

IN THE HIGH COURT OF JUDICATURE AT MADRAS

Dated : 23.09.2020

C O R A M

The Hon'ble Mr. A.P.SAHI, THE CHIEF JUSTICE
and
The Hon'ble Mr. Justice SENTHILKUMAR RAMAMOORTHY

W.A.No.593 of 2020
and
CMP.No.8303 of 2020

1. The Chairman
Tamil Nadu Medical Services Corporation Ltd.,
Board cum Principal Secretary,
Department of Health and Family Welfare
Government of Tamil Nadu,
Chennai-600 008. ...1st Appellant/2nd Respondent
2. Tamil Nadu Medical Services Corporation Ltd.,
(A Government of Tamilnadu Undertaking)
Rep. by its Managing Director,
No.147, Pantheon Road,
II Floor, Egmore,
Chennai-600 008. ... 2nd Appellant/3rd Respondent
3. The General Manager (Drugs)
Tamil Nadu Medical Services Corporation Ltd.,
No.147, Pantheon Road,
II Floor, Egmore,
Chennai-600 008. ...3rd Appellant/4th Respondent

..vs..

1. M/s.Jackson Laboratories Private Limited
A Private Limited Company registered under the
Provisions of the Companies Act, 1956
Represented by its Managing Director
Mr.Jugal Kishore
22-24 Majitha Road, Bye Pass
P.O.Khanna Nagar, Amritsar 143 004.
.. 1st Respondent/Petitioner
2. The Secretary to Government,
Health and Family Welfare (H2) Department,
Secretariat,
Chennai-600 009. ... 2nd Respondent/1st Respondent

PRAYER : Writ Appeal is filed under Clause 15 of Letters Patent, to set aside the order dated 28.02.2020 in W.P.No.25770 of 2019 and allow this appeal.

WP No.25770 o 2019 and WMP No.25218 of 2019:

Prayer: Petition filed under article 226 of the Constitution of India praying to issue a Writ of certiorari calling for the records on the file of the 1st respondent in issuing letter No.46953/H2/2017-16 dated 26/06/2019 and quash same.

For Appellants : Mr. V.M.Shivakumar
for M/s.Shivakumar
and Mr.Suresh

For Respondents : Mr.P.Ramesh Kumar

JUDGMENT

SENTHILKUMAR RAMAMOORTHY J.,

The subject matter of this writ appeal is the order of black listing dated 12.12.2017 whereby the first Respondent herein was black listed for a period of five years from 05.12.2017 to 04.12.2022 for the supply of a spurious drug, namely, specific batches of Carbimazole tablets I.P. 5 mg. The Appellant is the Tamil Nadu Medical Services Corporation Limited which issued the blacklisting order.

2. The facts and circumstances related to the filing of this appeal are as follows. The Appellants are a Government of Tamil Nadu undertaking which is engaged in the procurement and supply of drugs and medical equipment to Government Hospitals in the State of Tamil Nadu. Pursuant to purchase orders issued to the first Respondent herein, the first Respondent supplied Carbimazole Tablets I.P. 5 mg. during the period 2016 - 2017. Upon testing, the Appellants found that specific batches of the aforesaid tablets were not of standard quality. Therefore, a show cause notice dated 02.08.2017 was issued to the first Respondent. By the show cause notice, the first Respondent was informed that, as regards Batch No.T-12701, a survey sample was drawn by the Central Drugs Inspector and by testing the said survey sample, it was reported that the drug is of spurious quality by the Central Drugs Testing Laboratory. Consequently, a statutory sample was taken from the same batch and the report thereon was awaited as of the date of the show cause notice. The first Respondent was informed that, as per Clause 20.2.1(e) (iii) and 20.2.1(f) of the tender condition 2016-17, if the

sample fails in the quality test for ASSAY content of less than 50% as per the Government Analyst report and if three batches of a particular drug that are supplied by the supplier are reported to fail in the ASSAY content test, the product of the tenderer would be blacklisted for for two years. Accordingly, in terms of clause 20.2.4(i) of tender 2016-17, the first Respondent was called upon to show cause as to why action should not be initiated to blacklist the product as being not of 'standard quality'.

3. In addition, by the same show cause notice, the first Respondent was informed that upon receipt of the report from the Central Drug Testing Laboratory, if it is found that the drug is reported to be a spurious quality, the first Respondent would be liable to be blacklisted as per clause 20.2.1(f) & 20.2.2(c) of the tender conditions for a period of five years. Therefore, the first Respondent was called upon to provide an explanation within 7 days. By reply dated 18.08.2017, the first Respondent stated that the Joint Investigation Report shows that it is of standard quality. The Appellants were informed that these drugs were tested before acceptance and found to be of standard quality, and that it may have deteriorated later because it is a sensitive drug, which is required to be stored at a temperature below 30 degrees Celsius, and, consequently, if the said temperature is not maintained, the drug would deteriorate. The Appellants were requested to decide the case on merits by considering this explanation and also provide a personal hearing.

4. Thereafter, the analytical report dated 11.08.2017 was received from the Central Drugs Laboratory, Kolkatta, stating that the sample does not conform to I.P. with respect to identification and Assay of Carbimazole and that the sample is deemed to be spurious under Section 17B of the Drugs and Cosmetics Act, 1940 (the Drugs Act). By relying upon the aforesaid analytical report, the Appellants issued orders dated 07.12.2017 and 12.12.2017 whereby it was communicated that the first Respondent is blacklisted for a period of five years namely, from 05.08.2017 to 04.08.2022 for the supply of the spurious drug Carbimazole Tablets IP 5 mg (D.Code:270) as per the tender condition 20.2.2.(c) (2016-17) and for forfeiture of the security deposit. An appeal was filed against the blacklisting order dated 12.12.2017 before the Chairman, TNMSC Board, cum Principal Secretary, Department of Health and Family Welfare, Government of Tamil Nadu. The orders of blacklisting were also challenged by the first Respondent in W.P. Nos.34182 and 34186 of 2018 and these writ petitions were disposed of by directing that the appeal be disposed of within four weeks.

5. Pursuant thereto, the appeal was rejected by order dated 26.06.2019, wherein it was held that the order of blacklisting

was in accordance with the tender conditions. Consequently, the Health and Family Welfare Department through its Secretary upheld the order of the Appellants herein with regard to blacklisting of the first Respondent. This order dated 26.06.2019 was challenged in W.P. No.25770 of 2019, wherein the first Respondent had prayed for a Writ of Certiorari to quash the said order of the first Respondent therein. The aforesaid writ petition was partly allowed by order dated 28.02.2020, whereby the learned single Judge upheld the blacklisting of the product for a period of two years but set aside the blacklisting of the company for a period of five years. This order is impugned in this appeal.

6. We heard Mr.Shivakumar, the learned counsel for the Appellants, and Mr.P.Rameshkumar, the learned counsel for the first Respondent/Petitioner.

7. Mr. Shivakumar contended that the Appellant is a public sector undertaking engaged in the procurement of drugs and medical equipments for supply to Government hospitals in Tamil Nadu. It floated a tender for the procurement of Carbimazole Tablets IP 5 mg. and, as the successful bidder, purchase orders were issued to the first Respondent for the year 2016-2017. The tender conditions provided for blacklisting of both the product and the company. He submitted that the said blacklisting is required to be effected upon receipt of a report from the Government Analyst/Drug Testing Laboratory indicating that a particular drug is not of standard quality/adulterated/spurious/misbranded, if the explanation provided pursuant to a show cause notice is found to be unsatisfactory.

8. In the case at hand, the admitted position is that a show cause notice dated 02.08.2017 was issued to the first Respondent upon discovering that specific batches of Carbimazole Tablets supplied by the first Respondent were not of standard quality. In the said show cause notice, the first Respondent was specifically put on notice that a statutory sample had been sent to the Central Drug Testing Laboratory and that if it is reported by the said laboratory that the drug is of spurious quality, the first Respondent would be blacklisted for a period of five years. He further submitted that a reply was given by the first Respondent on 18.08.2017 to the said show cause notice. Accordingly, he contended that the principles of natural justice were adhered to before issuing the blacklisting order on 07.12.2017 and 12.12.2017.

9. He further submitted that as a public sector tendering authority, the Appellants are bound to take action in accordance with the tender conditions, especially because it is a matter

concerning public health. His next contention was that the learned single Judge examined the relevant documents, including the show cause notice, the reply thereto, and concluded that the principles of natural justice were duly complied with. In particular, he referred to paragraph 32, wherein the learned single Judge recorded that a personal hearing had been provided on 02.04.2019. The learned Judge also noted that the Appellate Authority concluded that the first Respondent was obligated to comply with and failed to comply with tender conditions and that, therefore, there is no merit in the appeal. He also pointed out that the learned Judge accepted the fact that an administrative order should not be interfered with unless there is a procedural violation.

10. After having concluded that the process of blacklisting complied with legal requirements in that regard, he contended that the learned single Judge should not have interfered with the blacklisting order. He further submitted that the learned Judge set aside the blacklisting of the first Respondent on the basis of the report from the Central Drug Laboratory, Kolkata to the effect that the drugs were not of spurious quality. This report was not provided to the Appellants by the first Respondent. Therefore, he submitted that the impugned order is liable to be set aside insofar as it set aside the order of blacklisting of the first Respondent for a period of five years.

11. On the contrary, the learned counsel for the first Respondent, Mr.P.Ramesh Kumar, submitted that the show cause notice dated 02.08.2017 pertains to the proposed blacklisting of the product for a period of two years. With regard to the testing of the statutory sample by the Central Drug Testing Laboratory, he contended that the first Respondent was merely put on notice about a possibility and that the said statement does not amount to a show cause notice for the purpose of blacklisting the company for five years. His next contention was that the drugs supplied by the first Respondent were of standard quality and that each batch was tested by the Appellants before acceptance. In spite of such testing and acceptance, the Appellants subsequently came to the conclusion that the drugs are not of standard quality because of poor storage conditions. In specific, his contention is that these drugs are required to be stored at a temperature less than 30 degree Celsius, whereas the Appellants did not maintain the requisite temperature at its storage warehouse and, therefore, the drugs may have deteriorated. He also contended that the impugned order with regard to the blacklisting of the drug had not been challenged by him and that the period of blacklisting was from 05.08.2017 to 04.08.2022 and that, out of the blacklisting period, almost three years have passed. For all

these reasons, he submitted that the impugned order is not liable to be interfered with.

12. We considered the submissions of the learned counsel for the respective parties and examined the materials on record.

13. The tender conditions specify as follows:
BLACKLISTING FOR QUALITY FAILURE

20.2.1 Quality Test by the Empanelled Laboratories of TNMSC

(f) If 3 batches of a particular drug supplied by the supplier is reported to be failing in ASSAY content (above 50% but below prescribed limit) and/or other parameters, then the particular drug of the firm shall be blacklisted after observing procedure laid down in Para 20.2.4 besides forfeiture of Security Deposit of that particular product(s).

(g) In all the cases the reports received from the Government Drug Testing Laboratory/decision of TNMSC Ltd will be conclusive and final and binding on the suppliers.

20.2.2 Quality Test by Statutory Authorities

(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 of 5 years from the date of intimation after observing procedure laid down in Para 20.2.4.

20.2.4. PROCEDURE FOR BLACKLISTING

(i) On receipt of report from Govt. Analyst/Drug Testing Laboratory indicating that a particular Drug is "Not of STANDARD QUALITY/ADULTERATED/SPURIOUS/MIS-BRANDED (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 drug of the product/company or firm as deemed fit besides forfeiture of security deposit."

In addition, we find that Section 18 of the Drugs Act prohibits the manufacture and sale of a drug which is not of standard quality, or is misbranded, adulterated or spurious.

14. The facts should be examined against this contractual and legal context. We find that the show cause notice dated 02.08.2017 draws reference to and even extracts the aforesaid clause, which empowers blacklisting of the company for 5 years, and calls upon the first Respondent to provide an explanation within 7 days as per the tender stipulation in this regard. Pursuant thereto, the first Respondent provided a response by reply dated 18.08.2017. Meanwhile, the analytical report dated 11.08.2017 was received from the Government Analyst of the Central Drug Laboratory, Government of India stating that the sample does not conform to I.P. with respect to identification and Assay of Carbimazole and that the sample is deemed to be spurious under Section 17B of the Drugs Act.

15. Upon receipt of the said report, the Appellants issued the order of blacklisting by following the tender conditions in that regard. The first Respondent carried the matter in appeal before the Health and Family Welfare Department. In the said appeal, a personal hearing was admittedly provided to the first Respondent and the records were examined before concluding that the first Respondent is bound by the tender conditions and that, therefore, no case is made out to interfere with the order of blacklisting.

16. The said appellate order dated 26.06.2019 was challenged in the writ petition. Upon considering the materials on record and the rival contentions, the learned single Judge recorded as follows:

"32. A perusal of the impugned order shows that a personal hearing had been afforded on 02.04.2019 and thereafter, the records had been perused and thereafter, holding that the petitioner had accepted the tender conditions, and had failed to supply drugs to the satisfaction of the quality control of the Central Drugs Laboratory, the appeal was dismissed. This order has been challenged in the present Writ Petition. It is trite to point out that a decision taken in an Administrative Order, can be rarely examined by the Court unless there is a procedural violation.

36. It is seen that one of the results showed that the drugs were spurious in nature. It was tested again. It was then held to be not of standard quality. The drugs were also tested at Central Laboratory, Kolkata, which again gave a result that the drugs were not of standard quality. Two show cause notices were issued to the petitioner. Personal hearing also granted to the petitioner. In the first instance, the petitioner did not take up the opportunity to attend personal hearing,

claiming that he could not travel from Punjab to Chennai. However, the impugned order contains the explanations which have been considered and only thereafter, the order blacklisting the petitioner had been passed.

17. Thereafter, the learned single Judge also took note of the limited scope for judicial review in such matters by referring to judgments of the Hon'ble Supreme Court. However, in paragraph 38, the learned Judge interfered with the order of blacklisting of the Company by relying upon a report of the Central Drug Laboratory, Kolkata, which is stated to have superseded previous reports. As correctly contended by Mr. Shivakumar, on judicial review, this Court is primarily concerned with the decision making process and does not sit in appeal over the decision. In this case, there are categorical findings by the learned single Judge that the decision making process does not suffer from infirmity. It is also pertinent to bear in mind that the Appellant is a drug procurement agency of the Government of Tamil Nadu and is bound to act in accordance with the tender conditions, including in respect of blacklisting. Therefore, in our view, the order of the learned single Judge to the extent of setting aside the blacklisting is not sustainable.

18. Nevertheless, blacklisting has severe civil consequences as held in a long line of judgments beginning from Erusian Equipment and Chemicals Ltd. v. State of W.B. (1975) 1 SCC 70. In a later judgment in Kulja Industries Ltd. v. Western Telecom Project BSNL, (2014) 14 SCC 740, the Supreme Court recognised that the power to blacklist is available to the State, as employer, even de hors a contractual clause subject to the power of judicial review not only on the principles of natural justice but also proportionality. After holding as under in paragraphs 17 and 25, the matter was remitted to the authority for reconsideration:

17. That apart, the power to blacklist a contractor whether the contract be for supply of material or equipment or for the execution of any other work whatsoever is in our opinion inherent in the party allotting the contract. There is no need for any such power being specifically conferred by statute or reserved by contractor. That is because "blacklisting" simply signifies a business decision by which the party affected by the breach decides not to enter into any contractual relationship with the party committing the breach. Between two private parties the right to take any such decision is

absolute and untrammelled by any constraints whatsoever. The freedom to contract or not to contract is unqualified in the case of private parties. But any such decision is subject to judicial review when the same is taken by the State or any of its instrumentalities. This implies that any such decision will be open to scrutiny not only on the touchstone of the principles of natural justice but also on the doctrine of proportionality. A fair hearing to the party being blacklisted thus becomes an essential precondition for a proper exercise of the power and a valid order of blacklisting made pursuant thereto. The order itself being reasonable, fair and proportionate to the gravity of the offence is similarly examinable by a writ court.

25. Suffice it to say that "debarment" is recognised and often used as an effective method for disciplining deviant suppliers/contractors who may have committed acts of omission and commission or frauds including misrepresentations, falsification of records and other breaches of the regulations under which such contracts were allotted. What is notable is that the "debarment" is never permanent and the period of debarment would invariably depend upon the nature of the offence committed by the erring contractor.

In *Liberty Oil Mills v. Union of India*, (1984) 3 SCC 465, the Supreme Court discussed situations, such as interim orders or emergencies, where it may not be possible to provide a pre-decisional hearing and a post-decisional hearing would satisfy the requirements of natural justice. In a more recent judgment related to blacklisting under the Drugs Act, the Supreme Court in *Medipol Pharmaceutical India Pvt. Ltd. v. Post Graduate Institute of Medical Research* [2020 SCC Online SC 638] recognized the resort to a post-decisional hearing on the basis of an appellate test lab report although, on the facts of the case, the Court concluded that the post-decisional hearing was an eye-wash.

19. In the case at hand, we find that the learned Judge has relied upon a report from the Central Drugs Laboratory, Kolkata, which is stated to have concluded that the drugs were not spurious. The learned counsel for the Appellants contended that

this report was not made available by the first Respondent to the Appellants. Keeping in mind the above fact and also taking into consideration the fact that the product ban has run its course, and almost three years have passed since the order of blacklisting, we are of the view that a post-decisional hearing by the Appellants with regard to the continuation of blacklisting is warranted in the interest of justice.

20. Accordingly, we permit the first Respondent to submit a representation to the Appellants within two weeks from the date of receipt of a web copy of this judgment requesting for reconsideration of the order of blacklisting of the first Respondent in light of the subsequent developments, including subsequent reports from the Central Drugs Laboratory, Kolkata and other material factors, if any. Upon receipt of such representation, the Appellants are directed to consider the same on merits and pass orders thereon within a period of four weeks from the date of receipt of the said representation.

21. Thus, the order of the learned single Judge is set aside insofar as the quashing of the order of blacklisting of the first Respondent for a period of five years is concerned and the Writ Appeal is disposed of with the above directions. There shall be no order as to costs. Consequently, connected miscellaneous petition is closed.

Sd/-

Assistant Registrar

//True Copy//

Sub Assistant Registrar

To

1. The Secretary to Government,
Health and Family Welfare (H2) Department,
Secretariat, Chennai-600 009.
2. The Chairman
Tamil Nadu Medical Services Corporation Ltd.,
Board cum Principal Secretary,
Department of Health and Family Welfare
Government of Tamil Nadu,
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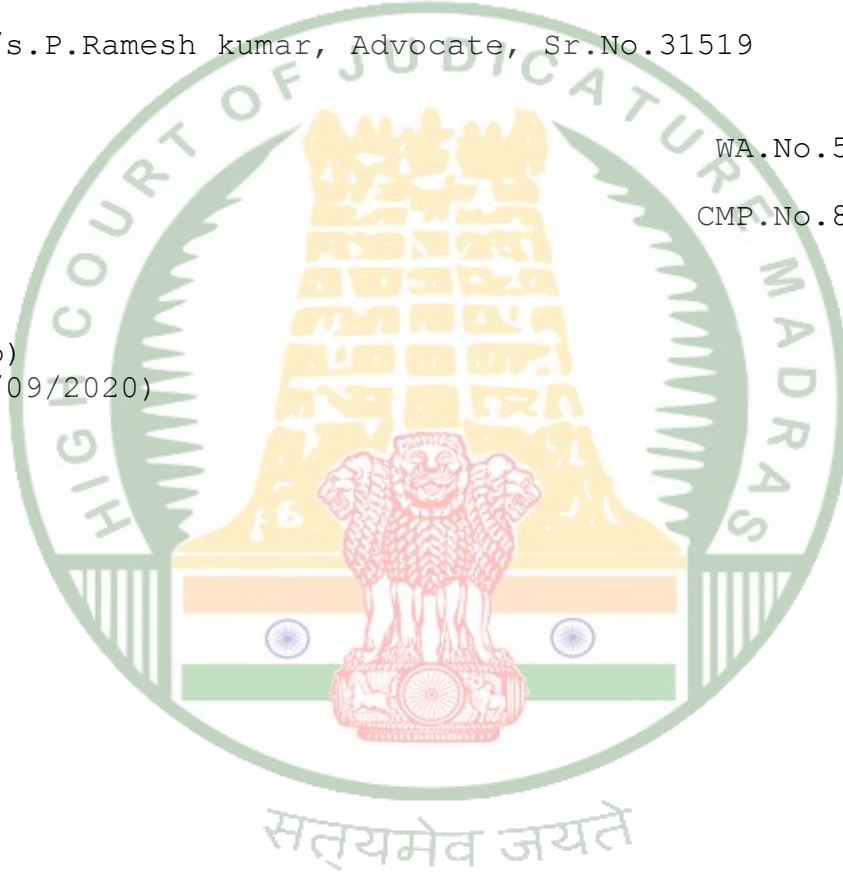
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+1cc to M/s.P.Ramesh kumar, Advocate, Sr.No.31519

WA.No.593 of 2020
&
CMP.No.8303 of 2020

vsn ii (co)
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