IN THE HIGH COURT OF JUDICATURE AT BOMBAY
BENCH AT AURANGABAD

915 WRIT PETITION NO. 1584 OF 2024

1. Mrs.Lata w/o Santosh Bide,
Age-54 years, Occu-Housework,
R/o At Post Jamkhed, Tal.Ambad,
Dist.Jalna

2. Vikas s/o Santosh Bide,
Age-22 years, Occu-Labour work,
R/o At Post : Jamkhed,
Tal.Ambad, Dist.Jalna -- PETITIONERS

VERSUS

1. The State of Maharashtra,
Through the Secretary,
Public Health Department,
Mumbai – 32,

2. The Chairman Authorization Committee
and Medical Superintendent Government
Medical College and Hospital,
Aurangabad

3. Centre Head,
Internal Hospital Committee,
Medicover Hospitals,
Aurangabad
For permission for Kidney Transplantation,
Medicover Hospitals,
Near Chistiya Police Chowki,
N-6, Cidco, Aurangabad -- RESPONDENTS

Mr.A.V.Pandao, Advocate for the Petitioners.
Mr.S.K.Tambe, AGP for Respondent Nos. 1 and 2.
Ms.Isha Sinha, Advocate for Respondent No.3.

(CORAM : RAVINDRA V. GHUGE AND
R.M. JOSHI, JJ.)

DATE : FEBRUARY 22, 2024

ORAL JUDGMENT :- (PER Ravindra V Ghuge, J)

1. RULE. Rule made returnable forthwith and heard finally by the consent of the parties.

2. The Petitioners have put forth prayer clauses B to F as under :-

"B) Call for the record and proceedings of the impugned order of dated 16/12/2023 passed by the respondent no.1.

C) By writ of certiorari, order or directions in the like nature, the impugned order passed by respondent no. 3 on dated 16/12/2023 may kindly be quashed and set aside and the application made by the petitioners.

D) By writ of mandamus, order or direction in the like nature, the respondents no. 1 to 3 be directed to grant approval for removal and transplant of Kidney of the petitioner no. 1 and 2 as submitted.

E) The petitioners may kindly be give liberty to proceed with the removal of one kidney of petitioner no. 1 Lata w/o Santosh Bide for transplantation to petitioner no.2 Vikas s/o Saontosh Bide in view of therapeutic purpose.

F) To direct the respondents to operate the operation of the petitioners considering the documents produced before the respondent no. 3 and

respondents no. 3 shall promptly and expeditiously act to save the life of the recipient Vikas s/o Saontosh Bide on humanitarian ground as early as possible."

3. On 09.02.2024, we had passed the following order :-

"1. The Head of the Legal Department of Respondent No.3/ Hospital has addressed us via the Video-Conferencing mode. She informs us about certain issues, which the Medical Department needs to look into considering that the case before the Court pertains to the transplantation of kidney. She submits that an affidavit in reply is necessary since the matter involves kidney transplantation from a live donor.

2. The learned Advocate for the Petitioner submits that the Petitioner is stable. After an affidavit in reply is filed, this matter could be heard.

3. Let Respondent No.3 enter an affidavit in reply by 16.02.2024.

4. ***List this petition on 22.02.2024 in the urgent orders category****."*

4. The Respondent No.3 / Hospital has entered it's affidavit in reply dated 16.02.2024 through the Authorized Signatory of the Hospital. The issue taken up by the Hospital before us is as regards the unquestionable medical clearance for a perfectly matching kidney

transplant from a live donor i.e. Petitioner No.1 to the Recipient i.e. Petitioner No.2. We are informed that Petitioner no.2 is the patient and he has been visiting the Respondent no. 3 hospital for dailysis. He is not an admitted patient (Indoor patient).

5. Considering the specific contents of the affidavit, we are reproducing paragraph Nos. 5.1 to 5.9 hereunder :-

"*5.1 Respondent No. 3 hospital is a multi-speciality hospital providing comprehensive medical services in the city of Aurangabad across various fields of healthcare. Respondent No. 3 is a law-abiding corporate entity and strictly observes the applicable laws, rules and regulations. Respondent No. 3 is a part of group company of "Medicover" which is a European healthcare group and provides world-class medical care to millions of people worldwide. One of the notable achievements of Respondent No. 3 is its successful execution of thousands of transplant surgeries across its hospitals in India. Respondent No. 3, namely Medicover Hospital, Aurangabad, is renowned for having some of the best medical professionals in the town of Aurangabad. Since its registration from October 2021, Respondent No. 3 Hospital has performed 115 kidney organ transplants with great patient satisfaction: Some of the challenging surgeries conducted by this hospital have been covered in national media. Some notable achievements of Medicover Hospital, Aurangabad, are:*

5.1.1 In February 2023, Medicover Hospital, Aurangabad, and its Nephrologist, Dr. Sandip Soni, (Doctor handling the case of Petitioners) performed India's first HIV-to-HIV kidney transplant involving different blood groups. While there have been only a few instances worldwide, including in India, of HIV transplants, this achievement gained coverage in leading medical Journals and media.

5.1.2 Medicover Hospital, Aurangabad, successfully performed a swap kidney organ transplant when there was no compatible donor within the patient's family. Therefore, they exchanged kidneys with another matched donor and recipient. This transplant surgery took place in the month of November 2023.

5.1.3 Medicover Hospital, Aurangabad, successfully performed a kidney organ transplant on February 7th, 2024, on an eleven- year-old boy and saved his life.

5.2 The pathbreaking organ transplant surgeries by the Respondent No. 3 Hospital indicate the exceptional efficiency and dedication to a process-driven approach and are a testimony of high level of professionalism and medical expertise. By employing these highly skilled medical professionals, the Respondent No. 3 hospital not only ensures the delivery of superior medical services but also seeks to transfer their expertise to local medical practitioners. Through training and collaboration with its European institutions, Respondent No. 3 hospital strives to uplift the capabilities of healthcare professionals in India, thereby contributing to the overall improvement of the healthcare infrastructure in our country. Copies of the media coverage are annexed as Exhibit 'B' colly.

5.3 Respondent No.3 considering, the complexity involved in transplant procedures and compliance of statutory requirements, particularly in the case of kidney transplants, the Respondent No. 3 hospital has implemented a comprehensive Standard Operating Procedure (SOP) on transplants. This SOP meticulously not only align with statutory provisions of central and state legislations but also to uphold the highest standards of medical practice and directions of regulatory bodies like National Organ and Tissue Transplant Organization (NOTTO) and State Organ and Tissue Transplant Organization (SOTTO). By establishing and adhering to such SOPs, Respondent No. 3 aims to ensure safety, efficacy, and ethical conduct of transplant procedures in its Hospitals all over the country. The Respondent No. 3 Hospital has established state wise SOP for organ transplant surgeries and the documentation is thoroughly reviewed by various team members before carrying out any organ transplant procedure.

5.4 In January 2022, the Petitioners consulted Dr. Sachin Soni for the first time, at the hospital of Respondent No. 3. It is submitted that Dr. Sachin Soni is one of the most renowned Nephrologist in India who specializes in, inter alia, kidney transplantations. He has more than 15 years of experience and advises patients from all over the world. The doctor is also highly respected in the medical field for his academic contributions for the numerous publications he has to his credit. Having completed MBBS from Government Medical College, Nagpur (in the year 2000), MD, DNB (Med) from Government Medical College, Nagpur (in the year 2004), MNAMS, DNB (Nephro) from National Board of Exam, New Delhi (in the year 2008), Fellow ISPD,

*Fellow ISN(Italy), the said doctor has held distinguished positions in various Institutions in India as well as outside the country. Presently, Dr. Sachin is Head of the Department of Nephrology in Medicover Hospital, Aurangabad (hereinafter referred to as 't**he Hospital**'),*

5.5 The Petitioner No. 2 consulted Dr. Sachin on 22.01.2022 and was advised to take a few blood tests. The reports of the diagnosis suggested the Petitioner was diagnosed with Chronic Kidney Disease 5 (CKD-5) and was advised to undergo dialysis on a regular basis or a kidney transplantation.

5.6 Thereafter, on 08.09.2023, Petitioner No. 1 came along with Petitioner No. 2, claiming to be the mother of Petitioner No. 2 and communicated to donate one of her kidneys to Petitioner No. 2. The Respondent doctor advised the Petitioners to meet the transplant coordinator and produce the relevant documents relating to establishing their relationship and undergo the necessary counselling in respect of transplant. The doctor also advised the Petitioners to undergo a series of medical tests including the Human Leukocyte Antigen (HLA) typing and cross matching to ascertain as to whether the donor's kidney would be a perfect match to the patient/recipient.

5.7 Upon undergoing the clinical tests, all documents, forms, affidavit consents and test reports of Petitioners and relatives were submitted with the Competent Authority of the Respondent No. 3 Transplant Committee. Upon perusing in detail the reports, the Petitioners were called for counselling and were explained in detail of the 'doubtful negative' observed in the cross-match test. Due to the above reason, the Respondent No. 3. Committee declined to approve the transplant case.

5.8 Respondent respectfully submits that the Petitioners have misconstrued or misunderstood certain medical information, leading them to draw incorrect conclusions or assertions. Thus, the allegations are based on conjectures and surmises.

5.9 Following the rejection of the organ transplant, the Petitioners may have acted with misguided motives and have selectively presented facts, choosing only those that support their case while omitting crucial records essential for a comprehensive understanding of the matter. This selective presentation, or "cherry-picking" of facts and information, have led to a distorted depiction of the true nature of rejection of the Petitioners' case by the Respondent No. 3 Hospital."

6. The Hospital has tendered a further reply in paragraph Nos. 6.1 to 6.7 and 7.2 to 7.4, as under :-

"6.1 I respectfully submit that the Petitioners have approached the court with misguided motives rather than a genuine pursuit of legal remedy. I respectfully further submit that Respondent No. 3 acknowledges the pain of Petitioners but the same cannot be translated to as a legal remedy. The Respondent No. 3 Hospital is a law-abiding hospital that meticulously adheres to legal and regulatory standards in all its operations. Furthermore, the decision-making process undertaken by the Respondent No. 3 Hospital, including the choice not to proceed further with the Transplant surgery, was conducted with utmost diligence and after a thorough review of all pertinent medical records of the Petitioners.

6.2 The Diagnostic Report, annexed as Exhibit-G in Page No.

80 in Petition, provided by the independent diagnostic laboratory "LifeCell Diagnostics" revealed concerning results regarding the CDC crossmatch (T&B cell) with DTT and AHG Augmentation (hereinafter referred to as "Cross-match test"), indicating a status of 'Doubtful Negative'. This specific laboratory test, known as the Complement-Dependent Cytotoxicity (CDC) crossmatch, is a critical component of the evaluation process in kidney organ transplantation. It assesses compatibility between the potential donor organ and the recipient's immune system by mixing Donor lymphocytes with recipient serum. Any reaction between recipient antibodies and donor cells may indicate potential incompatibility, posing risks to the success of the transplant. A result categorized as "Doubtful Negative" suggests the presence of significant antibody reactivity between the Donor i.e. Petitioner no.1 and Recipient i.e. Petitioner no. 2. It is pertinent to mention that similar findings and discussions surrounding such test outcomes have been documented in various reputable medical journals. To perform the kidney organ transplant safely, it is essential for the CDC cross match report to be Negative. It's crucial to note that the CDC cross match report being negative is confirmed in the Standard Operating Procedures (SOP) of the National Organ and Tissue Transplant Organization (NOTTO) which is a National level organization set up under Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. The requirement of Negative CDC crossmatch report for Kidney organ transplant is a fundamental requirement as prescribed by NOTTO and also observed in case precedents. Copy of the SOP by NOTTO is annexed hereto as Exhibit 'C'.

6.3 I respectfully submit that the Respondent No. 3 Committee found minor to major issues and only thereafter rejected the transplant procedure based on the above reasons.

6.4 I respectfully submit that the action of Respondent No. 3 be considered as an action taken in good faith as also provided under Section 23 of the Act. Respondent No. 3 has acted in good faith and not with any malicious intent or contravention of law. The Respondent No. 3 Hospital or its doctors did not have any personal motive to deny or reject the transplant procedure in the case of the Petitioners.

6.5 Respondent No. 3 Hospital further submits that it is still committed to prioritising the well-being of its patients and acknowledges the value of every life. Despite the challenges encountered in the transplantation process thus far, the Respondent No. 3 Hospital remains open to considering the transplant of the Patient provided the Petitioners are able to arrange a suitable Donor and ensure that all necessary legal and medical prerequisites are met.

6.6 Since the Donor i.e. Petitioner no. 1 is a woman, the Respondent No. 3 in compliance with Rule 22 of the Transplant of Human Organs and Tissues Rules, 2014 ("Rules") has to exercise greater caution.

6.7 Seen from any angle, the instant case against Respondent No. 3 is wholly unsustainable and liable to be quashed.

PARAGRAPH-WISE REPLY

7.2 Regarding Paragraph Nos. 4, 5 and 6: In so far as the contentions raised in Paragraph Nos. 4, 5 and 6 of the affidavit in support of the Petition are concerned, save and except what are matters of record, each and every statement and/or averments made therein is

denied and disputed and the Petitioners are put to strict proof thereof. It is submitted that consents were sought from the relatives of donor solely as per the requirements set out in the Act. In order to establish the relationship between the donor, donee and the relatives who were providing consent apart from Donor and recipient as mandated under Rules, the same were asked from the Petitioners. I respectfully submit that the patient's lymphocyte cross-match test report indicated doubtful negative results, which posed significant risks for the success of a kidney transplant. A clear negative report is required for a successful transplant, as a doubtful may result in rejection, including the possibility of hyperacute rejection during the transplantation process itself. It's important to note that the possibility of proceeding with the transplant in this case hinges on obtaining a clear negative repeat lymphocyte cross-match within a specified time frame (usually 72-96 hours) prior to the kidney transplant. It is misleading and incorrect to suggest that the Respondent No. 3 Hospital rejected the kidney transplant of Petitioner No.1 basis insufficient consent. It is pertinent to point out that nowhere in the Minutes dated 16.12.2023 ("Minutes") the reason for rejection is set out to be on the basis of non-provision of consent. Rather, the Petitioners, another son of Petitioner No. 1 and the husband of the Petitioner No. 1 were counselled and informed about the clinical inability to perform the transplant. The said aspect is also recorded at Serial Nos. 1 and 3 respectively of the Minutes. The Respondent No. 3 Hospital has a track record of successfully conducting around 115 kidney transplants. However, in the case of Petitioners, there were clinical grounds that led to the rejection of the transplant by the Respondent No. 3. The rejection of the transplant was based on

valid medical grounds and the failure to fulfill legal requirements. These reasons were thoroughly considered by the Respondent No. 3 Committee, thereafter, made the decision to reject the transplant proposal. It's important to clarify that the rejection of this particular transplant does not reflect a general policy of the hospital.

7.3 Regarding Paragraph Nos. 7 and 8: In so far as the contentions raised in Paragraph Nos. 7 and 8 of the affidavit in support of the Petition are concerned, save and except what are matters of record, each and every statement and/or averments made therein is denied and disputed and the Petitioners are put to strict proof thereof.

7.4 Regarding Paragraph Nos. 9, 10, 11, 12, 13, 14, 15 and 16: In so far as the contentions raised in Paragraph Nos. 9 to 16 of the affidavit in support of the Petition are concerned, save and except what are matters of record, each and every statement and/or averments made therein is denied and disputed and the Petitioners are put to strict proof thereof. The rejection of the transplant was based on valid medical concerns and the failure to fulfill statutory requirements. These reasons were thoroughly considered by the Hospital Authorization Committee, which made the decision to reject the transplant proposal. I respectfully submit that the reliefs sought by the Petitioners are not maintainable and hence Petition deserves to be dismissed in limine."

7. Taking into account the contents of the affidavit in reply of the hospital reproduced above, we could summarize by recording that if there is "negative cross match", it would indicate a zero risk for the donor as well as the recipient. However, if the said test returns a result

of “doubtful negative cross match”(*presence of significant antibody reactivity)*, it would indicate that there could be a serious concern about the recipient successfully receiving the kidney. Such a report is already generated by the competent committee comprising of highly specialized doctors, on 23.09.2023.

8. The learned Law Officer of the Hospital before us, who was permitted to address the Court in the absence of a lawyer (it was conveyed to us that the hospital did not have enough time to select a lawyer to represent it), is justified in contending that if a kidney transplant is to be performed in the backdrop of “doubtful negative cross match”, it would be in violation of the guidelines for “Kidney Transplantation Living Donor Criteria”. The details of the said guidelines are placed before us at page Nos. 129 to 133.

9. Reliance is also placed upon a decision delivered by the National Consumer Disputes Redressal Commission in **Mulkh Raj and Others Vs. Jaipur Golden Hospital and Others [2018(2) CPR 341 (NC)]**, wherein it has been observed in paragraph No.5 as under :-

“5. Now, the question is whether the negligence was occurred during

the treatment (RT) of the patient and whether there were lapses during the pre-operative assessment/treatment at OP/Hospital. On perusal of medical record, it is revealed that the patient got admitted in Jaipur Golden Hospital on 2.12.2006 for pre-operative investigations and dialysis. The kidney donor (patient's wife Pinki) was also examined, her laboratory investigations were done on 4.12.2006 and she was found to be compatible kidney donor for her husband. The patient was evaluated and confirmed that he was the case of ESRD. Initially, he was taken up on the program of Renal Replacement Therapy (RRT) and was stabilized on maintenance Hemodialysis (MHD) via Internal Jugular Vein by a Dual lumen catheter. After preliminary investigation, he was discharged in a stable condition on 5.12.2006 and asked to come for regular dialysis from home at least twice a week. The patient and his wife (donor) were admitted in OP/Hospital on 18.12.2006 further to complete remaining investigations and discharged on 21.12.2006 and called on 25.12.2006 for renal transplant, which was fixed on 26.12.2006. Thus, the donor's investigations were performed on out-patient basis. Dr. Lal Path Lab report dated 21.12.2006, the HLA - ABC and DR Tissue Cross Match report confirmed a "Negative cross match". As per the report, B-cell cross match was unequivocal. Thus, it was ideal for renal transplant. The OP had explained the patient that the donor being biologically unrelated, therefore, there was need for injection 'Zenapax'. The tissue matching report from Dr. Lal Path Lab was available on the date when operation was fixed. In my view, it was not a case of rejection of kidney. It was a graft dysfunction. In the case of rejected kidney, there will be less urine as a time advances and it was not in the instant case. It was the wrong perception of the patient that,

as per Dr. Lal Path Lab's report the donor was not suitable for RT. The complainant also alleged that Zenapax injection was given in the case of poor cross match and the injection was not kept in the refrigerator. It is pertinent to note that, RT was performed only after permission from the transplant committee of the hospital. Dr. Umesh CD. Nautiyal explained the patient and his wife about the details of renal transplant and after signed informed consent, the renal transplant was performed on 26.12.2006. Therefore, in my view, the OP/the treating doctors and the Nephrologist have followed the standard procedure in the instant case. Moreover, the Negative cross matching is pre-requisite for renal transplant. Thus, I do (sic. 'NOT") agree with the allegations of the patient and do not find any negligence in the pre-operative work-up of patient and the donor."

10. It is thus apparent that if the "negative cross matching" test result is a prerequisite for kidney transplant, this Court would not be justified in passing an order directing the hospital to proceed with the renal transplant in the backdrop of "doubtful negative cross match" test result. In view of the above, we conclude that Respondent No.3 / Hospital is justified in not proceeding with the renal transplant. We do not have the knowledge and expertise to scrutinize the test results and the contentions of the hospital, to arrive at a different conclusion. In fact, to put it in correct perspective, it would be inappropriate on our part to indulge into this exercise.

11. The learned Advocate for the Petitioner submits that the Petitioner may be permitted to approach any other hospital. We have no reason to comment on this request.

12. **This Petition is, therefore, disposed off**.

13. Rule is discharged.

(R.M.JOSHI, J.) **(RAVINDRA V. GHUGE, J.)**