

**NATIONAL CONSUMER DISPUTES REDRESSAL COMMISSION
NEW DELHI**

CONSUMER CASE NO. 14 OF 2010

.....Complainant(s)

Versus

1. BHATIA GLOBAL HOSPITAL & ENDOSURGERY
INSTITUTE & ORS.

2. R.S. BHATIA

NEW DELHI - 110 087

3. DR. INDU BHATIA

NEW DELHI - 110 087

DELHI

4. DR. ARCHANA DHAWAN BAJAJ

NEW DELHI - 110 087

DELHI

5. DR. INDIRA GANESHAN

6. DR. PARVEEN BHATIA

Medical Director, Bhatia Global Hospital & Endosurgery
Institute, 307-308, Ambika Vihar, Opposite Central School,
Paschim Vihar

NEW DELHI - 110 087

.....Opp.Party(s)

BEFORE:

HON'BLE DR. S.M. KANTIKAR,PRESIDING MEMBER

FOR THE COMPLAINANT :

Dated : 16 June 2023

ORDER

Appeared at the time of arguments

For the Complainants : Mr. Chaitanya, Advocate

For OP-1 to 4 : Mr. Amit Sharma, Advocate
Mr. Mukesh Garg, Advocate

For OP-5 : Mr. Angad Mehta, Advocate

For OP-6 : Ms. Manisha Singh, Advocate

Pronounced on: 16th June 2023

ORDER

In our country, mushrooming of ART centres has led to incorrect treatment of the innocent infertile couples. The specialist requires a correct knowledge about the physiology of ovulation as well as reproductive gynaecology. Routine gynaecologists without having in-depth knowledge, using incorrect protocols may be harmful. One must realise that the infertility patients are stressed both emotionally as well as financially. The instant complaint involves many burning issues like medical ethics, unfair practices and misleading advertisement.

1. In September 2008, the couple (the Complainants), on advice of Dr. Archana Dhawan Bajaj (OP-5), approached Bhatia Global Hospital and Endosurgery Institute (for short 'Bhatia Hospital'-OP-1) at New Delhi for Intra-Cytoplasmic Sperm injection (ICSI). The OP-4 Dr. Indu Bhatia and OP-5 have assured the couple about the success of ICSI.

2. Accordingly, on 13.10.2008, the couple got admitted in the OP-1 hospital and first step of ICSI procedure was completed. Thereafter, on 15.10.2008, embryo transfer was done in Ms . Her pregnancy was confirmed on 04.11.2008. She gave birth to female twins on 15.06.2009. The blood group of one of the twins revealed AB(+), which was not a possible outcome as the blood group of the parents was B (+) and O- Negative the mother and father respectively. Therefore, on 11.12.2009, Paternity test (DNA profile) was conducted at Centre for Cellular and Molecular Biology ("CCMB") Hyderabad. It revealed that the Complainant No. 2 was not the biological father of the twins. Being aggrieved the couple filed the instant Consumer Complaint to claim Rs. two crore as compensation for the alleged negligence and deficiency in service which created emotional stress, family discord, fear of genetically inherited diseases etc.

3. The Opposite parties filed their replies and denied negligence during treatment of the patient .

4. The **OPs - 1 to 4** submitted that the OP-1 is the hospital and OPs no. 2, 3 and 4 are its directors. It was submitted that there are several disputed and complicated questions of facts, therefore, could not be decided in summary proceedings, thus matter be referred to the Civil Courts. The OPs – 1 to 4 submitted that the procedure was performed by Dr. Archana Dhawan Bajaj (OP-5) and Dr. Indira Ganeshan (OP-6) the personal doctor of complainants. The OP-5 was not a regular doctor on the roll of the Hospital. The OP-1 has provided the space/accommodation for her I.V.F. Laboratory on usual consultancy terms of 75:25 ratio (75% to the Consultant & 25% to the Hospital). The I.V.F. laboratory set up by OP- 5 was absolutely separate & distinct from the hospital laboratory. The I.V.F. laboratory had been maintained & monitored by OP- 5 at her own costs. The Hospital & its directors are nowhere involved in any consultant's way of treating the patient and it is only the consultant who administers the treatment to the patient independently, without any knowledge, involvement of the hospital or its Directors.

5. The **OP-4** Dr. Indu Bhatia submitted that the Complainants' treatment was duly performed by Dr. Archana Dhawan Bajaj (OP-5) and Dr. Indira Ganeshan (OP-6) who are very competent in their fields and have specialization in the field. The laboratory, operation theatre etc. for I.V.F. had been set up by the OP-5 at her own costs & expenses and remained under her lock and key. The entire set-up including the salary of technicians, anaesthetist, and embryologist and nursing staff was done by OP-5. The staff of I.V.F. laboratory was not on the pay roll of the hospital.

6. The **OP-5** in her reply submitted that Dr. Indu Bhatia (OP-4) the Director of Global Fertility Centre in Bhatia Global Hospital was the sole in charge of the IVF lab/OT. All activities/procedures etc. were carried on after her approval/consent. She further submitted that as requested by the hospital management, she provide her services as an IVF specialist to the patients on normal consultancy terms of 50:50 ratio (50% Consultant, 50% Hospital). The understanding with hospital that all the infrastructure like the laboratory, Operation Theatre etc. for the IVF procedure would be set up by the OP-1 hospital, and all expenses of the assisting Doctors like the Anaesthetic Doctor, Ultrasonologist, nursing staff, etc. would be maintained and monitored by the hospital at their own cost. The billing of the patients would be done by the hospital under its name, and the hospital administration would be responsible for maintaining documentation of the admission, consent, patient history and discharge of the patient.

7. The OP-5 submitted that she was only a visiting consultant at OP-1. The IVF laboratory was established and maintained by OP-1. Her role was limited to extracting the oocytes (eggs) from the female patient. In the instant case the extracted the oocytes were handed over to the embryologist. The semen sample of the male (which in this case was received by OP-6) was then handed over to the embryologist, who then washed, cleaned and prepared. The washed sperm samples were labelled under the supervision of OP -6. The oocytes and sperm samples for incubation were then left in the incubator for a period of approximately 4 hours. During this period, the lab remain locked and the keys were handed over the staff of OP -1. Therefore, at no point of time, the keys of the IVF Lab were in custody of OP-5 either before or after the IVF procedure. The case sheet, along with the consent form were under the custody of the Hospital.

8. The **OP-5** further confirmed the mixing could have happened at two stages i.e. at the stage of collection of semen or during storage for four hours before insemination. In the instant case, at the time of collection of semen sample, on the insistence of the Complainants, one Mr. Sunil Gambhir, who was a close relative of the Complainants, was present in the I.V.F. laboratory and also in semen collection room. The sample of semen was then handed over to OP- 6 by Mr. Sunil Gambhir, therefore there was every possibility that the alleged mixing was done by Mr. Sunil Gambhir with the knowledge of Complainant no. 2. Thus, the complainants were in collusion & connivance with Dr. Indira Ganeshan (OP-6) with dishonest and malafide intention were blackmailing the OP-1 to 5 in a pre-planned and syndicated manner.

9. The **OP-6** in her reply submitted that she accompanied the complainants for their treatment on 13.10.2008 and 15.10.2008. The OP-5 agreed to perform ICSI on at OP-1 hospital, as the sperm count of Complainant no.2 was very low. The OP-4 was a Gynaecologist and Director, at the OP-1 hospital. The OP-6 further submitted that, she was not on the panel of the hospital nor engaged to conduct the procedure as she did not possess professional expertise. She was implicated though the procedure was performed by OP-5 with the active involvement of OP No.2- 4. She categorically denied that she handed over the sperms to OP-5 or any of her teammates. The ICSI was performed by OP-5 but she was mis-stating the sequence of events.

10. Heard the arguments at length from both the sides. Perused the entire material on record and gone through the evidence filed by the parties.

11. After thoughtful consideration, it is clear from the facts and the affidavits of OPs 1 to 4, OP-5 and OP-6 that cross-allegations were made between themselves. From the standard text books on 'Immuno-hematology', the genetic transmission of possible blood groups from parents to the baby is reproduced in the following table:

| Blood Groups of Parents | Possible Blood group of baby | Completely Impossible |
|-------------------------|------------------------------|-----------------------|
| A & A | A, O | B, AB |
| A & B | A, B, AB, O | None |
| A & AB | A, B, AB | O |
| A & O | A, O | B, AB |
| B & B | B, O | A, AB |
| B & AB | A, B, AB | O |
| B & O | B, O | A, AB |
| AB & AB | A, B, AB | O |
| AB & O | A, B | A B, O |
| O & O | O | A, B, AB |

Admittedly, the blood groups of twins differ from their parents. One of the twins was AB-Positive whereas the Complainant No.1 was B-Positive and Complainant No.2 was O-

Negative. Thus, it is clear that due to the negligence of OPs during ICSI or IVF procedure, such disaster occurred.

12. I have carefully perused the Paternity Test report dated 09.12.2009 issued by CCMB the institute of national repute. The report concluded that the children are not related to the Complainant No. 2, it means he was not biological father of the twins. The conclusion of CCMB is reproduced as below:

“It is therefore concluded that _____ is the biological mother of
Baby 1 of Mrs. _____ | Baby 2 of _____ but
_____ cannot be the biological father of the Baby 1 of
and Baby 2 of _____.”

13. Adverting to whether it was ICSI or IVF performed by OP-5. In the past, in year 2006, for 1st pregnancy, the couple underwent successful ICSI at Batra Hospital and gave birth to their first daughter. It is pertinent to note that the sperm count of the Complainant No. 2 was very low and therefore the procedure other than ICSI would not be successful for the instant couple. It is pertinent to note that word ‘**ICSI**’ was clearly mentioned in the prescriptions issued by OP-5. Even the hospital stationaries (prescription pads) show ICSI in the column of ‘services offered’. Even in the Discharge slip ‘ICSI’ was mentioned. Therefore, in my view the OP-5 performed ICSI, but not IVF. However, be that as it may, the procedure ICSI or IVF was not the primary cause for the different blood group of the twins.

14. The OPs throughout their evidences were pointing fingers to each other and resorting to shift their blame. In my view the OP-1 to 6 were collectively involved Assisted Reproductive Techniques (ART). The contention of OP-1 to 4 was that they are not responsible for the act of the OP- 5. It is pertinent to note that by their own admission the OP-1 to 4 have provided accommodation and facilities with work understanding in the ratio of 25:75 with the OP-5. The OP-6 was closely involved and associated with OP- 5 during the entire procedure. Moreover, OP- 6 was involved in 6-7 other IVF procedures in the same lab which proves it was joint involvement of the OPs. It also proves the role of OP-6 in the procedure.

15. Thus, considering the entirety, the instant case is of *Res Ipsa Loquitor*. There is no need to prove the negligent act of the OPs – 1 to 6. It was not a case of an error of judgment by the treating doctors during the ART procedure, but it sounds the unfair trade practices adopted by the OPs. They were pointing fingers to each other, and everyone wants to shirk way from responsibility and liability.

16. During arguments, the authenticity of report issued by CCMB was raised by the OPs. According to OPs since it was specifically stated in the report as “Private Case; No legal locus standi”. It was also mentioned that, ‘this report is **only for personal use and not for legal purpose**’. The contention of OPs - 1 to 4 that the tests were carried out at the back of them and as such the possibility of the alleged tests being forged, fabricated, and manipulated cannot be ruled out. I don’t find any force in the above submission. Moreover, by the disclaimer in the report ‘only for personal use and not for legal purpose’, the scientific

basis and interpretation of DNA (paternity test) will not lose its significance. The CCMB is one of the reputed govt. institutions and DNA analysis is accepted throughout the country. However, in the instant case to avoid such controversy and to give fair opportunity to the parties, vide Order dated 02.02.2023, the repeat paternity test was ordered for the twins from Department of Forensic Medicine at AIIMS, New Delhi. However, the AIIMS replied that they are not conducting DNA profiling now. Therefore, I proceeded with the report received from CCMB.

17. The next point for consideration is that who actually had done the alleged mixing of sperms. The suspicion goes on many like OP-5 or 6 or the staff or the Complainants themselves or by Mr. Sunil Gambhir who was present inside I.V.F. lab during the procedure. According to the OPs 1 to 4 & OP-5 that the complainants as well as Dr. Indira Ganeshan (OP-6) were that because of low sperm count of Complainant no. 2, there were less chances of conception in their case. But complainants and OP-6 wanted to have second child at any cost and therefore it was very much possible that they might have intentionally given the wrong sample to OP-5. It was due to the professional rivalry/jealousy towards Dr. Archana Dhawan Bajaj (OP-5), the OP-6 Dr. Indira Ganeshan might have intentionally given the wrong sample to Dr. OP-5. On 16.10.2008, the complainants left the hospital without collecting the bill and without paying it. Thus it clearly shows the collusion, connivance & malafide intentions of complainants to blackmail the OPs in a pre-planned manner. The stand taken by OPs appears just hypothetical, "*if and buts*" does not considered to be a cogent evidence. It itself proves the glaring lapses of OPs 1 to 6 that how a third person was allowed in IVF lab or during procedure. It also proves that no standard procedures were followed by OPs.

18. The role of Embryologist as a crucial person in the ICSI/ IVF procedure, it is missing in the instant case. The process of IVF is a complex process where first the ovum is extracted from the female and the partner is then required to provide semen sample (sperms) to the embryologist. The sample is then labelled and processed by the embryologist. He undertakes cleaning/ washing of the sperms, a complex scientific process. Thereafter, the ovum is fertilized with the washed sperm and the fertilized ovum is then reinserted into the uterine cavity of the individual patient which further pregnancy continues. In the instant case nothing is forthcoming about who was embryologist, who did the sperm washing, the procedure of fertilisation etc. According to OP-5 her role in the entire process was limited to the first and last step, i.e., extraction of the ovum/ova and reinsertion of the fertilized ovum/ova into the individual. However, I am of the view that, OP-5 and OP-6 were responsible for the entire procedure. They have not disclosed about embryologist. In the instant case, after the said incident, the hospital and directors (OPs - 1 to 4) have immediately got the premises vacated from OP-5 and since then the premises was not given to any other IVF consultant.

19. Now, adverting to the compensation, there is needed to consider the ripple effects of the gross negligence. It should be borne in mind that the infertile couple was eager and anxious to have a child of their own. The entire purpose of opting for an Artificial Reproductive Technology such as IUI, IVF, ICSI, ZIFT, GIFT etc. was to have good outcome. In the instant case due to the negligence of OPs the genetic link between the parents and their children has been severed. Its impact was on several social and ethical issues. The negligent act of OPs has caused parental confusion for the children and has left

the Complainants in the society for giving explanations to the children later in life. There is great anxiety about the medical history and future genetic disorders and future lifestyle.

20. The catena of judgments of Hon'ble Supreme Court, laid down different methods to determine '**just and adequate compensation**'. It was held that there is no restriction that courts can award compensation only up to what is demanded by the complainant. The Hon'ble Supreme Court in the case of **Sarla Verma & Ors. vs Delhi Transport Corp. & Anr**[1] held that compensation cannot be calculated in a perfect mathematical sense, cannot be precise and accurate, but has to be within certain broad guidelines, and within certain broad parameters. It was observed that:

“While it may not be possible to have mathematical precision or identical awards, in assessing compensation, same or similar facts should lead to awards in the same range. When the factors/inputs are the same, and the formula/legal principles are the same, consistency and uniformity, and not divergence and freakiness, should be the result of adjudication to arrive at just compensation.”

21. The Hon'ble Supreme Court in **Dr. Balaram Prasad vs. Dr. Kunal Saha & Ors.**[2] case very clearly mentioned that there were problems with using a strait-jacket formula for determining the quantum of compensation. It noted the problem in the following words:

“... this Court is skeptical about using a strait jacket multiplier method for determining the quantum of compensation in medical negligence claims. On the contrary, this Court mentions various instances where the Court chose to deviate from the standard multiplier method to avoid over- compensation and also relied upon the quantum of multiplicand to choose the appropriate multiplier ... this Court requires to determine just, fair and reasonable compensation on the basis of the income that was being earned by the deceased at the time of her death and other related claims on account of death of the wife of the claimant...”

Discussion

22. Assisted reproductive techniques (ART) raise complex ethical, social, and legal issues. Some people or groups are opposed to any form of technical interference in the 'natural process' of procreation. The use of assisted reproductive techniques (ARTs) in human raises the question of how to distinguish between what is a use and a misuse of an ART. The core ethical issues identified include the unnatural means of conception, inequitable access to ART due to its high cost, lack of regulatory body, safety of the procedure, and fate of the embryos. Other ethical problems are surrogacy, sex selection, and gamete donation. Thus there is the need to formulate cultural and context-specific guidelines to help address some of these ethical dilemmas. The painful experience of women that not achieved a full-term pregnancy, the burden and pain experienced by women undergoing ART treatment, and the

potential risks to women's health to be considered. There is no uniform protocol specifying the sequenced application of intrauterine insemination (IUI) followed by the enrolment of the woman in in vitro fertilization (IVF) or intracytoplasmic sperm injection (ICSI). There is need for non-technological solutions to infertility and the regulation of medical practice. There are challenges surrounding gamete and embryo donation, the use of surrogacy and gestational carriers, the possible deleterious effects of ART, and the need for regulations and laws to govern ART reporting and social inequities.

23. Now adverting to quantum of Compensation In the instant case, I took clue from the various judgments of Hon'ble Supreme Court. It is pertinent to note that the twin babies are grown now, 14 years and both are healthy. The parents for last 14 years have incurred expenses while bringing up the girls, the welfare, and education etc. It is uncertain about the quality of sperm about its genetic profile/inheritance. At this stage possibility of inherited genetic disorders is unpredictable. Therefore, in my view the complainants deserve adequate compensation. The blood group reports and the DNA profile clearly prove that the Complainant No.2 was not a biological father.

24. It is pertinent to note that the delivered twins are female. Certainly, the family genealogy has been irreversibly changed. They may carry the stigma and face difficulties in future. The OP-1 hospital and OP 2 to 4 have not followed the standard guidelines of ICMR. The OPs were just passing on their responsibility on one another. Therefore, the negligence of OP-1 to 6 has been conclusively established. The OP-1 hospital was duty bound to provide quality services, but indulged in misleading advertisement to allure the anxious infertile couples for ART and adopted unethical practices. In my view, the instant case is of deceptive and unfair trade practices adopted by the OPs who have forgotten professional ethics. Thus, OPs-1 to 3 the hospital and directors, also the OPs - 4 to 6 liable for the act of negligence and unfair trade practices. Thus, I fix the total lump sum liability of 1.5 Crore against the OPs.

25. Based on the foregoing discussion, the instant Complaint is partly allowed with following directions:

- (i) The OPs 1 to 3 are directed to pay jointly and severally Rs. 1 Crore and the OPs – 4 to 6 shall pay Rs. 10 lakh each to the Complainants.
- (ii) For the unfair trade practices, the OPs – 1 to 3 are directed to deposit Rs. 20 lakh in the Consumer Legal Aid Account of this Commission.
- (iii) The entire directions shall be complied within 6 weeks from today, failing which the entire amount shall carry interest @ 8% per annum till its realisation.
- (iv) The total awarded amount of Rs. 1.30 Crore shall be kept in the Fixed Deposit (in nationalised bank) in equal proportion in the names of each twin till both attain age of majority. The parents shall be nominee and they are permitted to withdraw periodic interest for the care and welfare of the child.

26. To sum up, I would like to put forth few crucial points in the larger interest of the infertile couple that:

1. ART clinics are moving to donor gametes very early and also when not indicated just to increase the success rate of the clinic. Moreover mixing of gametes and use of donor gametes is being done without the knowledge of the patient.

2. Mushrooming of ART clinics has led to incorrect treatment to patients. ART specialist requires a correct knowledge about the physiology of ovulation as well as reproductive gynaecology. Routine gynaecologists who do not have in-depth knowledge are also opening clinics as they think there is money in it. Incorrect protocols are being used and the treatment offered may not be correct. One must realise that the infertility patients are stressed both emotionally as well as financially and the incorrect treatment increases this. Use of adjuvant therapies which still does not have evidence increases the cost to the patient. Moreover mushrooming of the clinics has made rampant unethical practices in our country.

3. There is need for prompt and fixed time line for accreditation of ART clinics from the authorities.

27. There is need to make it mandatory for the ART Centres to issue the DNA profiling of baby(ies) born through ART procedures.

The copy of this Order be sent to the National Medical Council and Ministry of Health and Family Welfare, Govt. of India for the necessary directions to the ART Centres.

[1] 2009 (6) SCC 121

[2] (2014) 1 SCC 384

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DR. S.M. KANTIKAR
PRESIDING MEMBER