

IN THE HIGH COURT OF JUDICATURE AT MADRAS
DATED : 25.02.2020
CORAM

THE HONOURABLE MR.JUSTICE M.DHANDAPANI

Cr1.O.P.No.5980 of 2015

1.M/s.United Pharma Remedies
Rep. by R.Sathyabama
The Managing Partner

2.Ms.R.Sathyabama

3.M/s.Mahaa Bio
Rep. by K.R.Ravishankar
(Alias) Rajppa Ravishankar
The Managing Partner

4.K.R.Ravishankar
@ Rajappa Ravishankar
Managing partner,M/s Maha Bio ... Petitioners

Vs.

State rep by
Drugs Inspector,
Park Town I Range,
Office of the Assistant Director of Drug Control,
Zone-1, Chennai - 600 006. ... Respondent

Prayer:

Petition filed under Section 482 of Cr.P.C., seeking to call for the records on the file of the XV Metropolitan Magistrate, Chennai in C.C.No.3 of 2008 and quash the same.

For Petitioners : Mr.A.Vivekanandan
For Respondent : Mr.C.Iyyapparaj
Additional Public Prosecutor

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O R D E R

This criminal original petition has been filed seeking to call for the records on the file of the learned XV Metropolitan Magistrate, Chennai in C.C.No.3 of 2008 and to quash the same.

2.Petitioners 1 and 3 are the Manufacturer of Pharmaceutical products and petitioners 2 and 4 are the Managing Partners of petitioners 1 and 3. The respondent/ complainant

filed a complaint as against the petitioners and other accused for the contravention of Section 18(a) (i) read with 17 B(d) read with Punishable Section 27(C), Section 18 (C) read with punishable Section 27 (b) (ii), Section 18(C) read with condition 4 (i) of licence in form 21 B of Drugs and Cosmetics Act 1940 read with punishable Section 27 (d), Section 18 A read with punishable Section 28 and Section 18 B read with punishable Section 28 A of Drugs and Cosmetics Act, 1940. Challenging the same, this petition has been filed.

3.The facts of the case is that on 25.10.2005, during the inspection conducted by the complainant/ the Drugs Inspector, Park Town I Range, at the premises of Venus Agency, situated at No.5, Ground Floor, Nyniappa Naicken Street, Chennai - 3, the sample of Amoxycillin Caps 500 B.No.169, Manufacture date: November, 2004; Expiry date: October, 2006 manufactured by United Pharma Remedies, Chennai, was drawn for analysis under Form - 17 No.055057 dated 25.10.2005 and sent for analysis under Form - 18 to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, who in turn reported that the drug was 'not of standard quality' vide report No.02241-D/2005-06, dated 28.11.2005 for the reason that the sample does not conform to I.P. Specification for Amoxycillin capsules in respect of assay and that the sample is also deemed to be spurious since it has been substituted in part by another drug ampicillin.

4.Thereafter, the Drugs Inspector on 13.12.2005 investigated M/s.Venus Agency, Chennai and it was found that the firm had purchased 10 x 20 x 10 capsules of the above drug from M/s.Vasant Pharma, Chennai and sold 192 x 10 capsules. The balance quantity of unsold stock of 8 x 10 capsules of the subject drug was seized by the complainant under Form - 16 No.1774 and Mahazar both dated 13.12.2005 in the presence of two independent witnesses.

5.Thereafter, the complainant also investigated the premises of M/s.Ambica Pharmaceuticals at No.23, Raghunayakulu Street, Chennai, who was found to be one of the dealers of the subject drug. During the inspection, the firm was found to have purchased totally 370 x 20 x 10 capsules of the subject drug and had the balance of unsold stock of 25 x 20 x 10 + 14 x 20 capsules and the same were seized by the complainant under Form - 16 No.1773 dated 13.12.2005 and mahazar in the presence of two independent witnesses. The seized property was produced before the XV Metropolitan Magistrate, Chennai - 1 on 14.12.2005 under separate petitions and necessary B.No. was allotted.

6.Thereafter, the complainant issued a show cause notice on 05.01.2006 to M/s.Venus Agency, Chennai, for the contravention under Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940, for having sold the above said drug

which is spurious and the firm was directed to disclose the source of purchase under Section 18 A of the said Act. M/s.Venus Agency, Chennai, had sent a reply dated 19.01.2006 stating that the above said drug was

purchased from M/s.Vasant Pharma. The copies of sales bills and purchase bills were sent along with the reply.

7.The complainant also issued a show cause notice dated 05.01.2006 to M/s.Ambica Pharmaceuticals, Chennai, for the contravention of Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940, for having sold the above said drug which is spurious and the firm was directed to furnish the particulars of purchase under Section 18 A of the said Act. M/s.Ambica Pharmaceuticals, Chennai, had sent a reply dated 30.01.2006 furnishing the complete details of purchase and sales.

8.The complainant issued a show cause notice dated 06.01.2006 to M/s.Vasant Pharma, Chennai, for the contravention of Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940, for having sold the above said drug which is spurious and the firm was directed to disclose the particulars of purchase under Section 18 A of the said Act. M/s.Vasant Pharma, Chennai, had sent a reply dated 31.07.2006 stating that the above said drug was purchased from M/s.United Pharma Remedies and also from M/s.Mahaa Biio, Chennai/ Petitioners 1 and 3 herein.

9.Thereafter, the complainant issued a show cause notice on 14.08.2006 to M/s.United Pharma Remedies, Chennai, for the contravention of Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940, for having manufactured for sale and sold the spurious drug and the firm was directed to furnish the details of manufacturing, analysis and raw materials, purchase bills of raw materials, sales details of the above said drug as per Section 18 B of the said Act.

10.Simultaneously, the complainant issued another memo dated 14.08.2006 to M/s.Mahaa Biio, Chennai, for the contravention of Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940, for having manufactured and sold the spurious drug and the firm was also directed to furnish the details of manufacturing analysis, raw materials and sales details of the subject drug as per Section 18 B of the said Act.

11.M/s.United Pharma Remedies, Chennai, in their reply dated 09.09.2006 stated that the product complied all I.P.Specification tests and error might have erupted in the analysis made on the part of the complainant and M/s.Mahaa Biio,

Chennai, did not send any reply.

12. During the course of investigation, it was found that petitioners 1 and 3 remained closed for few months and it was also found that no wholesale licence has been issued to the third petitioner. Hence, on 21.03.2007, the complainant issued a show cause notice to the third petitioner for contravention of Section 18 (C) of the Drugs and Cosmetics Act, 1940 for having sold the drug Amoxycillin Caps I.P.500 B.No.169 to Vasant Pharma, Chennai, without holding any sales drugs licence to sell the drug and the firm was directed to furnish the particulars of purchase under Section 18 A of the said Act along with copies of purchase bills, sales bills and copy of partnership deed. The same was returned to the complainant undelivered.

13. Thereafter, after obtaining sanction order to prosecute the accused, a complaint was filed before the learned XV Metropolitan Magistrate, Chennai on 28.11.2007 and the same was taken on file as C.C.No.3 of 2008. Challenging the same, this criminal original petition has been filed.

14. The learned counsel appearing for the petitioners would submit that though the Drugs Inspector, Park Town - I Range, took samples of the drug namely, Amoxycillin Caps 500 B.No.169, with shelf life from November, 2004 till October, 2006 on 25.10.2005 and sent the same for analysis to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, sent the report only on 28.11.2005.

15. The learned counsel appearing for the petitioners would further submit that a show cause memo dated 14.08.2006, was issued to the first petitioner Company calling for explanation for the contravention of Section 18 (a) (i) read with Section 17 B (d) of the Drugs and Cosmetics Act, 1940 and the first petitioner sent a reply dated 09.09.2006 stating that the product complied all I.P. Specification tests and error might have erupted in the analysis made on the part of the complainant and disagreed with the test report and requested to refer the same and to do the needful. He would further submit that to prove their genuineness and quality of the product, the first petitioner also produced the concerned records.

16. The learned counsel appearing for the petitioners would further submit that the expiry date of the drug was October, 2006 and the complaint was filed before the learned Magistrate only on 28.11.2007, after the expiry of the shelf life of the drug.

17. The learned counsel appearing for the petitioners would

further submit that though the first petitioner requested to refer the same and to do the needful, a portion of the sample was not sent to CDRL, Calcutta 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. Accordingly, he prayed for allowing the criminal original petition.

18.The learned Additional Public Prosecutor would submit that though the first petitioner in the reply dated 09.09.2006 given to the show cause notice has requested to refer the same and to do the needful, they have not specifically mentioned to send a portion of the sample to CDRL, Calcutta, hence, the State is not bound to refer the sample for second analysis and would further submit that the procedure contemplated under Section 25 (3) of the Drugs and Cosmetics Act was complied with. He would further submit that all the issues raised are triable issues which has to be decided by the Trial Court after trial and not in this petition filed under Section 482 of Cr.P.C.

19.Heard the submissions made on either side and perused the materials available on record.

20.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)

21.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 25.10.2005 and was sent for analysis under Form 18, to the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, however, the Government Analyst (Drugs), Drugs Testing Laboratory, Chennai, sent the report only on 28.11.2005.

22.Further, the show cause memo was issued to the first petitioner Company only on 14.08.2006 and the petitioner sent a reply dated 09.09.2006 stating that the product complied all I.P.Specification tests and that the error might have erupted in the analysis made on the part of the complainant and disagreed with the test report and requested to refer the same and to do the needful. It implies that the petitioner has disagreed with the test report and has requested to send one portion of the sample to the CDRL, Calcutta.

23.However, 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.

24.Further, the expiry date of the drug was October, 2006 and the complaint was filed before the learned Magistrate only on 28.11.2007, after the expiry of the shelf life of the drug.

25.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.

26.This criminal original petition is accordingly allowed and the proceedings in C.C.No.3 of 2008 on the file of the learned XV Metropolitan Magistrate, Chennai, is hereby quashed, in respect of the petitioners alone. Consequently, connected miscellaneous petitions, if any, are closed.

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Sd/-
Assistant Registrar

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Sub Assistant Registrar

To

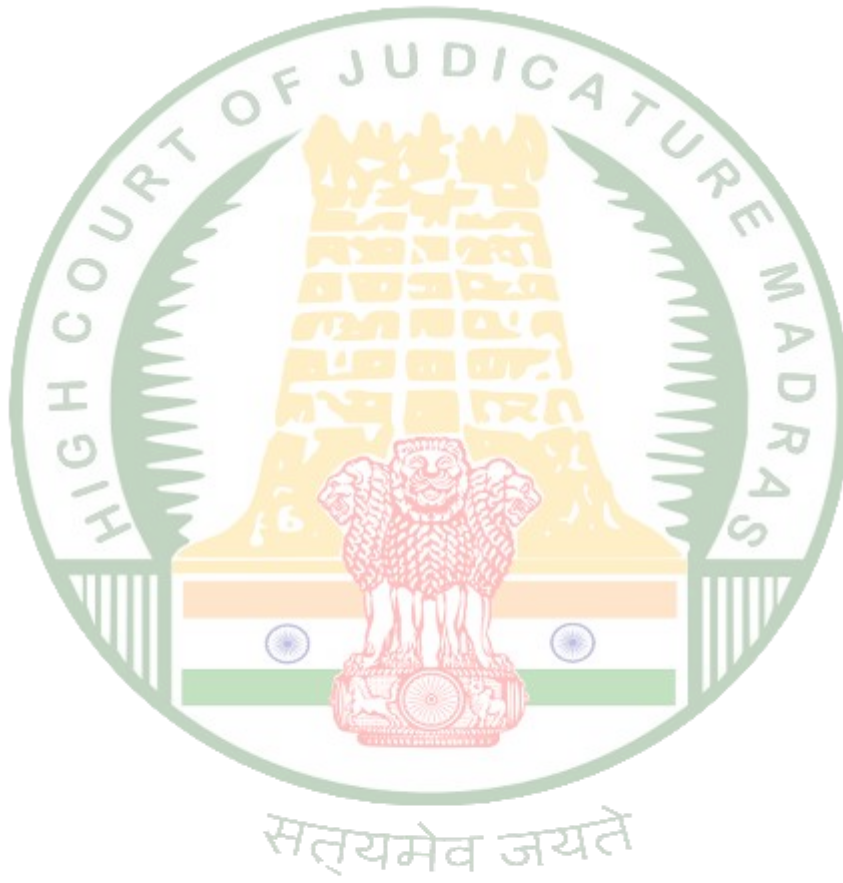
- 1.The XV Metropolitan Magistrate,
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 - 2.The Drugs Inspector,
Park Town I Range,
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Zone-1, Chennai - 600 006.
 - 3.The Public Prosecutor,
High Court of Madras,
Chennai 600 104.
- +1cc to Mr.A.Vivekanandan, Advocate SR.No.16621

srl(CO)
mst(27/05/2020)

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