IN THE HIGH COURT OF JUDICATURE AT MADRAS

Reserved on : 21.11.2023

Pronounced on : 29.11.2023

CORAM:

THE HONOURABLE MR. JUSTICE **G.K.ILANTHIRAIYAN**

Crl.O.P. No.28490 of 2017 and
Crl.M.P.No.16163 of 2017

1. M/s.Lupin Limited,
Represented by its Managing Director,
Dr.Kamal K.Sharma,
No.508/3, Inner Ring Road,
Madhavaram, Chennai-600 060.

2. Namita Srisrimal,
Authorized Signatory of
M/s.Lupin Limited,
No.508/3, Inner Ring Road,
Madhavaram, Chennai-600 060.

3. M/s.Lupin Limited
Represented by its Managing Director,
Dr.Kamal K.Sharma,
Vivekanand School Road,
Zirkpur, Chandigarh Highway Village,
Pabhat Zirakpur-140 105.

4. A.K.Kothari
Authorized Signatory of
M/s.Lupin Limited,
Vivekanand School Road,
Zirakpur,
Chandigarh Highway Village,
Pabhat Zirakpur-140 105. ... Petitioners

-Vs-

State rep. by
The Drugs Inspector,
Coimbatore II range,
Coimbatore Zone,
O/o.Assistant Director of Drugs Control,
219, Race Course Road,
Coimbatore-641 018. ... Respondent

PRAYER: Criminal Original Petition has been filed under Section 482 of Criminal Procedure Code, praying to call for the records of the impugned complaint in C.C.No.09 of 2012 dated 12.01.2012 on the file of the Hon'ble VI Judicial Magistrate Court, Coimbatore and quash the same.

For Petitioners : Mr.P.H.Aravind Pandian,
Senior Counsel for
Mr.V.Pravin Rathinam

For Respondent : Mr.L.Baskaran,
Government Advocate (Crl.Side)

ORDER

This Criminal Original Petition is filed to quash the proceedings in C.C.No.09 of 2012 dated 12.01.2012 on the file of the Learned VI Judicial Magistrate Court, Coimbatore thereby taken cognizance for the offences under Section 32 of Drugs and Cosmetics Act, 1940.

2. The respondent filed a complaint as against the accused under section 32 of Drugs and Cosmetics Act, 1940 (hereinafter referred as 'Act') for the contravention under section 18(a)(i) read with section 17(B)(d) of Drugs and Cosmetics Act 1940, which is punishable under section 27(c) of the said Act and contravention under section 18(c) of the Drugs and Cosmetics Act, 1940, which is punishable under section 27(d) of the said Act.

3. The crux of the complaint is that on inspection the Drug namely "ACEMIZ GEL" was drawn for analysis from M/s.Sri Anusuya Agencies, 1/2, K.R.Nagar, Veerapandi Pudur, Press Colony (Po), Coimbatore-19 under Form-17 and Form-18 and the same was sent to the Government Analyst (Drugs), DTL, Chennai-6 and the same was reported as Not of Standard Quality by the report dated 05.09.2011, on the ground that the sample does not conform to the label claim with respect to the content of Aceclofenac. It is seemed to be spurious since it has been partially substituted by Diclofenac Sodium. After issuance of show cause notice, a reply was sent and as per the reply, the subject drug was acquired from M/s.Medisales (India) Pvt., Ltd., No.508/3A, Inner ring road, Madhavaram, Chennai-600 060. On 15.09.2011, another show cause

notice was issued to M/s.Medisales (India) Pvt., Ltd.,. On receipt of the reply, revealed that the subject drug was acquired from Accused No.1 to 4 herein. Therefore, the Accused 1 to 4 were issued show cause notice and on their reply, revealed that they had valid license and they disclosed that the subject drug was acquired from Accused No.5 to 7. After issuance of show cause notice to the Accused No.5 to 7 and received reply, in which, they stated that they manufactured the subject drug for sale and distributed the said drug. Thereafter, inspection was made in the premises of Accused No.5 to 7 and the records were furnished to the authority. Based on the records, it is found that the subject drug was manufactured for sale and distributed by Accused No.5 to 7. The Accused No.5 to 7 firm are having valid manufacturing drug licence. Thereafter, the firm namely M/s.Sri Anusuya Agencies and M/s.Medisales (India) Pvt. Ltd., were given opportunity for plea as contemplated under section 19(3) of the said Act. On receipt of their plea, they were not added as an accused. Hence, the complaint.

4. On receipt of the said complaint, the Trial Court had taken cognizance in C.C.No.09 of 2012 for the offences punishable under section 32 of Drugs and Cosmetics Act 1940. The learned senior counsel appearing on behalf of

the petitioner submitted that the petitioners are arrayed as Accused No.1 to 4. Even according the respondent, the subject drug was manufactured by the Accused No.5 to 7. During the relevant period i.e., 2010-2011, the subject drug was manufactured by them in the month of February 2010 and its expiry date is January-2012 under a valid manufacturing license. As far as the petitioners are concerned, they have valid wholesale drug license under Form 20-B and 21-B in the Drugs and Cosmetics Rules, 1945 (hereinafter referred as 'Rules'). The respondent had issued erratum memo dated 30.11.2011, wherein it was admitted that the petitioners were inadvertently considered as manufacturer. Even then, they have been impleaded as Accused for the contravention of Section 18(a)(i) read with Section 17(B) (d) of the Act having stocked and sold the subject drug which is not of standard quality. The petitioners were not given an opportunity of plea as contemplated under section 19(3) of the Act. In fact other agencies, who were sold the subject drugs were given the opportunity of plea as contemplated under section 19(3) of the Act. However, the petitioners were not given the opportunity of plea, though they are also stand in the same footing of the other companies from whom the subject drug was taken for sample. The respondent also failed to follow the guidelines issued by the Government of India before initiation of

prosecution as against the petitioners. As per the guidelines issued by the Government of India dated 26.11.2010 as per Section 33P of the Act, thereby instructed the Drug Licensing Authorities to adhere the procedures prescribed in the guidelines by taking action on samples of drugs declared spurious or not of standard quality in the light of enhanced penalties under the Act, ensuring that while offenders are dealt with the Act, the confidence of the genuine manufacturers is not shakened and the growth of the industries is not hampered. As per the guidelines, contravention of Section 18(a)(i) r/w.17-B(d) is coming under the category of 'B'. As per the guidelines, the State Drug Control Departments shall constitute screening committees comprising of at least three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the cases where prosecutions are proposed to be launched. On submission of the report by the committee, the respondent ought to have launched prosecution. However, in the case on hand, the respondent failed to get any opinion from the screening committee and failed to follow the guidelines issued by the Government of India.

5. The respondent filed counter and Mr.L.Baskaran, learned Government Advocate (Crl.Side) submitted that the petitioners are Marketer of the subject

drug and the subject drug was manufactured by the Accused No.5 to 7. Therefore, the petitioners had committed contravention of Section 18(a)(i) r/w.17-B(d) of the Act. The petitioners possessed license Form 20B for sale/distribution of drugs. As per the condition, the responsibility to ensure the drugs is having valid product permission from the duly licensed manufacturers. The petitioners are not being manufacturers or not their agent for distribution thereof, shall be liable for contravention of Section 18 since they acquired the drug from the manufacturer who does not have valid product permission to manufacture the subject drug in specified combination which is in contravention of Section 18(c) r/w condition of license in Form25 for having manufactured for sale and sold the above drug. M/s.Sri Anusuya Agencies, Coimbatore and M/s.Medisales India Pvt., Ltd., Madhavaram, Chennai have purchased the subject drug from duly licensed wholesaler/distributor i.e., the petitioners herein. Therefore, there was no allegation in the complaint against them and they are entitled for plea under section 19(3) of the Act. As far as these petitioners are concerned, they had purchased the subject drugs from the Accused No.5 to 7 who do not have valid product permission/approval from the Licensing Authority. Therefore, the petitioners are not eligible for the plea as contemplated under section 19(3) of the Act.

6. Heard, the learned counsel appearing on either side.

7. These petitioners are arrayed as A1 to A4. Admittedly, the subject drug was taken sample from M/s.Sri Anusuya Agencies, Coimbatore wholesale distributor and who had valid license. On receipt of the reply for the show cause notice they had purchased the subject drug from M/s.Medisale India Pvt., Ltd., Madhavaram, Chennai. Therefore, they were issued show cause notice. On receipt of reply, it revealed that they had procured the subject drug from the petitioners herein. Though, the petitioners had valid wholesale license in Form 20B, 21B, they received subject drug from duly licensed manufacturer i.e., Accused No.5 to 7 who do not have valid product permission/approval from the valid licensing authority. That apart, the said drug was declared as Not of Standard Quality and also spurious one. It is not the case of the respondent that the petitioners had knowledge that Accused No.5 to 7 manufactured the subject drug without valid product permission/approval from concerned licensing authority. They had also no knowledge that the said Drug is not of standard quality and spurious one. Therefore, they are also entitled for the plea as contemplated under section 19(3) of the Act. Admittedly, they were not given an opportunity of plea to

raise their grounds by sufficient opportunity. Therefore, it is fatal to the case of the prosecution. Admittedly, the petitioners had possessed the subject drug as a wholesaler and they never done any marketing for selling the drug. Therefore, the alleged contravention does not apply to the petitioners, since they had valid license to possess the subject drug.

8. The Government of India issued guidelines to be followed by the State Governments to instruct their respective license regulatory authority to adhere procedures/guidelines for taking action on samples of drugs declared spurious or not of standard quality. This court already dealt with in respect of the guidelines issued by the Government of India in Crl.O.P.No.23142 and 23148 of 2019 dated 20.11.2023 as follows:

> *"14. As per guidelines, if the drug is not of standard quality, it is coming under category B. In the case of not of standard quality reports because of minor defects arising out of variations from the prescribed standards or contraventions of other provisions of chapter IV of the Act, administrative measures including suspension/cancellation or compounding offences may be restored to. Prosecution may only be launched where it is justifiably felt that above measures would not meet*

the ends of justice. The State Drug Control Departments shall constitute screening committees comprising of atleast three senior officers not below the level of Assistant Drugs Controllers or equivalent to examine the investigation reports of the case where prosecutions are proposed to be launched. The committee may submit written opinion on the investigation reports regarding their feasibility of taking legal action. The criminal intent or gross negligence should be taken into consideration while recommending actions like prosecution, etc., Care should be taken that charges framed are not based on inappropriate provisions which may be difficult to prove in the court of law in the absence of proper justification or evidence. Cases of failing of assay, brand name disputes and non renewal of manufacturing license in time should be examined on their merits before recommending prosecution in such cases."

9. The above case is squarely applicable for the case on hand, since the respondent failed to follow the guidelines issued by the Government of India. No screening Committee was constituted to examine the investigation reports

of the respondent and no opinion was submitted by the Committee in order to launch prosecution against the petitioners. The report submitted by the Government Analyst, Testing Lab, Chennai is as follows:

Analysis Done	Result of Analysis	Label Claim
Nature of packing and quantity of the sample received Description Identification	Received the sample in one collapsible tube and kept in a original carton Pale Yellow colour semisolid mass Does not answer the identification test for Aceclofenac. But it answers the identification test for "DICLOFENAC SODIUM". And also it answers the identification test for Methyl salicylate, Menthol and Benzyl alcohol	1X30gm (For External use only) Gel
Assay Estimation of	The sample is found to contain	The sample purports to contain
Acclorenue Methyl Salicylate	Nil 10.06%w/w (100.6%)	1.5% w/w 10% w/w
	4.82% w/w (96.4%)	5% w/w (Limit: 90% to 110% of label claim)
Diclofenac Sodium	0.648% w/w	

10. As per the report, the sample does not conform to Label claim with respect to the content of Aceclofenac. The sample is deemed to be spurious since it has been partially substituted by DICLOFENAC SODIUM. The said subject drug was manufactured and marketed by Accused No.5 to 7 herein.

Even according to the respondent, subject drug was procured by the petitioner as a stockist/wholesaler under valid license. It is relevant to extract contravention of Section 18(a)(i)r/w.18(B)(d) of the Act, hereunder:

For the contravention of

a) Section 18(a)(i) read with section 17(B)(d) of the Drugs and Cosmetics Act 1940 for having stocked for sale and sold a Not of standard quality drug namely Acemiz gel B.No:10016BAA, M/D:02/2010, E/D:01/2012, which is deemed to be a Spurious drug under section 17(B)(d) of the Drugs and cosmetics Act 1940, which is punishable under section 27(c) of the Drugs and Cosmetics Act, 1940."

The said contravention is not applicable to the petitioners. Therefore no contravention can be attributed as against the petitioners to initiate prosecution. Therefore, the initiation of prosecution as against these petitioners are vitiated and liable to be quashed.

11. Accordingly, the entire proceedings in C.C.No.09 of 2012 dated 12.01.2012 on the file of the learned VI Judicial Magistrate Court, Coimbatore is quashed as against the petitioners alone and this Criminal original Petition is allowed. Consequently, connected miscellaneous petition is closed.

29.11.2023

Index :Yes/No
Internet : Yes/No
Speaking order/non-speaking order
gvn

To

1) The VI Judicial Magistrate Court,
Coimbatore.

2) The Drugs Inspector,
Coimbatore II range,
Coimbatore Zone,
O/o.The Assistant Director of Drugs Control,
219, Race Course Road,
Coimbatore-641 018.

3) The Public Prosecutor,
High Court Madras.

G.K.ILANTHIRAIYAN, J.

gvn

Crl.O.P. No.28490 of 2017 and
Crl.M.P.No.16163 of 2017

29.11.2023