IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 04.01.2022

CORAM

THE HON'BLE MR.JUSTICE N.SATHISH KUMAR

Crl.O.P.No.29180 of 2017 and
Crl.M.P.Nos.16499 & 16500 of 2017

1. M/s.Hemant Surgicals India Ltd.,
Rep. by its Managing Director
Mr.Hanskumar Shah, No.647, Avijah Building,
6 & 7, Ground Floor, Girgaum Road,
Mumbai – 400 002.

2. Mr.Hanskumar Shah
Managing Director,
M/s.Hemant Surgicals India,
647, Avijah Building,
6 & 7, Ground Floor, Girgaum Road,
Mumbai – 400 002. ... Petitioners

Vs

The Drugs Inspector,
Coimbatore Range – I,
Office of the Assistant
Director of Drugs Control,
219, Race Course Road,
Coimbatore – 641 018. ... Respondent

PRAYER: Criminal Original Petition filed under Section 482 of Criminal Procedure Code, to call for the records in S.T.C.No.2708 of 2015 on the file of the learned Judicial Magistrate No.II, Coimbatore and quash the same.

For Petitioners : Mr.C.A.Diwakar

For Respondent : Mr.R.Kishore Kumar,
Government Advocate(Criminal Side)

O R D E R

This petition has been filed to quash the proceedings in S.T.C.No.2708 of 2015 on the file of the learned Judicial Magistrate No.II, Coimbatore filed against the petitioners for the offences punishable under Section 18(b) r/w Section 17(b) of the Drugs and Cosmetics Act, 1940 read with Rule 96(1)(xii) of the Drugs and Cosmetics Rules, 1945 for having imported stock for sale and distributed the misbranded drug JMS for single use infusion set sterile.

2. The allegation in the complaint is that while inspecting the first respondent firm it is found that they had stocked JMS for single use infusion set sterile and the sample is misbranded since it has not been properly labeled in the prescribed manner. The sample of the infusion set was taken on 06.02.2014 and sent to the Government analyst and the report is also received. Thereafter, show cause notice was issued for violation and prosecution has been launched.

3. The main contention of the learned Counsel for the petitioner is that the quality of the devices seized is not an issue and even in the report filed by the Government Analyst indicates that the samples have passed all the tests. The result of the analyst proves the fact that sample is in a good quality. It is his further contention that the devices have been imported and customs duty has been cleared by the Customs Department, Bombay and it is also cleared by the Assistant Director of Drugs at Bombay. Further, it is his contention that the complaint is nothing but misconceived the provisions of the law. The complaint proceeded as if the labeling has been done as per the Section 109A of the amended Rules of Drugs and Cosmetics Act.

4. It is his further contention that Rule 109A came into effect on 25.09.2014. Prior to the amendment, the labeling of the medical devices shall confirm to the Indian specifications laid down from time to time by the Bureau of Indian Standards, in addition to any other specifications prescribed in the said Rules. Therefore, it is his further contention that as per the Indian Standard Rules, Rule 9 (g) and (h), require labeling only year and month of expiry and the manufacturer name and supplier address alone to be noted which has been clearly carried out in all the devices. As the Infusion is classified as a medical device what was required at the relevant point of time is labeling as contemplated in the Indian Standard. Therefore, there is no violation. Only after the amendment of Rule 109A, the new requirement is sought to be added. Now, the private complaint has been proceeded as if there is a violation of Rule 96(1)(xii).

5. According to the learned Counsel, Rule 96(1)(xii) will not be applicable to the facts of the case, as samples lifted are only the substances which are intended to be used as components of drugs as per Section 3 (b) (iv) of the Drugs and Cosmetics Act. Therefore, it is his contention that Rule 96 is not applicable to this case. Hence, sought to quash the entire proceedings.

6. The learned Counsel for the respondent objected for quashment and it is his contention that whether Rule 96(1)(xii) or Rule 109A of the Drugs and Cosmetics Act is applicable or not has to be seen at the time of trial and not at this stage.

7. I had perused the entire materials.

8. The private complaint has been lodged for violation of Rule 96 of Drugs and Cosmetics Act. The Rule 96 deals with the manner of labeling and Rule 96(1)(xii) is as follows:

> "....
> Rule 96(1)(xii) – Drugs and their preparations including combinations with other drugs imported into the country shall bear on the label the license number and the drug which is imported proceeded by the words import, license, name and address of the importer."

9. It is relevant to note that the subject matter of inspection is only with regard to devices and not drugs and their preparation including combinations. It is only infusions which have been imported. The same has been cleared by the Customs Department which is not in dispute. Besides Additional Director of Drugs has also cleared while clearing the shipment. These facts are not in dispute. Section 3(b)(iv) of the Drugs and Cosmetics Act deals with devices which includes the devices. Though the drugs include such devices, what was imported is only devices intended for external use in the diagnosis and treatment. Therefore, the import license as required under Rule 96(1)(xii) will not apply to the facts of the present case.

10. It is also relevant to note that prior to the amendment of Rule 109A, the position of Rule is that the labeling of medical devices was confirmed to the Indian specifications laid down from time to time by the Bureau of Indian Standards in addition to any other specification provided in the said Rules. Indian Standard with regard to the infusion of equipment for medical use of the years 2003 and 1998 appended to the typed set particularly the Rule 9(1) require only year and month of expiry and name of manufacturer, or supplier's place and address alone to be printed on the infusion equipment. It has been done. Therefore, under Rule 96(1)(xii) the import license is not

required at the relevant point of time when the sample was taken on 06.02.2014, which is prior to the amendment of Rule 109A.

11. Further, the report of the Government Analyst itself indicates that the sample sent to the analysis is of the standard quality and had passed Sterility Test, BET Test, Abnormal Toxity Test. In such view of the matter, this Court is of the view that initiating of prosecution for violation of the Rules which was introduced at a later point of time, much after the sample is lifted and inspection is carried out, is nothing but a futile exercise.

12. Accordingly, the Criminal Original Petition is allowed and proceedings in S.T.C.No.2708 of 2015 on the file of the learned Judicial Magistrate No.II, Coimbatore against the petitioners for the offences punishable under Section 18(b) r/w Section 17(b) of the Drugs and Cosmetics Act, 1940 and Rule 96 (1)(xii) of the Drugs and Cosmetics Rules, 1945 is quashed. Consequently, connected miscellaneous petitions are closed.

Sd/-

Assistant Registrar (CS-VIII)

//True Copy//

Sub Assistant Registrar

vrc / kbs

To

1.The Judicial Magistrate No.II,
Coimbatore.

2.The Drugs Inspector,
Coimbatore Range – I,
Office of the Assistant
Director of Drugs Control,
219, Race Course Road,
Coimbatore – 641 018.

Crl.O.P.No.29180 of 2017 and
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SMI (CO)
PR (07/02/2022)