrete characters of the case or the interpretation of ECtHR case-law. From this perspective, the Costa and Pavan case seems to show some gaps within the reasoning of the Court which may lead to a different approach by the Grand Chamber: among others, the existence at the national level of an effective remedy; the partial reference to the relevant national case-law on PGD admissibility; the shallow analysis of the existence of a consensus among the Contracting States, substituted by a general reference to “data of comparative law”.

Nevertheless, the decision will inevitably have both direct and indirect effects at the national level, as it is already part of the normative journey which characterises the law 40/2004 towards a substantive rewriting of its normative content<sup>59</sup>. Although not effectively binding, the case has already produced a direct effect within the national legal system. Recently, the Tribunal of Cagliari confirmed the admissibility of PGD in case of a fertile couple that is carrying a genetic disease, as – according to the judge – PGD represents the logical consequence of the right to be adequately informed<sup>60</sup>. Significantly, the Tribunal refers to the Costa and Pavan case in order to ground an interpretation consistent with the constitution, which confirms the admissibility of PGD. According to the Italian Tribunal, the ECtHR has stated that when the antenatal diagnosis is allowed in order to protect the health of the woman, the PGD must also be legitimised, to restore the coherence of the whole legal framework. The decision of ECtHR has undoubtedly empowered Italian judges in opting for an interpretation allowing PGD, and the process towards a progressive and relentless redefinition of ART regulation in Italy is destined not to run out even in the case of an overturn by the Grand Chamber.

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<sup>59</sup> It is worth noting that a question of constitutionality on the ban of gametes donation for reproductive purposes provided by article 4 of the law is currently pending before the Constitutional Court.

<sup>60</sup> Tribunal of Cagliari, 9th November 2012.