

24.03.2023

sayandeep

Sl. No. 02

Ct. No. 05

WPA 1592 of 2023

Saswati Mohury & Anr.

-Versus-

The Union of India & Ors.

Ms. Deblina Lahiri

Mr. Mrinmoy Chatterjee

....for the petitioners

Mr. Siddhartha Lahiri

Ms. Mary Dutta

.....for the UOI

The petitioner nos. 1 and 2 are married to each other and are keen to have a child through Assisted Reproductive Technology (ART) as defined in The Assisted Reproductive Technology (Regulation) Act, 2021. The petitioners underwent Intra-uterine Insemination (IUI) procedure and similar other procedures from 2010 onwards in specialist fertility clinics in Chennai, Odisha and Chattisgarh. The petitioners explored ART in 2019 after successive failures in conceiving a child through IUI. The petitioner no. 1 was advised to undergo In vitro Fertilization (IVF) in December, 2019 but was unable to continue with the IVF by reason of the lockdown from March, 2020. The petitioners visited a fertility centre in Howrah in April, 2022 and were advised to undergo certain medical procedures. In July, 2022, the petitioners were

informed that petitioners were ineligible for undergoing ART as the petitioner no. 2 had crossed 55 years of age.

The present writ petition was filed in January, 2023 for declaration that section 21(g) of The Assisted Reproductive Technology (Regulation) Act, 2021 is ultra vires Articles 14 and 21 of the Constitution of India.

Section 21(g) of the Act requires a woman to be above the age of 21 years and below 50 years and a man to be above 21 years and below 55 years for being eligible for assisted reproductive technology services.

The first petitioner (wife) is now 46 years old and the petitioner no. 2 (husband) is 56 years.

According to learned counsel appearing for the petitioners, although the petitioner no. 1 is within the age limit of section 21(g), the petitioner no. 2 has crossed the age limit by just a year. Counsel submits that the petitioner no. 2 / husband was 52 years when the petitioners first tried for IVF in 2019 but crossed the age limit in July, 2022. Counsel submits that the petitioners have suffered emotional trauma and depression due to consecutive failures in conceiving a child. Counsel submits that section 21(g) offends Article 14 of the Constitution since a commissioning couple has been prohibited from seeking ART by reason of an artificial age bar between a man and woman without the support of any medical or expert evidence in the

matter. Counsel relies on the 129th Report on The Assisted Reproductive Technology (Regulation) Bill, 2020 which was presented before the Parliament on 19th March, 2021 to submit that the age-limit was recommended by the Parliament without any discussion in support of the recommendation. Counsel seeks an interim order pending a decision on the challenge to the vires of the Act.

Learned counsel appearing for the Ministry of Health and Family Welfare, Government of India, relies on three orders of the Supreme Court dated 26.9.2022, 9.1.2023 and 7.2.2023 to submit that the Supreme Court is considering a similar issue; namely a challenge to the vires of the 2021 Act including section 21(g) thereof.

The orders placed show that the Supreme Court requested the Board constituted by the Government Notification dated 4.8.2022 to examine the individual applications made before the Supreme Court and made the matter returnable in March 2023. The orders do not reflect that the Supreme Court requested the High Courts not to entertain writ petitions involving a similar issue. The Supreme Court has also not transferred matters pending before the High Courts to itself to decide on the vires of the 2021 Act. The judgment passed by the learned Single Judge of the Kerala High

Court on 19.12.2022 in a batch of writ petitions involving a similar question whereby the petitioners were permitted to continue their treatment under the ART Act is a case in point.

Moreover, the Constitution Bench decision of the Supreme Court in *State of West Bengal vs The Committee for Protection of Democratic Rights; (2010) 3 SCC 571* can meaningfully be referred to. In that case, the Supreme Court upheld the constitutional scheme framed for the judiciary whereunder the Supreme Court and the High Courts were held to be courts of record. The Supreme Court also referred to the wide powers vested in the High Courts under Article 226 of the Constitution.

The Assisted Reproductive Technology (Regulation) Act, 2021

The ART (Regulation) Bill was introduced in the Lok Sabha on 14.9.2020 and was referred to the Parliamentary Standing Committee on Health and Family Welfare. The Standing Committee sought for the views of stakeholders and presented the 129th Report on the ART (Regulation) Bill, 2020 before the Parliament on 19.3.2021.

The 129th Report on the ART (Regulation) Bill, 2020 reveals that the recommendation of the upper-age

limit for a woman and a man of 50 and 55 years, respectively, was made without a detailed discussion. The relevant part of the Report only refers to recommendations made by a Select Committee on the Surrogacy (Regulation) Bill, 2020. There is no discussion of the upper-age limit followed in countries outside India which shows varying limits and more significantly of countries like Germany, Spain, Portugal and UK where no upper-age limit has been prescribed at all. The Report also does not mention the impact of any Pre-implantation Genetic Testing for embryos or screening of the sperm cells taken from a man of advanced years or the perceived apprehension relating to sperm health of older men justifying fixing of the upper-age limit for a man under section 21(g)(ii).

The object of the Act, 2021 is to regulate and supervise the assisted reproductive technology clinics and the assisted reproductive technology banks and to prevent the misuse of reproductive technology services as also for addressing the issues of reproductive health where assisted reproductive technology is required for becoming a parent due to infertility, disease or social or medical concerns. Section 2(1)(a) defines “assisted reproductive technology” to mean all techniques that attempt to obtain a pregnancy by handling the sperm or the oocyte outside the human body and transferring the

gamete or the embryo into the reproductive system of a woman.

The Act has several 'silences' which do not provide any answers:

There are three other aspects which do not find any mention in the observations / recommendations of the Standing Committee Report.

First, the absence of any stop-gap measures for men, women and commissioning couples who availed of ART Services before the Act came into force on 25.1.2022 and were consequently caught within the age-bracket prohibition of section 21 (g) of the Act. In the present case, for instance, the petitioner no. 2 (husband) was 52 years old in 2019 when the petitioners visited the particular Fertility Clinic for treatment. The Act came into force on 25.1.2022 when the petitioner no. 2 was 55 years old and hence became ineligible under section 21(g) of the Act. The Standing Committee recommendations do not address the point as to what happens to this category of cases where persons who had undergone fertility procedures before the Act came into effect suddenly found themselves disqualified under section 21(g) during the course of their treatment. The Act does not make any saving provisions for these transitional cases.

Second, the Recommendations are also silent on the anomalous situation which may result where one of the individuals of the married couple (commissioning couple) may be within the permissible age-limit but would nonetheless not be entitled to ART if his/her partner crosses the age- limit.

Third, there is also no discussion on individual risk factors to pregnancy at an advanced maternal age against the increase in average life expectancy in India.

Further, on a prima facie assessment of the relevant provisions of The Assisted Reproductive Technology (Regulation) Act, 2021, there appears to be several ambiguities with reference to a "*commissioning couple*" as defined under section 2(1)(e) of the Act.

The ambiguities in the 2021 Act; those relevant for the instant adjudication are stated below :

1) Section 21(g) provides that the clinic shall apply assisted reproductive technology services (i) to a woman between 21 and 50 years of age and (ii) to a man between 21-55 years of age. Section 21(g) simply mandates the respective age limits of a 'woman' and a 'man' for ART as 2 separate entities without treating the 'man' and the 'woman' as a unit in the sense of being a "commissioning couple".

2) The omission to specify “commissioning couple” in section 21(g) is striking in its continued silence in the scheme of the Act.

(a) The expression “commissioning couple” has been defined in section 2(1)(e) as an infertile married couple who approaches an ART clinic or ART bank for obtaining authorised services. Hence, “commissioning couple” has been treated as a separate unit and an entity distinct from a ‘woman’ (or a man) in the statutory scheme.

(b) This would further be evident from the expression ‘woman’ which has been given a specific definition under section 2(1)(u) to mean any woman above the age of 21 years who approaches an ART clinic or ART bank for obtaining authorised services. Therefore, the separate identity given to a “commissioning couple” in section 2(1)(e) has not been carried to its logical conclusion in section 21(g) where the qualifying age of only a man and a woman has been described.

(c) Section 21 - “General duties of assisted reproductive technology clinic and banks” - makes repeated reference to “*commissioning couple*” and ‘*woman*’ through the gamut of the duties. The reference to these two entities is

found in section 21(c)(ii) and (iii), section 21(d), (e) and continues through section 21(j).

(d) Section 21(j) is significant since an obligation has been cast on the clinics and banks to provide all information related to “*enrollment of the commissioning couple, woman and gamete donors*” [section 21(j)(i)]. Here, apart from “commissioning couple” and “woman”, “gamete donors” have also been given a separate identity.

(e) Section 22 - “Written informed consent” - subsection (4) entitles any of the “*commissioning couple*” to withdraw his or her consent under section 22(1) at any time before the human embryos or gamete are transferred to the concerned woman’s uterus. Hence, under section 22(4), a “commissioning couple” has further been dissected into two individuals for withdrawing consent before the ART advances to the next stage. Remarkably, explanation (iii) to section 22(4) defines “parties” as including the commissioning couple or woman and the donors.

(f) Section 25(2)(a) mandates that the donation of an embryo after the Pre-implantation Genetic Diagnosis to an approved research laboratory for research purpose shall only be done with the

approval of the commissioning couple or the woman.

Therefore, the importance given to the individual identity of a “commissioning couple” as a unit separate and distinct from a “woman” or a “gamete donor” is curiously jettisoned in section 21(g) which ignores the combined entity of a commissioning couple altogether.

3) Although section 21(g) prescribes the eligible age-band of a man for availing ART services [21(g)(ii)], the Act does not define a ‘man’ anywhere within the statutory scheme. Further, section 21 mentions the categories of “commissioning couple”, “woman” and even a “gamete donor” several times without any reference to a “man” except in section 21(g)(ii). Significantly, the definition of a “commissioning couple” refers to an infertile married couple without any reference to whether a couple would consist of a man-woman, man-man, woman-woman or transgender persons.

4) The exclusion of “man” is all the more noticeable since a “gamete donor” has been defined in section 2(1)(h) as a person who provides sperm or oocyte with the objective of enabling an infertile couple or woman to have a child. Despite the omission, ‘sperm’

in section 2(1)(r) has been defined as “mature male gamete”.

5) Although, the age of a man under section 21(g)(ii) has been capped at 55 for being eligible for ART services, the Act does not specify the age of a “gamete donor”. This omission is significant when viewed with reference to the definition of a “gamete donor” under section 2(1)(h) as a person who provides sperm or oocyte for enabling an infertile couple or woman to have a child.

If the above omissions are read together it appears that the Act has discounted the relevance of a man as a part of a commissioning couple and even as a necessary part of ART altogether!

Hence, the omission to treat a commissioning couple as a separate unit coupled with the omission to prescribe an age for a gamete donor leads to the compelling argument : that of a woman’s age being the only relevant factor for a commissioning couple for availing of ART services.

The (In)equality Argument:

Article 14 of the Constitution, which prohibits the State from denying equal rights to any person before the law, is a grey area when viewed in the backdrop of The Assisted Reproductive Technology (Regulation) Act,

2021. The Act creates an unequal division between an unmarried, single woman and a married woman who is a part of a “commissioning couple” as defined in section 2(1)(e). While the former is eligible for ART services from 21 to 50 years, a married woman whose husband/counterpart crosses 55 years would fall within the mischief - and the grey area - of section 21(g) of the Act. The Act foists an indefensible fetter on a married woman with regard to ART while disentangling the statutory stranglehold from an unmarried woman. Indeed, the inequality thus created is absurd and defies logic.

The argument of Article 14 of the Constitution falling by the wayside is therefore completely reasonable. The constitutional safeguards cannot also be permitted to be overridden rough-shod. Men and women are entitled to equal rights to marriage and to have a family as articulated in Article 16(1) of the Universal Declaration of Human Rights. *Suchita Srivastava v. Chandigarh Administration*; (2009) 9 SCC 1 reiterated a woman’s right to make reproductive choices as a dimension of personal liberty as understood under Article 21 of the Constitution. Needless to say, a woman can exercise her reproductive choice to procreate as well as to abstain from procreating. The right cradles a

woman's freedom to choose birth-control methods as well as the right to carry a pregnancy to its full term.

A legislative enactment seeking to curb a woman's right to reproductive choices and means for parenthood, must be founded on clear medical evidence of domain experts. The curtailment must in any event be tested on the benchmarks of legislative competence, manifest arbitrariness, irrational considerations and violation of fundamental rights.

This Court also wishes to add that the framers of the law must not be presumed to have enacted a statute which will operate inequitably and result in harsh consequences. The aforesaid gives rise to the presumption that if the law operates unjustly in a given case, the legislature must have intended to exempt such cases from the scope of the statute. After all, the legislature lays down broad and general rules to govern and leaves the determination of specific cases to the courts to do justice.

The Act contemplates interim relief

- Under section 2(1)(f) of the Act "embryo" means a developing or developed organism after fertilization till the end of 56 days from the day of fertilization. Section 22(2) debars the clinic from cryo-preserving any human embryos or gamete without specific

instructions and consent in writing from all the parties seeking ART. Explanation (i) of section 22 defines “cryo-preseve” as freezing and storing of gametes, zygotes, embryos, ovarian and testicular tissues.

- Section 28(2) provides that the gamete of a donor or embryo shall be stored for a period of not more than 10 years after which period the gamete or embryo shall be allowed to perish or be donated to a research organisation registered under the Act for research purposes with the consent of the commissioning couple.
- Section 29 prohibits sale, transfer or use of gametes, zygotes and embryos or any part thereof or any information related thereto, directly or indirectly to any party within or outside India except transfer of own gametes or embryos for personal use with the permission of National Board.
- Section 42(2)(v) and (w) empowers the Central Government to make rules for the standards for the storage and handling of gametes, human embryos and the manner for obtaining the consent of the commissioning couple for perishing or donating of a gamete or embryo under section 28(2) of the Act.

- Rule 16 of the Assisted Reproductive Technology (Regulation) Rules, 2022 requires the consent of the commissioning couple or individual for perishing or donating the gamete of a donor or embryo in the format as specified in Forms 9 and 10 of the Rules. Forms 9 and 10 relate to “Consent for Freezing of Embryos” and “Consent for Freezing of Gametes/Sperm/Oocytes”, respectively.

The above provisions indicate that cryo-preservation of any human embryo is permissible with the written consent of all the parties seeking ART. As stated above, cryo-preservation includes freezing and storing of embryos. Storage of an embryo is also allowed for a period of 10 years beyond which the embryo may either be permitted to perish or be donated to a registered research organisation for research purposes with the consent of the commissioning couple. Therefore, the Act contemplates grant of interim order for preservation of the embryo.

It is also of significance that the petitioners have affirmed their consent for freezing of embryos in Form 9 which is the statutory form recording consent under Rules 13(1)(f)(iv) and 16 of the 2022 Rules. The consent in Form 9 is part of the affidavit filed by the petitioners.

Are the petitioners entitled to interim relief?

The balance of convenience for grant -or refusal- of interim relief weighs in favour of the petitioners for the following reasons. The petitioners started their first treatment in 2006 at Apollo Hospitals, Chennai. Since this procedure was unsuccessful, similar procedures were repeated in 2010-2011 in other fertility clinics in Odisha and Chhattisgarh. The petitioners sought to avail of ART in 2019 whereupon the petitioner no. 1 was made to undergo further tests and thereafter advised to undergo IVF in December, 2019. The petitioners however could not proceed with the treatment by reason of the lockdown from March, 2020 onwards. The disruption caused by the Covid-19 Pandemic continued till March, 2022 after which the petitioners again visited the particular Fertility Centre in April, 2022. The petitioners were informed of the age-bar under section 21(g) of the Act when the petitioners returned to the Fertility Centre in July, 2022 for continuation of the procedure.

The narration of the above chain of events would show that the petitioner no. 1 (wife) was 42 years old and the petitioner no. 2 (husband) was 52 years when they first visited the fertility clinic in 2019. Therefore, the petitioner no. 2 was well within the age limit of a

“man” under section 21 (g)(ii) of the Act which prescribes a age-cap of 55 years. The petitioner no. 2 crossed the upper-age limit of 55 years only recently and is now 56 years old. The question of giving any kind of interim relief to the petitioners will become more of a challenge with each passing day as the ineligibility of the petitioner no. 2 would increase with a possible delay in the adjudication of the present writ petition. Simply put, the petitioners cannot afford to wait for availing of ART services until the final adjudication on the vires of the 2021 Act. This Court is therefore of the view that the petitioner no. 2, as the male counterpart of the commissioning couple and having crossed the prescribed age by just a year, has established a case for interim relief.

This Court is alive to the fact that grant of interim relief may amount to final relief in the present facts. However, such an apprehension would be allayed on the ground that the ultimate relief claimed is for declaring section 21(g) of the Act as ultra vires Articles 14 and 21 of the Constitution. The interim order is only in aid of the final relief and in consideration that time is of the essence in the matter. The petitioners may not be in a position to sustain a long-drawn litigation on purely physiological constraints. There is hence every reason to consider the prayer for interim relief in light of the

peculiar attending factors which have been brought to the attention of the Court.

Thus, the material placed before the Court and the balance of convenience unmistakably show that the petitioners have made out a case for interim relief. The preparation for Assisted Reproductive Technology should be permitted to start as further delay may frustrate the petitioners' long-standing wish to have a child. There shall accordingly be an interim order permitting collection of the sperm of the petitioner no. 2 for preparation of the embryo with a donor egg. The embryo shall be preserved till disposal of the writ petition. The direction is given on Dr. Shiuli Mukherjee of the Fertility Center mentioned in paragraph 13 of the writ petition. Dr. Mukherjee is permitted to conduct requisite tests and procedures in aid of the interim order.

Further, the constitutionality of section 21(g) of the Assisted Reproductive Technology (Regulation) Act, 2021 raises important issues on identity, fragmentation of social units and certain inalienable rights and must be decided after the respondents are given an opportunity to file their affidavits. The respondent Ministry of Health and Family Welfare shall bring its objection on record by way of an affidavit-in-opposition within 3 weeks from date; reply within 2 weeks

thereafter. The affidavit shall also address the challenge to section 21(g) of The Assisted Reproductive Technology (Regulation) Act, 2021 as being ultra vires Articles 14 and 21 of the Constitution.

List this matter after 5 weeks. Parties shall be at liberty to mention the matter any time before that.

(Moushumi Bhattacharya, J.)