IN THE HIGH COURT OF JUDICATURE AT CALCUTTA

CIVIL APPELLATE JURISDICTION

APPELLATE SIDE

RESERVED ON: 11.05.2023
DELIVERED ON:19.05.2023

CORAM:

THE HON'BLE MR. CHIEF JUSTICE T.S. SIVAGNANAM

AND

THE HON'BLE MR. JUSTICE HIRANMAY BHATTACHARYYA

MAT NO. 669 OF 2023

(I.A. NO. CAN 01 OF 2023)

WITH

MAT NO. 296 OF 2023

(I.A. NO. CAN 01 OF 2023)

M/S. SAFECARE RUBBER PRODUCTS PRIVATE LIMITED AND ANOTHER

VERSUS

THE STATE OF WEST BENGAL AND OTHERS

Appearance:-
Mr. Pradip Kumar Tarafder, Advocate.
Mr. Sambuddha Dutta, Advocate.

...For the Appellants

Mr. Debasish Ghosh, Advocate.
Ms. Debraj Sahu, Advocate.

...For the State

JUDGMENT

(Judgment of the Court was delivered by T.S. SIVAGNANAM, CJ.)

1. Both these intra-Court appeals have been filed by the writ petitioner, MAT No. 296 of 2023 is against an interim order passed in the writ petition on 6th February, 2023 and MAT No. 669 of 2023 is challenging the order dated 21st March, 2023 by which writ petition was dismissed. The appellant filed the writ petition challenging a notice issued by the respondent, the Health Services Department of West Bengal dated 09.12.2022 and the email communication dated 15.12.2022 pertaining to the notice of e-tender for procurement of gloves by the Department. The petitioner also sought for issuance of a writ of mandamus to forbear the respondents from giving effect to the circular dated 30th September, 2022 issued by the Drug Controller General of India issuing certain guidelines with regard to the license to be obtained from the Central Licensing Authority or the State Licensing Authority.

2. The first appellant is a company registered under the Companies Act having its registered office at Cochin, Kerala State and the second respondent is its Director. The appellant company is engaged in the manufacture of latex surgical gloves which fall under Class B Medical Devices that is low moderate risk category. The Medical Devices Rules, 2017 was notified on 31st January, 2017. In terms of Rule 8 of the said Rules, the State Dugs Controller shall be the State Licensing Authority designated as the competent authority for enforcement of the 2017 Rules, inter alia, in relation to manufacture for sale and distribution of Class A or Class B medical devices. By notification dated 11th February, 2020, the Ministry of

Health and Family Welfare Department notified the Medical Devices Amendment Rules, 2020 and Rule 19 A was inserted. In terms of Sub-rule (1) of Rule 19A Chapter IIIA captioned "Registration of Certain Medical Devices" was made applicable to all devices notified under Clause b of Section 3 of the Act except the medical devices and devices specified in the annexure of the each schedule of the said Rules. In terms of Sub-rule (2), the medical devices referred in Sub-rule (1) shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Association for this purpose. The proviso states that the registration under Chapter IIIA shall be of voluntary basis for a period of 18 months from the commencement of the said Chapter and thereafter it shall be mandatory as specified in the proviso contained in second column of the Serial No. 7 as inserted by the Rule 3 of the 2020 Amendment which states that such exemption shall cease after a period of 30 months for low risk Class A and low moderate risk Class B and after a period of 42 months for moderate high risk Class C and high risk Class D devices respectively from the date of the notification of the Rules. During August-September, 2022 various associations and stakeholders submitted representations with the Central Drugs Control Organization requesting not to disrupt the business operations of the manufacturers and suppliers. By circular dated 30th September, 2022 published on 20:41:38 hours, it was made known that if an existing importer/manufacturer is already importing/manufacturing any Class A or Class B medical devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30th September, 2022, as the case may be, for grant

of import/manufacturing license in respect of the said devices under the provisions of the 2017 Rules, the said application shall be deemed valid and the importer/manufacturer can continue to import/manufacture the said devices upto 6 months from the date of issue of the circular or till the time the Central Licensing Authority or State Licensing Authority, as the case may be, takes a decision on the said application, whichever is earlier. The appellant's case is that the circular was published around 8:41 P.M. on 30th September, 2022 and the appellant was left with only about 3 hours 19 minutes before midnight of 30th September, 2022 to comply with the requirement which was thoroughly inadequate. The appellant had to prepare all documents which were necessary for filing the application thereafter to fill up the form in Form No. MD-3 and thereafter upload the application in digital format in the online system and this took considerable length of time and the appellant filed an application Class B for latex surgical gloves on 31st October, 2022 and remitted the requisite fee of Rs. 5500/-.

3. The Health Services Department of West Bengal issued notice inviting e-tender for procurement of gloves for years from the date of award of contract by notification dated 14th November, 2022 and a corrigendum was issued on 22.11.2022. The appellant participated in the tender process and submitted their bid documents. On 9th December, 2022 the Deputy Director of Health Services, Central Medical Stores, West Bengal issued a notice in respect of shortfall/findings through the technical bid evaluations, inter alia, requesting bidders to submit their justification with the necessary comments through email, against the shortfall/findings found by the

Evaluation Committee within 4 P.M. of 19th December, 2022. The name of the appellant company featured in the said list wherein it has been stated "MD-5/M-3 not submitted. Apply for MD-5 in MD-3 after 30.09.2022". The appellant would further state that they submitted their justification on 12.12.2022 to the Deputy Secretary of Health Services Department stating that the appellant has already applied for the license in Form MD-3 and the same is under process and license would be issued shortly in favour of the appellant. On 15th December, 2022 by email the Central Medical Stores informed the appellant that as per CDSCO order dated 30.09.2022 the manufacturer has to apply in "MD-3 on or before 30.09.2022. She/he has applied on 30.09.2022 or before can continue the business for 6 months so you must submit the same". On 19.12.2022 the appellant submitted representation that they have already submitted Form MD-3 and the same is being processed and requested to delete the remark of shortfall. Further, the appellant would state that the time stipulated in the circular issued by the Drug Controller is thoroughly inadequate and the same cannot be a condition precedent for not considering the bid document submitted by the appellant. Therefore, the appellant would contend that the condition imposed in the circular is an unreasonable condition denying the appellant a meaningful opportunity to comply with the conditions imposed in the circular. The circular gives illegal and undue benefit to some of the bidders who have filed the application within the time period of 30.09.2022 and the same is arbitrary. Further, it is submitted that the respondent Department acted in violation of Article 14 of the Constitution of India inasmuch as a similarly placed person namely, Vijayalakshmi Health and Surgicals Pvt.

Ltd., though their technical bid was evaluated and shortfall was pointed out, stating that MD-5 or MD-3 not submitted, in the final evaluation the technical bid was found to be acceptable and the financial bid was directed to be opened whereas the appellant being similarly placed was held to not satisfy the requirement under the circular and, therefore, their technical bid was rejected by decision dated 10th January, 2023. On the same day a communication was sent by email to the appellant that the tender has been rejected during technical evaluation by the duly constituted committee and the reason for rejection was also furnished. It is submitted that in the said communication it has been stated that in case of any clarification or feedback, the appellant may contact the Tender Inviting Authority (TIA). The appellant had intimated by email dated 16.01.2023 about the filing of the writ petition before this Court and with utmost haste on 17.01.2023, two of the bidders were selected and work was awarded to them. Thus, the respondent department not only waived and relaxed the conditions in favour of one of the bidders, acted with undue haste and mala fides can be presumed on account of such hastive action. In support of such contention the learned Advocate appearing for the appellant placed reliance on the decision of the Hon'ble Supreme Court in ***W. B. Electricity Board Versus Patel Engineering Co. Ltd. Ors.[1], Bhadursinh Lakhubhai Gohil Versus Jagdishbhai M. Kamalia and Ors.[2], Inderpreet Singh Kahlon and***

[1](2001) 2 SCC 451
[2](2004) 2 SCC 65

Others Versus State of Punjab and Ors.[3] and ***State of Haryana and Anr. Versus Narendra Soni and Ors.***[4]

4. The learned Advocate appearing for the respondent State of West Bengal submitted that since the appellant did not qualify in the technical bid inasmuch as they did not comply with the license condition prior to the cut off date in terms of the circular issued by the Government of India, the technical bid was rightly rejected and, thereafter the financial bid of the other qualified bidders were examined and the work orders have been issued in favour of two of the bidders by proceedings dated 17th January, 2023. It is submitted that the circular issued by the Drugs Controller General of India dated 30th September, 2022 is binding on the State Government and a go-by cannot be given to the said circular. That apart, there was no prohibitory order granted in the writ petition and, therefore, the respondent authorities were entitled to proceed with the tender evaluation and the same was done in accordance with the conditions in the notification and the successful bidders have been awarded the tender. With this submission the learned advocate prayed for dismissal of these appeals.

5. We have heard Mr. Pradip Kumer Tarafder, learned Advocate appearing for the appellant assisted by Mr. Sambudhha Dutta, Advocate and Mr. Debasish Ghosh and Mr. Debraj Sahu, learned Advocates appearing for the Authorities for State of West Bengal.

6. The first aspect which we propose to deal is with regard to the submission of the learned Counsel for the appellant that the action of

[3](2006) 11 SCC 356
[4] (2017) 14 SCC642

rejecting the technical bid of the appellant and accepting the technical bid of Vijayalakshmi Health and Surgicals Pvt. Ltd. is arbitrary and discriminatory. When the technical bids were open, the evaluation committee have published the shortfall/findings with regard to each of the bids. In respect of the appellant, the findings of the evaluation committee were to the effect "MD-5/ M-3 not submitted. Apply for MD-5 in MD-3 after 30.09.2022". In respect of Vijayalakshmi Health and Surgicals Pvt. Ltd., the findings of the evaluation committee were "MD-5 or MD-3 not submitted".

7. After receiving the response from all the 23 bidders, the Evaluation Committee took up for consideration each of the submissions and in so far as the appellant the remarks were "*rejected due to MD-5/3 not submitted. The bidder sent communication through email on 30.12.2022 that they applied in MD 3 on 31.10.2022 i.e. after the stipulated date of 30.09.2022 (as per CDSCO guidelines)*". In so far as Vijayalakshmi Health and Surgicals Private Limited, the remarks recorded by the Evaluation Committee was "*financial bid may be opened*". Thus, the findings of the Evaluation Committee was clearly communicated to the appellant after taking note of their response to the earlier communication and after noting that the appellant had applied in MD 3 only on 31.10.2022 i.e. after the date stipulated in the circular dated 30.09.2022 issued by the Central Government. So far as Vijayalakshmi Health and Surgicals Private Limited, the Evaluation Committee found the technical bid to be acceptable and therefore recommended for opening of the financial bid. In the writ petition, the appellant has not impleaded Vijayalakshmi Health and Surgicals Private Limited nor any specific plea of discrimination has been raised in the writ

petition and the plea of discrimination is raised for the first time during the course of argument which cannot be accepted. In any event, the appellant having not fulfilled the conditions as stipulated in circular issued by the Central Government cannot be heard to say that there has been discrimination between them and Vijayalakshmi Health and Surgicals Private Limited. Therefore, the argument that there has been discrimination and arbitrariness on this ground deserves to be rejected and accordingly stands rejected.

8. The appellant had challenged the circular issued by the Central Government dated 30.09.2022 for better appreciation, the circular is quoted hereunder:-

F. No. 29/Misc/03/2022-DC (257)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

FDA Bhawan, New Delhi
Dated the 30th September, 2022

CIRCULAR

Subject: Regulation of all Class A & B Medical Devices under Licensing regime, w.e.f 01.10.2022, as per G.S.R. 102(E) dt 11.02.2020 - Regarding.

The Ministry of Health & Family Welfare (MoHFW) has published notification vide S.O. 648 (E) dated 11.02.2020 specifying all medical devices under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940, which is effective from 01.04 2020.

In order to regulate all the medical devices, MoHFW has published G.S.R. 102 (E) dated 11.02.2020 for regulation of such devices in phase wise manner. As per the said notification the Class A & B medical devices will be under licensing regime from 01.10.2022.

In the meantime, representations from various Associations and Stakeholders have been received by this office, requesting that the business continuity should not be disrupted due to the implementation of licensing regime w.e.f. 01.10.2022 for Class A & B medical devices.

In view of the above, it has been decided that, in case, if an existing importer/ manufacturer who is already importing / manufacturing any of Class A or Class B Medical Devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30.09.2022, as the case may be, for grant of import / manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/ manufacturer can continue to import / manufacture the said device(s) up to 6 months from the date of issue of this order or till the time, the Central Licensing Authority or State Licensing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

Digitally Signed by Dr. V.G. Somani
Date: 30-09-2022 20:41:38
Reason: Approved
(Dr. V. G. Somani)
Drugs Controller General (I)

To
All Stakeholders/Associations
Copy to:
1. All State Drugs Controllers.

2. All Zonal/Sub-Zonal offices of CDSCO

3. All Port offices.

9. In terms of the said circular, it was made known to all the stakeholders and associations that the Ministry of Health and Family Welfare has published notification dated 11.02.2020 specifying all the medical devices under the sub clause(IV) of Clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 effective from 01.04.2020. Further it was informed that in order to regulate all medical devices, the Ministry of Health and Family Welfare has published the notification dated 11.02.2020 for regulation of devices in phase wise manner and as per the said notification, the class (A)

and (B) medical devices will be under licensing regime from 01.10.2022. The Government of India took note of the representations from various associations and stakeholders requesting that the business continuity should not be disrupted due to the implementation of the licensing regime with effect from 01.10.2022 for class A and B medical devices. Taking note of the said representation, the Government of India decided that in case an existing importer/manufacturer who is already importing/manufacturing in class A or class B medical devices, has submitted application to Central Licensing Authority or State Licensing Authority on or before 30.09.2022 for grant of import/manufacturing licenses in respect of the said devices, the said applications shall be deemed valid and the importer/manufacturer can continue to import/manufacture the said devices up to 6 months from the date of issue of the circular dated 30.09.2022 or till the time the Central Licensing Authority or the State Licensing Authority, as the case may be, takes a decision on the said application whichever is earlier.

10. The arguments of the learned advocate appearing for the appellant is that the circular was uploaded only about 8:40 PM on 30.09.2022 and there was less than four hours time within which it is impossible to upload the application in the digital format and the circular is liable to be struck down. The learned single bench noting that there was a challenge to the circular directed notice to be issued to the Union of India which order was not complied with but an appeal was preferred against the order in MAT No. 296 of 2023.Subsequently as and when the writ petition was listed, it appears that the appellant sought for adjournment on the grounds that MAT No. 296 of 2023 was pending and the learned writ court having found that the notice

has not been served on the Union of India dismissed the writ petition against which MAT No. 669 of 2023 has been filed.

11. Firstly, we need to see as to whether the interpretation given by the appellant to the circular is correct. The appellant cannot dispute that the Ministry of Health and Family Welfare published notification dated 11.02.2020 specifying all medical devices under Section 3(b)(IV) of the Drugs and Cosmetics Act, 1940 to be effective from 01.04.2020. Subsequently, the notification dated 11.02.2020 was issued for regulation of such devices in phase wise manner and as per the said notification, the class A and B medical devices will be under licensing regime from 01.10.2022. Thus, the notification published on 11.02.2020 had informed all the stakeholders and associations that the licensing regime for Class A and B medical devices will be effective. Therefore, the appellant cannot be heard to say that the period of more than two and a half years was insufficient for them to apply for the license. Subsequently, representations were given stating that on account of such conditions, the continuity of the business should not be disrupted. This representation was considered and an order in the nature of relaxation was issued by circular dated 30.09.2022 mandating that if an existing manufacturer has submitted his application for grant of license on or before 30.09.2022, the said application shall be deemed to be valid and the manufacturer can continue to manufacture the devices up to six months from the date of issue of the circular dated 30.09.2022 or till the licensing authority takes a decision on the said application, whichever is earlier. Therefore, if the appellant was a vigilant manufacturer nothing prevented the appellant to apply for the license within the stipulated time as the

appellant was made/deemed to have been made known that class A and B medical devices will be under the licensing regime was from 01.10.2022. This was made known by regulation published on 11.02.2022. Therefore, the argument that there was less than four hours was left for the appellant to upload the application is an argument which deserves to be outrightly rejected. In any event, we find there is no arbitrariness or illegality in the circular issued by the Central Government dated 30.09.2022.The products manufactured by the appellant, surgical gloves is admittedly a medical device falling under class B. There is no fundamental right for the appellant to claim that without registration/license, he should be permitted to continue his manufacturing activities. The Ministry of Health and Family Welfare is fully empowered under the Drugs and Cosmetics Act to specify the medical devices which requires compulsory license. Therefore, the plea that there was arbitrary exercised of power or the circular was unreasonable etc. are devoid of substance and stands rejected.

12. The next submission of the learned advocate for the appellant was that the respondent had acted in undue haste, their action was a jerk reaction and if the action was done with undue haste, malafides could be presumed. For the said submission, reliance was placed on the decision of the Hon'ble Supreme Court in ***Bahadursinh Lakhubhai Gohil***, ***Indrapeet Singh Kahlon and Others***, ***Narendra Soni and Others***. The argument of the undue haste is based upon the email received by the appellant on 10.01.2023. To be noted that on 10.01.2023, the decision of the Evaluation Committee rejecting the bid of the appellant and the other bidders was uploaded. The email sent by the Tender Inviting Authority on 10.01.2023

informs the appellant about the rejection of the technical bid along with the reasons for rejection. In the said email, it has been stated "*in case of any clarification or feedback, you may conduct Tender Inviting Authority (TIA)*". The appellant would submit that on 16.01.2023, they had intimated about the filing of the writ petition and also furnish a scanned copy of the writ petition along with the annexures and forwarded the same to all the respondents and on 17.01.2023, yet the work order has been issued to the two successful bidders. This, according to the appellant is a knee jerk reaction.

13. Firstly, the email received on 10.01.2023 is an auto generated mail from the e-procurement system and the appellant was advised not to reply to the said email ID. The communication was intimating the rejection of the technical bid of the appellant. On 16.01.2023, the email was sent stating that the writ petition has been filed and it is likely to appear on 19.01.2023, however it is seen that the writ petition was heard on 06.02.2023 wherein the learned writ court has recorded that the facts submitted on behalf of the writ petitioner do not entitle the writ petitioners to any interim relief. However, noting that there has been a challenge to the circular of the Central Government, notice to the 7th respondent was directed to be taken and the matter was directed to be listed in the second week of March 2023. Challenging this order dated 06.02.2023, MAT No.296 of 2023 was filed. Thus, much before the writ petition could be heard for any interim relief, the work order has been issued. The auto generated email dated 10.01.2023 is only an intimation of the reasons for rejection of the appellant's technical bid and the evaluation of the financial bid of the other eligible bidders was

under taken and two of the bidders were awarded the contract and notice in this regard was issued on 16.01.2023. We find that there is absolutely no material to establish any undue haste in the matter. More so when there was no order interdicting the Tender Inviting Authority from proceeding further with the evaluation of the financial bid of the bidders whose technical bid was found acceptable. Therefore, we are of the view that there has been no undue haste and no malafides can be presumed. In any event, there is no specific plea of malafide pleaded in the writ petition and merely using the word "malafide" cannot brand the action of the official respondents as being malafide.

14. One more faint plea was raised with regard to the relaxation of a rule or a condition in the tender and it was submitted that such relaxation granted in favour of the Vijayalakshmi Health and Surgicals Private Limited was illegal. To support such contention, the decision of the Hon'ble Supreme Court in ***Patel Engineering Company Limited and Others*** was referred. As pointed out earlier, Vijayalakshmi Health and Surgicals Private Limited have not been impleaded as respondent in the writ petition. There is no specific allegation of any alleged relaxation or waiver of tender conditions granted in favour of the said entity. Thus, based on presumptions, we cannot arrive at a conclusion that there has been any relaxation. We having found that the action of the respondents in rejecting the technical bid of the appellant to be fully justified and the appellant having not come within the zone of consideration of their financial bid cannot maintain a challenge to the award of the tender in favour of the third parties. Thus, the appellant has not made out any case for interfering with the tender process or the

award of contract in favour of the third parties who were not impleaded in the respondents in the writ petition. Thus, the writ petition being devoid of merits is liable to be dismissed.

15. In the result, the appeals and the writ petitions are dismissed for the reasons set out by us in the preceding paragraphs. No costs.

(T.S. SIVAGNANAM, CJ.)

I Agree.

(HIRANMAY BHATTACHARYYA, J.)

(P.A- PRAMITA/SACHIN)

High Court
सत्यमेव जयते
Calcutta