

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 25.04.2017

CORAM :

THE HON'BLE MR. JUSTICE M.V.MURALIDARAN

Crl. O.P.No.15641 of 2011 and
M.P.No.1 of 2011 and
Crl.M.P.No.5897 of 2017

1.Lupin Ltd.,
Logistics Park,
Survey No.332/1, Village Nimji,
Nagpur - 441 501,
Rep. by Dr.K.K.Sharma,
Managing Director.

2.Dr.K.K.Sharma,
Managing Director of
Lupin Ltd.,
Nagpur - 441 501.

... Petitioners

Vs.

State, rep by S.K.Arumugam,
Drugs Inspector,
Salem I Range I/c,
No.7, Thiruvalluvar Street,
Subramania Nagar,
Salem - 5.

.. Respondent

PRAYER: Petition under Section 482 of the Code of Criminal Procedure to call for the records of the complaint in C.C.No.247 of 2010 before the Judicial Magistrate Court No.II, Salem and quash the same as against the petitioners.

For Petitioners : Mr.N.R.Elango, Sr. Counsel
for Mr.T.D.SelvanBabu

For Respondent : Mr.B.RameshBabu
Government Advocate(Criminal Side)

ORDER

Seeking quashment of the proceedings initiated vide complaint in C.C.No.247 of 2010 on the file of the Judicial Magistrate No.II, Salem, the petitioners, who are arraigned as accused 5 and 6, have filed this criminal original petition.

2. The facts in a nutshell are as under: According to the petitioners, they are marketing agents of the drug named "Enthusia - 50 mg" that is manufactured by M/s.Hetero Drugs Limited, Hyderabad, who is the first accused in the complaint.

3. The main allegation against the petitioners is qua non compliance of packaging norms of the above drug as per Section 18(a)(1) read with Section 17(b) of the Drugs and Cosmetics Act, 1940. It is the specific allegation against the petitioners that the drug Enthusia 50 tablets does not comply with the labelling provisions of the Drugs and Cosmetics Act, as required under Rule 96 and thus the said drug falls under "Misbranded Drugs" as per Section 17(b) of the Drugs and Cosmetics Act.

4. The respondent issued a show cause notice to the petitioners and upon receipt of the same, the first petitioner replied stating that the inner pack contains all relevant details in consonance with the Drugs and Cosmetics Act, but for accounting purpose, the petitioners were mentioning the particulars on outer cartons in the invoices and also informed that based on the observations, the petitioners have started mentioning details in outer cartons as well, duly enclosing a sample of outer carton with all particulars as contemplated.

5. The respondent authority, not being satisfied with the explanation submitted by the petitioners, initiated the impugned proceedings and the Judicial Magistrate Court No.II, Salem, issued summons directing the petitioners to appear before the said Court to answer the complaint. Hence, the present petition.

6. It is the contention of Mr.N.R.Elango, learned Senior Counsel appearing on behalf of the petitioners that the petitioners are not manufacturers of the product, but are only marketing the same and, therefore, they are not liable to be prosecuted in view of the express provision of Section 19(3) of the Drugs and Cosmetics Act, 1940, for violation of Section 18 of the said Act. He added that as per Rule 96(3)(i) of the Drugs and Cosmetics Rules, 1945, the particulars shall be printed or written in indelible ink either on the label borne by a container or vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale and inasmuch as the prescribed particulars are printed on the label of the contained, the rule has been complied with and no violation can be justified.

7. He further submitted that, immediately on noticing the observation of the respondent, the petitioners have incorporated

the particulars even on the outer packing to satisfy the authorities and, therefore, there does not exist any valid ground warranting the petitioners to answer the charges levelled against them.

8. He further submitted that the petitioners are only marketing the product and they are not manufacturing or labelling the drug, which process is done by a different company, namely Hetero Drugs Limited, which is a licensed manufacturer.

9. In any event, it is argued that in respect of an offence alleged to have been committed on 20.12.2004, cognizance was taken on 6.9.2008, after nearly four years, when the maximum punishment prescribed is one year imprisonment. He hastened to add that the Court below ought not to have clubbed unrelated and independent charges against different accused in a single complaint and tried them together.

10. On the contrary, the learned Government Advocate (Criminal Side) justified the action initiated by the respondent authority and pleaded for dismissal of the petition.

11. I heard Mr.N.R.Elango, learned Senior Counsel for Mr.T.D.Selvan Babu, learned counsel for the petitioner and Mr.B.Ramesh Babu, learned Government Advocate (Criminal Side) for the respondent and perused the documents available on record.

12. At the outset, it is to be noted that even at the time of admission of this petition, an order of interim stay was passed on 8.7.2011 and the same holds good even as on date. By dint of such interim order, the proceedings in C.C.No.247 of 2010 on the file of the Judicial Magistrate No.II, Salem, had not been proceeded against the petitioners and no steps have been taken by the respondent to vacate the said interim order.

13. In the case on hand, it is beyond any cavil that the petitioners are only marketing agents of the drug and are not manufacturers. The manufacturer of the drug is M/s.Hetero Drugs Limited, Hyderabad. The main complaint against the petitioners is non-compliance of packaging norms of the above drug as per Section 18(a) (1) read with Section 17(b) of the Drugs and Cosmetics Act, 1940,

14. Section 17 of the Act deals with misbranded drugs, while Section 18 of the Act deals with Prohibition of manufacture and sale of certain drugs and cosmetics. At this juncture, it is appropriate to refer to Section 19 of the Act, relevant portion of which is as under:

"Section 19. Pleas.-

(1) and (2) ...

(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves-

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it."

15. In the case on hand, the petitioner is, admittedly, not a manufacturer and it is their plea that M/s.Hetero Drugs Limited, Hyderabad, is the manufacturer of the drugs. It is also their plea that the drugs were kept intact and all particulars had been stated in the inner packing and the outer cover is used only for packing purpose and only the particulars in the outer packing are stated in the invoice. Nothing has been placed on record by the respondent or across the bar to show that the petitioner is a manufacturer. Therefore, as a natural corollary, by virtue of Section 19 of the Act, referred supra, the provisions of Section 18 are inapplicable.

16. Furthermore, Rule 96(3)(i) of the Drugs and Cosmetics Rules, provides that the particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container or vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on the label enclosed therein. It is the specific plea of the petitioner that the prescribed particulars have been printed on the label of the container in which the drugs were packed and sold and nothing to prove the negative has been placed by the respondent.

17. In such view of the matter, this Court finds no prima facie material to proceed against the petitioners, who are only marketing the products manufactured by M/s.Hetero Drugs Limited. Therefore, the proceedings in C.C.No.247 of 2010 on the file of

the Judicial Magistrate Court No.II, Salem, are quashed insofar as the petitioners are concerned. No costs. Consequently, M.P.No.1 of 2011 and Crl.M.P.No.5897 of 2017 are closed.

Sd/-
Assistant Registrar(CS VI)

//True Copy//

Sub Assistant Registrar

vs

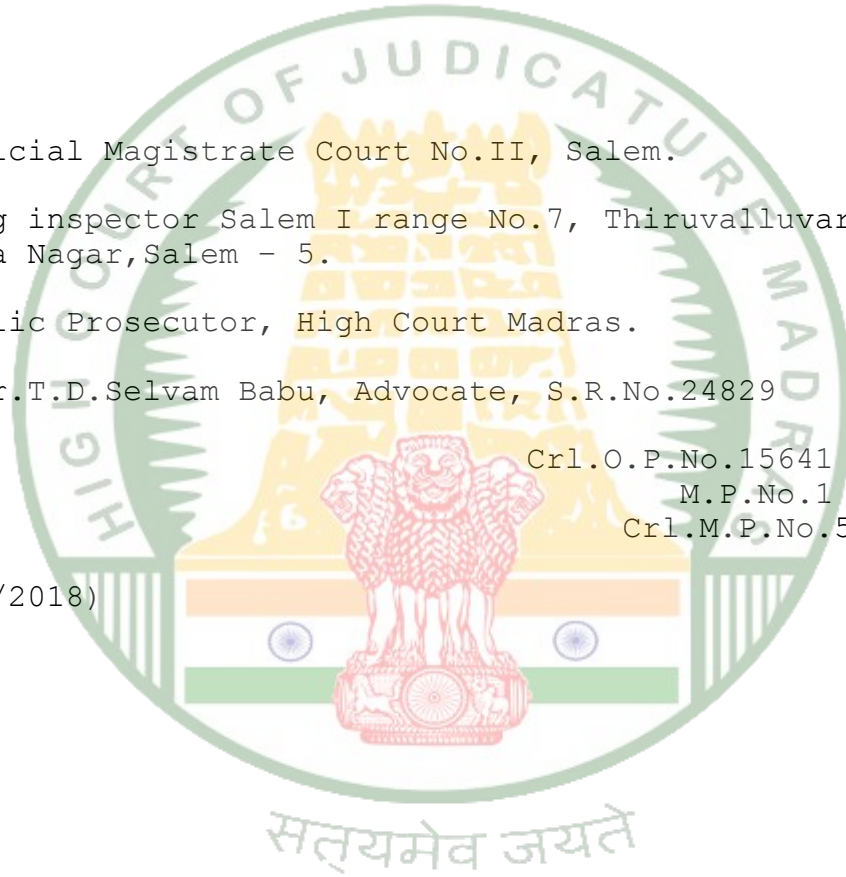
To

- 1.The Judicial Magistrate Court No.II, Salem.
- 2.The Drug inspector Salem I range No.7, Thiruvalluvar Street, Subramania Nagar, Salem - 5.
- 3.The Public Prosecutor, High Court Madras.

+2cc to Mr.T.D.Selvam Babu, Advocate, S.R.No.24829

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M.P.No.1 of 2011 and
Crl.M.P.No.5897 of 2017

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