

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

FOURTH SECTION

CASE OF NEDESCU v. ROMANIA

(Application no. 70035/10)

JUDGMENT

STRASBOURG

16 January 2018

FINAL

16/04/2018

This judgment has become final under Article 44 § 2 of the Convention. It may be subject to editorial revision.



In the case of Nedescu v. Romania,

The European Court of Human Rights (Fourth Section), sitting as a Chamber composed of:

Ganna Yudkivska, President,

Vincent A. De Gaetano,

Paulo Pinto de Albuquerque,

Faris Vehabović,

Iulia Motoc,

Carlo Ranzoni,

Georges Ravarani, judges,

and Marialena Tsirli, Section Registrar,

Having deliberated in private on 12 December 2017,

Delivers the following judgment, which was adopted on that date:

PROCEDURE

- 1. The case originated in an application (no. 70035/10) against Romania lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by two Romanian nationals, Mrs Daniela Nedescu and Mr Călin Nedescu ("the applicants"), on 26 November 2010.
- 2. The applicants were represented by Ms Diana-Elena Dragomir, a lawyer practising in Bucharest. The Romanian Government ("the Government") were represented by their Agent, Ms Catrinel Brumar, from the Ministry of Foreign Affairs.
- 3. The applicants alleged that they had suffered a violation of their rights under Article 8 of the Convention because they had not been able to use their embryos to have another child after the embryos had been seized by the prosecuting authorities in 2010.
- 4. On 6 November 2012 the application was communicated to the Government.

THE FACTS

I. THE CIRCUMSTANCES OF THE CASE

5. The first applicant, Mrs Daniela Nedescu, is married to the second applicant, Mr Călin Nedescu. They were born in 1976 and live in Bucharest.

6. In 2008 the applicants, who were childless but wanted to have children, decided to try assisted reproduction at a private clinic, the S. Clinic.

It appears that the S. Clinic had previously applied to the National Transplant Agency ("the Transplant Agency") for authorisation to function as a cell and tissue bank and user in accordance with the legal requirements, an application which was still pending completion in 2008.

- 7. Following an ovarian stimulation and *in vitro* fertilisation, seven embryos were obtained, of which three were transferred immediately to Mrs Nedescu, who became pregnant and gave birth.
- 8. The four remaining embryos were frozen and put in storage at the S. Clinic in November 2008 with a view to their future use by Mrs Nedescu.
- 9. On 15 July 2009 the procedure for obtaining the required authorisation from the Transplant Agency was completed and the S. Clinic was authorised to act as a medical centre that could function as a storage bank for genetic material.
- 10. On 24 July 2009, following a criminal investigation into the delivery of the above authorisation, the Directorate for the Investigation of Organised Crime and Terrorism attached to the Prosecutor General's Office of Romania (DIICOT) closed the S. Clinic, seized all the genetic material found there, including the applicants' embryos, and transferred it to the Mina Minovici Institute of Forensic Medicine ("the IFM").

The applicants' embryos and those of other couples were kept in containers. Each container had different vials for each set of embryos.

11. It appears from a DIICOT report dated 9 November 2009 that the embryos of more than 240 families were seized at the S. Clinic.

As with other patients of the Clinic, the applicants were neither informed of the seizure, which they learned about from the media, nor consulted about the transfer of the seized embryos from the S. Clinic to the IFM.

- 12. On 13 March 2010 the applicants requested that DIICOT allow them to retrieve their embryos as they wished to undergo a new assisted reproduction procedure in another clinic. They pointed out that it was of the utmost importance that they be allowed to retrieve the embryos rapidly since the storage period was to expire in August 2010 and there was a strict procedure for the transfer.
- 13. On 30 March 2010 DIICOT allowed the applicants to recover the embryos directly from the IFM. They had to be accompanied by an embryologist and provide a special container with liquid nitrogen.
- 14. On 21 July 2010 the applicants went to the IFM accompanied by an embryologist, however, they were not allowed to retrieve the embryos. They were asked instead to show that the Transplant Agency had approved the transfer.

- 15. The first applicant, under the supervision of a specialist doctor, therefore attempted to have a new ovarian stimulation in the hope of creating new embryos.
- 16. However, on 18 August 2010, while being treated for premature menopause, she underwent a medical examination which revealed that her state of health did not allow her to undergo another ovarian stimulation.
- 17. The applicants joined the criminal proceedings instituted against the administrative board of the S. Clinic and the doctors practising within or in cooperation with it, and sought damages under domestic tort provisions for not being able to use the embryos. In an interlocutory judgment of 29 November 2010 the applicants' action was dismissed for lack of victim status on the grounds that the IFM's refusal to allow them to recover the embryos had no link with the crimes allegedly committed by the accused. The applicants were directed to bring a claim for damages before a civil court.
- 18. The applicants therefore resumed their efforts to retrieve the embryos deposited with the IFM, but were not successful.
- 19. In November 2010 they brought an action before the Bucharest Court of Appeal against the Transplant Agency and the Ministry of Health, seeking to obtain the agency's authorisation to transfer their embryos to an authorised clinic, in Romania or abroad, where Mrs Nedescu could try again to become pregnant.
- 20. On 12 December 2010 Mrs Nedescu had another examination, which led to the same conclusions as on 18 August 2010.
- 21. On 13 December 2010 the Transplant Agency informed the applicants that it refused to approve a transfer of the embryos. It stated that DIICOT had moved the embryos to the IFM unlawfully as the institute had never obtained the required permit to act as a tissue and cell bank. The provisions of the Code of Criminal Procedure relied on by DIICOT had also not provided any guarantees for the safety of the embryos deposited with the IFM.
- 22. At a hearing on 22 March 2011 the applicants asked the Court of Appeal to order the transfer of the embryos from the IFM to a private clinic of their choice located in Sibiu, the P. Clinic, which was authorised to carry out assisted reproduction and act as a genetic material storage bank.
- 23. The court dismissed the applicants' application on the same day. It relied on the provisions of section 148(4) and (5) of the Health Care Reform Act. It found that the Transplant Agency's refusal to allow the transfer of the embryos had been lawful since neither the S. Clinic nor the IFM had been accredited or authorised to function as genetic material banks and the transfer of genetic material could only be performed between institutions authorised to function as such storage banks.
- 24. The applicants appealed against the judgment to the High Court of Cassation and Justice.

25. On 12 October 2011 DIICOT appointed a public hospital, the P.S. Hospital, as the new legal custodian for all the embryos, including the ones belonging to the applicants.

The transfer of the embryos to the new custodian took place on 19 October 2011. According to a report drafted by the judicial authorities on that occasion, Ms A.M., the doctor from P.S. Hospital who took delivery of the embryos, drew up a disclaimer to the effect that the genetic material listed in the inventory accompanying the embryos had been received without any prior checks of the vials, that it had not been possible for her to check each individual item owing to the absence of the embryologist who had participated in the initial freezing and that the procedures in use at that time were different from those used by the first custodian.

26. On 20 December 2011 the High Court of Cassation and Justice allowed the appeal against the judgment of 22 March 2011 and ordered the Transplant Agency to implement the prosecutor's decision to return the embryos by allowing their transfer from the IFM to an authorised clinic or hospital of the applicants' choice in Romania or abroad.

It found, firstly, that the Transplant Agency, which was organised as a structure within the Ministry of Health, had been duly informed about the investigating authorities' decision to deposit the material seized at the S. Clinic with the IFM, and that, secondly, the Ministry of Health had signed the record drawn up at the end of the procedure for moving the embryos to the IFM, together with the investigating authorities.

It held that in so far as the Transplant Agency's task was to coordinate the activities of procuring, processing, preserving, storing, approving and distributing human tissue and cells in Romania, there had been no legal grounds for it to interfere with the implementation of the prosecutor's decision to return the embryos to the applicants.

The High Court further relied on the Government's observations submitted to the Court in the case of *Knecht v. Romania* (no. 10048/10, 2 October 2012), from which it could be seen that the investigating authorities had authorised Ms Knecht to retrieve her embryos from the IFM, and that the Government's understanding was that Ms Knecht had been lawfully entitled to arrange for their transfer to an authorised clinic. The High Court stressed that Mr and Mrs Nedescu's embryos had been stored in the same container as those belonging to Ms Knecht. There was therefore nothing to prevent them from arranging the transfer of their embryos to an authorised clinic or hospital of their choice, in Romania or abroad.

Lastly, the court granted costs and fees of 4,000 Romanian lei (RON) to the applicants.

27. On 26 March 2012 DIICOT informed the applicants that the prosecutor had appointed P.S. Hospital as the new legal custodian of their embryos. They therefore had to agree on a transfer date with that institution in order to retrieve the embryos.

- 28. The applicants contacted P.S. Hospital, which informed them on 27 September 2012 that they could only retrieve the embryos if they were accompanied by a representative from the Transplant Agency, an embryologist from the S. Clinic, where the embryos had been stored initially, and a DIICOT representative.
- 29. On 1 November 2012 P.S. Hospital informed the applicants that in order to retrieve their embryos they had to agree on a date, obtain an authorisation document from the Transplant Agency, make sure a certified specialist embryologist was present and provide a special container with liquid nitrogen from an accredited transportation company.
- 30. On 12 November 2012, in reply to a request from the applicants, P.S. Hospital informed them that it could not transfer the remaining embryos to Mrs Nedescu as they had only been appointed as a custodian by DIICOT. Nevertheless, the applicants could attempt to obtain new embryos at the hospital which could then be transferred to her.
- 31. In a letter dated 7 January 2013 to the Government Agent, a representative of P.S. Hospital reiterated that the embryos could only be retrieved after prior approval from the Transplant Agency and that an embryologist from the S. Clinic and a DIICOT representative had to be present.

It also stated that they declined any responsibility for the identification, quality and viability of the frozen embryos deposited with the IFM because DIICOT had not organised any individual identification when the embryos had been transferred. The hospital could therefore only assume that the embryos belonging to the Nedescus were among those that had been transferred to it. The hospital reiterated that the IFM had no authorisation to function as a genetic material bank (for tissues and cells).

Furthermore, the hospital did not only have the task of implementing DIICOT's decision to allow the applicants to remove the embryos and ensure respect for the conditions that the removal be made in the presence of an embryologist and include the provision of a container with liquid nitrogen. It also had to comply with the relevant legislation on the removal and transfer of genetic material and with the conditions set down by the Transplant Agency in a decision of 3 June 2011, Decision no. 5.

The representative also stated that the existing embryos could be transferred to the mother at the hospital but that the hospital's own doctors would not carry out the procedure as they could not assume any responsibility owing to the quality of the embryos. However, the hospital preferred that such a transfer be performed elsewhere.

32. On 16 January 2013 the applicants applied to DIICOT to be appointed custodians of their own embryos. They indicated that they were able to bear the costs of becoming custodians.

A DIICOT prosecutor informed the applicant's lawyer by telephone that the application had been rejected.

In a letter dated 18 April 2013 to the Government's Agent, a DIICOT chief prosecutor stated that the cost of appointing the applicants as custodians was very high and that the judicial bodies involved had no competence to make such a decision. In any event, "no formula allowing for consensus among all the parties involved has so far been identified".

33. Following the criminal investigation of the S. Clinic (see paragraph 10 above), the High Court of Cassation on 21 October 2014 found its managers, owner and the then director of the Transplant Agency guilty of association for the purposes of creating a criminal group. It handed down various prison sentences.

II. RELEVANT DOMESTIC LAW

A. Health Care Reform Act (Law no. 95/2006)

- 34. The Act is divided into seventeen titles, covering a wide array of subjects specific to public health. Title VI contains provisions covering the procurement and transplant of organs, tissues and cells of human origin used for therapeutic purposes, the donors of organs, tissues and cells of human origin, the donation and transplant thereof and the financing of transposes transplant activity. It into national legislation Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards for the quality and safety of the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells.
- 35. Section 143 provides that the National Transplant Agency is responsible for "the coordination, supervision, approval and implementation of any provisions regarding transplant activities".
- 36. The relevant subsections of section 148, which deals mainly with the procurement and transplant of tissues and cells from dead bodies, provide as follows:
 - "(4) Procured tissue and cells of human origin can be used immediately for transplants or can be processed and deposited in tissue and cell banks, accredited with or approved by the National Transplant Agency.
 - (5) Any transplant of tissue and cells of human origin may be processed only from banks accredited with or approved by the National Transplant Agency ..."

According to subsection 9, the import or export of tissue and cells has to be specifically authorised by the National Transplant Agency in the manner referred to in Annex 7 (export of tissue and cells from dead bodies) and 9 (import), and must be carried out in accordance with the relevant customs legislation.

B. Orders of the Minister of Public Health no. 1225 of 1 July 2008 and no. 1009 of 6 July 2010

37. The Orders listed a number of establishments, including the P. Clinic in Sibiu, which were authorised to function as tissue and cell banks and users, but neither the S. Clinic nor the IFM were included.

C. National Transplant Agency Decision no. 5 of 3 June 2011

38. The decision reads as follows:

Article 1

"From the date of the current decision the transfer of biological material on the territory of Romania between clinics that are legally authorised and accredited must be performed in strict accordance with the following specifications:

- the procedure for freezing and preserving the embryos;
- the freezing method used: vitrifying or slow freezing;
- the freezing kit used and the name of the manufacturer;
- if a freezing kit was prepared, the components and exact proportions used in the preparation process;
 - the stage of development of the embryos at the time of freezing;
- documents allowing for the identification of the embryos and their position inside the transport container;
 - documents proving ownership of the embryos;
- documents proving that keeping the embryos in the cell bank does not present a danger of contamination (in other words, the results of medical tests of the couple during *in vitro* fertilisation treatment);
- the conditions of storage of the embryos (with appropriate evidence, for instance temperature charts).

Article 2

"All private and public medical institutions shall implement the provisions of the current decision."

D. Romanian Criminal Code

39. Article 118, in force until 2014, read as follows:

"The following property can be subjected to special confiscation:

- (a) the proceeds of carrying out an act forbidden by the criminal law;
- (b) property which was used, in any way, in the commission of a crime, if it belongs to the criminal or, if it belongs to someone else, where that person knew what it would be used for ...;

(c) property produced, modified or adapted for the purpose of committing a crime, if it has been used for the commission of the crime and if it belongs to the criminal. If the property belongs to someone else, confiscation is ordered if the creation, modification or adaptation was made by the owner or by the criminal with the owner's knowledge;

...

- (e) the proceeds of carrying out an act forbidden by the criminal law, if they are not returned to the victim or used to compensate the victim;
 - (f) property which cannot be possessed by law.

..."

E. Romanian Criminal Procedure Code

40. In its relevant parts concerning the procedure for the seizure of property during a criminal investigation, the code in force at the time of the events, in June 2009, reads as follows:

Article 163

"Precautionary measures are those measures taken during a criminal trial by the prosecutor or by the court and consist of freezing assets, by ordering the seizure of movable and immovable property with a view to a subsequent special confiscation, remedying damage suffered as a result of the crime and to guaranteeing the enforcement of a fine.

Precautionary measures taken with a view to remedying damage can be ordered in respect of property belonging to the accused or the person facing civil liability.

Precautionary measures taken with a view to guaranteeing the enforcement of a fine can be ordered in respect only of property belonging to the accused.

...'

Article 165

- "(1) The authority that enforces the seizure (*sechestru*) must identify and value the property in question; it may, if need be, have recourse to experts.
- (2) Perishable goods, objects made of precious metal or jewels ... works of art ... and money which have been seized shall in all cases be taken away.

...

(9) If there is a danger of alienation, the other movable items that have been seized will be sealed or also taken away, and a custodian can be appointed."

Article 166

"(1) The body that carries out the seizure draws up an official report on all the acts performed under Section 165, including a detailed description of the property seized and specifying its value ... Objections to the seizure by the parties and other interested persons are also mentioned.

..."

Article 168

- "(1) The defendant, the party with civil liability, as well as any other interested person, may complain about the precautionary measure and the means of its enforcement to the prosecutor or to the court at any stage in the proceedings.
- (2) An appeal can be lodged separately against the decision of a court. An appeal does not suspend execution.
- (3) If after completion of a criminal trial no complaint has been lodged against the enforcement of the precautionary measure, it may be challenged under the civil law."

Article 169

- "(1) Where prosecutors or courts finds that property taken from a defendant, or from any other person who received them in his or her custody, is the property of the victim or has been wrongly taken away from him/her, they order the return of those items to the victim. Any other person who claims a right over the confiscated property can ask under Article 168 for enforcement of that right and the return of the property.
- (2) Confiscated property is only returned if it does not impede the search for the truth and the just settlement of the case, and it imposes on the person to whom it is returned an obligation to retain it until the issuing of a final decision."

III. COUNCIL OF EUROPE DOCUMENTS

- A. Recommendation 1046 (1986) of the Parliamentary Assembly of the Council of Europe on the use of human embryos and foetuses for diagnostic, therapeutic, scientific, industrial and commercial purposes
- 41. The relevant parts of the Recommendation read as follows:
 - "...5. [The Parliamentary Assembly] Considering that, from the moment of fertilization of the ovule, human life develops in a continuous pattern, and that it is not possible to make a clear-cut distinction during the first phases (embryonic) of its development, and that a definition of the biological status of an embryo is therefore necessary;
 - 6. Aware that this progress has made the legal position of the embryo and foetus particularly precarious, and that their legal status is at present not defined by law;
 - 7. Aware that adequate provisions governing the use of living or dead embryos and foetuses do not at present exist;
 - 8. Convinced that, in view of scientific progress which makes it possible to intervene in developing human life from the moment of fertilisation, it is urgent to define the extent of its legal protection;
 - 9. Having regard to the variety of ethical opinions on the question of using the embryo or the foetus or their tissues, and to the conflicts between values which arise;
 - 10. Considering that human embryos and foetuses must be treated in all circumstances with the respect due to human dignity..."

B. Council of Europe Convention on Human Rights and Biomedicine ("Oviedo Convention") of 4 April 1997

42. In its relevant parts the Oviedo Convention reads as follows:

Article 2 – Primacy of the human being

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

Article 18 - Research on embryos in vitro

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

Article 27 - Wider protection

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

IV. EUROPEAN UNION INSTRUMENTS

- 43. The relevant parts of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards for the quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells provide as follows:
 - "(2) The availability of human tissues and cells used for therapeutic purposes is dependent on Community citizens who are prepared to donate them. In order to safeguard public health and to prevent the transmission of infectious diseases by these tissues and cells, all safety measures need to be taken during their donation, procurement, testing, processing, preservation, storage, distribution and use.

•••

(7) This Directive should apply to tissues and cells including haematopoietic peripheral blood, umbilical-cord (blood) and bone-marrow stem cells, reproductive cells (eggs, sperm), foetal tissues and cells and adult and embryonic stem cells.

...

(13) The donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human applications should comply with high standards of quality and safety in order to ensure a high level of health protection in the Community. This Directive should establish standards for each one of the steps in the human tissues and cells application process.

•••

(16) Tissues and cells used for allogeneic therapeutic purposes can be procured from both living and deceased donors. ...

(20) Any establishment may also be accredited as a tissue and cell establishment, provided it complies with the standards.

...

(25) An accreditation system for tissue establishments and a system for notification of adverse events and reactions linked to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells should be established in the Member States.

...

(28) An adequate system to ensure the traceability of human tissues and cells should be established. This would also make it possible to verify compliance with quality and safety standards. Traceability should be enforced through accurate substance, donor, recipient, tissue establishment and laboratory identification procedures as well as record maintenance and an appropriate labeling system.

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Article 5 - Supervision of human tissue and cell procurement

1. Member States shall ensure that tissue and cell procurement and testing are carried out by persons with appropriate training and experience and that they take place in conditions accredited, designated, authorised or licensed for that purpose by the competent authority or authorities.

...

Article 6 - Accreditation, designation, authorisation or licensing of tissue establishments and tissue and cell preparation processes

1. Member States shall ensure that all tissue establishments where activities of testing, processing, preservation, storage or distribution of human tissues and cells intended for human applications are undertaken have been accredited, designated, authorised or licensed by a competent authority for the purpose of those activities.

...

4. The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation or licensing of a tissue establishment or of a tissue or cell preparation process if inspections or control measures demonstrate that such an establishment or process does not comply with the requirements of this Directive.

...

Article 8 - Traceability

- 1. Member States shall ensure that all tissues and cells procured, processed, stored or distributed on their territory can be traced from the donor to the recipient and vice versa. This traceability shall also apply to all relevant data relating to products and materials coming into contact with these tissues and cells.
- 2. Member States shall ensure the implementation of a donor identification system which assigns a unique code to each donation and to each of the products associated with it.
- 3. All tissues and cells must be identified with a label that contains the information or references allowing a link to the information referred to in Article 28(f) and (h).

4. Tissue establishments shall keep the data necessary to ensure traceability at all stages.

..

Article 10 - Register of tissue establishments and reporting obligations

- 1. Tissue establishments shall keep a record of their activities, including the types and quantities of tissues and/or cells procured, tested, preserved, processed, stored and distributed, or otherwise disposed of, and on the origin and destination of the tissues and cells intended for human applications, in accordance with the requirements referred to in Article 28(f). ...
- 2. The competent authority or authorities shall establish and maintain a publicly accessible register of tissue establishments specifying the activities for which they have been accredited, designated, authorised or licensed.

...

CHAPTER III DONOR SELECTION AND EVALUATION

Article 12 - Principles governing tissue and cell donation

1. Member States shall endeavour to ensure voluntary and unpaid donations of tissues and cells.

Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which compensation may be granted.

•••

Article 13 - Consent

1. The procurement of human tissues or cells shall be authorised only after all mandatory consent or authorisation requirements in force in the Member State concerned have been met.

•••

Article 15 - Selection, evaluation and procurement

1. The activities related to tissue procurement shall be carried out in such a way as to ensure that donor evaluation and selection is carried out in accordance with the requirements referred to in Article 28(d) and (e) and that the tissues and cells are procured, packaged and transported in accordance with the requirements referred to in Article 28(f).

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CHAPTER IV PROVISIONS ON THE QUALITY AND SAFETY OF TISSUES AND CELLS

Article 16 - Quality management

1. Member States shall take all necessary measures to ensure that each tissue establishment puts in place and updates a quality system based on the principles of good practice.

..

- 3. Tissue establishments shall take all necessary measures to ensure that the quality system includes at least the following documentation:
 - standard operating procedures,
 - guidelines,
 - training and reference manuals,
 - reporting forms,
 - donor records,
 - information on the final destination of tissues or cells.
- 4. Tissue establishments shall take all necessary measures to ensure that this documentation is available for inspection by the competent authority or authorities.
- 5. Tissue establishments shall keep the data necessary to ensure traceability in accordance with Article 8.

Article 19 - Tissue and cell reception

1. Tissue establishments shall ensure that all donations of human tissues and cells are subjected to tests in accordance with the requirements referred to Article 28(e) and that the selection and acceptance of tissues and cells comply with the requirements referred to in Article 28(f).

...

3. Tissue establishments shall verify and record the fact that the packaging of human tissue and cells received complies with the requirements referred to in Article 28(f). All tissues and cells that do not comply with those provisions shall be discarded.

•••

- 5. Tissue establishments shall ensure that human tissues and cells are correctly identified at all times. Each delivery or batch of tissues or cells shall be assigned an identifying code, in accordance with Article 8.
- 6. Tissue and cells shall be held in quarantine until such time as the requirements relating to donor testing and information have been met in accordance with Article 15.

Article 21 - Tissue and cell storage conditions

1. Tissue establishments shall ensure that all procedures associated with the storage of tissues and cells are documented in the standard operating procedures and that the storage conditions comply with the requirements referred to in Article 28(h).

- 2. Tissue establishments shall ensure that all storage processes are carried out under controlled conditions.
- 3. Tissue establishments shall establish and apply procedures for the control of packaging and storage areas, in order to prevent any situation arising that might adversely affect the functioning or integrity of tissues and cells.

..

- 5. Member States shall ensure that tissue establishments have agreements and procedures in place to ensure that, in the event of termination of activities for whatever reason, stored tissues and cells shall be transferred to other tissue establishment or establishments accredited, designated, authorised or licensed in accordance with Article 6, without prejudice to Member States' legislation concerning the disposal of donated tissues or cells, according to the consent pertaining to them."
- 44. The relevant provisions of the Charter of Fundamental Rights of the European Union (2007/C 303/01) are worded as follows:

Article 1 - Human dignity

"Human dignity is inviolable. It must be respected and protected."

Article 7 – Respect for private and family life

"Everyone has the right to respect for his or her private and family life, home and communications."

45. In a judgment of 18 October 2011 (C-34/10 Oliver Brüstle v. Greenpeace e.V.) the Court of Justice of the European Union ("the CJEU") clarified the legal definition of the "human embryo": "any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any nonfertilised human ovum whose division and further development have been stimulated by parthenogenesis". The CJEU further ruled that Article 6(2)(c) of Directive 98/44 excluded an invention from patentability where the technical teaching which is the subject-matter of the patent application would require the prior destruction of the human embryo. The Advocate General Yves Bot recalled in his opinion delivered on 10 March 2011 on that matter that "Directive 98/44 prohibits the patentability of the human body, at the various stages of its formation and development, including germ cells" and asserted that "human dignity is a principle which must be applied not only to an existing human person, to a child who has been born, but also to the human body from the first stage in its development, i.e. from fertilisation" (§ 96).

V. OTHER INTERNATIONAL INSTRUMENTS

46. The relevant parts of the Universal Declaration on Bioethics and Human Rights adopted by UNESCO's General Conference on 19 October 2005 provide as follows:

"The General Conference,

•••

Recognizing that, based on the freedom of science and research, scientific and technological developments have been, and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms,

...

Also recognizing that decisions regarding ethical issues in medicine, life sciences and associated technologies may have an impact on individuals, families, groups or communities and humankind as a whole,

...

Proclaims the principles that follow and adopts the present Declaration.

...

Principles

Within the scope of this Declaration, in decisions or practices taken or carried out by those to whom it is addressed, the following principles are to be respected.

Article 3 - Human dignity and human rights

- 1. Human dignity, human rights and fundamental freedoms are to be fully respected.
- 2. The interests and welfare of the individual should have priority over the sole interest of science or society.

,,

THE LAW

I. SCOPE OF THE APPLICATION

- 47. The applicants stated in their application that they reserved the right to raise a complaint under Article 2 of the Convention over an infringement of the right to life if their embryos became unviable owing to the acts of the authorities.
- 48. The Court notes that the applicants did not eventually complain about a breach of the right to life under Article 2 of the Convention, did not provide any information about the viability of their embryos and made no further submissions in that respect.
- 49. The Court will accordingly examine the application solely from the standpoint of the rights provided for by Article 8.

II. ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

- 50. The applicants complained that, as a whole, the authorities' behaviour had amounted to a disproportionate interference with their private and family life because for more than six years they had not been allowed to use their embryos for a new assisted reproduction procedure and had thus lost the possibility to have another child. They relied on Article 8 of the Convention, which reads as follows:
 - "1. Everyone has the right to respect for his private and family life, his home and his correspondence.
 - 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

A. Admissibility

51. The Government argued at the outset that the State could not be held responsible for acts committed by private persons, such as the S. Clinic, and relied in that regard on *Borghi v. Italy* (dec., no. 54767/00, ECHR 2002-V (extracts)) and *Kiratli v. Turkey* (dec., no. 6497/04, 2 September 2008). They submitted that the applicants and the S. Clinic alone had been responsible for the fate of the embryos and the fact that it had been impossible to use them.

They further argued that, as had been pointed out in the interlocutory judgment of 29 November 2010, the applicants could have lodged a separate civil action against the doctors from the S. Clinic to seek damages under the tort liability provisions of the Civil Code, but had failed to do so.

52. The Court notes that the applicants' complaint concerned the refusal of the various institutions involved in the custody of the embryos after their seizure to return them at all, even though that had been allowed by the judicial authorities.

The Government's preliminary objections that the application is incompatible *ratione personae* and its objection as to the non-exhaustion of domestic remedies must therefore be dismissed.

53. The Court notes that the complaint is not manifestly ill-founded within the meaning of Article 35 § 3 (a) of the Convention. It further notes that it is not inadmissible on any other grounds. It must therefore be declared admissible.

B. Merits

1. The parties' submissions

(a) The applicants

- 54. The applicants complained that since 2010 they had been unable to use their embryos, deposited successively with the IFM and P.S. Hospital following their seizure by DIICOT, which had prevented them from attempting to have another child and had amounted to an interference with their right to respect for their private and family life. That interference had been neither lawful nor proportionate to the aim pursued.
- 55. They stressed that they had lawfully stored their embryos at the S. Clinic with a view to a future transfer to the mother. They had chosen that clinic because their doctor had been using its facilities. They had not been aware at the time, and could not have been aware, that the S. Clinic had not had the necessary authorisation, as later alleged. The S. Clinic had been well established. It had been operating for almost a decade, had been located near the Transplant Agency in the city centre, less than 800 metres from the main Government building. It had had a huge banner and clear signs outside, and had worked in partnership with other well-established and well-known authorised medical facilities and doctors. Moreover, the S. Clinic had obtained the required authorisation to store genetic material.
- 56. The authorities' interference with their private and family life had not been provided for by law. First of all, DIICOT's decision to deposit the confiscated embryos with the IFM, which had not possessed the required authorisation to store genetic material, had been unlawful.

In addition, the Transplant Agency's refusal to implement the prosecutor's decision ordering the return of the embryos had had no legal basis, nor had the Transplant Agency's refusal to obey the decision of the Supreme Court of Justice allowing the applicants to arrange the transfer of the embryos to a clinic of their choice by setting conditions that had been impossible to fulfil.

- 57. The applicants also complained that DIICOT's decision to transfer their embryos from the IFM to P.S. Hospital had been made without informing them beforehand or consulting them.
- 58. Moreover, the requirements laid down by the new legal custodian, P.S. Hospital, for allowing the applicants to retrieve their embryos had been impossible to meet in practice and had in any event been unlawful.
- 59. The applicants also submitted that they had never received an official reply from DIICOT to their request to be appointed custodians of their own embryos. They could easily be transferred to them without harming other embryos as they were stored in separate vials.

- 60. The applicants submitted that all the above acts had shown a lack of consistency in respect both of domestic legislation and its implementation by the relevant State authorities.
- 61. As a result of those acts the applicants had been put in a situation where they could neither remove their embryos nor use them.

The situation also had to be looked at in the light of the fact that Mrs Nedescu's health did not allow her to undergo new stimulation treatment in order to obtain new embryos. If their embryos became unviable or were damaged, their chances of having another child would be irretrievably lost.

Overall, the matters complained of constituted an interference which was disproportionate to the aim pursued.

62. Lastly, the applicants stressed that their case was of general importance since there were hundreds of other families in a similar situation as they had deposited their embryos at the S. Clinic and were unable to use them on account of the authorities' behaviour.

(b) The Government

- 63. The Government referred at the outset to *Knecht v. Romania* (no. 10048/10, 2 October 2012), which had concerned a similar complaint. The case had been lodged by Ms Knecht, whose embryos had been stored in the same container as those of the applicants. The Court had found that although there had been an interference with the applicant's right to respect for their private life that interference had been in compliance with the requirements of paragraph 2 of Article 8. The Government argued that the same reasoning should be applied in the present case.
- 64. The measures taken by the authorities had pursued the aim of preventing crime and protecting the health and the rights and freedoms of others. In the present case, the Romanian authorities had not exceeded the wide margin of appreciation enjoyed by the State in the matter of assisted reproduction.

First of all, the prosecution authorities' seizure of the genetic material found at the S. Clinic had been justified and devoid of any arbitrariness. The applicants had been able to ask for the return of their embryos from the IFM. In addition, its refusal to return the embryos without the consent of the Transplant Agency had been in compliance with domestic regulations.

Secondly, the High Court of Cassation and Justice had on 20 December 2011 allowed the transfer of the embryos to P.S. Hospital, which had been authorised to function as a genetic material bank. The conditions set by P.S. Hospital for allowing the applicants to withdraw their embryos did not appear to be unreasonable, bearing in mind that the applicants could only use their embryos in a way which did not breach domestic legislation or the administrative regulations of the competent authorities.

In addition, the applicants had failed to substantiate their statement that Mrs Nedescu's health had prevented her from undergoing another IVF procedure in P.S. Hospital.

2. The Court's assessment

- (a) Whether there was an interference with the applicants' rights under Article 8
- 65. The Court is called to determine in the first place whether the facts of the present case fall within the scope of the applicants' rights under Article 8 of the Convention.
 - (i) The principles established in the Court's case-law
- 66. Court recalls the principles laid-down in its case-law on Article 8 of the Convention, particularly as they were restated in its recent judgment of *Paradiso and Campanelli v. Italy* [GC] (no. 25358/12, §§ 159-160), ECHR 2017):
 - "159. The Court reiterates that the notion of "private life" within the meaning of Article 8 of the Convention is a broad concept which does not lend itself to exhaustive definition. It covers the physical and psychological integrity of a person (see *X and Y v. the Netherlands*, 26 March 1985, § 22, Series A no. 91) and, to a certain degree, the right to establish and develop relationships with other human beings (see *Niemietz v. Germany*, 16 December 1992, § 29, Series A no. 251-B). It can sometimes embrace aspects of an individual's physical and social identity (see *Mikulić v. Croatia*, no. 53176/99, § 53, ECHR 2002-I). The concept of private life also encompasses the right to "personal development" or the right to self-determination (see *Pretty v. the United Kingdom*, no. 2346/02, § 61, ECHR 2002-III), and the right to respect for the decisions both to have and not to have a child (see *Evans v. the United Kingdom* [GC], no. 6339/05, § 71, ECHR 2007-I, and *A, B and C v. Ireland* [GC], no. 25579/05, § 212, ECHR 2010).
 - 160. In its judgment in the case of *Dickson v. the United Kingdom* ([GC], no. 44362/04, § 66, ECHR 2007-V), concerning the refusal to grant the applicants a prisoner and his wife artificial insemination facilities, the Court concluded that Article 8 was applicable, in that the refusal of artificial insemination facilities at issue concerned their private and family lives, specifying that those notions incorporate the right to respect for their decision to become genetic parents. In the case of *S.H. and Others v. Austria* ([GC], no. 57813/00, § 82, ECHR 2011) which concerned couples wishing to have a child using gametes from donors the Court held that the right of a couple to conceive a child and to make use of medically assisted reproduction for that purpose is also protected by Article 8, as such a choice is an expression of private and family life."
- 67. In that case the Court further held that a genuine intention on behalf of the applicants to become parents, which implied that a major part of their lives was focused on realising their plan to become parents, in order to love and bring up a child, was relevant both for their right to respect for their decision to become parents, and for their personal development through the role of parents that they wished to assume vis-à-vis the child; it concluded

that the facts of the case fell within the scope of the applicants' private life (*Paradiso and Campanelli*, cited above, §§ 163-164).

- 68. The Court had also held that an applicant's ability to exercise a conscious and considered choice regarding the fate of her embryos concerned an intimate aspect of her personal life and triggered the application of Article 8 of the Convention from the standpoint of the right to respect for private life (*Parrillo v. Italy* [GC], no. 46470/11, § 159, ECHR 2015.
- 69. Finally, in the case of *Vo v. France* [GC] (no. 53924/00, ECHR 2004-VIII) the Court held as follows, in respect of the nature and degree of protection due to a human embryo:
 - "84. At European level, the Court observes that there is no consensus on the nature and status of the embryo and/or foetus (see paragraphs 39-40 above), although they are beginning to receive some protection in the light of scientific progress and the potential consequences of research into genetic engineering, medically assisted procreation or embryo experimentation. At best, it may be regarded as common ground between States that the embryo/foetus belongs to the human race. The potentiality of that being and its capacity to become a person [...] require protection in the name of human dignity, without making it a "person" with the "right to life" for the purposes of Article 2.

...'

- (ii) Application of the above-mentioned principles to the instant case
- 70. In the present case the Court considers that the joint parental project of the applicants, who wish to have a child by making use of assisted procreation using their own embryos is an intimate aspect of their private life (see also *Knecht*, cited above, § 54).
- 71. Unlike the applicant in *Knecht*, the Court notes that the complaint in this case was neither about the seizure of embryos nor the refusal of a court to return embryos to a clinic of the applicants' choice as the judicial authorities had allowed such a return (compare and contrast *Knecht*, cited above, §§ 57-62).
- 72. The applicants' complaint concerned the refusal by the various administrative authorities to actually carry out the return of the remaining embryos that had been created at the S. Clinic, despite orders from the judicial authorities, which in turn prevented them from the possibility of having another child (see paragraphs 8 and 50 above).
- 73. The Court notes in particular that following the seizure of their embryos and their being deposited with the IFM, the applicants attempted on numerous occasions to recover them, but failed each time. On 21 July 2010 the IFM, where the embryos had been deposited first of all, refused to allow the applicants to retrieve them (see paragraph 14 above). On 13 December 2010 the Transplant Agency notified the applicants of its refusal to allow recovery of the embryos (paragraph 21 above). On 22 March 2011 the Bucharest Court of Appeal refused to allow the recovery

of the embryos by way of their transfer to a clinic of the applicants' choice (paragraph 23 above). Finally, P.S. Hospital, the new custodian appointed on 26 March 2011, refused to allow the retrieval ordered by DIICOT, which would have implemented the High Court of Cassation's decision of 20 December 2011 (see paragraph 26 above), as it on each occasion set different conditions for such a retrieval and for a transfer to Mrs Nedescu. On 27 September 2012 the condition set by the hospital was the presence of a representative from the Transplant Agency and of the embryologist from S. Clinic; on 1 November 2012 the hospital said it required an authorisation document from the Transplant Agency and the presence of a certified embryologist and a special container; on 12 November 2012 it told the applicants that it refused to transfer the embryos to Mrs Nedescu; and on 7 January 2013 it informed the Government that the embryos could only be retrieved if the Transplant Agency gave its prior approval and it also required the presence of an embryologist from the S. Clinic and a DIICOT representative (see paragraphs 26-29 above).

- 74. A request by the applicants to be appointed custodians of their own embryos was likewise rejected on 18 April 2013 (see paragraph 32 above).
- 75. In view of the above considerations, the Court finds that preventing the applicants from retrieving their embryos as ordered by the High Court of Cassation constituted an interference with their right to respect for their private life.

(b) Compliance with Article 8 § 2

76. Such an interference will be contrary to Article 8 unless it is "prescribed by law", pursues one or more of the legitimate aims set out in paragraph 2 and is "necessary in a democratic society" (see, among many other authorities, *Campbell v. the United Kingdom*, 25 March 1992, Series A no. 233, § 34; *Enea v. Italy* [GC], no. 74912/01, § 140, ECHR 2009; and *Roman Zakharov v. Russia* [GC], no. 47143/06, § 227, ECHR 2015).

77. The Court reiterates that the wording "in accordance with the law" requires the impugned measure both to have some basis in domestic law and to be compatible with the rule of law, which is expressly mentioned in the Preamble to the Convention and inherent in the object and purpose of Article 8. The law must thus be adequately accessible and foreseeable, that is, formulated with sufficient precision to enable the individual – if need be with appropriate advice – to regulate his conduct (see, among many other authorities, *Rotaru v. Romania* [GC], no. 28341/95, § 52, ECHR 2000-V *S. and Marper v. the United Kingdom* [GC], nos. 30562/04 and 30566/04, § 95, ECHR 2008). The foreseeability requirement also means giving individuals an adequate indication as to the circumstances in which and the conditions on which the authorities are entitled to resort to measures

affecting their rights under the Convention (see *Fernández Martínez v. Spain* [GC], no. 56030/07, § 117, ECHR 2014 (extracts)).

- 78. The Court must therefore determine whether the various institutions' actions or omissions that interfered with the applicants' private life were in line with the lawfulness requirement of Article 8 § 2, as set out above.
- 79. In that regard, it notes at the outset that the Government have not relied on any specific legal provisions in support of their submission that the interference was provided for by law.

The Court will therefore assess the lawfulness of the interference having regard to the information at its disposal, notably the reasoning of the domestic courts and other institutions involved.

- 80. The return of the embryos or their transfer to a clinic of the applicants' choice was allowed in straightforward fashion by the judicial authorities: on 30 March 2010 by DIICOT, which had taken the seizure measure in the first place (see paragraph 13 above), and on 20 December 2011 by the High Court of Cassation and Justice (see paragraph 26 above). While the seizure of the embryos, which is not a grievance in the current case, appears to have been based on Article 163 of the Criminal Procedure Code because of the criminal proceedings against the S. Clinic (see paragraph 40 above), neither the subsequent deposit of the embryos with the IFM within the framework of the criminal proceedings nor the conditions for their retrieval from either the IFM or the new custodian appear to have had a clear basis in domestic law.
- 81. The Court takes note of the provisions which regulate the storage and use of genetic material (see paragraphs 34 to 36 and 38 above), which were relied on directly or indirectly by some of the authorities and institutions when they refused to implement the judicial authorities' decisions to put an end to the seizure measure and order the return of the embryos, and also when they set additional conditions for implementing those decisions (see paragraphs 21, 23 and 31).
- 82. It further notes that despite those provisions, the various institutions involved disagreed on the conditions under which the DIICOT order to return the embryos could be carried out. One disagreement was on the need for prior approval by the Transplant Authority: the IFM, the Court of Appeal and P.S. Hospital considered that the Transplant Agency's approval was required (see paragraphs 14, 23, 29 and 31 above), while DIICOT did not. The High Court, in turn, found that the requirement for such approval was unlawful (see paragraphs 13, 26 and 27 above).

Moreover, the new custodian, P.S. Hospital, repeatedly argued that DIICOT's depositing of the embryos with the IFM had been unlawful as the IFM had not been authorised to function as a genetic material bank. It also considered that moving the embryos from the IFM to the Hospital had been carried out in violation of the lawful requirements for such a transfer.

- 83. Lastly, the Court cannot ignore the fact that P.S. Hospital considered that the flaws in the legal procedures related to the depositing, moving and handling of the embryos had been such that it seemed to be impossible to identify with certainty which embryos belonged to the applicants. It also stated that it could only store the embryos and could not perform any other operations with them (see paragraph 31 above).
- 84. In the light of the above, the Court finds that the manner in which the judicial and administrative authorities involved implemented and interpreted the relevant legal provisions concerning the seizure, the storage following such a seizure and the return of the applicants' embryos was incoherent and thus lacked the required foreseeability.
- 85. In conclusion, the Court finds that the interference with the applicants' right to respect for their private life was not provided for by law within the meaning of Article 8 § 2 of the Convention.
- 86. That being so, the Court is not required to determine whether the interference pursued a legitimate aim and, if so, whether it was proportionate to the aim pursued.
- 87. There has accordingly been a violation of Article 8 of the Convention.

III. APPLICATION OF ARTICLE 41 OF THE CONVENTION

88. Article 41 of the Convention provides:

"If the Court finds that there has been a violation of the Convention or the Protocols thereto, and if the internal law of the High Contracting Party concerned allows only partial reparation to be made, the Court shall, if necessary, afford just satisfaction to the injured party."

A. Damage

- 89. The applicants claimed 50,000 euros (EUR) in respect of non-pecuniary damage. They submitted that as a result of the authorities' interference with their right to respect for their private life they had lost the chance to have a second child and had thus suffered distress, humiliation and frustration, which had been exacerbated by the unlawful nature of the interference.
 - 90. The Government contested the claim.
- 91. The Court considers that the applicants must have sustained non-pecuniary damage which cannot be compensated for solely by the finding of a violation. Having regard to the nature of the violation found (see paragraph 84 above), and making its assessment on an equitable basis, the Court awards the applicants jointly EUR 7,000 in respect of non-pecuniary damage, plus any tax that may be chargeable.

B. Costs and expenses

- 92. The applicants also claimed EUR 5,580 for legal costs and expenses incurred both at the domestic level and during the proceedings before the Court, which they wished to be paid directly to their representative. A contract of legal assistance and a detailed document were submitted indicating a fee of EUR 80 per hour and the precise dates and the overall number of hours worked in preparing the case.
- 93. The applicants' representative argued that the number of hours spent on the case was not excessive and was justified by its complexity and detailed nature. The time was also justified by repeated attempts to obtain information on developments at the domestic level, on the background of a lack of coherence in the authorities' reactions. As to the hourly fees, the representative argued that they were well below the average normally charged by law firms in Bucharest, that is EUR 200 per hour.
- 94. The Government objected and argued that the amount claimed was excessive. They also pointed out that the applicants had already been granted RON 4,000 (some EUR 880), covering costs for the proceedings before the domestic courts (see paragraph 26 above).
- 95. The Court reiterates that in order for costs and expenses to be reimbursed under Article 41, it must be established that they were actually and necessarily incurred and were reasonable as to quantum (see, for example, *Nilsen and Johnsen v. Norway* [GC], no. 23118/93, § 62, ECHR 1999-VIII, and *Boicenco v. Moldova*, no. 41088/05, § 176, 11 July 2006). In accordance with Rule 60 § 2 of the Rules of Court, itemised particulars of all claims must be submitted, failing which the Court may reject the claim in whole or in part.
- 96. In the present case, the Court notes that the applicants have set out their claims in an itemised and precise manner. Regard being had to the documents in its possession and the above criteria, which it deems to have been satisfied in the present case, the Court considers it reasonable to award EUR 4,700 for costs and expenses for the proceedings before the Court, plus any tax that may be chargeable to the applicants, to be paid to the applicants' representative.

C. Default interest

97. The Court considers it appropriate that the default interest rate should be based on the marginal lending rate of the European Central Bank, to which should be added three percentage points.

FOR THESE REASONS, THE COURT, UNANIMOUSLY,

- 1. Declares the application admissible;
- 2. Holds that there has been a violation of Article 8 of the Convention;

3. Holds

- (a) that the respondent State is to pay the applicants, jointly, within three months from the date on which the judgment becomes final in accordance with Article 44 § 2 of the Convention, the following amounts, to be converted into the currency of the respondent State at the rate applicable at the date of settlement:
 - (i) EUR 7,000 (seven thousand euros), plus any tax that may be chargeable, in respect of non-pecuniary damage;
 - (ii) EUR 4,700 (four thousand seven hundred euros), in respect of costs and expenses, to be paid to the applicants' representative, plus any tax that may be chargeable to the applicants;
- (b) that from the expiry of the above-mentioned three months until settlement simple interest shall be payable on the above amounts at a rate equal to the marginal lending rate of the European Central Bank during the default period plus three percentage points;
- 4. *Dismisses* the remainder of the applicants' claim for just satisfaction.

Done in English, and notified in writing on 16 January 2018, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

Marialena Tsirli Registrar Ganna Yudkivska President