BEFORE THE MADURAI BENCH OF MADRAS HIGH COURT

Reserved on	Delivered on
12.09.2018	20.09.2018

CORAM:

THE HONOURABLE MR. JUSTICE N. ANAND VENKATESH

CRL.OP (MD).No.16361 of 2018
and
Crl.MP(MD).Nos.7256 & 7257 of 2018

1. Poddar Pharmaceuticals Pvt.Ltd.,
   E-35, Indl. Area, Haridwar,
   Uttarakhand - 249401
   rep. by its Managing Director
   Mr.Vinay Kumar Jain, S/o. Prakash Chand Jain.

2. Vinay Kumar Jain,
   S/o. Prakash Chand Jain (45/m)
   Managing Director,
   Poddar Pharmaceuticals Pvt.Ltd.,
   E-35, Indl. Area, Haridwar,
   Uttarakhand - 249401 ... Petitioners/Accused 1&2

.Vs.

State represented by
Drugs Inspector Aranthangi Range
O/o, the Asst. Director of Drugs Control,
Thanjavur Zone, Thanjavur-1. ... Respondent

Prayer: Criminal Original Petition filed under Section 482 of Cr.P.C, 1973, to call for records in S.T.C. No. 214 of 2018 pending in the Hon'ble Court of Judicial Magistrate at Aranthangi and QUASH the same.

For Petitioners : Mr.R.Pon Karthikeyan
For Respondent : Mr.M.Chandra sekaran
Addl.Public Prosecutor

ORDER

This petition has been filed seeking to quash the Criminal Proceedings initiated by the respondent in S.T.C.No. 214 of 2018, on the file of the Judicial Magistrate, Aranthangi, for the Contravention of Section 18(a) (i) & 18B of the Drugs and

Cosmetics Act 1940, Punishable under Section 27(d) & 28A of the said Act (hereinafter called "the Act").

2. The case of the prosecution is that on 20.09.2016, the Drugs Inspector took a sample of Diethyl Carbamazine Citrate IP Tablets, B.No: TY-125, M/D: 04/2016, E/D: 03/2018 Mfg. By M/s. Podder Pharmaceuticals Pvt. Ltd., for analysis from the Government Hospital, Arandhangi, Pudukkottai District, and the sample was sent for analysis to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai-06. The sample was tested and the Government Analyst by his report dated 21.12.2107, observed that the Drug is "Not of Standard Quality" as defined in Act and Rules and does not conform to the General Description for Tablet and to IP specification for Diethyl carbamazine Citrate Tablets with respect to the content of Diethyl carbamazine Citrate.

3. The respondent issued show cause memo to the Pharmacist of the Government Hospital, Arandhangi, and also the stockist, namely Drug Warehouse, Tamilnadu Medical Services Corporation Ltd, pointing out the findings of the Government Analyst and got the information that the manufacturer of the Drug is M/s.Poddar Pharmaceuticals Pvt. Ltd. By a show cause memo dated 06.01.2018, the petitioners were informed about the report given by the Government Analyst and a copy of the Analyst report along with a portion of the sample drawn was also sent to the petitioners, and petitioners were called upon to give their explanation to the show cause memo.

4. The petitioners by their letter dated 14.02.2018 (posted on 01.03.2018) and which was received on 07.03.2018 by the respondent, gave their reply stating that they do not accept the report of the Government Analyst. The respondent not being satisfied with the reply, proceeded to file a Criminal complaint against the petitioners for the contravention of the provisions of the Act. This complaint was taken on file by the court below and summons were issued to the petitioners. The petitioners have filed this petition to quash the said complaint.

5. The learned counsel for the petitioners made the following submissions:

a) The sample was tested and report was furnished beyond 60 days in violation of Rule 45 of the Drugs and Cosmetics Rules and the sample was not kept in proper storage.

b) Only a copy of the report Form-13 was given and whereas the Act stipulates the furnishing of the original report and the show cause memo was sent to the petitioners, even before the respondent came to know that the petitioners are the manufacturers and therefore the respondent has pre-decided the issue.

c) The shelf life of the Drug expired in March 2018 and the Criminal complaint itself has been filed only after the expiry date of the Drug and therefore the petitioners have lost a

valuable right to get the sample tested by the Central Drug Laboratory and therefore, a vital defence has been taken away, which is in violation of Section 24(3) of the Act.

d) The Government Hospital, Arandhangi and the Drug Warehouse, Tamilnadu Medical Services Corporation Ltd., Pudukkottai, did not maintain the Drug as per the stipulation which is clearly shown in the cover of the Tablet itself and that is the reason for the deficiency found by the Analyst and it is not due to the manufacturer's fault.

e) The learned Counsel relied upon the following Judgments to support his contentions:

(i) Tata Chemicals Limited *Vs* ***Commissioner of Customs (Preventive), Jamnagar*** reported in ***(2015) 11 Supreme Court Cases 628.***

(ii) Northern Minerals Limited and Others *Vs* ***Rajasthan Government and Another*** reported in ***(2016) 12 Supreme Court Cases 298.***

(iii) Embiotic Laboratories (P) Ltd., rep. by its Director, *Vs* ***Drugs Inspector, Erode I Range*** reported in ***2013 (2) MWN (Cr.) 567 in High Court of Madras.***

(iv) Alfred Bergs & Co (I) Pvt. Ltd., rep. by its Director & Kamelsh Jain *Vs* ***State represented by Drugs Inspector, Thirunelveli II range*** *in* ***Crl.O.P(MD) No.18084 of 2013 and M.P.(MD) No.1 of 2013.***

(v) M/s. Cadila Pharmaceuticals Limited, rep. by its Managing Director, Rajiv Modi *Vs* ***A. Sashi, Drug Inspector, Arumbakkam Range I,*** *in* ***Crl.O.P. No.4461 of 2013.***

6. This Court has considered the submissions made by the learned counsel for the petitioners carefully.

7. It is an admitted case that Tablet in question was manufactured by the petitioners. The shelf life of the Tablet expires in March 2018. This Tablet was supplied to the Warehouse by the Petitioners namely Drug Warehouse, Tamilnadu Medical Services Corporation Ltd., and in turn this Tablet was sent by the Stockist to the pharmacy at the Government Hospital, Arandhangi. The sample was taken on 20.09.2016 and one portion of it was immediately sent to the Drugs Testing Laboratory which received the same on 26.09.2016. The test was conducted in the Laboratory and a report dated 21.12.2017 was given to the effect that the Tablet is "Not of Standard Quality" as defined in the Act and Rules and the sample does not conform to General Description for Tablets and to IP specification for Diethyl Carbamazine Citrate Tablets with respect to the content of Diethyl Carbamazine Citrate. It is therefore clear that the sample reached the Drugs Testing Laboratory within 6 days from the date on which the sample was taken by the Drugs Inspector.

8. The report does not state as to when, the Drug was tested. The statutory form only contains the date of the report. The submission of the learned counsel that Rule 45 of the Drugs and Cosmetics Rules, 1945 mandates testing of the sample and furnishing report within 60 days, is only directory in nature and the violation does not by itself vitiate the report of the Drugs Testing Laboratory. The date on which the test was conducted and the conditions under which the Tablets were kept, are all matters for trial and the same cannot be taken into consideration at the stage of quashing a complaint.

9. The next submission made by the learned counsel for the petitioners that the stockist namely Drug Warehouse, Tamilnadu Medical Services Corporation Ltd., Pudukkotai and the pharmacist, Government Hospitals, Arandhangi, did not keep the Tablets in accordance with the stipulation provided for storage, is also a factual question which can be gone into only at the time of trial and not at the stage of considering the petition to quash under Section 482 of Cr.P.C.

10. The main submission made by the learned counsel for the petitioners that the petitioners have lost a valuable defence provided to them under Section 24(3) and Section 24(4) of the Act, is also not sustainable for the following reasons;

11.The petitioners received the show cause memo dated 06.01.2018 along with the report of the Government Analyst and also a portion of sample drawn for analysis. The petitioners ought to have given a reply along with the request to send a sample to the Central Drugs Laboratory, within 28 days from the date of the receipt of the copy of the letter along with the report, as per Section 25(3) of the Act. In this case, the petitioner has given a reply dated 14.02.2018 to the respondent. Even though the reply is dated 14.02.2018, it was actually sent through post only on 01.03.2018 and the same is evident from the specific averment made in the complaint. Therefore, the reply itself was sent beyond 28 days from the date of the receipt of the show cause memo and the report. Even in the reply, the petitioners have not specifically expressed their intention to send the sample to the Central Drugs Laboratory within 28 days of the receipt of the show cause memo and report. Admittedly, the shelf life of the Drug was up to March 2018 and the petitioners could have easily sought for sending the sample to the Central Drugs Laboratory to get an independent report and sustain their defence. However, for reasons best known to the petitioners, they neither gave the reply within 28 days nor did they express their intention to send the sample for test to the Central Drugs Laboratory. The petitioners having failed to do so, cannot make a complaint against the respondent now, after the shelf life is already over in March 2018 itself. The petitioners in fact failed to take advantage of valuable right available to them under

Section 25(3) of Act.

12. The Judgment cited by the learned counsel for the petitioners in ***Tata Chemicals Limited .****Vs.* ***Commissioner of Customs (Preventive), Jamnagar*** reported in ***(2015) 11 SCC 628*** will not have any application in the present case as that was case under the Customs Act, where the samples drawn were not in accordance with the stipulation and therefore, the Hon'ble Supreme Court held that the Department cannot rely upon the test report in order to apply a particular notification to the product in question.

13. The next Judgment relied by the learned counsel for the petitioner, is ***Northern Minerals Limited and Others .***Vs. ***Rajasthan Government and Another*** reported in ***(2016) 12 SCC 298***, which was a case under the Insecticides Act, 1968. In the said Act, there is a provision under Section 24, which is very similar to provision under Section 25 of the Act. By interpreting the said provision, the Hon'ble Supreme Court has held that indication of the intention to send the sample to the Central Laboratory is not only available to the person from whom the sample was drawn, but also to any other accused person against whom the proceedings are initiated. Therefore, if the ratio is applied in the present case, even though the sample was drawn from the Government Hospital, Aranthangi, since the respondent proceeded against the petitioners in their capacity as manufactures, the petitioners also had the right to express their intention to send the sample Drugs to the Central Drugs Laboratory, within 28 days of the receipt of the the report. However, the petitioners failed to exercise this right. Therefore, the Judgment cited by the learned counsel for the petitioners will not help the case of the petitioners.

14. The other Judgments cited by the learned counsel for the petitioners are all cases, where this court has taken a view that the delay in filing the complaint after the shelf life of the Drug, will also vitiate the complaint. In all those cases, it is seen that the petitioners had expressed their intention to send the sample to the Central Drugs Laboratory and by then, the shelf life of the Drug came to an end. Therefore, this court found that the petitioners have lost their valuable right. However in this case, the petitioners had such a right very much available, when they received the show cause memo and the report and the petitioners failed to give a reply nor expressed their intention to send the sample within 28 days to the Central Drugs Laboratory. Therefore, those Judgments will not apply to the present case.

15. This court in ***Laborate Pharmaceuticals India Ltd., rep. by its Director Ajay Bhatia and Others*** .Vs. ***State, rep. by the Drugs Inspector, Tondiarpet – II range, Zone-I, Chennai 600 006*** reported in ***(2016) 4 MLJ (Crl) 110*** had an opportunity to deal with a case

which was similar to the present case. The relevant portion of the Judgment is extracted here under:

(i) On observing the label on the subject drug, the respondent found that it has been manufactured by Laborate Pharmaceuticals India Ltd. (A1). Therefore, the respondent issued a show cause notice on 22.03.2012 to Laborate Pharmaceuticals India ltd. (A1), enclosing a copy of the Analyst's report, as required under Section 25(2) of the Act. Laborate Pharmaceuticals India Ltd.(A1) sent a reply letter dated 14.05.2012 acknowledging receipt of the show cause notice on 04.04.2012. In the reply to the show cause notice, Laborate Pharmaceuticals India Ltd. (A1) contended that they have to licence to manufacture the subject drug, but, the drug would not have been properly stored by the retailer and at the Government laboratory.

(ii) It may be necessary to state here that Laborate Pharmaceuticals India Ltd. (A1) did not elect to adduce evidence controverting the Government Analyst's report, as required under Section 25(3) of the Act.

(iii) As stated above, as per Section 25(3) of the Act, if any person wants to adduce evidence controverting the Government Analyst's report, a request should be made within 28 days from the date of receipt of the show cause notice. In this case, the show cause notice was issued on 22.03.2012 and in the reply letter dated 14.05.2012, Laborate Pharmaceuticals India ltd. (A1) did not elect to adduce evidence controverting the Government Analyst's report and only in the communication dated 13.09.2012, they asked for sending the sample to the Central Laboratory. Hence, a belated request well beyond 28 days fixed by the statute cannot be entertained.

(iv) Since the reply given by Laborate Pharmaceuticals India Ltd. (A1) was not satisfactory, the respondent obtained sanction from the Government and filed a complaint against Laborate Pharmaceuticals India Ltd. (A1) and their Directors for various offences under the Act, challenging which the petitioners/accused are before this Court.

(v) As regards the other submission of the learned counsel for the petitioners that the petitioners have lost their valuable right in having second sample sent to the Central Laboratory for re-analysis, this Court is of the considered view that the accused had not elected to repudiate the Government Analyst's Report within 28 days as required under Section 25(3) of the Act. Had the accused elected to adduce evidence controverting the Government Analyst's report in terms of the Act, there can be force in the submission of the learned counsel for the petitioners. In this case, the complaint has been filed on 28.11.2012 before the expiry of the shelf life

of the drug, which, even according to the petitioner is three years.

16. The Judgment cited supra, will have a direct application to the present case. This Court has held that if the accused person did not elect to repudiate the Government Analyst's report within 28 days, as required under Section 25(3) of the Act and has not elected to adduce evidence controverting the Government Analyst's report by getting the sample tested by the Central Drugs Laboratory, the accused person cannot be permitted to turn around and complain before this Court that the private complaint was filed by the respondent after the shelf life of the Drug. The prosecution under this Act is not a lis between two private individuals, but, is intended for securing and safeguarding public health. When substantiated Drug is manufactured and supplied in the market, Courts must be doubly careful dealing with such cases. Therefore, unless a very strong ground is made out by quoting mandatory statuary violation, Courts should not quash the complaint at the threshold stage. It is always open to the petitioners to establish their defense, during the course of trial.

16. This court does not find any ground to quash the proceedings in exercise of its powers under Section 482 of Cr.P.C. Accordingly, this Criminal Original Petition stands dismissed. Consequently, connected miscellaneous petitions are closed.

17. The learned counsel for the petitioner would submit that the second respondent is a resident of Uttharhand, therefore his personal appearance may be dispensed with. Accepting the said submission the presence of second petitioner before the trial court shall be dispensed with on the condition that he shall be present at the time of questioning under section 313 of Cr.P.C, and at the time of passing judgment. The petitioner shall be represented by a counsel during all hearings and the counsel representing the petitioner will cross examine the prosecution witness on the day when they are examined in chief.

Sd/-
Assistant Registrar (CS-I)

/True Copy/

Sub Assistant Registrar (CS-)

To

1. The Judicial Magistrate,
Arantangi.

2. The Drugs Inspector,
   Aranthangi Range,
   O/o, the Asst. Director of Drugs Control,
   Thanjavur Zone, Thanjavur-1.

3. The Additional Public Prosecutor,
   Madurai Bench of Madras High Court,
   Madurai.

+ 1 CC TO Mr.R.PON KARTHIKEYAN, ADVOCATE IN SR No. 85566

JEN
TE/PM/SAR-4 : 29/10/2018 : 8P/5C

Order in
CRL.OP (MD)No.16361 of 2018
20.09.2018