

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

% Reserved on : 12.07.2011
Date of Decision : 08.08.2011

+ WP (C) No.1661/2011

MEDICAL POINT (I) LTD.

...PETITIONER

Through: Mr.T.K.Ganju, Sr.Adv.
with Mr.Siddharth Silwal,
Mr.Dhruv Kapur,
Mr.Vijayender Kumar, Advs.

Versus

UNION OF INDIA & ORS.

...RESPONDENTS

Through: Mr.Ravinder Aggarwal, CGSC
with
Mr.Nitish Gupta, Advocate
for R-1/UOI.

Mr. Mehmood Pracha,
Mr.Sumit Babbar and
Mr.Faraz Iqbal, Advocates for
R-2 and R-3/AIIMS.

Mr. Rajeev K.Virmani, Sr.Adv.
with Ms.Rashmi Virmani and
Mr.Ashish Kothari, Advocates
for R-4/Johnson & Johnson.

CORAM:

HON'BLE MR. JUSTICE SANJAY KISHAN KAUL

HON'BLE MR. JUSTICE RAJIV SHAKDHER

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| 1. | Whether the Reporters of local papers may be allowed to see the judgment? | YES |
| 2. | To be referred to Reporter or not? | YES |
| 3. | Whether the judgment should be reported in the Digest? | YES |

SANJAY KISHAN KAUL, J.

1. The petitioner alleges respondent nos.2 & 3, All India Institute of Medical Sciences (AIIMS) and its Director, for adoption of Decision Oriented Systematic Analysis (DOSA) so as to make the tender conditions in respect of purchase of Gas Plasma Sterilizers tailor-made for respondent no.4.
2. A notice inviting tender was published by respondent no.2/AIIMS through its Director/respondent no.3, in the Times of India on 13.10.2010 for purchase of Gas Plasma Sterilizers vide Tender Reference No.XX/131/Ortho/2010-2011/FSC-I. The petitioner claims to have submitted its tender along with the relevant documents on 21.10.2010, well before the

last date of submission of tender dated 15.11.2010. The tenders were opened as scheduled on 16.11.2010 and the petitioner was called upon by respondent no.2 vide its letter dated 01.02.2011 for a demonstration meeting on 09.02.2011. The petitioner claims that though it was present in the demonstration meeting as scheduled with all original catalogues of Gas Plasma Sterilizer, it was not able to make available the Gas Plasma Sterilizer as the same had been put up for demonstration in another hospital in Ahmedabad and this fact is stated to have been verbally informed to respondent no.2. The petitioner addressed a communication dated 09.02.2011, which was received by respondent no.2 on 10.02.2011, informing that on one occasion its Gas Plasma Sterilizer was kept under trial in the main OT of AIIMS from 17.05.2010 to 22.05.2010 against the tender enquiry no.1-13/H/M&E/200-10. The petitioner stated that during that trial, the Gas Plasma Sterilizer had been used for sterilization of all types of OT instruments including surgical instruments, endoscopes, lumen items,

catheters, ET tubes etc. and was found to be as per the requirement.

3. The grievance of the petitioner is that the tender conditions included unjustified clause, arbitrary, unreasonable & discriminatory clauses being clause/term no. 11 & 14 with the object of awarding the tender to R-4. The present writ petition under Articles 226 of Constitution of India which has been filed on 11.03.2011 seeking quashing of these clauses/terms being 11 & 14 of the tender. These specifications are as under:

“11. Should be approved by US FDA, CE & EPA.

14. The Sterilizer should be recommended by the IFU's of reputed Device Manufacturers of endoscopes, bone cutters, arthroscope, batteries and power tools to ensure compatibility of sterilizer with instruments.”

4. The petitioner has alleged in the writ petition that in the last one year, seven tenders for purchase of plasma sterilizers were invited by various departments of respondent no.2 out of which two have been awarded to respondent no.4 as their equipment was

US FDA approved. The petitioner claims to have made various representations seeking amendment of these clauses, but to no avail. The representations annexed show that the first one dated 16.12.2009 was in respect of a prior tender enquiry no. 53/CNC/NS/09-10/ST for Advanced Low Temperature (H2O2) Gas Plasma Sterilizer while the subsequent one dated 13.09.2010 was for tender enquiry no.47/CNC/CTVS/10-11/ST for Low Temperature Hydrogen Peroxide Gas Plasma Sterilizer. The petitioner further pleads that in various other institutions where tenders were invited for Gas Plasma Sterilizers, the requirement was for US FDA or CE or EPA certificate i.e. any one would suffice. The petitioner admits that he was not able to succeed even in those tenders because of other restrictive clauses like past performance.

5. To buttress its arguments in this regard, learned senior counsel for the petitioner has cited the case of Gharda Chemicals Limited v. Central Warehousing Corporation; 118 (2005) DLT 159 (DB) wherein, while

observing that the eligibility criteria should have a nexus with the object which is sought to be achieved, it was stated as under:

“The guidelines (CVC Circular dtd 17.12.2002) highlight the fact that the purpose of any selection procedure is to attract the wider participation of reputed and capable firms. It emphasizes that while framing any criteria, the scope and nature of work, experience of the firms in the same field and their financial soundness have to be kept in mind.”

(emphasis supplied)

Learned senior counsel for the petitioner in this regard has also referred to the judgment of the Supreme Court in UOI v. Dinesh Engineering Corporation; (2001) 8 SCC 491 wherein it was held as under:

“Public authorities even in contractual matters should not have unfettered discretion and in contracts having commercial element even though some extra discretion is to be conceded in such authorities, they are bound to follow the norms recognized by courts while dealing with public property.

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Therefore, merely because the authority has certain elbow room available for use of discretion in accepting offer in

contracts, the same will have to be done within the four corners of the requirements of law, especially Article 14 of the Constitution.”

6. The writ petition is resisted by the respondents. It is stated in the counter affidavit filed on behalf of respondent nos.2 & 3 that the petitioner failed to even fulfil the requirement of demonstration of the quoted model as required by tender clause 23 which reads as under:

“The tenderers may be required to demonstrate the quoted model of the equipment during the technical evaluation, if required, failing which their bids/offer shall be rejected. The firms are intimated that they should get ready for demonstration and only one-week time will be provided for arrangement of demonstration and no request for extending time for demonstration will be entertained. Failure to demonstrate, their offer will be summarily rejected.”

(emphasis supplied)

7. The demonstration meeting was scheduled for 09.02.2011 when a representative of the petitioner was present, but it is an undisputed fact that the petitioner did not give the demonstration during the

technical evaluation stage. Despite the failure of the petitioner, it was given a chance to clarify the technical points and comply with the technical specifications. The deficiencies in the case of the petitioner are stated to be not one but five. No challenge was laid in the writ petition to any other condition. In para 7 of the affidavit of respondent nos.2 & 3, affirmed on 19.03.2011, these deficiencies have been set out in tabular form, which are as under:

S.No.	Technical Specifications	Compliance
1.	Should be mobile (with locking mechanism for wheels? And should weigh less than 450 kgs.	The model quoted by the petitioner weighed 480 kgs. Compared to maximum permissible weight of less than 450 kgs.
2.	Should be approved by US FDA, CE & EPA	Quoted model does not have all the required certificates, but have only CE instead of all the three certificates as per the tender condition and only self declaration about EPA approval instead of EPA certificate issued by the Environmental Protection Agency, United States.
3.	The system should use the minimum quantity of sterilant to deliver dry terminal sterilization which should be less than 3-5 ml per cycle to ensure safety of instruments against corrosion.	Quoted model uses 8 ml (4 ml x 2 times per cycle) sterilant per cycle which is far more than 3-5 ml. per cycle.
4.	The sterilizer should be recommended by the IFUs	The petitioner did not provide IFUs of the

	of the reputed device manufacturers of endoscopes, bone cutters, arthroscope, batteries and power tools to ensure compatibility of sterilizer with instrument.	reputed device manufacturer of endoscopes, bone cutters, arthroscope etc. Lack of evidence of compatibility and efficacy of sterilizer with instruments used routinely is potentially hazardous. Rather to mislead the respondents, the Petitioner has furnished the letters from the different users rather than giving the recommendations from reputed manufacturers.
5.	Sterilant should be in cassette with leak proof indicator and should be air shippable for easy transportation.	Petitioner has offered the sterilant in 140 ml bottle instead of cassette without leak proof indicator.

8. The tender of the petitioner was rejected on all the aforementioned grounds in pursuance to the order passed on 22.03.2011. The respondent nos.2 & 3 filed another affidavit on 10.05.2011 *inter alia* stating the reasons how the technical specifications are not met by the petitioner, the position regarding seven tenders floated and the rationale for adoption of the US FDA norms. It has been explained that the US FDA is a statutory body which certifies that the medical products, devices and drugs for human use are safe. Since India does not have any such authority for any

new technology or drug, reliance was being placed upon US FDA certification to ensure safety of equipment, devices etc. for human use. The objective is stated to be to ensure the safety protocol from the operational safety point, safety of the patients, safety of the medical staff and from the environmental safety point. It has also been explained that while most of the equipments with FDA have a CE mark, the *vice versa* is not true. The CE deals with the European standards while the FPA deals with the environmental aspect. The monopoly in favour of respondent no.4 has been denied as there were various other companies, other than respondent no.4, who participated in the tenders earlier floated by various departments of respondent no.2 and complied with the requirement of possessing the US FDA certificate.

9. The incorporation of clause 14 as aforesaid requiring the sterilizer to be recommended by IFUs (Instructions for Use) of reputed manufacturers of endoscopes, bone cutters, arthroscope, batteries and power tools is to ensure compatibility with instruments and this is

stated to be a standard practice being followed elsewhere where the manufacturers recommend use of a particular type of a product to ensure that the durability and safety of the device is not compromised at the user's end.

10. The respondent no.4 was initially not impleaded as a party as the tender had been awarded. However, on an application being filed on 03.05.2011, the said party was impleaded in the present proceedings keeping in mind the nature of allegations made in the writ petition and a separate counter affidavit was filed by the said respondent no.4.
11. In the counter affidavit filed on behalf of respondent no.4, the attention of this court has been invited to the compliance statement submitted by the petitioner to respondent no.2 for purposes of tender, where against the tender specifications, the petitioner has made the endorsement "*Yes, we comply, certificate attached.*" And "*Yes, we comply.*" respectively. It is the say of respondent no.4 that the petitioner participated in the tender stating that it complied with the conditions and

thus having not succeeded in the tender, cannot now be permitted to turn around and allege that these clauses were creating a monopoly. This is apart from the fact that the petitioner has falsely alleged that it complied with the requirement of impugned clauses though it did not do so and the petitioner having been exposed filed the present writ petition.

12. The respondent no.4 has alleged concealment and misrepresentation of facts before this Court. It is the say of respondent no.4 that the petitioner had participated in a previous tender bearing no.1-13/H/M&E/2009-10 for the same product and had given documents purported to be IFUs of foreign manufacturer of devices, which on enquiry, were found to be non-existent and that tender was scrapped. The petitioner is stated to be in the know of all the conditions and even previously participated in the tenders issued by respondent no.2, while a picture was sought to be given in the present case as if these clauses were inserted for the first time. Even in the earlier tenders, the petitioner was objecting to the

tender conditions requiring presence in the market for certain period of time, but no challenge was laid to the impugned clauses incorporated in those earlier tenders.

13. The respondent no.4 has sought to rely upon the judgment of the Supreme Court in K.D.Sharma Vs SAIL; (2008) 12 SCC 481 to non-suit the petitioner on this ground alone, relevant portion of which is reproduced as under:

“The jurisdiction of the Supreme Court under Article 32 and of the High Court under Article 226 of the Constitution is extraordinary, equitable and discretionary. It is, therefore, of utmost necessity that the petitioner approaching the writ court must come with clean hands, put forward all the facts before the court without concealing or suppressing anything and seek an appropriate relief. If there is no candid disclosure of relevant and material facts or the petitioner is guilty of misleading the court, his petition may be dismissed at the threshold without considering the merits of the claim.

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While exercising extraordinary power a writ court would certainly bear in mind the conduct of the party who invokes the jurisdiction of the court. If the applicant makes a false statement or suppresses any material fact or attempt to mislead the

court, the court may dismiss the action on that ground alone and may refuse to enter into the merits of the case. The rule has been evolved in the larger public interest to deter unscrupulous litigants from abusing the process of court by deceiving it.”

14. The petitioner is the sole authorized distributor of Gas Plasma Sterilizer manufactured by Beijing Derun Technology Co.Ltd., which is the holding company of MuDanjiang Plasma Physical Application Technology Co.Ltd. The respondent no.4 has emphasized that the petitioner has not even filed a document showing its approval by EPA, but it has filed a letter/declaration from a private company namely Beijing Derun Technology Co.Ltd. stating that the plasma sterilizer being manufactured by that entity and sold by the petitioner in India are approved by EPA. This is stated to be, thus, a self-certification from EPA. Even Beijing Derun Technology Co.Ltd. is stated not to manufacture the sterilizers as according to the CE certification filed by the petitioner, it is Mudanjiang Plasma Physical Application Technology Co.Ltd, which is the manufacturer of the sterilizer offered by the petitioner.

The respondent no.4 has also emphasized on the failure of the petitioner to comply with the conditions of physical demonstration of the equipment.

15. It is stated by respondent no.4 that as per the guidelines issued by the Ministry of Health and Family Welfare in respect of the import of various medical devices, US FDA and CE approval/certification has been acknowledged and made acceptable for medical devices for being eligible for import in India. The petitioner, it is alleged, cannot call upon this Court to vary the terms of the tender settled by an expert body. A reliance in this regard has been placed upon the judgment of the Supreme Court in Tata Cellular Vs. Union of India;(1994) 6 SCC 651 where it has been that the power of judicial review of a Court in government contracts is a limited one.
16. The said respondent has explained that the Low Temperature Hydrogen Peroxide Gas Plasma Sterilizer uses a low-temperature hydrogen peroxide gas plasma technology to sterilize safely and effectively all the instruments and medical devices used in operation

theatres and for invasive procedures and surgeries. This requires utmost protection to the patients, users, instruments and environment in healthcare facility. Such sterilizers exploit the synergism between peroxide and low temperature gas plasma (an excited or ionized gas) to rapidly destroy microorganisms. On completion of sterilization process based on this technology, no toxic residues remain on the sterilized items. The technology is particularly suited to the sterilization of heat and moisture sensitive instruments used in surgery, like cameras, scopes, batteries, polymer based reusable instruments, fiber optic cables etc. since process temperatures do not exceed 50°C and sterilization occurs in a low moisture environment. The new models of sensitive and expensive medical instruments and devices are launched periodically. The new models comprise of combinations of different metal alloys, polymers and adhesives. These are very sensitive to temperature, pressure, concentration of sterilant and time of exposure. Thus, any attempt to sterilize with such instruments/devices may result in

improper sterilizing or damage to the devices sterilized in the sterilizer. It is for this reason that the condition requiring recommendations by IFUs of reputed device manufacturers is stipulated.

17. The role of three entities has been explained. The US FDA is responsible for safety, efficacy and security of human and veterinary drugs, biological products, medical devices, food supply, cosmetics and products that emit radiation by regulating the manufacture, marketing and distribution of products. The premarketing approval of all medical devices as well as overseeing the manufacturing, performance and safety of these devices is also done by US FDA. The CE marking on a product is a manufacturer's declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. The United States Environmental Protection Agency (EPA) has a primary responsibility for enforcing the environmental statutes and regulations of the United States. Since the medical institutions in India

are also now demanding the best available sterilizers for their institutions, the requirement of US FDA, CE and EPA approvals ensure that the instruments meet with the highest standards and there can be no objection to the expert body providing for highest standards.

18. The annexures to the counter affidavit show that the guidelines for import and manufacture of medical devices in India and the regulatory status *inter alia* refer to the US FDA clearance/approval and EU medical device directive (CE certificate). The CE marking is actually an abbreviation of French phrase “*Conformite Europeene*” which literally means “European Conformity”. It is the manufacturer’s declaration that the product complies with the essential requirements of the relevant European health, safety and environmental protection legislation. On the other hand, the FDA approval envisages the US Food and Drug Administration conducting inspections of medical device manufacturers to ensure that they comply with the

regulations about the device safety and effectiveness. If a medical device violates FDA law, FDA can take action to enforce compliance and ensure public health – two main tools being Warning Letters and Recalls. US Environmental Protection Agency (EPA) has a primary responsibility for enforcing many of the environmental statutes and regulations of the United States and as such is granted explicit enforcement authority in environmental statutes. The EPA regulations help to ensure that facilities take steps to prevent oil spills, chemical accidents and other emergencies and implement planning and response requirements.

19. The petitioner in the rejoinder sought to deal with the other objections raised by respondent nos.2 & 3 about the technical feasibility of the sterilizer of the petitioner. It has emphasized on the circulars issued by the CVC for purposes of fixation of broad parameters in cases where the equipment/plant to be procured is of complex nature and the procuring organization may not possess the full knowledge of the various technical solutions available in the market.

The petitioner has also sought to label the equipment of respondent no.4 as lacking in technical specifications since the cycle temperature of equipment of respondent no.4 is 55°C though the technical specification provides it to be in 40-50°C range.

20. Another aspect emphasized in the rejoinder for the first time is that it has come to the knowledge of the petitioner that respondent no.4 has been served with a Warning Letter issued by the US FDA in regard to Sterrad 100S (stated to be quoted by respondent no.4 in the tender) and other models to the effect that the models on inspection were found adulterated. This model is stated to have been recalled throughout the world including India. This information is stated to have concealed by respondent no.4 from respondent nos.2 & 3. The petitioner has also sought to deal with each of the technical specifications not complied by it. So far as the weight of the petitioner's equipment is concerned, a technical justification is sought to be given why it is not significant. The petitioner admits

that it does not have a US FDA certificate though it has a CE certificate. The EPA certificate is not issued by the US EPA, but is a self-certification by the manufacturer. On the issue of minimum quantity sterilant to deliver dry terminal sterilization to be less than 3-5 ml per cycle to ensure safety of instruments against corrosion, this is stated not to be a disadvantage. Similarly, in respect of the petitioner's offer of the sterilant in a 140 ml bottle instead of cassette without leak proof indicator, the same is sought to be justified. The requirement in respect of the sterilizer to be recommended by the IFUs is also stated to be without any basis.

21. In a nutshell, the petitioner seeks to claim that the though it does not meet with the five parameters as set out by respondent nos.2 & 3, these should also be waived or are not essential. Interestingly, another stipulation of a US FDA approved biological indicator with 24-hour readout time for faster validation of the sterilization process is not disputed as apparently the petitioner complied with the same.

22. In view of the allegations made by the petitioner regarding the actions of the US FDA qua respondent no.4 made for the first time in the rejoinder, respondent no.4 in pursuance to the leave granted, filed an additional affidavit affirmed on 04.07.2011. It has been explained in the affidavit that the letter dated 12.03.2010 being the Warning Letter by the US FDA did not cite any product performance, efficacy or safety deficiencies but rather required improvements in some of the internal processes of ASP. The Warning Letter did not lead to recall, seizure or injunction or any other enforcement action by US FDA. The registration of the Gas Plasma Sterilizer continues to remain in force by US FDA for which the Establishment Registration and Device Listing Certificate, downloaded from the website of the US FDA on 02.07.2011, has been annexed to the affidavit. There is, thus, stated to be no impediment in the sale of the product in question. There were some problems detected with the oil mist filter noticed by the ASP in the year 2008 which were corrected by replacing the

same with the new filters and providing for more frequent preventive maintenance actions. Since 2009, all the sterilizers in question are to be fitted with improved filters. The recall was stated to be a voluntary action which was intimated to the US FDA.

23. It is in the conspectus of the aforesaid pleadings of the parties, that various aspects arise for consideration of this Court.

WRIT PETITION BEING A BELATED ACTION

24. The first aspect is the plea raised about the delays and laches on the part of the petitioner in approaching this Court. The tender was floated on 13.10.2010 and the tender conditions were known. The petitioner participated in the tender claiming that it met with all the requirements. Thus, the petitioner did not make any grievance at the stage of notice inviting tender though there could be no doubt in the mind of the petitioner about the understanding of the terms and conditions including the impugned clauses. The plea of learned counsel for the petitioner that the petitioner understood the clause as requiring approval of either

US FDA or CE or EPA cannot be accepted in view of the clear stipulation in the clause and the grievance made by the petitioner in respect of earlier tender having a similar condition. It is only after the petitioner failed to meet these technical specifications that after a period of five months from the notice inviting tender, the petitioner filed the present writ petition.

25. In matters of awarding of tenders, the grievance must be made immediately before the Court as otherwise it may result in the tender process itself being delayed or frustrated. The present case is one where the challenge is sought to be laid to the terms and conditions of the notice inviting tender. If the petitioner was aggrieved by the same, the occasion to challenge the same arose in October, 2010. Instead of challenging the conditions at that stage, the petitioner participated in the tender on the basis of a declaration that it complied with the terms and conditions and having not being successful in the tender, on technical grounds, sought to raise the issue about the terms and conditions of the tender.

26. In view of the aforesaid, in our considered view, the delay on the part of the petitioner in making the grievance in question is fatal to the present writ petition and on that ground alone, the writ petition is liable to be dismissed.

THE CHALLENGE TO THE TWO CLAUSES OF NOTICE INVITING TENDER

27. The petitioner seeks to challenge clauses 11 & 14 of the notice inviting tender. The petitioner claims that the requirement of approval by all the three agencies – US FDA, CE & EPA – is tailor-made for respondent no.4. Thus, a reverse engineering process has been deployed in terms whereof, to achieve the objective of respondent no.4 succeeding in the tender, certain conditions have been stipulated. It is, thus, a decision-oriented systematic analysis (DOSA). It is not disputed that an expert body of AIIMS sat to make out the different terms and conditions. This expert body had a varied membership of the Head of the Department, Medical Superintendent, Head of the Department of related discipline, concerned faculty member, an

external expert to be nominated by the Director of the related discipline, Joint Secretary (FA), DGHS or his nominee, the Stores Officer and Financial Advisor. The original records in this behalf have also been produced by respondent nos.2 & 3. The composition of the expert body itself, in our considered view, demonstrates that experts from varied fields relevant for the decision making process were involved in providing the specifications. In this regard, the Supreme Court has also held in Air India Ltd. v. Cochin International Airport Ltd & Ors.; (2000) 2 SCC 617 that the State can choose its own methods to arrive at a decision and fix its own terms of invitation to tender, subject to the norms, standards and procedures laid down, which are not open to judicial scrutiny.

28. The role of the US FDA, CE & EPA has also been explained and the reason for the stipulation of all three agencies. In India, there is no authority providing for any such norms and, thus, respondent nos.2 & 3 have considered it appropriate to accept the certification of US FDA which is a compliance and

enforcement agency. Stringent norms are sought to be provided specifically keeping in mind the use of the equipment in question for orthopaedic surgeries. US FDA conducts inspection of medical device manufacturers to ensure that there is due compliance with the regulations in respect of device safety and effectiveness. Thus, a duly constituted administrative body looks into the various aspects and the incorporation of that condition in the tender cannot be doubted. Insofar as the CE marking is concerned, the material downloaded from the website shows that the same is a manufacturer's declaration that the product complies with the essential requirements of the European health, safety and environmental protection legislation. It is, thus, a declaration by the manufacturer. The EPA certificate is issued in respect of the environmental aspects and it has been explained that the said terminology is used for the US EPA certification. Interestingly, even here, the nature of the certificates submitted by the petitioner as an agent for sale of the Chinese products leaves

something to be desired as they are not issued by the relevant agencies, the same being in the nature of self-certification. A decision taken by such an expert body consisting of varied persons of different fields coupled with the participation in the tender of more than one technically qualified party belies the plea of the petitioner that the exercise was a DOSA with the object of favouring respondent no.4.

29. The grievance raised by the petitioner in respect of clause 14 requiring the sterilizer to be recommended by IFUs of device manufacturers see also meet the same fate. The rationale for this has been duly explained by both the sets of respondents i.e. the sterilizer when used with the relevant equipment must be compatible so that there are no complications. Such a condition cannot be said to be a mindless exercise or an exercise to favour respondent no.4.

NON CONFORMITY AND MIS -DECLARATION BY THE PETITIONER

30. It is an undisputed position that the petitioner while submitting the tender has categorically stated that it

complied with the clauses/terms 11 & 14 which it subsequently sought to challenge. These, declarations were found to be false. There can be really no dispute about it. The petitioner had full knowledge that it did not comply with these conditions yet sought to indicate in the compliance statement, at the relevant page, that it complied with it. The petitioner cannot be permitted to say that since the certificates in its favour were available and were annexed, it makes no difference. The petitioner clearly gave a false declaration in the compliance statement.

31. The matter is not only concerned with the two clauses/terms impugned by the petitioner, but the other non-compliance on the part of the petitioner. It is once again undisputed that the petitioner did not comply with clause 23 which required a demonstration. On the relevant date, the representatives of the petitioner were present, but without the equipment which was stated to be unavailable due to a demonstration elsewhere. The petitioner sought to cover up its failure by claiming

that in respect of an earlier tender, the equipment had been made available. This can hardly be a justification. The petitioner could have been knocked out at that stage itself, but the respondent nos.2 & 3 in their wisdom still decided to look into the aspect of technical requirements being met by the petitioner. The petitioner failed to comply even with other technical specifications in respect of weight of the instrument not being less than 450 kg, the system using the minimum quantity of sterilant, the sterilant to be in cassette with a leak proof indicator. The petitioner cannot be permitted to say that even these conditions, which the petitioner claims to have complied with in its compliance statement, which in fact it did not comply with, should be treated as irrelevant. The petitioner seeks to re-write the tender conditions to suit its own convenience. It is not the function of this Court to re-write a tender which has been finalized by an expert body. The reliance placed by the petitioner on the CVC guidelines is misplaced for the reason that they deal with a situation where

the decision making body may not have expertise in the matter. The AIIMS can hardly be said to be a body not having expertise to deal with the nature of medical equipments it seeks to purchase. The petitioner, thus, clearly failed to fulfil various clauses of the tender conditions and on such failure belatedly sought to challenge some of the conditions. In our considered view, there can be no doubt that the petitioner was rightly technically disqualified.

THE ALLEGATION OF THE PETITIONER OF NON-COMPLIANCE BY RESPONDENT NO.4 AND THE WARNING LETTER BY US FDA TO RESPONDENT NO.4

32. The petitioner not being successful in the tender itself, seeks to make allegations against respondent no.4 so that respondent no.4 is knocked out and a fresh tender process is initiated. One of the pleas raised is that of non-conformity of a condition of the tender by respondent no.4. This is regarding the requirement of a cycle temperature of 40-50⁰C while in case of respondent no.4 the cycle temperature of its instrument, as per brochure, is 55⁰C. The respondent

no.4 has explained that the cycle temperature of its product is stated to be less than 55°C in the brochure while the white paper provided by respondent no.4 with the tender clearly states that the cycle temperature of its sterilizer is reported to be less than 50°C. There is, thus, no mis-declaration in this case by respondent no.4.

33. Learned counsel for respondent nos.2 & 3 rightly pointed out that the scrutiny of the tender was still in progress when the petitioner approached this Court seeking to stall it. It is always open to respondent nos.2 & 3 to seek necessary clarifications in this behalf from respondent no.4. As far as the effect of Warning Letter is concerned, the additional affidavit filed by respondent no.4 lucidly explains the position. The powers of FDA were earlier explained which included the power to direct recall of the product or cancellation by the US FDA. Neither of the two things occurred in the present case. There was no recall, seizure or injunction by the US FDA, but on the other hand, the US FDA certificate continues to subsist in respect of

the product in question. The recall was with respect to the oil mist filter and that aspect is stated to have been corrected. The petitioner can, thus, hardly make a grievance in this behalf.

THE ALLEGATION OF RESPONDENT NO.4 QUA THE PETITIONER REGARDING A PAST TENDER

34. At the request of respondent no.4, the records of the tender no.1-13/H/M&E/09-10 were called for as it is the plea of respondent no.4 that the petitioner had even earlier made a false declaration. The bidders as per the terms and conditions of the tender had submitted IFUs of reputed device manufacturers. The petitioner while submitting the tender had given a letter of endorsement by Olympus Korea Company Limited. This letter of endorsement dated 26.08.2010 had been signed by Mr.C.S.Lee as Marketing Manager. The records of this tender show that respondent no.2 sought a clarification regarding the letter of endorsement by Olympus Korea Company Limited. On clarification being sought, respondent no.2 received a communication from Olympus Medical Systems India

Pvt. Limited to the effect that as per their Tokyo Office and Olympus Korea, no such letter had been issued and there was no Marketing Manager by the name of Mr.C.S.Lee in Olympus Korea office. A serious note was taken of this matter with a direction to further enquire into it. The notings in the file show that the allegations made qua the certification by a hospital in Ahmedabad about its user was not found to be correct, but no final picture could emerge about the certification from Olympus Korea as no direct communication was received from Japan. The tender itself was cancelled. We do feel that the matter should not have been put to rest only on the basis that the clarification of petitioner should be accepted of non-forgery of certificate as the tender was being cancelled. The local entity Olympus Medical Systems India Pvt. Ltd. had clarified that no such certificate was issued. This is stated to have been done on the basis of verification both from Japan and Korea. The matter needed to be investigated further. We consider it appropriate that respondent no.2/AIIMS should look

into the matter further to verify whether the certification submitted by the petitioner was fabricated as undoubtedly grave doubt has been cast on the same and this may impact any future dealing with the petitioner.

CONCLUSION

35. We are unequivocally of the view that the present writ petition filed by the petitioner is belated, the tender submitted by the petitioner was with wrong declarations and facts, the petitioner having been exposed, sought to challenge the terms and conditions of the tender to somehow prevent the award of the tender. The explanations forthcoming from the petitioner as to how he understood the terms and conditions of the tender are unacceptable in view of an earlier tender and the stand of the petitioner. The writ petition is a commercial adventurism by the petitioner to somehow delay the award of the tender. Also, the petitioner has not come with clean hands before this Court.

36. The writ petition is devoid of any merit whatsoever and is liable to be dismissed with actual costs as per the bill of costs and fees filed by the parties in view of what has been set out hereinabove and the conduct of the petitioner. The costs payable by the petitioner as per the bill of costs and fees is, thus, quantified at Rs.37,000/- to respondent nos.2 & 3 and Rs.14,65,339/- to respondent no.4. Ordered accordingly.

SANJAY KISHAN KAUL, J.

AUGUST 08, 2011
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RAJIV SHAKDHER, J.