

*** IN THE HIGH COURT OF DELHI AT NEW DELHI**

% Judgment Reserved on: 17th March, 2016
Judgment Delivered on: 11th May, 2016

+ W.P.(C) 673/2016

TTK HEALTHCARE LIMITED Petitioner

versus

GNCT OF DELHI & ORS Respondents

Advocates who appeared in this case:

For the Petitioner : Mr Gurukrishna Kumar, Senior Advocate with Ms Sneha Iyer
and Mr B.Anand.

For the Respondents: Mr Peeyoosh Kalra and Mr Ankit Khurana for GNCTD.

CORAM:-

HON'BLE MR JUSTICE BADAR DURREZ AHMED

HON'BLE MR JUSTICE SANJEEV SACHDEVA

JUDGMENT

SANJEEV SACHDEVA, J

1. The petitioner has filed the present petition seeking quashing of tender floated by Govind Ballabh Pant Hospital, respondent No.3, being e-tender No.F-82-2(58)/GBPH/OTE/CTVS/2015-16 for Cardio thoracic Vascular Systems (CTVS) Group-E Part-II (Prosthesis) 2015-2016 for supply of disposable, prosthesis, re-usable accessories & instruments for use in Govind Ballabh Pant Hospital, New Delhi, insofar as it relates to the item "Bi-leaflet heart valve" and for a

further direction to the said respondent to include the generic specification of “Mechanical Mono-leaflet Heart Valve” in the said tender.

2. The contention of the petitioner is that the petitioner is a manufacturer of mono-leaflet heart valve. The said mono-leaflet heart valve is an indigenously manufactured heart valve developed in India to meet the needs of low costs cardiac valve. It is contended that the mono-leaflet heart valve has been successfully implanted in several patients over the years and has been proved to be very successful. It is contended that since the year 1990, merely 100,000/- implantations have taken place using the said mono-leaflet heart valve. It is contended that the mono-leaflet heart valve is very well accepted by well-known heart surgeons across the country. It is also being exported to several countries. It is contended that the Heart Valve Division of the petitioner Company has been accredited with ISO 9001:2008 and IS013485:2003 by BSI (British Standards Institution).

3. It is contended that in the tenders so far floated by the said respondent, the mono-leaflet heart valve, indigenously manufactured, were included. However, in the impugned tender, the respondent No.3 has excluded mono-leaflet heart valve and has invited bids for only for bi-leaflet heart valve.

4. Normally, Courts would be very reluctant to interfere in tender matters, more so, in respect of the items for which the tender is issued and bids invited. It is purely within the domain of the tender inviting authority to specify the items, for which the bids are invited. However, the facts of the present case turned out to be very peculiar. When the respondents were asked whether any conscious decision was taken by them to exclude mono-leaflet heart valve and to opt for bi-leaflet valves, the answer of the counsel for the respondent was in the affirmative. It was contended by the respondents that a conscious decision was taken to exclude mono-leaflet heart valve to opt for bi-leaflet heart valve.

5. A short affidavit has been filed on behalf of the respondent. The relevant portion of the same reads as under:-

“5. It is submitted that as per the Medical Research, it is established that non-FDA/Indian manufactured valves are not safe in patients. Artificial heart valve is put in the heart is in constant touch with blood. There is high probability of blood clot formation on the Valve. This clot causes valve dysfunction and death. This clot can also go to brain leading to paralyses of various body parts and due to this reason lifelong blood thinning drugs(Warfarin/Acitrom) is mandatory for the patients. It is submitted that if patient is given high dose of blood thinning drugs, there is high incident of brain hemorrhage and death. Malfunction of valve is usually fatal. Hence high standard in this device is essential as

far as design and material is concerned. At present worldwide current practice is to put FDA approved heart valve because of safety concern.

6. It is most respectfully submitted that the experience of using non-FDA/Indian single disc valve in Respondent No.3 Hospital is not very good. Disc of this valve is not metallic, so it is not seen on fluoroscopy (X-Ray). Echo is not always available in emergency and is also not very specific. It is further submitted that in case of two leaflets even if one leaflet is not functioning, then also patients reaches hospital in emergency however, in case of single disc they die either at home or on the way to hospital.

7. It is submitted that at present worldwide current practice is to put bi-leaflet valve (two leaflets). Single leaflet valves (even those with FDA approval) are now withdrawn from the market."

6. The affidavit of the Respondent refers to certain medical research and further contends that non-FDA/Indian manufactured valves were not safe in patients. It is contended that there is a high probability of blood clot formation on the valve, which could lead to death or paralysis of various body parts. It is contended that worldwide the current practice is to put FDA approved heart valves because of safety concerns. It is further contended that worldwide the current practice is to put bi-leaflet valves (two leaflets). Single leaflet valve (even those with FDA approval) is now withdrawn from the market.

7. The respondents were specifically asked to produce the records to show the material placed before the tender inviting authority and the consideration of this aspect by the tender inviting authority. The respondents failed to do so. The candid answer was that there is nothing available on record to show that any such material or research was available before the tender inviting authority or considered by it. The answer merely was that it is a current worldwide practise. However it was not substantiated by any material. The respondents candidly admit that there is no material available on record to show that any technical committee or authority ever considered this aspect. No opinions or complaints from any doctor or hospital or authority were available on record with regard to the two valves. It appears that this stand has been taken for the first time in the counter-affidavit. The records admittedly do not contain any material to substantiate the stand taken in the affidavit by the Respondent.

8. In view of the fact that there is apparently no material available on the records of the respondent and any consideration of any material on the part of the respondents to exclude Indian manufactured mono-leaflet valves, the exclusion thereof, in the said tender, is thus not justified. In view of the peculiar facts and circumstances of the case, we are constrained to interfere in the said item in the subject tender.

9. The subject tender in respect of bi-leaflet heart valve is

accordingly quashed. The respondents would, however, be free to float a fresh tender. In case the respondents choose to once again exclude mono-leaflet heart valves and invite bids for bi-leaflet heart valves, they shall be entitled to do so only after a Technical Committee considers all the relevant material and recommends it.

10. The writ petition is accordingly allowed in the above terms. There shall be no order as to costs.

SANJEEV SACHDEVA, J

BADAR DURREZ AHMED, J

MAY 11, 2016
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