



* IN THE HIGH COURT OF DELHI AT NEW DELHI

% Judgment reserved on: 11.12.2024

Judgment delivered on: 16.01.2025

+ W.P.(C) 17140/2024 & CM APPLs. 72771-72/2024

M/S HEMOGENOMICS PVT LTD

....Appellant

versus

UNION OF INDIA & ANR.

....Respondents

Advocates who appeared in this case:

For the Petitioner: Mr. Kirti Uppal, Sr. Advocate with Mr. Apoorv

Shukla, Mr. Puneet Chahar, Mr. Prabhleen A. Shukla, Mr. Vindhya Mohan Aggarwal and Ms.

Riya, Advocates.

For the Respondents: Mr. Vikram Jetly, CGSC with Ms. Shreya Jetly,

Advocate for R1.

Mr. Tarun Johri with Mr. Ankur Gupta and Mr.

Vishwajeet Tyagi, Advocates for R2.

CORAM:

HON'BLE THE ACTING CHIEF JUSTICE HON'BLE MR. JUSTICE TUSHAR RAO GEDELA

JUDGMENT

TUSHAR RAO GEDELA, J.

1. Present writ petition has been filed under Article 226 of the Constitution of India, 1950 assailing the decision of the respondent *vide*





order dated 25.11.2024 whereby the bid of the petitioner was rejected, and further seeking a direction to the respondents to consider the petitioner's bid.

- 2. The petitioner is a private limited company, *inter alia*, engaged in import of testing kits and its reagents which are used for testing/screening/detecting of Human Immunodeficiency Virus (HIV), Hepatitis B virus (HBV), and Hepatitis C virus (HCV) in the blood of the donors as well as confirming HIV/HBV/HCV antibody diagnosis (Testing Kits).
- 3. On 02.02.2024, respondent no.2/HLL Infra Tech Services Ltd. floated Tender No.HITES/PCD/AIIMS-II/106/2023-24 for the supply of Fully Integrated and Fully Automated Walk away compact Nucleic Acid Testing System, for the institutions getting upgraded under the Pradhan Mantri Swasthya Suraksha Yojna (PMSSY) for respondent no.1.
- 4. The petitioner claims to have submitted its bid against the said tender to respondent no.2 on 21.03.2024. Subsequently, certain amendments were carried out in the tender. Pursuant thereto, the petitioner re-submitted its bid on 02.04.2024, 13.04.2024 and 15.04.2024.
- 5. The petitioner claims to have received the Import License under the Medical Device Rules, 2017 on 26.03.2024, which was issued by the Central Drugs Standard Control Organization, Directorate General of Health Services, Ministry of Health & Family Welfare (Medical Device & Diagnostic Division) (hereafter *CDSCO*). As per the said license, site of the legal manufacturer and actual manufacturer is indicated as United States of





America and Switzerland, respectively.

- 6. Respondent no.2 by its email dated 16.05.2024 sought technical clarification from the petitioner, who responded *vide* its letter dated 17.05.2024. In answer to another clarification *vide* email dated 27.08.2024, sought in respect of commercial terms by the respondent no.2, the petitioner *vide* its communication dated 09.09.2024 clarified that the petitioner is not an agent of any other company. The petitioner claims that it had further clarified that its agreement with Grifols (HK) Limited would not violate any condition of the tender or the General Financial Rules, 2017 (hereafter the *GFRs*, 2017), since the said company is only a subsidiary of Grifols Diagnostics Solutions, USA. The petitioner states that despite such clarification, respondent no.2 rejected the bid of the petitioner *vide* impugned decision dated 25.11.2024 by merely stating "non-compliance of the land border clause no.5 mentioned in Qualification Criteria of Tender Document."
- 7. Aggrieved thereof, the petitioner issued a legal notice to respondent no.2 on 27.11.2024 against arbitrary and unilateral rejection of its tender application on the allegation of non-fulfillment of condition under Rule 144 (xi) of the GFRs, 2017. However, no response was received, constraining the petitioner to approach this Court.

CONTENTIONS OF THE PETITIONER:-

8. Mr. Kirti Uppal, learned senior counsel appearing for the petitioner submits that the impugned communication dated 25.11.2024 is arbitrary,





capricious and does not take into consideration the clarification submitted by the petitioner and ought to be quashed and as a consequence thereof, the bid of the petitioner should be considered by the respondents.

- 9. He states that the Import Licence dated 26.03.2024 issued to the petitioner under the Medical Devices Rules, 2017 by the CDSCO, categorically indicates the details of petitioner's overseas manufacturer and manufacturing site. As per the said Import Licence, the Legal Manufacturing Site is "M/s. Hologic Inc., 10210 Genetic Center Drive, San Diego, California-92121, United States of America" and the Actual Manufacturing Site is "M/s. Stratec Switzerland AG, Neuwiesenstrasse 4 8222 Beringen, Switzerland".
- 10. Learned senior counsel contended that petitioner's bid has been rejected for non-compliance of the land border restriction in Clause 5 of Section IX Qualification Criteria, in the subject tender document, which stipulates that any bidder from a country which shares land border with India will be eligible to bid in any procurement only if the bidder is registered with the Competent Authority, as specified in Annex I of order No.F.7/10/2021-PPD(1) dated 23.02.2023 and the bidder must comply with all provisions in the said order. He contends that the said Clause 5 could not have disqualified or disentitled the petitioner's bid for further consideration in the tender process since the legal manufacturing site at USA and the actual manufacturing site at Switzerland obviously do not share land border with India. In other words, the provisions of Clause 5 would not be





applicable.

- 11. Referring to the order dated 23.02.2023 of the Ministry of Finance, Department of Expenditure, Procurement Policy Division, in respect of Public Procurement No.4 and the restrictions under Rule 144 (xi) of the GFRs, 2017, he states that having regard to the fact that neither the manufactures are from a country which shares land border with India, nor the petitioner has a Specified Transfer of Technology (ToT) arrangement with an entity from a country, which shares land border with India, thus, the requirement of registration as per Clause nos.2 or 3 of the order dated 23.02.2023 would not be applicable to the case of the petitioner. It is thus contended that the rejection of the petitioner's bid on this ground is untenable in law.
- 12. He further submits that as per the terms of the tender, the petitioner approached Grifols Diagnostics Solutions, USA (hereafter *GDS*) to issue a Manufacturer's Authorisation to enable the petitioner to participate in the subject tender. It is contended that as GDS has offices in various countries for the administrative convenience, the Grifols (HK) Ltd. (subsidiary of GDS), being the nearest office situated in Hong Kong, had issued the Manufacturer's Authorization Form (hereafter *MAF*) as stipulated in Section XIV of the tender document. He emphasized that in the said MAF, it is clarified that Grifols (HK) Ltd. is not participating directly in the tender and have appointed the petitioner to supply and provide after sales service for their products. He further contended that the said authorization also





complied with the condition stipulated in Clause 15 of the General Conditions of Contract by extending full warranty and additionally confirmed that it would be responsible for the satisfactory execution of the contract.

13. Dilating further, learned senior counsel referred to the clarificatory letter dated 09.09.2024 of the petitioner to submit that it was categorically asserted that the bidder in the present case is the petitioner; that the petitioner is not a subsidiary of any other company; and importantly, the petitioner is not an agent of Grifols (HK) Ltd. He emphasized that the petitioner had entered into a Distribution Agreement with Grifols Diagnostic Solutions, USA on a Principal to Principal basis and not a Principal to Agent basis. He further submitted that in Para 3 of the said letter, it was further clarified that the petitioner is the bidder company incorporated in India and the products are manufactured either in USA or Switzerland, which do not share land border with India. He emphasized that Grifols (HK) Ltd. is a regional office of GDS and has been given authority to sign the MAF and the same is merely an administrative arrangement of the GDS which is based in USA. Thus, the prohibition in either Clause 5 of the tender document or Rule 144 (xi) of the GFRs, 2017 has not been violated by the petitioner, entailing rejection of its bid by the respondents. Thus, he prays that present petition be allowed.

CONTENTIONS OF THE RESPONDENT:-

14. Learned counsel appearing for the respondents stoutly opposed the





submissions of the petitioner. He straightaway invited the attention of this Court to the MAF submitted by Grifols (HK) Ltd. as stipulated in Section XIV of the tender document. He submits that the plain reading of the said MAF clearly discloses that Grifols (HK) Ltd. considers itself as a manufacturer and treats the petitioner as its agent. According to learned counsel, the fact that Grifols (HK) Ltd. (situated in Hong Kong) claims itself to be manufacturer and shares land border with India, would itself violate Clause 5 of the tender document. That apart, he emphasized that the meaning of the word "Bidder" as per Clause 12 of the Order (Public Procurement No.4) dated 23.02.2023, particularly sub clause (e) would cover an Indian agent of an entity which shares land border with India. Equally, he drew attention to the definition of "Agent" stipulated in Clause 14 of the said order, which also covers the case of the petitioner. He emphasises that Clause 5 of the tender document clearly indicates that the petitioner would have to comply with the Order (Public Procurement No.4) dated 23.02.2023 as also Rule 144 (xi) of the GFRs, 2017. Clearly, the petitioner had not complied with the said conditions.

15. So far as the clarificatory letter of the petitioner dated 09.09.2024 is concerned, learned counsel for the respondent submits that the contents are self-serving and contrary to the MAF and cannot be looked into for questioning the impugned rejection order. His contention is that the petitioner ought to have obtained such authorization letter from GDS (USA) and not Grifols (HK) Ltd. According to him, the clarificatory letter would





not come to the rescue of the petitioner. That apart, he laid emphasis on the fact that neither the Grifols (HK) Ltd., nor the petitioner is registered with the Competent Authority as specified in Annexure-I of the order dated 23.02.2023. Hence, the said non-registration would be violative of Clause 2 of the Order (Public Procurement No.4) dated 23.02.2023 and as such, the petitioner's bid was rightly disqualified from the bid process as non-responsive.

16. Learned counsel also relied upon the judgment of a Coordinate Bench of this Court in *Wipro GE Healthcare Pvt. Ltd vs. Union of India and Anr.*, *Neutral Citation No.2023:DHC:8487-DB* dated 29.11.2023, particularly para nos.17 & 18. He states that the present petition be dismissed with exemplary cost.

ANALYSIS AND CONCLUSION:-

- 17. The controversy in the present case revolves around the issues as to (i) whether the petitioner is an agent of Grifols (HK) Ltd. and; (ii) whether the petitioner has violated Clause 5 of the tender document and Rule 144 (xi) of the GFRs, 2017.
- 18. So far as the issue no.(i) is concerned, the stellar document is the MAF tendered by the Grifols (HK) Ltd. in compliance of conditions specified in Section XIV of the tender document. This Court principally relies upon this document since this was submitted by the petitioner along with its bid document and is a document of first instance. It would be apposite to reproduce the said MAF. The same is set out hereunder:





"Attachment I

<u>SECTION -XIV</u> <u>MANUFACTURER'S AUTHORISATION FORM</u>

The CEO
HLL Infra Tech Services Limited
Procurement and Consultancy Division
B-14 A, Sector -62, Noida -201307, Uttar Pradesh.

Dear Sir,

Ref: Tender Enquiry Document No: HITES/PCD/AIIMS-11/106/2023-24 Dated 02-02-2024

We GRIFOLS (HK) LIMITED who are proven and reputable manufacturers of Fully automated systems and reagent assay kits performing blood screening Nucleic Acid Testing for certain infectious diseases commercialized under the Procleix Trademark having factories at 10210 Genetic Center Drive, San Diego 91121 California (USA) do hereby authorize M/s HEMOGENOMICS PVT. LTD, having office at 3rd floor, Site no. 26, Opp. Indian Petrol Bunk, New BEL Road, Near M.S. Ramaiah. Hospital, Bangalore 560054, to submit a tender, process the same further and enter in to a contract with you against your requirement as contained in the above referred Tender documents for the above goods manufactured by us.

We also state that we are not participating directly in this tender for the following reason(s):

We have appointed M/s HEMOGENOMICS PVT. LTD to supply and provide after sales service for our products.

We further confirm that no supplier or firm or individual other than Messrs. HEMOGENOMICS PVT. LTD, having office at 3rd floor, Site no. 26, Opp. Indian Petrol Bunk, New BEL Road, Near M.S. Ramaiah Hospital, Bangalore 560054 is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.





We also hereby extend our full warranty, CMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorised agent.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly".

Yours faithfully For and on behalf of GRIFOLS (HK) LIMITED"

[Emphasis supplied]

It is manifest that the entire letter plainly establishes that Grifols (HK) Ltd. is projecting itself to be a reputed manufacturer of Fully Automated Systems and Reagent Assay Kits authorizing the petitioner to submit a tender, process the same and enter into a contract with the respondent for the goods manufactured by it. It also clearly admits of not participating directly in the tender and having appointed the petitioner to supply and provide after sales service of its products. The intention to treat the petitioner as its authorized agent is clearly specified and spelt out. Keeping the aforesaid in mind, it is clear that the clarificatory letter dated 09.09.2024, in effect, seeks to dilute the assertions made in the documents furnished with self-serving statements.

19. In the above backdrop, it is relevant to also consider the definition of "Bidder" as per Clause 12 and "Agent" as per Clause 14 of the Order





(Public Procurement No.4) dated 23.02.2023. The said Clauses 12 and 14 read thus:

- "12. "Bidder (or entity) from a country which shares a land border with India" for the purpose of the Order means
- (a) An entity incorporated, established or registered in such a country; or
- (b) A subsidiary of an entity incorporated, established or registered in such a country; or
- (c) An entity substantially controlled through entities incorporated, established or registered in such a country; or
- (d) An entity whose beneficial owner is situated in such a country; or
- (e) An Indian (or other) agent of such an entity; or
- (f) A natural person who is a citizen of such a country; or
- (g) A consortium or joint venture where any member of the consortium or joint venture falls under any of the above

13. ...

14. "Agent" for the purpose of the Order is a person employed to do any act for another, or to represent another in dealings with third persons.

[Note:

- i. A person who procures and supplies finished goods from an entity from a country which shares a land border with India will, regardless of the nature of his legal or commercial relationship with the producer of the goods, be deemed to be an Agent for the purpose of this Order.
- ii. However, a bidder who only procures raw material, components etc. from an entity from a country which shares a land border with India and then manufactures or converts them into other goods will not be treated as an Agent.]"

[Emphasis supplied]

A plain reading of sub-Clause (e) of Clause 12 clearly indicates that the petitioner has to be considered as an Indian agent of Grifols (HK) Ltd. since it shares land border with India. This coupled with the fact that the





petitioner is admittedly not registered as an Agent in terms of Clause 2 of order dated 23.02.2023, would clearly disentitle the petitioner from seeking consideration of its bid.

20. It is also relevant to note Clause nos.2 and 3 of the Order (Public Procurement No.4) dated 23.02.2023 which read thus:-

"Requirement of registration:

- 2. Any bidder from a country which shares a land border with India will be eligible to bid in any procurement whether of goods, services (including consultancy services and non-consultancy services) or works (including turnkey projects) only if the bidder is registered with the Competent Authority, specified in Annexure I.
- 3. Any bidder (including an Indian bidder) who has a Specified Transfer of Technology (ToT) arrangement with an entity from a country which shares a land border with India will be eligible to bid in any procurement whether of goods, services (including consultancy services and non-consultancy services) or works (including turnkey projects) only if the bidder is registered with the Competent Authority, specified in Annexure I."

It is not the petitioner's case that Grifols (HK) Ltd. is registered in terms of Clause 2 of the order dated 23.02.2023. In terms thereof, the restriction under Rule 144 (xi) of the GFRs, 2017 would disqualify the petitioner.

21. Apart from the above, the petitioner has not placed on record any document to show that Grifols (HK) Ltd. has an administrative arrangement with the Grifols Diagnostic Solutions (USA). Thus, we find no infirmity with the respondents giving credence to the contents of the MAF over the self-serving clarificatory letter dated 09.09.2024.





22. Interestingly, learned senior counsel for the petitioner had drawn attention of this Court to the affidavit dated 20.03.2024 submitted by the petitioner along with the tender documents in respect of the land border sharing declaration as stipulated under Restrictions under Rule 144 (xi) of the GFRs, 2017. It would be apposite to extract the said affidavit hereunder:

"PROFORMA 'B'

(On Non-Judicial Rs. 100/- Stamp paper duly Notarised)
AFFIDAVITE FOR LAND BORDER SHARING DECLARATION
(Reference: Restrictions under Rule 144 (xi) of the General financial Rule
(GFRs), 2017)

Date: 20-Mar-2024

Tender Ref. no. {Tender ID}: Tender Enquiry Document No: HITES/PCD/AIIMS-11/106/2023-24 Dated 02-02-2024

Name of the Tendered Item: Fully Integrated and Fully Automated Walk away compact Nucleic acid testing System Name of the Bidder: Hemogenomics Pvt. Ltd.

Quoted Model: Procleix Panther System and Procleix Ultrio Elite Assay

<u>Name & Address of Original Equipment Manufacturer of quoted model:</u> Grifols (HK) Limited

- (i) Actual Manufacturing Site: 10210 Genetic Center Drive, San Diego 91121 California (USA)
- (ii) Legal Manufacturing Site: 10210 Genetic Center Drive, San Diego 91121 California (USA)

It is hereby declared that in line with Order no. F.7 /10/2021-PPD (1) (Public Procurement No. 4) dated 23.02.2023 issued by MoF, Govt. of India regarding restrictions on procurement from a bidder of a country which shares a land border with India, We hereby confirm the following:

i) We Hemogenomics Pvt. Ltd (Name of the Bidder) have read the above





order and; I certify that our company (as a bidder) and the quoted item against the above tender:

is not from such country

□ if from such a country, has been registered with the Competent Authority (if applicable, registration from Competent Authority is to be enclosed).

I hereby certify that our company (as a bidder) fulfills all criteria of the above order {Order no.F.7/10/2021-PPD (1) (Public Procurement No.4) dated 23.02.2023} and is eligible to be considered.

ii) We have read the clause regarding restrictions on procurement from a bidder having Transfer of Technology (ToT) arrangement. I certify that we (as a bidder) and our quoted item against the above tender do not have any ToT arrangement requiring registration with the Competent Authority.

The information provided above are true and we understand that any deviation, if found, the procuring entity has right to initiate legal action against us including debarment/blacklisting.

Seal & Signature

Surendra Kumar Jain Assistant General Manager

Place & Date: Delhi, 20-03-2024"

[Emphasis supplied]

Intriguingly, though the affidavit of the petitioner claims to be in terms of the restriction under Rule 144 (xi) of the GFRs, 2017, yet, the name and address of the Original Equipment Manufacturer of the quoted model is stated to be Grifols (HK) Ltd. Despite the above, the affidavit goes on to depose that the quoted item is not from a country which shares land border with India. It appears that the declaration itself is misleading. When this





affidavit is read in conjunction with the MAF, it is clear that the respondent's view that the petitioner has violated the condition as set out in Clause 5 of the tender document read with restriction under Rule 144 (xi) of the GFRs, 2017 warrants no interference in these proceedings. Undoubtedly, the affidavit itself declares that Grifols (HK) Ltd. is the manufacturer. The company, Grifols (HK) Ltd. is located in Hong Kong, part of mainland China, and shares land border with India.

- 23. In view of the above, we are of the firm and considered opinion that the petitioner has rightly been disqualified by the respondent in terms of Clause 5 of the tender document read with restriction under Rule 144 (xi) of the GFRs, 2017 as mentioned in Order (Public Procurement No.4) dated 23.02.2023.
- 24. Learned counsel for the respondent relied upon *Wipro GE Healthcare Pvt. Ltd.*(*supra*), wherein the Court had, in similar set of facts, held that the petitioner therein was having one of its manufacturing sites in China, thus, was required to be registered as per Clause 2 of the order dated 23.02.2023. The relevant paras of the said judgement are extracted hereunder:-
 - "17. Further contention of the petitioner that Indian Equipment Manufacturer is its wholly owned subsidiary i.e., Wipro GE Medical Device Manufacturing Pvt. Ltd. having manufacturing facility at Bangalore and there is certificate issued by Atomic Energy Regulatory Board in favour of Wipro GE Medical Device Manufacturing Pvt. Ltd and CE certificate was given by it at the time of submission of its bid from GE Hangwei Medical Systems Co. Ltd. was only to show conformity of a medical device and same does not show manufacturing by a bidder from





a country which shares land border with India.

18. A bare perusal of the CE certificate as well as the documentary audit dated 14.02.2022 submitted by the petitioner with its bid document shows the manufacturer is GE Hangwei Medical Systems Co. Ltd., China, a Chinese company. Further perusal of Certificates dated 22.03.2023 and Certificate of Conformity also show Bangalore site alleged by the Petitioner as manufacturing site of its wholly owned subsidiary Wipro GE Medical Device Manufacturing Pvt. Ltd., is in fact one of the manufacturing sites of GE Hangwei Medical Systems Co. Ltd., China. Even in the affidavit dated 10.07.2023 petitioner mentions the actual manufacturing site for quoted model Revolution maxima 128 Slice CT as GE Hangwei Medical Systems Co. Ltd., China. Thus, the bid of petitioner was not in line with OM dated 23.02.2023. The status of petitioner could at best be of an agent requiring registration under Clause 2 of above OM but admittedly there is no registration furnished as per Clause 2. Admittedly, the petitioner participated in the tender with the above requirements mentioned in the email dated 30.06.2023, hence it is now not open to petitioner to object to said requirement of seeking an affidavit in terms of the OM dated 23.02.2023 vide email dated 30.06.2023."

- 25. Accordingly, this Court also concurs with the view of the learned Coordinate Bench in *Wipro GE Healthcare Pvt. Ltd.* (supra).
- 26. In view of the aforesaid, we do not find any merit in the present petition and the same is, accordingly, dismissed.
- 27. Pending application, if any, also stand disposed of.

TUSHAR RAO GEDELA, J

VIBHU BAKHRU, ACJ

JANUARY 16, 2025/*rl*