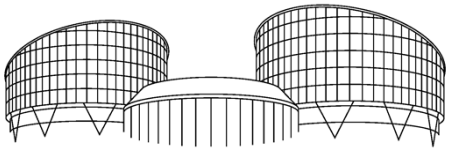

EUROPEAN COURT OF HUMAN RIGHTS
COUR EUROPÉENNE DES DROITS DE L'HOMME

FIRST SECTION

CASE OF LIA v. MALTA

(Application no. 8709/20)

JUDGMENT

Art 8 • Private and family life • Refusal of couple's request for a self-funded second homologous *in vitro* fertilisation procedure, on the basis of the wife's age, not in accordance with a law of sufficient quality • Interpretation and application of impugned age-limit provision by administrative and judicial authorities lacking required foreseeability

STRASBOURG

5 May 2022

FINAL

05/08/2022

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

In the case of Lia v. Malta,

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

Marko Bošnjak, *President,*
Péter Paczolay,
Alena Poláčková,
Erik Wennerström,
Raffaele Sabato,
Lorraine Schembri Orland,
Ioannis Ktistakis, *judges,*
and Renata Degener, *Section Registrar,*

Having regard to:

the application (no. 8709/20) against the Republic of Malta lodged with the Court under Article 34 of the Convention for the Protection of Human Rights and Fundamental Freedoms ("the Convention") by two Maltese nationals, Mr Gilbert Lia and Ms Natasha Lia ("the applicants"), on 5 February 2020;

the decision to give notice to the Maltese Government ("the Government") of the application;

the observations submitted by the respondent Government and the observations in reply submitted by the applicants;

the comments submitted by the Non-Governmental Organisation, Ordo Iuris, that was granted leave to intervene by the President of the Section;

Having deliberated in private on 5 April 2022,

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

INTRODUCTION

1. The case concerns the decision to refuse the applicants' request for a self-funded, second cycle of Intracytoplasmic Sperm Injection (an *in vitro* fertilisation procedure), using the applicants' gametes, on the basis that the second applicant had reached forty-three years of age. The applicants invoke Article 8 alone and in conjunction with Article 14 of the Convention.

THE FACTS

2. The applicants were born in 1980 and 1971 respectively and live in Attard. The applicants were initially represented by Dr H. Mula and later by Dr M. Paris, both lawyers practising in Pieta`.

3. The Government were represented by their Agents, Dr C. Soler, State Advocate, and Dr J. Vella, Advocate at the Office of the State Advocate.

4. The facts of the case may be summarised as follows.

THE CIRCUMSTANCES OF THE CASE

A. Background to the case

5. The applicants were married on 20 May 2012. After unsuccessful attempts at having children, they were given medical advice that the only remedy to have children was by means of assisted procreation *in vitro* fertilisation ("IVF").

6. On 27 September 2014 the second applicant, aged forty-two years, underwent Intracytoplasmic Sperm Injection ("ICSI"), using her own ova, at a private hospital, at the State's expense. The treatment was provided by the Government of Malta free of charge to subjects satisfying the Maltese Embryo Protection Authority's (hereinafter referred to as "the Authority") protocol (hereinafter "the protocol") established by Chapter 524 of the Laws of Malta, namely the Embryo Protection Act (see Relevant Legal Framework below).

7. The treatment was not successful and consequently the applicants requested another cycle of treatment on 31 August 2015. After a thorough medical assessment of the potential mother, Dr J.M., on behalf of the applicants, requested the treatment to be carried out in November 2015 when the second applicant would have been forty-three years and eleven months old.

8. On 14 September 2015 the Authority refused the request stating *inter alia* that:

> "With reference to the attached scan and the below communication, EPA [the Authority] discussed your case as presented. However, EPA is still bound by the present law as it is today, whilst [it] also cannot deviate further from the protocol terms as stated in Chapter 6 of the said protocol. In respect of this, EPA unanimously decided that the request cannot be approved."

9. At the time of the second applicant's request for a second cycle, the age bracket endorsed by the Parliament of Malta on an annual basis was that between twenty-five and forty-two years, a requisite which in the applicants' opinion was in breach of their right to family life and the right not to be discriminated against. They also considered that they had fulfilled the other two criteria required, namely, being married and that according to medical advice they had reasonable prospects of success.

10. Following the refusal by the Authority, the applicants communicated on various occasions with the Authority in order to have an explanation which was never tendered.

11. Consequently, on 4 April 2016 the applicants filed a judicial letter in the Civil Court (First Hall) in its constitutional competence addressed to the Authority pointing out the breach of the fundamental right to family life. The Authority replied that it was guided by the protocol as established by law and approved by medical experts in the field.

B. Constitutional redress proceedings

1. First-instance

12. On 9 March 2017 the applicants instituted constitutional redress proceedings before the Civil Court (First Hall) in its constitutional competence (hereinafter "the court"). They considered, firstly, that the concession, granted by Section 6 of Chapter 524 of the Laws of Malta, to have a protocol outlining guidelines in the sector had to be in line with the law and fundamental human rights and that secondly, the failure to fulfil these standards meant that the Government had to intervene to rectify such a breach within the protocol. They noted that the Government had been informed every year about the applicable age bracket and that, this notwithstanding, the Government failed to stop what the applicants believed to be discriminatory treatment arising from the protocol adopted by the Authority. They thus considered that the refusal of the authorities in their case, and the fact that the protocol only allowed access to IVF procedures between the age of twenty-five and forty-two constituted a breach of their right to private and family life and their right not to be discriminated against, and asked the court to declare these breaches accordingly. They relied on Articles 8 and 14 of the Convention, and the Maltese Constitution. They further asked the court to declare the refusal decision null, to order the medical examination of the second applicant to assert whether there existed any supplementary risks, in the absence of which, that she be authorised to undergo treatment, and to liquidate damage.

13. During these proceedings the following testimony was produced:

The second applicant declared that the couple had tried to make the requested cycle in Spain, which would have been approved, but it was too expensive and they could not afford it. She insisted that if the couple were on a better financial footing they could have become parents, but as a result of their financial situation (which did not allow them to pursue treatment abroad) and the age-limit set in Malta she had been discriminated against.

14. The first applicant confirmed the above, noting that in the first month they had already disbursed five thousand euro and could not afford it. He insisted that the medical assessment of his wife should have determined whether she was eligible or not, and not her age. He considered that they had been discriminated against because no other law set an age-limit for people to have children, and because they were not in a financial position to travel abroad to obtain treatment.

15. Dr J.M. testified that, when examined, the second applicant was in good health conditions for a pregnancy, having a good quality reserve of ova, and that she was still able to bear children. He explained that although no specific reason for the refusal was given by the Authority, it was clear that the reason was because of her age since this was the only requisite which was not satisfied. He emphasized that the second applicant had been perfectly

healthy for another cycle of IVF but was obstructed by what was spelled out in the protocol.

16. S.A., in representation of the Authority, confirmed that: every application of persons over the age of forty-two (four applications in all) had always been refused; the first cycle was given to the applicant by way of priority since she was almost forty-three years of age; she was also allowed to fertilise three ova as opposed to two; the Authority adhered strictly to the protocol with regard to the age of the applicants; in this case the second cycle, which the applicants were going to pay for themselves, could not be acceded to, solely, because the second applicant was above the maximum age, this was irrespective of the fact that the protocol indicated the age bracket as being "desirable". She further explained that the protocol was drafted after lengthy discussions with the association of paediatrics and the association of gynaecologists and obstetricians and other stake holders, including others who already operated IVF in the private sector, it had then been presented in Parliament in 2013. She also presented a list of criteria which had to be fulfilled for authorisation to be granted, which had been drawn up by Drs M.S. and M.F. in representation of the Malta College of Obstetricians and Gynaecologists and Drs P.S. and J.M. in representation of the Malta Paediatric Association, who had been consulted on the matter.

17. Prof M.B. (the clinical director of the gynaecology and maternity department, who had been consulted on the drafting of the law) considered that the crux of the case was one of ageism. Although he had various issues with the law – in so far as it had not allowed sperm donation or surrogacy – he had not been very critical of the age-limit. He considered that not all persons of the same age were in the same situation and thus disagreed with a mandatory age-limit, noting that in fact the protocol referred to the word "desirable". Thus, he could agree with the protocol which referred to the age bracket being desirable, in the context of the laws in force at the time. However, he conceded that the chances were that the ova gathered from a woman aged forty-three would be of a of lesser quality, resulting in a poor success rate (4-5%). Such harvesting could have allowed an element of exploitation which the law sought to avoid so to protect women from such exploitation and the negative psychological impact that came with it. He nevertheless was of the view that a woman of forty-three years of age, who had a good reserve of ova, should have a right to decide (following consultation with her doctor and subsequent informed consent regarding the prospects of success) on whether to proceed or not with the procedure – but only in the absence of exploitation. He further noted that procedures had been authorised and made available to women under twenty-five years of age when there were problems with the male partner's sperm.

18. Dr M.S. and Dr M.F., both medical consultants specialising in Obstetrics and Gynaecology, who had not been involved in drafting the protocol, stated that such treatment could have negative effects on a woman,

such as hyper stimulation syndrome, which could cause various serious complications such as loss of blood from the ovarian puncture sites, damage to the bowel and infections; since the law did not provide for donor gametes, and thus only the woman's ova could be used, an age-limit had to be set; the maximum age of forty-two years indicated in the protocol was dictated by the very low chance of success (less than 10%) when performed on women having that age using their own ova. Apart from that, there was a high risk of miscarriage – meaning that these women would need more cycles of stimulation with all the risks that they carry. There was also a high probability that they would require interventions such as dilation and curettage in the case of a miscarriage. They further explained that in certain countries the maximum age [for a woman to undergo treatment] could extend to fifty years or more because of the opportunity of donor gametes. They also mentioned a 73% chance of abnormal birth when a woman was older than forty and used her own ova.

19. Dr P.S. specialised in paediatrics, who had also been consulted in the drafting of the protocol, averred that women in advanced age during pregnancy can suffer complications for them and the child. He referred to multiple pregnancies and hyper stimulation syndrome and the life-threatening consequences it could have (such as fluid in the lungs or kidney failure). He noted that the protocol had been drafted based on the English model and explained that the cut-off date of forty-two years was chosen since, after such age, the risks outweighed the benefits. He mentioned that at that age the risks for both the mother and the child existed both in assisted as well as natural procreation. As to the word "desirable" used in the protocol, he explained that it aspired to the optimum, but it did not mean that one could not go beyond. The protocol provided guidelines and was not to be interpreted restrictively. In his view, the ability of a women to undergo the procedure was to be established by a medical examination and relevant tests, which would provide a comprehensive and objective picture of any problems the couple may have, and not on the woman's identity card details.

20. By a judgment of 28 September 2018, the court rejected the defendants' plea of non-exhaustion of ordinary remedies and on the merits found against the applicants.

21. It considered that the crux of the issue was the interpretation of the protocol by the Authority exercising its powers under the Embryo Protection Act. It was clear, from the testimony brought forward, that despite the word "desirable" the Authority interpreted the age-limit as a mandatory condition. In the court's view, the protocol had been adopted after serious consideration and discussion with relevant stakeholders, including four experts. The guidelines were set out so that IVF would be of least peril to the mother and the embryo, and so that it would be successful. The majority of the experts agreed about the problems involved in relation to women aged over forty-two, both in respect to natural procreation and even more in respect of medically

assisted procreation (where a woman was induced to produce more than one ovum in each cycle). The risks involved were not negligible. One could not ignore that the embryo's health depended on that of the mother, and that an abnormal foetus could also be a result.

22. The court agreed that the reason why an age-limit had to be fixed was that the law, at the time, had not allowed the use of donor gametes. This was no longer the case. However, the court considered that the State had the right to regulate the procedures which i) it was not obliged to provide and ii) it was providing free of charge. It was the State's duty to protect state coffers and it was not in doubt that the expenses related to such treatments were high. Thus, bearing in mind the statistics and the fact that the State was offering such a service, as well as the risks involved after a certain age and the negative impact both on the success of the procedure and the embryo, later foetus or child, it considered that by means of the protocol, the State had provided a fair and proportionate balance between the applicants' right to respect for private and family life and that of society in general, also considering that any future health problems of the mother and child would also be covered by state coffers. However, it sympathised with the applicants' argument concerning the word "desirable" which could lead to a certain uncertainty and considered that any maximum age should be explicitly provided for, save determined exceptions (as provided, for example, in the amended law where donor gametes were now allowed and the age of collection of ova was limited to thirty-six, save listed exceptions).

23. In addition, the court considered the applicants' discrimination complaint being two-pronged, based on age and financial situation. It found that the protocol did not give rise to discriminatory treatment on the basis of age since all the persons of the same age had been treated the same, and people below the relevant age group had also been excluded from the procedure. Neither had there been any discriminatory treatment *vis-à-vis* other individuals of the same age who could have children without assistance (and thus were not in an analogous position to the applicants), nor wealthier individuals who could travel abroad to obtain such treatment (as anyone in the same financial bracket as the applicant faced the same impediment). Thus, neither the promulgation of the protocol nor its interpretation could give rise to discrimination.

24. The applicants were ordered to pay court expenses amounting to 2,149 euros (EUR).

2. Appeal

25. The applicants appealed against the entirety of the judgment. They argued, in particular, i) that the first-instance court had made a wrong assessment of the facts in so far as it considered that the applicants were seeking the financial aid of the State which was not the case, ii) the authority had a discretion to decide whether to authorise the procedure as the term

"desirable" in the protocol meant that the maximum age-limit had not been mandatory as applied by the Authority – thus their wrong interpretation had rendered the applicants' hopes of having children nugatory and iii) it was untrue that the protocol had been put in place after proper consultation – M.F. and M.S. had not been involved in the drafting of the protocol, M.B. disapproved of the interpretation given by the Authority as to the age-limit being mandatory, and P.S. had only testified that the Government adopted the system in place in the United Kingdom.

26. By a judgment of 27 September 2019 the Constitutional Court confirmed the first-instance judgment.

27. The Constitutional Court considered that what was important in the case was not who had been consulted in the drafting of the protocol but whether in the medical sphere there was justification for imposing such time-limits. It observed that, while it was true that the protocol did not make the age bracket mandatory, such limitation was nevertheless justified, and the Authority was entitled to apply such a limitation in all the cases before it. The State had a duty to protect public health and limit risks to individuals so that a balance could be reached between the interest of private citizens to procreate and the State's duty to ensure a healthy society, as well as avoiding the exploitation of women. The State was so conscious of its duty to safeguard public health that health care was, for the most part, free of charge in Malta.

28. The fact that the age-limit indicated was not mandatory did not mean that the Authority, using its discretion, and on the basis of medical findings, could not decide to apply that age-limit. While the Authority had the discretion to decide to go beyond the age bracket, it also had the discretion to apply it. Even the applicants' doctor testified that the offspring had more chances of complications (*xi ħaġa*), but that it was then based on the woman's decision once the situation would have been explained and her having given informed consent. However, according to the Constitutional Court, this could not be left solely to the discretion of the parents. The Authority's decision and that of the first-instance court were supported by the experts who testified and thus the appeal could not be upheld, and it was unnecessary to examine the other grounds of appeal. Costs were to be borne by the applicants.

RELEVANT LEGAL FRAMEWORK AND PRACTICE

29. IVF became available in Malta, in a restricted measure, as of 2012 by means of the Embryo Protection Act, Chapter 524 of the Laws of Malta (hereinafter 'the Act'). At the time the law only allowed for homologous techniques (i.e. having recourse to the gametes of the couple) as opposed to heterologous techniques (i.e. having recourse to gametes external to the couple) which were not provided for.

30. Section 2 of the Act, at the relevant time, provided a requisite that the candidate had to be a prospective parent. For the candidates to qualify as

prospective parents they had to be either legally married or obtained the age of majority and having a stable relationship.

31. Section 5 of the Act, in so far as relevant, read as follows:

> "Any prospective parent shall have access to medically assisted procreation procedures:
>
> Provided that these procedures may only be resorted to where there is a reasonable chance of success and the procedures do not entail any known undue risk to the health of the woman or child, beyond those already well known as inherently associated with the procedure itself."

32. Section 6 of the Act in so far as relevant, read as follows:

> "Whosoever –
>
> ...
>
> (b) intentionally fertilizes more than two egg cells from one woman within one treatment cycle:
>
> Provided that in exceptional cases the medical practitioner in charge of the medically assisted procreation may decide to transfer up to a maximum of three fertilized egg cells from one woman within one treatment cycle provided that this is done in accordance with a protocol established in writing by the Authority after consulting the associations which, according to law, represent the medical practitioners who exercise their profession in the fields of obstetrics and paediatrics. Such a protocol shall include, without prejudice to other criteria, clear criteria regarding the age of the woman who will be participating in such a procedure and after how many cycles in accordance with paragraph (b) may the medical practitioner decide to fertilize up to a maximum of three egg cells:
>
> Provided further that the above-mentioned Protocol may be substituted by a Protocol agreed upon by the Authority and the associations which, according to law, represent the medical practitioners who exercise their profession in the fields of obstetrics and paediatrics which specifies in a detailed manner the best medical practice in the field of medically assisted procreation. If such an agreement on a Protocol between the Authority and the associations cannot be agreed upon, then the Protocol established in writing by the Authority under the first proviso shall apply:
>
> Provided further that authenticated copies shall be sent within two days to the Minister responsible for Health and the Speaker of the House of Representatives. The Speaker of the House of Representatives, or in his absence the Deputy Speaker, shall put the authorised copy of the document on the Table of the House on the next first Parliamentary sitting:
>
> Provided further that where the person is a medical practitioner, no criminal proceedings can be undertaken against that medical practitioner if the medical practitioner is strictly acting in good faith and according to the Protocol mentioned;
>
> ...
>
> shall be guilty of an offence and, on conviction, shall be liable to the punishment of a fine (*multa*) of not less than five thousand euro (€5,000) and not exceeding fifteen thousand euro (€15,000) or to imprisonment not exceeding three years or to both such fine and imprisonment ..."

33. The protocol at the relevant time provided:

> "For the purpose of this Protocol, the EPA [Embryo Protection Authority] feels that it is desirable that the woman, who is entitled to treatment should be between the age of 25 and 42 years ..."

34. Subsequently, in 2018, it was amended to reflect changes in the Act which came into force on 1 October 2018 and introduced heterologous techniques. The amended protocol included the following:

> "... 6.3 it further establishes that the woman whose own oocytes have been retrieved after the woman reached the age of 36 years will only be allowed to undergo treatment up to the maximum age of 42 years ...
>
> 6.4 It further establishes that the woman referred in Guidance Note 6.3 above, if after undergoing treatment up to the maximum age of 42 years will still have cryopreserved embryos, then the maximum age of that woman will be extended to 48 years.
>
> 6.5 It further establishes that the woman who is entitled to treatment should be between the age of 18 and 48 years if using donated oocytes.
>
> 6.6 Prospective parent / parents referred in Guidance Notes 6.2 to 6.5 above are referred to treatment if they have one of the following:
>
> (a) identified causes of infertility amenable to treatment by IVF e.g. bilateral tubal occlusion, azoospermia, and
>
> (b) unexplained infertility for two years (this includes mild endometriosis or mild male factor infertility)
>
> 6.7 The maximum permissible age of the prospective parent for implantation of embryos shall be 48 years in all cases ..."

35. According to the witness testimony of the chief executive officer of the Authority, the procedure to apply for authorisation to pursue IVF was, at the relevant time, as follows. It was the consultant medical practitioner of the clinic where the procedure would take place, chosen by the couple, who would seek authorisation via an application with the Authority, not the couple themselves. The authority would receive a list of couples who were to pursue IVF; in the case of the second cycle, the Authority would also receive a separate list. The latter would include the names of the couples, who, in their consultant's view should benefit from an authorisation to have three ova fertilised instead of two. Only the Authority could give such permission, as the law only provided for the fertilisation of two ova. Requests concerning specific cases would also reach the Authority, such as preservation of gametes due to oncology. Everything that was brought before the Authority, including situations falling squarely within the law and the protocol, would be discussed by the Authority, and the relevant clinic would then be informed of the reply. In the case of refusal, the couple would be informed.

RELEVANT INTERNATIONAL MATERIAL

36. According to the information compiled by Ordo Iuris, on the basis of information collected and published by the European Society of Human Reproduction and Embryology, and not challenged by the parties, the situation in the member States of the Council of Europe in relation to IVF accessibility and limitations is as follows[1]:

Albania: The age-limit for women is 50 years. The egg donor's age-limit is 35 years. The procedure is available to infertile heterosexual couples. Limitations concern both private and public funded treatment.

Austria: The age-limit for women is their natural cycle. The egg/sperm donor's age-limit is 35 years. This limitation applies both to private and the public-funded procedure. The public funded procedure is limited to four cycles.

Belgium: The general age-limit for women is 45 years for oocyte retrieval, and 47 years-old for embryo transfer. Access to the public-funded procedure is limited to women under the age of 43.

Bosnia and Herzegovina: No age-limit. The public-funded treatment is limited to two cycles.

Bulgaria: The age-limit for women is 51 years. For the public-funded procedure, the age-limit for women is 43 years. The egg donor's age-limit is 35 years for non-relatives and 37 years for relatives. The procedure is available to infertile heterosexual couples, lesbian couples, and single women.

Croatia: The age-limit for women is 42 years. The public-funded procedure is limited to four cycles.

Cyprus: The age-limit for women is 50 years, but the public-funded treatment is limited to women under the age of 45.

Czech Republic: The age-limit for women is 49 years. The public-funded procedure is limited to four cycles.

Denmark: The age-limit for women is 45 years. For the public-funded procedure the age-limit is 40 years.

Estonia: The age-limit for women is 50 years. For the public-funded treatment the age-limit is 40 years.

France: For the public-funded procedure the age-limit is 43 years, otherwise it is the normal reproductive age as assessed by specialists.

Germany: Access to the public-funded procedure is limited to women between the age of 25 and 39. The public-funded procedure is also limited to three cycles per woman.

Greece: The age-limit for women is 50 years.

1. The information compiled does not always specify whether the age-limits apply to procedures whereby the women uses her own ova, as opposed to donated ova, and/or whether account is taken of recourse to cryopreservation.

Hungary: For the public-funded procedure, the age-limit for women is 45 years. The public-funded procedure is limited to five cycles and five additional ones, if a child was born within the first four cycles.

Iceland: There is no age-limit. There can be a maximum of four public-funded cycles performed.

Ireland: No public-funded treatment centres or age-limit exist.

Italy: The age-limit for women is 50 years, for the public-funded procedure the age-limit is 46 years. There can be a maximum of six public-funded cycles.

Latvia: No age-limit. The public-funded procedure is limited to women between the age of 18 and 38. All clinics are completely private, but they may perform the procedure under public funds.

Lithuania: There is no general age-limit, apart from the one for the public-funded procedure, which is 42 years. The public-funded procedures are limited to two cycles.

Republic of Moldova: There is no general age-limit, but the public-funded procedure is limited to women under 40 years of age. The limit for the public-funded procedure is one cycle.

Montenegro: The age-limit for the public-funded procedure is 44 years. No age-limit otherwise. The public-funded procedure is limited to three cycles.

Netherlands: The age-limit for women is 49 years, but for the public-funded procedure the limit is 42 years.

North Macedonia: No age-limit. The procedure is limited to three cycles for the first child, three cycles for the second child, and three cycles for the third child.

Norway: No age-limit.

Poland: No age-limit. However, the public-funded IVF at local level in several regions is available only for women of a certain age, usually no more than 40-43 years.

Portugal: The age-limit for women is 50 years, but for the public-funded treatment the limit is 40 years of age.

Romania: The general age-limit for women is 48 years, but for the public-funded procedure the limit is 40 years of age.

Russian Federation: No age-limit.

Serbia: No general age-limit, but for the public-funded treatment the age-limit for women is 42 years.

Slovak Republic: The general age-limit for women is 50 years.

Slovenia: The general age-limit for women is her natural reproductive age, but for the public funded treatment, the limit is 42 years. The public-funded treatment is limited to six cycles for the first child and four cycles for the next one.

Spain: The general age-limit for women is her natural reproductive age, but accessibility to public funding is limited to women under 40 years old. The public-funded treatment is limited to three cycles.

Sweden: No limitation for private treatment, but the age-limit for public-funded treatment is 40 years.

Switzerland: No age-limit.

Turkey: No general age-limit, but for the public-funded treatment, the age-limit for women is 39 years old. The public-funded treatment is limited to three cycles.

Ukraine: The age-limit for public-funded procedures is 39 years old, there is no general age-limit otherwise.

United Kingdom: No general age-limit for women, but public-funded treatment is available to women up to the age of 42 years.

37. According to the Council of Europe Principles set out in the report of the Ad Hoc Committee of Experts on Progress in the Biomedical Sciences (CAHBI), 1989, techniques of human artificial procreation may be used only where there is a reasonable chance of success and there is no significant risk of adversely affecting the health of the mother or the child.

THE LAW

ALLEGED VIOLATION OF ARTICLE 8 OF THE CONVENTION

38. The applicants complained that they had suffered a breach of Article 8 of the Convention as a result of the refusal of their request for the second IVF cycle.

> "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

39. The Court notes that it is not disputed between the parties that Article 8 is applicable. Indeed "private life", is a broad term, encompassing, *inter alia*, elements such as 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-IV; *A, B and C v. Ireland* [GC], no. 25579/05, § 212, 16 December 2010; and *Paradiso and Campanelli v. Italy* [GC], no. 25358/12, § 163, 24 January 2017). The Court has also held that the right of a couple to conceive a child and to make use of medically assisted

procreation for that purpose is protected by Article 8, as such a choice is an expression of private and family life (see *S.H. and Others v. Austria* [GC], no. 57813/00, § 82, ECHR 2011, and *Knecht v. Romania*, no. 10048/10, § 54, 2 October 2012).

40. The Court further notes that this complaint is neither manifestly ill-founded nor inadmissible on any other grounds listed in Article 35 of the Convention. It must therefore be declared admissible.

B. Merits

1. The submissions of the parties

(a) The applicants

41. The applicants complained under Article 8 of the Convention that by refusing their request for the second IVF cycle, the Authority did not provide a fair balance between the competing public and private interests. They noted that given the word "desirable" in the protocol in relation to the age bracket, the authorities should have assessed the second applicant on her situation and not in the abstract, solely on her age. The noted, in particular, that the term "desirable" was intended to provide a flexible discretion to the Authority which according to the same protocol should have provided a case-by-case assessment. Nevertheless, the authority had failed to act accordingly.

42. The Authority's refusal had not been in accordance with the law as it had not been in line with the definition of prospective parent as defined in Section 2 of Chapter 524 of the Laws of Malta, nor was it within the parameters of Section 6 of the protocol which did not forbid procedures for women under twenty-five or over forty-two years of age. The first-instance constitutional jurisdiction had itself noted that the word "desirable" created uncertainty (see paragraph 22 *in fine* above). Relying on the testimony of S.A. (see paragraph 16 above) the applicants noted that it had solely been the Authority's wrong interpretation of the protocol which led to the impugned refusal.

43. The applicants also questioned the Government's reliance on the consultation process behind the making of the protocol and whether the Authority had really consulted with the associations which, according to law, represented the medical practitioners who exercised their profession in the fields of obstetrics and pediatrics, as it had been mandated to do by Section 6 of the Act. They noted that experts in obstetrics and pediatrics, namely, M.F. and M.S., who testified before the constitutional jurisdictions, had not been consulted in the drafting of the protocol and M.B. and P.S., who had been consulted, confirmed that the age-limit had not been mandatory.

44. Relying on the maxim *ubi lex voluit dixit*, the applicants also noted that Sections 10-12 of the Act listed prohibitions related to medically assisted procreation and included prohibitions on: the selection of sex; cloning;

unauthorised fertilisation, unauthorised embryo transfer; and unauthorised fertilisation after death; but the Act didn't list any prohibition on age, other than in relation to the age of majority. Moreover, in line with Section 5 of the Act and the testimony of P.S. (see paragraph 19, *in fine*, above) only a medical examination could ascertain the second applicant's eligibility. This had not been done, thus, the refusal could not be considered lawful.

45. The applicants also considered that the age-limit being set by Government at forty-two was not a measure necessary in a democratic society, as it was not based on any risk but solely on success-rate statistics. They noted that the mere fact that Malta did not sign or ratify the Council of Europe Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS. No. 164) did not mean it could disregard human rights standards.

46. In their case, in particular, the refusal had not been necessary, given that, as testified by the only practitioner who examined the second applicant, she had been totally able to bare children at the time (see paragraph 15 above). It was thus incomprehensible why a blanket refusal, as opposed to a medically determined decision, fulfilled any pressing social need. By adopting a general stance based on age and ignoring the experts' considerations as well as medical advice concerning the applicant specifically, the Authority had unilaterally destroyed the applicants' possibilities of becoming natural parents.

(b) The Government

47. The Government questioned whether the applicants were challenging the lawfulness of the measure - which they considered had not been done at the domestic level. In any event, in the Government's view the refusal decision of the Authority had been in accordance with the law, namely the protocol, which established an age bracket of between twenty-five and forty-two years of age. In other words, a woman would be allowed to undergo IVF procedures until the age of forty-three minus one day, thus making the law clear, foreseeable and accessible, as also shown by the constant strict adherence to the protocol in practice. The Government submitted that lawfulness did not require the law to provide absolute certainty, but rather foreseeability that was sufficient to allow a person to regulate their conduct.

48. According to the Government, the protocol had been drawn up following consultation with members of the medical profession in the fields of obstetrics and paediatrics, as confirmed by the first-instance constitutional jurisdiction, and the age-limit set had been based on purely medical reasons. The stipulated age-limit was set in order to protect the health of the nation and the rights and freedoms of others, and the Authority's decision to reject the applicants' request for authorisation for a second IVF cycle was in furtherance of the same legitimate aim. There were many risks associated

with carrying out such a procedure, and the older the woman, the greater the risks not just for herself, but also for the foetus and the child that she would eventually give birth to. They referred to the expert testimony obtained during the domestic proceedings (see paragraphs 18 and 19 above).

49. The Government emphasised that the State had a responsibility to ensure, in introducing such procedures and making them available to the public, that it maintained a balance and a sense of proportionality between the rights of the individual and the public interest. Bearing in mind the risk after forty-two years of age, the protocol had achieved this balance. While the applicant argued that the Authority should have subjected the second applicant to further medical tests, none of the experts who testified in the proceedings suggested that there was a level of physical fitness above the age of forty-two that would bring the risk of ovarian hyper stimulation syndrome to an acceptably low level. None of them had suggested that the risk of excess fluid in the lungs, or kidney failure, or the risk of miscarriage once pregnant, depended on the physical fitness of the woman. Indeed, the health status of the woman undergoing IVF, particularly the process of ovarian stimulation and egg retrieval, did not lower to any considerably appreciable amount the life-threatening risks that came with it above a certain age. The State had to therefore impose a limit of forty-two years of age to protect the health of the persons involved in this procedure. According to the Government, that age-limit also protected women from exploitation and all persons from having an undue and false hope that IVF could work and be effective at any age. The Government denied that the success rate was the sole reason for determining whether a person should be allowed to carry out an IVF procedure.

50. In the light of the wide margin available to States to legislate in the field, the Maltese State had certainly reached the right balance in determining eligibility. Moreover, in relation to the present case, the Government noted that the State had done all that was in its power to do in order to assist the applicants. In fact, when the applicants requested authorisation from the Authority for the first cycle of IVF treatment, the Authority authorised the fertilisation of three eggs, as opposed to the two, in order to give the applicants a greater chance of success. They also placed the applicants at the top of the list of patients, giving them priority, in the next IVF cycle. Apart from that, given that the national hospital had not yet been licensed to carry out IVF procedures, the Authority allowed the applicants to carry out the procedure at a private hospital at the expense of the Government.

51. Lastly, they noted that more recent amendments to the law referring to an age-limit of forty-eight years (which came to be once Malta opened up to gamete donation, see paragraph 34 above), had not changed the eligibility conditions of persons in her situation. Nor had they changed generally as regards persons who were over forty-three years of age, unless they either i) had cryopreserved eggs which would have been extracted before reaching the age of thirty-six, or ii) they used donated eggs (extracted from a women aged

between eighteen and thirty-six). In both these situations the risks associated with ovarian stimulation and egg retrieval remained low.

(c) The third-party intervener

52. Ordo Iuris were under the impression that the present case dealt with prerequisites for the reimbursement of IVF expenses from public funds and considered that there was no right to free of charge IVF under the Convention. They noted that virtually everywhere limitations were imposed with regard to access to public-funded IVF. The age-limit for women seeking public funding varied between thirty-eight years old in Latvia, to forty-six years old in Italy (see paragraph 36 above). These regulations were often connected with the assumption that the efficiency of the IVF depended on the age of the woman undergoing the treatment. Indeed, in light of the medical research, success rates in IVF procedure declined with women's age, specifically after the mid-thirties. Part of this decline was due to a lower chance of getting pregnant from artificial insemination, and part was due to a higher risk of miscarriage with increasing age, especially over the age of forty.

53. In their opinion, since the case touched on an area where there was no common ground between the member States, the State should have a wide margin of appreciation. One of the obvious procedural limitations to public-funded IVF should be defining the health conditions that must be met by a woman who wants to access such procedures as acknowledged by Council of Europe soft-law standards (see paragraph 37 above). Relying on the Court's case-law, they noted that it was not contrary to Article 8 for a State to adopt rules of an absolute nature which serve to promote legal certainty and, in their view, publicly funded IVF was one of the areas where this should be possible.

2. The Court's assessment

(a) General principles

54. The Court reiterates that although the object of Article 8 is essentially that of protecting the individual against arbitrary interference by the public authorities, it does not merely compel the State to abstain from such interference. In addition to this primarily negative undertaking, there may be positive obligations inherent in an effective respect for private and family life. These obligations may involve the adoption of measures designed to secure respect for private and family life, even in the sphere of the relations of individuals between themselves. The boundaries between the State's positive and negative obligations under Article 8 do not lend themselves to precise definition. The applicable principles are nonetheless similar. In particular, in both instances regard must be had to the fair balance to be struck between the competing interests (see *Evans*, cited above, § 75, and *S.H. and Others*, cited above, § 87).

55. An interference will be in breach of Article 8 of the Convention unless it can be justified under paragraph 2 of Article 8 as being "in accordance with the law", pursuing one or more of the legitimate aims listed therein, and being "necessary in a democratic society" in order to achieve the aim or aims concerned (ibid. § 88).

56. The expression "in accordance with the law" requires, firstly, that the impugned measure should have some basis in domestic law. Secondly, it refers to the quality of the law in question, requiring that it should be accessible to the person concerned – who must moreover be able to foresee its consequences – and compatible with the rule of law. The phrase thus implies, *inter alia*, that domestic law must be sufficiently foreseeable in its terms to give 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), and *Nedescu v. Romania*, no. 70035/10, § 77, 16 January 2018). Moreover, domestic law must indicate with reasonable clarity the scope and manner of exercise of the relevant discretion conferred on the public authorities so as to ensure to individuals the minimum degree of protection to which citizens are entitled under the rule of law in a democratic society (see, for example, *Radu v. the Republic of Moldova*, no. 50073/07, § 28, 15 April 2014, and *Unifaun Theatre Productions Limited and Others v. Malta*, no. 37326/13, § 78, 15 May 2018).

57. The Court also reiterates that it is primarily for the national authorities, notably the courts, to interpret and apply domestic law. However, the Court is required to verify whether the way in which the domestic law is interpreted and applied produces consequences that are consistent with the principles of the Convention as interpreted in the light of the Court's case-law (see *Cocchiarella v. Italy* [GC], no. 64886/01, §§ 81 and 82, ECHR 2006-V, and *Benedik v. Slovenia*, no. 62357/14, § 123, 24 April 2018).

58. In order to determine whether an impugned measure was "necessary in a democratic society" the Court has to consider whether, in the light of the case as a whole, the reasons adduced to justify it were relevant and sufficient for the purposes of Article 8 § 2 (see *Knecht*, cited above, § 58, and *Parrillo v. Italy* [GC], no. 46470/11, § 168, ECHR 2015).

59. A number of factors must be taken into account when determining the breadth of the margin of appreciation to be enjoyed by the State when deciding any case under Article 8 of the Convention. Where a particularly important facet of an individual's existence or identity is at stake, the margin allowed to the State will normally be restricted (see *Evans*, cited above, § 77, and the cases cited therein). Where, however, there is no consensus within the member States of the Council of Europe, either as to the relative importance of the interest at stake or as to the best means of protecting it, particularly where the case raises sensitive moral or ethical issues, the margin

will be wider (see *Evans*, cited above, § 77; *Fretté v. France*, no. 36515/97, § 41, ECHR 2002-I; *Christine Goodwin v. the United Kingdom* [GC], no. 28957/95, § 85, ECHR 2002 VI; and *A, B and C v. Ireland*, cited above, § 232).

60. The Court has previously held that the use of IVF treatment gave rise to sensitive moral and ethical issues against a background of fast-moving medical and scientific developments. It is why in such a context, in the absence of clear common ground among the member States, the Court has previously held that the margin of appreciation to be afforded to the respondent States is a wide one (see *S.H. and Others*, cited above, § 97, and *Paradiso and Campanelli*, cited above, § 194). The State's margin in principle extends both to its decision to intervene in the area and, once it has intervened, to the detailed rules it lays down in order to achieve a balance between the competing public and private interests (ibid; *Knecht*, cited above, § 59, and *Evans*, cited above, § 82).

61. However, this does not mean that the solutions reached by the legislature are beyond the scrutiny of the Court. It falls to the Court to examine carefully the arguments taken into consideration during the legislative process and leading to the choices that have been made by the legislature and to determine whether a fair balance has been struck between the competing interests of the State and those directly affected by those legislative choices (see *S.H. and Others*, cited above, § 97, and *Parrillo*, cited above, § 170).

(b) Application of the general principles to the present case

62. The Court will approach the case as one involving an interference (see *S.H. and Others*, cited above, § 88, and *Knecht*, cited above, § 58) as it concerns the State's decision to deny the applicants' access to IVF procedures which were available to the population and which they sought to pay for themselves.

63. The Court reiterates that, first and foremost, for an interference to be justified under Article 8 § 2, it must be in accordance with the law (see paragraph 55 above).

64. In so far as the Government argued that the lawfulness of the measure was not disputed before the domestic courts, the Court observes that both at first-instance and on appeal the applicants asserted that while the law referred to the word "desirable" the authority incorrectly applied the criterion as a mandatory one (see, for example, paragraph 25 above). Further, the first-instance court considered that the crux of the case was precisely the interpretation given to the protocol and considered that the word "desirable" could lead to some uncertainty (see paragraphs 21 *in primis* and 22 *in fine* above), and the Constitutional Court agreed with the applicants' argument that the age-limit was not mandatory noting, however, that the authority had the discretion as to whether to apply it or not (see paragraphs 27 and 28

above). It follows that the applicants' arguments concerning the lawfulness of the measure were raised at the domestic level and dealt with by the domestic courts. There is therefore no reason for this Court not to delve into the matter.

65. It is not disputed that the decision to reject the applicants' application was based on the impugned provision of the protocol. The Court will firstly examine the quality of that law. The Court observes that there is no *ad hoc* enabling provision for the protocol in the principal Act. Rather, the enabling provision, allowing for the creation of the protocol, in the Embryo Protection Act (as stood in 2013) lies in its Section 6 which deals with unlawful procedures and creates criminal offences (see paragraph 32 above). However, in the absence of any arguments in this respect before the Court, it is not necessary to examine the matter or question the validity of the protocol on that basis. It also notes that the applicants have not claimed that the protocol had not been accessible.

66. As to whether the law (the protocol) was foreseeable, the Court considers that as argued by the applicants, the age-limit was not mandatory as the protocol clearly stated that it was only "desirable" for the eligible candidate to be below forty-three years of age (see paragraph 33 above). Indeed, both constitutional jurisdictions agreed with this evident interpretation and considered that the age limitation was not mandatory, and the Constitutional Court precisely held that the Authority could, in their discretion and on the basis of medical findings, decide to apply it or not (see paragraphs 27 and 28 above). The latter interpretation was also supported by the two experts who testified in the proceedings and had been involved in the drafting of the protocol (see paragraph 17 and 19). The protocol therefore provided for a certain flexibility. Nevertheless, it is not disputed that the Authority interpreted the age-limit as being mandatory and applied it accordingly (see, for example, S.A.'s testimony and the findings of the constitutional jurisdictions to this effect), without any considerations related to the medical situation of the candidates, or reference to any other pertinent reasoning. As a result, the administrative and judicial authorities gave different interpretations of the same legal provision. Furthermore, the Court cannot but note that the interpretation applied to the applicants – which left no room for flexibility – was the less favourable one to them, and the one most at odds with the clear wording of the law, as supported by its drafters as well as the highest courts of the land.

67. It follows that, at the relevant time, the way in which the judicial and administrative authorities involved interpreted and applied the impugned legal provision (which was not referred to in any other law) was incoherent and thus lacked the required foreseeability (see, *mutatis mutandis*, *Nedescu*, cited above, § 84). In this connection, the Court notes that the first-instance constitutional jurisdiction had explicitly sympathised with the applicants about the uncertainty caused by the word "desirable" (see paragraph 22

above) and the Court observes the new formulation following relevant amendments, whereby the protocol, now unequivocally reads "will only be allowed to undergo treatment up to the maximum age of 42 years" (see paragraph 34 above).

68. In conclusion, the interference suffered by the applicants had not been in accordance with a law of sufficient quality. That being so, the Court is not required to examine further aspects of the lawfulness requirement, or to determine whether the interference pursued a legitimate aim and, if so, whether it was proportionate to the aim pursued.

69. There has accordingly been a violation of Article 8 of the Convention.

ALLEGED VIOLATION OF ARTICLE 14 OF THE CONVENTION TAKEN IN CONJUNCTION WITH ARTICLE 8

70. The applicants complained that they suffered discrimination contrary to that provided in Article 14 of the Convention, which reads as follows:

> "The enjoyment of the rights and freedoms set forth in [the] Convention shall be secured without discrimination on any ground such as sex, race, colour, language, religion, political or other opinion, national or social origin, association with a national minority, property, birth or other status."

71. Bearing in mind the conclusion at paragraph 69 above the Court does not consider it necessary to examine separately the admissibility and merits of this complaint.

APPLICATION OF ARTICLE 41 OF THE CONVENTION

72. 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."

C. Damage

73. The applicants claimed 4,296.43 euros (EUR) in respect of pecuniary damage representing costs undertaken in medical tests and medicine in relation to the second attempted IVF procedure and EUR 60,000 in non-pecuniary damage. The legal representative indicated the firm's bank account to receive payment of all the sums awarded by the Court.

74. The Government challenged the pecuniary claim as being unconnected to any violation, and the non-pecuniary claim as being excessive.

75. The Court does not discern any causal link between the violation found and the pecuniary damage alleged; it therefore rejects this claim.

However, it awards the applicants EUR 8,000 in respect of non-pecuniary damage, plus any tax that may be chargeable.

76. As requested, the amount awarded is to be paid directly into the bank account designated by the applicants' representative (see, for example, *Denisov v. Ukraine* [GC], no. 76639/11, § 148, 25 September 2018 and the Practice Direction to the Rules of Court concerning just satisfaction claims, under the heading payment information).

D. Costs and expenses

77. The applicants also claimed EUR 3,406.67 for the costs and expenses incurred before the domestic courts and EUR 2,000 for those incurred before the Court.

78. The Government did not contest the domestic court costs but noted that the applicants had not substantiated their costs before this Court.

79. According to the Court's case-law, an applicant is entitled to the reimbursement of costs and expenses only in so far as it has been shown that these were actually and necessarily incurred and are reasonable as to quantum. In the present case, regard being had to the documents in its possession and the above criteria, the Court considers it reasonable to award the applicants, jointly, the sum of EUR 2,500, plus any tax that may be chargeable to the applicants, for the proceedings before the domestic courts and to reject the claim for costs in relation to the proceedings before this Court. As requested, the amount awarded is to be paid directly into the bank account designated by the applicants' representative.

E. Default interest

80. 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 complaint concerning Article 8 admissible;

2. *Holds* that there has been a violation of Article 8 of the Convention;

3. *Holds* that there is no need to examine the admissibility and merits of the complaint under Article 14 in conjunction with Article 8 of the Convention;

4. *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:

(i) EUR 8,000 (eight thousand euros), plus any tax that may be chargeable, in respect of non-pecuniary damage;

(ii) EUR 2,500 (two thousand and five hundred euros), plus any tax that may be chargeable to the applicants, in respect of costs and expenses;

(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;

5. *Dismisses* the remainder of the applicants' claim for just satisfaction.

Done in English, and notified in writing on 5 May 2022, pursuant to Rule 77 §§ 2 and 3 of the Rules of Court.

Renata Degener Registrar	Marko Bošnjak President