

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated : 20.02.201
Orders Reserved on 13.02.2019
Orders Delivered on 20.02.2019

CORAM

THE HONOURABLE MR.JUSTICE K.RAVICHANDRABAABU

W.P.No.27911 of 2018
and
W.M.P.Nos.32463 and 32465 of 2018

M/s.ZEE Laboratories,
47, Gondpur Industrial Area,
Paonta Sahib 173025,
District:Sirmour,
Himachal Pradesh. ...Petitioner

Vs.

Tamil Nadu Medical Services
Corporation Ltd.,
No.417, Pantheon Road,
IInd Floor, Egmore,
Chennai 600 008,
Rep. by its General Manager. ...Respondent

PRAYER: Writ Petition filed under Article 226 of the
Constitution of India for issuance of a Writ of Certiorari
to call for the records relating to the impugned order in
Ref.No.DIC056/TNMSC/QC/2016-17 dated 12.12.2017 passed by
the respondent herein and to quash the same.

For Petitioner : Mr.P.Subramanian

For Respondent : Mr.V.M.Shivakumar

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O R D E R

The petitioner is aggrieved against the order of the
respondent dated 12.12.2017, wherein and whereby, the
petitioner was blacklisted for a period of 5 years from
11.12.2017 to 10.12.2022 for the supply of spurious drugs
"Risperidone" Tablets USP 2 mg (D.Code No.529) and further
by forfeiting the security deposit paid by the petitioner
for the year 2015-2016, amounting to Rs.10,88,923/-.

2.The case of the petitioner is as follows:

The petitioner Firm is carrying on Pharmaceuticals business for the past more than 20 years. The petitioner firm was awarded with contract for the supply of the drug namely, "Risperidone tablets USP 2 Mg (D.Code:529)" for the year 2015-2016, pursuant to the tender notification issued by the respondent. The respondent placed orders with the petitioner Company to supply the said medicine and the petitioner firm has supplied the same. The total number of batches of the subject matter medicine supplied by the petitioner firm is 12. The petitioner firm was served with a show cause notice dated 02.05.2017, calling for explanation alleging that the sample does not conform to USP specification and that the sample is deemed to be spurious, since it is substituted by another drug, which is not claimed on the label. The petitioner submitted their explanation on 19.05.2017. The Government Analyst was alleged to have reported that the subject matter tablets Batch No.415-1282, Manufacturing date 10.01.2015, expiry date -09-2017, as not of standard quality. The Drug Inspector, Chennai, upon Inspection on 24.11.2016, informed the petitioner about the report alleged to have been given by the Government Analyst. The petitioner did not agree with the alleged test report of the Government Analyst, as the petitioner firm has challenged by reanalysing the sample by the Appellate Laboratory, viz., Central Drugs Laboratory (CDL), Kolkata for the test for content of "Risperidone" under section 25(3) of the Drugs and Costumes Act, 1940 and accordingly, requested the respondents to await for the outcome of the reanalysis by the said Appellate Laboratory before taking the final decision. Suddenly, without any further notice, the respondent issued the impugned order. The State Drug Controller of Himachal Pradesh had already imposed a punishment of suspension of permission to manufacture for the sale and distribution of the subject matter drug for a period of 180 days from 20.02.2017. Therefore, the impugned order dated 12.12.2017 is in violation of law and amounts to doubly jeopardy.

3. A counter affidavit is filed by the respondent, wherein it is stated as follows:

The respondent is a Nodal Agency for procurement and distribution of drugs, etc., for about 11,000 Government medical institutions all over Tamilnadu. The respondent has been following the provisions of the Tenders Act and has been following the two cover system viz., Cover A and Cover B viz., Technical bid and price bid respectively. Clause 20 of the terms and conditions of the tender deals with blacklisting for quality failure. Clause 20.2.2(c) empowers the respondent to blacklist the Company/firm for a

period of five years, if a single batch of product supplied by the Company/firm declared as adulterated/spurious/misbranded by the Government Authorities during the shelf life of the product supplied, irrespective of tender period. After observing the procedure laid down in the paragraph No.20.2.4, which deals with the procedure for blacklisting, the Drug Inspector, Villivakkam, Chennai, has tested the subject matter drug, supplied by the petitioner to the respondent, and found the same to be spurious. A show cause notice was issued and an explanation was called for from the petitioner. No response has been received from the petitioner for such grave defect. Hence, a reminder letter dated 02.05.2017 was issued to the petitioner. The petitioner responded belatedly on 19.05.2017 stating that they have independently tested the sample in their possession and that the test report was contrary to the report of the Government Analyst. The respondent had enquired about the sample with the Drugs Inspector, Villivakkam, Chennai, who had confirmed that the sample has been sent to the Central Drug Laboratory for reanalysis. Further, the Drugs Inspector provided copy of the Analytical Report in Form 2 bearing Ref.No.2-1/2017-SS/CC-21/2738 of Director in charge, Central Drug Laboratory, Kolkata, which indicates that the sample does not conform to USP with respect to the test for identification and ASSAY/content of Risperidone. The Central Drug Laboratory has also stated that the sample is found to contain Ondansetron and the sample is deemed to be spurious under Section 17-B of the Drugs and Cosmetics Act and Rules. The admission by the petitioner that the State Drug Controller of Himachal Pradesh had already imposed punishment of suspension of permission to manufacture or sale and distribution of the subject matter drug for a period of 180 days, would clearly show that the product of the petitioner has not complied with the quality standards prescribed in the Drugs and Cosmetics Act, 1940. The petitioner has not challenged the report of the Director in charge, Central Drug Laboratory, Kolkata and hence, they are estopped from making contrary averments in the present writ petition. The tender condition under clause 20.2.1 (g) clearly provides that the report of the Government Analyst is final and binding on the tenderer.

4. Mr.P.Subramaniam, learned counsel for the petitioner submitted as follows:

Under Section 25(3) of the Drugs and Cosmetics Act, 1940, the petitioner is entitled to adduce contra evidence against the analyst report. The petitioner made a request on 10.12.2016 for reanalysing from the Appellate Laboratory, CDL, Kolkata for the "Test for Content of

Respiridrone". The said request was not considered. However, it is seen that the said Kolkata Lab has tested the sample just ten days before its expiry. Therefore, such testing is not valid. Consequently, the report submitted by the Central Lab, Kolkata, is also not valid and therefore, based on such report, the impugned order cannot be passed. In support of his contention, the learned counsel relied on the following case laws:

i) (2008) 7 SCC 196, Medicamen Biotech Limited vs. Rubina Bose,

Drug Inspector;

ii) CDJ 2010 MHC 2534, M/s.Pondy Chemicals, rep. by its Managing

Partner vs. The State rep. by N.Gunasekaran;

iii) CDJ 2016 SC 446, M/s.Northern Minerals Ltd., vs Rajasthan Government;

iv) 1981 3 SCC 131, M/s.North Bihar Agency vs State of Bihar;

v) 2015 (4) MLJ (Cri) 56, Embiotic Laboratories (P) Ltd. vs. State of Tamilnadu;

vi) CDJ 2010 MHC 6951, M/s.Unicure (India) Pvt. Ltd. vs State rep. by M.N.Sridhar, Drugs Inspector;

vii) 1982-Criminal Law Journal 2285, Drug Inspectors vs. M/s.Modern Drugs.

5. Per contra, the learned counsel appearing for the respondent contended that when the respondent is only the Nodal Agency for procurement of the drugs and when they imposed the impugned punishment only as per the terms and conditions of the contract between the parties, based on the report submitted by the competent Laboratory, the petitioner is not entitled to question the impugned punishment, when they have admittedly allowed the report submitted by the said Laboratory to become final, conclusive and binding, as, admittedly, the petitioner has not challenged the said report in a manner known to law so far. Therefore, he submitted that the case laws relied on by the petitioner's counsel, all touching upon the manner in which the testing has to be done, are not applicable to the facts and circumstances of the present issue pending before this Court.

6. Heard both sides.

7. The petitioner is aggrieved against the order of blacklisting them for a period of five years and also forfeiting the security deposit. Admittedly, the respondent is a nodal agency for procurement and distribution of drugs, etc., for the Government institutions all over Tamilnadu. For procuring and distributing the drugs, etc., the respondent floats tender. There is no dispute to the fact that the one of the terms and conditions of the tender, more particularly, clause 20.2.1 to 4 deal with blacklisting for quality failure.

8. Clause 20.2.2(c) stipulates as follows:

"20.2.2

...(c) If a single batch of any product (s) supplied by the company/firm declared as Adulterated/Spurious/Misbranded by the Government Authorities during the shelf life of the product supplied irrespective of tender period, the company/firm shall be blacklisted for a period 5 years from the date of intimation after observing procedure laid down in Para 20.2.4."

9. Clause 20.2.4 deals with the procedure for blacklisting, which reads as follows:

"PROCEDURE FOR BLACKLISTING

(i) On receipt of report from Govt. Analyst/Drug Testing Laboratory indicating that a particular item/Drug is "NOT OF STANDARD QUALITY/ADULTERATED/SPURIOUS/MISBRANDED (As the case may be), a show cause notice shall be issued to the supplier calling for explanation within 7 days from the date of notice. On receipt of explanation from the supplier, the Managing Director, TNMSC may take appropriate action on merits of the case and impose penalty including the blacklisting of the particular of the particular item of the product/company or firm as deemed fit besides forfeiture of security deposit.

(ii) If a particular item of the drug has been blacklisted according to the procedure stated above, the supplier is not eligible to participate in any of the tenders for that particular item floated by the TNMSC until the period of blacklisting is over.

(iii) If a supplier company/firm is

blacklisted according to the procedure stated above, such supplier is not eligible to participate in any of the tenders floated by the TNMSC until the period of blacklisting is over."

10. Thus, from the perusal of the above said clauses dealing with the blacklisting of a particular item or the product or the company or the firm, it is evident that, if a particular item of the drug has been found or declared as adulterated or spurious by the competent Government Authorities during the shelf life of the product, the respondent is entitled to blacklist the particular Company/firm for a period of five years. Here, in this case, the facts narrated above would disclose that the Appellate Laboratory at Kolkata has also found the subject matter drug as spurious and that the said finding rendered by the Appellate Laboratory has not been questioned by the petitioner so far. Under such circumstances, I failed to understand as to how the petitioner is justified in challenging only the consequential action viz., blacklisting the petitioner, leaving the main report of the Appellate Laboratory unchallenged.

11. Even otherwise, it is seen that clause 22, which deals with resolution of dispute between the parties contemplates that a dispute or difference arising between the respondent and the supplier relating to any matter arising out of or connected with the agreement shall be settled in accordance with the Arbitration and Conciliation Act, 1996. Therefore, it is apparent that the dispute between the parties arising out of the impugned order is a matter to be resolved in accordance with the Arbitration and Conciliation Act, 1996 and not by resorting to filing a writ petition, as has been done in this case. Even otherwise, as rightly pointed out by the learned counsel for the respondent, the petitioner has not questioned the final report submitted by Central Drugs Laboratory, Kolkata so far, which states that the sample does not conform to USP with respect to the test for identification and ASSAY/content of Risperidone and that the sample is deemed to be spurious under Section 17-B of the Drugs and Cosmetics Rules. So long as the said report issued by the Central Drug Laboratory, Kolkata, is not questioned by the petitioner and it is also admitted by them that they already suffered a punishment of non production for 180 days at the hands of State Drug Controller, Himachal Pradesh, I do not think that the petitioner is entitled to maintain the present writ petition challenging the impugned punishment. However, as I have already pointed out that there is an arbitration clause, it is for the petitioner to

work out their remedy by resorting to arbitral proceedings.

12. In view of the above stated facts and circumstances, I am of the view that the decisions relied on by the learned counsel for the petitioner, which are admittedly dealing with the issue as to how the test has to be conducted, will not come to rescue of the petitioner for considering the present issue, since the challenge before this Court is not against the test report but on the other hand, it is against the punishment imposed by the respondent based on such test report, which is not questioned so far. Accordingly, the writ petition is disposed of by granting liberty to the petitioner to agitate the matter by way of arbitral proceedings. No costs. The connected miscellaneous petitions are closed.

Sd/-

Assistant Registrar(CS)

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Sub Assistant Registrar

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To
The General Manager,
Tamil Nadu Medical Services
Corporation Ltd.,
No.417, Pantheon Road,
IInd Floor, Egmore,
Chennai 600 008,

+1cc to Mr.V.M.Shivakumar , Advocate SR.No. 15632
+1cc to Mr.P.Subramanian , Advocate SR.No. 15312

W.P.No.27911 of 2018

A.SK(07/03/2019)

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