



BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

DATED: 22.06.2017

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THE HON'BLE MR.JUSTICE P.N.PRAKASHCrl.O.P.(MD) No.6938 of 2017 and
Crl.M.P.(MD) Nos.4682 & 4683 of 2017

1. M/s.Haseeb Pharmaceuticals Pvt. Ltd.,
Plot No.F-9/15, MIDC, Nagpur-440 016,
Rep. by its Managing Director
Thiru.Yusuf Safi Badar (Age 62 years)
F/N: Safi Shaikh Abde Badar.
2. Thiru.Yusuf Safi Badar
F/N: Safi Shaikh Abde Badar,
Managing Director of
M/s.Haseeb Pharmaceuticals Pvt. Ltd.,
Plot No.F-9/15, MIDC, Nagpur-440 016 ... Petitioners/A1 & A2

-vs-

State represented by
Senior Drugs Inspector i/c,
Tirunelveli Zone,
O/o.Assistant Director of Drugs Control,
Tirunelveli Zone,
C-36, 25th Cross Street, Maharaja Nagar,
Tirunelveli-11. ... Respondent/Complainant

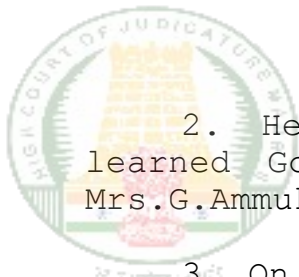
Prayer: Petition filed under Section 482 of Code of Criminal Procedure to call for the records in STC No.1305 of 2014 pending in the Honourable Court of Judicial Magistrate, Tenkasi and quash the same and pass such further or other orders and thereby render justice.

For Petitioners : Mr.T.D.Selvan Babu
For Respondent : Mr.K.Anbarasan
Govt. Advocate (Crl.Side)

Reserved on	Pronounced on
16.06.2017	22.06.2017

ORDER

This petition has been filed to call for the records in STC No.1305 of 2014 on the file of Judicial Magistrate, Tenkasi and quash the same.
<https://hcservices.ecourts.gov.in/hcservices/>



2. Heard the learned counsel for the petitioners and the learned Government Advocate (Crl.Side) appearing for the State. Mrs.G.Ammukutty, Senior Drugs Inspector was present.

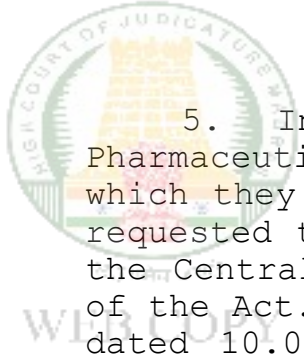
3. On 15.04.2013, the Senior Drugs Inspector, Tirunelveli Zone visited the store of the Government Head Quarters Hospital, Tenkasi and lifted a sample of the drug **Compound Sodium Lactate (Ringer Lactate Solution for injuection) Injection** in accordance with the provisions of the Drugs and Cosmetics Act, 1940 (in short "the Act") andn one sample was sent for analysis in Form 18 to the Government Analyst (Drugs Special), Kings Institute, Guindy, Chennai. The test report dated 30.09.2013 given by the Government Analyst showed that the sample was not of standard quality. It may be necessary to extract the operative portion of the report as under:

"In the opinion of the undersigned, the sample referred to above is not of standard quality as defined in the Drugs and Cosmetics Act, 1940 and rules thereunder:

REPORT: The sample does not conform to the requirement for Sterility. The sample is not of standard quality."

4. The Assistant Director of Drugs, Tirunelveli issued a show cause notice dated 09.01.2014 to M/s.Haseeb Pharmaceuticals Pvt. Ltd., enclosing a copy of the test analysis report and also calling upon them to give the following particulars under Section 18-B of the Act:

1. Certified Xerox copy of the drug licenses held by the firm.
2. Names, Age Father's Name and residential address of the partners/Directors of the firm.
3. Total Quantity of the subject drug manufactured.
4. Distribution details.
5. Certified Xerox copy of the Batch Manufacturing Record for the subject drug.
6. Certified Xerox copy of the analytical report for the raw material and finished products of the subject drug.
7. Certified Xerox copy of the in-process Control Register for the manufacture of the subject drug.
8. Certified Xerox copy of the raw materials record for the manufacture of
9. Certified Xerox copy of the test report of the packing materials for manufacture of the subject drug.
10. Certified Xerox copy of the Master Formula record for the manufacture of subject drug.
11. Certified Xerox copy of the stability studies any conducted in respect of the drug.
12. The person incharge and responsible for the day to day contact of the business.
13. Certified copy of Article of memorandum and association."



5. In response to the show cause notice, M/s.Haseeb Pharmaceuticals Pvt. Ltd., sent a reply letter dated 17.01.2014, in which they repudiated the test report of the Government Analyst and requested the authorities to send the sample for further testing to the Central Drug Laboratory as per the provisions of Section 25(4) of the Act. M/s.Haseeb Pharmaceuticals Pvt. Ltd., also sent a letter dated 10.02.2014 to the Senior Drugs Inspector stating that they have not received the second sample as required under Section 23(4) (iii) of the Act. As regards the demand of the authorities to furnish particulars under Section 18-B of the Act, M/s.Haseeb Pharmaceuticals Pvt. Ltd., took the following stand in their letter dated 10.02.2014:

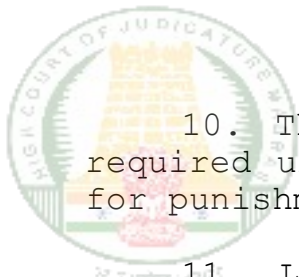
"We will provide you with all the particulars/documents as instructed to us in your letter dt.09/01/2014 once the sealed portion of the subjected drug is and subsequent report of retesting is received and it is established that the report is of the product manufactured by us."

6. Pending the request of M/s.Haseeb Pharmaceuticals Pvt. Ltd. for sending the sample to the Central Drug Laboratory for re-testing, the Senior Drugs Inspector filed a complaint in STC No.1305 of 2014 before the Judicial Magistrate, Tenkasi for the offences under Section 32 r/w Section 36-A of the Drugs and Cosmetics Act, 1940 for the contravention under Section 18(a)(i) and Section 18-B, which is punishable under Section 27(d) and Section 28-A of the said Act against M/s.Haseeb Pharmaceuticals Pvt. Ltd. and its Managing Director Yusuf Safi Badar, challenging which, both the accused are before this Court.

7. Learned counsel for the petitioners submitted that pursuant to the request made by the petitioners to send the second sample to the Central Drug Laboratory, the same was sent and the test report dated 04.02.2015 shows that the sample conforms to IP with respect to the test for "Sterility". Therefore, he submitted that the entire prosecution should be quashed inasmuch as under Section 25(4) of the Act, the report of the Central Drug Laboratory shall be a conclusive evidence of the facts stated therein.

8. This Court perused the report and the learned Government Advocate (Crl.Side), on instructions from Mrs.G.Ammukutty, Senior Drugs Inspector fairly conceded this aspect.

9. As rightly pointed out by the learned counsel for the petitioners, the report of the Central Drug Laboratory supersedes the report of the State Laboratory. In this case, the report of the Central Drug Laboratory states that the sample conforms to IP with respect to the test for "Sterility" and therefore, the petitioners cannot be prosecuted for the offence under Section 27(d) of the Act. Hence, the prosecution of the petitioners for the offence under Section 27(d) of the Act is hereby quashed.



10. The petitioners are bound to provide the particulars as required under Section 18-B of the Act, for which, they are liable for punishment under Section 28-A of the said Act.

11. Learned counsel for the petitioners submitted that the petitioners are ready and willing to submit all the particulars as required under Section 18-B of the Act to the Drugs Authorities. In the opinion of this Court, it is too late in the day for this Court to accept the offer, especially in the light of the fact that a complaint has been filed and the Court has also taken cognizance of the offences. Therefore, the petitioners shall appear before the Trial Court and furnish all the particulars sought for by the Drugs Authorities to the Magistrate and to the Drugs Authorities, because, the petitioners are supplying very important drugs to the Government Hospitals in Tamil Nadu and therefore, the authorities should have the details for their record purpose.

12. If the petitioners submit the particulars required under Section 18-B of the Act, that can be a mitigating circumstance for giving a lesser sentence to the petitioners in the event of their conviction by the Trial Court.

13. In the result, this petition is partly allowed and the prosecution of the petitioners in STC No.1305 of 2014 on the file of Judicial Magistrate, Tenkasi is hereby quashed only in respect of the offence under Section 27(d) of the Act alone. Consequently, connected miscellaneous petitions are closed.

Sd/-

Assistant Registrar (CS-II)

/True Copy/

Sub Assistant Registrar

To:

1. The Judicial Magistrate, Tenkasi.
2. The Senior Drugs Inspector i/c,
Tirunelveli Zone,
O/o.Assistant Director of Drugs Control,
Tirunelveli Zone,
C-36, 25th Cross Street, Maharaja Nagar,
Tirunelveli-11.
3. The Additional Public Prosecutor
Madurai Bench of Madras High Court, Madurai.

+ 1 CC TO Mr.R.PON KARTHIKEYAN, ADVOCATE IN SR No. 61492

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TE/KP/SAR-IV : 06/07/2017 : 4P/5C

ORDER IN

CrI.O.P.(MD)No.6938 of 2017 and

CrI.M.P.(MD) Nos.4682 & 4683 of 2017

22.06.2017