

IN THE HIGH COURT OF JUDICATURE AT MADRAS

DATED : 10.01.2020

CORAM

THE HONOURABLE MR.JUSTICE M.DHANDAPANI

Cr1.O.P.No.27312 of 2013

1.M/s.Alfred Berg & Co. (I) Pvt. Ltd.,
Rep. by its Director,
Thiru Chandrakanth R Jain

2.Mr.Chandrakanth R Jain

3.Mr.Kanthilala R Jain

4.Mr.Dheeraj C.Jain

5.Mr.Kamalesh Kumar R Jain ... Petitioners/A1 to 5

Vs.

The State of Tamil Nadu Rep by
Ms.Deepa Joseph
Drugs Inspector, Purasawalkom Range,
Zone II, Chennai 600 006. ... Respondent/Complainant

Prayer:

Petition filed under Section 482 of Cr.P.C., seeking to call for the records relating to the criminal case in C.C.No.351/2011 on the file of the learned X Metropolitan Magistrate, Egmore and to quash the same as illegal.

For Petitioners: Ms.R.Anitha
for M/s.Ramasamy Law Associates

For Respondent : Mr.C.Iyyapparaj
Additional Public Prosecutor

O R D E R

This criminal original petition has been filed seeking to call for the records relating to the criminal case in C.C.No.351 of 2011 on the file of the learned X Metropolitan Magistrate, Egmore and to quash the same as illegal.

2.The first petitioner Company is the Manufacturer of Pharmaceutical products and the petitioners 2 to 5 are the Directors of the first petitioner Company. The first petitioner

Company among other medicines is a Manufacturer of Cetrizine HCL Tablets 10 mg., a drug which is being manufactured under license in its factory premises situated at C-28, SIDCO Pharmaceutical Complex, Alathur - 603 110.

3.The facts of the case is that the then Drugs Inspector, Purasaivakkam Range, took samples of the drug namely, Cetrizine HCL Tablets 10 mg. B.No.CET-06 M/D 03/2009 D/E 02/2011, from the premises of Perumalpet Health Post, Purasaivakkam, Chennai, for analysis and intimation vide Form 17 dated 20.07.2009 for the same drawn was numbered as 078002. The above sample which was drawn was sent for analysis under Form 18 dated 20.07.2009 to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, who in turn reported that the drug was "Not of Standard Quality" vide report under Form 13 No 00912-D/2009-10, dated 22.11.2010 and that the sample does not conform to IP specifications for Cetrizine HCL Tablets with respect to dissolution, related substances and to the contents of Cetrizine HCL Tablets.

4.After receiving copy of the analytical report, the Drugs Inspector on 24.11.2010 issued a letter to the Medical Officer, Perumalpet Health Post, requesting him to disclose the name and address of the supplier of the subject drug as per Section 18 A of the Drugs and Cosmetics Act, 1940. In the reply letter dated 24.11.2010, the Medical Officer, Perumalpet Health Post, disclosed that the impugned drug was received from Central Medical Store, Chindadaripet, Chennai.

5.Thereafter, the Drugs Inspector on 25.11.2010 had written to the Medical Store Officer, Central Medical Store, Chindadaripet, to disclose the name and address of the person/ persons from whom the subject Drug was acquired as per Section 18 A of the Drugs and Cosmetics Act, 1940. The Medical Store Officer, Central Medical Store, Chindadaripet, in his reply dated 20.12.2020 had disclosed that the said drug was supplied by the District Drug Warehouse, TNMSC, Anna Nagar. Thereafter, a letter was addressed to the Ware House I/c TNMSC, Anna Nagar, to disclose the particulars and in turn the TNMSC, vide letter dated 01.12.2010 had stated that the subject drug was purchased directly from the first petitioner herein.

6.Thereafter, a show cause memo dated 01.12.2010, was issued to the first petitioner Company calling for explanation for the contravention under Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940, for having manufactured for sale and sold a Not of Standard Quality drug.

7.The petitioners sent a reply dated 22.12.2010 stating that they were doubtful about the storage of the sample in the Drug

Testing Lab and disagreed with the test report and requested to send one portion of the sample to the CDRL but had not submitted the documents as called for in the show cause notice as per Section 18 B of the Drugs and Cosmetics Act. The Investigating Officer on 30.12.2010 sent a detailed report to the Director of Drugs Control to accord sanction for prosecution and on 02.02.2011, the Directorate of Drugs Control accorded sanction to prosecute the petitioners herein.

8. Accordingly, a complaint was filed before the learned X Metropolitan Magistrate, Egmore on 07.02.2011 and the same was taken on file as C.C.No.351 of 2011. Challenging the same, this criminal original petition has been filed.

9. The learned counsel appearing for the petitioners would submit that though the then Drugs Inspector, Purasaivakkam Range, took samples of the drug namely, Cetrizine HCL Tablets 10 mg., on 20.07.2009 and sent the same for analysis under Form 18, dated 20.07.2009, to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, sent the report only on 22.11.2010.

10. The learned counsel appearing for the petitioners would further submit that a show cause memo dated 01.12.2010, was issued to the first petitioner Company calling for explanation for the contravention under Section 18 (a) (i) of the Drugs and Cosmetics Act, 1940 and the petitioners sent a reply dated 22.12.2010 stating that they were doubtful about the storage of the sample in the Drug Testing Lab and disagreed with the test report and requested to send one portion of the sample to the CDRL.

11. The learned counsel appearing for the petitioners would further submit that the Investigating Officer sent a detailed report to the Director of Drugs Control to accord sanction for prosecution only on 30.12.2010 and thereafter, on 02.02.2011, the Directorate of Drugs Control, Tamil Nadu accorded sanction to prosecute the petitioners herein and a complaint was filed before the learned X Metropolitan Magistrate, Egmore on 07.02.2011 and the same was taken on file as C.C.No.351 of 2011.

12. The learned counsel appearing for the petitioners would further submit that the expiry date of the drug was February, 2011 and the complaint was filed before the learned Magistrate only on 07.02.2011, almost during the expiry of the shelf life of the drug. The learned counsel would further submit that IP 2007 effective from 22.11.2010 stipulates storage of tablets as

'store protected from moisture at a temperature not exceeding 30 C'. Hence, if the conditions in the lab are not upto the IP standards, results of analysis will vary.

13.The learned counsel appearing for the petitioners would further submit that the petitioners request for sending portion of the sample to the CDRL, Calcutta, was not entertained and hence the valuable right of the petitioners under Section 25 (3) of the Drugs and Cosmetics Act was lost. The learned counsel would further submit that the petitioners Company was not given opportunity before the expiry of the shelf life of the product and thereby, they have lost their valuable right for sending the same for second Analysis and therefore, the prosecution launched by the respondent is not sustainable in the eye of law.

14.This Court also heard the submissions made by the learned Additional Public Prosecutor.

15.It is useful to extract hereunder the relevant portion of the decision of the Hon'ble Apex Court reported in (1999) 8 SCC 190 (State Of Haryana vs Unique Farmaid (P.) Ltd. and Ors.):

"11.Sub-section (1) of Section 30 which appears to be relevant only prescribes in effect that ignorance would be of no

defence but that does not mean that if there are contraventions of other mandatory provisions of the Act, the accused have no remedy. Procedure for testing the sample is prescribed and if it is contravened to the prejudice of the accused, he certainly has right to seek dismissal of the complaint. There cannot be two opinions about that. Then in order to safeguard the right of the accused to have the sample tested from Central Insecticides Laboratory, it is incumbent on the prosecution to file the complaint expeditiously so that the right of the accused is not lost. In the present case, by the time the respondents were asked to appear before the Court, expiry date of the insecticide was already over and sending of sample to the Central Insecticides Laboratory at that late stage would be of no consequence. This issue is no longer res integra. In The State of Punjab v. National Organic Chemical Industries Ltd., JT (1996) 10 SC 480 this Court in somewhat similar circumstances said that the procedure laid

down under Section 24 of the Act deprived the accused to have sample tested by the Central Insecticides Laboratory and adduce evidence of the report so given in his defence. This Court stressed the need to lodge the complaint with utmost dispatch so that the accused may opt to avail the statutory defence. The Court held that the accused had been deprived of a valuable right statutorily available to him. On this view of the matter, the court did not allow the criminal complaint to proceed against the accused. We have cases under the Drugs and Cosmetics Act, 1940 and the Prevention of Food Adulteration Act, 1954 involving the same question. In this connection reference be made to decisions of this Court in *State of Haryana v. Brij Lal Mittal & Ors.*, [1998] 5 SCC 343 under the Drugs and Cosmetics Act, 1940; *Municipal Corporation of Delhi v. Ghisa Ram*, AIR (1967) SC 970; *Chetumal v. State of Madhya Pradesh & Anr.*, [1981] 3 SCC 72 and *Calcutta Municipal Corporation v. Pawan Kumar Saraf & Anr.*, [1999] 2 SCC 400 all under the Prevention of Food Adulteration Act, 1954.

12. It cannot be gainsaid, therefore, that the respondents in these appeals have been deprived of their valuable right to have the sample tested from the Central Insecticides Laboratory under sub-section (4) of Section 24 of the Act. Under sub-section (3) of Section 24 report signed by the Insecticide analyst shall be evidence of the facts stated therein and shall be conclusive evidence against the accused only if the accused do not, within 28 days of the receipt of the report, notify in writing to the Insecticides Inspector or the Court before which proceedings are pending that they intend to adduce evidence to controvert the report. In the present cases Insecticide Inspector was notified that the accused intended to adduce evidence to controvert the report. By the time the matter reached the court, shelf life of the sample had already expired and no purpose would have been served informing the court of such an intention. The report of the Insecticide Analyst was, therefore, not conclusive. A valuable right had been

conferred on the accused to have the sample tested from the Central Insecticides Laboratory and in the circumstances of the case accused have been deprived of that right, thus, prejudicing them in their defence."

(emphasis supplied)

16.The decision cited supra is squarely applicable to the present case on hand, since the sample of the drug in the present case was taken on 20.07.2009 and was sent for analysis under Form 18, dated 20.07.2009, to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, however, the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, sent the report only on 22.11.2010.

17.Further, the show cause memo was issued to the first petitioner Company only 01.12.2010 and the petitioners sent a reply dated 22.12.2010 stating that they were doubtful about the storage of the sample in the Drug Testing Lab and disagreed with the test report and requested to send one portion of the sample to the CDRL.

18.The Investigating Officer sent a detailed report to the Director of Drugs Control to accord sanction for prosecution only on 30.12.2010 and on 02.02.2011, the Directorate of Drugs Control, Tamil Nadu accorded sanction to prosecute the petitioners herein and the complaint was filed before the learned X Metropolitan Magistrate, Egmore on 07.02.2011. The expiry date of the drug was February, 2011 and the complaint was filed before the learned Magistrate, almost during the expiry of the shelf life of the drug.

19.Further, the petitioners request for sending portion of the sample to the CDRL, Calcutta, was not entertained and hence the valuable right of the petitioners under Section 25 (3) of the Drugs and Cosmetics Act was lost. The first petitioner Company was not given opportunity before the expiry of the shelf life of the product and thereby, the petitioners have lost their valuable right for sending the same for second Analysis.

20.In view of all the above and taking note of the delay in launching the prosecution, I am of the opinion that the prosecution launched against the petitioners/ accused will cause serious prejudice to them as they have lost their valuable right for sending the sample for second analysis. Hence, I have no hesitation to allow this criminal original petition.

21.This criminal original petition is accordingly allowed and the proceedings in C.C.No.351 of 2011 on the file of the learned X Metropolitan Magistrate, Egmore, is hereby quashed. Consequently, connected miscellaneous petitions, if any, are closed.

Sd/-
Assistant Registrar(CCC)

//True Copy//

Sub Assistant Registrar

To

- 1.The X Metropolitan Magistrate Court,
Egmore, Chennai.
- 2.-Do- Thro' The Chief Metropolitan Magistrate,
Egmore, Chennai.
- 3.The Public Prosecutor,
High Court of Madras,
Chennai 600 104.

+1cc to M/s.S.Ramaswamy Law Associates, Sr.2856

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srg 21/02/2020