IN THE HIGH COURT OF JUDICATURE AT MADRAS

ORDERS RESERVED ON	ORDERS PRONOUNCED ON
16.03.2022	16.06.2022

CORAM

THE HONOURABLE MR.JUSTICE G.CHANDRASEKHARAN

CRL.O.P.NO.555 OF 2016
AND
CRL.M.P.NO.261 OF 2016

1. M/s.Zest Pharma,
   Rep. By its Partner Shri.Sudhir Vora,
   S/o.Late.Navneetlal Vora.

2. Shri.Sudhir Vora,
   S/o.Late.Navneetlal Vora,
   Partner of Zest Pharma.

3. Smt.Shweta Vora,
   W/o.Sudhir Vora,
   Partner of Zest Pharma.

4. Sri.Sanjay Zatakia,
   S/o.Late.Shanthilal Zatakia,
   Partner of Zest Pharma.

5. Shri.Jalinder Kakde,
   Person Incharge Cum Authorised
   Signatory of Zest Pharma. ... Petitioners/Accused

.Vs.

The State Rep. By
The Drugs Inspector,
Coimbatore II Range,
Office of Assistant Director Of Drugs Control,
Coimbatore Zone,
No.219, Race Course Road,
Coimbatore - 641 018. ... Respondent/Complainant

PRAYER:-

This Criminal Original Petition is filed under Section 482 Cr.P.C. to call for the records of the proceedings in

S.T.C.No.776 of 2015 on the file of learned Judicial Magistrate No.VII, Coimbatore and quash the complaint.

For Petitioners : Mr.AR.L.Sundaresan
Senior Counsel
For Mr.T.D.Selvan Babu

For Respondent : Mr.E.Raj Thilak
Additional Public Prosecutor

ORDER

This petition is filed to call for the proceedings in STC No.776 of 2015 on the file of learned Judicial Magistrate No.VII, Coimbatore and to quash the complaint.

2. Respondent filed this complaint against the petitioners for the contravention of the offences under section 18(a)(i) of Drugs and Cosmetics Act, 1940 punishable under Section 27(d) of the Act. The sample of Rabtek, Rabeprazole Tablets IP (20mg) was drawn for analysis by the Deputy Inspector, Coimbatore from ESI Dispensary, Madhukarai. The sealed sample was sent to Government Analyst (Drugs), Drugs Testing Laboratory, Chennai. The test report dated 10.12.2013 declared the sample as not of standard quality for the reason that sample does not confirm to IP specification for Rabeprazole Tablets with respect to the content of cf Rabeprazole Tablets sodium (61.05%) and to the dissolution in buffer medium. The sample medicine disclosed that the subject drug was supplied by Central Medical Stores (ESIS), Coimbatore. It was informed by Central Medical Stores that the drug was acquired from M/s.Zest Pharma (first accused). The quantity purchased was 1,00,000 (One lakh) tablets under the purchase invoice No.ZT/2192 dated 30.01.2013. On 05.02.2014, a show cause memo was sent to M/s.Zest Pharma along with the third portion of the sealed sample calling for the explanation for the contravention of Section 18(a)(i) of the Drugs and Cosmetics Act, 1940 for manufacturing and selling not of standard quality drug. The Investigating Officer sought particulars required under Section 18B of the Drugs and Cosmetics Act, 1940. On 18.03.2014, a reply was received from M/s.Zest Pharma stating that it manufactured and released for sale and distribution only after it was reported as of standard quality by their in-house quality controller. It is also stated that it has re-analysed the said drug batch from their control reference sample and found that as per IP monograph, it complies with the content of Rabeprazole sodium and also in dissolution parameter. It sent sample from it control reference sample to NABL accredited Laboratory for complete analysis as per IP. It has also informed that it has recalled and sent withdrawal letter to all the

institutions to whom the drug was sold. On 30.04.2014, the Investigating Officer submitted a report requesting the matter to be referred to the concerned State Drug Controlling Authority, Madhya Pradesh for taking further action, since the manufacturing unit is situated there. On 14.05.2014, the Investigating Officer received a letter from the Director of Drugs Control calling for the proposal for prosecution against M/s.Zest Pharma. On 23.05.2014, Investigating Officer wrote a letter to the Director of Drugs Control requesting the constitution particulars of M/s.Zest Pharma and permission to go to Indore for manufacture level investigation. He received the permission on 29.05.2014. Investigating Officer along with Asok Goyal, Drug Inspector, Indore carried out inspection on 05.06.2014 at the premises of M/s.Zest Pharma at Indore. During the investigation, certified copies of the documents are produced through Jalinder Kakde. The officer of M/s.Zest Pharma informed that the product permission to manufacture and sale in respect of NSQ (Not of Standard Quality) of the said drug was withdrawn. The manufacture of Rabteck Rabeprazole Tablets IP 20 mg is not of standard quality and is in violation of 19(a) of the Drugs and Cosmetics Act, 1940. On 11.05.2014, Investigating Officer sent a detailed report to the Director of Drugs Control to get sanction to prosecute the case. Sanction was accorded by the Director of Drugs Control. Therefore, the complaint.

3. This complaint was taken cognizance by the learned Judicial Magistrate No.VII in S.T.C.No.776 of 2015. Challenging the said taking cognizance, this petition is filed.

4. Learned counsel for the petitioners submitted that the first petitioner is a licensed drug manufacturing unit and has manufactured with due licence manufacture. Rabteck RabeprazoleTablets IP 20mg was manufactured with due licence and approval required under law. Petitioners maintained required quality and standard as per law for the manufacture and distribution of the drugs. The complaint is liable to be quashed for the delay in filing the complaint on 26.06.2014 for the drug that expired on 30.06.2014, giving no option for the accused to exercise right under Section 24(5) of the the Drugs and Cosmetics Act, 1940 to send the sample to Central Research Laboratory, Calcatta. The first summon itself was issued only on 06.11.2015. Respondent did not send the second sample for analysis, though the petitioners challenged the report of the Government Analyst and made specific request for sending the sample to the Central Research Laboratory, Calcutta. Petitioners lost their valuable opportunity of challenging the report of the Government Analyst due to the belated filing of the complaint. Delay in filing the complaint and depriving the accused the opportunity to send the second sample for analysis to the Central Research Laboratory, Calcutta, is fatal to the

case of the complainant. The sample was not sent to Government analysis forthwith. The Government analyst took six months to analyse the sample. The complaint against all the partners and employees of the first petitioner is violative of Section 24 of the Drugs and Cosmetics Act, 1940, since they are not responsible for the conduct of the business by the first petitioner. Thus, learned counsel for the petitioners prayed for quashing the complaint.

5. Learned counsel for the petitioner relied on the judgment reported in (2008) 7 SCC 196 in Medicamen Biotech ..vs.. Rubina Bose, Drugs Inspector for the proposition that the filing of the complaint belatedly at the verge of the expiry of self life of the drug would deprive the accused the valuable right under Section 25(3) and 25(4) of the Act. That deprivation would necessitate the quashing of the proceedings. Judgment reported in (2001) 4 SCC 382 (Amery Pharmaceuticals ..vs.. State of Tamil Nadu) is relied for the proposition that the manufacturer who is not entitled to be supplied with the copy of the report of the Government Analysis Laboratory must have the liberty to challenge the correctness of the statement stated in the report by resorting to any other mode by which such facts can be disproved. He can also avail himself of the remedy indicated in sub-section 4 of Section 25 of the Act by requesting the Court to send other samples remaining in the Court to be tested in the Central Drugs Research Laboratory. Judgment reported in 2017 SCC OnLine 632 (Laborate Pharmaceuticals ..vs.. State of Tamil Nadu) is relied for the proposition that when the self life of the drug expired on the date of taking cognizance, the Magistrate could not send the sample for re-analysis by the Central Laboratory.

6. Judgment reported in 2021 SCC OnLine SC 1012 (Dayle De'souza ..vs.. Government of India through Deputy Chief Labour Commissioner) is relied for the proposition that there is primary responsibility on the part of the complainant to make specific averment as required under law in the complaint so as to make the accused vicariously liable. Judgment reported in 2015 SCC OnLine Mad 9818 (Embiotic Laboratories ..vs.. State of Tamil Nadu by Drugs Inspector) is relied for the proposition that the denial of the valuable right under Sections 25(3) and 25(4) of the Act would result in quashing the proceedings. For the same proposition, the order passed in Crl.O.P.(MD) No.18084 of 2013 in Alfred Berg & Co.Lt..vs.. State represented by Drugs Inspector is relied.

7. In reply, learned Additional Public Prosecutor submitted that it is the petitioners, who do not avail the opportunity under Section 25(3) of the Act. Proper procedures had been followed before instituting the case against the petitioners.

There is no merit in this petition and is liable to be dismissed. Learned Additional Public Prosecutor appearing for the respondent relied on the judgment reported in (1998) 5 SCC 343 (State of Haryana ..vs.. Brij Lal Mittal and others) for the proposition that the right to get the sample examined by the Central Drugs Laboratory through the Court before which the prosecution is launched arises only after the person concerned notifies in writing the Inspector or the Court concerned within 28 days from the receipt of the copy of the report of the Government Analyst that he intends to adduce evidence in contravention of the report. For the same proposition, learned counsel for the respondent relied the judgment reported in (2011) 13 SCC 72 (Glaxosmithkline Pharmaceuticals Limited and another ..vs.. State of Madhyap Pradesh).

8. Considered the rival submissions and perused the records.

9. From the case set out in the complaint and the submissions made by the counsel appearing for the parties, it is clear that the sample of Rabteck Rabeprazole tablets IP 20 mg is lifted from ESI Dispensary on 30.04.2013. The sample was sealed and one of the samples was sent to the Government Analyst for analysis. The Government Analyst in his report in Form-13 had declared that the sample is 'not of standard quality' for the reason that the sample does not confirm to IP specification for Rabeprazole tablet with respect to the content of cf Rabeprazole sodium (61.05%) and to dissolution in buffer medium. This is the cause for filing this complaint. The grievance of the petitioners/accused is that the drug Rabteck Rabeprazole was manufactured in January 2013. Its expiry date was June 2014. However, the complaint in this case was filed only on 26.06.2014. Summons for appearance was sent to accused for the first hearing on 06.11.2015. Before the date fixed for first hearing, the self life of drug expired. Petitioners were deprived of the right to send the sample available in the Court to the Central Drugs Laboratory, Kolkatta for analysis. This right was denied even after the petitioners sent a letter dated 20.03.2014 requesting the sample to be sent to Central Drug Laboratory, Calcutta for analysis. The denial of this opportunity deprived the petitioners the chance of proving their case that the drug is perfectly in order and it is not the drug to be classified as 'not of standard quality'.

10. This contention of the petitioner is stoutly denied by the respondent and it is contended that there is no letter dated 20.03.2014 was received from the petitioners. The letter dated 20.03.2014, now produced, is created falsely for the purpose of this case. In this regard, the Drugs Inspector Thiru. S.Balamurugan filed an affidavit stating that the letter dated 20.03.2014 is produced for the first time before this Court and

it is not brought to the notice of the respondent during the investigation. The Drug Inspector received a reply dated 10.03.2014 for the show cause notice dated 03.02.2014. The reply was received on 17.03.2014. Once again petitioners sent a letter dated 10.03.2014 with verbatim particulars by correcting the letter dated 10.03.2013 as 10.03.2014. The acknowledgment card submitted for the letter dated 20.03.2014 pertains to the copy of the letter dated 10.03.2013, which was corrected as 10.03.2014.

11. From the aforesaid diametrically opposite position taken by the parties as to the letter dated 20.03.2014, it is apparent that the factum of issuance of reply dated 20.03.2014 by the petitioners is seriously disputed by the respondent. This aspect has to be necessarily enquired into only during the trial. Be that as it may, Section 25 of the Drugs and Cosmetics Act, 1940 reads as follows:-

> "25. Reports of Government Analysts.—
>
> (1) The Government Analyst to whom a sample of any drug 1 [or cosmetic] has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.
>
> (2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken 4 [and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A], and shall retain the third copy for use in any prosecution in respect of the sample.
>
> (3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken 5 [or the person whose name, address and other particulars have been disclosed under section 18A] has, within twenty -eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.
>
> (4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his

> intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused cause the sample of the drug 1 [or cosmetic] produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.
>
> (5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct."

12. Section 25(3) reads that, the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under Section 18(A) within 28 days of the receipt of the report, should notify in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in contravention of the report.

13. Section 25(4) gives another option that if the sample is not tested or analysed by the Central Drugs Laboratory under sub-section 3, the Court may of its own notion or in its discretion, at the request either of the complainant or accused, cause the sample of the drug produced before the Magistrate, to be sent for test or analysis to the Central Drugs Laboratory.

14. The grievance of the petitioners is that in view of the delayed filing of the complaint just four days before the expiry of the self life of the drug, petitioners lost the opportunity of sending the sample to the Central Drugs Laboratory under Section 25(4) of the Act. Not only that it is submitted that through a letter dated 20.03.2014, petitioners requested the second sample to be sent to the Central Drugs Laboratory for analysis. Of course, as already said, sending the letter dated 20.03.2014 is seriously disputed by the respondent. The consideration of the judgments relied by the learned counsel appearing for the parties, especially the judgment reported in (1998) 5 SCC 343 (cited supra) and (2011) 13 SCC 72 (cited supra) shows that the right to get the sample examined by the Central Drugs Laboratory through the Court arises, only after the person concerned notifies in writing to the Inspector or the Court concerned, within 28 days from the date of receipt of copy of the report of the Government Analyst, that he intends to

adduce evidence in contravention of the report. Respondent accepted the letter dated 10.03.2013, which was corrected as 10.03.2014 sent by the first petitioner. Admittedly, this letter does not contain any reference with regard to the request of the petitioners to send the sample to the Central Drugs Laboratory. Only in a letter dated 20.03.2014, the request for sending the sample to the Central Drugs Laboratory, Calcutta is made. Therefore, the fact which requires serious consideration of this Court is whether the letter dated 20.03.2014 was really sent by the petitioners to the respondent.

15. Respondent's contention is that the letter dated 20.03.2014, now produced, is created for the purpose of this case. This is the serious allegation, which is required to be considered by the Court. This disputed, vital and basic fact cannot be decided by this Court without proper evidence. It is the job of the trial Court to receive evidence from both the sides and decide whether the letter dated 20.03.2014, now produced before the Court, was actually sent by the petitioners. If the letter was sent as claimed by the petitioners, then the respondent has to necessarily fail. If the letter dated 20.03.2014 is not sent as claimed by the respondent, then it is for the trial Court to decide the case on merits on the basis of the evidence to be adduced by the parties. Other issues raised by the parties are left open to the trial Court to decide. In this view of the matter, this Court finds that this is not a fit case for quashing. This case has to go for a full-fledged trail for it to reach its logical conclusion.

16. In this view of the matter this Criminal Original Petition is dismissed. The trail Court is directed to dispose the case on merits and in accordance with law, without being influenced by any of the observations made by this Court in this order. Consequently, connected Miscellaneous Petition is closed.

Sd/-
Assistant Registrar(CCC)

//True Copy//

Sub Assistant Registrar

Mra

To:

1. The Judicial Magistrate No.VII,
   Coimbatore.

2. The Drugs Inspector,
Coimbatore II Range,
Office of Assistant Director Of Drugs Control,
Coimbatore Zone,
No.219, Race Course Road,
Coimbatore - 641 018.

3. The Public Prosecutor,
High Court, Madras.

+2ccs to Mr.T.D.Selvan Babu, Advocate, S.R.No.36479

CRL.O.P.NO.555 OF 2016 AND
CRL.M.P.NO.261 OF 2016

CA(CO)
PBS/06/07/2022