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Committee on Economic, Social and Cultural Rights

**Views adopted by the Committee under the Optional
Protocol of the Covenant concerning communication
No. 22/2017***

<i>Communication submitted by:</i>	S.C and G.P (represented by counsel, Cesare Romano)
<i>Alleged victim:</i>	The authors
<i>State party:</i>	Italy
<i>Date of communication:</i>	20 March 2017
<i>Date of adoption of Views:</i>	7 March 2019
<i>Subject matter:</i>	Regulation of in vitro fertilization.
<i>Procedural issues:</i>	Committee's competence <i>ratione temporis</i> ; exhaustion of domestic remedies; Status of victim
<i>Substantive issues:</i>	Right to sexual and reproductive health and informed consent.
<i>Articles of the Covenant:</i>	3, 10, 12 and 15
<i>Articles of the Optional Protocol:</i>	3 (2) (b), (d) and (e)

* Adopted by the Committee in its sixty-fifth session (18 February-8 March 2019).

1.1 The authors of the communication are S.C. and G.P., a woman and a man of Italian nationality born in 1969 and 1978 respectively. The authors submit that the State party has violated their rights under the articles 10, 12 (1) (2) (c) and (d), and 15 (1) (b), (2) and (3), all read in conjunction with article 2(1)¹ of the International Covenant on Economic, Social and Cultural Rights. The Optional Protocol entered into force for the State party on 20 February 2015. The authors are represented by counsel.

1.2 In the present Views, the Committee first summarizes the information and the arguments submitted by the parties (paras. 2.1–5.2) then considers the admissibility and merits of the communication and, lastly, draws its conclusions and issues recommendations.

A. Summary of the information and arguments submitted by the parties

The facts as submitted by the author

2.1 In 2008, the authors visited a private clinic, in Italy, specialized in assisted reproductive technology, to seek assistance to conceive a child. A first *in vitro* fertilization (IVF) cycle procedure was carried out. The authors requested the clinic at least six embryos be produced per *in vitro* fertilization (IVF) procedure, that these embryos be subject to Pre-implantation Genetic Diagnosis (PGD) to identify possible “genetic disorders”, and that the embryos with such disorders be not transferred into S.C.’s uterus. The private clinic replied that such request was not authorized by Law 40/2004 and could therefore not be accepted.

2.2 Law 40/2004 regulates the use of assisted reproductive technology in Italy. It prohibits any clinical and experimental research on human embryos. Originally, Law 40/2004 limited the number of embryos to be produced during an *in vitro* fertilization cycle to three; it also prohibited pre-implantation genetic diagnosis; mandated the simultaneous transfer in the uterus of all embryos, regardless of their viability or genetic disorders; and prohibited the cryopreservation of embryos. However, over the years, the scope of the law was reduced by a series of decisions by the Constitutional Court, which found parts of it incompatible with the Italian Constitution, and with the European Convention on Human Rights.

2.3 The authors filed a lawsuit against the private clinic before the Court of Florence (*Tribunale di Firenze*). On 12 July 2008, the Court issued provisional measures, ordered the clinic to carry out Pre-implantation Genetic Diagnosis (PGD), and referred the matter to the Constitutional Court for ruling. While waiting for the decision on the constitutionality of Law 40/2004, only three embryos were produced. Pre-implantation Genetic Diagnosis (PGD) revealed that all three embryos were affected by multiple hereditary osteochondromas,² and, thus, they were not transferred in S.C.’s uterus.

2.4 On 8 May 2009, the Constitutional Court declared that articles 14.2 and 14.3 of Law 40/2004 were unconstitutional, insofar as article 14.2 imposes the creation of a maximum of three embryos per *in vitro* fertilization cycle, and the duty to transfer all of them simultaneously in uterus, and that article 14.3 does not provide that the transfer of the embryos should be made without prejudice to the health of the woman.

2.5 In October 2009, the authors tried a second *in vitro* fertilization cycle at the same private clinic. This time, ten embryos were produced. For technical reasons, pre-implantation genetic diagnosis could be carried out only on six of the ten embryos. Only one out of the six diagnosed embryos was determined to be free of multiple hereditary osteochondromas, but was graded “average quality,” with a low chance of nesting if transferred in the uterus. SC declined to have the “average quality” embryo transferred in her uterus. However, the private clinic’s personnel insisted that, according to their understanding of Law 40/2004, consent to

¹ The authors invoked articles 10, 12 (1) (2) (c) and (d), and 15 (1) (b), (2) and (3), all read in conjunction with article 2 (1) of the Covenant in their introduction but did not raise article 2 (1) in any of their specific allegations under each of the articles invoked autonomously.

² The authors explain that multiple hereditary osteochondromas exostosis (also known as exostoses or osteochondromas) is a hereditary genetic disorder that causes bones deformations through youth and adolescence. They submit that the disorder is not only painful, but that it is also emotionally distressing because the deformities are visible to the naked eye. It is highly transferable, with a high penetrance, and has severe detrimental effects on human health.

transfer in the uterus of embryos can only be revoked before fertilization has taken place. The authors submit that the personnel threatened S.C. with a lawsuit if she insisted in not having the embryo transferred. Because of this threat, SC agreed to have the embryo transferred in her uterus, but, eventually, she suffered a miscarriage.

2.6 The other nine embryos were cryopreserved. The authors requested the surrender of the cryopreserved embryos affected by multiple hereditary osteochondromas or untestable to donate them to be used in scientific research. However, the private clinic refused the authors' request, holding that article 13 of Law 40/2004 prohibited research on embryos.

2.7 On 30 March 2012, the authors filed a lawsuit against the private clinic and the State party, represented by the President of the Council of Ministers before the Court of Florence. They requested the Court to order the private clinic to surrender the embryos, and to determine the validity of S.C.'s decision not to have the embryos transferred in her uterus. They also requested the Court to declare the State's responsibility for violating its own Constitution, and to order a pecuniary compensation of 5,000€ and a non-pecuniary compensation as the Court finds appropriate.

2.8 On 7 December 2012, the Court of Florence referred the matter to the Constitutional Court pursuant to article 700 of the Code of Civil Procedure. The Constitutional Court was called to determine the compatibility of articles 6.3 (regarding the revocation of the consent before fertilization) and 13 (regarding the prohibition of research on embryos) of Law 40/2004 with the Constitution, as a matter of urgency.

2.9 On 22 March 2016, the Constitutional Court found the Court of Florence's request inadmissible.³ Firstly, it stated that the claim concerning the irrevocability of the consent was moot, after S.C. eventually agreed to have the embryo transferred to her uterus. It also stated that the claim related to the possible withdrawal of S.C.'s consent in the context of future *in vitro* fertilization treatments was speculative. Thirdly, the Court found that the conflict had multiple ethical and juridical implications related to the balance between the right to enjoy the benefits of scientific progress and its applications (and the related benefits) and the rights of the embryo, and that these issues divide jurists, scientists and society. The Court stated that the legislative power is the proper governmental branch to strike the balance between rights of the embryo and right to enjoy the benefits of scientific progress and its applications, not the Constitutional Court itself; it called on the legislative to consider "the views and calls for action (...) deeply rooted at any given moment in time within the social conscience".

2.10 The authors claim that they have exhausted all domestic remedies since the decision of the Constitutional Court is final and not subject to appeal. Concerning the requirement established in article 3 (2) (b) of the Optional Protocol, the authors claim that although the main events occurred prior to 20 February 2015, date of entry into force of the Optional Protocol for the State party, the decisions adopted thereafter reflect a continuing violation of their rights.

The complaint

3.1 The authors claim that the State party has violated their right to enjoy the benefits of scientific progress and its applications under article 15 (1) (b) of the Covenant. By prohibiting the research on embryos, Law 40/2004 interferes with scientific progress, slowing down the search of a cure for various diseases, which, they allege, is a violation of the authors' right to enjoy the benefits of scientific progress and its applications.

3.2 They also consider that this prohibition has violated their right to participate in scientific research. In this connection, the authors argue that Law 40/2004 has prevented them from participating in scientific research by donating their embryos affected by a genetic disorder. The cumulative effect of the prohibition of research on embryos and the declaration of unconstitutionality of the prohibition of Pre-implantation Genetic Diagnosis (PGD) has created a situation where embryos affected by a genetic disorder that will not be transferred, cannot be used for scientific research, nor disposed. In the State party, it is legal for scientific research to use stem cell lines that have been created abroad through the destruction of

³ See Constitutional Court, 84 of 2016, judgement of date 30 March 2012.

embryos, which results in a contradictory situation. The authors submit that the effectiveness of embryo research depends both on the characteristics and quantity of available embryos. The prohibition of research on embryos is arbitrary because it is based on a notion of an embryo that is not scientific. According to scientific research, an embryo is formed between ten to twelve days after the fertilization, whereas in Italian law, it is considered that an embryo exists from the day of the fertilization. The authors explain that human embryos are widely used for the production of stem cells, which is essential for scientific research on life-threatening illnesses such as diabetes, Alzheimer, Parkinson, cancer and heart diseases among many other purposes. The great potential of stem cells research is yet to be achieved. The authors note that in *Parrillo v. Italy*, the European Court of Human Rights⁴ considered that the complainant's ability to exercise a choice regarding the fate of the embryos concerned an intimate aspect of her personal life and related to her self-determination. It was considered that the application of Law 40/2004 resulted in an interference with the applicant's right to private life. Furthermore, the Universal Declaration of Human Rights (the Universal Declaration), in its Spanish and French versions, provide the right to "participar" or "participer" (take part) in scientific advancement and its benefits.⁵ Although the wording of the Covenant differs slightly, the authors allege that it should be interpreted in light of the Declaration and holistically, taking into account articles 15 (2) and 15 (3). In view thereof, the authors consider that the Covenant protects the right of everyone to participate in scientific research.

3.3 The authors also consider that Law 40/2004 violates their right to enjoy the benefits of scientific progress because they suffer the consequences of this research being slowed down. S.C. is an asymptomatic carrier of multiple hereditary osteochondromas and nine out of ten of the embryos the authors have produced were either affected by this genetic disorder or could not be tested. Unless a cure for multiple hereditary osteochondromas is found, their chances of conceiving a child are slim. S.C. also has family members who are affected by this illness. Nonetheless, the authors are prevented from contributing to the scientific research for its cure by donating the affected embryos to this end.

3.4 The authors further argue that their rights under article 15(2) of the Covenant have also been violated. In this connection, they submit that Law 40/2004 prevents the State party from fulfilling the duty to develop and disseminate scientific developments. Prohibiting the research on human embryos makes it harder for scientists to realize the potential of research on stem cells and hinders the spreading of scientific knowledge and applications within the scientific community and society at large. The authors note that in *Artavia Murillo v. Costa Rica*,⁶ the Inter-American Court of Human rights determined that the right to enjoy the benefits of scientific progress includes accessing medical technology necessary to exercise the right to private life and reproductive freedom to found a family.

3.5 The authors claim that article 15(3) has also been violated by the State party because it blocks the research on embryos without a legitimate purpose. Whilst freedom of research is not absolute, the authors submit that it can only be restricted to protect other rights, and in the present case there is no contradicting right to be protected as the concerned embryos will never grow and are left for ever in a frozen limbo.

3.6 The State party has violated the authors' right to health under article 12 of the Covenant, in particular 12 (1) and 12 (2) (c) and (d) because Law 40/2004 cannot provide for adequate physical and mental health. Firstly, Law 40/2004 is arbitrary and introduces a restriction that is not reasonable or justified, as the ban on research does not distinguish between viable and non-viable embryos. Law 40/2004 has become increasingly incoherent over the years following successive decisions of the Constitutional Court, resulting in clinics and practitioners not having a clear understanding of the applicable legislation and leading to a violation of the authors' right to access information on their reproductive rights. In *S.H*

⁴ See European Court of Human Rights, *Parrillo v. Italy* (application No. 46470/11), judgment of 27 August 2015. Para. 159.

⁵ Universal Declaration of Human Rights, article 27.

⁶ See Inter-American Court of Human Rights, *Artavia Murillo et al v. Costa Rica*, (communication No. 257), judgment of 28 November 2012, para. 146.

and others v. Austria, the European Court of Human Rights⁷ observed that artificial reproductive treatments is an area in which contracting States must constantly review their legislation. Italy has failed to develop and adapt its legislation on this issue. This was also noted by the Italian Constitutional Court in its judgment of 22 March 2016.⁸

3.7 Secondly, the law prohibits scientific research on embryos, even when they are affected by genetic disorders that make them not transferable. Thirdly, it hinders scientific research on multiple hereditary osteochondromas, other transmissible genetic disorders and stem cells. The authors point out that as a result, their right to health is violated since they cannot attempt to conceive again, unless a cure for multiple hereditary osteochondromas is found.

3.8 Fourthly, the law does not specify whether consent to transfer an embryo in uterus can be withdrawn after fertilization. In this connection, the authors consider that S.C.'s right to health was violated when she was forced to endure transfer into her uterus of an embryo against her will and she was not given the opportunity to withdraw her consent. If the State party's concern is that the withdrawal of consent may be used to circumvent the prohibition of production of embryos for scientific research, there are less restrictive ways to achieve this end, such as limiting the frequency with which a person can donate embryos or the total number of embryos that can be donated. The transfer of the embryo resulted in a miscarriage, which causes both long-term physical and psychological effects. The authors note that according to general comment no. 14 on the right to the highest attainable standard of health, the obligation to respect everyone's right to health requires States to refrain from "denying or limiting equal access for all persons, including refraining from applying coercive medical treatments and deliberately limiting access to contraceptives and other means of maintaining sexual and reproductive health".⁹ The authors argue that this uncertainty regarding whether or not consent to transfer can be withdrawn after fertilization has prevented them from trying to conceive again, thus violating their right to health, and in particular reproductive health.

3.9 Finally, the applicable law violates the obligation to take steps for the "prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "... those necessary for ... the creation of conditions which would assure to all medical service and medical attention in the event of sickness" as mandated by article 12 (2-c) and (d) for the reasons stated in paragraphs 3.3 and 3.4 above.

3.10 The authors claim that Italy violated article 10 of the Covenant because it failed to provide the widest possible protection and assistance to the authors, as a family, as well as other couples in Italy who are or will be in similar situations. The authors have the desire to try in vitro fertilisation treatments again with the aim to conceive a healthy child, but only if pre-implantation genetic diagnosis confirm that the newly produced embryos are viable. Since Law 40/2004 is silent as to whether consent to transfer can be withdrawn after fertilization, and the Constitutional Court has not weighed in on the issue, they are deterred from trying of conceiving again. The authors further claim that if a woman cannot decline the transfer in her uterus of an embryo that, on the basis of objective criteria, is deemed to have "low chances of success", and if she does not want to take the high risk of a miscarriage, then she cannot freely decide the number, spacing, and timing of her children. The continuing silence of the State party on the question of the withdrawal of embryonic transfer post in vitro fertilisation violates the rights of S.C., as well as of any woman in a similar situation, to choose if, when, and how to establish her family.

3.11 In terms of reparations, the authors request the State party to take measures to ensure non-repetition, including replacing Law 40/2004 with a new law that takes into consideration all international human rights obligations that the State party has committed to, all relevant decisions of the Italian Constitutional Court, the European Court of Human Rights, and the Committee. Alternatively, the authors consider that some provisions of Law 40/2004 must be amended to ensure non-repetition: articles 13 and 14.1 must contain a definition of embryo

⁷ See European Court of Human Rights, *S.H. and others v. Austria* (application No. 57813/00), judgement of 3 November 2011, para. 118.

⁸ *Op. cit.*

⁹ See the Committee's General Comment No. 14 (2000) on the Right to the Highest Attainable Standard of Health (E/C.12/2000/4), para. 33.

that allows research and experimentation on blastocysts and embryos up to 14 days after fertilization or when they are affected by a genetic disorder or are otherwise non transferrable into uterus. Article 6 must specify that consent to transfer an embryo in the uterus can be withdrawn. Finally, the authors request compensation for physical, psychological and moral damages, and to have their legal costs reimbursed.

State party's observations on the admissibility and merits of the communication

4.1 On 12 March and 16 April 2018, the State party submitted its observations on the admissibility and merits of the communication.

4.2 The State party notes that the authors prevailed in their challenge to the limit of three embryos per in vitro fertilization cycle as, on 1 April 2009, the Constitutional Court declared article 14.2 of Law 40/2004 unconstitutional insofar as it imposes the creation of a maximum of three embryos and 14.3 insofar as it does not provide that the transfer of the embryos should be made without prejudice to the health of a woman. The unconstitutionality of these articles stem from the principles of reasonableness and equality (article 3 of the Constitution) and the right to health (article 32 of the Constitution). The authors also raised the question of the irrevocability of consent to transfer in the uterus of the embryos after fertilization, but this question was inadmissible as it was irrelevant to the authors' case.

4.3 On 22 March 2016, the Constitutional Court ruled on the authors' second lawsuit against the clinic and the Italian Republic and declared inadmissible the authors' request for the unconstitutionality of article 6.3 (regarding the prohibition to withdraw consent after fertilisation) and article 13 (1) (3) (regarding the prohibition of research on embryos other than with the aim of their own protection).

4.4 The State party further asserts that the Constitutional Court has also found many of the provisions of Law 40/2004 unconstitutional. On 29 April 2014, the Constitutional Court declared articles 4 (3), 9 (1) and (3) and article 12 (1) of the law unconstitutional insofar as they ruled out recourse to heterologous fertilisation. On May 2015, it declared articles 1 (1) – (2) and 4 (1) unconstitutional; and on 21 October 2015, it declared article 13 (3) (b) and (4) unconstitutional too.

4.5 The State party recalls the status of the Constitutional Court is one of the highest guardians of the Constitution. It may receive complaints from public authorities regarding the constitutionality of regional or State norms or acts. It therefore monitors how authorities respect the Constitution and arbitrates when there are disagreements between central and local authorities. Courts may also raise questions of constitutionality to the Constitutional Court when their decisions depend on a law which constitutionality is questioned. The Constitutional Court's decisions cannot be appealed. When the Court declares a law or an act unconstitutional, it ceases to have effect in the Italian legal order.

4.6 The State party considers that the facts of the authors' case do not indicate any violation of the Covenant. It, however, does not question the competence of the Committee to examine the admissibility and merits of this communication.

Authors' comments on the State party's observations

5.1 On 27 March 2018, the authors submitted that the State party had merely restated the domestic remedies pursued by the authors and presented the role of the Constitutional Court without replying to their allegations.

5.2 They requested the Committee to proceed to examine the communication on its admissibility and merits without further delay.

B. Committee's consideration of admissibility

6.1 Before considering any claim contained in a communication, the Committee must decide, in accordance with the Optional Protocol, whether or not the communication is admissible.

6.2 The Committee takes note that the State party has not challenged the admissibility of the communication. It nonetheless considers necessary to clarify various elements in that regard.

6.3 The Committee notes that the authors' filed a civil suit against the Centre for Assisted Reproduction and the Republic of Italy before the Court of Florence, that referred the matter to the Constitutional Court. The Constitutional Court ruled on the matter on 22 March 2016. The Committee notes that the Constitutional Court's decisions cannot be appealed. The Committee concludes that the authors have exhausted domestic remedies in accordance with article 3 (2) (a) of the Optional Protocol.

6.4 The Optional Protocol entered into force in the State party on 20 February 2015. In accordance with article 3 (2-b) of the Optional Protocol, the Committee must declare a communication inadmissible when the facts that are the subject of the communication occurred prior to the entry into force of the Optional Protocol for the State party concerned unless those facts continued after that date. Other human rights treaties include a similar *ratione temporis* provision, giving rise to various interpretations; therefore, the Committee deems it useful to clarify the meaning of this condition of admissibility.

6.5 The Committee notes that, in order to determine whether a communication satisfies the admissibility criterion established in article 3 (2-b) of the Optional Protocol, it is necessary to distinguish between the "facts" allegedly amounting to a violation of the Covenant and their "consequences" or "effects". As the Committee has noted, an act that may constitute a violation of the Covenant does not have a continuing character merely because its effects or consequences extend in time.¹⁰ Therefore, when the facts constituting a violation of the Covenant occurred before the entry into force of the Optional Protocol for the State party concerned, the mere fact that their consequences or effects have not been extinguished, after the entry into force, is not sufficient grounds for declaring a communication admissible *ratione temporis*. If no distinction were made between the acts that gave rise to the alleged violation and its ongoing consequences or effects, the *ratione temporis* admissibility criteria established in the Optional Protocol, relating to the Committee's competence to consider individual communications, would be virtually irrelevant.¹¹

6.6 For the purposes of article 3 (2-b) of the Optional Protocol, the "facts" are the sequence of events, acts or omissions which are attributable to the State party and may have given rise to the alleged violation of the Covenant. As the Committee has noted in previous Views, the judicial or administrative decisions of the national authorities are also considered to be part of the facts when they are the outcome of proceedings directly related to the initial events, acts or omissions that gave rise to the violation and could have provided reparation for the alleged violation in accordance with the law in force at the time. When these proceedings take place after the entry into force of the Optional Protocol for the State party concerned, the admissibility requirement established by article 3 (2-b) does not prevent finding a communication admissible. Indeed, when a victim exercises these remedies, the national authorities have been provided an opportunity to put an end to the violation in question and to provide reparation.¹²

6.7 The Committee notes that all claims raised by the authors are related to two facts: first, the transfer of the authors' embryo into S.C.'s uterus without her consent; and second, the refusal by the clinic to surrender the embryos so that they could be donated for their use in scientific research.

6.8 Regarding the refusal to accept S.C.'s withdrawal of her consent, to have the embryo transferred to her uterus, the fact that the author continues to suffer the consequences of the transfer and of the miscarriage she suffered does not, as such, lead to this transfer losing its

¹⁰ See *Merino Sierra v. Spain* (E/C.12/59/D/4/2014) para. 6.7; *Ana Esther Alarcon Flores and 116 others acting as a group of individuals v. Ecuador* (E/C.12/62/D/14/2016, para. 9.7. See also *Yearbook of the International Law Commission 2001*, vol. II (Part Two), draft articles on responsibility of States for internationally wrongful acts, p. 60, para. 6 of the commentary on article 14 (Extension in time of the breach of an international obligation).

¹¹ See *Alarcón Flores v. Spain* (E/C.12/62/D/14/2016) para. 9.7.

¹² *Ibid* para. 9.8.

instantaneous character. The Committee however notes that in its ruling of 22 March 2016, the Constitutional Court addressed the authors' civil claim regarding the transfer of the embryo into S.C.'s uterus against her will through a question of constitutionality. In accordance with the rule recalled in paragraph 6.6 above, the Committee notes that the Constitutional Court's decision was issued after the Optional Protocol had entered into force on 20 February 2015. Consequently, the claims related to the consequences of the transfer of the embryo to S.C.'s uterus despite her wish clearly expressed to the doctors of the clinic to withdraw her consent, are admissible *ratione temporis*.

6.9 As relates to the refusal by the clinic to surrender the embryos, the Committee notes that the clinic is still in possession of these embryos and that the authors still have the intention to donate them for scientific research. The refusal to surrender them could be waived at any time and the refusal to do so therefore has a continuing character. All claims in that regard shall hence be considered as falling within the jurisdiction of the Committee *ratione temporis*.

6.10 The Committee therefore considers that the authors' claims cannot be considered inadmissible under article 3 (2-b) of the Optional Protocol.

6.11 The Committee notes that the authors present two different claims with very different legal grounds. The first claim is that their right to health has been violated because the woman was compelled to have an embryo with low possibilities of nesting transferred to her uterus, against her will, and that she eventually suffered a miscarriage. They also argue that the uncertainty created by the law regarding whether the consent to the transfer can be withdrawn after fertilization prevents them from trying to conceive again through an in vitro fertilization procedure, thus violating their right to health and to form a family. In relation to this claim, the Committee considers the authors have sufficiently substantiated that they might be victims of a violation of rights enshrined in the Covenant in accordance with article 3(2)(e) of the Covenant.

6.12 The second claim of the authors concerns the prohibition for them to donate the nine embryos left to scientific research. They argue that this prohibition violates their rights to enjoy the benefits of scientific progress and restricts freedom of research under article 15 of the Covenant and their right to health under article 12 (2) (c) and (d).

6.13 The Committee considers that this second claim is inadmissible because the authors have not sufficiently substantiated that they may claim to be victims of a violation of their rights enshrined in the Covenant because of this prohibition of donating the embryos to scientific research. The reasons are as follows.

6.14 Article 2 of the Optional Protocol restricts the *locus standi* for submitting communications to the real or potential victims of a violation of Covenant rights. The Committee may not examine a communication *in abstracto*: it may not assess whether an action or an omission of a State party is compatible with the Covenant, unless such action or omission has affected the author. The protocol does not establish an *actio popularis* that would allow persons, other than those who can arguably be considered as victims, to ask the Committee to analyze *in abstracto* the compatibility with the Covenant of a law or a policy of the State Party. The burden of substantiating their status as real or potential victims of a violation of these rights is on the authors. A failure to meet this requirement leads the communication to be considered inadmissible.

6.15 The Committee understands that communications might be filed by authors who are not in all cases represented by lawyers or jurists trained in international human rights law. Therefore, the admissibility requirements have to be interpreted in a flexible manner, without resulting in the imposition of unnecessary technical requirements, to avoid creating obstacles to the presenting of communications to the Committee. However, for the Committee to enter in the merits of a communication it is necessary that the facts and the claims presented by the authors show, at least *prima facie*, that they might be actual or potential victims of a right enshrined in the Covenant.

6.16 The Committee takes note of the authors' allegation that Law 40/2004 violates their right to enjoy the benefits of scientific progress under articles 12(2)(c) and (d) and 15 because, by preventing them from donating their embryos to science, it "slows down" the research on

multiple hereditary osteochondromas, an illness for which S.C. is an asymptomatic carrier. They argue also that some members of their family suffer this illness and might benefit of the research conducted on these embryos. Thus, this argument of the authors is that the donation of these specific embryos would benefit them directly as it would have a clear impact on the research on multiple hereditary osteochondromas that would allow to find a cure or a better treatment to this disease, or would make possible to avoid hereditary transmission by asymptomatic carriers as SC. Had the authors provided sufficient evidence that there was a probable, or at least a reasonable, link between the donation of these specific embryos and the development of better treatments for this disease or the reduction of the probabilities of its hereditary transmission that would benefit them personally, their claim would have been admissible. However, the petition does not substantiate the existence of this link. The submission is very detailed in showing the possibilities that research on embryos or stem cells might have for the advancement of medical sciences or the treatment of certain diseases, such as Alzheimer. But the petition does not provide any minimum evidence that the donation of these specific embryos would produce any concrete benefit for the authors in relation to multiple hereditary osteochondromas. It is not at all even clear that these embryos would be employed on the research of this disease. Thus, the argument of the benefits for the authors remains in that aspect speculative. Consequently, the Committee has to conclude that this first argument is not enough to sufficiently substantiate their claim regarding the prohibition of the donation of embryos to scientific research.

6.17 The second argument proposed by the authors to support their claim is in fact a recognition that they want to donate the embryos to scientific research in general, even if that research has not any meaningful possibility to benefit them directly. Thus they argue that the restriction on their possibility to donate their embryos imposed by Law 40/2004 violates their right to participate in scientific research, which they consider to be part of the Covenant. It is not necessary for the Committee to analyse on this occasion if the Covenant incorporates or to what extent a right for every person to take part in scientific research; in any case, the authors have the burden to show that they really intended to take part in a scientific endeavour. However the authors have not substantiated this claim as they simply argue that they wanted to donate their embryos to science, so that others would be able to perform scientific research. The petition is detailed concerning the nature and possible impact of research on embryos on science and develop legal arguments to defend the existence of a right to participate on science in the Covenant. However, the authors do not substantiate in any meaningful manner that a donation of an embryo is really a form of participation in a scientific research. The Committee concludes that this second argument does not sufficiently substantiate either the authors' claim that the prohibition on donating their embryos violated their rights under the Covenant.

6.18 The third argument made by the authors regarding the prohibition to donate the embryos is that freedom of research was infringed because the restriction imposed by Law 40/2004 violates the obligation of States "to respect the freedom indispensable for scientific research", thereby violating article 15(3). However, the authors have never claimed that they intended to perform themselves any scientific research, so in reality they are not claiming that they might be victims of a violation of their freedom of research. In that respect, they do not have the status of victims or potential victims, because their intent was that the Committee evaluate in the abstract if the limitations established by Law 40/2004 are in conformity with the Covenant, which goes beyond the competence of the Committee under the Protocol.

6.19 For the reasons stated above, the Committee concludes that the authors have not sufficiently substantiated their first two first arguments in relation to their claim regarding the prohibition to donate the embryos. The Committee also considers that the authors do not have the status of victims to present a communication in relation to their third argument thereof. Thus, under articles 2 and 3(2)(e) of the Optional Protocol, the communication is declared inadmissible in relation to the claim that the prohibition to donate the embryos violated the rights of the authors under article 15 of the Covenant.

6.20 The Committee notes that the rest of the communication meets the other admissibility requirements established in the Protocol and, accordingly, declares the remainder of the claims under articles 10 and 12 admissible and proceeds to their consideration on the merits.

C. Committee's consideration of the merits

Facts and legal issues

7.1 The Committee has considered the present communication taking into account all the information provided to it, in accordance with the provisions of article 8 of the Protocol.

7.2 The authors submit that they undertook two in vitro fertilization cycles: the first one with three embryos, all of which were affected by multiple hereditary osteochondromas, that were therefore not transferred in S.C.'s uterus, and the second one with ten embryos, out of which only one was determined to be free of multiple hereditary osteochondromas, but was graded of "average quality," that is, with a low chance of nesting. S.C. declined to have the "average quality" embryo transferred in her uterus but she was informed that she could not waive her consent to transfer the embryo to her uterus, and was threatened with a lawsuit if she refused to do so. Because of the threat of litigation, S.C. felt compelled to agree to have the embryo transferred, but she subsequently suffered a miscarriage. The other nine embryos were cryopreserved. The Committee notes that the State party does not challenge the author's account of the facts as presented.

7.3 The authors submit that the transfer of the embryo in S.C.'s uterus against her will constitute a violation of their right to the highest attainable standard of health. They further submit that the uncertainty created by the lack of clarity of the current provisions regarding the right of women to waive their consent to the transfer of embryos, violates their rights under articles 10 and 12 of the Covenant because it prevents them from trying to conceive again through an in vitro fertilization procedure.

7.4 In the light of the Committee's conclusion on the relevant facts and the claims made by the authors, the communication raises two central questions: whether the transfer of an embryo into S.C.'s uterus without her consent was a violation of her right to health; and whether the uncertainty created by the law regarding whether the consent to the transfer of embryos can be withdrawn after fertilization constitutes a violation of the authors' right to the highest attainable standard of health under article 12 and to the protection of their family under article 10. These basic legal questions necessitate the prior examination of two other questions: (i) the scope of the right to the highest attainable standard of health and its relation with gender equality (ii); and what are the permitted limitations to article 12.

Access to reproductive health and gender

8.1 The Committee recalls that "(t)he right to sexual and reproductive health is also indivisible from and interdependent with other human rights. It is intimately linked to civil and political rights underpinning the physical and mental integrity of individuals and their autonomy, such as the rights to life; liberty and security of person; freedom from torture and other cruel, inhuman or degrading treatment".¹³ The Committee also recalls that "(t)he right to sexual and reproductive health entails a set of freedoms and entitlements. The freedoms include the right to make free and responsible decisions and choices, free of violence, coercion and discrimination, regarding matters concerning one's body and sexual and reproductive health."¹⁴ Additionally, "[v]iolations of the obligation to respect occur when the State, through laws, policies or actions, undermines the right to sexual and reproductive health. Such violations include State interference with an individual's freedom to control his or her own body and ability to make free, informed and responsible decisions in this regard. (...) Laws and policies that prescribe involuntary, coercive or forced medical interventions, including forced sterilization or mandatory HIV/AIDS, virginity or pregnancy testing, also violate the obligation to respect."¹⁵

8.2 The Committee indeed considers necessary paying a specific attention to the specific allegations raised by the authors that are related to the right to reproductive health and physical integrity of Ms. S.C. In that regard, the Committee recalls that "(t)he experiences of

¹³ Ibid, para. 10.

¹⁴ See General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights (E/C.12/GC/22), para. 5.

¹⁵ Ibid. paras. 56-57.

women of systemic discrimination and violence throughout their lives require comprehensive understanding of the concept of gender equality in the right to sexual and reproductive health. Non-discrimination on the basis of sex, as guaranteed in article 2 (2) of the Covenant, and the equality of women, as guaranteed in article 3, require the removal of not only direct discrimination but also indirect discrimination, and the ensuring of formal as well as substantive equality. Seemingly neutral laws, policies and practices can perpetuate already existing gender inequalities and discrimination against women. Substantive equality requires that laws, policies and practices do not maintain, but rather alleviate, the inherent disadvantage that women experience in exercising their right to sexual and reproductive health.¹⁶

8.3 The Committee recalls that, as part of State party's obligations under article 3, "it is incumbent upon States parties to take into account the effect of apparently gender-neutral laws, policies and programmes and to consider whether they could result in a negative impact on the ability of men and women to enjoy their human rights on a basis of equality."¹⁷

Permitted limitations to the right to the highest attainable standard of health

9. Article 12 of the Covenant, is not absolute and may be subject to such limitations as permitted by article 4 of the Covenant. The Committee recalls that the Covenant's limitation clause, article 4, is primarily intended to protect the rights of individuals rather than to permit the imposition of limitations by States. Consequently a State party imposing a restriction on the enjoyment of a right under the Covenant has the burden of justifying such serious measures in relation to each of the elements identified in article 4. Such restrictions must be in accordance with the law, including international human rights standards, compatible with the nature of the rights protected by the Covenant, in the interest of legitimate aims pursued, and strictly necessary for the promotion of the general welfare in a democratic society.¹⁸

Lack of consent and violation of the right to health

10.1 The Committee takes note of the first claim presented by the authors under article 12, namely, that S.C.'s right to health was violated when she was compelled to have an embryo transferred to her uterus against her will. The Committee notes that this transfer led to a miscarriage, which she has considered traumatising. The Committee recalls that the right to health includes the right to make free and informed decisions concerning any medical treatment a person might be subject to. Thus, laws and policies that prescribe involuntary, coercive or forced medical interventions violate the State's responsibility to respect the right to health. The Committee further observes that forcing a woman to have an embryo transferred into her uterus clearly constitutes a forced medical intervention. The Committee concludes that, in the circumstances of this case, the facts presented before it constitute a violation of S.C.'s right to health, as enshrined by article 12 of the Covenant.

10.2 The Committee considers that, when relevant information presented in a communication indicates, *prima facie*, that a law that disproportionately affects women violates the obligation of the State party to ensure the equal right of men and women to the enjoyment of the right that has allegedly been violated, it is for the State party to show that it has fulfilled its obligations under article 3 of the Covenant.

10.3 The Committee recalls that the requirement of equality between women and men, as guaranteed by article 3, requires that laws, policies and practices do not maintain, but rather alleviate, the inherent disadvantage that women experience in exercising their right to sexual and reproductive health and that, seemingly neutral laws, can perpetuate already existing gender inequalities and discrimination against women. The Committee notes that Law 40/2004, as interpreted in the authors' case, restricts the right of women undergoing the treatment to waive their consent, leading to possible forced medical interventions or even

¹⁶ Ibid para. 26-27.

¹⁷ See General comment No. 16 (2005). The equal right of men and women to the enjoyment of all economic, social and cultural rights (art. 3 of the International Covenant on Economic, Social and Cultural Rights) (E/C.12/2005/411) para. 18.

¹⁸ See Committee's General Comment No. 14 (2000) on the Right to the Highest Attainable Standard of Health (E/C.12/2000/4), para. 28.

pregnancies for all women undergoing in vitro fertilisation treatments. It considers that, even if, presumably, this restriction on the right to withdraw one's consent affects both sexes, it places an extremely high burden on women. The Committee notes that the possible consequences on women are extremely grave, constituting a direct violation of their right to health and physical integrity. It concludes that the transfer of an embryo to S.C.'s uterus without her valid consent constituted a violation of her right to the highest attainable standard of health and her right to gender equality in her enjoyment of her right to health, constituting a violation of article 12, read alone and in conjunction with article 3 of the Covenant.

Legal uncertainty to withdraw consent and violation of the right to health.

11.1 The Committee takes note of the second claim presented by the authors under article 12: that, the uncertainty created by the law regarding whether the consent to the transfer can be withdrawn after fertilization prevents them from trying to conceive again, thus violating their right to health. As experienced by the authors, S.C. has been unable to withdraw her consent after fertilisation and the authors have reasons to fear that they might experience a similar situation if they intend again an in vitro fertilization. Consequently, the Committee acknowledges that the authors are prevented from accessing in vitro fertilization treatments. The Committee considers that it follows that Law 40/2004 imposes a restriction on the authors' right to health as it prevents their access to a health treatment that is otherwise available in the State party.

11.2 Restrictions to rights protected under the Covenant must comply with the limitations provided for in article 4 of the Covenant. The Committee recalls that, according to article 4, restrictions must be "compatible with the nature of these rights. The Committee has found that the prohibition to withdraw one's consent to the transfer of an embryo constituted a violation of the right to health as it can lead to forced medical interventions or even forced pregnancies. This prohibition touches upon the very substance of the right to health and goes beyond the kind of restriction that would be justified under article 4 of the Covenant. This prohibition, or at least the ambiguity concerning the existence of this prohibition, is at the origin of the author's inability to access in vitro fertilization treatments. Consequently, the Committee finds that the restriction is not compatible with the nature of the right to health and that the facts presented before it disclose a violation of article 12 of the Covenant with regards to both authors.

11.3 Having found that the restriction on the authors' access to in vitro fertilisation treatment violates the authors' rights under article 12, the Committee does not consider it necessary to examine the authors' claims under article 10.

11.4 Finally, the Committee notes that most of the problems raised by the authors in their petition are associated with the ambiguities, even possible inconsistencies, of the regulation of the State party in relation to in vitro fertilization and possible research on embryos and stem cells. These ambiguities are due, in part, to the fact that Law 40/2004, approved in 2004, has been subject to important but piecemeal modifications made by several decisions of the Constitutional Court. Besides, the Committee is aware that this is a field in which social visions evolved deeply and science and techniques have a dynamic development. For those reasons, and as stressed by other human rights bodies¹⁹, States should update permanently their regulations to harmonize them with their human rights obligations and with the evolution of society and scientific progress. In the State Party this seems even more urgent.

D. Conclusion and recommendations

12.1 In the light of the information provided and the particular circumstances of the case, the Committee considers that the prohibition of the withdrawal of the female author's consent to have an embryo transferred to her uterus and the restriction of both their access to reproductive rights constitute a violation of article 12 with regard to both authors, and article 12 read in conjunction with article 3 of the Covenant with regard to S.C.

¹⁹ See European Court of Human Rights, *S.H. and Others v. Austria* (application No. 57813/00), judgment of 3 November 2011. Paras. 117-118.

12.2 The Committee, acting under article 9 (1) of the Optional Protocol, is of the view that the State party violated article 12 in conjunction with article 3, and articles 12 of the Covenant. In the light of the Views contained in the present communication, the Committee makes the following recommendations to the State party.

Recommendations in respect of the authors

13. The State party is under an obligation to provide the authors with an effective remedy, including by: (a) establishing the appropriate conditions to enable the authors' right to access in vitro fertilization treatments with trust that their right to withdraw their consent to medical treatments will be respected; (b) ensuring that the female author is protected from any unwanted medical intervention and that her right to make free decisions regarding her own body is respected; (c) awarding S.C. adequate compensation for the physical, psychological and moral damages suffered; and (d) reimbursing the authors for the legal costs reasonably incurred in the processing of this communication.

General recommendations

14. The Committee considers that the remedies recommended in the context of individual communications may include guarantees of non-repetition and recalls that the State party has an obligation to prevent similar violations in the future. The Committee considers that the State party should ensure that its legislation and the enforcement thereof are consistent with the obligations established under the Covenant. In particular, the State party has the obligation to:

(a) Adopt appropriate legislative and/or administrative measures to guarantee the right of all women to take free decisions regarding medical interventions affecting their bodies, in particular ensuring their right to withdraw their consent to the transfer of embryos to their uterus;

(b) Adopt appropriate legislative and/or administrative measures to guarantee the access to all reproductive treatments generally available and to allow all persons to withdraw their consent to the transfer of embryos for procreation, ensuring that all restrictions to the access to these treatments comply with the criteria provided by article 4;

15. In accordance with article 9 (2) of the Optional Protocol and rule 18 (1) of the provisional rules of procedure under the Optional Protocol, the State party is requested to submit to the Committee, within a period of six months, a written response, including information on measures taken in follow-up to the Views and recommendations of the Committee. The State party is also requested to publish the Views of the Committee and to distribute them widely, in an accessible format, so that they reach all sectors of the population.
