IN THE HIGH COURT OF JUDICATURE AT BOMBAY
BENCH AT AURANGABAD

CRIMINAL WRIT PETITION NO. 606 OF 2005

1. Vijay Prakash
Age : Major, Occupation : Director,
M/s. Bestochem Formulations (I) Ltd.
Plot No. 471, Udyog Vihar,
Phase III, Gurgaon-122016.

2. Greesh Juneja
Age : Major, Occupation : Director,
M/s. Bestochem Formulations (I) Ltd.
Plot No. 471, Udyog Vihar,
Phase III, Gurgaon-122016.

3. Romesh Sharma
Age : Major, Occupation : Director,
M/s. Bestochem Formulations (I) Ltd.
Plot No. 471, Udyog Vihar,
Phase III, Gurgaon-122016. … Petitioners
(Orig. Accused)

Versus

State of Maharashtra
through S. M. Dalal,
Drugs Inspector,
Food & Drug Administration,
Maharashtra State, Aurangabad,
District Aurangabad. … Respondent-
(Orig. Complainant)

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Mr. A. D. Soman, Advocate for the Petitioners.
Mr. P. K. Lakhotiya, APP for Respondent-State.

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CORAM : V. K. JADHAV, J.
RESERVED ON : 27/09/2018
PRONOUNCED ON : 22/11/2018

JUDGMENT :-

1. By way of this criminal writ petition, the petitioners are praying for the following relief:

> (B) The proceedings of R.C.C. No. 970/2004 filed in the Court of Chief Judicial Magistrate, Aurangabad against the petitioners under Section 18(a)(i) punishable under Section 27(d) read with Section 34 of Drugs and Cosmetics Act, 1940 may kindly be quashed and set aside and petitioners may kindly be discharged from all the charges as mentioned above.

2. Brief facts giving rise to the present writ petition are as follows:

a. The petitioners/accused are the Directors of M/s. Bestochem Formulations (I) Ltd. (for short, “the company”), which is a pharmaceutical company registered under the Companies Act, 1956 having its manufacturing unit at plot no. 471, Udyog Vihar, Phase III, Gurgaon-122016. The respondent/complainant is the Drugs Inspector, Food and Drug Administration, Maharashtra State, Aurangabad. The company manufactures various biological items in tablet section and various drugs including the product

"Multi-Aid" at its manufacturing unit at Gurgaon after getting various licenses from the concerned Government departments. Thus, the drugs produced by the company of the petitioners are approved by the Government authorities and the same are marketed by dealers and distributors appointed by the company.

b. The present respondent/complainant visited the premises of one of the dealers of petitioners' products, namely, M/s. Archana Medical, Khadkeshwar, Opp. Anjali Cinema, Aurangabad on 10.10.2003 and drew samples of 4x1x6x8 capsules in four portions of the drug, namely, Multi-Aid capsules of Batch No.2888 manufactured in the month of March 2003 having expiry date as 08/2004. The said sample was sent to the Government Analyst, Drugs Control Laboratory, Mumbai (M.S.) for test and analysis as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder (for short, "the Act of 1940" and "the Rules"). It is the case of respondent that as per report dated 07.01.2004 (report no. M/5042/2003) received from the Government Analyst, the sample does not give identification test for Vitamin "A" and content of calcium pantothenate in the sample is less than the permissible limit (i.e. 74.1% of labelled amount).

c. On the basis of the said report, an inquiry was made with M/s. Archana Medical, from whom the said sample was drawn, as to from which source the said supply is made. The proprietor of M/s. Archana Medical disclosed that he has purchased the said batch of drug from M/s. Nirmal Agencies, Pune. On 03.02.2004, the respondent/complainant with Drug Inspector Mr. P.M.Patil visited the premises of M/s. Nirmal Agencies, Fursungi at Pune and during inquiry, the in-charge of the said agency informed that the said stock of capsules of drug Multi-Aid is purchased from the company of petitioners. Thereafter, the said report was sent to the company of petitioners and it was asked to produce various documents. The company submitted its reply. Thereafter, on 04.03.2004, the respondent alongwith panch witness visited the shop premises of M/s. Archana Medical, Aurangabad and seized the stock of the said batch.

d. The respondent filed Misc. Application No. 437 of 2004 on 05.03.2004 before learned Chief Judicial Magistrate regarding custody of seized drug as per Section 23(5)(b) of the said Act, for which, permission was granted by the court. The petitioners submitted the documents on 07.04.2004 as required by the respondent. The respondent filed complaint R.C.C. No.970 of 2004

before the Chief Judicial Magistrate, Aurangabad for the offence under Section 18(a)(i) punishable under Section 27(d) r/w Section 34 of Drugs and Cosmetics Act, 1940. Hence this criminal writ petition.

3. Learned counsel for the petitioners submits that the complaint filed by the respondent is not maintainable as the petitioners have not committed any offence as alleged in the complaint. The products manufactured by the petitioners' company are having high standards and by following the procedure and ratio laid down and as per the Indian Pharmacopoeia, 1996. The respondent has drawn six samples of various products manufactured by the company. All the products, of which samples have been taken, are good standard products except the product Multi-Aid which is shown as substandard because of vitamin-A. The company has been permitted by the drug license to use vitamin-A and the company is using the vitamin-A in the form of “palmitate”. However, the analytical laboratory has reported that the product Multi Aid does not give identification of vitamin-A. Learned counsel submits that identification is not the only criteria to declare any product sub-standard quality. Had the respondent got tested the said product, it would have been noticed that the same contains

percentage of vitamin-A. The allegations in the complaint are wrong and illegal because as per the General Notes printed in Indian Pharmacopoeia, 1996 at page no.14, it is specifically indicated that the identification tests described under the monograph are not necessarily sufficient to establish absolute proof of identity. However, on this ground alone, the complaint R.C.C. No. 970 of 2004 came to filed against the petitioners.

4. Learned counsel for the petitioners further submits that vitamin-A is mixed in two forms i.e. (i) palmitate and (ii) Acitier. Palmitate is only in character whereas Acitier is crystal granule. The petitioners are mixing vitamin-A in palmitate form which can be identified by the analysis 'Assay'. However, the Government Analyst has totally and completely relied upon the identification tests described under the monograph of vitamin-A Acetate. The Government Analyst should have carried out the analysis 'Assay' from which a specific and true conclusion would have been arrived at as to whether the product is up to the standard or not. However, without carrying out the Assay, only on the basis of identification test the Government Analyst concluded in the report that the said product Multi-Aid is sub-standard because of vitamin-A. The said aspect was brought to the notice of respondent by the petitioners

vide letter dated 22.06.2004 alongwith relevant extract of Indian Pharmacopoeia. However, without considering the same, the respondent has hurriedly filed the complaint.

5. Learned counsel further submits that the petitioner also got the product tested from a renowned laboratory, namely, M/s. SGS Laboratory, Gurgaon wherein it clearly shows that the product in question is of standard quality and there is no deviation. Copy of the said report of SGS Laboratory, Gurgaon was also sent to the respondent vide letter dated 02.04.2004 stating therein that the petitioners are using vitamin-A palmitate and the same should not be tested for vitamin-A. It was also mentioned in the said letter that the petitioners have tested the sample of same batch from the SGS India Pvt. Ltd. which is also an authorized laboratory of India and its report confirms all the protocol in the sample and it is of standard quality.

6. Learned counsel further submits that the petitioners received the letter dated 11.02.2004 issued by the respondent alongwith test report No.M/5042/2003 dated 07.01.2004, to which the petitioners have replied by letter dated 26.02.2004 stating therein

that the the petitioners totally disagree to the report of the Government Analyst as the petitioners are manufacturing the said product since 1995 and never came across any sub-standard complaint against the product. In the said letter dated 26.02.2004, the petitioners also requested the respondent Drugs Inspector to send the sample for re-testing either at C.D.L. Bombay or Calcutta. Hence, the test report dated 07.01.2004 was challenged by the petitioners within the time period of 28 days after its receipt as prescribed under Section 25(4) of the Act.

7. Learned counsel for the petitioners lastly submits that the petitioners' company is well reputed and manufacturing quality products which are of international standard. The product in question is also manufactured under high standard quality, inspection and control observations and also maintaining accurate ratio in the product of various raw materials used for manufacturing Multi-Aid capsules. The batch which has been seized and which is the subject matter of present complaint has also gone through a strict quality control and inspection procedure and there is no deviation of any type as alleged by the respondent. The petitioners have been falsely implicated for the alleged offence

when there are no ingredients to show that they have committed any illegalities in manufacturing the product Multi-Aid. Learned counsel submits that the petitioners are liable to be exonerated from the charge of offence under Section 18(a)(i) punishable under Section 27(d) read with Section 34 of the Drugs and Cosmetics Act, 1940 and Rules thereunder.

8. Learned counsel for the petitioners, in order to substantiate his contentions, placed reliance on the following decisions:

1. ***Medicamen Biotech Limited and Another vs. Rubina Bose, Drug Inspector***, reported in ***(2008) 7 SCC 196,***

2. ***Municipal Corporation of Delhi vs. Ghisa Ram***, reported in ***AIR 1967 SC 970,***

3. Judgment dated 21.06.2010 delivered by this Court (Nagpur Bench) in Criminal Application No. 3439 of 2006 [***Shivkumar alias Shiwalamal Narumal Chugwani Proprietor of Kanhaiya General Stores vs. State of Maharashtra at the instance of Subhash Madhukar Choudhary***],

4. Judgment of this Court dated 27.10.2016 in Criminal Writ Petition No. 28 of 2003 with other writ petitions [***Anandkumar s/o Satyanarayan Loya and another vs. The State of Maharashtra and another***],

5. Judgment of this Court dated 19.09.2016 in Criminal Application No. 2116 of 2005 [***R. Shridhar vs. State Department of Agriculture and Ors.***] and

6. Judgment of this Court (Coram: Smt. Vibha Kankanwadi, J.) dated 10.07.2018 in Criminal Application No. 06787 of 2017 [***M.Sea Pharmaceuticals Pvt. Ltd. and another vs. The State of Maharashtra and another***]

9. Learned APP submits that though the petitioners were in receipt of the report of Government Analyst, they did not challenge the said report under Section 25(3) of the Act within 28 days before the Drug Inspector or the concerned Court. After launching prosecution against the petitioners on 14.07.2004, the respondent/complainant informed the petitioners vide letter dated 03.08.2004 about the same. The letter dated 02.04.2004, as stated by the petitioners to have been sent to the respondent, was not received by the respondent. However, the respondent received a letter dated 07.04.2004 issued by the petitioners wherein it was not mentioned about petitioners' intention to challenge the report of Government Analyst before the Central Drugs Laboratory and even otherwise, the said letter is after the prescribed period of 28 days. The report of Government Analyst given in form no.13 is

valid and conclusive evidence until the same is challenged under Section 25(4) of the Act and the sample is tested by the Central Drug Laboratory. In the present case, the petitioners have not challenged the said report within 28 days either before the Drug Inspector or before the concerned court. Thus, the Government Analyst's report become conclusive evidence. Learned APP further submits that the Government Analyst has carried out the test by referring the official method and journals which is also mentioned in his report. He analyzed the sample as per the specification of the ingredient mentioned on the label. Vitamin-A is labeled as Vitamin-A IP on the label and the Government Analyst analyzed the sample as per the Indian Pharmacopoeia monograph. The identification Test for the vitamin done by the Government Analyst shows absence of vitamin-A in the sample. Therefore, if vitamin-A is not available in the sample, then, Assay for vitamin-A is not required. The procedure followed by the Government Analyst is correct as per Rule 46 of the Act and the report becomes conclusive as per Section 25(4) of the Act.

10. Learned APP further submits that the petitioners have played mischief with the respondent by sending a forged letter dated

26.02.2004. The letter received by the respondent dated 26.02.2004 is different than the forged letter dated 26.02.2004 which the petitioners are now claiming to have been sent to the respondent. The petitioner never sent the alleged letter to the respondent, nor the respondent received such kind of letter within the prescribed period. The letter received by the respondent is sent from Meerut dated 26.02.2004, however, the forged letter dated 26.02.2004 is shown to have been sent from Gurgaon. On verification of both the letters, it can be seen that the letter actually received by the respondent is printed on the letter head of Meerut office and the same address also appears on the envelop of the said letter. However, the address on forged letter dated 26.02.2004 is mentioned as Gurgaon office. The alleged letter dated 26.02.2004 shown by the petitioners at page 74 of the memo was not received by the respondent. The petitioners have not come with clean hands and therefore, the petition needs to be rejected.

11. It is the case of the petitioners that despite the fact that the petitioners had controverted the accuracy of the report of Government Analyst, the fourth sample had not been sent to the Central Drugs Laboratory for retesting and analysis. Per contra, the

respondent-State submits that the petitioners could not claim that the fourth sample should be sent to Central Drugs Laboratory unless the requirement of Subsection (3) of Section 25 of the Act of 1940 is complied with. The petitioners had not informed the Drug Inspector within the prescribed period that they intended to adduce evidence to controvert the report and as such, the report of the Government Analyst shall be evidence of the facts stated therein and such evidence shall be conclusive.

12. In the backdrop of above submissions, it is necessary to examine the legal provisions. Section 25 of the Act of 1940 is reproduced herein below:

> "**25. Reports of Government Analysts**.- (1) The Government Analyst to whom a sample of any drug 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.
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> (2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18-A, 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 or the person whose name, address and other particulars have been disclosed under section 18-A 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 analyses 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 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."

13. A bare reading of the aforesaid provisions would indicate that the said provisions prescribe certain obligations as well as provide safeguards for a person from whom a drug has been seized for analysis or testing as Section 25(3) specifies that unless such a person controverts the correctness of the report submitted by the Government Analyst within 28 days in writing that he intends to adduce evidence to controvert the report of the analyst, it would be deemed to be conclusive evidence of the quality of the drug, whereas, Subsection (4) of Section 25 obliges the Magistrate on the request of the complainant or the accused or on his own motion to send the fourth sample which has been disputed for fresh testing to the Director of the Central Drugs Laboratory.

14. In the case of ***State of Haryana vs. Brij Lal Mittal & Ors.,*** reported in ***1998 (5) SCC 343***, the Supreme Court held that a person could not claim that the fourth sample should be sent to the Central Drugs Laboratory unless the requirement of sub-section (3)

of Section 25 was complied with. In para 5 of the judgment in ***Brij Lal Mittal's*** case, the Supreme Court has made the following observations:

> "5. From a bare perusal of sub-section (3) it is manifest that the report of the Government Analyst shall be evidence of the facts stated therein and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address or other particulars have been disclosed under Section 18-A (in this case the manufacturers) has within 28 days of the receipt of the report notified in writing the Inspector or the Court before which any proceeding in respect of the sample are pending that he intends to adduce evidence in controversion of the report. Sub-section (4) also makes it abundantly clear that the right to get the sample tested by Central Government Laboratory (so as to make its report override the report of the Analyst) through the Court accrues to a person accused in the case only if he had earlier notified in accordance with sub-section (3) his intention of adducing evidence in controversion of the report of the Government Analyst. To put it differently, unless requirement of sub-section (3) is comped with by the person concerned he cannot avail of his right under sub-section (4)."

15. In the instant case, the petitioners seek quashing of the proceedings of R.C.C. No.970 of 2004 on two grounds. Firstly, that though the petitioners have controverted the accuracy of the report of Government Analyst within 28 days of the receipt of the copy of the report and notified the same in writing to the Inspector that the petitioners intend to adduce evidence in controversion of the report, the sample has not been sent for a test or analysis to the Central Drugs Laboratory and secondly, that in terms of the provisions of Section 25(4), the petitioners could not even request the Magistrate to send the sample for testing or analysis to the Central Drugs Laboratory since the shelf life of the drug was expired in the month of August 2004 itself, when the complaint was filed in the month of July, 2004.

16. It is therefore necessary to examine as to whether there is compliance of the provisions of Section 25(3) of the Act of 1940. Admittedly, the respondent/complainant has received the Government Analyst's report on 07th January 2004, and on 7th/11th February 2004 the respondent/complainant has sent a copy of the test report dated 07th January 2004 to the petitioners. It is the case of the petitioners that the petitioners had sent a letter dated

26.02.2004 notifying their intention of adducing evidence in controversion of the Government analyst's report. The petitioners claim that within the prescribed period of 28 days, as contemplated in Subsection (3) of Section 25 of the Act of 1940, they have notified in writing through the aforesaid communication to the Inspector that they intend to adduce evidence in controversion of the report. Mr. Rajgopal Mulchand Bajaj, Drug Inspector in the office of the Joint Commissioner, Food and Drug Administration, Aurangabad, has filed an affidavit-in-reply dated 02.11.2017 wherein, in para 3, he has stated that the petitioners had sent a letter dated 26.02.2004 from Meerut office through RPAD vide receipt no.1249 and the petitioners had also sent one more letter which was received on 27.08.2004 and in that letter, the petitioners had annexed a photocopy of the letter dated 26.02.2004 with postal receipt of no.1249. Mr. Rajgopal Bajaj, the Drug Inspector has specifically stated in his affidavit-in-reply that the petitioners had played mischief with the respondent as well as with the Court as the petitioners had sent only one letter dated 26.02.2004, however, they had created another forged letter dated 26.02.2004. It has been specifically stated that the letter dated 26.02.2004 has been sent from Meerut office and the forged letter

shown to have been sent from Gurgaon. The letter dated 26.02.2004, which is shown to have been sent from Gurgaon, was never received by the respondent/complainant.

17. On careful perusal of the record and proceedings and the original copy of the postal receipt no.1249 and the contents of the letter sent from Meerut dated 26.02.2004, *prima facie* it appears that the petitioners have not notified their intention to controvert the report of the Government Analyst to the Drug Inspector and have not expressed their intention to adduce evidence in controversion of the report. It is for the trial court to appreciate the relevant documents during the course of trial. However, *prima facie* it appears that the said postal receipt no. 1249 has been used cleverly to draft another letter shown to have been sent on 26.02.2004 from Gurgaon office. *Prima facie*, it appears that the petitioners have prepared the said letter with a sole intention to claim benefit of Subsections (3) and (4) of Section 25 of the Act of 1940. I find that the petitioners have not approached this Court with clean hands. If it is so, then the cases relied upon by the learned counsel for the petitioners are not helpful to the petitioners in any manner. There is no question of considering the shelf life of

the drug when *prima facie* it appears that the petitioners have failed to notify their intention to adduce evidence in controversion of the report within 28 days in terms of the provisions of Subsection (3) of Section 25 of the Act of 1940. In view of the same, the petition is liable to be dismissed. However, it is for the trial court to appreciate the documentary evidence adduced by the parties on its own merit without getting prejudiced by any of the observations made herein above. Hence, the following order:

ORDER

I. Writ Petition No.606 of 2005 [Vijay Prakash and others vs. State of Maharashtra] is hereby dismissed.

II. Rule stands discharged. The Writ Petition is disposed of accordingly.

(V. K. JADHAV, J.)

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